

Access to Medicine Index 2021

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index



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The Access to Medicine Foundation is an independent non-profit organisation based in the Netherlands. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access.

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The challenge for pharma companies: become a catalyst not a barrier



I hope you are well and able to look ahead to an era where real change is possible. This 7th Access to Medicine Index was prepared amid the coronavirus pandemic – the worst public health crisis in a century – which has thrown the chronic problem of inequitable access to medicine into sharp relief. Despite laudable moves by some pharmaceutical companies to curb profits to help fight the crisis, the stark reality is that billions of people in low- and middle-income countries are still at the back of the queue for vaccines and treatments.

It does not have to be this way. The Access to Medicine Index provides a guide to the practical, proven steps that can be taken by multinational pharmaceutical companies to improve access to life-saving medicines. Importantly, these measures will not only help the world's poor but also improve companies' long-term business sustainability.

Industry leaders and policymakers must learn from this pandemic and commit to ensure fair access to all essential medicines, whether for communicable or non-communicable diseases, from antiviral treatments and antibiotics to insulin and cancer therapies. This requires change in how a company runs, how it manages its R&D pipeline and how it offers its products to people worldwide.

Chronic access problems persist

My organisation has spent more than 15 years tracking the pharma industry's contribution to global health. Over that time, we have seen undeniable progress. More companies today are taking seriously the access problems faced by people in low- and middle-income countries. Nonetheless, corporate decisions on chronic problems relating to pricing and availability of medicines mean that the industry is still too often a barrier to better healthcare rather than a catalyst for improvement. In the world's poorest households, medicines remain the biggest single element of healthcare costs and the price is often crippling. Many times, they are simply unavailable.

Our 2021 Index spells out what needs to be done and case studies of what works in practice: from supporting efforts to build local capacity; to pairing R&D projects with clear access plans; and to resetting the industry's research priorities so that they also address the specific needs of people living on low incomes.

A pivotal time to leverage the power of science

Although companies are inching ahead when it comes to embedding access into their business practices, activity still concentrates on too few diseases and too few countries, thus benefiting only a fraction of the people in need. What is more, most of the effort is being made by only a small number of firms, creating a fragile situation where any retreat could have dire consequences.

I believe the past year has demonstrated the pivotal importance of scaling up and supplying affordable medicines for the many, rather than premium-priced products for the few. By investing in fair access to medicine for the poorest and most vulnerable among us, we are also investing in a fair, peaceful and prosperous global community. The power of science to help humanity – whether through new vaccines for common pathogens or novel drugs for rare diseases – is remarkable. But these breakthroughs will only truly deliver for the world if they reach all who need them.

A handwritten signature in blue ink that reads "Jayasree K. Iyer". The signature is fluid and cursive.

Jayasree K. Iyer
Executive Director
Access to Medicine Foundation

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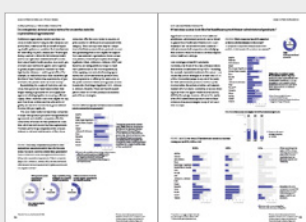
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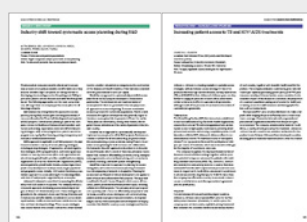
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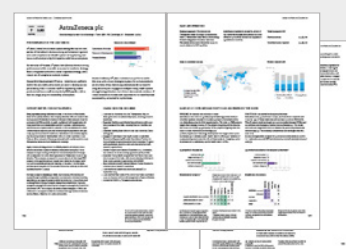
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Executive Summary

Globally each year, millions of people suffer illness and death because the vaccines, medicines and diagnostic tests that they need are either unavailable or unaffordable. For the world to achieve the Sustainable Development Goals by 2030, access to medicine must continue to expand, particularly for the people living in low- and middle-income countries, who account for 83% of people alive today. Pharmaceutical companies have a unique role to play here, as they have the capacity to develop urgently needed health products and to improve products' availability across socioeconomic divides.

The Access to Medicine Index evaluates and compares how far 20 of the world's leading pharmaceutical companies go in fulfilling this role. By ranking them on their performances every two years, the Index spurs companies to compete and collaborate on priority access-to-medicine topics, while identifying best practices, areas of progress and gaps where more action is urgently needed. The methodology is updated every two years in line with developments in access to medicine following a wide-ranging multi-stakeholder dialogue.

SIGNS OF PROGRESS

In 2021, the Index finds that pharmaceutical companies continue to inch forward when it comes to embedding access to medicine into business practices in low- and middle-income countries. There are signs of progress in a range of areas, from the setting of access-related performance incentives, to processes to ensure access to future products, to efforts to evaluate the impact of access initiatives. Yet actions to address access to specific products remain focused on a few products and a few countries, with the same handful of emerging markets benefiting most often.

As in 2018, a small number of diseases are the main focus of companies' R&D activity, with cancers accounting for more than two thirds of projects analysed. Among infectious diseases, HIV and AIDS, tuberculosis and malaria once again receive most attention, with COVID-19 newly joining the group in 2020. A small group of companies once

again account for the bulk of the R&D projects that the global health community considers a priority, underscoring a worrying dependency on just a few large players.

KEY FINDINGS

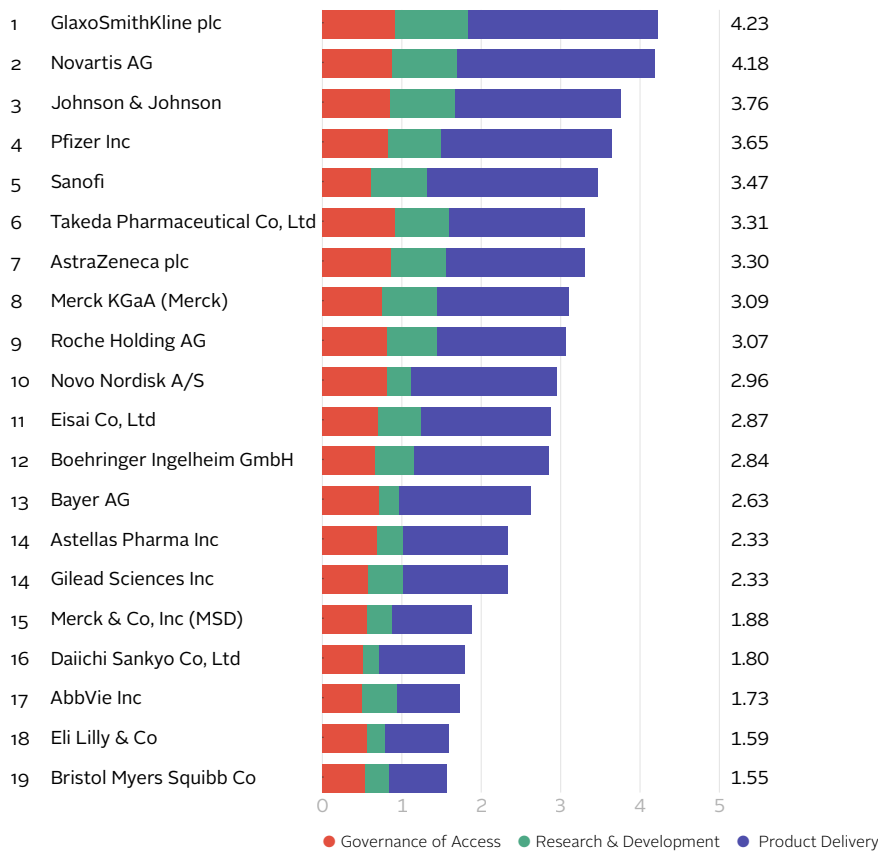
- Eight companies are moving to systematically pair candidates in their R&D pipelines with plans for making them accessible in low- and middle-income countries soon after the products are launched onto markets. Late-stage pipelines are not yet fully covered by access plans.
- Companies are addressing access for the poor for less than half of key products analysed. Low-income countries, as classified by the World Bank, are most consistently overlooked.
- The pipeline of medicines and vaccines has filled up for coronavirus patients (from zero to 63 projects), yet is virtually empty for other pathogens that pose a pandemic risk, such as Nipah, Zika and SARS. The 20 companies have empty pipelines for ten of the 16 emerging infectious diseases (EIDs) identified by WHO and others.

INDUSTRY RESPONSE TO COVID-19

The pandemic has led to an increase in COVID-19 R&D, yet there is little evidence of preparedness for the next pandemic, particularly when it comes to R&D for other EIDs. The pandemic has emphasised the need for a diverse range of private and public sector entities to engage in EID research well before epidemics break out.

The pandemic has also revealed some companies' agility, for example in leveraging existing networks to support local pandemic responses, and in responding to actual or projected supply chain disruptions. However, the benefits for people in low- and middle-income countries have been unequal and limited. Ending a pandemic requires suitable products to be developed and then fairly distributed so that people in low- and middle-income countries are not last in line or left behind altogether.

2021 ACCESS TO MEDICINE INDEX – OVERALL RANKING



2021 RANKING ANALYSIS

GSK retains the No. 1 position, yet only slightly ahead of Novartis. The leaders are followed by Johnson & Johnson, Pfizer and Sanofi. The two leading companies are in close competition, both providing evidence that additional patients were reached through access strategies such as equitable pricing and voluntary licensing initiatives. GSK’s performance in R&D is a significant factor in its retention of the top spot. It has access plans covering the largest proportion of late-stage projects (20/25). Novartis closes in on the No. 1 position through its performance in Product Delivery, and stands out for being the only company to apply equitable access strategies in at least one low-income country for all products assessed. Pfizer is newly in the top 5, and leads when it comes to addressing access to self-administered products across different regions and socio-economic groups, also demonstrating increases in patient reach. Near the bottom of the ranking, Astellas, AbbVie and Daiichi Sankyo are the only companies that do not have an access-to-medicine strategy with a business rationale. Bristol Myers Squibb takes the bottom rank with limited evidence of access initiatives across the areas measured.

LEADERS PER TECHNICAL AREA

Governance of Access

GSK and Takeda lead, followed closely by Novartis. All three demonstrate strong responsible business practices either by enforcing stringent compliance processes across their operations or by setting viable staff incentives.

Research & Development

GSK leads with the largest pipeline comprised of projects that target well-established treatment priorities, and has a structured process to develop access plans for all projects. Novartis and Johnson & Johnson follow, scoring well in all areas.

Product Delivery

Novartis leads, targeting multiple countries and patient populations across the income pyramid with equitable pricing strategies and responsible IP management. GSK is second, and both companies leverage their know-how and resources to address local access barriers through their capacity building initiatives.

FINDINGS PER TECHNICAL AREA

Governance of Access

- Only 11 companies demonstrate good practice by embedding their access-to-medicine strategy within their overall business strategy and across all therapeutic areas where they are active, indicating that access thinking is incorporated consistently within the company.
- More than half of the companies provide managers and senior executives with incentives to achieve access-to-medicine goals. Top-level accountability is likely to filter into the rest of the company and can help enable teams to deliver on access-to-medicine initiatives.
- Over half of the companies have incentives that are not wholly linked to sales. By moving away from rewards pegged primarily against sales targets, companies can limit the risk of over-selling products.
- Eight companies demonstrate best practice by applying all the compliance controls looked for by the Index, i.e., processes for checking and detecting non-compliance that might negatively affect access to medicine, supported by rigorous monitoring and auditing.

Research & Development

- The 20 companies have 1,073 R&D projects in the pipeline for the 82 diseases, conditions and pathogens in scope – those that cause the greatest burden in low- and middle-income countries. More than 80% of people alive today live in low- and middle-income countries and face the bulk of the global burden imposed by these diseases.
- During the period of analysis, 17 of the 20 companies were active in R&D for COVID-19. A total of 63 projects for COVID-19 patients were in development.
- Over 70% (149/211) of the internationally identified R&D priorities for low- and middle-income countries remain unaddressed by the companies in scope. This includes maternal health conditions such as hypertensive disorders of pregnancy, and diseases such as Bunyaviral diseases,

several diarrhoeal diseases and sexually transmitted infections (STIs).

- The 2021 Index identified 440 projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are deemed by the Index to also offer a clear public health benefit for people living in low- and middle-income countries, e.g., projects aiming for heat stability or with clinical trials running in countries in scope.

Product Delivery

- Of the 757 marketed products analysed, 75% are medicines. More than half these products target non-communicable diseases, while few target neglected tropical diseases such as snakebite envenoming and trachoma. The majority of companies are patent holders of at least one medicine listed on the WHO EML.
- The countries in scope with the most registration filings mainly include upper-middle-income countries, such as Brazil and Thailand. The countries with the least filings include politically unstable countries, e.g., Somalia and South Sudan, or have small populations such as Tuvalu and Vanuatu.
- Access strategies with the biggest potential impact on access to medicine are strategies that aim to make products affordable for all patients across the income pyramid. The Index finds that many poorer countries still do not benefit significantly from pharma companies' access strategies.
- 19 companies report working in some form of a partnership to address supply challenges: e.g. collaborating with supranational partners to supply medicine, liaising with governments and purchasers on demand forecasting, and working with local distributors to tackle supply barriers.

2021 Access to Medicine Index

The 2021 Access to Medicine Index provides a finely detailed picture of how 20 of the world's largest pharmaceutical companies' take action to address access to medicine. The Index reports on these companies' access-related policies and practices based on an analysis of 33 indicators, concerning 106 low- and middle-income countries and 82 diseases, conditions and pathogens.

The Index is used as a tool for driving change in the pharmaceutical industry. It identifies best practice, tracks progress and shows where critical action is still needed. This first section of the report provides the core analyses of how the 20 companies in scope performed with the 2021 overall Index ranking, Key Findings, and two special reports on COVID-19 and pandemic preparedness, and a look at how the industry is improving in access to medicine.

INDEX RANKING

- Pharma companies inch forward in integrating access to medicine into business practices
- How the companies compare in 2021

KEY FINDINGS

- Eight companies adopt processes to ensure all new products are rapidly accessible in low- and middle-income countries
- Less than half of key products are covered by pharma companies' access strategies in poorer countries
- While R&D for COVID-19 has increased, other pandemic risks go unaddressed

SPECIAL REPORTS

- How are companies responding to COVID-19 and are they prepared for the next potential pandemic?
- Is the industry doing more to improve access to medicine?

INDUSTRY TRENDS

Pharma companies inch forward in integrating access to medicine into business practices

Pharmaceutical companies continue to inch forward when it comes to embedding access to medicine into business practices in low- and middle-income countries. There are signs of progress in how they are integrating access to medicine into governance structures, R&D processes and monitoring efforts. Yet efforts to address access to specific products still remain focused on a few countries.

The most notable progress is in planning ahead during R&D to make future products accessible: eight companies are developing approaches for systematically ensuring all R&D projects are paired with plans to increase access in poorer countries soon after launch (these have yet to be applied across late-stage projects). The industry has stepped up efforts to understand the outcomes of their access-related activities, and more companies are evaluating initiatives to build local capacity and strengthen health systems than in 2018. All 20 companies have now set specific goals and targets for improving access, and more companies are deploying business models that explicitly include people at the base of the income pyramid. There is also movement in responsible promotional practices, with three additional companies adopting rewards schemes that decouple sales agents' incentives from sales targets only (now 12 companies).

Nearly all companies have stepped up their efforts to strengthen local health and pharmaceutical capacity. Collectively, they have been engaging in more and better-quality initiatives to build R&D or supply chain capacities, or strengthen health systems, than in 2018. However, activities continue to focus on a subset of countries. Manufacturing initiatives are mainly focused on emerging markets such as China, India and Brazil, whereas supply chain and health system strengthening initiatives are mainly in sub-Saharan Africa.

When it comes to specific actions to improve access to individual products, there is less evidence of progress or good performance. Less than half of late-stage R&D projects are so far covered by an access plan, while efforts to improve access to existing products, for example through equitable pricing, voluntary licensing or product donations, remain limited to a narrow range of countries. Almost 42% of the 154 products analysed did not have evidence of access strategies in any of 106 countries in scope. Where products are paired with access strategies, low-income countries* are most consistently overlooked, despite being home to approximately 700

million people. The countries that are most often targeted are generally wealthier, namely Brazil, China, India and Mexico. Furthermore, there typically remains a large gap between the first time a product is registered anywhere, and its first registration in a low- or middle-income country. Voluntary licensing remains limited to a few products targeting a few diseases, such as HIV/AIDS and hepatitis C.

R&D dominated by cancers and COVID-19

As in 2018, a handful of diseases are the main focus of companies' R&D activity. Cancers dominate the pipeline for non-communicable diseases, accounting for more than two thirds of projects. Among infectious diseases, HIV and AIDS, tuberculosis and malaria once again receive most attention, with COVID-19 newly joining the group in 2020. These account for more than half of projects in the communicable disease pipeline. In the same period, projects targeting neglected tropical diseases decreased from 90 to 86, while R&D targeting maternal and neonatal health conditions such as neonatal sepsis and maternal haemorrhage increased, but only slightly, from 9 projects to 11, accounting for just 1% of R&D projects.

R&D targeting coronaviruses surged in 2020, from zero projects in 2018 to 63 projects, reflecting a clear and vigorous response to the COVID-19 pandemic. However, the other 15 emerging infectious diseases (EIDs) in scope receive very little R&D attention, despite being identified by WHO and Policy Cures Research as posing an epidemic or pandemic risk. The 20 companies are not developing any products for 10 of the 16 EIDs listed as priority.

As in 2018, a small group of companies account for the bulk of the R&D projects that the global health community considers a priority. GSK, Johnson & Johnson, Merck,* Eisai and Pfizer account for 56% of such projects. Looking beyond projects that target established priorities, the 20 companies are developing 440 R&D projects with evidence of offering a clear public health benefit to patients in LMICs, led by AstraZeneca, Bristol Myers Squibb and Johnson & Johnson.

*Low-income countries (LICs) as classified by the World Bank.

***Merck KGaA (Darmstadt, Germany)

2021 ACCESS TO MEDICINE INDEX – OVERALL RANKING

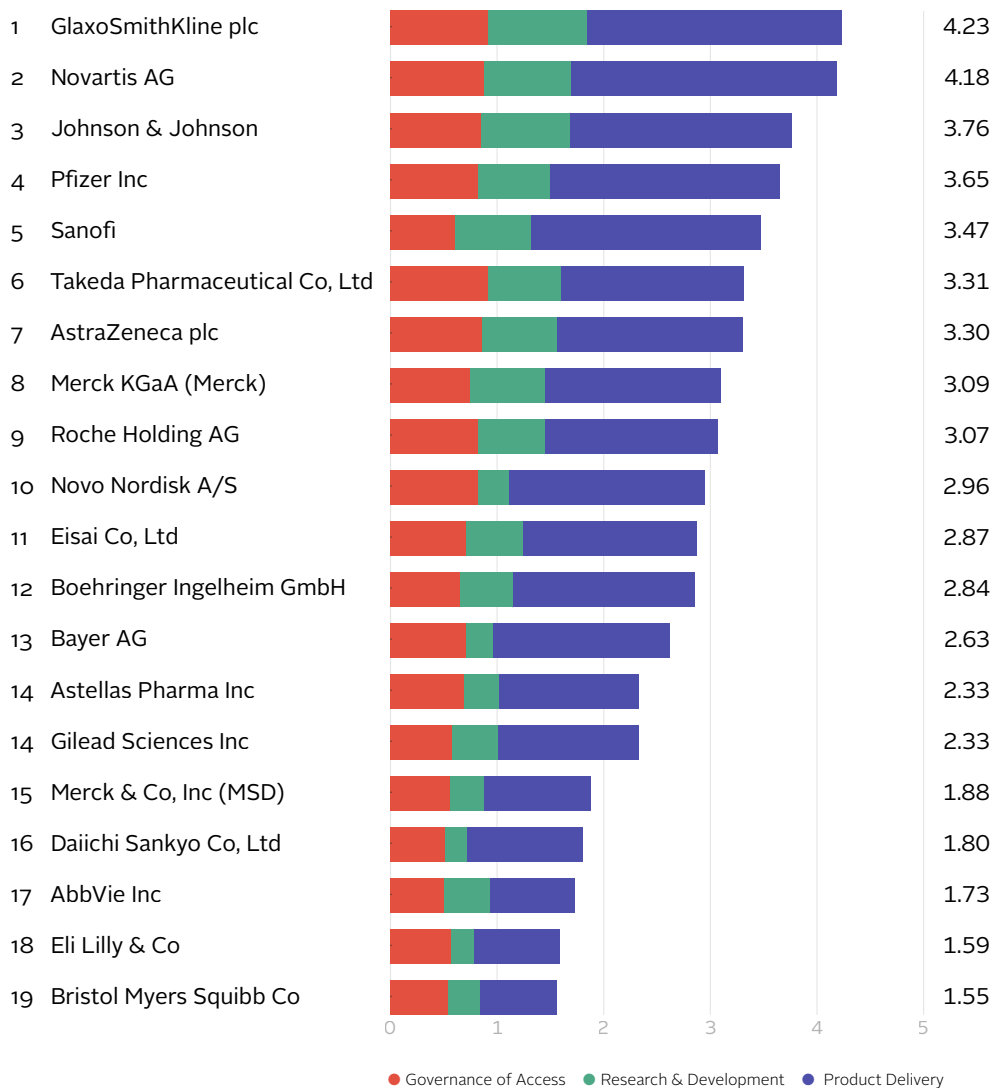


Figure 1

Pfizer joins top 5

GSK retains its number one position, yet only slightly ahead of Novartis. Pfizer moves into the top five. Johnson & Johnson and Sanofi complete the top five companies. Eight of the top ten companies, including the leaders, are setting a new best practice of systematic access planning during R&D.

Leaders match actions to specific needs

Leading companies perform well across all areas of measurement. They take a mature approach to managing access, addressing access to specific products in poorer countries as well as emerging markets. They are committed to R&D for global health priorities*** as well as needs of people in low- and middle-income countries.

Addressing access inches toward standard practice

There is progress in companies integrating access to medicine into governance structures, R&D processes, and monitoring efforts. Yet initiatives addressing access to specific products remain focused on a few products and countries.

2021 Index focuses on core role for pharma

Achieving the SDGs and UHC by 2030 means delivering health products to everyone in need, wherever they live. Success depends on pharma companies moving to systematically address access at all levels of the health system: from the level of the patient and healthcare professional; through infrastructure challenges; to regulatory systems.

***As defined by WHO and Policy Cures Research.

How the companies compare in 2021

GSK retains the No. 1 position, yet only slightly ahead of Novartis. Pfizer is new in the top 5. The two leaders are characterised by a mature approach for managing access to medicine that is integrated with their core businesses, and show strong commitment to R&D that targets global health priorities as well as the specific health needs of people living in low- and middle-income countries. They apply access strategies to specific products in poorer countries as well as in emerging markets, and aim to reach people living at different levels of the income pyramid. The middle-ranking companies fall into two categories; although they are all consistently good performers, some stand out by taking the lead in specific areas, while others miss out on a higher ranking due to their comparatively small R&D pipelines. The lowest-ranked group comprises five companies that show little transparency and perform poorly across all areas. Three of the five companies have yet to develop an overarching approach for their access activities.

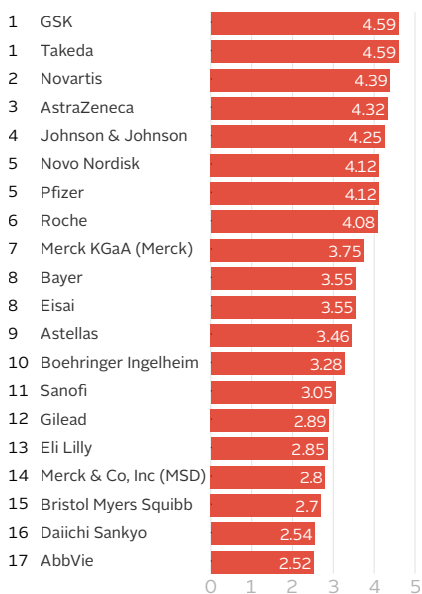
Two companies set a strong lead to follow

The top two companies, GSK followed by Novartis, are in close competition and are leading performers across the three main areas of measurement: governance of access, research & development and product delivery. For example, they implement equitable access strategies for the majority of products analysed, taking patients' ability to pay into account, and providing evidence that additional patients were reached through their access strategies. They continue to address local access barriers through capacity building initiatives, while evaluating the outcomes of their activities.

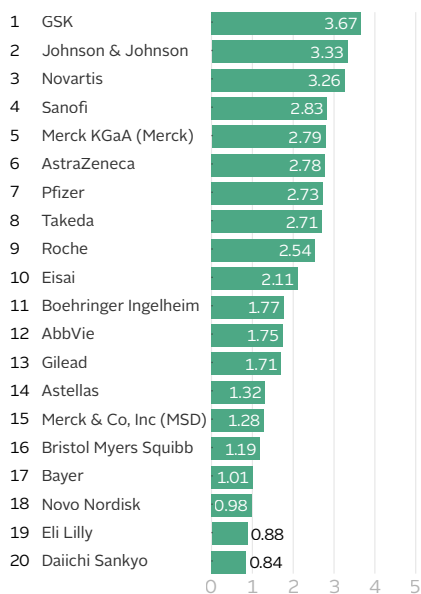
GSK has the largest pipeline of projects targeting established R&D priorities (81) and of late-stage projects covered by access plans (20/25). Novartis stands out for being the only company to apply equitable access strategies in at least one low-income country for all products assessed, as well as for implementing scalable and inclusive business models.

FIGURE 2. Rankings per Technical Area

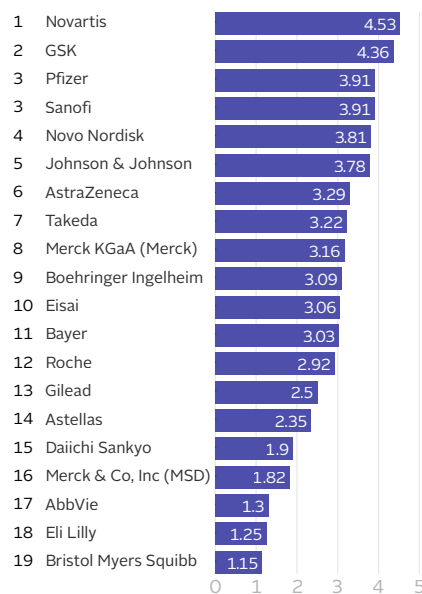
GOVERNANCE OF ACCESS



RESEARCH & DEVELOPMENT



PRODUCT DELIVERY



Close competition among high-ranking group

The companies ranked 3rd to 9th compete closely in multiple areas. They have all incorporated access-to-medicine across the different areas of their businesses, with an access-to-medicine strategy that is linked to a business rationale. The majority are also implementing structured processes for developing access plans during R&D. With the exception of **Pfizer**, however, these companies do not keep pace with the two leaders when it comes to taking a patient's ability to pay into consideration.

Johnson & Johnson leads this group in 3rd place. It has a robust set of compliance controls to safeguard its governance efforts, performs well in capacity building, and has access plans in place for a relatively large proportion of its relevant R&D (79% of late-stage projects). **Pfizer** follows in 4th and newly in the top five, applying access strategies to the majority of products analysed. It leads in addressing access to self-administered products across different regions and socio-economic groups, demonstrating increases in patient reach. Together with **Sanofi** in 5th, these two companies perform well in capacity building for manufacturing, supply and health system strengthening. Sanofi is also notable for its strong performance in product donations.

Takeda in 6th performs particularly well in equitable access strategies for health-care practitioner administered products and access planning. It falls behind in areas such as product registration, local manufacturing and product donations. **AstraZeneca** in 7th is a leader in its approach to intellectual property management, committing to not enforce patents in most Least Developed Countries, low-income countries, and a subset of lower-middle income countries and upper-middle income countries, as well as disclosing patent status for its products in scope. **Merck*** takes 8th place, with a relatively large R&D pipeline, and strong involvement in IP-sharing agreements and donation programmes. However, it misses opportunities to improve access to products in lower-middle and low-income countries, as does **Roche**, which closes the group in 9th place. Roche has scaled up its Global Access Programme, a long-running inclusive business model now running in 82 countries and covering four additional infectious diseases.

Lower-middle group have small pipelines in common

The companies ranked 10th to 14th have small R&D pipelines targeting the diseases in scope. **Novo Nordisk** in 10th also has equitable pricing strategies for the products analysed, and has launched a new demand planning platform to prevent shortages and stockouts, which includes both commercial

sales and humanitarian sales. Following closely behind are **Boehringer Ingelheim** and **Eisai**, with average performances across all areas. **Boehringer Ingelheim** has increased the coverage of access plans across its late-stage pipeline, and has launched In Reach Africa to strengthen NCD care in Kenya. **Eisai** maintains its strong performance in product donations, and remains committed to eliminating lymphatic filariasis. **Bayer** (13th), **Gilead** (14th) and **Astellas** (14th) all have at least one R&D project that targets a priority and is covered by an access plan. **Bayer** has taken concrete steps to improve the accessibility of products analysed, filing to register the majority of its most recently approved products in priority countries. It has also begun publishing patent statuses and disclosed a new commitment not to enforce patents in all low-income countries. **Astellas** is one of the few companies in scope not to have applied its access-to-medicine strategy across its business, yet it does set access-related incentives for its CEO.

Poor performances from lowest-ranking companies

The tail is populated by five companies that place in the bottom quartile in the three main areas of measurement due to poor performance: **MSD[†]** (15th), **Daiichi Sankyo** (16th), **AbbVie** (17th), **Eli Lilly** (18th); **Bristol Myers Squibb** (19th). **AbbVie**, **Bristol Myers Squibb**, **Eli Lilly**, **Gilead** and **MSD** are among the least transparent companies in scope, choosing not to disclose information across a range of issues, nor to make relevant information available in the public domain. With the exception of **Bristol Myers Squibb**, they did however continue to engage with the Index on specific data points, with **AbbVie** and **Gilead** disclosing additional details not already in the public domain.

Together with **Astellas**, **AbbVie** and **Daiichi Sankyo** are the only companies in scope of the Index that do not have an access-to-medicine strategy linked to a business rationale. **Bristol Myers Squibb** takes the bottom rank. Since 2018, **Bristol Myers Squibb** has narrowed its global health focus by leaving many areas in the infectious disease product development space.

*Merck KGaA (Darmstadt, Germany)

†Merck & Co., Inc (Kenilworth, NJ, United States).

KEY FINDING 1 – R&D

Eight companies adopt processes to systematically address access to medicine for all new products

Eight companies are taking the lead in integrating systematic access planning into their development processes. They are developing structured approaches for pairing each R&D project with a plan for rapidly ensuring people living in low- and middle-income countries gain access soon after the first global launch.

This represents a significant expansion in good practice since the previous Index, when Novartis was noted as the first to begin mainstreaming access planning across its pipeline. Joining Novartis in 2021 are AstraZeneca, GSK, Johnson & Johnson, Merck*, Pfizer, Sanofi and Takeda, comprising 40% of companies in the Index. Advance planning during the late stages of clinical development can accelerate the speed at which new products become accessible to people living in low- and middle-income markets. For example, Pfizer's new approach stipulates that planning for access begins two years before a product is launched.

An access plan can comprise a range of activities, from prioritising countries with the highest disease burdens during registration, to strengthening supply chains to ensure all populations gain fair access. Access planning enables companies to pursue a sustainable presence in low- and middle-income countries, by balancing commercial interests with their responsibility to support efforts to provide equitable access. The demand for access planning is gaining momentum among global health actors, including the World Health Organization, which is developing access planning principles to accompany its list of priority R&D targets.

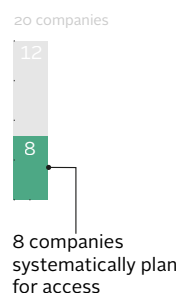
In 2021, the Index examined to what extent 20 of the world's largest pharmaceutical companies are engaging in access planning during clinical trial phases II and III. It examined projects that target 82 diseases, conditions and pathogens that impose a high or disproportionate burden in low- and middle-income countries. It looked for access

plans such as registration filings, equitable pricing schemes or voluntary licensing arrangements.

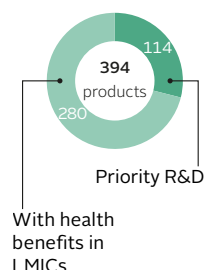
Systematic approaches yet to close gap in access planning

While the systematic approach is starting to become mainstream, not all late-stage R&D projects are yet supported by an access plan. To date, GSK goes furthest, covering 80% of its relevant projects with access plans, followed by Johnson & Johnson, Pfizer, Takeda, Novartis and Sanofi.

Companies' engagement in R&D and access planning is driven by clear priorities or demand from global health stakeholders. The 20 companies have 394 projects in late-stage development that target either established global health priorities (114) or offer benefits to people living in low- and middle-income countries (280). The first category comprises projects that target diseases or specific product gaps that global health stakeholders have already established as an R&D priority. These reflect global priorities such as coronavirus, malaria, tuberculosis and HIV, and are commonly the focus of public-private Product Development Partnerships (PDPs) or other donor-supported initiatives. For such projects, many PDPs systematically require advance access planning. The second category comprises projects that, based on the Index's criteria**, would constitute a clear health benefit for people living in low- and middle-income countries but have not been the focus of large donor-supported initiatives or R&D prioritisation initiatives. In such cases, companies can still develop advance access plans, whether or not a public-sector partner requires it. Overall, 59% of the projects in the priority R&D category, and only 31% of those in the second category, have evidence of an access plan.



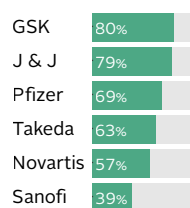
394 late-stage projects



59% of priority R&D projects are supported by access plans

31% of R&D projects with benefits for LMICs are supported by access plans

Top 6 companies with access planning



R&D projects with access plans

* Merck & Co, Inc (Kenilworth, NJ USA)

† Merck KGaA (Darmstadt, Germany)

What does systematic access planning look like?

- **ViiV Healthcare**, majority owned by **GSK** with **Pfizer** and **Shionogi**, develops access plans for all projects once Phase II trial results are positive.
- **Novartis** aims to have the access planning process for all new products underway by phase II of development. The company's approach is outlined in its Access Principles, with a focus on needs-based R&D, medicines affordability and on contributing to health system strengthening.**
- **Pfizer** has expanded its access planning processes during development from vaccines to all products, and launched a global pricing and access strategy, initiating access planning for all products across markets at least two years pre-launch. Each plan is finalised well in advance of launch. Access plans include guidance on equitable pricing, as well as innovative arrangements and approaches that support broad access and affordability.

FIGURE 3. Eight companies are moving to make access planning mainstream

In 2018, Novartis was the only company in the Index to be developing a systematic approach to access planning. Now eight companies are making such moves: these are AstraZeneca, GSK, Johnson & Johnson, Merck*, Novartis, Pfizer, Sanofi and Takeda.

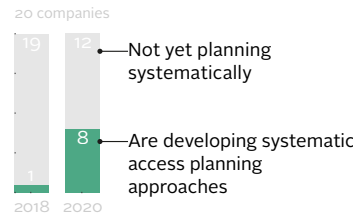
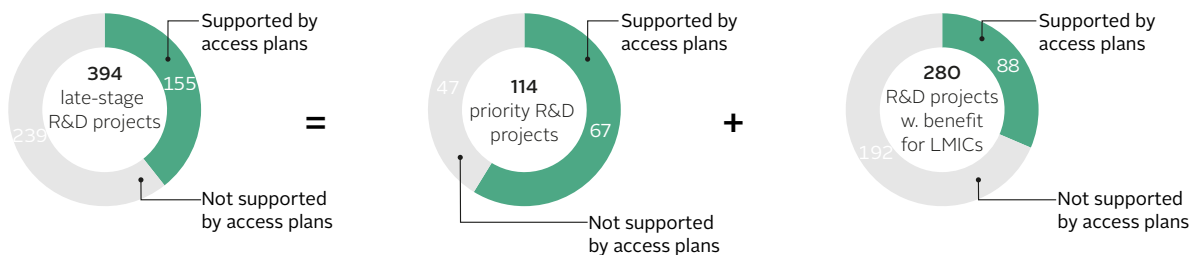


FIGURE 4. Majority of late-stage R&D projects are not supported by access plans

The 20 companies in scope have 394 R&D projects in late-stage development that either target established global health priorities or offer clear public health benefits for low- and middle-income countries. The majority of these are not yet supported by an access plan.



WHAT NEXT?

An opportunity for pharma industry to become driver for access

The Index concludes that, as access planning does not yet cover even half of late-stage projects, it is encouraging that eight companies are integrating access planning fully into their development processes, including for projects without donor involvement. This signals that access planning should begin to increase as more projects enter later clinical phases and could become standard across the industry. To have maximum impact, access plans should have a broad geographic focus, explicitly aiming to reach the majority of people affected by a disease or in need of a vaccine or new diagnostic tool.

If this happens, people living in low- and middle-income countries, especially resource-limited settings or remote areas, will no longer need to be last in line for pharmaceutical innovations, which is key for achieving universal health coverage (UHC). Pharmaceutical companies can become a main driver for rapid access to innovative health products in low- and middle-income countries. This shift could be accelerated if donors that focus on areas of R&D that are not yet prioritised for global health, such as cancer and diabetes, stimulate early access planning for the projects they support.

KEY FINDING 2 – ACCESS TO PRODUCTS

Less than half of key products are covered by pharma companies’ access strategies in poorer countries

Many of the world’s poor countries still do not benefit significantly from access strategies being implemented by the world’s largest pharmaceutical companies. The 2021 Access to Medicine Index shows that less than half of key products controlled by 20 large companies are being offered through access strategies in countries classified by the World Bank as either lower-middle income countries (LMICs) or low-income countries (LICs). The shortfall is particularly acute in LICs, which are most consistently overlooked by companies despite being home to almost 700 million people. The Index looked at 199 medicines, vaccines, diagnostics and vector control products. These constituted those products that are considered essential for a well-functioning healthcare system and for which large companies hold a controlling position regarding access – determined either through patents or their dominance of the market. In such situations, the responsibility is with companies to facilitate access through measures such as equitable pricing, voluntary licensing and, for the most vulnerable populations, through product donations.

Low coverage across product categories

Currently, only 13% of critical products (8/60) that need to be administered by healthcare professionals (HCPs) – including, for example, injectable treatments for cancer – are covered by access strategies in at least one LIC. For self-administered medicines – which are often pills – the figure is 26% (24/94; see Figure 5, next page).

In LMICs, these proportions jump, to 42% (25/60) for HCP-administered products and 43% (40/94) for self-administered ones (see Figure 5, next page). Further up the income ladder, the picture is better, with approximately half of products covered by an access strategy in at least one upper middle income country (UMIC). Worryingly, however, 42% of the HCP-administered and self-administered products analysed did not have

evidence of access strategies in any of 106 countries in scope (64/154 products in total). This reveals a widespread lack of consideration for how people living in these countries will gain access to these products, which are largely controlled by the companies in question.

Products that are procured through international agreements, where governments pool their purchasing power, are best served by access strategies. LICs are typically covered by international agreements, driven by organisations such as Gavi, the Vaccine Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria. Further, four out of five of these products are also offered by the companies to countries outside of these agreements on pro-access terms.

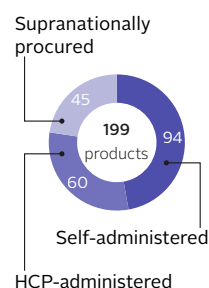
How far do access strategies reach?

Data on the extent to which access initiatives helped medicines reach more patients was supplied by 11 of the 20 companies, and covers only a few products. This suggests a gap in knowledge and transparency in how to reach the millions of people without access to medicine.

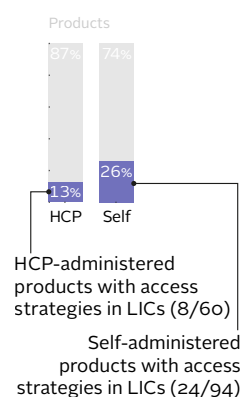
In all cases, the greatest reach is achieved in UMICs. Among HCP-administered medicines, the numbers of people who benefited from access strategies for oncology treatments ranges between 100 and 31,000 patients, while for asthma it is 100 to 10,000, and for ischaemic heart disease and stroke less than 100 to 238,000. Access strategies for self-administered therapies reach more patients – ranging from 100 to approximately 1.65 million in the case of diabetes and 1,000 to 70,000 for hypertensive heart disease.

The examples of access strategies captured in this analysis clustered around the same emerging markets, particularly China, Brazil and Mexico. Among LMICs, the examples cluster around India, Philippines and Egypt. Among LICs, Uganda, Ethiopia and Nepal stand out from a much thinner

199 key products controlled by pharma companies



Few access strategies target LICs



† Merck & Co, Inc (Kenilworth, NJ USA)
‡ Merck KGaA (Darmstadt, Germany)

line-up.

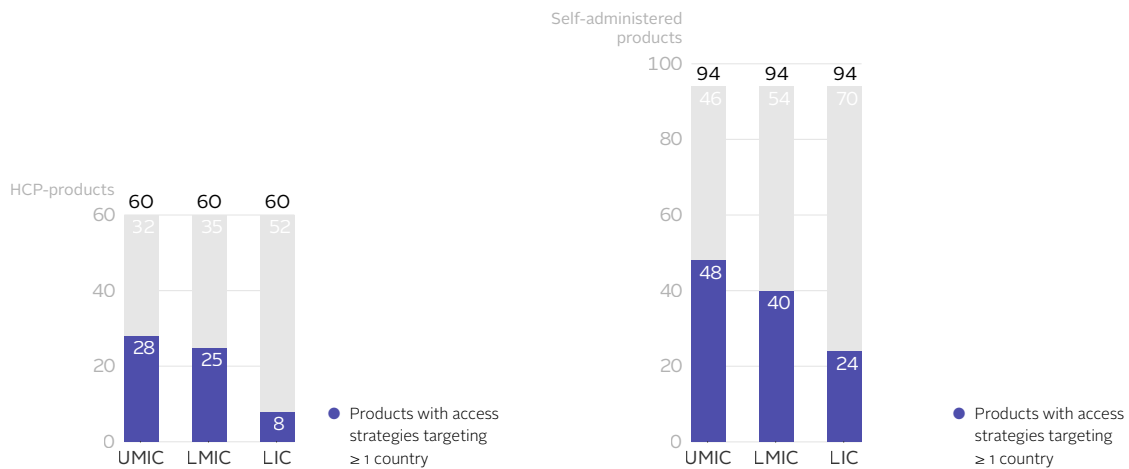
Which companies stand out?

A few companies stand out for their consistent use of access strategies across the products analysed. These include Novartis, which exhibits leading practice across HCP- and self-administered products, as well as those procured at a supranational level by organisations such as UNICEF and Global Fund. Other stand-outs identified in the Index include Pfizer, for self-administered

products; Takeda for HCP-administered products; and GSK, Johnson & Johnson and Sanofi for supranational products. The majority of the HCP-administered products with access strategies (78%) are also supported by capacity building, although once again those initiatives largely overlook LICs. For most of these products, specialist capacities, expertise or equipment is needed to make the diagnosis, select the right treatment and monitor outcomes and side effects.

FIGURE 5. Low-income countries are most consistently over-looked by access strategies

Low-income countries are most consistently overlooked by pharmaceutical companies' access strategies, particularly for products that need to be administered by healthcare practitioners.



WHAT NEXT?

Robust strategies with wide geographic scope are key to improving access at scale

A lot more still needs to be done. Solving the access to medicine problem is fundamentally a question of taking action at scale: industry needs to reach more people with more products across a wider range of the world's poorest countries. Current industry access arrangements do not go far enough, and many of the world's most vulnerable patients are still not receiving the life-saving medicines they need, especially in LMICs and LICs. Future strategies need to be more transparent and cover a wider range of countries, people and treatments. While a 10-year analysis of Index trends published in 2019 found there had been an increase in access and affordability strategies by pharma companies, it is clear that progress is still only gradual. For example, many companies

remain reluctant to enter into voluntary licensing arrangements, even for countries where they do not have a presence. Such licensing agreements currently remain confined to medicines for HIV and AIDS, hepatitis C, and now COVID-19. Since 1977, the World Health Organization has worked with more than 150 LICs and LMICs to develop Essential Medicines Lists (EMLs) – vital tools for ensuring universal health coverage, which is one of the UN's Sustainable Development Goals. However, access to many of the newer and more expensive products on these lists will ultimately be determined in large part by industry action, underscoring the need for pharma companies to expand their use of access strategies to more products and countries.

KEY FINDING 3 – COVID-19

R&D for COVID-19 has increased, yet other pandemic risks go unaddressed

Despite years of warnings that novel coronaviruses were among the pathogens most likely to cause a global health emergency, the pharmaceutical industry, as well as society at large, was ill-prepared for the COVID-19 pandemic. In the period before the start of the pandemic, R&D pipelines targeting pathogens most likely to cause a pandemic were largely empty. However, after the pandemic hit, the portfolio of experimental drugs and vaccines to treat coronavirus filled up – while the R&D effort by 20 of the world’s largest pharmaceutical companies into other priority emerging infectious diseases (EIDs) remains alarmingly low.

The need for greater preparedness against specific global disease outbreaks has been apparent since at least 2016, when the World Health Organization (WHO) published its R&D Blueprint for Action to Prevent Epidemics. Yet out of 16 pathogens identified by the WHO and Policy Cures Research as posing a pandemic or serious epidemic risk, the Index shows that the companies examined have R&D projects against just six of them. The vast majority of these projects – 63 out of 76 – are recent additions to treat or improve outcomes for patients with COVID-19. In 2018, the Index found zero R&D projects targeting coronaviruses.

Research activity is at an extremely low level even for the few cases where there is work being done, such as the mosquito-borne chikungunya virus that has spread rapidly in recent years, including across the Americas, Africa and in India. From the companies in scope, there are just 13 R&D projects across five non-coronavirus diseases and zero for the remaining ten. Those ten diseases also had empty pipelines in 2018.

Research activity against EIDs is concentrated among a few companies. In 2020, 17 companies are targeting coronavirus. Nine companies are targeting other EIDs: Bayer, Boehringer Ingelheim, Eisai, Gilead, Johnson & Johnson, MSD,[†] Merck,[‡] Roche and Takeda. These diseases could be the next ones to cause death rates to spike and to stall the global economy. They matter more than ever

in today’s inter-connected world that presents viruses with heightened opportunities to spread at the speed of a jet plane, increasing the risk of future pandemics.

Large pharma companies’ respond to COVID-19
Large research-based pharmaceutical companies have a critical role to play in preparing for the next pandemic. While academic groups and small biotech companies can pioneer new research ideas, big companies are essential in ensuring rapid development and access to vaccines, therapeutics and diagnostics, including providing the capacity for scaled-up manufacturing and global distribution without disrupting supply chains leading to shortages and stock-outs.

Many large companies have moved to fulfil this role in response to COVID-19, helping to facilitate the development and deployment of vaccines in record time. However and to a large extent, this industry only mobilised against COVID-19 once it became clear that the outbreak affected rich as well as poor countries, thereby opening up the possibility of substantial recurring pharmaceutical revenues. Yet, not all pandemics lead to the creation of such a substantial market for new products. Without sustained commitment by large pharmaceutical companies to pandemic preparedness, the world will remain worryingly vulnerable to pandemics and epidemics, particularly those that mainly affect low-income countries.

Few projects suitable for resource-limited settings

The COVID-19 pandemic has seen a range of responses by pharmaceutical companies. Apart from for projects developed within the Access to COVID-19 Tools (ACT) Accelerator, there was little evidence in the first months of the pandemic response of structures for ensuring access to COVID-19 vaccines and treatments in poorer countries. By June 2020, only seven out of 24 late-stage coronavirus projects analysed (Phase II or III) were covered by an access plan, such as a licensing agreement or pricing commitment.

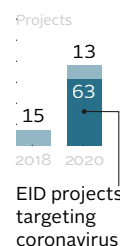
Empty pipelines for 10 emerging infectious diseases



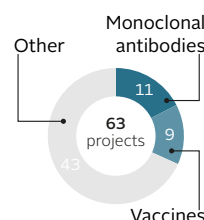
Chikungunya hotspots in 2020

| Country | Cases |
|----------|--------|
| India | 22,587 |
| Chad | 38,633 |
| Colombia | 158 |
| Thailand | 10,397 |
| Malaysia | 2,374 |

Increase in EID R&D concentrates on coronaviruses



9 vaccines for COVID-19 in the pipeline



[†] Merck & Co, Inc (Kenilworth, NJ USA)

[‡] Merck KGaA (Darmstadt, Germany)

Out of 63 projects, only five are antivirals, nine are vaccines, and 11 are antibody-based treatments. Amongst the projects, there are several existing medicines that are repurposed for COVID-19 patients. Unfortunately, many of the non-vaccine products in development will be challenging for low- and middle-income countries to get to patients, either due to their comparatively high

cost or because of technical requirements – for example, monoclonal antibodies that need to be administered by sterile infusion, may need monitoring and require highly specialised health workers and sophisticated diagnostics. Some vaccines, too, are less suitable for resource-poor settings because of their high cost and the need for ultra-cold storage.

FIGURE 6. Pharmaceutical companies are not targeting priority pathogens with epidemic potential through R&D

Excluding coronaviruses, pathogens with pandemic potential where pharma companies are active in R&D show very small pipelines in 2020. Out of 16 pathogens, 10 have empty pipelines.

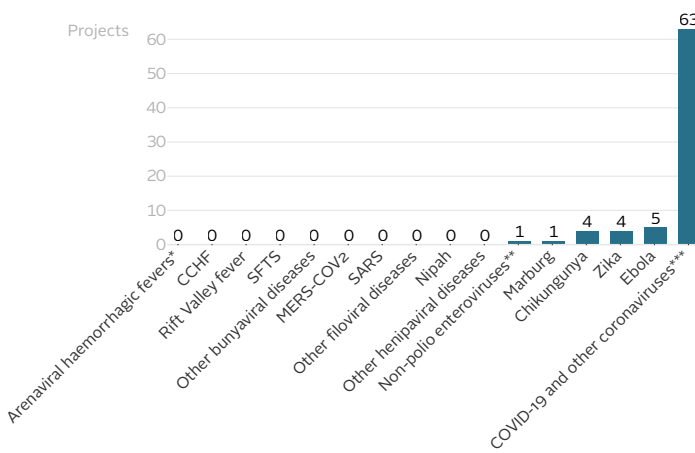


FIGURE 7. Are companies preparing for a future pandemic?

This figure shows the number of R&D projects and companies targeting diseases identified by WHO and Policy Cures Research as emerging infectious diseases, and how this has changed since 2018.

| Disease flagged as an epidemic/pandemic risk | R&D projects | | Active companies | |
|---|--------------|------|------------------|------|
| | 2018 | 2020 | 2018 | 2020 |
| Arenaviral haemorrhagic fevers (incl. Lassa fever) | 0 | 0 | 0 | 0 |
| Chikungunya | 3 | 4 | 3 | 4 |
| Crimean-Congo haemorrhagic fever | 0 | 0 | 0 | 0 |
| Ebola | 7 | 5 | 5 | 4 |
| Emergent non-polio enteroviruses (including EV71, D68) | 1 | 1 | 1 | 1 |
| Marburg | 1 | 1 | 1 | 1 |
| Middle East resp. syndrome coronavirus (MERS-CoV) | 0 | 0 | 0 | 0 |
| Nipah | 0 | 0 | 0 | 0 |
| Other bunyaviral diseases | 0 | 0 | 0 | 0 |
| Other filoviral diseases | 0 | 0 | 0 | 0 |
| Other henipaviral diseases | 0 | 0 | 0 | 0 |
| Other highly pathogenic coronaviral dis. (incl. COVID-19) | 0 | 63 | 0 | 17 |
| Rift Valley fever | 0 | 0 | 0 | 0 |
| Severe acute respiratory syndrome (SARS) | 0 | 0 | 0 | 0 |
| Severe fever with thrombocytopenia syndr. (SFTS) | 0 | 0 | 0 | 0 |
| Zika | 3 | 4 | 3 | 4 |

WHAT NEXT?

Prepare for the next pandemic through EID R&D and broader use of IP-sharing and other tools

Arrangements for preparing for and preventing future pandemics exist but are precariously positioned, due in part to weak engagement by the research-based pharmaceutical industry. The lesson of COVID-19 is that pandemic preparedness requires a robust and diverse range of private and public sector entities to engage in research against EIDs. This must include companies that can accelerate the passage of products through clinical development and approval, and manufacture and supply at global scale without disrupting existing activities. Vaccines take at least a year to develop, even at an accelerated pace. R&D targeting EIDs must begin before epidemics break out, for example to develop platform technologies or to share IP to accelerate discovery-stage R&D.

The Index shows that, before COVID-19 struck, there was very little engagement in EID research by large pharmaceutical companies, despite clear prioritisation by WHO and others. Incentives for pharmaceutical companies to engage were

limited, as many EIDs offered little in terms of commercial prospects, such as Ebola, Zika, dengue fever and malaria. To counter this in-built reluctance to engage, there are organisations such as the Coalition for Epidemic Preparedness Innovations (CEPI) focused on developing vaccines, Gavi, the Vaccine Alliance, to enable sustainable vaccine markets, and the Access to COVID-19 Tools (ACT) Accelerator, which includes IP-sharing, launched by WHO and partners.

Ending a pandemic requires suitable products to be developed and fairly distributed so that people in low- and middle-income countries are not last in line or left behind altogether. The lag in access planning, despite hefty public funding for much R&D, suggests that pharmaceutical companies must do more: demonstrate a sustained commitment to invest more in EID R&D; embed equitable distribution into their strategies; and show greater flexibility on sharing intellectual property.

* Including Lassa Fever
** Including EV71, D68

*** Other highly pathogenic coronaviral diseases (incl. COVID-19). Includes products that are being repurposed to improve patient outcomes.

CCHF: Crimean-Congo haemorrhagic fever
SFTS: Severe fever with thrombocytopenia syndrome
MERS-COV2: Middle East respiratory syndrome coronavirus
SARS: Severe acute respiratory syndrome

SPECIAL REPORT: COVID-19 AND PANDEMIC PREPAREDNESS

How are companies responding to COVID-19 and are they prepared for the next potential pandemic?

COVID-19 has exposed gaps in the current health and pharmaceutical systems. There continues to be a heavy dependency on donors to sustain access mechanisms and an increasing reliance on only a few large pharmaceutical companies to ensure supply. This is mainly due to the lack of local manufacturing capacity and the preoccupation of some pharmaceutical companies with high profit margins, particularly within the US market, which limits their ability to play a vital role in curbing this pandemic globally.

Prior to 2020, there had been little engagement in emerging infectious disease research and only a handful of large companies remain in the development of new antibiotics.

Despite rapid action from some companies in response to the COVID-19 pandemic, the fragility of the industry is troubling when it comes to halting the pandemic. Actions are concentrated amongst few players, repeating a pattern as shown by our research into the pharmaceutical companies' responses to global health priorities.

A larger group of companies is needed, both to address the health needs of COVID-19 patients and to prepare for the next pandemic. Companies still have an important role to play in sharing their expertise and intellectual property, contributing manufacturing capacity and securing supply and affordability of their products.

This section describes how some companies responded to COVID-19 across the following areas and shed light on what is needed from the industry to prepare for the next potential pandemic:

- 1 Research & Development
- 2 Intellectual Property (IP) sharing
- 3 Patents and licensing
- 4 Supply
- 5 Health systems
- 6 Conclusions and next steps

RESEARCH & DEVELOPMENT

R&D targeting COVID-19

During the period of analysis*, 17 of the 20 companies in the scope of the Index were active in R&D for COVID-19 patients. They had a total of 63 projects in their pipelines for COVID-19 patients. Of these, only five are antivirals, with nine vaccines and 11 antibody-based treatments. The rest aim to repurpose existing medicines for COVID-19 patients. Prior to the COVID-19 outbreak, no companies were conducting R&D on coronaviral diseases. While there are products being developed for treating COVID-19 patients, there was little evidence for structures for ensuring access to these products in low- and middle-income countries. Seven out of 24 late-stage coronavirus projects

analysed (Phase II or III) were covered by an access plan, such as a licensing agreement or pricing commitment.

The Index has assessed R&D projects targeting 16 diseases identified by WHO and Policy Cures Research as emerging infectious diseases (EIDs), including coronaviruses such as COVID-19.^{1,2} Such diseases pose the greatest public health risk due to their epidemic potential and/or because there are insufficient or no countermeasures. The majority of these diseases are unaddressed, with no companies involved in R&D for 10 of the 16 emerging infectious diseases identified.

9 vaccines for COVID-19 in the pipeline

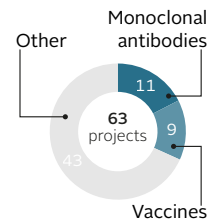


FIGURE 8. 17 companies in the Index are developing medicines and vaccines for COVID-19**

GSK has most COVID-19 projects in the pipeline (16), including two monoclonal antibodies and one vaccine.

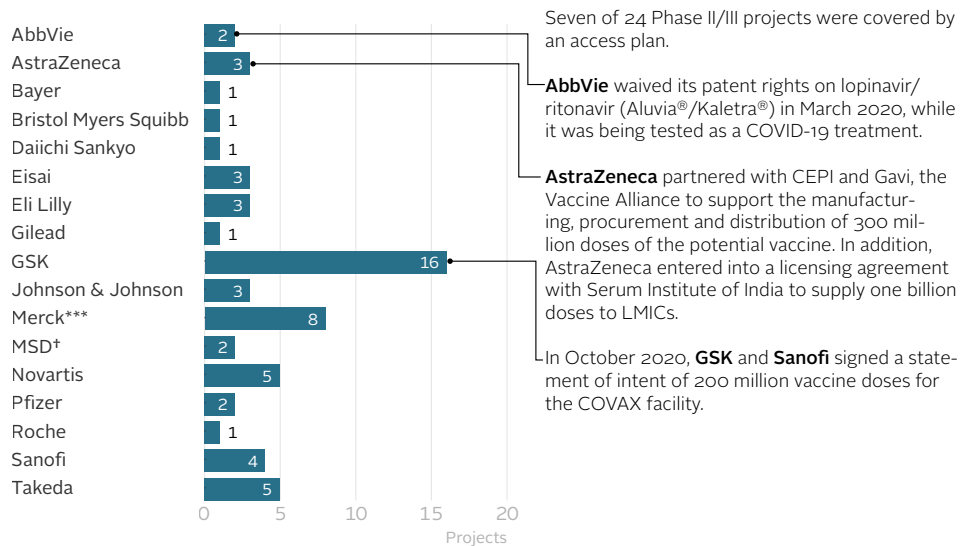


FIGURE 9. Are companies preparing for a future pandemic?

This figure shows how many R&D projects target 16 diseases identified by WHO and Policy Cures Research as emerging infectious diseases (EIDs).^{1,2} Such diseases pose a public health risk due to their epidemic potential and/or because there are insufficient or no countermeasures. The figure shows that there is little engagement in epidemic or pandemic preparedness as the majority of EIDs (10/16) are unaddressed by the companies in scope.

| Disease flagged as an epidemic/pandemic risk | R&D projects | | Active companies | |
|---|--------------|------|------------------|------|
| | 2018 | 2020 | 2018 | 2020 |
| Arenaviral haemorrhagic fevers (incl. Lassa fever) | 0 | 0 | 0 | 0 |
| Chikungunya | 3 | 4 | 3 | 4 |
| Crimean-Congo haemorrhagic fever | 0 | 0 | 0 | 0 |
| Ebola | 7 | 5 | 5 | 4 |
| Emergent non-polio enteroviruses (including EV71, D68) | 1 | 1 | 1 | 1 |
| Marburg | 1 | 1 | 1 | 1 |
| Middle East resp. syndrome coronavirus (MERS-CoV) | 0 | 0 | 0 | 0 |
| Nipah | 0 | 0 | 0 | 0 |
| Other bunyaviral diseases | 0 | 0 | 0 | 0 |
| Other filoviral diseases | 0 | 0 | 0 | 0 |
| Other henipaviral diseases | 0 | 0 | 0 | 0 |
| Other highly pathogenic coronaviral dis. (incl. COVID-19) | 0 | 63 | 0 | 17 |
| Rift Valley fever | 0 | 0 | 0 | 0 |
| Severe acute respiratory syndrome (SARS) | 0 | 0 | 0 | 0 |
| Severe fever with thrombocytopenia syndr. (SFTS) | 0 | 0 | 0 | 0 |
| Zika | 3 | 4 | 3 | 4 |

* 1 June 2018 - 31 May 2020

** Some of the 63 projects identified for COVID-19 are not included in this figure as the companies responsible have not given permission for them to be disclosed.

*** Merck KGaA, Darmstadt, Germany

† Merck & Co., Inc., Kenilworth, NJ USA

INTELLECTUAL PROPERTY (IP) SHARING

Sharing IP to accelerate COVID-19 R&D

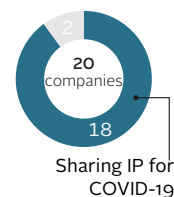
The Index also examines whether companies share intellectual property (IP) assets with other researchers under terms designed to improve access to medicine. By sharing assets such as compound libraries, proprietary processes or technologies, companies can speed up the development of much needed new products.

In response to COVID-19, certain tools were created to accelerate R&D. Listed in Table 1 are IP sharing platforms in which companies participated during the period of analysis.

Eighteen companies reported sharing IP assets with third-party researchers for COVID-19 research: AbbVie, Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, MSD,

Merck, Novartis, Pfizer, Roche, Sanofi and Takeda. However, companies are not involved in such platforms for all the other emerging infectious diseases identified.

In addition to COVID-19, companies mainly engage in IP-sharing agreements for HIV/AIDS, malaria, tuberculosis and neglected tropical diseases (NTDs). Like COVID-19, R&D and access to these areas are largely financed through public funding. None of the IP sharing agreements or platforms are designed to deal with the wide range of emerging infectious diseases threatening to cause the next pandemic. There is a need to expand beyond the existing focus of IP sharing agreements to improve preparedness for a potential future pandemic.



Merck engages in most IP sharing for COVID-19

TABLE 1. Which companies are participating in IP sharing platforms and partnerships for the treatment of COVID-19?* This chart show the various tools and platforms used by the 18 companies in scope to share assets such as compound libraries, proprietary processes or technologies, to speed up the development of COVID-19 treatments.**

| Initiatives to share IP | Companies |
|--|---|
| The Access to COVID-19 Tools (ACT) Accelerator | Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, MSD, Merck, Novartis, Pfizer, Sanofi |
| WHO Solidarity Trial | Merck |
| INSERM Discovery Trial | Merck |
| Corona Accelerated R&D in Europe – IMI 2 CARE Actions | AbbVie, Astellas, Bayer, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis, Pfizer, Takeda |
| NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) | AbbVie, AstraZeneca, Bristol Myers Squibb, Eli Lilly, GSK, Johnson & Johnson, MSD, Novartis, Pfizer, Roche, Sanofi, Takeda |

Merck has provided interferon beta-1a (Rebif®) to WHO for use in its global SOLIDARITY trial and to the INSERM Discovery Trial. Merck has committed not to enforce patents on Rebif® against WHO and INSERM partners, if it proves to be a safe and effective treatment.

*This table reflects the companies that are engaging in sharing IP assets for COVID-19 during the period of analysis (1 June 2018 - 31 May 2020).

**One additional IP sharing initiative was disclosed by two companies under confidentiality.

** More companies joined the Access to COVID-19 Tools (ACT) Accelerator after the period of analysis ended (31 May 2020)

Responsible IP management to boost access

Once a medicine or vaccine is approved for the treatment or prevention of COVID-19, companies have the responsibility to ensure that these treatments reach the populations in need. A rising concern amongst countries is that once a treatment or vaccine is approved for sale, the availability and accessibility will be limited. In October 2020, India and South Africa called upon the World Trade Organization (WTO) to allow countries to neither grant nor enforce patents and other IP rights to COVID-19 medicines, vaccines, diagnostics and other technologies for the duration of the pandemic.

Case in focus: licensing of lopinavir/ritonavir (Aluvia®/Kaletra®) and remdesivir (Veklury®)

In March 2020, it was announced that AbbVie would waive its global patent rights on lopinavir/ritonavir (Aluvia®/Kaletra®), an HIV medicine, which was being tested as a COVID-19 treatment. With this move, it became the only research-based pharmaceutical company to open the market for more producers of this treatment to enter the market.

In May 2020, Gilead signed a non-exclusive voluntary licensing agreement for remdesivir (Veklury®) with generic medicine manufacturers in Egypt, India and Pakistan to further expand its supply. The licence allows the generic

medicine manufacturers to manufacture remdesivir (Veklury®) for distribution in 127 countries, covering nearly all LMICs. However, several countries, including China, Brazil, Peru, Bolivia, Colombia, Ecuador, Paraguay and Mexico, are left out of the licensing agreement. When countries are not included in a licence agreement, the company must still ensure sufficient supply of the product to all segments of the population of these countries.

In 2020, WHO extended an invitation to manufacturers of therapeutics against COVID-19 (such as dexamethasone by GSK and remdesivir (Veklury®) by Gilead) to submit an Expression of Interest (EOI) for Product Evaluation to the WHO Prequalification Unit.³ This step could help facilitate the registration of these treatments in low- and middle-income countries.

Non-enforcement of patents or voluntary licences (e.g. AbbVie's lopinavir/ritonavir (Kaletra®) and Gilead's remdesivir (Veklury®)) enables generic medicine manufacturers to manufacture and supply the product in certain geographic areas, which can result in greater accessibility. Such measures have positive effects on access beyond COVID-19, as some of these products are key treatments needed across a wider range of infections, including HIV/AIDS.

ACCESS AND SUPPLY

Ensuring equitable access to products in response to COVID-19

While the world waits for COVID-19 treatments and vaccines to become available and accessible, it is important that vulnerable populations are supplied with essential medicine and diagnostics, for NCD and respiratory diseases. For example, in July 2020, Novartis launched a not-for-profit portfolio for the treatment of symptomatic COVID-19. The portfolio included 15 medicines from Sandoz, Novartis's generic medicine division, and was made available at zero-profit to governments in up to 79 low-income countries (LICs) and lower-middle income countries during the pandemic and until a vaccine or a cure is available. The medicines include amoxicillin, ceftriaxone, clarithromycin, colchicine, dexamethasone, dobutamine, fluconazole, heparin, levofloxacin, loperamide, pantoprazole,

prednisone, prednisolone, salbutamol, vancomycin. This launch was followed by a collaboration between Novartis and the African Union (AU) through the Africa Medical Supplies Platform (AMSP) to facilitate the supply of these medicines to the AU member state.

In response to COVID-19, companies engaged in various donations including financial contributions, equipment such as PPE, medicines for the treatment or diagnosis of COVID-19, medicines for co-infections or underlying diseases posing a risk for the disease pathway such as diabetes. Of all these potential activities, the Index solely looks at product donations.

TABLE 2. **Which companies donated products in response to the COVID-19 pandemic?**

Nine companies engaged in ad-hoc donations in response to COVID-19. Notably, Novo Nordisk made the first ever insulin donation to the WHO.

| Company | Donation |
|----------------------|--|
| AstraZeneca | 20,000 AMP Rapid Test SARS-COV-2 IgG/IgM produced through AMEDA Labordiagnosics GmbH. It is used for rapid detection of COVID-19 in response to a request from the Egyptian Ministry of Health. |
| Bayer | Bayer donated a total of 13 products to respond to secondary infections and several other medications for vulnerable patients in a total of 27 countries in scope of the Index, including chloroquine (Resochin®) and the antibiotic moxifloxacin (Avelox®). |
| Boehringer Ingelheim | Boehringer Ingelheim donated ambroxol hydrochloride (Mucosolvan®) ampules to help treat patients with pneumonia. |
| Daiichi Sankyo | Daiichi Sankyo has made product donations to primary care facilities in Wuhan City. |
| GSK | GSK donated over 42,000 product units, including paracetamol (Panadol® Winasorb®), amoxicillin/clavulanic acid (Augmentin™), the influenza vaccine (Fluarix®) and the measles, mumps, rubella vaccine (Priorix®) in a total of 14 countries in scope of the Index. |
| Novo Nordisk | Novo Nordisk donated the 'normally sold quantity' of products, insulin and glucagon, sold to all humanitarian organisations for a period of six months between April and September 2020. During this period Novo Nordisk also covered shipment costs. The donation covered 50 LMICs. |
| Roche | Roche donated tocilizumab injection (Actemra®) to China and Ecuador and reagents equivalent 500 SARS - CoV - 2 testing to Vietnam. |
| Sanofi | Sanofi donated hydroxychloroquine to 13 countries in scope of the Index. |
| Takeda | Takeda donated human albumin (Flexbumin®) to the China Red Cross Foundation. |

Building resilient supply chains in a pandemic

As a result of the COVID-19 outbreak, 2020 saw huge spikes in supply chain disruption. Production and exports, for example, in China and India — the world's largest producers of active pharmaceutical ingredients (APIs) and generic medicines — were impacted by efforts to limit the spread of the virus through national lockdowns and border closures. This in turn affected supply chains worldwide with knock-on effects downstream and throughout the year. At the same time, the demand for certain products, such as antibiotics and antivirals, increased. Some companies reported measures in response to these disruptions, such as re-allocating stock to local distribution centres, increasing safety-stocks, increasing API stocks, assessing alternative, innovative supply methods and routes.

Action needed in two broad areas of supply

In view of COVID-19, it is important that companies ensure (i) the continuous supply of their current portfolio and (ii) that the supply chains are prepared for new treatments and vaccines to be deployed widely.

I. Ensuring continuous supply

At least eight companies reportedly took measures in response to/in anticipation of the supply disruptions caused by COVID-19. For example, Bayer, GSK, Novo Nordisk and Novartis mobilised dedicated teams to provide support and guidance to local and global supply chain activities, aimed at ensuring continuous supply of the existing portfolio. AstraZeneca redistributed all finished pack inventory from the global level to the local level and increased finished good safety stocks (see page 87 for more information). AstraZeneca and Novartis also reportedly explored alternative shipment routes.

II. Preparing the supply chain

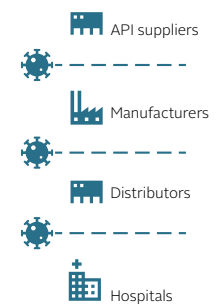
In January 2020, Johnson & Johnson partnered with WHO, the World Economic Forum (WEF), the World Bank Group, the International Organization for Migration (IOM), UNICEF, UPS, Henry Schein and Agility, and launched the Pandemic Supply Chain Network (PSCN) with the aim of increasing access to supply chain functionalities and assets from end-to-end anywhere in the world. Johnson & Johnson is the only pharmaceutical company currently involved in this initiative. The PSCN established the African Cold Chain System Coalition to assess the market risks of the cold chain system. To determine whether the existing cold chain system would allow the international

health sector to effectively respond to a pandemic, the coalition aims to develop market intelligence and risk assessment tools to be used by stakeholders to continually monitor the changing dynamics of the cold chain market. This market intelligence would support preparedness and response activities for any pandemic or large-scale health emergency response.

The focus of the African Pandemic Cold Chain System Coalition is to provide an overview of the African cold chain industry, to identify the key cold chain challenges in Africa, and to identify areas where private companies, like Johnson & Johnson, can collectively help in building cold chain capacity.

Johnson & Johnson conducted a series of cold chain assessments in sub-Saharan Africa to identify gaps and areas where private companies like Johnson & Johnson can help in building cold chain capacity. Building on this initial mapping and gap analysis, the coalition aims to develop assessment tools to provide ongoing cold chain assessment capability for countries and partners. This will be disseminated to countries to continuously use, refine and integrate the tools into the health sector response measures.

COVID-19 disrupted global API and medicine supplies



HEALTH SYSTEM STRENGTHENING

Supporting health systems in LMICs

Health systems around the world have been hit hard by the COVID-19 pandemic. Awaiting the development, approval and global roll-out of a COVID-19 vaccine, the pandemic has put additional pressure on health systems and exposed existing gaps. Some companies have taken measures to support health systems by often leveraging or adapting the networks and activities they were already implementing. For example, additional funding and budget savings from Healthy Heart Africa, were repurposed towards supporting healthcare facilities in containing the spread of the infection, including handwashing, awareness raising related activities and the provision of PPE.

Bayer and PATH shifted their focus in their community health workers training and outreach programmes in Senegal from malaria to COVID-19. Furthermore, Bayer engaged in a partnership with Access Afya (AA) on COVID-19 with the aim of improving access to primary healthcare services in Kenya during the COVID-19 pandemic. The initiative aims at incorporating COVID-19 risk assessments into AA's digital medical portal, training local entrepreneurs on telemedicine and strengthening the service for severe cases.

A total of six companies reported adapting their existing activities to include COVID-19.* While the ability to utilise existing networks and partnerships allows for rapid mobilisation and efficiency, there is a risk that the initial focus becomes neglected.

Alongside the direct effect of COVID-19 on people's health, studies have suggested that it will indirectly result in millions of deaths from other communicable diseases such as malaria, TB and HIV/AIDS due to reallocation of resources. Additionally, the large dependency on few suppliers in regions like sub-Saharan Africa has resulted in shortages, risking the rise of substandard and falsified medicines.

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*The Index did not ask companies to report on changes in their activities as a result of COVID-19. Therefore, this does not depict the full extent of company activity.

IN SUMMARY

The industry's response to COVID-19 has been vigorous in some regards, but revealed little preparedness for the next pandemic

COVID-19 is showing the industry how to accelerate R&D and better prepare for the next pandemic but challenges remain. The lesson of COVID-19 is that pandemic preparedness requires a robust and diverse range of private and public sector entities to be aligned and engaged in research against EIDs. Partners must accelerate the passage of products through clinical development and approval, and manufacture and sup-

ply at global scale. R&D targeting EIDs must begin before epidemics break out, for example to develop platform technologies or to share IP to accelerate discovery and development. Ending a pandemic requires suitable products to be developed and fairly distributed so that people in low- and middle-income countries are not last in line or left behind altogether.

What next?

- More companies engage in emerging infectious diseases R&D, yet the vast majority of these efforts (80%) are focused on COVID-19. There is little preparedness for the next pandemic: there are no projects in the pipeline for 10 of the 16 diseases identified as the greatest public health risk.
- The lag in access planning for COVID-19 R&D, despite hefty public funding, suggests that pharmaceutical companies and their partners must do more to embed equitable distribution into their strategies so that many more people can quickly benefit.
- COVID-19 has revealed some companies' agility and adaptability as part of their health system strengthening efforts, leveraging existing networks in response to COVID-19. However, the shift of focus away from crucial public health issues may hinder progress in other disease areas.
- A limited number of companies have shown the ability to react to and anticipate significant supply chain disruptions. As part of these responses, companies need to ensure that low- and middle-income countries are not over-
- looked. Given that some vaccines need to be stored at temperatures as low as -80 degrees Celsius, the companies manufacturing them must ensure that cold-chain supply and storage challenges are accounted for and resolved so that the vaccines can be rapidly deployed upon approval.
- Beyond COVID-19, initiatives such as the non-enforcement for AbbVie's lopinavir/ritonavir (Aluvia®/Kaletra®), the Novartis not-for-profit portfolio and Novo Nordisk's first ever insulin donation to the WHO have positive effects on access. Some of these products are key treatments needed across a wide range of diseases, including HIV/AIDS. Such efforts should continue after the COVID-19 pandemic.
- Companies need to make sure that when vaccines are approved, doses are fairly distributed according to population vulnerability and needs. In November 2020, high-income countries had bought up more than 50% of the volume of the leading candidate doses, representing only 14% of the world population.⁴

Case in point: is the industry ready for a pandemic driven by AMR?

In addition to the identified emerging infectious diseases, antibiotic resistance (AMR) poses a threat to global health, already causing more than 700,000 deaths each year, including more than 200,000 infant deaths.⁵ Antibiotics are used for treatment in nearly all cases of severe COVID-19, leading thus to an increasing number of bacteria becoming resistant to these antibiotics.⁶ The antibiotics pipeline is running dry as companies continue to leave the antibiotic space with only 34 projects for eight infections by 12 companies in 2020. In addition, eight companies are developing 27 vaccines for antibiotic-resistant pathogens.

As a result, effective antibiotics are needed more urgently than ever by communities around the world. New antibiotics must be developed to replace those that lose their effectiveness. However, to maintain effectiveness they must also be used conservatively in order to slow down the rise of resistance in future.

The role for pharmaceutical companies is clear: to develop new medicines to replace ones that no longer work, make them available and accessible to those who need them and find new ways to ensure antibiotics are produced and promoted responsibly.

SPECIAL REPORT: PROGRESS ANALYSIS

Is the industry doing more to improve access to medicine?

The first Access to Medicine Index, published over ten years ago, established a baseline measure of what 20 of the world's largest pharmaceutical companies were doing for the two billion worldwide without access to medicine. The following pages comprise an update to the Foundation's Ten-Year Analysis of how pharmaceutical companies are responding to global health priorities. It was published in 2019 based on data collected between 2008 and 2018.

The analysis presented here is based on the comparison of the Access to Medicine Index 2021 main findings with the Access to Medicine Index 2018 and the 10-year analysis results. Although the methodology has been updated with a new robust framework since 2018, viable comparisons have been drawn in the three core technical areas (Governance of Access, Research and Development and Product Delivery) assessed by the Index to drive action in the industry.

GOVERNANCE OF ACCESS

Pharmaceutical companies align business with access to medicine

In the last 12 years the number of companies developing inclusive business models has increased from 6 to 12, showing that companies are more willing to expand access to their health products for patients at the base of the income pyramid. Between 2014 and 2018 the number of inclusive business models identified by the Index remained roughly equal to six. The 2018 Index analysis identified that five of the existing inclusive business models were scaled up and one new business model was introduced.

The 2021 Index findings show that five new companies have updated their business rationale and adopted an inclusive model. A total of 15 business models have been newly launched by seven companies, while six existing inclusive business models have been scaled up to include additional countries in scope since 2018 (see Table 3).

The increasing number of companies implementing new inclusive business models and scaling up the existing ones suggests there is more commitment to considering the vulnerability of different patient groups which may face additional barriers to access within countries in scope of the Index. The scale-up in the last 4 years indicates

that local strategies have been successful, sustainable in the long term and adaptable to different contexts. Such features are deemed necessary to expand access of health products and meet the different needs across countries and segments of the populations.

In addition, the 2021 Index findings show that all the pharmaceutical companies included in the analysis have set targets and goals related to access-to-medicine initiatives, demonstrating an improvement since 2018 (Figure 10).

The 2021 Index analysis has also established a slight improvement in the companies' risk management of unethical marketing. Since 2018, the number of companies decoupling sales agents' rewards from sales volume targets only has risen from 9 to 12 (see Figure 11).

Besides, the number of companies where board members are directly responsible for access to medicine targets has increased from 11 to 12 in the last two years. The change in the company's governance system will hopefully facilitate a more effective implementation of access to medicine initiatives.

TABLE 3. Use of inclusive business models continue to expand

| | 2014 | 2016 | 2018 | 2020 | |
|---|------|------|------|------|--|
| Companies running inclusive business models | 6 | 5 | 7 | 12 | Most enduring inclusive business models <ul style="list-style-type: none"> • Novartis' Health Family since 2007 • Novo Nordisk's BoP programme since 2010 • GSK's Live Well since 2015 • Roche's Global Access Programme since 2015 |
| New inclusive business models | 2 | 7 | 1 | 15 | |
| Scaled-up inclusive business models | 4 | - | 5 | 6 | |

FIGURE 10. Since 2018, all companies have access-to-medicine goals and targets

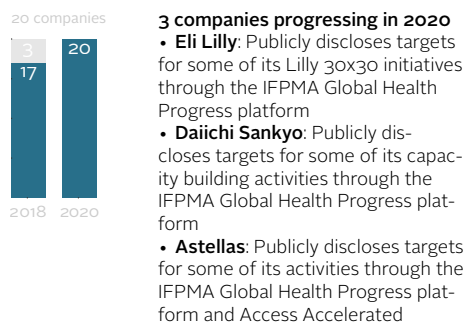


FIGURE 11. Since 2018, more companies have decoupled agent rewards from sales targets



RESEARCH & DEVELOPMENT

Progress in R&D since 2018

Although the R&D analysis methodology has changed since the 2018 Index report, comparison of the numbers of projects targeting R&D priorities as set by the global health community were still possible*. The analysis reached the conclusion that the pharmaceutical companies demonstrated higher investment in research projects to meet the needs of patients living in low- and middle-income countries.

The analysis showed that most of the R&D projects assessed in the 2021 analysis target diseases which are considered priority for global health by WHO and Policy Cures Research. Since 2018, the number of R&D projects targeting priority diseases has increased from 38% to 66% (Figure 12).

Specifically, the number of neglected tropical diseases (NTDs) projects has risen from 80 to 85 in the last two years and R&D projects targeting tuberculosis (TB) increased by 13%. In contrast, malaria and HIV/AIDS pipeline projects have slightly decreased by one and two products, respectively.

Yet, one product for malaria has recently received market approval and several products for HIV/AIDS have been submitted to the regulatory agencies for approval. The longitudinal analysis also showed that the number of R&D projects targeting maternal and neonatal health conditions has increased from 9 to 10 since 2018.

With regard to the health products newly introduced to the market, the Index 10-year analysis showed that at least 171 new health products had been approved since 2010. In the last two years, another 78 health products have been marketed, making the total number of new product approvals to at least 249 since 2008.

However, most of the newly approved products still target the more profitable non-communicable diseases over communicable diseases. The 2021 analysis showed that only two recently approved products target NTDs.

FIGURE 12. Increased R&D focus on health priorities

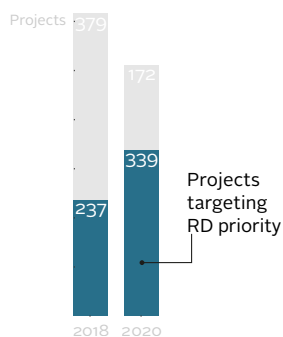
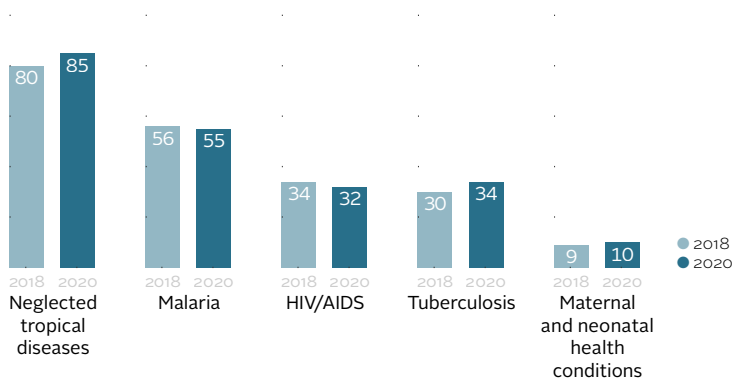


FIGURE 13. Since 2018, the number of projects for Neglected Tropical Diseases (NTDs) has increased, while the number of HIV/AIDS and malaria projects experienced a slight drop



*Due to differences in the analytical methodology of 2018 and 2020, some of the R&D projects included in the 2021 Index analysis were not considered for this analysis.

PRODUCT DELIVERY

Slight increase in donation programmes, inconsistent uptake of voluntary licensing, but patent transparency keeps improving

Pricing strategies, voluntary licensing and donation programmes are the three main tools the pharmaceutical companies can employ to expand access to medicine. The longitudinal analysis results show that licensing and donations have been used differently among the companies in the past 12 years. The pricing strategies assessment methodology has been changed since 2018 Index report, therefore data comparison was not feasible.

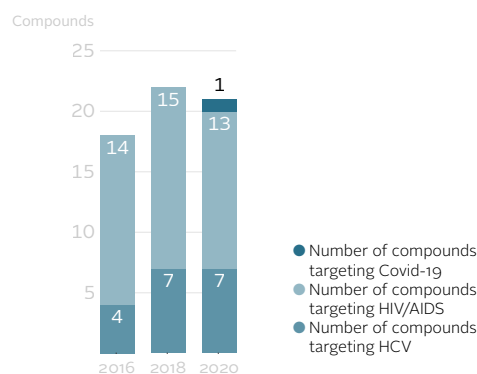
Licensing strategies

According to the 10-year analysis report, the number of companies entering into voluntary licensing or non-assert agreements remained equal to seven. Between 2010 and 2018 the number of licensed compounds steadily rose after which it dropped slightly.

The number of licensed compounds had increased from 18 to a maximum of 22 between 2016 and 2018, with new compounds for hepatitis C treatment (3) and HIV (1) marketed and licensed. Between 2018 and 2020, the patents of two compounds for HIV and therefore, the two respective voluntary licences expired, making the total number of licensed marketed compound 20 in 2020.** In October 2020, remdesivir (Veklury®) received FDA approval for the treatment of Covid-19, and the company patent holder, Gilead, signed a non-exclusive voluntary agreement to expand supply of the medicine, making the total number of licensed marketed compound 21 in 2020.**

This longitudinal analysis demonstrates that licensing has remained confined to a small group of companies and diseases. Nevertheless, it has the potential to be a more beneficial tool which can lead to expanding access to more products targeting a range of diseases and more countries in need and specifically non-communicable diseases.

FIGURE 14. A marketed product has been newly covered by voluntary licensing in the last two years.**



**One licensed investigational compound was not included in the analysis to align the data from the previous ATMI report. Please refer to the dedicated licensing fig

ure analysis for the number of licensed compounds included in the analysis.

Outside the period of analysis (September 2020), MSD entered into a non-exclusive

voluntary licensing agreement with two generic medicine manufacturers for HIV/AIDS treatment doravirine.

Donation programmes

The number of companies engaging in donation programmes for neglected tropical diseases (NTD) as well as the number of structured programmes have increased in the last 12 years. This reveals an increment in adopting donation as a pro-access tool and the companies’ commitment to ensuring access to their donated products. Since 2019, the Rabies Free Pakistan (RFP) initiative has started, while some existing donation programmes targeting the same disease and offering the same products have been merged into one single programme, resulting in a total of 14 donation programmes targeting NTDs in the 2021 Index analysis.

Disclosure of patent status

Disclosing patent status information is another way to improve access to medicine, specifically by facilitating increased supply as well as affordability. Transparency on the patent status (where patents are filed) gives greater certainty to international drug procurers and generic medicine manufacturers when planning the manufacture and/or supply of generic products.

Since 2014 the number of companies disclosing at least some information have constantly been increasing. According to the 2021 analysis, almost all the companies share patent status data for some of their products with stakeholders. Most of the data is shared through the online database Pat-INFORMED, while few companies self-publish patent information online.

FIGURE 15. Has company response to NTD donations changed since 2018?



FIGURE 16. Donation programmes for NTDs

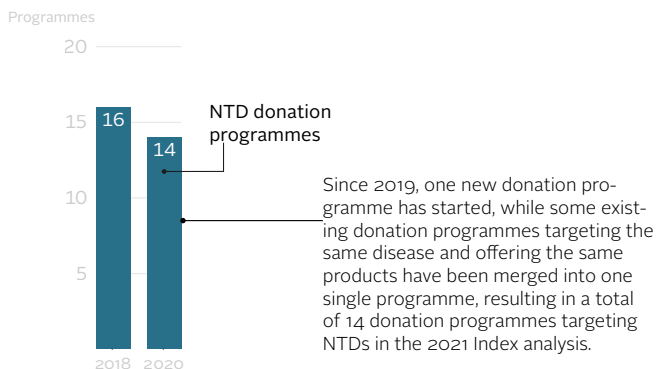
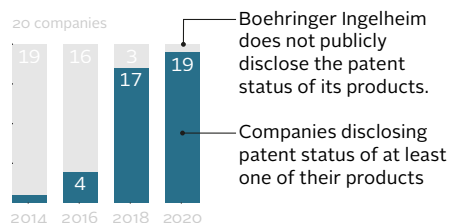


FIGURE 17. How transparent have companies been regarding patent status?



CAPACITY BUILDING

Progress in health system strengthening, supply and R&D capacity building, leaving manufacturing behind

Health system strengthening, manufacturing and supply capacity building initiatives represent additional ways in which the pharmaceutical companies can improve access to medicine and address issues in health product availability and accessibility (e.g. appropriate prescription, efficient administration).

The 2021 Index findings suggest that the pharmaceutical companies have been engaging in more and better-quality health system strengthening initiatives compared to the 2018 Index analysis. As a result, a higher number of initiatives meets the Good Practice Standards – among others, integration with local health systems, good governance structures and measurable goals. In addition, more companies measure outcomes and some companies track the impact of the related strategies on health outcomes. These results suggest that in the last two years the companies have adopted a more sensitive and solid approach to ensure the quality of their initiatives and that they meet the health needs of specific patient populations and communities.

According to the 2021 Index findings, pharmaceutical companies have improved in the supply chain and R&D capacity building areas, as well. Since 2018, the number of pharmaceutical companies engaging in building supply chain capacity has increased from 12 to 13 while the number of companies engaging in R&D capacity building decreased from 13 to 12. Yet, in both areas the number of initiatives has increased from 30 to 46 and 37 to 40 in the last two years, respectively. Furthermore, more and more initiatives meet the Good Practice Standards, reflecting a greater commitment to implementing better-quality supply strategies that can have a sustainable impact and are in alignment with the needs of local communities and health stakeholders.

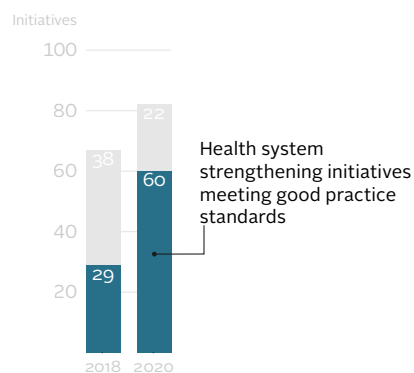
However, companies' efforts remain focused on the same geographic regions and disease areas as in 2018, with most R&D capacity building initiatives focusing on communicable diseases in sub-Saharan Africa.

In contrast to health system strengthening and supply chain strategies, the number and the quality of manufacturing capacity building initiatives has decreased in the last two years, suggesting an overall negative trend in this area. Although the number of companies implementing manufacturing initiatives is still 15 as in 2018, with technology transfers leading the local manufacturing strategies, the number of initiatives meeting the Good

Practices Standards is lower. Companies specifically fail to demonstrate ways in which their initiative aims for sustainability and the outcomes of these projects on local capacity are often not measured.

In addition, most of the initiatives remain confined to a few countries, including India, China and Brazil. These results suggest that companies' efforts and investments in manufacturing are mostly directed towards emerging markets. More endeavours are required in this area to further expand geographic scope. Furthermore, initiatives need to be refined in terms of quality of products and tailored to the local demand.

FIGURE 18. Remarkable progress in health system strengthening initiatives



Technical Areas

In supporting the pharmaceutical industry, the Index aims to provide valuable insights which can be translated into actionable strategies for greater access to medicine in low- and middle-income countries across the entire spectrum of the 82 diseases, conditions and pathogens in scope. The most recent methodology review, in 2019, resulted in a tighter analytical framework for this Index. In 2021, the Index focuses more tightly on the core areas where companies have the biggest role and responsibility for improving the availability and accessibility of medicines and health products.

The 2021 analytical framework consists of three broad Technical Areas: **Governance of Access, Research and Development** and **Product Delivery**. There is a total of 14 Priority Topics which are assessed against a total of 33 performance indicators.

The 2021 Index includes relevant data from 1 June 2018 to 31 May 2020. The analysis is based on data collected by the Access to Medicine Foundation on companies' websites, annual reports, corporate social responsibility (CSR) reports and partner websites, as well as information submitted to the Index directly by the companies. It also draws on other information available in journals and sourced from institutions, databases and think tanks such as WHO, Policy Cures Research, Access Observatory, Medicines Patent Pool.

Each of the following Technical Areas feature:

- An overview of how the Index assesses company performance;
- A ranking of the 20 pharmaceutical companies detailing what separates the best and worst performers and;
- Detailed figure-led analyses identifying industry strengths, weaknesses, trends and opportunities.

GOVERNANCE OF ACCESS

CONTEXT

Adopting an access to medicine mindset and incorporating it into the business strategy is a core prerequisite for the pharmaceutical companies to increase their patient reach in low- and middle-income countries facing a high disease burden. The active engagement of their workforce through various incentives can further contribute to the implementation of such a mindset across the company. Yet, companies need to promote ethical marketing practices and ensure compliance with each country's regulatory and anti-corruption laws, while demonstrating transparency in reporting their access outcomes.

Governance of Access touches upon two major topics: Governance and Strategy and Responsible Business Practices. This Technical Area looks at the governance, planning, implementation and integration of access to medicine initiatives into the companies' overall corporate strategy and the extent of staff incentivisation towards fostering access to medicine. It also explores the companies' ethical marketing and disclosure policies as well as their measures to prevent any corrupt or non-compliant activity in their business operations that could hinder progress in access to medicine.

PERFORMANCE INDICATORS

In this Technical Area, the companies' performance is assessed against the following indicators:

- Integration of an access-to-medicine strategy within the overall corporate strategy across all therapeutic areas
- Incentivisation of senior management and other personnel towards achievement of access to medicine goals
- Public disclosure and measurement of governance activities, including mitigating conflicts of interest
- Compliance and responsible promotional practices
- Public support of the Doha Declaration on TRIPS and Public Health

WHAT DOES BEST PRACTICE LOOK LIKE

The companies demonstrating best practice in Governance of Access are proactive in implementing solid company-wide compliance controls and audits to reduce corruption risk across their business operations, including third-party collaborations.

Board-level committees are directly responsible for promoting and rewarding the effective access strategies for their portfolio, ensuring that the access to medicine mindset starts at the top level and is embedded into their business decisions, even in their employee performance reviews.

In addition, companies performing strongly in Governance of Access are actively engaged in measuring the progress and outcomes of their access to medicine initiatives in low- and middle-income countries. This, in turn, enables them to establish systematic frameworks to evaluate their long-term impact on patient populations and national health systems, alike. Among the companies analysed, attention is particularly directed toward increasing access to innovative medicines in sub-Saharan Africa, home to a considerable number of underserved communities.

INSIGHTS

1. More than half of the companies incorporate access to medicine into their business strategy across all their therapeutic areas.
2. More than half of the companies provide managers and senior executives with incentives to achieve access-to-medicine goals.
3. Less than half of the companies apply comprehensive auditing and control mechanisms to prevent and fight corruption.
4. Through external tools and partners, companies aim for ethical compliance and assess the impact of their initiatives.

FIND OUT MORE

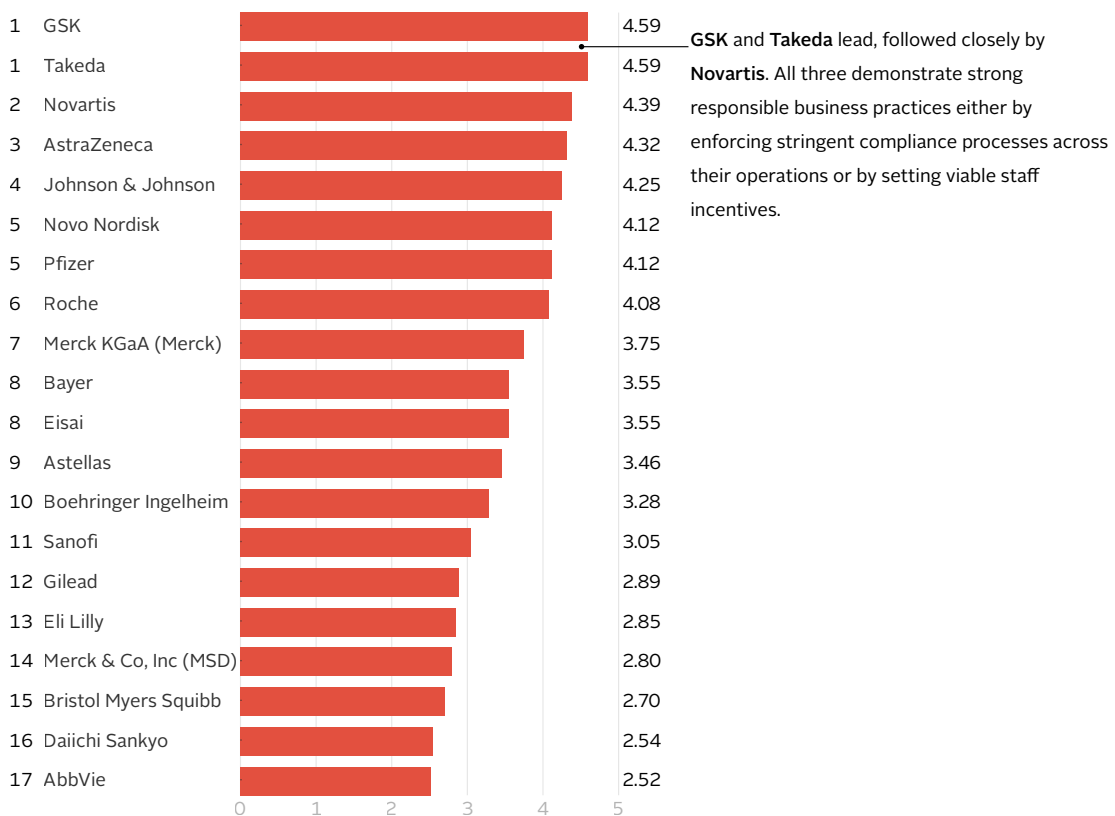
| | |
|----------------------------------|----|
| Sub-ranking | 37 |
| Governance, strategy & practices | 38 |

This section features a detailed figure-led analysis identifying industry strengths, weaknesses, trends and opportunities as of the time of writing. For a fine grained view of individual company activity in this Technical Area, see the Report Cards, page 127.

HOW THE COMPANIES PERFORM

Responsible business practices give top-performing companies the leading edge

FIGURE 19. Governance of Access Ranking



What separates the best and worst performers

Out of the 20 companies assessed, 17 have established an access to medicine strategy with measurable objectives. The top five companies have an access-to-medicine strategy which consistently extends to all therapeutic areas they are involved in. This pack of companies also have access-related incentives in place for senior managers, including CEOs.

Mid-performing companies deliver mixed results. Overall, they lack one or more control mechanisms looked for by the Index to mitigate the risk of non-compliance within their operations in low- and middle-income countries, including

contracted third parties. They perform relatively poorly when it comes to transparency on transfers of values made to healthcare professionals in countries in scope.

Companies with a low performance in this Technical Area merely have general commitments to improve access to their products, but have no concrete strategy embedded in their business model.

GOVERNANCE, STRATEGY AND RESPONSIBLE BUSINESS PRACTICES

How do companies prioritise access to medicine?

Greater access to medicine for low- and middle-income countries starts with strong leadership and an actionable strategy. Without a clear, long-term access-to-medicine strategy, with low- and middle-income countries at the centre of companies' business operations, life-saving products may not

made available to the patients who shoulder the greatest share of global disease burden. Achieving this balance requires companies to view access to medicine as a strategic issue and to manage it as such.

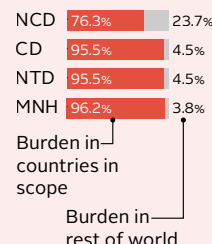
What does an access-to-medicine strategy look like and what can it achieve?

Essentially, an access-to-medicine strategy is a business strategy specifically intended to improve access to medicine in low- and middle-income countries. It should cover all portfolio products and therapeutic areas, including new innovative medicines, and it must be aligned with the companies' overall corporate strategy. It includes the following:

- A clear business rationale
- Long-term objectives
- Measurable targets
- Evaluation and monitoring processes

Such strategies not only improve patient reach and address the needs of underserved communities but they also offer pharmaceutical companies considerable benefits:

- New market opportunities (i.e. expanding profitability to new markets, often with large populations, with a business potential or expanding profitable business opportunities in existing markets);
- New customers and business relationships;
- Improved recruitment (i.e. attracting talent in low-, middle- and high-income countries);
- An overall improvement in company resilience in different market conditions.

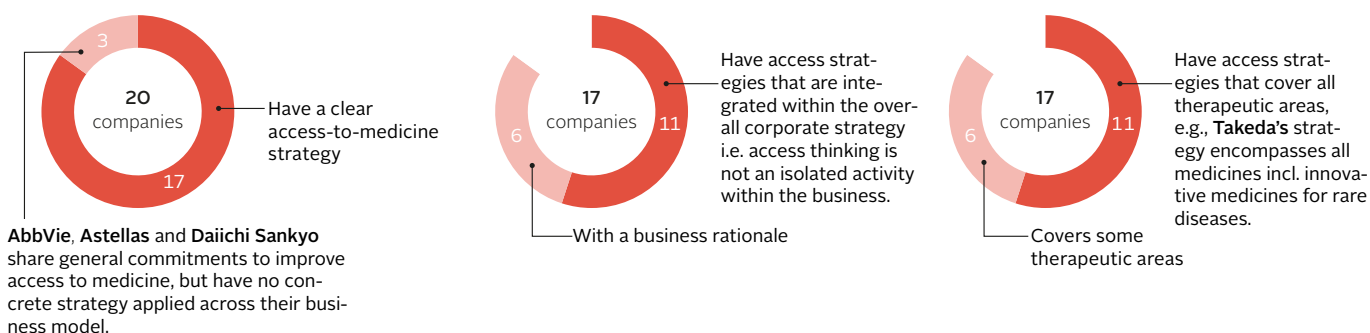


Strategise access

Most companies have an access-to-medicine strategy with established objectives. However, only eleven out of 20 companies are demonstrating good practice by embedding their

access-to-medicine strategy within their overall corporate strategy, and thus across all therapeutic areas they are involved in. This indicates that the access mindset is incorporated consistently within the company.

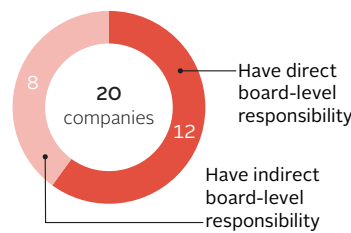
FIGURE 20. Do companies have strong access-to-medicine strategies in place?



Prioritising access to medicine at the top level

To ensure progress towards access to medicine, the strategy needs to be a priority at the highest level. Top-level accountability is likely to filter into the rest of the company – incentivising a culture whereby access is a priority for senior-level staff and the rest of the organisation – and can help enable teams within the company to deliver on access-to-medicine initiatives. Over half the companies in scope assign responsibility directly with the board, helping to ensure top-level accountability for access, with a long-term horizon.

FIGURE 21. Is access-to-medicine a priority at the highest level?

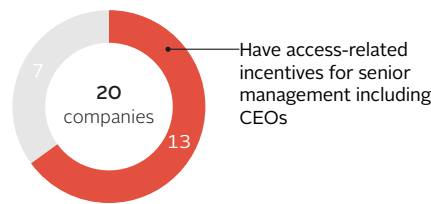


Over 50% of companies prioritise
As in 2018, over half of the companies demonstrate evidence of assigning direct board-level responsibility for access, increasing the chance that access-related objectives are given attention, remain on track and are achieved.

Incentivising action

Financial and non-financial (e.g. awards) incentives at a managerial level, from the CEO to the country-level managers, can help achieve access-related objectives. If a CEO has key performance indicators (KPIs) specifically linked to access-to-medicine objectives, access is more likely to be an important goal of the whole organisation. Over half of the companies have access-related incentives at the top level: Astellas, AstraZeneca, Bayer, Daiichi Sankyo, Eisai, Eli Lilly, Gilead, GSK, Novo Nordisk, Novartis, Pfizer, Sanofi, Takeda.

FIGURE 22. Are senior management incentivised to achieve access-related goals?



Most companies incentivise access

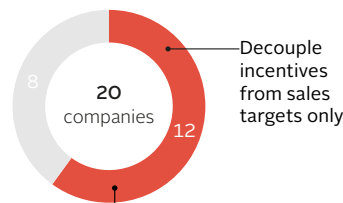
- **Novartis'** CEO has management targets for access to medicine tied to its annual performance plan. The CEO's access to healthcare objective are published in its annual report.
- The CEOs of some companies such as **GSK, Novartis, Pfizer** with incentives linked to its Purpose Blueprint strategy and **Takeda** have incentives based on access targets. Others, such as **Sanofi's** CEO, have incentives linked to Corporate Social Responsibility (CSR) targets, which can include improving access to medicine. **Gilead's** CEO has incentives specifically linked to expanding access to hepatitis C products, while **Eisai's** CEO has incentives related to non-tropical disease (NTD) elimination as part of its mission.

Johnson & Johnson has access-related KPIs for regional managers, including the Head of Global Public Health Africa team and senior executives, but there is limited evidence that the CEO is also directly incentivised toward access goals. However, the CEO oversees progress against Johnson & Johnson's Health for Humanity goals, which includes access-related KPIs.

Managing financial incentives

If incentives can encourage employees to work towards achieving access-related goals, (e.g. KPIs aiming at promoting the delivery of access set for CEOs), sales volume-based incentives can conversely jeopardise access to medicine. It is common practice that the sales agent's bonuses and rewards are linked to sales volume, which in turn is increasing the risk of mis-selling (i.e. the act of selling a product to a person when it is not necessary or not adapted for them) or over-selling products. Yet, in recent years more and more companies are moving away from rewards pegged primarily against sales targets. Companies can limit the occurrence of misconduct by changing their sales incentive structures and adopting a balanced scorecard approach decoupling such incentives from sales volume targets only. This can result in a balance between the aim to increase access to medicine and the risk of over-use. In the 2018 Index, nine companies demonstrated evidence of decoupling agents' incentives for sales volume targets only. In 2021, 12 companies are doing so. There is still room for improvement in the area of sales practices, as the variable salary for sales agents represents at least 20% of their total income for most companies. The higher the fixed income is, the better, as it decreases the chance of performance being based on sales

FIGURE 23. How many companies decouple incentives from sales targets only?



12 companies decouple

- Over half of companies have incentives that are not wholly linked to sales. **Astellas, Bayer** and **Johnson & Johnson** newly demonstrate evidence of looking at additional components such as ethical behaviour and other qualitative measures to determine the agents' balanced scorecard.
- **Johnson & Johnson** reports including qualitative metrics in its agents' variable compensation system, such as technical knowledge and quality of services delivered to healthcare professionals.
- Sales approaches might be different depending on product types, for example, **Johnson & Johnson** reports that for some products including a treatment for TB, it does not deploy sales and marketing representatives to facilitate sales due to the public health need.

A balanced scorecard approach can include not only sales volume metrics but also look at e.g. distinction in practice related to antimicrobial resistance, market uptake for priority products, safeguards in place to ensure ethical practices.

volumes. This also applies to sales volume targets, which can be aggregated at different levels: individual, team, division, country, global; the further such incentives are from the individual, the better.

How do companies ensure their access strategies are not undermined by non-compliance or corrupt behaviour?

Pharmaceutical companies operate in an environment where the pressure on profits and a fiercely competitive landscape along with country-level stakeholder pressures could increase the temptation on employees to engage in inappropriate, unethical behaviour and corrupt activities. The World Health Organization recognises that corrupt activities in the health sector presents a threat to global health and access to medicine.¹ Research demonstrates that corruption in the health sector constitutes a risk of undermining the achievement of the UN SDGs and Universal Health Coverage targets.² This risk maybe be exacerbated in low- and middle-income countries, where governance and health systems might be weaker than in high-income countries.¹ Compliance controls are key to ensuring that governance actions promoting access to medicine are not negatively affected (e.g. by undermining confidence in the industry, diverting scarce resources from health budgets, impacting prices or limiting drug availability).

The Index looks for a strong internal control framework for ensuring compliance: i.e., processes for checking and detecting non-compliance, supported by rigorous monitoring and auditing. The 2021 Index finds that all companies have auditing mechanisms in place; however, only eight demonstrate evidence of all controls looked for by the Index (see Appendix II).

Have any cases been recently settled that relate to breaches of law or compliance issues?

Many low- and middle-income countries might have weaker regulatory or law enforcement capacity to impose measures against unethical marketing or corruption. Hence, cases of breaches are often not identified by such regulatory or law enforcement entities, and not exposed publicly. Nevertheless, breaches do occur in these countries which is why the Index continues to look at any breaches for unethical marketing practices, corrupt practices, anti-competitive practices, misconduct in clinical trials in the countries in scope, when they are put into public light. The Index looks at settlements and judgements regarding breaches of internationally recognised codes of conduct, laws and regulations which occurred in countries in the scope during the period of analysis.

Within the period of analysis, the Index noted the settlement of one bribery case. Sanofi settled to pay more than USD 25 million with the US

FIGURE 24. How do companies monitor compliance?

| Companies | Auditing | Country risk-based assessment | Fraud-specific risk assessment | Live monitoring system | Third-party compliance systems |
|----------------------|-----------|-------------------------------|--------------------------------|------------------------|--------------------------------|
| AbbVie | ● | ● | ● | ● | ● |
| Astellas | ● | ● | ● | ● | ● |
| AstraZeneca | ● | ● | ● | ● | ● |
| Bayer | ● | ● | ● | ● | ● |
| Bristol Myers Squibb | ● | ● | ● | ● | ● |
| Boehringer Ingelheim | ● | ● | ● | ● | ● |
| Daiichi Sankyo | ● | ● | ● | ● | ● |
| Eisai | ● | ● | ● | ● | ● |
| Eli Lilly | ● | ● | ● | ● | ● |
| Gilead | ● | ● | ● | ● | ● |
| GSK | ● | ● | ● | ● | ● |
| Johnson & Johnson | ● | ● | ● | ● | ● |
| MSD | ● | ● | ● | ● | ● |
| Merck | ● | ● | ● | ● | ● |
| Novo Nordisk | ● | ● | ● | ● | ● |
| Novartis | ● | ● | ● | ● | ● |
| Pfizer | ● | ● | ● | ● | ● |
| Roche | ● | ● | ● | ● | ● |
| Sanofi | ● | ● | ● | ● | ● |
| Takeda | ● | ● | ● | ● | ● |
| Total | 20 | 12 | 12 | 11 | 20 |

Pfizer reports conducting data-driven country risk assessments that provide a holistic view of potential risk and enable market-specific mitigation, including risk-based country audits.

Eight companies in scope demonstrate best practice by applying all compliance controls looked for by the Index, see Appendix II for more information.

Securities and Exchange Commission (SEC) in September 2018 to resolve charges alleging that some of its subsidiaries made corrupt payments to gain business from 2011 to 2015, potentially in violation of the Foreign Corrupt Practices Act of 1977 (FCPA), in a number of countries, including in Yemen and Palestine, which are in scope of the Index.³

Evidence of breaches or other anti-competitive behaviours, as assessed in the Index, is however not a reflection of the company's overall performance, but rather provides an insight into risk mitigation controls which are in place or may have been lacking.

Stronger strategy, stronger outcomes

The 2021 Index is seeing clear evidence of how an access-to-medicine strategy infiltrates key areas of access. For example, two leading companies in this area of analysis, GSK and Novartis, demonstrate strong performances in multiple technical areas and topics assessed in the Index, including access strategies, capacity building and R&D.

An increasing number of companies is operating in low-income countries, for example by setting up countries offices such as Bayer in Ethiopia or developing targeted approaches (see Inclusive Business models page 80) such as Takeda with its comprehensive Blueprint for Innovative Access to Healthcare model. During the COVID-19 pandemic, more companies are applying their access-to-medicine strategies towards new treatments and vaccines, to help address the increasing risk of disruption in healthcare systems as the pandemic deepens.⁴ For example, Johnson & Johnson reports that its Global Public Health unit, which focuses on improving health outcomes for vulnerable populations, now includes COVID-19 in its efforts to tackle epidemics and pandemics.

In parallel, companies ought to enforce more control mechanisms aiming at preventing non-compliant activities which can cause barriers to access, and to encourage responsible business practices across their operations. Transparency and goal communication are also essential; they inform external stakeholders of the companies' activities and progress on such access-to-medicine strategies and they allow accountability. Most companies perform well in their public reporting of commitments, measurable targets and objectives of access-related activities, for example through their annual or corporate social responsibility reports or via partner platforms such as the IFPMA Global Health Progress and the Access Observatory. Furthermore, the Index continues to encourage companies to publicly disclose the outcomes of their access activities. For example, Johnson & Johnson shows good practice in public disclosure of outcomes, consistently sharing all its goals and targets for access activities and the progress made in relation to the Health for Humanity Goals since 2016.

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- 2 The Ignored Pandemic – Transparency International Health Initiative <http://ti-health.org/wp-content/uploads/2019/03/IgnoredPandemic-WEB-v2.pdf>. Accessed December 22, 2020.
- 3 U.S. Securities and Exchange Commission. Sanofi Charged With FCPA Violations. <https://www.sec.gov/news/press-release/2018-174>. Accessed December 22, 2020.
- 4 Toor J, Adams ER, Aliee M, et al. Predicted Impact of COVID-19 on Neglected Tropical Disease Programs and the Opportunity for Innovation. *Clin Infect Dis*. September 2020. doi:10.1093/cid/ciaa933

RESEARCH & DEVELOPMENT

CONTEXT

Research and Development focuses on Product Development, Access Planning and R&D Capacity Building. Pharmaceutical companies need to develop health products which are urgently needed and offer a clear public health benefit in LMICs, while ensuring that such products are rapidly and widely accessible by the target populations. Affordability, accessibility and availability are, thus, crucial aspects to be considered for the pipeline. Companies also need to contribute to local R&D capacity building empowering local researchers to address relevant needs.

PERFORMANCE INDICATORS

The companies' performance in this Technical Area is assessed against the following indicators:

- Access plans in place covering the company's pipeline, particularly projects addressing urgent treatment needs (priority R&D)
- Access plans in place for projects offering a clear public health benefit in low- and middle-income countries
- Post-trial access to medicine for clinical trial participants
- R&D capacity building initiatives meeting all Good Practice Standards (see Appendix IV)

WHAT DOES BEST PRACTICE LOOK LIKE

Best performing companies acknowledge that access plans need to be elaborated in the early stages of their health products' clinical development to ensure equitable and broad patient access. Top-performing companies establish concrete access planning frameworks and processes which are implemented across their pipelines, both in house and collaborative. Such frameworks consider, among other factors, affordability and therapeutic needs, while leaders' strategies include voluntary licensing, WHO prequalification, tiered pricing and patient assistance programmes. Also important is companies' intention to safeguard and secure access to investigational treatments for clinical trial participants after the end of trials.

Noteworthy is the focus on the voluntary licensing of the paediatric formulation of dolutegravir (DTG), which broadens and accelerates access for the paediatric patients living with HIV, and the income- and country-tailored approach to offering the dengue vaccine.

INSIGHTS

1. The Index captured 1,073 R&D projects for the 82 diseases, conditions and pathogens in scope.
2. During the period of analysis, 17 of the 20 companies were active in R&D for COVID-19 patients. A total of 63 projects for COVID-19 patients were in development.
3. Over 70% (149/211) of the established R&D priorities for low- and middle-income countries remain unaddressed by the companies in scope.
4. The R&D projects targeting TB and NTDs have increased, but the HIV/AIDS and malaria projects have decreased.

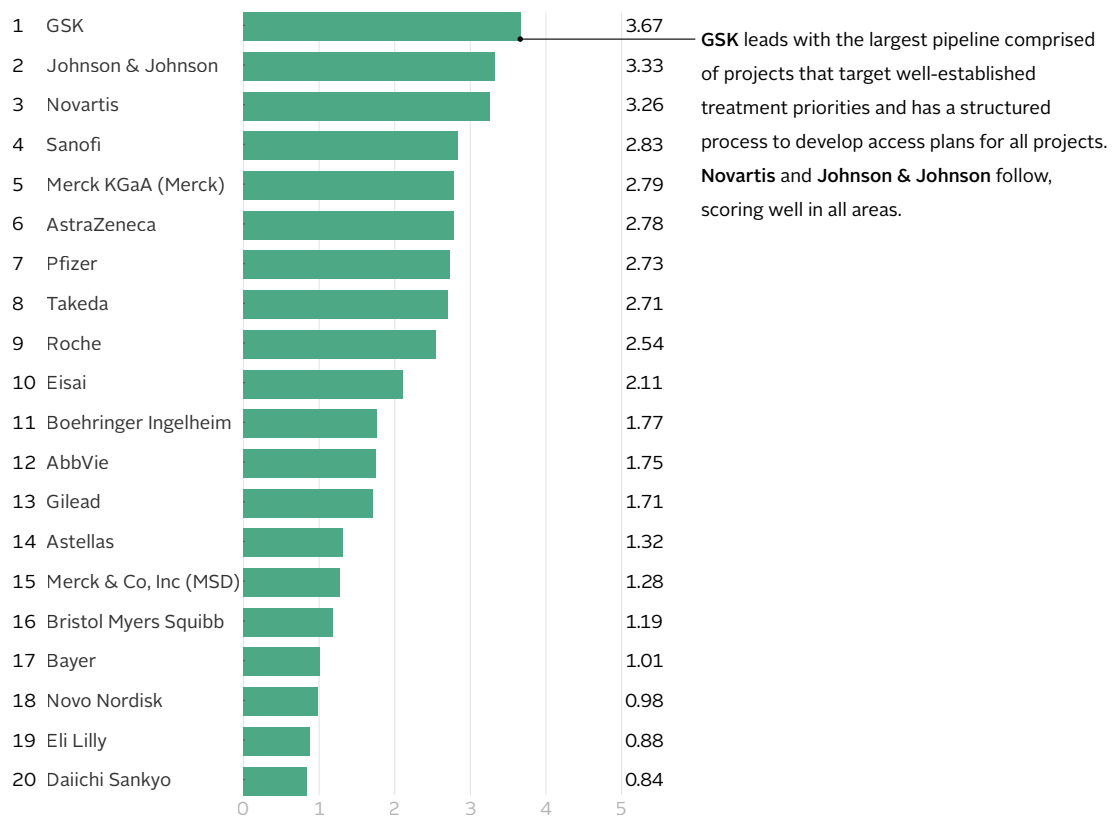
| FIND OUT MORE | Page |
|------------------------|------|
| Sub-ranking | 43 |
| Research & Development | 44 |

This section features a detailed figure-led analysis identifying industry strengths, weaknesses, trends and opportunities as of the time of writing. For a fine grained view of individual company activity in this Technical Area, see the Report Cards, page 127.

HOW THE COMPANIES PERFORM

Leaders pull ahead by addressing R&D priorities and planning ahead for access

FIGURE 25. Research & Development Ranking



GSK leads with the largest pipeline comprised of projects that target well-established treatment priorities and has a structured process to develop access plans for all projects. Novartis and Johnson & Johnson follow, scoring well in all areas.

What separates the best and worst performers

The leading company answering calls to carry out priority R&D is **GSK**, shouldering 22% of the total number of priority projects, followed by **Johnson & Johnson** (14%). **AstraZeneca** has the most projects with a clear public health benefit for low- and middle-income countries followed by **Bristol Myers Squibb**, **Merck*** and **Roche**. Almost all projects assessed target non-communicable diseases, focusing mostly on cancer and diabetes mellitus. In terms of quality of access plans, **GSK** and **Novartis** stand out as they consider multiple access components such as affordability, availability and supply of projects to a greater extent. Eight companies (**AstraZeneca**, **GSK**, **Johnson & Johnson**, **Merck**, **Novartis**, **Pfizer**, **Sanofi** and

Takeda) are mainstreaming access planning, meaning they are developing and/or implementing a structured approach to accompany all projects with access plans.

The mid-ranking pack of companies score quite closely, with differences in pipeline size and access plan coverage. Most companies in this group engage in building R&D capacity in low- and middle-income countries, though some show a stronger performance in meeting the Good Practice Standards. Lower-tiered companies did not provide evidence for most of their projects about how they plan ahead for access during R&D or if they aim to build local R&D capacity.

*Merck KGaA (Darmstadt, Germany)

RESEARCH & DEVELOPMENT

Are companies developing health products that are urgently needed and offer a clear public health benefit?

Breakthroughs in drug discovery can lead to new and innovative vaccines and medicines. Yet, these breakthroughs are valuable only if they reach the people who need them. Nowadays, products are often designed with little regard for resource-poor settings with a high disease burden, thus making people living in low- and middle-income countries last in line for treatments or leaving them without access to new, more effective health products. The reasons for such shortfalls in access in those countries are multiple and can range from lower commercial market potential, technical challenges, lack of an appropriate formulation (e.g. cold chain requirement or paediatric formulations) for under-resourced health systems and substandard and falsified (SF) products. This is why the treatment needs of people in low- and middle-income countries, as well as their ability to pay should be considered during the development of new medicines, vaccines and diagnostics. The availability and accessibility of these products marks a critical step for achieving the Sustainable Development Goal (SDG) of Universal Healthcare Coverage (UHC) by 2030.

Setting R&D priorities

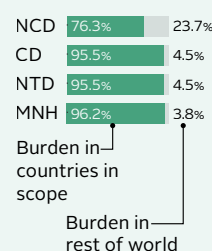
In view of the above, there is a huge call for action from the global health community for R&D that targets the needs of people living in low- and middle-income countries. The World Health Organization (WHO) and Policy Cures Research, an independent R&D-focused policy group, have published lists of the most urgently needed new products to help spur action in this area. The lists comprise a total of 50 diseases and 211 product gaps in scope. The pharmaceutical companies' response to these priorities can have a considerable effect on increasing access to medicine. On top of that, the COVID-19 pandemic has made governments, pharmaceutical companies, investors and other health stakeholders recognise the urgent need to

mobilise, collaborate and coordinate towards new treatments and vaccines. But developing urgently needed products is only one half of the equation. When new products leave the pipeline, they must be made widely available and affordable to all patients, regardless of where they live or their economic circumstance.

R&D for low- and middle-income countries

The WHO and Policy Cures Research priority lists do not include every single product needed by patients in low- and middle-income countries, even though they may have a clear public health benefit. There are many more specific effective treatments needed for non-communicable diseases (NCDs) but these are missing in current priority lists, as there is no consensus on priorities for these products. As a result, people in more vulnerable countries and communities may not be considered as priority during the development phase of these projects. For example, products may not be tested for heat stability — an issue for some low- and middle-income countries where proper storage facilities of medicines at low temperatures are lacking. As clinical trials are being conducted in low- and middle-income countries, companies should consider the needs of patients in low- and middle-income countries and reduce the risk of further delays in access to the newest medicines in the countries that need them the most. For this reason, companies should not only answer calls to carry out priority R&D, but also ensure that all products are suitable and accessible for populations in low- and middle-income countries.

Low- and middle-income countries shoulder the bulk of disease burdens



Answering a call for action, Sanofi and DNDi developed the first all-oral treatment for sleeping sickness. That same year, it was approved in DRC in 2019, where 85% of cases were reported.

What R&D projects does the 2021 Index analyse?

The 2021 Index assesses companies' efforts to engage in R&D for 82 diseases, conditions and pathogens in scope (i.e. those that cause the greatest burden in low- and middle-income countries). It assesses R&D activity against:

- 1 Defined and published R&D priority lists.** WHO and Policy Cures Research have identified 211 specific medicines, vaccines, diagnostic tests or other products that are urgently needed by people living in low- and middle-income countries (hereinafter termed 'priority R&D'); covering a total of 50 diseases.
- 2 Other diseases or products that have not yet been independently established as priority by global health stakeholders,** but have a clear public health benefit in low- and middle-income countries. The Index uses a set of criteria to identify such projects (see Appendix I).

FIGURE 27. What does each company pipeline look like?

The 2021 Index finds that 19 out of 20 companies are developing the 374 priority R&D projects identified. Novo Nordisk is the only company in scope that is not active in priority R&D. All 20 companies are developing projects with a clear public health benefit to patients in low- and middle-income countries.

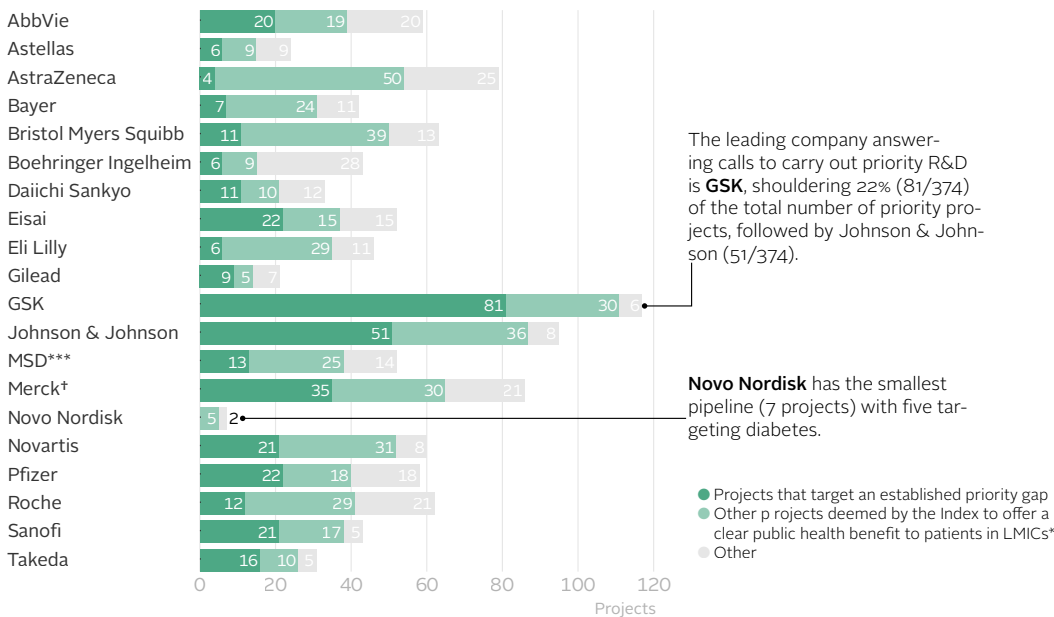
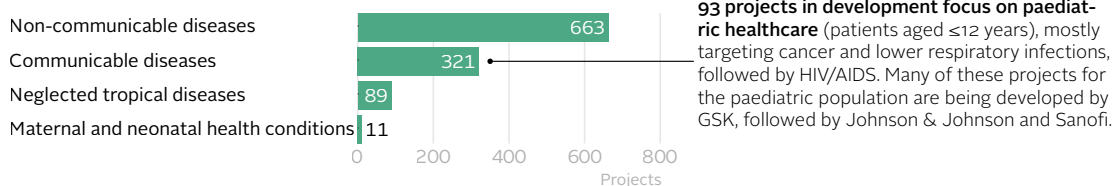


FIGURE 28. Projects for NCDs dominate the collective pipeline

The chart shows which diseases are the focus of the 1,073 R&D projects captured by the Index. The diseases with the most R&D projects are cancer (461) followed by coronaviral diseases (63), malaria (56), lower respiratory infections (45) and HIV/AIDS (41).**



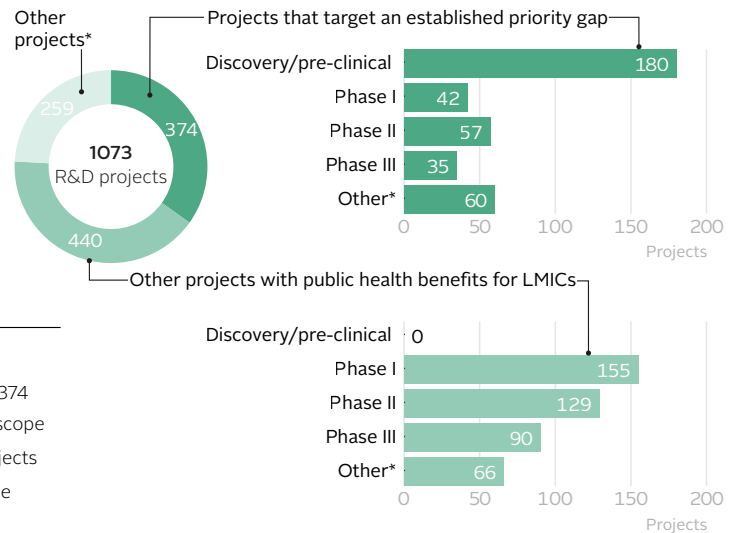
* Other includes projects that are market approved, subject to first global registration, have a technical lifecycle and projects that follow a different development cycle (e.g. diagnostics).

** The total is the sum of all projects counted. Some projects fall into several disease categories.

***Merck & Co, Inc (Kenilworth, NJ USA)
†Merck KGaA (Darmstadt, Germany)

FIGURE 26. How many projects did the 2021 Index capture?

The 20 companies in scope of the Index are developing a total of 1,073 R&D projects for the 82 diseases, conditions and pathogens assessed by the Index.** 374 of these target a priority R&D gap as identified by global stakeholders, while 440 offer a clear public health benefit for people in low- and middle-income countries.



PRIORITY R&D

Responding to calls for priority R&D

WHO and Policy Cures Research have identified 211 specific medicines, vaccines, diagnostic tests or other products that are urgently needed by people living in low- and middle-income countries.^{1,2,3,4,5,6} The charts below identify which companies in scope are aligning their R&D activities with these priorities. All projects in the pre-clinical and clinical

stages of development were included for this analysis. Table 4 (page 47) lists the products that have been identified as a priority by WHO and Policy Cures Research for low- and middle-income countries, showing the priority gaps that receive no attention from the companies in scope and those that receive the most.

FIGURE 29. How many priority R&D projects are in development?

Almost 35% (374 of 1,073) of the R&D projects target an established priority product gap. All projects in the pre-clinical and clinical stages of development were included for this analysis.

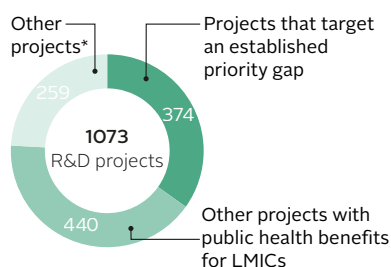


FIGURE 31. By disease, how does the priority R&D pipeline break down?

The majority of priority R&D projects focus on malaria, HIV/ AIDS and coronaviral diseases (i.e. COVID-19), with the most projects for communicable diseases in pre-clinical phase. More than half of the malaria projects (62%) and more than a third of the tuberculosis projects (36%) are developed under Product Development Partnerships (PDPs). This figure does not include projects where the Index could not determine the phase of development.

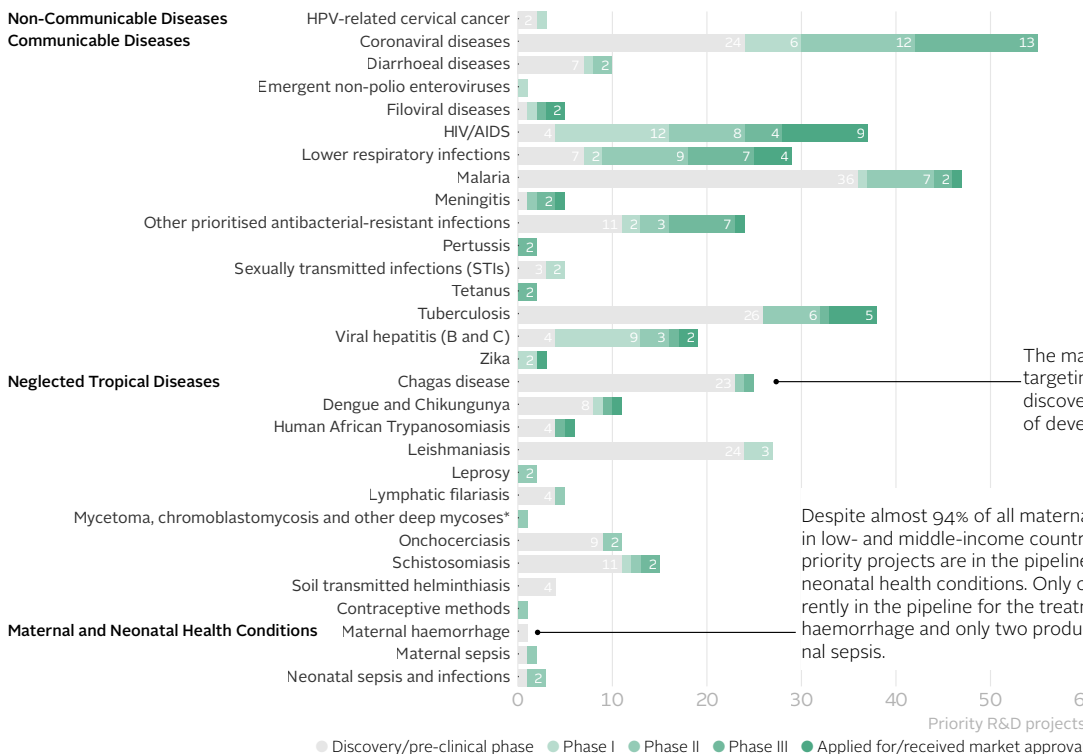
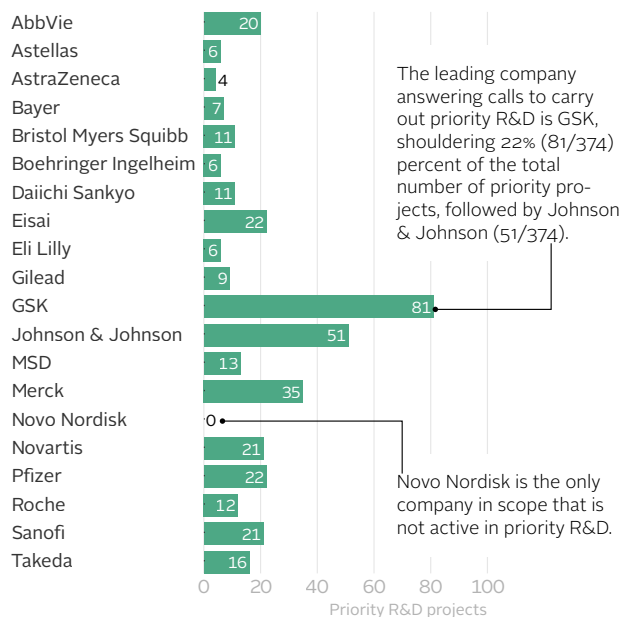


FIGURE 30. Which companies are developing projects targeting established priority R&D gaps?



The leading company answering calls to carry out priority R&D is GSK, shouldering 22% (81/374) percent of the total number of priority projects, followed by Johnson & Johnson (51/374).

Novo Nordisk is the only company in scope that is not active in priority R&D.

The majority of the projects targeting NTDs are still in the discovery/pre-clinical phase of development.

Despite almost 94% of all maternal deaths occurring in low- and middle-income countries⁷, only 11 R&D priority projects are in the pipeline for maternal and neonatal health conditions. Only one product is currently in the pipeline for the treatment of postpartum haemorrhage and only two products target maternal sepsis.

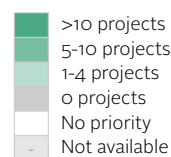
TABLE 4. Which established R&D priorities go unaddressed?

A total of 149 of the 211 identified priority gaps are unaddressed. This includes maternal health conditions, such as hypertensive disorders in pregnancy and diseases such as Bunyaviral diseases, Buruli ulcer and several diarrhoeal diseases and sexually transmitted infections (STIs). Noteworthy is the increase in projects targeting COVID-19; however, product gaps remain unaddressed for the other highly pathogenic coronaviral diseases.

COVID-19 demonstrates companies' ability to rapidly mobilise in the face of priorities, but how can we better prepare for the next pandemic? See page 20.

| Disease, conditions and pathogens | Medicines | Vaccines (Preventive) | Vaccines (Therapeutic) | Diagnostics | Microbicides | Vector Control Products | Devices (for reproductive health only) | Gaps Remaining |
|--|-----------|-----------------------|------------------------|-------------|--------------|-------------------------|--|----------------|
| Arenaviral haemorrhagic fevers (Lassa fever) | 0 | 0 | 0 | 0 | - | - | - | 4 |
| Crimean-Congo haemorrhagic fever | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| Rift Valley fever | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| Severe fever with thrombocytopenia syndrome (SFTS) | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| Other bunyaviral diseases | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| Buruli ulcer | 0 | 0 | 0 | 0 | - | - | - | 3 |
| HPV-related cervical cancer | 0 | 1 | 1 | 1 | - | - | - | 1 |
| Chagas disease | 25 | 0 | 1 | 0 | - | 1 | - | 2 |
| Contraceptive methods | 1 | - | - | - | - | - | 0 | 1 |
| •Other highly pathogenic coronaviral diseases* | 41 | 10 | 0 | 4 | - | 0 | - | 2 |
| Chikungunya | 1 | 1 | 0 | 1 | - | 1 | - | 1 |
| Dengue | 8 | 1 | 0 | 0 | - | 1 | - | 2 |
| Cholera | 0 | 0 | 0 | 0 | - | - | - | 4 |
| Cryptosporidiosis | 4 | 0 | 0 | 0 | - | - | - | 3 |
| Enterotoxigenic E.coli (ETEC) infections | - | 0 | - | 0 | - | - | - | 2 |
| Enteroaggregative E. coli (EAEC) infections | - | 0 | - | 0 | - | - | - | 2 |
| Giardiasis (lambliaosis) | - | - | - | 0 | - | - | - | 1 |
| Rotaviral gastroenteritis | - | 0 | - | - | - | - | - | 1 |
| Shigellosis | 0 | 3 | 0 | 0 | - | - | - | 3 |
| Typhoid and paratyphoid fever (S. typhi, S. paratyphi A) | 0 | 1 | 0 | 0 | - | - | - | 3 |
| Non-typhoidal S. enterica (NTS) | 0 | 1 | 0 | 0 | - | - | - | 3 |
| Emergent non-polio enteroviruses (including EV71, D68) | 0 | 1 | 0 | 0 | - | - | - | 3 |
| Ebola | 2 | 3 | 0 | 0 | - | 0 | - | 3 |
| Marburg | 0 | 1 | 0 | 0 | - | 0 | - | 4 |
| Other filoviral diseases | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| Nipah | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| Other henipaviral diseases | 0 | 0 | 0 | 0 | - | 0 | - | 5 |
| HIV/AIDS | 33 | 3 | 1 | 2 | 0 | - | - | 1 |
| Human African trypanosomiasis | 6 | 0 | 0 | 0 | - | 1 | - | 3 |
| Pre-eclampsia | 0 | 0 | 0 | 0 | - | - | - | 2 |
| Leishmaniasis | 27 | 0 | 0 | 0 | - | - | - | 3 |
| Leprosy | 2 | 0 | 0 | 0 | - | - | - | 3 |
| Leptospirosis | - | - | - | 0 | - | - | - | 1 |
| S. pneumoniae** | - | 3 | - | 0 | - | - | - | 1 |
| Influenza | - | 6 | - | - | - | - | - | 0 |
| Respiratory syncytial virus (RSV) | - | 6 | - | - | - | - | - | 0 |
| Lymphatic filariasis | 5 | - | - | 0 | - | 0 | - | 2 |
| Malaria (P. falciparum,P. vivax) | 45 | 3 | 0 | 1 | - | 3 | - | 1 |
| Postpartum haemorrhage | 1 | - | - | - | - | - | 0 | 1 |
| N. meningitidis, Cryptococcal meningitis | 0 | 4 | 0 | 0 | - | - | - | 3 |
| Mycetoma | 1 | - | - | 0 | - | - | - | 1 |
| Group B Streptococcus | - | 3 | - | - | - | - | - | 0 |
| Onchocerciasis | 4 | 0 | - | 0 | - | 0 | - | 3 |
| Rheumatic fever | - | 0 | - | - | - | - | - | 1 |
| Schistosomiasis | 9 | 0 | 0 | 3 | - | 1 | - | 2 |
| Chlamydia | - | 0 | 0 | 0 | - | - | - | 3 |
| Gonorrhoea | 1 | 2 | 0 | 0 | - | - | - | 2 |
| Herpes simplex virus type 2 (HSV-2) | 0 | 1 | 0 | 0 | - | - | - | 3 |
| Human T-cell lymphotropic virus type 1 (HTLV-1) | 0 | 0 | 0 | 0 | - | - | - | 4 |
| Syphilis | 0 | 0 | 0 | 0 | - | - | - | 3 |
| Other sexually transmitted infections (STIs) | 0 | 0 | 0 | 0 | - | - | - | 4 |
| Hookworm diseases | 0 | 0 | - | - | - | - | - | 2 |
| Strongyloidiasis | 0 | 0 | - | 0 | - | - | - | 3 |
| Trichuriasis | 0 | 0 | - | - | - | - | - | 1 |
| Ascariasis | 0 | 0 | - | - | - | - | - | 1 |
| Snakebite envenoming | 0 | 0 | - | 0 | - | - | - | 2 |
| Taeniasis/cysticercosis | 0 | - | - | 0 | - | 0 | - | 3 |
| Trachoma | - | 0 | - | 0 | - | - | - | 2 |
| Tuberculosis | 35 | 1 | 0 | 3 | - | - | - | 1 |
| Hepatitis B | 12 | - | 2 | 1 | - | - | - | 0 |
| Hepatitis C | 2 | 0 | - | 1 | - | - | - | 1 |
| Zika | 0 | 2 | 0 | 0 | - | 1 | - | 3 |
| Disease X*** | - | - | - | - | - | - | - | 0 |
| Other prioritised antibacterial-resistant infections† | 11 | 13 | 1 | 0 | - | - | - | - |

* Including Middle East respiratory syndrome coronavirus (MERS-CoV), Severe acute respiratory syndrome (SARS). This number includes all Covid-19 projects.
 **There are 31 projects in the pipeline targeting lower respiratory infections. However, the targeted priority pathogen is not clear for all projects.
 ***Disease X is defined by WHO as a pathogen currently unknown to cause human disease that could cause a serious international epidemic. Priority R&D for this disease is restricted to platform technologies that enable cross-cutting R&D preparedness that is also relevant for an unknown Disease X. Not included in the remaining gaps.
 † This WHO priority pathogen list does not define specific products needed.

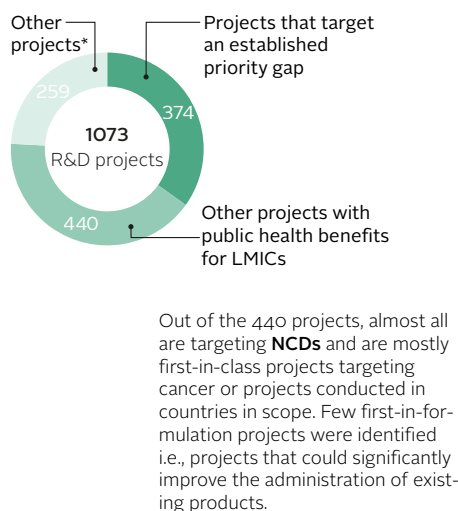


R&D FOR LOW- AND MIDDLE-INCOME COUNTRIES

Developing other projects with a clear public health benefit for low- and middle-income countries

Thirty-two of the 82 diseases and conditions in scope of the Index have not yet been established as priority by global health experts. For these 32 diseases, the Index used a set of criteria to determine which of the projects targeting these diseases offer a clear public health benefit to patients in low- and middle-income countries, for example, projects aiming for heat stability or with clinical trials running in countries in scope. The charts below show the number of such projects identified and the companies who are developing them. Only projects in the clinical stages of development were included for this analysis (Phase I onwards).

FIGURE 32. How many projects offer a clear public health benefit to patients in low- and middle income countries?

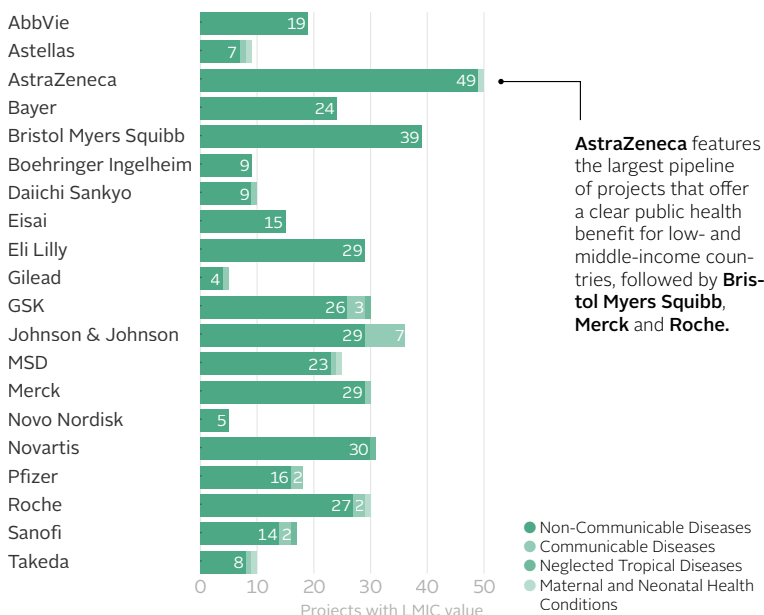


Target product profiles

Companies can optimise the development of products (including access planning and pricing) by including the needs of patients in low- and middle-income countries in their target product profiles. An example of such a target product profile is the profile set up by the WHO Preferred Product Characteristics. The WHO's Department of Immunization, Vaccines and Biologicals has formulated WHO's preferences for new vaccines in the priority disease areas.⁹ These product profiles promote the development of new products with high public health impact that are suitable for use in low- and middle-income countries.

Although the Index finds evidence that the companies in scope are developing projects that offer a clear public health benefit to patients in low- and middle-income countries, there is no guarantee that these products will be made accessible to these populations. With the vast majority of the projects targeting NCDs and with 86% of premature NCDs deaths occurring in low- and middle-income countries⁸, companies should have concrete plans in place — known as *access plans* — that help ensure these products are accessible and affordable for patients in low- and middle-income countries once they become available on the market.

FIGURE 33. Which companies are developing other projects with a clear public health benefit to patients in low- and middle income countries?



Standout projects include:

- The first oral GLP-1 agonists for the treatment of Type 2 diabetes mellitus (Novo Nordisk, Pfizer);
- The Fasentra® (benralizumab) auto-injector pen for asthma (AstraZeneca) that can be self-administered;
- The HISCL series immunoassay system which is a potential blood-based Alzheimer's diagnostic test that could reduce costs of testing (Eisai);
- The Baqsimi® nasal glucagon for severe hypoglycaemia in adults, adolescents and children aged 4 years and over with diabetes mellitus (Eli Lilly).

ACCESS PLANNING

Do companies plan ahead to ensure their products are accessible to patients in low- and middle-income countries?

New medicines, vaccines and other life-saving products must be made rapidly available in low- and middle-income countries as soon as they have been approved for sale. This requires tactical planning throughout the development phase. Access plans can comprise a range of activities from prioritising countries with the highest disease burdens for registration, equitable pricing strategies, sufficient supply commitments, non-exclusivity in specified countries, waiving of patent rights and royalty-free provisions. Such access plans help facilitate the availability, accessibility, affordability and supply of products for patients in countries within the scope of the Index (see Table 2). Access plans are expected for projects that are in clinical development Phase II and onward ('late-stage projects').

Yet, there is no 'one-size-fits-all-products' approach. Different therapeutic areas, products, etc. dictate different access needs. Access plans tend to be developed through collaboration with global health donors and Product Development Partnerships (PDPs), including the Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Drugs for Neglected Diseases initiative (DNDi), International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), Medicines for Malaria Venture, TB Alliance, Wellcome, PATH and Unitaid. Companies can, however, also apply such plans to in-house projects independently, especially for their late-stage R&D projects.

Access plans:

- Registration
- Non-exclusive voluntary licensing
- Patent waivers
- Supply and demand plans
- WHO prequalification
- Product donations

Are companies planning to make new products quickly accessible after launch?

Sanofi

Sanofi has registration plans in place for dupilumab (Dupixent®) for the treatment of asthma in several UMICs and LMICs.

GSK

GSK's access plan for its dolutegravir paediatric project by ViiV healthcare includes registration commitments, WHO pre-qualification, 15 non-exclusive, royalty-free voluntary licences (14 with the Medicines Patent Pool), partnership with CHAI/Unitaid and two generic manufacturers. ViiV Healthcare has committed to supply the 5 mg dispersible tablet at the cost of manufacture plus distribution costs until generics are available, in all low income, all least developed and all sub-Saharan African countries. In middle income countries a flexible pricing approach applies.

GSK

GSK's tafenoquine (Krintafel/Kozenis®) for the treatment of Plasmodium vivax malaria, was developed in collaboration with the Medicines for Malaria Venture (MMV). Implementation studies in Brazil, Ethiopia, and Thailand will be made possible through the Bill & Melinda Gates Foundation and MMV. Tafenoquine (registered as Kozenis, in malaria endemic coun-

tries) will be made available on a 'not-for-profit' basis. Furthermore, there is no IP associated with tafenoquine.

Johnson & Johnson

Johnson & Johnson reports supply and demand plans in place for its investigational adult vaccine for respiratory syncytial virus. If development is successful, the company's supply chain strategy is designed to support the anticipated need across countries over time and the vaccine is expected to be available globally, including LMICs.

Merck

Praziquantel is in clinical trials for treatment of female genital schistosomiasis. Merck states final access would be targeted to sub-Saharan Africa and would include a plan for affordable, accessible and sustainable treatment. Meanwhile, in the context of Merck's commitment to schistosomiasis elimination in the context of non-for-profit efforts, a praziquantel donation program for use in adults is opened (agreed in the recent Memorandum of Understanding with WHO for all sub-Saharan African countries in need to treat schistosomiasis.)

Merck

Merck is committed to providing access to avelumab (Bavencio®) through several avenues. Avelumab for the treatment of Non-small-cell lung carcinoma recent clinical trials involved sites in Index countries: Brazil, China, Colombia, Mexico, Peru, South Africa, Ukraine and Thailand. Merck commits to undertake clinical trials only in countries where the company intends to register and ensure access to the medicines. This program runs within the global strategic alliance with Pfizer Inc. aimed at developing and commercializing avelumab as a single agent as well as in various combinations to treat cancer indications.

Roche

Roche's access plan for its ovarian cancer treatment, atezolizumab with bevacizumab and chemotherapy, consists of registration plans for Bangladesh in 2021, Armenia in 2022, Bolivia in 2021, Brazil in 2020, Cambodia (year not available yet), Colombia in 2020, China (year not available yet), Dominican Rep in 2020, Ecuador in 2020, El Salvador in 2020, Egypt (year not available), Ghana in 2020, Guatemala in 2020, Guyana in 2020, Honduras in 2020, India in 2021, Indonesia in 2020, Iran in 2021, Kosovo in 2021, Morocco in

2021, Mexico in 2020, Nicaragua in 2020, Pakistan in 2021, Paraguay in 2021, Peru in 2021, Thailand in 2020, Turkmenistan in 2021, Ukraine in 2021 and Vietnam in 2021.

Takeda

Takeda's access plan for its dengue vaccine focuses primarily on countries with the highest unmet medical need. The company commits to registering the vaccine in dengue-endemic areas, WHO prequalification, in-country tiered pricing strategies and voluntary licences.

How many companies have access plans in place for their late-stage R&D projects?

The 2021 Index looked at access plans across two categories, projects that target established global health priorities i.e. priority R&D projects, and other projects that, based on the Index's criteria, would also constitute a clear health benefit for people living in low- and middle-income countries.

Of the 20 companies, 19 have provided evidence of access plans implemented for at least one project during R&D. Boehringer Ingelheim had no late-stage priority projects during time of analysis. When comparing the same priority projects in 2018 and 2020, five projects have gained access plans.

Most projects that target an R&D priority are covered by access plans, mainly because they are conducted within PDPs. By contrast, projects targeting a disease that has not yet been established as a priority by global health stakeholders tend to be covered by fewer access plans. The Index finds that eight companies are taking the lead in integrating access planning into all their development processes. They are developing structured approaches for pairing each R&D project with a plan for rapidly ensuring people living in low- and

middle-income countries gain access at launch. This represents a significant expansion in good practice since the previous Index, when Novartis was noted as the first to begin mainstreaming access planning across its pipeline. Joining Novartis in 2020 are AstraZeneca, GSK, Johnson & Johnson, Merck, Pfizer, Sanofi and Takeda, comprising 40% of companies in the Index.

FIGURE 34. **Eight companies are moving to make access planning mainstream**

In 2018, Novartis was the only company in the Index to be developing a systematic approach to access planning. Now eight companies are making such moves: these are AstraZeneca, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Sanofi and Takeda.

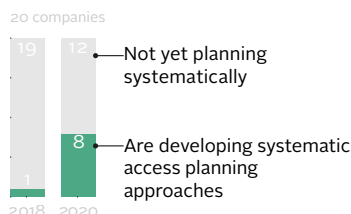


FIGURE 35. **Majority of late-stage R&D projects are not supported by access plans**

The 20 companies in scope have 394 R&D projects in late-stage development that either target established global health priorities or offer clear public health benefits for low- and middle-income countries. The majority of these are not yet supported by an access plan.

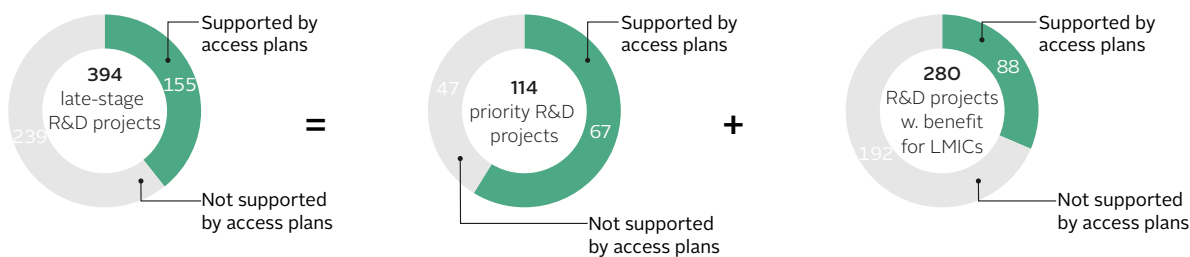
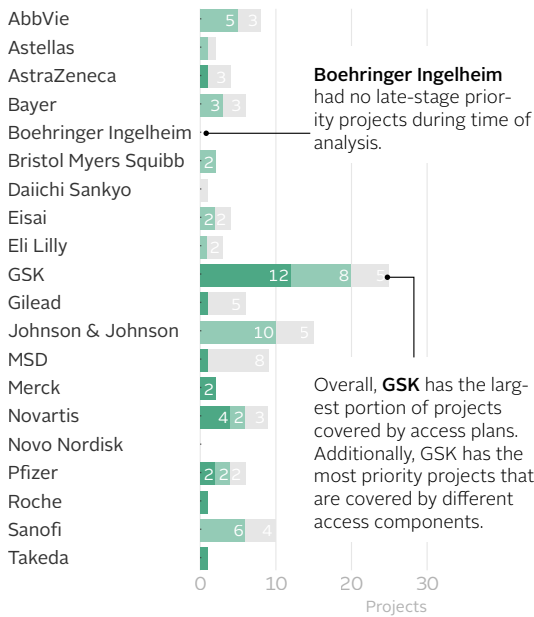


FIGURE 36. Which companies have comprehensive access plans in place for their late-stage R&D projects?

This chart shows which companies are planning ahead, looking at the proportion of their late-stage pipelines that are supported by access plans and whether these plans are comprehensive. In other words, if they include all of the following access components: affordability, availability, supply and breadth (covering more than five countries in scope). In general, access plans

are mostly focused on availability rather than affordability or supply. Priority R&D projects tend to be covered by stronger and more comprehensive access plans. GSK has the largest proportion of projects that are covered by different access components.

Late-stage priority R&D projects with access plans (67/114)



Late-stage projects with a public health benefit for low- and middle-income countries with access plans (88/280)

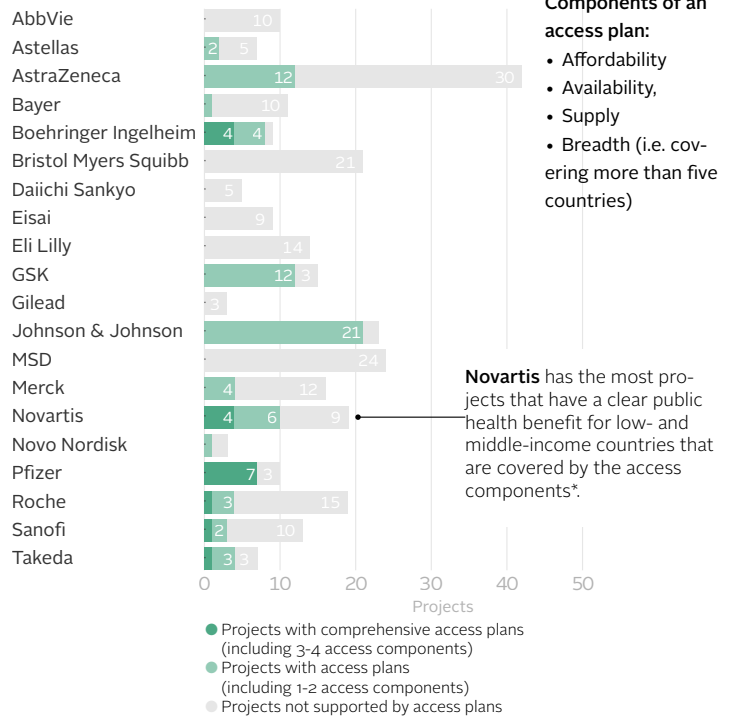
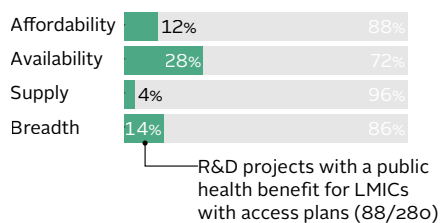
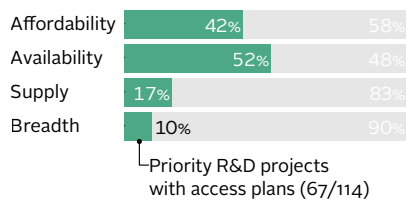


FIGURE 37. Which access components are mostly included in companies' access plans?

Of the priority R&D projects with access plans, most (52%) take availability into account. Of the projects that are deemed to have a clear public health benefit in LMICs, only 12% of access plans take affordability into account.



Opportunity for pharmaceutical industry to become driver for access

The Index concludes that, as access planning does not yet cover even half of late-stage projects, it is encouraging that eight companies are integrating access planning fully into their development processes, including for projects without donor involvement. This signals that access planning should begin to increase as more projects enter later clinical phases, and could become standard across the industry. If this happens, people living in low- and middle-income countries, especially resource-limited settings or remote areas, will no

longer need to be last in line for pharmaceutical innovations, which is key for achieving universal health coverage (UHC).

Pharmaceutical companies can become a main driver for rapid access to innovative health products in low- and middle-income countries. This shift could be accelerated if donors that enter into areas that are not yet prioritised for global health, such as cancer and diabetes, stimulate early access planning for the projects they support.

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PRODUCT DELIVERY

CONTEXT

Product Delivery covers a wide spectrum of related topics, ranging from registration and licensing to intellectual property sharing and health system strengthening. Product Delivery assesses the companies' post-development actions on the ground to ensure they offer equitable access to their products and overcome any local barriers in accessing hard-to-reach markets and patient populations.

PERFORMANCE INDICATORS

In this Technical Area, the companies' performance is assessed against the following indicators:

- Disclosure of patent statuses and public commitment not to enforce patents
- Intellectual property (IP) sharing with third parties
- Use of non-assertion and/or licensing agreements to enable generic medicine manufacturing and supply
- Product registration in high-burden countries
- Access strategies in place for three types of products: healthcare professional-administered, self-administered and supranationally procured
- Manufacturing and supply chain capacity building initiatives
- Continuous product supply
- Health system strengthening initiatives
- Inclusive business models, scaled up to reach more populations at the base of the income pyramid
- Reporting mechanisms for substandard and falsified (SF) medicines
- Product donations in response to expressed treatment needs along with structured donation programmes aimed at the elimination, eradication or control of Neglected Tropical Diseases

WHAT DOES BEST PRACTICE LOOK LIKE

Equitable pricing strategies are at the heart of patient-oriented business operations. Top-performing companies consider affordability and continuous supply to increase patient reach at all levels of the income pyramid. They enter into supranational procurement agreements and develop patient assistance programmes (PAP) to provide personalised, income-tailored support based on intra-country pricing solutions and economic conditions.

As part of their health system strengthening initiatives, high-performing companies focus on educating and training health workers, raising public awareness and collaborating with local stakeholders. Mental disorders, cervical cancer, stroke, HIV/AIDS and non-communicable diseases are prioritised in their agenda due to the high incidence rates in certain countries and regions.

Lastly, product donations continue to play an important role in eliminating, eradicating or controlling some diseases that affect populations living in low- and middle-income countries. For people living in poverty, donations may be their only chance of getting access to the treatment they need. Companies engaging in structured donation programmes to eliminate, eradicate or control the Neglected Tropical Diseases meet and exceed the WHO-determined goals as they donate their products indefinitely and to larger patient populations.

INSIGHTS

1. Medicines represent 75% of the companies' portfolios, while 61% of the total health products target non-communicable diseases (NCD).
2. Registration filings of NCD products occur less often in low- and middle-income countries compared to products for other diseases.
3. Five companies have scaled up six inclusive business models to reach more countries and more patients at the base of the income pyramid.
4. Capacity building initiatives for manufacturing capacities are focused on China, Brazil and India and expansion of geographic scope is needed.

FIND OUT MORE

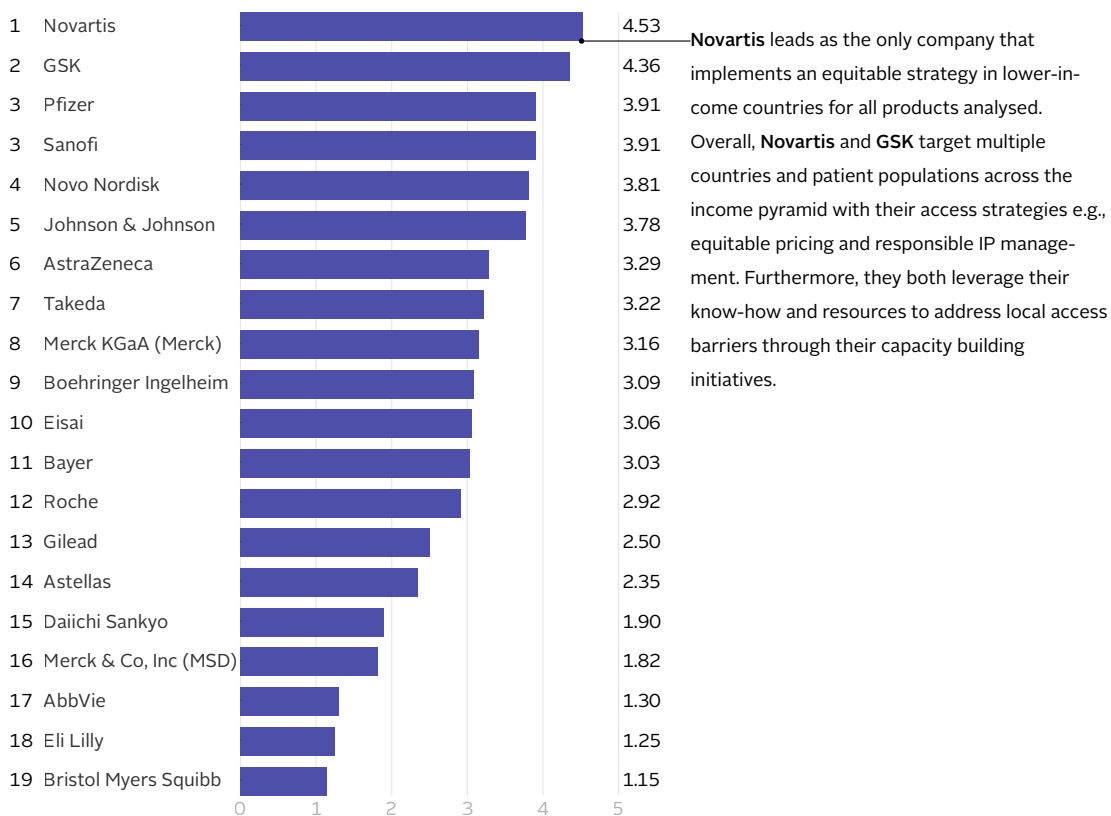
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These sections feature detailed figure-led analyses identifying industry strengths, weaknesses, trends and opportunities as of the time of writing. For a fine grained view of individual company activity in this Technical Area, see the Report Cards, page 127.

HOW THE COMPANIES PERFORM

Leaders expand their product delivery approach to boost access for lower-income countries

FIGURE 38. Product Delivery Ranking



Novartis leads as the only company that implements an equitable strategy in lower-income countries for all products analysed. Overall, Novartis and GSK target multiple countries and patient populations across the income pyramid with their access strategies e.g., equitable pricing and responsible IP management. Furthermore, they both leverage their know-how and resources to address local access barriers through their capacity building initiatives.

What separates the best and worst performers

The top six companies in this area take more steps to try and reach more populations in need. They perform strongly in access strategies and registering their products widely in high-burden countries in scope. As well as supply chain capacity, the six companies perform well in building local manufacturing capacity, albeit focusing mostly on upper-income countries, and are particularly strong in health system strengthening initiatives.

In contrast, middle performing companies generally use a less diverse range of equitable access strategies and tend to focus on upper- and middle-income countries rather than lower-income countries. They exhibit varied performances in this

Technical Area due to their mixed approaches to registration, IP management, supply and manufacturing capacity building.

The lowest ranked companies are markedly less transparent than their peers across several areas of assessment. They perform poorly when it comes to registration and access strategies.

PORTFOLIO ANALYSIS

What products do companies have in their portfolios?

The purpose of this portfolio analysis is to provide an overview of the health products and the diseases targeted assessed in the 2021 Index. It also aims to identify for which products there is a more urgent need of improving/implementing new strategies to expand access to medicine

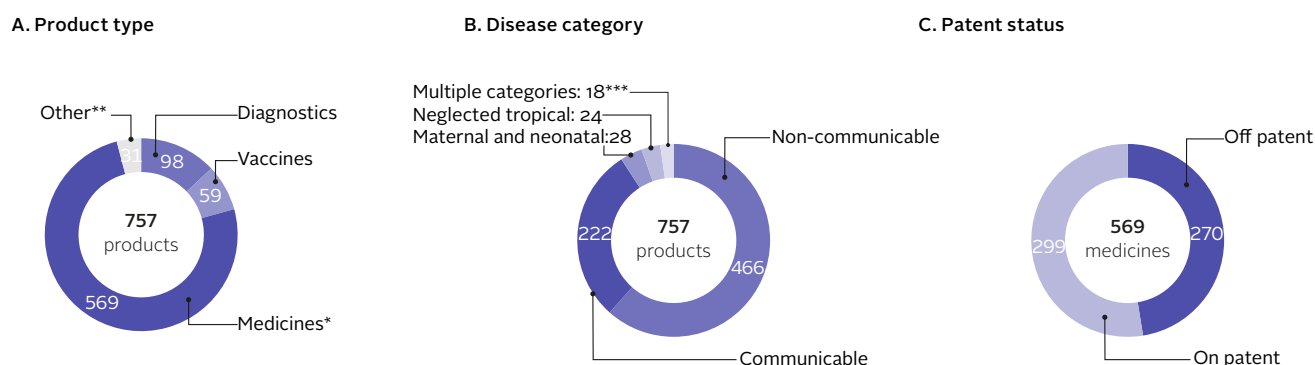
in the low- and income countries. The products have been selected based on several inclusion criteria from a list provided by each of the 20 largest pharmaceutical companies included in the report. Please refer to Appendix I for further details about inclusion criteria.

Portfolio analysis shows all companies have essential medicines or vaccines

Medicines represent the largest share of the 757 health products included in the Index analysis. Other products include platform technologies and vector control products. More than half of the health products in scope target non-communicable diseases (NCDs), while the least attention is being paid to neglected tropical diseases. For this analysis, only the patent status of medicines has been assessed.

This analysis also shows which medicines produced by the companies in scope are listed on the WHO Model Lists of Essential Medicines (EML), and among these, which are on and off patent. Data on the non-EML medicines are provided, as well. The majority of companies are patent holders of at least one medicine listed on the EML. Bristol Myers Squibb and Roche, in particular, have eight and seven out of the total on-patent medicines on the EML, respectively (figure 40).

FIGURE 39. Most health products are on-patent medicines targeting NCDs



- No products targeting the following NTDs:
- Buruli
 - Dracunculiasis
 - Mycetoma
 - Onchocerciasis
 - Scabies
 - Snakebite envenoming
 - Trachoma
 - Yaws

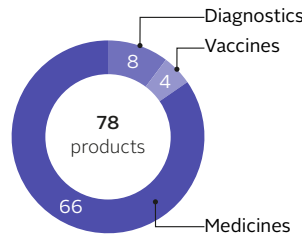
*Medicines includes the 22 contraceptive methods and device analysed in the 2021 ATMI Index.

**Other includes vector control products and platform technology. See Appendix VII for definitions.

*** Multiple categories refers to products targeting more than one disease belonging to different disease categories.

FIGURE 40 Sixty-six medicines received market approval during the period of analysis

This chart shows the proportion of the health products which received at least one regulatory approval by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) or the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for a product targeting a disease in scope.



Some of the recently approved products target priorities established by global health stakeholders, such as the new Ebola vaccine, a new antibiotic for drug-resistant infections, multiple products for multidrug-resistant tuberculosis (MDR TB), a new indication for a drug and three new diagnostics and an oral drug for endometriosis. Other approvals include a new intranasal spray for treatment-resistant major depressive disorder, a debilitating condition with limited treatment options.

FIGURE 41. The majority of companies are patent holders of essential medicines[§]

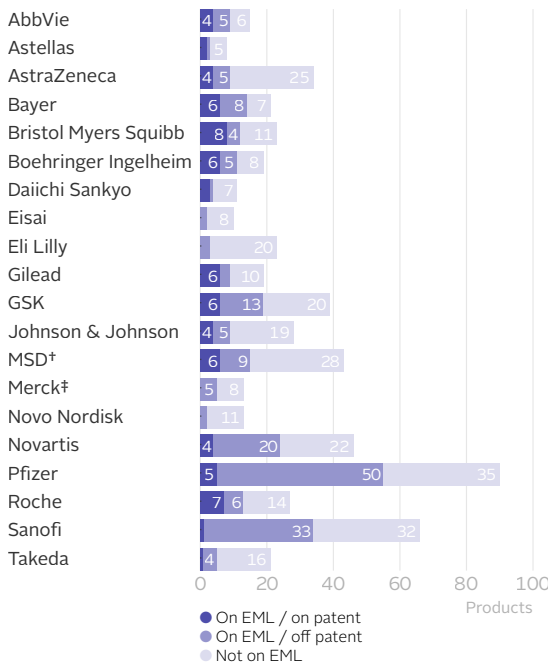
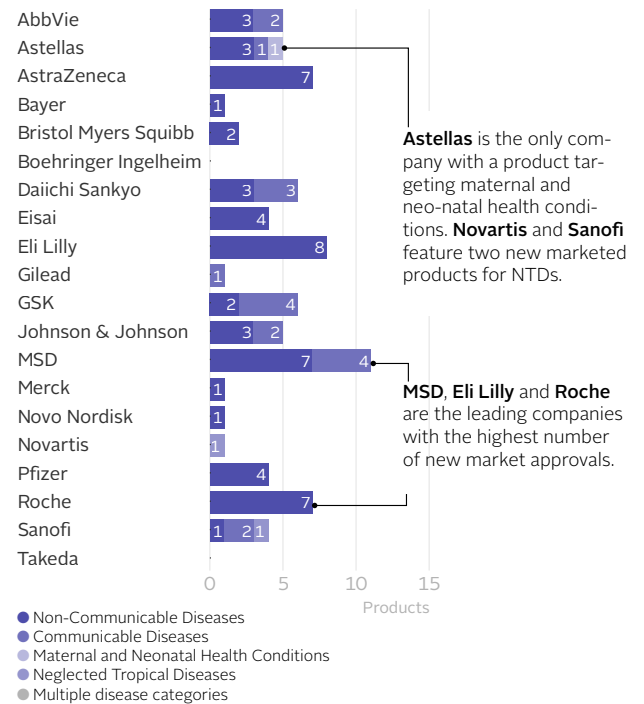


FIGURE 42. New market approvals per company by disease category



Astellas is the only company with a product targeting maternal and neo-natal health conditions. Novartis and Sanofi feature two new marketed products for NTDs.

MSD, Eli Lilly and Roche are the leading companies with the highest number of new market approvals.

‡ Merck KGaA (Darmstadt, Germany)
 † Merck & Co., Inc (Kenilworth, NJ, United States).
 § Index portfolio medicine considered alternative treatments to the medicine

listed on the WHO EML and associated with the square box sign, were counted as part of the WHO essential medicine list.

REGISTRATION

Which markets do pharmaceutical companies target for registration?

Besides certain exceptional circumstances (e.g. global access programmes), registration is a key step to introducing a medical product into a country. Registration with the national regulatory authorities enables distribution, marketing and, by extension, patient access to life-saving products across the country. In lower-income countries, the registration of newly launched products typically occurs less frequently and usually later than in higher-income ones with larger markets.

Registration challenges

There are various reasons why a company may or may not file a product for registration in a specific country:

- Competing products already on the domestic market
- Policies on pricing transparency
- Unclear local regulatory requirements
- Health authorities lacking capacities for processing registration dossiers
- Political instability
- Conflict or economic sanctions

What the Index measures

The Index assessed a sample of the 20 companies' recently marketed products to gain an insight into their registration practices in countries in scope i.e., 106 low- and middle-income countries with high burdens of disease and/or high inequality. The Index looked at whether companies filed to register their most recently launched products in low- and middle-income countries. The companies submitted up to a maximum of 10 recently launched products to the Index for analysis, resulting in a total of 182 products.

Therefore, the Index looks for companies filing new products for registration both widely across low- and middle-income countries and rapidly i.e. within 12 months of first global registration, starting where the need for the product is greatest. This is particularly important for products that are innovative or superior to those already on the market. Filing to register new products rapidly in low- and middle-income countries is a critical step in facilitating more widespread access.

Overcoming access challenges

In response to some of these challenges, certain bodies and programmes have been established are already providing companies with support for product registration:

- The World Health Organization's (WHO) prequalification system¹
- The WHO Collaborative Registration Procedure²
- The African Medicines Regulatory Harmonization (AMRH) programme³
- The African Medicines Agency (AMA)⁴

Which countries do companies target?

The countries in scope with the most registration filings mainly include upper middle-income countries (UMICs) and low- and middle-income countries with a large volume of patients or higher possibility of revenue. In contrast, the countries receiving the lowest number of registration filings include politically unstable countries, e.g., Somalia and South Sudan, or have small populations such

as Tuvalu and Vanuatu. Twelve countries did not receive any registration filings. These countries are collectively home to more than 30 million people. Some of these countries have a high burden of non-communicable diseases (NCDs). For example, Kiribati, Micronesia, Fed. Sts., Tonga, Lesotho, Solomon Islands and Eswatini are featured in the top 10 high burden countries* for diabetes mellitus.

FIGURE 43: The ten countries with the most registration filings are UMICs

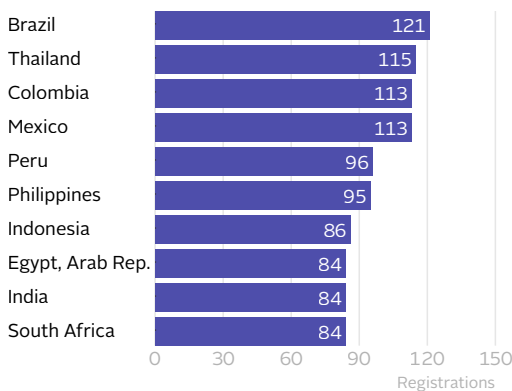
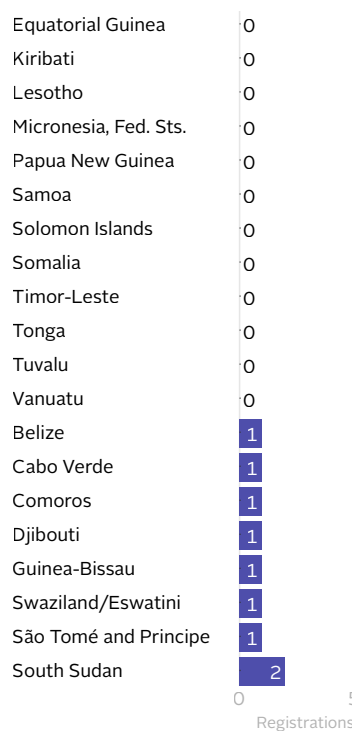


FIGURE 44: Which countries have the fewest registration filings?



Countries with the lowest filings

The 20 countries with the lowest number of registrations are home to more than 47 million people.

One product stands out

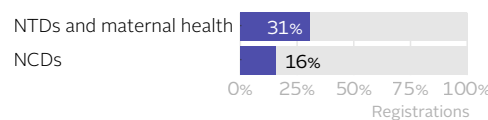
AbbVie's HIV/AIDS product lopinavir/ritonavir (Aluvia®/Kaletra®) is the only product registered in Cabo Verde, Comoros, Djibouti, Guinea Bissau, Swaziland/Eswatini and São Tomé and Príncipe. There are two potential reasons for this: 1) the product has been on the market for a considerable period of time (first global registration in 2000); 2) HIV/AIDS has the highest level of intervention and prioritisation by global health stakeholders – treatments tend to be procured through supranational entities (i.e. pool procurement mechanisms).

Which diseases do most product registration filings concern?

Overall, products for neglected tropical diseases (NTDs) and maternal and neonatal health conditions are registered more widely than products for non-communicable diseases (NCDs). The Index found that on average, the products for NTDs and maternal and neonatal health conditions are registered in twice as more countries than products for NCDs. This can be due to product development partnerships which demand access provisions, including registration, and the existence of supranational procurement mechanisms. Such incentives do not exist for many NCDs except for those products eligible for supranational procurement (donor-enabled pooled procurement).

FIGURE 45. Registration filings are lowest for NCD products

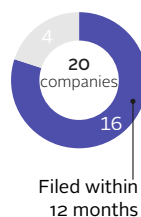
Products for neglected tropical diseases (NTDs) and maternal and neonatal health conditions are registered in twice as more countries than products for NCDs.



* relevant top 10 high burden countries for diabetes(disease-specific subset of countries with the highest burden of disease) according to IHME global burden of disease study.

Do companies rapidly register their products where the need is the greatest?

Filing for registration in low- and middle-income countries within 12 months is not consistent and there is still a large time gap between the first global product registration and registration in these countries. Overall, companies do not always prioritise the countries with the highest burden of disease when filing for registration of their recently launched products.



16 companies filed at least one product for registration in countries in scope within 12 months after first global registration

FIGURE 46. Most companies have filed a recently launched product* for registration in countries in scope within 12 months after first global approval**

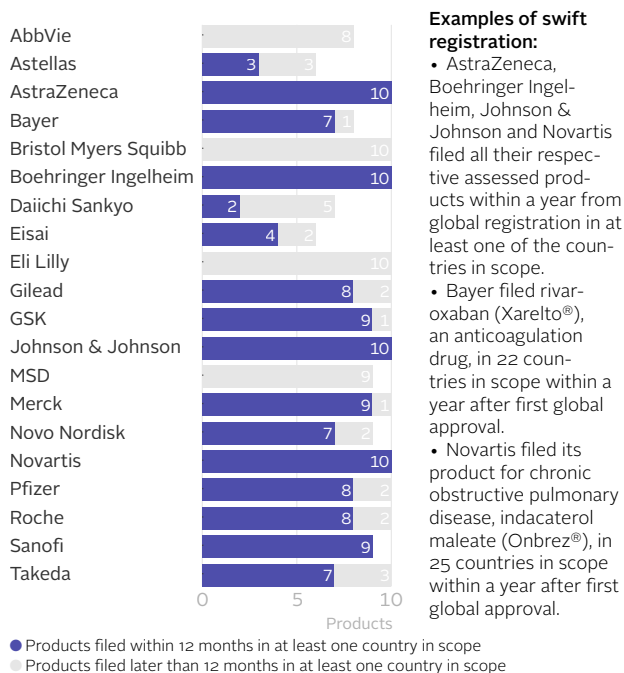
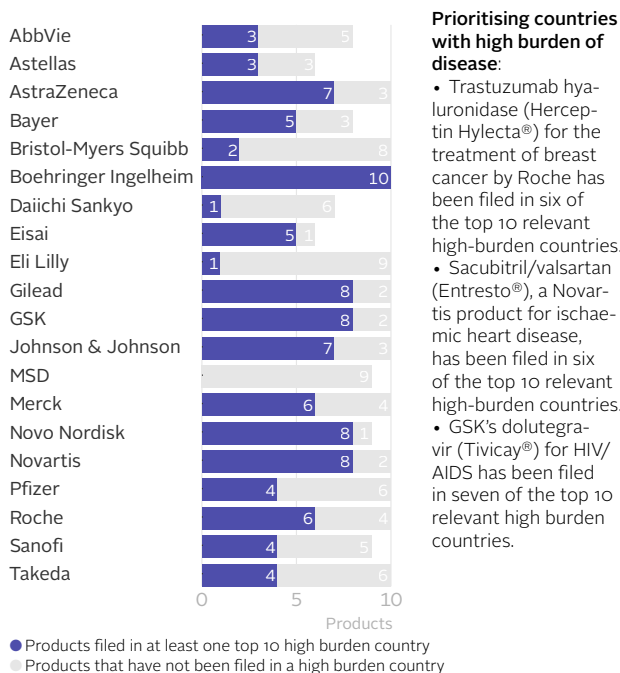


FIGURE 47. Few products* are registered in the 10 highest-burden countries***



How some companies are overcoming registration challenges

Challenge: Regulatory authority requirements

ROCHE

How: Atezolizumab (Tecentriq®) is one of the most widely registered oncology treatments. Roche filed the product for registration in 37 countries in scope, in 21 of which registration occurred within 12 months of first global registration in the USA. This is noteworthy as often filing biological products for registration in low- and middle-income countries can be a disincentive as dossier submission for these products can be lengthy and burdensome. Some regulatory authorities may also lack the technical expertise to assess the dossier, resulting in significant delays.

Challenge: Regulatory capacity

GILEAD

How: Sofosbuvir/velpatasvir (Epclusa®) by Gilead for viral hepatitis C, is now on the WHO's prequalification list and is filed in 24 countries in scope. The inclusion in the list guarantees quality and can accelerate access in countries with weak regulatory systems. In 2020, the WHO Prequalification Unit issued an invitation to manufacturers of therapeutics against COVID-19 (dexamethasone and remdesivir (Veklury®)) to submit an Expression of Interest for Product Evaluation. This provides an important opportunity to help facilitate the registration of those treatments in low- and middle-income countries.

Challenge: Delays in regulatory approvals

GILEAD

How: Through emergency approval from regulatory authorities, Gilead first received emergency approval for remdesivir (Veklury®) in May 2020 from the US Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and conditional approval by the European Medicines Agency (EMA) in June 2020. By partaking in the WHO prequalification process, the company can facilitate registration in low- and middle-income countries for this treatment. The products received full approval by the FDA in October 2020.

* The companies submitted up to a maximum of 10 recently launched products to the Index for analysis. For some companies (AbbVie, Bristol Myers Squibb, Eli Lilly, MSD) the exact registration sta-

tus of their latest products within LMICs could not be reported as no data was provided/verified or was available in the public domain during the period of analysis.

** Registered in at least one country in scope within 12 month of first global approval.

*** Registered in at least one relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease).

Opportunity for companies to prioritise countries with high burden of disease

Companies do not always prioritise low- and middle-income countries when it comes to registering their products for sale. Several new bodies and programmes have been established to help provide companies with support for product registration, for example, the African Medicines Agency (AMA). Companies should engage more systematically with these programmes including WHO's prequalification and collaborative registration procedures, to facilitate registration in low- and middle-income countries that might lack capacity to assess dossiers in a timely manner. Importantly, companies need to prioritise countries with the highest disease burdens when planning for registration, especially for products on the WHO Essential Medicines List (EML). This requires tactical planning throughout the research and development phase. Such access planning can help facilitate registration and rapid access to new products in a higher number of countries.

REFERENCES

- 1 World Health Organization. WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control): Medicines/Finished Pharmaceutical Products. <https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products?page=6> Accessed: December 22, 2020.
- 2 World Health Organization (WHO). Collaborative Procedure for Accelerated Registration | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control). <https://extranet.who.int/pqweb/medicines/collaborative-procedure-accelerated-registration> Accessed September 30, 2020.
- 3 NEPAD. African Medicines Regulatory Harmonisation (AMRH) | AUDA-NEPAD. <https://www.nepad.org/programme/african-medicines-regulatory-harmonisation-amrh> Accessed September 30, 2020.
- 4 African Union. African Medicine Agency (AMA) Treaty | African Union. <https://au.int/en/pressreleases/20200205/african-medicine-agency-ama-treaty> Accessed September 30, 2020.

ACCESS STRATEGIES

How do companies ensure worldwide access to their products?

In 2019, the UN Member States adopted a political declaration on Universal Health Coverage (UHC), committing to expanding access to essential quality health services, affordable and effective medicines, vaccines and technologies to reach an additional three billion people by 2030. Recognised as having the biggest potential impact on affordability, pharmaceutical companies play a crucial role alongside governments in making this a reality for many patients living in low- and middle-income countries.

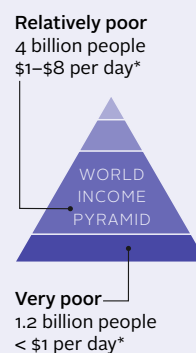
Ultimately, affordability depends on who is paying and the constraints they face. This is why pharmaceutical companies must think in terms of who is going to pay. This can range from government-run health systems to patients paying out of pocket right across the income pyramid – including those at the very base. Access strategies with the biggest potential impact on UHC are strategies that aim to make products affordable for all patients across the income pyramid.

Defining access strategies

In general, companies can use three main access strategies to increase access to medicine in countries in scope:

- **Equitable pricing strategies:** Setting prices within the ability of specific populations to pay, with reference to a range of socioeconomic factors;
- **Responsible intellectual property (IP) management:** Licensing agreements under pro-access terms and/or pledges not to enforce patents to facilitate generic entry; and
- **Product donations:** Identifying populations with no capacity to pay for the new product and donating products as appropriate in collaboration with local partners.

Yet, there is no ‘one-size-fits-all-products’ approach to access to medicine. How companies consider access can depend on the product. For example, medicines that need to be administered by a healthcare professional can face a number of diverse access challenges in low- and middle-income countries — particularly in weaker healthcare systems where there may be poor infrastructure and patchy health services. Self-administered products, on the other hand, such as oral tablets and capsules, can be generally taken without the support of a healthcare professional and thus require a different access approach. Vaccines and HIV/AIDS treatments tend to be supranationally procured: they are bought by multilateral organisations, such as GAVI or the Global Fund to fight AIDS, Tuberculosis and Malaria, which means pharmaceutical companies are operating in a different market landscape.



Certain groups face additional access constraints including women, persons with disabilities, children, indigenous peoples, men who have sex with men and people living with mental health conditions.

What sample of products did the Index assess?

To see how companies tailor their access strategies to reach a larger proportion of the income pyramid and how they overcome product-specific access barriers when dealing with different products, the Index looked at three different categories of products (see table 5 for a full description):

- Supranationally procured products
- Healthcare practitioner (HCP)-administered products**
- Self-administered products**

For each category, the Index analysed a sample of a maximum of five products per company, resulting in a total of 199 medicines and vaccines that are considered essential for a well-functioning healthcare system and for which large companies hold a controlling position regarding access – determined either through patents or their dominance of the market.

* Based on the definition used by: Business Call to Action. Implementing Inclusive Business Models. How Business Can Work With Low-Income Communities.; 2015. <https://www.unglobalcompact.org/library/3161>.

Accessed December 18, 2020.

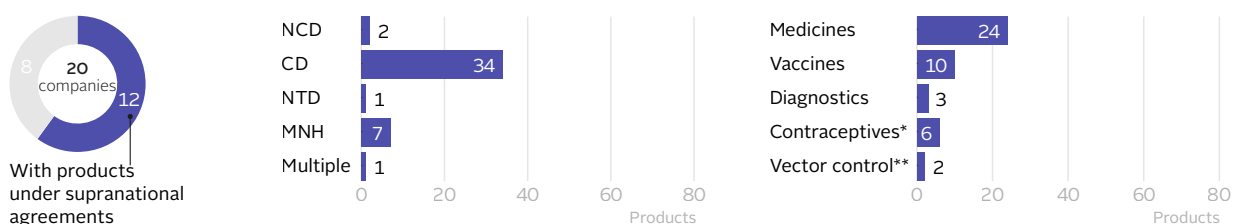
** Weak access strategies with a low performance score were not included in this analysis. For a fine grained view of individual company access strategies, see the Report Cards.

Report Cards.

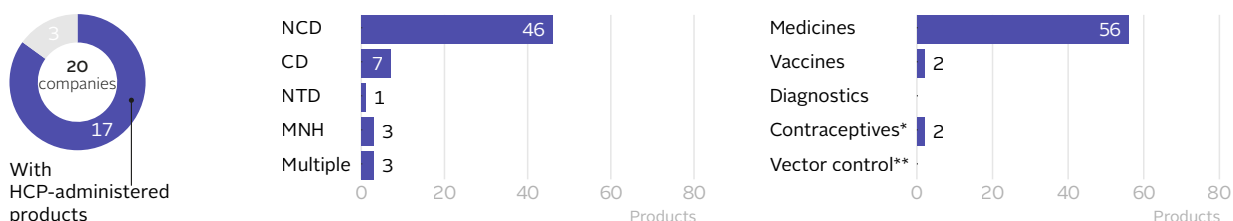
Please note, for this analysis, the Index analysed a sample of the companies’ portfolio products, looking at a maximum of five products per company (199 products in total).

FIGURE 48. Breakdown of sample products assessed

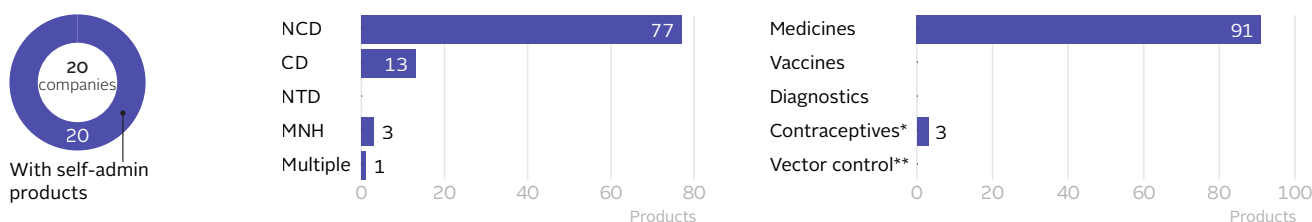
Supranationally procured products: 45



Healthcare-practitioner (HCP) administered products: 60



Self-administered products: 94



Products can fall into multiple categories.

NCD: Non-communicable diseases
 CD: Communicable diseases
 NTD: Neglected tropical diseases
 MNH: Maternal and neonatal conditions
 * Include methods and devices
 ** Vector controls and products

TABLE 5. Defining the three categories of products assessed by the Index

| Product Type | Definition | Assessment |
|---|--|--|
| Supranationally procured products | Products linked to international pooled procurement, advance market commitments, market-shaping facilities and significant public funding and donor support. These products include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria and neglected tropical diseases (NTD). Companies which do not market these products were not analysed in this indicator. | The Index assessed whether companies apply equitable pricing strategies to products for the supranational agreements and in countries outside of these agreements i.e., non-eligible countries. |
| Healthcare-practitioner (HCP) administered products | Products that often require either hospital administration of the product or the attention of a skilled healthcare professional during administration such as IV-administered cancer treatments and antibiotics. Companies which do not market these products were not analysed in this indicator. | The Index assessed whether companies factor in the ability to pay from both the public sector (i.e., national authorities and public insurance) and private sector (private insurance and 'out of pocket market'), whether they take additional steps to maximise the patient reach through, for example, voluntary discounts to reduce co-pay, patient assistance programmes, product donations and whether the strategy increases patient reach. For each product, the company was asked to provide examples of access strategies for one upper-middle-income country (UMIC), one lower-middle-income country (LMIC) and one low-income country (LIC). |
| Self-administered products | Products that can be administered by the individual patient and are not necessarily prioritised by governments or by the global health community (typically, treatments for other non-communicable diseases, such as diabetes, stroke, hypertension and heart disease). | The Index assessed whether companies factor in the ability to pay from both the public sector (i.e., national authorities and public insurance) and private sector (private insurance and 'out of pocket market'), whether they take additional steps to maximise the patient reach through, for example, voluntary discounts to reduce co-pay, patient assistance programmes, product donations and whether the strategy increases patient reach. For each product, the company was asked to provide examples of access strategies for one upper-middle-income country (UMIC), one lower-middle-income country (LMIC) and one low-income country (LIC). |

Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

SUPRANATIONALLY PROCURED PRODUCTS

Do companies extend access terms for countries outside supranational agreements?

Multilateral organisations tend to purchase vaccines or medicines for heavy burden diseases such as HIV/AIDS, malaria and TB, on behalf of buyers e.g. health systems or countries. Such mechanisms for controlling HIV/AIDS, malaria and TB emerged during a period in which the link between health and human rights had established itself as a distinct area of public health practice. As a result, governments and multilateral agents came together to greatly expand access to medicine for these high-burden diseases — and to great effect. For example, 22 million lives have been saved through the Global Fund Partnership, a partnership of governments, the private sector and civil society.¹

By predicting the supply of medicines and vaccines, these practices have helped solved challenges relating to procurement and supply management including logistics to securing sufficient supply. Often, countries need to be eligible for support from these entities and the criteria for eligibility are based on income level, gross national income (GNI) per capita etc.

The 2021 Index looked at how many companies in scope have products procured via supranational agreements and whether companies offer the same terms of access for their products to countries which are not covered by these agreements. The best performing companies in this area are Johnson & Johnson and Novartis. In fact, these

companies offer the same terms to any non-eligible country for all the products assessed in this category. This is an important step for companies to facilitate access to these products in countries graduating from or not eligible for support from supranational organisations. Seven companies (AbbVie, Bristol Myers Squibb, Boehringer Ingelheim, Gilead, Johnson & Johnson, MSD* and Novartis) are taking additional steps to reach more patients across the income pyramid, by either applying non-exclusive licensing agreements, non-assert declarations, product donation programmes or offering the same price as the public sectors to NGOs serving lower-income households. Boehringer Ingelheim, GSK, Johnson & Johnson, Novartis, Pfizer and Sanofi expand patient reach for all their products assessed as part of these strategies.

FIGURE 49. How many companies have products under supranational agreements and do they offer the same terms of access to countries outside these agreements?

Twelve companies in scope have eligible portfolio products falling under supranational agreements. Only six companies (Bayer, GSK, Johnson & Johnson, MSD, Novartis and Sanofi) offer the same terms of access to both eligible countries and non-eligible countries.

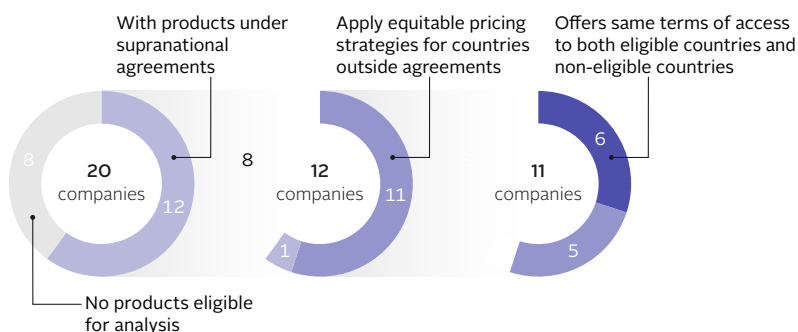
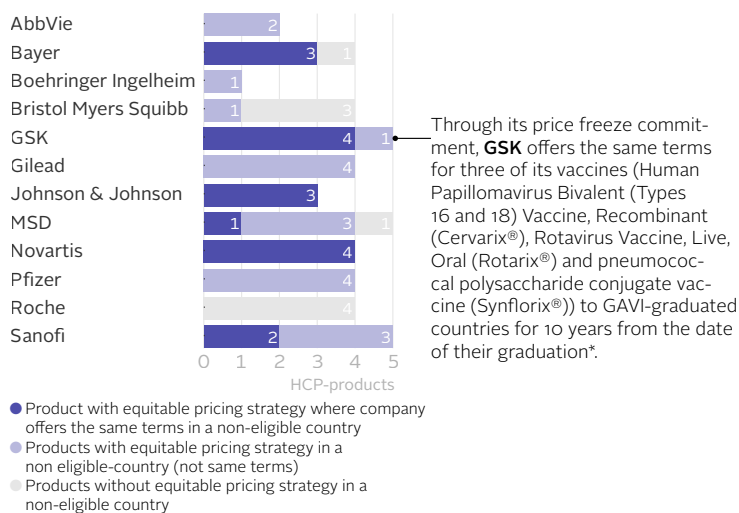


FIGURE 50. Which companies facilitate access to countries outside supranational agreements?



*Merck & Co, Inc (Kenilworth, NJ USA)

Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

HCP-ADMINISTERED PRODUCTS

What does access look like for healthcare practitioner-administered products?

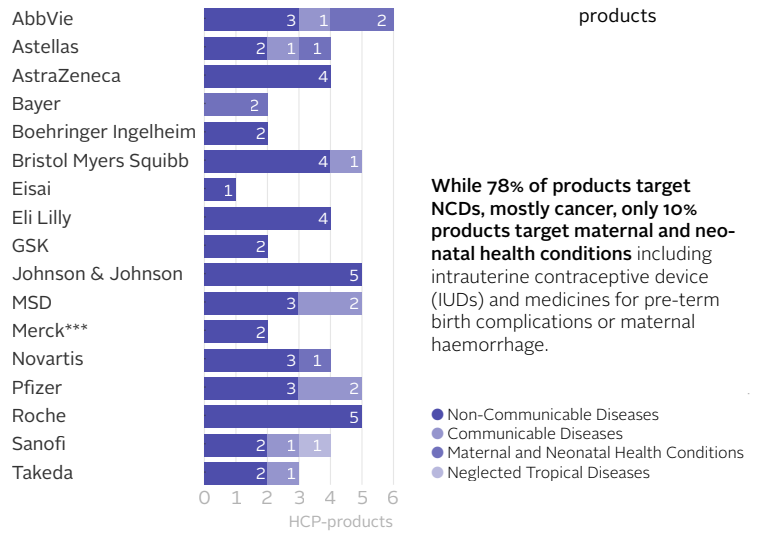
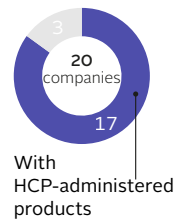
Significant barriers to access to the healthcare practitioner-administered products can be linked to gaps in local healthcare infrastructure — particularly in low- and middle-income countries — with pharmaceutical companies acknowledging that access to these medicines is at times dependent on healthcare settings.

Low coverage across HCP-products

Currently, only 8 out of 60 (13%) critical products that need to be administered by HCPs – including, for example, injectable treatments for cancer – are covered by access strategies in at least one LIC. In LMICs, this number jumps to 25 out of 60 (42%) for HCP-administered products. Further up the income ladder, the picture is better, with approximately half of products covered by an access strategy in at least one upper middle income country (UMIC). Worryingly, however, 28 out of 60 (47%) of the HCP-administered products did not have evidence of access strategies in any of 106 countries in scope.

FIGURE 51. Which companies have HCP-supported products and what diseases do they target?

17 companies in scope have these products in their portfolio. A total sample of 60 products was assessed.**



While 78% of products target NCDs, mostly cancer, only 10% products target maternal and neonatal health conditions including intrauterine contraceptive device (IUDs) and medicines for pre-term birth complications or maternal haemorrhage.

FIGURE 52. Few access strategies for HCP-products target LICs

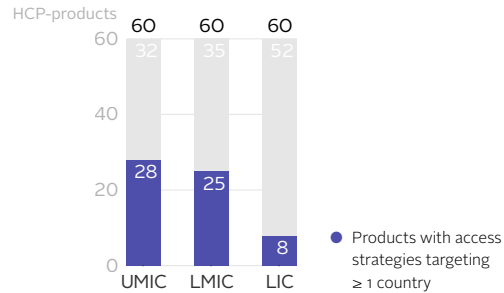
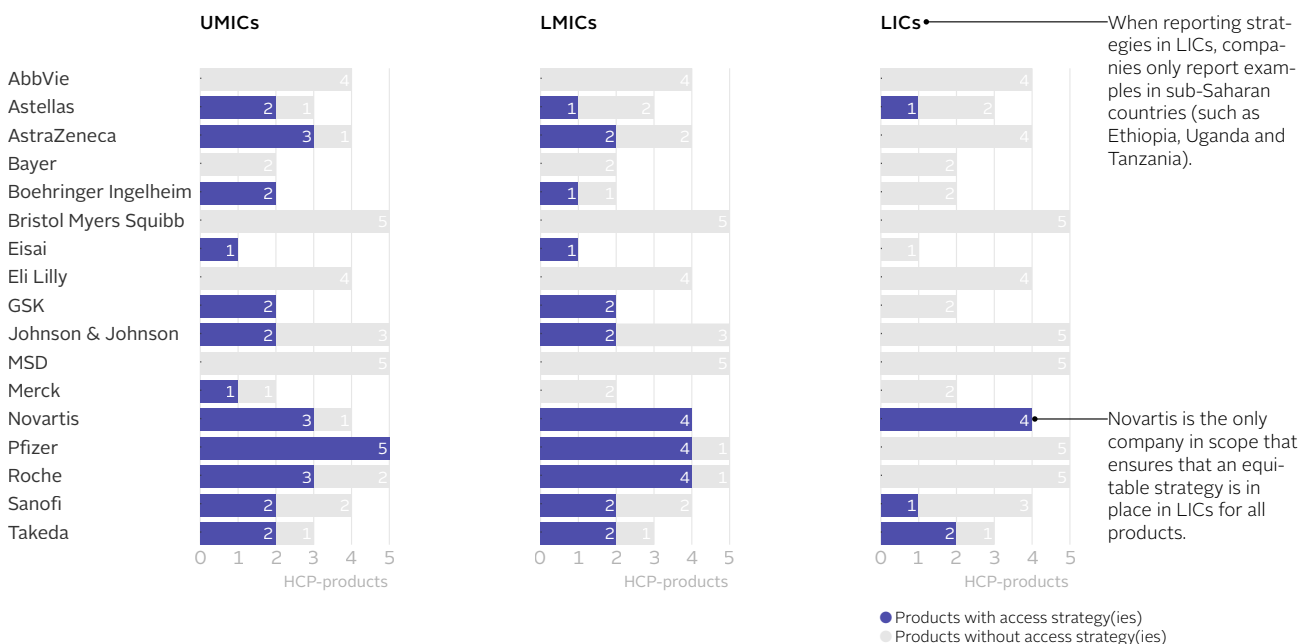


FIGURE 53. How many HCP products are covered by an access strategy across UMIC, LMICs, LICs?



** A product can target multiple diseases corresponding to multiple disease areas.

***Merck KGaA (Darmstadt, Germany)

Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

Considering people’s ability to pay for HCP-administered products

The Index looked at whether companies factor in the purchasing ability to shape their access strategies for HCP-administered products. Payors and distribution channels can vary depending on the context. For example, some countries in scope have strong public sectors or reimbursement systems. In other countries, some medicines are only available in the private sector meaning patients pay out of pocket or are reimbursed by private insurance firms with or without patient co-pay for the patient. Products assessed in this category are often delivered directly to the hospital/clinic or health centre where the patient receives the treatment. The Index expects companies to have access strategies in place that cover all patients in the countries assessed, independently of the channel by which they access the product. To that end, the Index looked at whether companies consider ability to pay in either public or private sector or both.

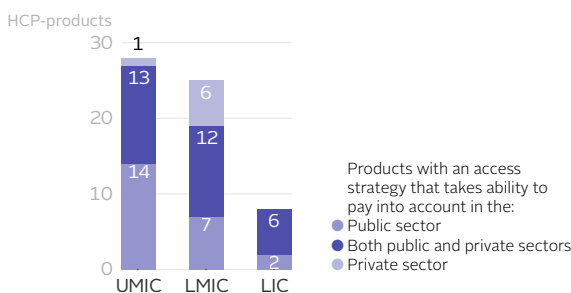
Are access strategies for HCP-products reaching patients in need?

The Index also looked for evidence of patient reach as a result of companies’ access strategies. For almost all the products where the Index assessed that the companies applied an access strategy in a particular country, evidence of patient reach was provided. However, an apparent increase in patient reach was demonstrated by eight companies for only a handful of products (11 out of 28 in UMICs, 10 out of 25 in LMICs and one out of eight in LICs).

In general, companies reported an increase in patient reach for the following products:

- Products that were newly listed on national reimbursement lists (e.g. in China or Thailand) or newly integrated in treatment guidelines (e.g. inclusion of purified rabies vaccine cultured on Vero cells (Verorab®) into clinical rabies guideline). In such cases, it can lead to huge increase in patient reach (from a few hundreds to millions of patients depending on the disease and country).
- Products for which companies take additional steps to increase affordability for all patients by, for example, putting in place patient assistance programmes (PAP) that offer tailored prices or financial support depending on patient income levels. In this case, the increase in the number of patient reach can be more gradual (from a few patients to thousands).

FIGURE 54. For HCP-products, where do companies mainly consider people’s ability to pay?

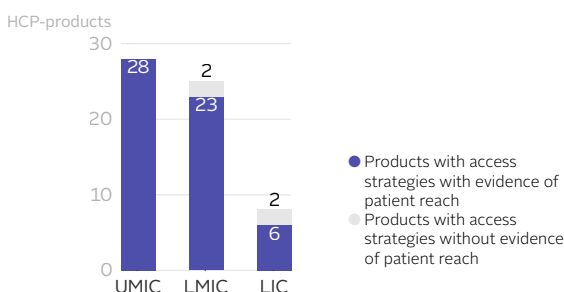


Companies take a varied approach when considering ability to pay:

- Access strategies in countries in scope are driven by patient assistance programmes set by companies at the local level and not by large scale programmes implemented globally, such as lowering pricing.
- In UMICs, when companies have an access strategy, they consider ability to pay in the public sector in almost all instances, whereas in the private sector, ability to pay is considered in only half of the access strategies. This is because public sectors in UMICs are likely more developed and better structured than in LMICs and LICs.

- China (UMIC) is an example of a country where once the product is included on the National Reimbursed Drugs List, it becomes almost exclusively paid for by the public authorities.
- In LICs, when companies have an access strategy, they consider ability to pay in the public sector for all products. They also consider ability to pay in the private sector for six of the eight products. If there is no reimbursement for the remaining two products, they are not likely to be available in the private sector.

FIGURE 55. Evidence of patient reach from access strategies covering HCP-products



Example of patient reach for HCP-products ranges for a few disease areas:

- For oncology treatments the reach ranges from less than 100 patients in some countries to more than 31,000 in a UMIC.
- For asthma treatments the reach ranges from approximately 100 patients in some countries to 10,000 in a UMIC.
- For ischaemic heart disease and stroke treatment the reach range approximately from less than 100 patients in one LMIC to 238,000 in a UMIC.

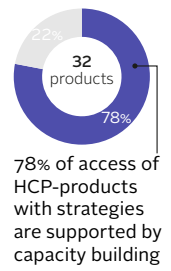
Please note, for this analysis, the Index analysed a sample of the companies’ portfolio products, looking at a maximum of five products per company (199 products in total).

The majority of the HCP-products with access strategies are also supported by capacity building†

To increase access, 11 companies (Astellas, AstraZeneca, Boehringer Ingelheim, Eisai, GSK, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi and Takeda) report taking steps to help strengthen healthcare systems such as building diagnostics capacity or training healthcare professionals. The products assessed in this category, by definition, require 'extra capacity' (i.e., specialised care) to be administered. For most of these products, a specialist needs to write the prescription. In addition, special diagnostic equipment is often required

to make the initial diagnosis and select the right treatment. Once the treatment is administered, equipment for follow-up to monitor outcomes and side effects are needed.

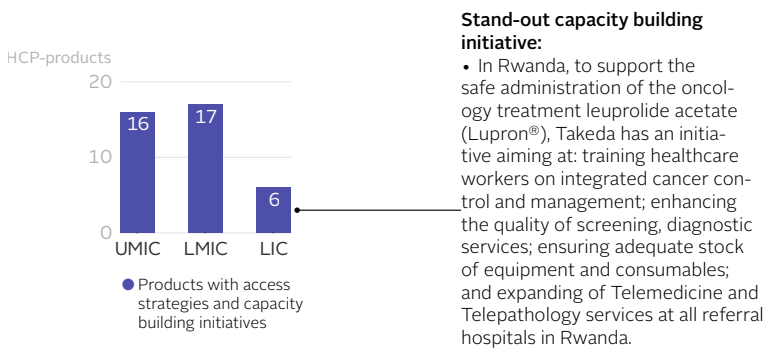
Some health systems in countries in scope lack such capacity and are not ready to absorb innovative products which might deter companies from entering the market. This, however, can be an opportunity for companies to engage in capacity building initiatives, as they often have the know-how, resources and strategic incentives to help fill these gaps.



11 companies with capacity building initiatives in place:

- Astellas
- AstraZeneca
- Boehringer Ingelheim
- Eisai
- GSK
- Johnson & Johnson
- Novartis
- Pfizer
- Roche
- Sanofi
- Takeda

FIGURE 56. Majority of access strategies combine capacity building to help strengthen health systems



†Some products have access strategies with capacity building initiatives in multiple countries.

Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

SELF-ADMINISTERED PRODUCTS

What does access look like for self-administered products?

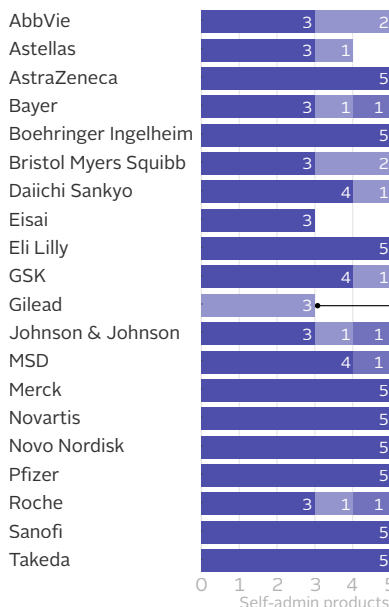
Self-administered products are defined as those products which are easier to be administered by the individual patient. Such products are particularly useful in LMICs and resource-limited health systems. To assess how companies tailor their access strategies for these products, the Index looked at whether companies have access strategies for these products and whether their strategies cover all patients independently of their income levels. This assessment focused on consideration of ability to pay in the public and/or private sectors and any additional steps to increase affordability and patient reach.

Low coverage across products

Most self-administered products target NCDs (78 out of 94). Of these, 28% (22 out of 78) are self-administered oncology products, representing a much smaller proportion than HCP-administered products. For self-administered medicines – which are often pills targeting NCDs – only 24 out of 94 (26%) products are covered by access strategies in at least one LIC. This figure jumps to 40 out of 94 (43%) in LMICs. Similar to HCP-administered products, approximately half of products are covered by an access strategy in at least UMIC. However, 36 out of 94 (38%) self-administered products analysed did not have evidence of access strategies in any of 106 countries in scope.

FIGURE 57. How many companies have self-administered products and what diseases do they target?†

All 20 companies in scope have these products in their portfolio. A total sample of 94 products was assessed.



Gilead is the only company with products targeting communicable diseases only, namely hepatitis C with a product like sofosbuvir (Sovaldi®).

22 products are for diabetes
All of Novo Nordisk's medicines assessed in this area are for the treatment of diabetes. The other products assessed here that target NCDs are for cardiovascular diseases, asthma or mental health conditions etc.

- Non-Communicable Diseases
- Communicable Diseases
- Maternal and Neonatal Health Conditions
- Neglected Tropical Diseases

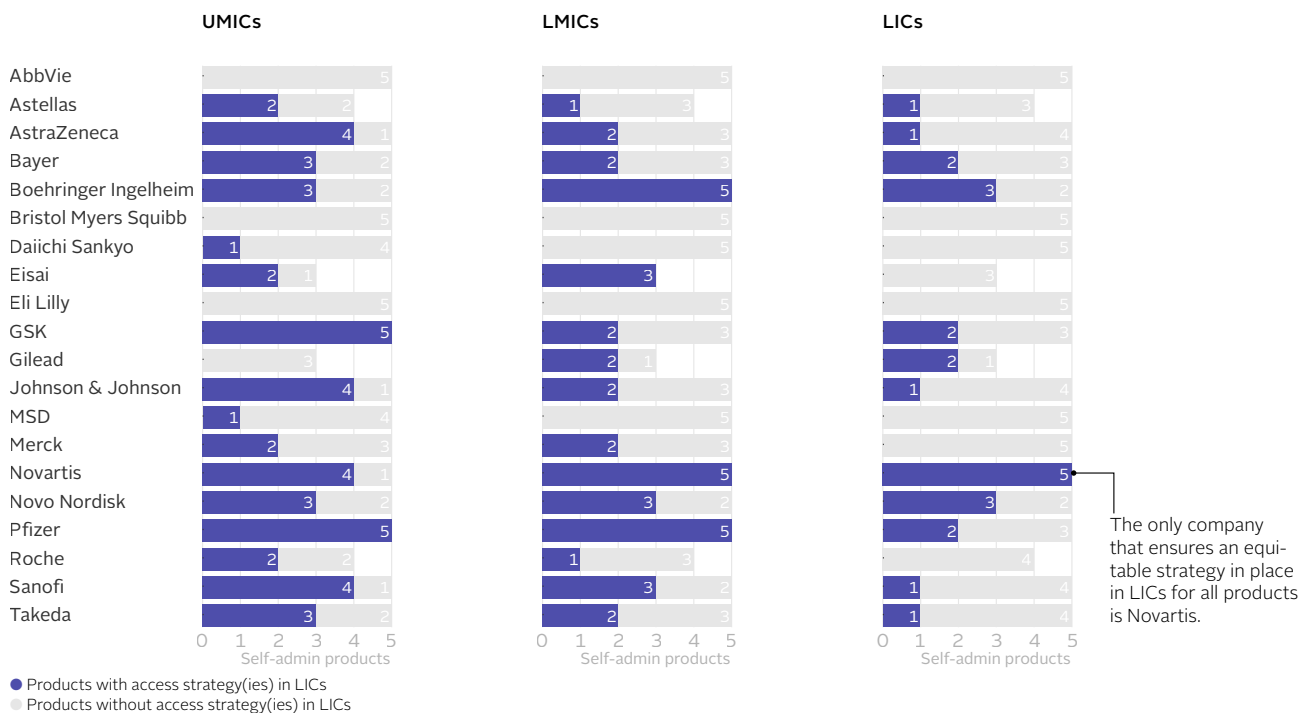
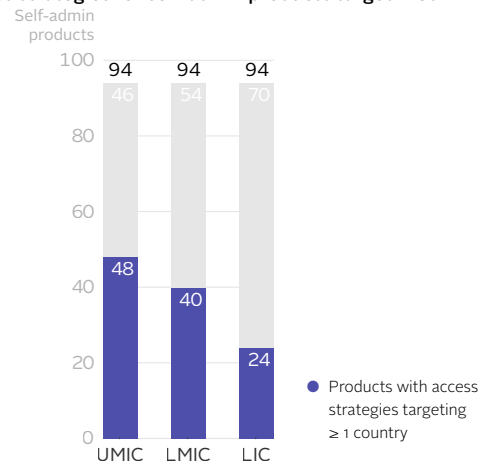
† A product can target multiple diseases across multiple disease areas.

Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

FIGURE 58. How many self-administered products are covered by an access strategy across UMIC, LMICs, LICs?

This chart looks the proportion of self-administered products with access strategies in UMICs, LMICs and LICs. Of the 94 products analysed, 51% (48 out of 94) fall under access strategies in UMICs, 43% (40 out of 94) in LMICs and 26% (24 out of 94) in LICs. The results are comparable to what was found for HCP-administered products, yet a difference can be seen in LICs, where companies apply more often access strategies for self-administered products in these countries.

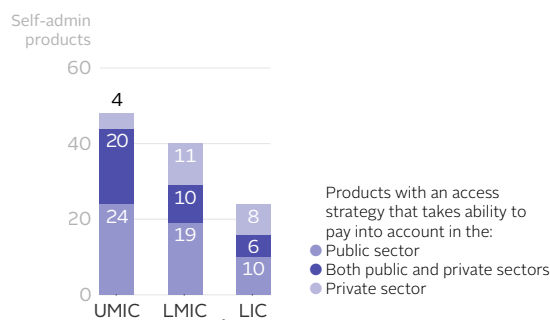
Few access strategies for self-admin products target LICs



Considering people's ability to pay for self-administered products

When looking at access strategies the Index assessed whether companies consider people's ability to pay into account. In general, access strategies for self-administered products that take into account ability to pay are more often found in private settings when compared with HCPs products.

FIGURE 59. For self-administered products, where do companies mainly consider people's ability to pay?



In UMICs, when companies have an access strategy, they consider ability to pay in the public sector in almost all instances and ability to pay in the private sector in half of the access strategies.

In both LMICs and LICs the Index sees more access strategies where companies consider only the private sector. This can be attributed to the multiple factors such as weaker public sectors and prioritisation of the wealthy population in those countries.

Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

Are access strategies for self-administered products reaching patients in need?

The Index also looked for evidence of patient reach as a result of companies' access strategies for self-administered products. An apparent increase in patient reach was demonstrated by ten companies for only a handful of products (16 out of 48 in UMICs, 9 out of 40 in LMICs, 5 out of 24 in LICs).

Example of patient reach ranges for a few disease areas for self-administered products:

- For treatments for diabetes mellitus, the reach ranges from less than 100 patients in some LICs to approximately 1.65 million in a LMIC.
- For asthma treatments, the reach ranges from under a thousand patients in a LICs to approximately 800,000 in an UMIC and a LMIC.
- For treatment for hypertensive heart disease, the reach ranges from under 1,000 patients in an LMIC to approximately 70,000 patients in a UMIC.

FIGURE 60. Evidence of patient reach from access strategies covering self-administered products

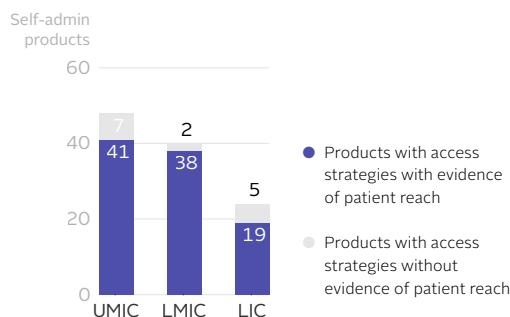
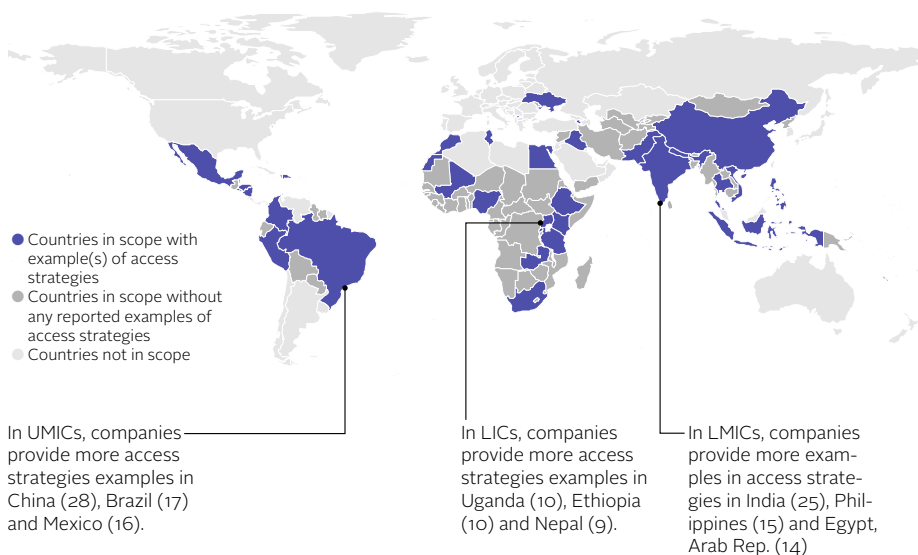


FIGURE 61. Companies report examples of access strategies for HCP- and self-administered products in only a handful of countries

The examples provided by companies in this analysis tend to focus on the same countries, mainly UMICs and LMICs. The next step, for example, will be to apply the example of good practices such as equitable intra-country pricing strategies more widely.



Please note, for this analysis, the Index analysed a sample of the companies' portfolio products, looking at a maximum of five products per company (199 products in total).

People living in lower-income countries are overlooked

Companies need to consider every aspect of the income pyramid. While the Index sees some good examples of access strategies, patients in low-income countries are still being overlooked. This is the case across all products, including healthcare professional-administered and the self-administered products.

Access strategies for supranationally procured products are generally better structured and applied more widely thanks to the presence of international organisations shaping the markets and the incentives already in place for the diseases targeted (HIV/AIDS, vaccines, malaria, tuberculosis etc.). Companies, however, can apply similar access terms to other products within their portfolio.

Local patient access programmes are still driving access strategies overall (outside supranational agreements). To address the challenge of affordability more efficiently, companies should look at implementing price reductions or price segmentation (such as second brand approach or patient assistance programmes) in more countries, especially in LICs.

In most of the strategies assessed by the Index, the patient reach reported in countries does not match the disease burden and several companies are still not transparent in reporting numbers. When companies address affordability, they should start where the need is the biggest. Companies should also be transparent on numbers of patients reached in order for access gaps to be identified and filled.

The good practices shown in this analysis indicate that some companies are stepping up their access mindset, e.g. Novartis, expanding their focus beyond lower middle-income countries and upper middle-income countries. GSK, Johnson & Johnson and Sanofi are performing well in one of the three product categories, namely the supranationally procured products, while Takeda stands out for HCP-administered products and Pfizer for self-administered products. These practices must be equitable for all, including those at the base of the income pyramid.

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LICENSING AND IP MANAGEMENT

Are companies engaging in voluntary licensing to expand access?

How large R&D-based pharmaceutical companies manage their intellectual property (IP) impacts the availability and affordability of medicines. For example, when rights-holding companies enable generic medicine manufacturers to develop generic version of their medicines, it can increase affordability, support supply, foster competition and ultimately improve access. This is achieved through the use of a non-exclusive voluntary licence – one important approach among many to making a product accessible.

This impact has been demonstrated by the game-changing engagement between large R&D-based companies and generic medicine manufacturers in the global market for HIV/AIDS medicines. Generic medicine manufacturers were authorised to enter markets in low- and middle-income countries and speed the entry of generic – often

cheaper – medicines into these markets. This is thanks in large part to a coordinated and sustained commitment from the industry, governments, NGOs and organisations such as the Global Fund and the Medicines Patent Pool (MPP).

The MPP was formed as a means to accelerate and encourage the process of voluntary licensing. It was established in 2010 to negotiate licence terms with patent holders of HIV treatments and subsequently expanded to tuberculosis (TB) and hepatitis C in 2015. Since then, MPP has expanded its mandate to new disease areas including cancer, cardiovascular diseases, diabetes and COVID-19 to help increase generic access to more patented products, particularly those on the WHO Essential Medicines List (EML) and those with strong potential for future inclusion.¹

What is a non-exclusive voluntary licence?

The practice of IP-holding companies to voluntarily grant generic manufacturers (non-exclusive) permission to develop and manufacture generic versions of patented medicines. When such agreements are transparent and include access terms this helps to increase affordability and improve access. However, not all voluntary licences are transparent and do not necessarily include access terms as they can involve strong geographical limits (e.g. limited to least developed countries [LDCs] only).

What are non-assert declarations?

Pledges by rights holders not to enforce patents in certain territories or under certain conditions, allowing a generic version of a patented medicine to be produced.

What does this section look at?

Pharmaceutical companies should manage their IP rights responsibly and openly to ensure they do not limit access to medicine for lower-income and vulnerable populations. While the 2021 Index did not score companies in this area*, it highlighted activities relating to companies' non-assertion declarations and their licences that promote access. Examples include cases where the company agrees access-oriented, transparent non-exclusive voluntary licences with clauses that facilitate affordability and supply of quality products.

* See Appendix II for scoring guidelines

How many compounds are covered by licences in 2021 compared to 2018?

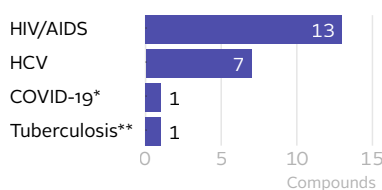
The 2021 Index has identified 20 marketed compounds from six companies that are covered by non-exclusive voluntary licences or non-assert declarations. Compared to 2018, only two compounds have been added including glecaprevir/ pibrentasvir (Mavyret®) from AbbVie. Some previously licensed compounds are now off patent (e.g. abacavir (Ziagen®) developed by GSK). AbbVie, Bristol Myers Squibb and Gilead engage in both HIV/AIDS and hepatitis C licences, while GSK (through ViiV Healthcare), Johnson & Johnson, and MSD engage solely in HIV/AIDS licences. During the period of analysis, no new licences for approved products outside viral hepatitis and HIV/ AIDS have been agreed. However, for Pfizer's investigational compound for TB treatment, sutezolid, a licence was agreed with the MPP during the period of analysis to facilitate its clinical development. Gilead also had a licence that

was agreed during the period of analysis for an investigational treatment, remdesivir (Veklury®), approved by the FDA for COVID-19 in October 2020.

TRIPS flexibilities have limited support

When it comes to endorsing the rights of national governments to grant compulsory licences or deploy IP systems flexibly as needed, the pharmaceutical industry remains hesitant. This is shown in the companies' limited public support for the flexibilities in the international IP system (as set out in the World Trade Organization's [WTO] 2001 Doha Declaration on the TRIPS Agreement and Public Health). The TRIPS agreement includes flexibilities for WTO member states to (among other things) set aside patent rights to protect public health. In 2021, just over half of the companies assessed by the Index publicly support TRIPS flexibilities, while often expressing reservations about the use of compulsory licences.

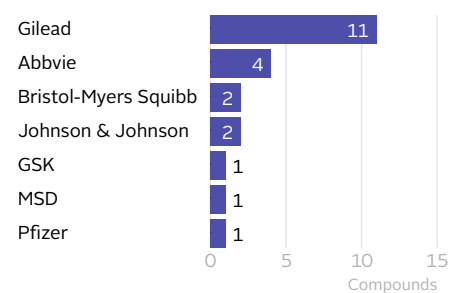
FIGURE 62. Twenty-two compounds are covered by licensing agreements or non-assert declarations by the companies.†



Pfizer agreed a licence with the MPP in October 2019 to facilitate the clinical development of its investigational compound, sutezolid for the treatment of TB.***

Gilead's licence for remdesivir, allows nine other companies to manufacture and distribute in 127 countries. The details of this licence are not publicly available.

FIGURE 63. Seven companies with non-exclusive voluntary licences or non-assert declaration in 2021

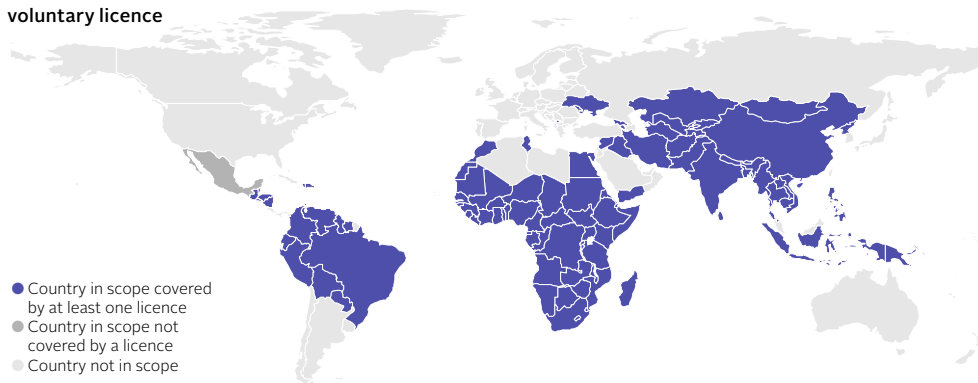


Which countries do companies' licences cover?

In relation to the geographic scope, the Index assessed whether companies' licences covered countries in scope i.e., 106 low- and middle-income countries with high burdens of disease and/or high inequality. The 2021 Index finds that upper middle-income countries (UMICs) are more likely to be excluded from non-exclusive licensing

agreements. For instance, Mexico is not covered by any licence; Brazil and China are covered by only one licence for lopinavir/ritonavir (now covered by a non-assert declaration) for HIV/AIDS. Compared to low-income countries (LICs), they have greater purchasing power and thus represent more attractive commercial markets for companies.

FIGURE 64. Countries in scope covered by at least one non-exclusive voluntary licence



* Approved for emergency use only in the USA and Japan during period of analysis (approved by FDA in October 2020).
 ** Investigational project, licence to facilitate the clinical development of sutezolid.

*** Outside of the period of analysis (December 2020), this product was sub-licensed in a collaboration between the MPP and the Bill & Melinda Gates Medical Research Institute (Gates MRI) to advance

the development of sutezolid-containing TB drug regimens. The sublicense allows access to Pfizer's preclinical, phase I and phase IIa clinical study data and results.

† Outside the period of analysis (September 2020), MSD entered into a non-exclusive voluntary licensing agreement with two generic medicine manufacturers for HIV/AIDS treatment doravirine.

What do these licences look like?

When looking at the quality of these licences, meaning whether the agreements contain clauses or terms that facilitate access, the Index concludes that the licences negotiated with the MPP contain the most access-enabling terms. To assess the quality of the licences, the Index looks for the presence of specific terms or clauses in the agreement:

- Licence agreed prior to or shortly after approval of originator product;
- Ability to manufacture and freely source active pharmaceutical ingredient (API);
- Ability to supply countries where no granted patents are infringed (including where compulsory licences are issued);
- Optional provision for technology transfer;
- Absence of no challenge clauses;
- Provisions to facilitate rapid registration of product (e.g. willingness to supply data for registration, data exclusivity waivers, etc);
- Quality assurance in line with WHO requirements

TABLE 6. How do companies' help facilitate access through their licences?

| Company name | Compounds licensed or non-assert declarations | Indication | Examples of agreements and/or commitments to help facilitate greater access |
|----------------------|---|--|---|
| Abbvie | Glecaprevir Pibrentasvir Lopinavir** Ritonavir** | HCV HCV HIV/AIDS HIV/AIDS | <ul style="list-style-type: none"> • AbbVie's licence for glecaprevir and pibrentasvir agreed with MPP include six out of seven access terms looked for by the Index to enable access. It does not include a provision for technology transfer. • AbbVie committed in March 2020, in the light of the COVID-19 pandemic, not to enforce the patents applying to lopinavir/ritonavir globally. |
| Bristol Myers Squibb | Atazanavir Daclatasvir | HIV/AIDS HCV | <ul style="list-style-type: none"> • Both licences agreed with MPP. • Licence for daclatasvir* includes all seven clauses that enable access, such as provision for technology transfer and provision to facilitate rapid registration, agreed within a year after product approval. • Licence for atazanavir includes several of the access clauses such as ability to manufacture and source APIs without restriction and provision for rapid registration. |
| Gilead | Bictegravir Cobicistat Elvitegravir Emtricitabine Ledipasvir Sofosbuvir Tenofovir Alafenamide Tenofovir disoproxil fumarate Velpatasvir Voxilaprevir Remdesivir* | HIV/AIDS HIV/AIDS HIV/AIDS HIV/AIDS HCV HCV HIV/AIDS HIV/AIDS HCV HCV Covid-19 | <ul style="list-style-type: none"> • Licences for HCV treatments were directly agreed with generic companies before product approval, except for sofosbuvir for which the licence was agreed within a year after launch. The licences include terms that enable access such as provision for rapid registration, quality assurance and technology transfer provisions. • Licences for HIV/AIDS products were negotiated with the MPP. Those licences are high quality and include six or all seven clauses looked for by the Index. Licences for tenofovir alafenamide, cobicistat, bictregravir and elvitegravir were all agreed before approval or within a year. |
| GSK | Dolutegravir*** | HIV/AIDS | GSK has two agreements with the MPP for dolutegravir, one for the paediatric formulation and one for the adult formulation. The licences contain all access clauses looked for by the Index to enable access that that enable access, only the provision for technology transfer is not part of the licences. |
| Johnson & Johnson | Darunavir** Rilpivirine | HIV/AIDS HIV/AIDS | <ul style="list-style-type: none"> • Johnson & Johnson agree not to enforce patents for darunavir in LDCs and SSA countries. In 2015 the company extended its commitment to paediatric formulation. • The details of the agreements for rilpivirine are not publicly available. |
| MSD† | Raltegravir | HIV/AIDS | Licence covers only the paediatric formulation. It was agreed directly with the MPP and includes the majority of the terms that the index is looking for. However no provision for technology transfer was included in the agreement. |
| Pfizer | Sutezolid* | Tuberculosis | N/A (investigational compound) |

*Licences for investigational products during period of analysis

**Products for which the respective companies made a commitment not to enforce patents (non-assert declaration)

*** Pfizer hold % in ViiV share, which market dolutegravir

†In March 2020 Bristol Myers Squibb announced that they are discontinuing daclatasvir in countries where the product is no longer routinely prescribed there are other therapeutic options available. Following the lapse / withdrawal of

the marketing authorization in each country, the patents in that country will also be allowed to lapse. In the interim period between the lapse / withdrawal of a marketing authorization and patent expiry, the company will not enforce its patents in that country.)

‡ Merck & Co., Inc., Kenilworth, NJ USA

Licensing — a tool to address children's needs

Children in low- and middle-income countries are one of the most vulnerable yet neglected populations when it comes to access to certain treatments for diseases like HIV, TB and hepatitis C. It can take years for treatments to be approved for use in children, in part due to the risks and limitations associated with clinical trials that include paediatric patients. As a result, few child-friendly treatments are available for these diseases. Over the years, non-exclusive voluntary licences have played a role in accelerating the development and uptake of adapted formulations of optimal paediatric HIV, TB and hepatitis C drugs.

The 2021 Index finds that four compounds have been agreed specifically for paediatric HIV treatments: dolutegravir (Tivicay®) by GSK, lopinavir/ritonavir (Aluvia®/Kaletra®) by AbbVie and raltegravir (Isentress®) by MSD. These licences can help

accelerate access to treatments for children living with HIV/AIDS on condition that there is effective uptake of the licence by generic medicine manufacturers and the product is marketed in a licensed territory. In the case of raltegravir (Isentress®), the uptake is low, only one sub-licensee has agreed to manufacture the treatment in a licensed territory.

The licence for dolutegravir (Tivicay®) by GSK could have a high impact on the HIV/AIDS in children as a dolutegravir-based antiviral regimen is considered to be among the best current treatments for HIV in children and adolescents.³ The licence for dolutegravir covers the largest territory (102 countries in scope), including all sub-Saharan countries and it has the highest uptake by generic medicine manufacturers. A total of 14 sub-licensees have agreed to manufacture the treatment on the license territory.

Opportunities still exist to improve licensing coverage and performance

Licensing for marketed products remains confined to just a few diseases: HIV/AIDS, hepatitis C and, as of 2020, coronavirus. Opportunities for increased engagement from companies are prominent, including licensing medicines that are included on the WHO EML, products that received a favourable clinical assessment and highlighted for future inclusion (e.g. SGLT2 inhibitors for diabetes, oncology medicines with high ESMO clinical benefit score) in order to facilitate affordable access in low- and middle-income countries (see report cards for identified products). In fact, companies can partner with the MPP whose expanded mandate focuses specifically on the coverage of such medicines and newly included COVID-19 treatments.

With 5.7 billion people, MICs are home to the majority of the world's poor and shoulder the largest share of the global disease burden. Approximately 22 million people with HIV/AIDS live in MICs, which accounts for more than half

of the total population of people living with HIV/AIDS. Companies can expand their geographic licence territories to cover these countries and improve access to the poorer population.

It should also be pointed out that licensing does not guarantee supply. Challenges still occur for generic medicine manufacturers such as registration hurdles in some countries where the originator did not file for registration, smaller markets which can deter generic medicine manufacturers from entering those countries. All this means availability and affordability can remain barriers for many countries. In that regard, patent holders have a responsibility to ensure access to products where generic medicine companies do not take up licences, by taking other steps toward registration and by using access strategies (equitable pricing strategies, donations and others) to reach patients in all markets and from all the income pyramid levels.

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PRODUCT DONATIONS

Are companies’ donations programmes sustaining elimination efforts?

Donations of medicines by pharmaceutical companies can be a route of access to medicine for the poorest populations. They play a distinctive role in settings where patients have a very limited ability to pay and can reinforce company commitments to eliminate or even eradicate diseases. In fact, donation programmes play an important role in the management of, among others, neglected tropical diseases (NTDs). These diseases are closely related to poverty due to inadequate sanitation systems, close contact with infectious vectors, domestic animals and livestock, and they cause important burdens at the national or local level.

As such, in 2012, the World Health Organization (WHO) developed a strategy with clear targets to be achieved by 2020 in order to overcome the global impact of NTDs. The purpose of this roadmap was to drive action among the

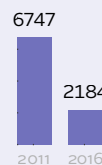
pharmaceutical industry, governments and civil society to help boost prevention, control, elimination and eradication of this diverse group of diseases. That same year, a group of partners comprised of governments, pharmaceutical companies and donors – now collectively known as Uniting to Combat NTDs – met in London to support the roadmap, signing the London Declaration on Neglected Tropical Diseases. This endorsement brought together key partners who committed to collaborating to combat NTDs. Pharmaceutical companies, in particular, donated a range of existing medicines for 10 NTDs that were identified as needing urgent action.

Since then, the NTD roadmap together with the London Declaration has led to unprecedented progress in the implementation of large-scale NTD preventive treatment, case management and care.

98% reduction in Guinea worm cases



Human African Trypanosomiasis (sleeping sickness) cases are down



NTDs and their goals in the London Declaration:

Eradication:

- Dracunculiasis

Elimination:

- Lymphatic filariasis
- Leprosy
- Human African Trypanosomiasis
- Trachoma

Control:

- Onchocerciasis
- Schistosomiasis
- Soil transmitted helminths
- Chagas disease
- Leishmaniasis

Safeguarding progress against NTDs for the next decade

Despite major progress, not all goals were met by 2020. In the coming decade, the progress made so far against NTDs will not only need to be sustained but also scaled up. With the launch of a new 2021–2030 NTD roadmap in April 2020, the London Declaration commitments will need to be renewed to ensure the global response is fully realised. This is why in June 2020, the Government of Rwanda organised an event to join Uniting to Combat NTDs at a high-level global summit in Kigali. Yet as a consequence of the COVID-19 pandemic, the Kigali Summit on NTDs was postponed, risking a delay in the fulfilment of the pledges.

Momentum in the form of company commitment to end the NTD burden is now needed to safeguard progress, especially as the COVID-19 pandemic has disrupted health systems globally, posing a severe threat to major NTD interventions.

How the Index assesses NTD donation programmes

The Index looks at how companies remain engaged and committed to ensuring access to their donated products for diseases where NTD elimination, eradication and control goals are possible. It considers the scale (geographic scope and timeline) and patient reach of the companies’ donation programmes, whether such commitment has a time limit and whether it has been shared publicly. Although donation programmes fill an important gap, companies have a responsibility to ensure that their programmes lead to sustainable improvements in access to medicine. This means ensuring populations can continue to access donated products for as long as they are needed — both during an endemic period and after.

What do companies' NTD programmes look like?

The 2021 Index identified 14 donation programmers for NTDs by 11 companies in scope, running in between one and 74 countries. These 14 structured donation programmes target 11 out of 20 NTDs identified by WHO. Eisai, GSK, Merck*, MSD** and Sanofi have committed to donating their medicines as from 2020 and until elimination, eradication or control goals are achieved for the targeted disease. In six (out of 14) programmes, the company expanded its initiatives beyond the 2020 roadmap goals, for example, Merck has expanded the target population to include all age groups for the treatment of schistosomiasis.

FIGURE 65. Fourteen NTD donation programmes by companies in scope

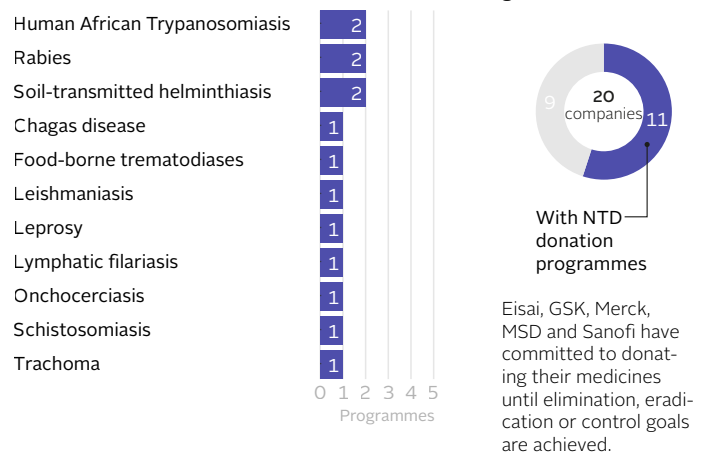


TABLE 7. A breakdown of companies' NTD programmes

The table shows the 14 NTD donation programmes for which 11 companies are donating products in between one and 74 countries.

| Company | Disease/condition and product | Geographic scope / number of countries | Year of first donation | Year of planned end | Expanded beyond stated goals |
|----------------------|--|--|------------------------|------------------------------|---|
| Bayer | Chagas disease; Human African Trypanosomiasis Nifurtimox (Lampit®), suramin (Germanin®) | Unknown | 2002 | 2021 | No efforts to expand donation beyond the stated goals |
| Boehringer Ingelheim | Rabies Rabisin® | 1 | 2019 | 2030 | Optimising the rabies control approach with animal health experts from Boehringer Ingelheim and providing collars for vaccinated dogs to prevent dog bites. |
| Eisai | Lymphatic filariasis Diethylcarbamazine citrate (DEC) | 24 | 2013 | Until goals achieved | No efforts to expand donation beyond the stated goals |
| GSK | Lymphatic filariasis Albendazole (Zentel®) | 39 | 1998 | Until goals achieved | Supplying albendazole if a previously validated country identifies an area of ongoing transmission that would jeopardise validation of elimination. |
| GSK | Soil transmitted helminthiasis Albendazole (Zentel®) | 45 | 2011 | 2020 | No efforts to expand donation beyond the stated goals |
| Gilead | Leishmaniasis Amphotericin B liposome (AmBisome®) | 6 | 2011 | 2020 | No efforts to expand donation beyond the stated goals |
| Johnson & Johnson | Soil transmitted helminthiasis Mebendazole (Vermox®, Vermox® Chewable) | 33 | 2006 | 2025 | Expanding its target population to include women of reproductive age. |
| MSD** | Lymphatic filariasis Onchocerciasis Ivermectin (Mectizan®) | 27 | 1998 1987 | 2020 Until goals achieved | A community-directed approach to improve mass-treatment in remote areas. |
| MSD | Rabies Nobivac® Rabies | 3 | 2006 | 2030 | Expanding the target population to other areas of rabies outbreaks, including India and Africa. |
| Merck* | Schistosomiasis Praziquantel (Cesol®) | 42 | 2007 | Until goals achieved | Expanding its target population to include all age groups. |
| Novartis | Food-borne trematodiasis Triclabendazole (Egaten®) | 21 | 2005 | 2022 | No efforts to expand donation beyond the stated goals |
| Novartis | Leprosy Multidrug therapy combination (Lamprene®/Rimactane®/Dapsone®) | 74 | 2000 | 2020 | No efforts to expand donation beyond the stated goals |
| Pfizer | Trachoma Azithromycin (Zithromax®) | 29 | 1998 | 2025 | No efforts to expand donation beyond the stated goals |
| Sanofi | Human African Trypanosomiasis Eflornithine (Ornidyl®), fexinidazole (Fexinidazole Winthrop®), melarsoprol (Arsobal®), pentamidine (Pentacarinat®) | 21 | 2001 | Until goals achieved | No efforts to expand donation beyond the stated goals |

The rabies control approach is optimised with animal health experts from **Boehringer Ingelheim** and by providing collars for vaccinated dogs to prevent dog bites.

GSK has also committed to supplying albendazole if a previously validated country identifies an area of ongoing transmission that would jeopardise validation of elimination.

MSD is using a community-directed approach to improve mass treatment in remote areas.

Merck is expanding its target population to include all age groups.

*Merck KGaA, Darmstadt, Germany
**Merck & Co., Inc., Kenilworth, NJ USA

Looking beyond NTDs

For diseases that cannot be eliminated or eradicated such as non-communicable diseases (cancer, diabetes, etc.), patients generally need ongoing, long-term and often life-long treatments. Such diseases do not, by definition, allow for long-term sustainable donation programmes. While such programmes are not included in the analysis, the Index highlights these relevant programmes where possible.

A total of 20 donation programmes are being run by 12 companies for NCDs, communicable diseases and maternal & neonatal health conditions in between one and 37 countries. For most programmes, there is no planned end date.

TABLE 2: Which companies are running donation programmes other than NTDs?

| Disease category | Company | Disease/condition and product | Geographic scope / number of countries | Year of first donation |
|---|----------------------|---|--|------------------------|
| Communicable Diseases | Bayer | Malaria Fludora® Fusion | 1 | 2019 |
| | GSK | Malaria RTS,S malaria vaccine Plasmodium falciparum (Mosquirix™) | 3 | 2019 |
| | Gilead | HIV/AIDS Emtricitabine/tenofovir disoproxil fumarate (Truvada®) | 1 | 2017 |
| | Gilead | HIV/AIDS Emtricitabine/tenofovir disoproxil fumarate (Truvada®) | 1 | 2003 |
| | Johnson & Johnson | HIV/AIDS Rilpivirine (Edurant®) | 1 | 2014 |
| | Johnson & Johnson | HIV/AIDS Darunavir (Prezista®), etravirine (Intelence®) | 11 | 2014 |
| | Pfizer | Cryptococcal meningitis (associated with HIV/AIDS) Fluconazole (Diflucan®) | 9 | 2000 |
| Maternal and Neonatal Health Conditions | Bayer | Contraceptive methods Levonorgestrel releasing intrauterine system (LNG-IUS) | 24 | 2003 |
| Non-Communicable Diseases | AbbVie | Bipolar disorder, epilepsy, migraine, infectious diseases Beractant (Survanta®), clarithromycin (Biaxin®) | 1 | 2013 |
| | AbbVie | Respiratory distress in newborns Beractant (Survanta®) | 6 | 2015 |
| | AbbVie | Respiratory distress in newborns Beractant (Survanta®) | 1 | 2013 |
| | AstraZeneca | Cancer (breast cancer) Anastrozole (Arimidex®), fulvestrant (Faslodex®) | 1 | 2008 |
| | Bristol Myers Squibb | Cancer (leukaemia) Dasatinib (Sprycel®) | 15 | 2017 |
| | Eli Lilly | Diabetes mellitus, mental health conditions, cancer Insulin lispro, human insulin analog (Humalog®), gemcitabine (Gemzar®), olanzapine (Zyprexa®), fluoxetine hydrochloride (Prozac®) | 1 | 2000 |
| | Eli Lilly | Diabetes mellitus (paediatric) Insulin lispro, human insulin analog (Humalog®) | 37 | 2009 |
| | Johnson & Johnson | Schizophrenia, bipolar disorder Haloperidol decanoate (Haldol® Decanoate), risperidone (Risperdal®) | 6 | 2006 |
| | Novartis | Cancer (leukaemia, gastrointestinal stromal tumor) Imatinib (Glivec®), nilotinib (Tasigna®) | 33 | 2002 |
| | Novo Nordisk | Diabetes mellitus (paediatric) Insulin human (rDNA) (Actrapid®), isophane human insulin (Insulatard®), biphasic human insulin (Mixtard®) | 14 | 2009 |
| | Pfizer | Cancer Axitinib (Inlyta®), bosutinib (Bosulif®), crizotinib (Xalkori®), temsirolimus (Torisel®) | 22 | 2015 |
| | Takeda | Cancer (leukaemia) Ponatinib (Iclusig®) | 12 | 2015 |

Eli Lilly's Life for a Child programme covers the highest number of countries out of all programmes for NCDs, communicable diseases and maternal & neonatal health conditions. It is aimed at paediatric diabetes care.

Expanding goals to help sustain efforts

Companies have a responsibility to ensure that donation programmes lead to sustainable improvements in access to medicine. This means ensuring populations can continue to access donated products for as long as they are needed. This may involve companies making a firm donation commitment until a disease is eliminated or eradicated, specifically through the renewal of the London Declaration commitment.

To date, company commitments are scattered for these donation programmes as there has been no renewal of the London Declaration yet. However, companies can still renew commitments aligning with the WHO Roadmap for NTDs 2021-2030 to reach the goal of ending NTDs by 2030.

For programmes where this is not possible (for example, those targeting NCDs), it may entail establishing transition plans for patients to

access the product once the programme ends. For example, Novo Nordisk is donating insulin to 14 countries and is continuously working with the governments of these countries to ensure the sustainability of diabetes treatment by donating until the governments provide it.

To safeguard the path to progress against NTDs and help ensure that progress in ending NTDs is sustained, all companies with an NTD donation programme can expand the donation beyond the WHO-stated goals, e.g. by donating medicine for populations beyond WHO's target population, like leaders do. GSK, Merck and MSD demonstrate best practice by publicly committing to the donation until eradication, elimination or control goals are achieved and by expanding the donation beyond these goals.

PRODUCT DELIVERY: INCLUSIVE BUSINESS MODELS

Are companies reaching into low-income markets?

The world's lowest income countries face some of the biggest barriers with regard to access to medicine. Patients in these countries often pay out of pocket for their medicines and healthcare, leaving little money for living expenses. In the past, the conventional pharmaceutical marketing model did not consider such populations in its customer base, leaving untapped markets with underserved (base of the pyramid) communities behind. Reaching into such markets can be met with challenges due to weaker health systems or supply chain inefficiencies, but it remains important for companies to do so to reach poorer populations and low-income countries.

Business models that specifically focus on low-income communities in their value chain do exist. Known as inclusive business models, they aim to identify access constraints and tackle market

What does an inclusive business model look like?

Inclusive business models show ways in which companies can directly address barriers to access for specific communities. They introduce a tailored approach to current business models so that they are better directed towards the base of the pyramid for the long term. They can complement pricing, licensing, donations and capacity building initiatives, recognising that conditions in low-and middle-income country markets can be vastly different from higher income markets. Generally, companies tend to start on a small scale to identify and overcome hurdles before expanding to further low-income countries or more underserved populations within one country.

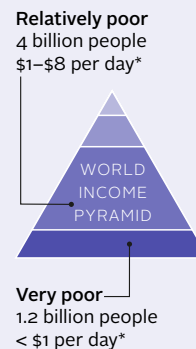
inefficiencies to create opportunities on both sides of the market transactions, for business and patients alike. As they explicitly aim to be inclusive of underserved populations, these business models can also meet the access needs of vulnerable populations including, but not limited to, children, girls and women, LGBTQI+, people living with HIV and people living with mental health conditions who can face additional barriers to access due to, for example, stigma. Business models ought to be commercially sustainable, either cost-neutral or ideally generating revenue.

With ten years to achieve the Sustainable Development Goals and Universal Health Coverage (UHC) by 2030, inclusive market-based solutions play an important role in bridging the gap by including low-income/vulnerable populations into viable business models.

What the Index measures

In order to ensure inclusive business models are successful in effectively meeting the needs of populations at the base of the pyramid, the Index looks for evidence that companies measure the outcomes of their inclusive business and whether they are/strive to be:

- Long-term models to continue growth;
- Financially sustainable to scale up and deliver value;
- Integrated with a national health system to secure a sustainable future.



How many business models are aimed at the base of the pyramid and/or vulnerable populations?

In 2021, a total of 21 inclusive business models were identified out of 77 initiatives submitted or assessed through publicly available sources. The remaining initiatives were excluded from analysis as they did not target the base of the pyramid or were considered, for example, capacity building or pricing strategies including patient assistance programmes.

Six inclusive business models have scaled up. Five companies demonstrate evidence of scaling up six inclusive business models, GSK, Merck, Novo Nordisk, Novartis and Roche.** By expanding their activities to more diseases, regions and healthcare systems, these models are reaching more patients at the base of the pyramid, including specific populations facing access barriers. The five companies stand out for measuring the outcomes of their models, e.g. by continuously tracking the number of patients reached, helping to assess the inclusivity of their models and the progress made.

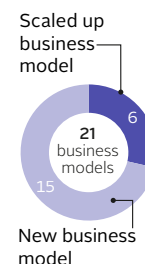


TABLE 9. Five companies are scaling up a range of inclusive business models

| | | |
|---|---|--|
| <p>GSK, 2015 Live Well Target: Underserved rural and semi-rural communities; Zambia Partners: Barclays, a UK-based multinational investment bank and financial services company</p> <p>Aim: A social enterprise model which builds and supports local distributor networks through community health entrepreneurs (CHEs). It addresses supply chain constraints. Scale up: From 20 communities in 2018, to five additional communities; 385 new CHEs since 2016 (from 47 to a total of 432). Live Well also implemented a new peer-to-peer training methodology aiming at improving efficiency of training and retention rate of CHEs and one new location on Zambia/DRC borders to reach refugees. GSK measures outcomes, including the number of CHEs trained and number of communities reached, and reports working towards financial sustainability with potential new partners to support delivery.</p> | <p>NOVO NORDISK, 2010 The Base of the Pyramid (BoP) programme Target: Low-income patients; Ghana, India, Kenya, Morocco, Nigeria, Senegal Partners: Local partners, including Ministries of Health</p> <p>Aim: To improve diabetes care for the working poor by providing training to healthcare professionals, patient education to improve self-management and ensuring a stable, affordable supply of insulin. Scale up: From five to six countries, including one additional country in scope, Morocco; and with new facilities in countries (e.g. opening of a ninth diabetes support centre in Ghana in 2019). Model generating long-term revenue for the company with more people getting the right treatment and reporting adherence to treatment, thus increasing sales of insulin. A third party, Dalberg, is expected to perform evaluations of the model in Ghana, Nigeria and Senegal for 2020.</p> | <p>NOVARTIS, 2015 Novartis Access Program for NCDs Target: Salvador, Ethiopia, Kenya, Moldova, Nigeria, Pakistan, Rwanda, Uganda, Vietnam Partners: Local NGOs (for capacity building aspects)</p> <p>Aim: Novartis Access uses portfolio approach to address affordability for products for non-communicable diseases. Scale up: To seven additional countries since 2018, with additional plans to roll out in Colombia, Tanzania and Zimbabwe in the future. Does not set all prices at USD 1 as it planned to when the model was launched, but it considers affordability at the local level to set prices. A Boston University study highlighted issues with patient adherence to the model, underlining that patients tend to get diagnosed in the public sector but buy medicines in the for-profit sector. In light of this, the Novartis Access Program was launched in the private sector in Kenya, Nigeria, Tanzania and Uganda in 2018.</p> |
| <p>MERCK, 2018 Curafa™ Target: Low-income patients; Kenya Partners: Amref Health Africa; Access Afya</p> <p>Aim: The Curafa™ programme establishes local primary healthcare centres. Scale up: Increase to more patients (reaching about 30,000 people), more workers trained within the same five clinics since 2018 and integrated within the national healthcare system with Access Afya. Merck sold the model to Access Afya, a local social enterprise, in 2020. This demonstrates continuity and integration within the national healthcare system.</p> | <p>NOVARTIS, 2007 Healthy Family Target: People at the base of the pyramid; Cameroon, India, Kenya, Vietnam, Uganda Partners: Local partners</p> <p>Aim: Health camps focused on disease prevention, awareness and treatment, tailored to local health priorities and customs, including a wide range of essential medicines. Scale up: One additional country in scope, Uganda. Model is divided in two parts: a commercial section and social activities (including e.g., awareness raising). Revenues generated in the commercial section are intended to compensate for the costs of social activities. Continuous scale up to more regions since 2007. Outcomes: the company tracks the number of health camps' participants, number of patients diagnosed, prescriptions filled.</p> | <p>ROCHE, 2015 The Global Access Program (GAP) Target: 82 countries including low- and middle-income countries Partners: UNAIDS; CHAI; the Global Fund.</p> <p>Aim: To provide better access to diagnostic testing for HIV/AIDS in 82 countries, including multiple countries in scope of the Index. Scale up: Model expanded from its focus on HIV/AIDS to include tuberculosis, Hepatitis B and C and human papillomavirus (HPV). It develops sustainable pricing policies with innovative R&D with the goal to making diagnostic tests more accessible and useable. Progress is measured by partners (e.g. UNAIDS) and Roche tracks the number of tests distributed (e.g. it reports 2,929,964 early infant HIV diagnosis tests between June 2018 and the first quarter of 2020).</p> |

** In contrast, in the Ten-Year Analysis published in 2019, the Foundation reported 10 such models. Four have been terminated (e.g. the Novartis ComHIP programme for patients with hypertension), transferred to other businesses (e.g.

Merck's Suswastha initiative) or demonstrated no current status of ongoing activity targeting the base of the pyramid.

New pilots aim to tackle barriers to access for vulnerable populations

In 2021, 15 models from eight companies have been newly identified since the 2018 Index. These 16 models include pilot projects where companies

have not yet demonstrated complete financial sustainability but share their vision of how they see these projects replicable, scalable and sustainable as well as the expected outcomes for targeted populations.

TABLE 10. **More companies are trialling inclusive business models in low- and middle-income countries.**

Of these 15 models, many have a strong focus on access to primary healthcare and non-communicable diseases (NCDs) care. No company has yet engaged in a model specifically designed to improve access to mental health care in low- and middle-income countries. However, Boehringer Ingelheim's programme Akiba Ya Roho includes mental health support in its primary healthcare facilities.

| | | | |
|--|---|--|--|
| <p>BAYER iBreast exam Target: Women in remote areas; India, Brazil Partner: UE Life Sciences</p> | <p>that it plans to bring to scale. Outcomes are yet to be measured by Bayer's partner and results to be shared in the company's sustainability reports.</p> | <p>BOEHRINGER INGELHEIM Partnership with Jacaranda Maternity Target: Pregnant women; Kenya Partner: Jacaranda Maternity</p> | <p>BOEHRINGER INGELHEIM Partnership with Healthy Entrepreneurs Target: Rural communities; small farmers; Kenya Partners: Community Health Entrepreneurs; Ashoka, global NGO with a network of social entrepreneurs</p> |
| <p>Aim: The model provides a tool to enhance early breast cancer diagnosis in India and Brazil via a tactile sensor technology and trained operators. It aims to expand mass breast cancer screenings in the most remote areas globally and address barriers to access, including affordability. The tool is implemented in communities and hospitals which have a follow-up plan in place so that women screened can access care. The goal is to bring the model to scale in India and replicate it in Brazil and other countries. UE Life Sciences has a commercialised business model and has further scaled up its operations in India. A first clinical trial has been conducted in Brazil. Outcomes relating to the implementation of iBreast exam as a tool are yet to be measured by Bayer's partner and results to be shared in the company's sustainability reports.</p> | <p>BAYER Partnership with BISA Target: People living in poverty, young women, people living in rural areas; Ghana, Senegal Partners: Bayer Foundation; BISA</p> <p>Aim: The model provides a health application enabling access to direct remote medical consultations, with the aim to address economic disparities, high cost and barriers to access healthcare in rural areas, also taking into account unmarried women who may face additional discrimination in certain settings. Model piloted in two countries in scope of the Index. BISA aims at reaching financial sustainability based on a premium services model, including commission payments from pharmacies or premium users' subscription fees. Outcomes are yet to be measured by Bayer's partner and results to be shared in the company's sustainability reports.</p> | <p>Aim: To deliver NCD care to pregnant women with NCD-related complications, through the development of a specific independent business unit within the maternity.</p> <p>New since 2019; the company states it is a social initiative with a goal to generate profit. The company reports 2,200 people, including pregnant women, screened for NCDs during the pilot phase.</p> <p>BOEHRINGER INGELHEIM Akiba Ya Roho Target: People in informal settlements living on USD3 - USD35 per day, Nairobi Kenya Partner: Access Afya</p> <p>Aim: To provide an end-to-end model for primary care adapted for urban informal settlements (i.e. slums) in Kenya by implementing small clinics. The model addresses access to healthcare constraints for patients with NCDs, including diabetes, hypertension and peer-to-peer mental health support.</p> | <p>Aim: To deliver end-to-end NCD care, including diabetes and hypertension, to rural communities by using community health entrepreneurs (CHEs). New since 2019; the company reports 36 CHEs trained to date and put on the NCD programme in addition to 32 from pilot phase; plans to scale up to more CHEs generating small income and a goal to be financially sustainable with its social investment.</p> <p>BOEHRINGER INGELHEIM Partnership with Yako Medical Target: Out-of-pocket patients; Lagos, Nigeria Partner: Yako Medical, a social venture</p> <p>Aim: To provide primary healthcare facilities with access to NCD screening technology and support a digital patient data management platform for under-equipped hospitals or clinics receiving mostly uninsured patients; works by creating a pay-per-use model taking into account affordability and adherence. Yako Medical was founded in 2016; Boehringer Ingelheim newly involved with a goal to make the model profitable. Outcomes: The company reports 860 people screened at primary care facilities with Yako Medical equipment during the 2019 pilot phase.</p> |
| <p>BAYER Partnership with Access Afya (AA) on COVID-19 response Target: Local communities; Kenya Partner: Access Afya (AA)</p> | <p>BAYER MUTTI Target: Out-of-pocket patients; Ghana, Nigeria Partner: mPharma, Ghana</p> | <p>New since 2019; the pilot generated small profit within six months. The company reports having reached 21,000 patients for screening and is measuring outcomes with plans to scale up with more patients screened and accessing treatment through Access Afya's clinics.</p> | |
| <p>Aim: To improve access to primary healthcare services in Kenya during the COVID-19 pandemic. The initiative aims at incorporating COVID-19 risk assessments into AA's digital medical portal, training local entrepreneurs on telemedicine and strengthening the service for severe cases. New model ongoing since 2020. AA, the implementing partner, has developed a social model of clinics</p> | <p>Aim: To provide deferred reimbursement for out-of-pocket payments of treatment for Degenerative Valve Disease and other CV diseases. New since 2019; Bayer reports on expectations of sustainability once mPharma can make a margin. Outcomes are yet to be measured by mPharma, which provides the data for Bayer to audit.</p> | | |

BOEHRINGER INGELHEIM

Partnership with Chronic Drugs Medical Scheme (CdMS)

Target: Lower middle-income patients in rural and urban areas; Nairobi and Kisumu County, Kenya
Partner: CdMS, a social venture

Aim: To aggregate orders from small hospitals and clinics and help deliver NCD medicines to them directly from pharmaceutical companies at discounted prices, ensuring lower costs for patients. The scheme can benefit patient access in African countries by helping to lower high procurement costs and prices of medicines, in part due to engorged pharmaceutical value chain with multiple intermediaries. New since 2018; the company reports having generated small revenue, with 50 hospitals enrolled during the pilot and goals to be profitable.

GILEAD

Mobile Health Smiles Wallets

Target: Patients living in informal settlements; Nairobi, Kenya
Partner: PharmAccess

Aim: To use technology and digital health solutions to record and better accommodate underserved communities living in slums, including mostly vulnerable women and children, with free health services through the M-TIBA platform (a mobile health wallet) and through services provided by Gertrude's Hospital clinics in Nairobi. The model is now based on small co-payments. Gilead has been involved between 2016 and 2018 (it is newly included); it finished in June 2018, but has continued in a different form as the Afya Program under the supervision of Gertrude's Hospital's, which also receives financial support from the company, but shares limited information publicly. The company reported an initial goal to reach 50,000 people and had reached over 71,000 people by its transition time in July 2018.

JOHNSON & JOHNSON

Partnership with Jacaranda Maternity

Target: Pregnant women; children; Kenya
Partner: Jacaranda Maternity

Aim: Jacaranda is a maternity hospital focused on providing affordable and patient-friendly care. As part of Johnson & Johnson Impact Ventures, supported by the Johnson & Johnson Foundation, the company partners with the hospital with the aim to create a more economically sustainable model, enabling the hospital to improve maternal health outcomes for low-income women and their children at a larger scale. Since 2019 Johnson & Johnson Impact Ventures has been supporting the expansion of the hospital to address the needs of low-income pregnant women in Nairobi's pre-urban areas. With this new model, the hospital plans to create two more maternity hospitals over the next two years, with the goal to reach almost double the patients per year.

JOHNSON & JOHNSON

Partnership with Southlake Medical Centre

Target: Low-income workers and communities in Naivasha flower district, Kenya
Partners: Ingo Investments; Sumerian Partners

Aim: Primary healthcare model for low-income workers to address access issues including access to primary and secondary healthcare by setting consultations at a low, affordable price. Revenue is generated through fees and paid walk-ins consultations at the Medical Centre. The company will measure outcomes through impact indicators such as numbers of low-income patients treated, number of safe deliveries or number of patients receiving HIV care. Johnson & Johnson Impact Ventures, supported by the Johnson & Johnson Foundation, is newly supporting the Medical Centre's expansion of this initiative to a more comprehensive and sustainable economic model. It reports a goal to grow services in 2020 and maintain an average out-of-pocket cost of USD 2 per patient visit. Johnson & Johnson Impact

Ventures, supported by the Johnson & Johnson Foundation, reports a commitment of USD 15 million to support social entrepreneurs, with a model leveraging the company's scientific and business expertise, as well as its financial resources.

NOVARTIS

Novartis Africa Sickle Cell Disease Flagship Program

Target: People living at the base of the pyramid, vulnerable populations; Ghana
Partners: The Sickle Cell Foundation, Ghana; Ministry of Health, Ghana.

Aim: To step up treatment and outcomes in sickle cell disease in sub-Saharan Africa, including through training workers on treatment administration. Novartis reports negotiating treatment provision at a low cost via the country government to enable the model to scale up while covering a minimum of costs for the company. New since roll-out in Ghana in 2019, with projections of financial sustainability; Novartis shares a goal to ensure sustainability within healthcare system at the end of this five-year programme. Outcomes: The company reports over 20,000 treatments delivered to date, through 11 trained treatment centres, and private distribution channels, with expectations to cover needs for a year. Reports plans to include Uganda; Tanzania; Congo, Rep; Senegal and Kenya next.

SANOFI

Ngao Ya Afya

Target: Low- and middle-income populations; Kenya
Partners: PharmAccess Foundation; CarePay

Aim: To provide digital access to NCD care via M-TIBA, thus facilitating access to affordable and quality diabetes and hypertension care through a mobile technology connecting patients, payers and providers without transaction costs. A selection of medicines (including non-Sanofi products) is also made available in clinics using the platform at a discounted price. New pilot ongoing since 2018. The company reports a goal to be cost-effective. It reports an estimated 798 people diagnosed, out of 9,750 screened in 2019. Outcomes including the

number of patients diagnosed and on treatment are measured by PharmAccess and shared with Boston University.

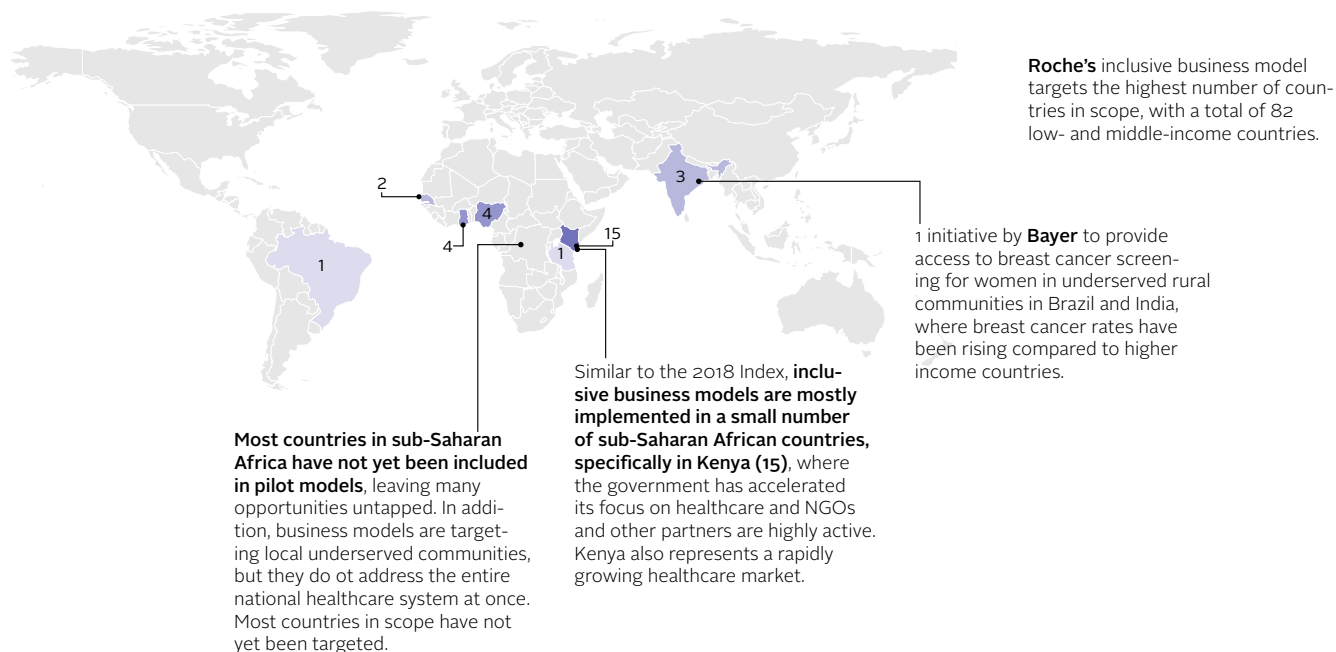
TAKEDA

Blueprint for Innovative Healthcare Access

Target: Local communities, out-of-pocket patients; Kenya, Rwanda
Partners: Local partners

Aim: To address access constraints for NCDs for patients (including cancer and diabetes) from end to end through partnerships, i.e. by building capacity, providing funding, treatment and delivering implementation of activities including e.g. training healthcare workers and screening patients for diabetes. New, launched in Meru county, Kenya in 2019 and Rwanda in 2020. Goal to reach financial sustainability by involving local and national governments and considering affordability by lowering costs of medicine. The company reports over 800 healthcare workers trained in the first nine months of the initiative in 2019. Outcomes are measured through Duke University Innovations in Healthcare and Broadreach's Access to Health Impact framework and are yet to be reported on in 2020.

FIGURE 66. Which countries do these inclusive business models target?



What is the key driver behind inclusive business models?

What sets the companies apart in this analysis from the companies without inclusive business models is a clear access-to-medicine strategy that is rooted within the company’s business model. An access-to-medicine strategy is intended to improve access to medicine in all countries, including low-income countries and is integrated in the overall corporate strategy (see page 38 for more information). This indicates that not only can such a strategy provide better access, but it can also create opportunities for the company that may otherwise not be realised. An inclusive

business model is a concrete product of a wider access-to-medicine strategy. For example, in 2019 Novartis launched a new strategy aimed at maximising patient reach across all income levels by focusing on affordability strategies and social business models, specifically in sub-Saharan Africa. Since then, Novartis has been working on expanding access to treatment for sickle cell disease across sub-Saharan Africa, starting with Ghana, with plans to reach ten additional countries by 2022. Furthermore, Novartis leads in the consistent use of good quality pricing strategies across the income pyramid (see page 62).

Scale-up and replication to more countries and diseases is needed

It should be pointed out that inclusive business models are only one of the many important pieces of the access puzzle and companies are key partners in advancing UHC. Inclusive business models help ensure that different socioeconomic groups have access to healthcare, but currently they are mostly limited to intra-country settings. To make inclusive business models truly successful, scale-up and replication in more countries and for more diseases is needed. At the core of their business, companies still need to adopt other components of access plans, such as the implementation of rapid registration processes. Once products are registered, companies should systematically apply access strategies (e.g. equitable pricing strategies, licensing etc.) to ensure access to medicine is affordable for all income tiers in low- and middle-income countries.

SUPPLY, QUALITY & MANUFACTURING

How do companies help safeguard the supply and quality of their products?

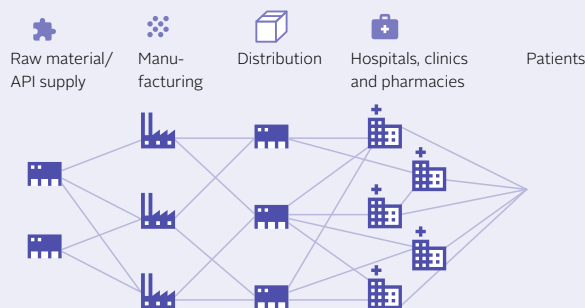
With just ten years left to achieve the Sustainable Development Goals and Universal Health Coverage (UHC) by 2030, this brings a new sense of urgency to the challenges and inefficiencies posed by complex supply chains.

Pharmaceutical companies have a crucial role to play in safeguarding the supply of high-quality medicines globally, especially in hard-to-reach populations where health systems may be weak. Access to such products is key in achieving UHC as the delivery of effective and affordable treatments will lead to a more inclusive healthcare system and cost-effectiveness. Any savings due to improved delivery and access can be used to strengthen health systems.¹

How companies perform overall

Measures taken by companies, such as demand forecasting and keeping safety stocks, are strategic business decisions to increase operational resilience. Yet, some companies are engaging in these practices to a greater extent than others in countries in scope with the aim to ensure continuous supply and build resilience in the case of disruptions. Companies also collaborate with stakeholders outside of their usual business partners on forecasting and data sharing and work with contract manufacturing organisations on quality manufacturing. Such collaboration, however, is predominantly limited to India, China and Brazil, leaving many countries behind, for example in sub-Saharan Africa. There is also a lack of larger-scale supply chain building initiatives in partnership with national governments which would allow continuous and time-efficient supply of medicines with a greater patient outreach.

Pharmaceutical supply chains are complex fraught with inefficiencies leading to shortages and poor-quality meds



What is needed by companies to ensure the continuous supply of medicines in low- and middle income countries?

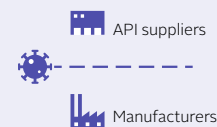
- Measures in place that help strengthen a company's own supply chain both upstream and downstream such as: working with multiple API suppliers, having safety stocks in place, and being agile and responsive to any changes they identify;
- Collaboration with local partner manufacturers, distributors and logistics providers to identify bottlenecks and improve capacity for appropriate supply chain and manufacturing management. This is particularly important for low- and middle-income countries where supply chains can be particularly complex in private, public and NGO market sectors.

API suppliers are concentrated



Hubei province in China is one of the biggest production hubs for APIs

COVID-19 disrupted global API and medicine supplies



SUPPLY

Which companies are taking steps to secure the supply of products in low- and middle income countries?

The 2021 Index finds that 19 companies disclose at least one measure to ensure continuous supply in at least one country in scope. The remaining company, Bristol Myers Squibb, did not disclose details to the Index, and information was not available in the public domain. The 19 companies report working in some form of a partnership to address supply challenges: e.g. collaborating with supranational partners to supply medicine, liaising with government and purchasers on demand forecasting and working with local distributors to tackle supply barriers. However, these measures are applied to only a few products and only in a few countries, thus not addressing the scale of the access challenge. Companies take various measures to ensure the continuation of their business activities, especially for major brands, such as forecasting and keeping safety stocks.

Enhancing supply resilience during a pandemic

During the period of analysis, eight companies, namely AstraZeneca, Bayer, GSK, Johnson & Johnson, Merck*, Novo Nordisk, Novartis and Pfizer reportedly took measures in response to/in anticipation of the supply disruptions in low- and middle-income countries caused by COVID-19. Such disruptions included reduced air freight capacity and border closures. Measures involved, among others, closer collaboration with local distributors, re-allocating stock to local distribution centres, increasing safety-socks, increasing API stocks and assessing alternative innovative supply methods and routes. These practices can be rolled out across the board and put into place by other companies to ensure future resilience of supply chains — a crucial step in preparing for the next potential pandemic.

How to ensure resilient supply chains for the next pandemic?

- Local collaboration
- Dual sourcing of API
- Re-allocation of stock
- Increasing safety stocks
- Assessing alternative routes

FIGURE 67. 19 companies report some activity in areas that aim to ensure continuous supply

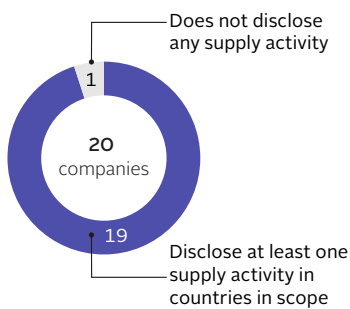
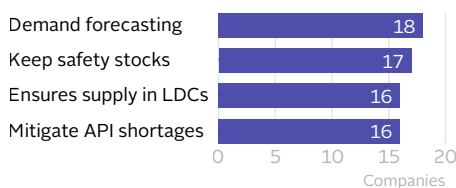


FIGURE 68. Overview of companies' activities to help ensure the uninterrupted supply of products



How one company ensured the supply of its full portfolio during the COVID-19 pandemic

ASTRAZENECA

What: Despite the reduced air freight capacity and other supply restrictions due to COVID-19, AstraZeneca reports that it has maintained supply of its entire portfolio of medicines to markets around the world, including countries in scope of the Index.

How: (1) Supply acceleration: pushing all finished pack inventory from its supply sites into its distribution centres around the world, positioning close to customers, adding approximately two weeks of additional stock; (2) Business Continuity Planning (BCP) inventory ramp-up: finished goods safety stock increased by 30 days across the globe and bulk production increased by seven days to respond to demand surges and support contingency planning; (3) Logistics BCP activation: activation of AstraZeneca Logistics War Room & Logistics Supplier BCPs. The company assessed and activated 140 new freight routes between February and May 2020. Emergency air freight capacity was also established for Brazil, Peru, Colombia, Egypt, Kenya, Iran, Iraq, Indonesia and the Philippines as well as new seaports to import products into India and Angola.

* Merck KGaA, Darmstadt, Germany

TABLE 11. **How can companies help ensure the continuous supply of their products?**

This table lists the priority activities for companies to help ensure the uninterrupted supply of their products, along with notable examples (where data was available) of company activity in each area.

| | | |
|--|--|--|
| <p>DEMAND FORECASTING</p> <p>The use of short- and long-term forecasting mechanisms to ensure sufficient APIs and finished products meet future demand of products</p> <p>For bedaquiline (Sirturo®), Johnson & Johnson reports deriving demand forecasting from three sources:</p> <ol style="list-style-type: none"> 1) Primary and secondary market research; 2) Utilisation of a surrogate product with similar global disease distribution and patient profile to assess speed and depth of adoption. 3) Orders of bedaquiline (Sirturo®) are monitored from the donation programme and use in high burden countries to predict and understand trends in demand. | <p>DATA SHARING</p> <p>The exchange of information with external stakeholders to optimise supply</p> <p>For the distribution of diethylcarbamazine (DEC), for the treatment and prevention of lymphatic filariasis, Eisai uses the NTDeliver system to estimate the volume of supply per country, and to track and share distribution information with WHO and other pharmaceutical companies.</p> <p>Bayer and MSD** participate in the Global Family Planning Visibility and Analytics Network (VAN) of the Reproductive Health Supplies Coalition, which captures data from multiple sources along the supply chain to improve supply chain visibility, offering a platform to assess supply needs and enhance time and cost-effective supply. Currently, a pilot is ongoing in Nigeria and Malawi.</p> | <p>SAFETY STOCKS</p> <p>Sufficient safety stocks of APIs and/or finished products to prevent stockouts</p> <p>Merck reports keeping a safety stock of finished goods (between 1 and 3 months) in all their distribution centres as well as inventory of semi-finished products and a strategic stock of API. Gilead holds a safety stock of unlabelled bottles to fill gaps in supply. Boehringer Ingelheim reports stockpiling of the API empagliflozin, (for Jardiance®, Synjardy® and Glyxambi®) with 8 months coverage.</p> |
| <p>ENSURING API AVAILABILITY</p> <p>Working with multiple API suppliers to ensure resilience against supply disruptions</p> <p>Sanofi produces 70% of its APIs internally throughout its own industrial network and has sufficient capacities to also supply other pharmaceutical manufacturers. For the remaining APIs, the company collaborates with a portfolio of suppliers and provides multi-sourcing arrangements from different regions. A global supply continuity approach is in place, including a mono-sourcing exit programme to extend back-up solutions. Priority is put on essential medicines, key products and product launches.</p> | <p>COLLABORATION</p> <p>Engaging with governments and stakeholders to inform on issues that may affect the supply chain</p> <p>For specific products and in low- and middle income countries where there is no Pfizer presence, the company reports working with supranational partners including UNICEF, Gavi, and the Bill and Melinda Gates Foundation to forecast and manage supply. Activities include monitoring of inventory level in countries and validating country orders.</p> <p>Takeda reports working with the countries' Ministry of Health to, among others, inform them regarding stock issues (i.e. a legal responsibility to flag low stock of an essential medicine). It reports working with hospitals, governments, regulators on issues like communicating demand forecasts and non-commercial supply.</p> | <p>ENSURING SUPPLY IN LDCS</p> <p>Companies take additional measures to ensure supply in LDCs</p> <p>GSK reports working with a hub in Karachi, Pakistan, which provides demand forecasting for the region, including LICs and LDCs such as Ethiopia, Malawi, Rwanda and Zambia. Johnson & Johnson reports that their Global Public Health (GPH) Supply Chain team has a dedicated GPH order management team in place that is mainly focused on the orders from institutional buyers, such as PAHO, WHO, UNICEF, MSF, Chemonics and PEPFAR, working in LDCs and LICs.</p> |

** Merck & Co., Inc., Kenilworth, NJ USA

QUALITY

Preventing poor-quality medicines from reaching pharmacy shelves

Many low- and middle-income countries have a long and complex product distribution chain. As a result, product diversion or the introduction of expired, substandard and falsified products into the distribution chain becomes relatively easy.

Pharmaceutical companies can help combat the issue of substandard and falsified products by reporting identified cases to the national health authorities and/or WHO Rapid Alert in a timely manner, thus enabling prompter action.

1 in 10 products circulating in low- and middle-income countries are substandard or falsified²

FIGURE 69. How do companies report substandard and falsified medicine?

Most companies have a policy or approach to report confirmed cases of substandard and falsified medicines to national health authorities and/or WHO Rapid Alert. Over half of the companies are doing so in less than ten days.



Six companies lead
Astellas, AstraZeneca, Eisai, GSK, Novartis and Takeda, by having a policy to report cases in less than ten days and demonstrating strong approaches (including visual inspection e.g. confirmation of mislabelling, or packaging data verification) to allow faster action to withdraw the product from the market, thus meeting all stakeholder expectations.



CAPACITY BUILDING

Looking beyond the product to help build resilient supply chains in LMICs

For many low- and middle income countries with limited resources, the infrastructure required for the proper procurement, delivery, logistics and storage of medicine is often lacking. Large pharmaceutical companies typically have both the know-how and strategic incentives to help fill these gaps. Drawing on their vast expertise, pharmaceutical companies can engage with local stakeholders with a view to strengthening supply practices. They can also support local manufacturing by transferring their knowledge and expertise to local manufacturers in low- and middle income countries. Such capacity building activities can help increase the availability of quality-assured, safe and effective medicine and healthcare. These initiatives need to be held to high standards to ensure the related activities are both responsible and impactful. This requires action to measure, evaluate and report on the evidence of the impact of initiatives.

What the Index measures

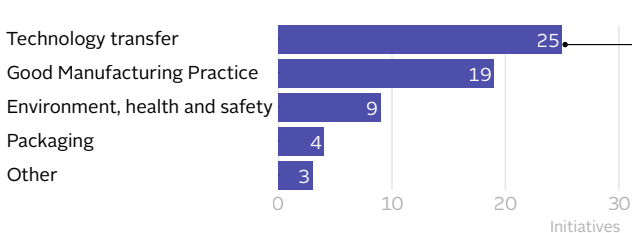
For both the manufacturing and the supply chain capacity building areas, companies could submit no more than five initiatives per area. This means that a total of 100 initiatives per area could be submitted. A total of 60 manufacturing and 68 supply chain capacity building initiatives were submitted, of which 42 and 46 were included for assessment. Initiatives were included if they met the following criteria:

- takes place during the period of analysis and in a country in scope of the Index
- is in partnership with a local third-party actor
- addresses specific local needs and/or gaps

The Index assessed whether the initiatives are guided by clear, measurable goals or objectives, measure outcomes and have long term aims/achieve integration within the system. These are known as Good Practice Standards (GPS). Please refer to Appendix IV for more information.

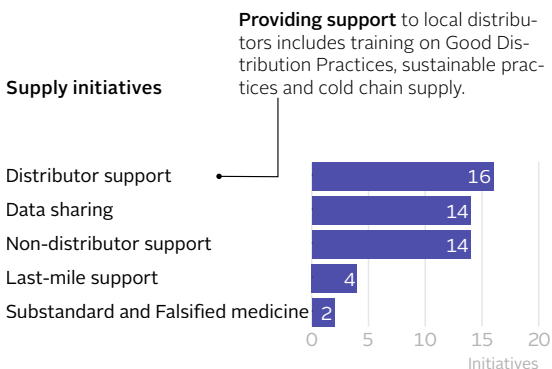
FIGURE 70. Focus of companies' initiatives for strengthening manufacturing and supply capacity

Manufacturing initiatives



Through technology transfers (25 of 42), an originator company transfers technology and knowledge on a specific drug development process to a manufacturing site in countries in scope of the Index. Of the 25 technology transfer initiatives, four target cancer medicine and four target HIV treatments. Other products include treatments for diabetes, malaria, tuberculosis and measles-rubella vaccines.

Supply initiatives



How two companies use technology transfers to accelerate generic and paediatric medicine availability

GILEAD AND GSK

How: Gilead provides technology transfer support to manufacturers that hold licences to produce generic versions of Gilead's HIV and hepatitis C treatments as well as remdesivir (Veklury®) which has been approved for emergency use in patients with COVID-19. To accelerate the development of a child-friendly formulation of dolutegravir (Tivicay®), an on-patent first-line treatment for HIV, GSK provided a technical information package and technical support to two generic manufacturers in India, Mylan Laboratories Limited and Macleods Pharmaceuticals. Both companies submitted their application for the paediatric dolutegravir application to the US FDA while GSK's paediatric formulation of dolutegravir (Tivicay®) was still under review, greatly accelerating the timeline of generic medicine availability. The initiative took place in partnership with the Clinton Health Access Initiative (CHAI) and received financial support from Unitaid.

Ensuring safe vaccine storage and measuring the outcome

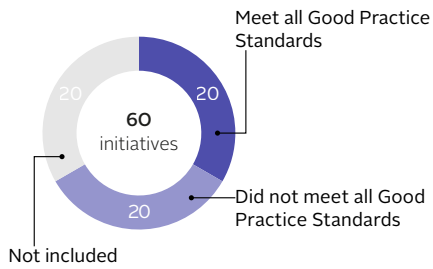
GSK

What: GSK strengthens vaccine storage at airport facility in Nigeria

How: After discovering that vaccines shipped to Nigeria were being exposed to continued temperature deviations whilst in the storage terminal before clearing customs, GSK worked with TO1, the airport operator at Lagos airport, to ensure that the airport storage facilities meet operational standards and stable temperatures can be maintained to ensure safe vaccine storage. As a result of these efforts the terminal facility has been recertified for vaccine supply, benefiting multiple vaccine suppliers that utilise the storage facilities at the terminal. GSK measures outcomes by tracking (1) temperature deviations from site to market, (2) Customs Clearance Lead Times, (3) end-to-end supply lead time and (4) market On-Time and In-Full (OTIF).

FIGURE 71. How many capacity building initiatives for manufacturing and supply meet all Good Practice Standards?

Manufacturing initiatives



| Company | Meet all Good Practice Standards | Did not meet all Good Practice Standards |
|----------------------|----------------------------------|--|
| AstraZeneca | 0 | 1 |
| Bayer | 0 | 1 |
| Boehringer Ingelheim | 0 | 2 |
| Daiichi Sankyo | 0 | 2 |
| Eisai | 0 | 2 |
| Gilead | 1 | 0 |
| GSK | 4 | 1 |
| Johnson & Johnson | 2 | 3 |
| Merck | 1 | 4 |
| Novo Nordisk | 2 | 0 |
| Novartis | 3 | 1 |
| Pfizer | 3 | 1 |
| Roche | 0 | 2 |
| Sanofi | 4 | 1 |
| Takeda | 0 | 1 |

Measuring outcomes

The vast majority of the initiatives are guided by clear, measurable goals or objectives, but several companies fail to demonstrate that they measure outcomes. For AbbVie, Astellas, Bristol Myers Squibb and Eli Lilly, capacity building initiatives could not be reported on as no data were provided/verified or was available in the public domain during the period of analysis.

Supply initiatives



| Company | Meet all Good Practice Standards | Did not meet all Good Practice Standards |
|----------------------|----------------------------------|--|
| Bayer | 2 | 0 |
| Boehringer Ingelheim | 0 | 4 |
| Eisai | 0 | 1 |
| GSK | 5 | 0 |
| Johnson & Johnson | 4 | 1 |
| MSD | 3 | 0 |
| Merck | 1 | 1 |
| Novo Nordisk | 3 | 1 |
| Novartis | 3 | 2 |
| Pfizer | 4 | 1 |
| Roche | 0 | 4 |
| Sanofi | 2 | 3 |
| Takeda | 1 | 0 |

How can companies improve their efforts to strengthen manufacturing and supply capacity?

Companies can engage more in initiatives that align with or are designed by governments and local authorities. Currently, 27 out of 46 supply chain capacity building initiatives are in partnership with a local or national authority, such as the Ministry of Health.

The country and product scope of company efforts are limited. Initiatives and supply chain measures, both within their own supply chain and when building capacity, too often focus on few countries and products. For example, of the 25 initiatives that include a technology transfer, four take place in more than one country in scope of the Index. Also demand

forecasting efforts, safety stocks, dual API sourcing and data sharing are far from covering the full geographic scope and product portfolio of companies.

Specifically, for remote and hard-to reach areas, last-mile supply is lagging behind. Infrastructure constraints and vehicle limitations cause suboptimal and long delivery times for medicines with special storage requirements. Companies demonstrate limited evidence that they engage in last-mile supply within their own supply chain, especially in LDCs and remote areas, while at the same time few capacity building initiatives included activities on last-mile supply.

FIGURE 72. Where do companies focus their manufacturing capacity building initiatives?

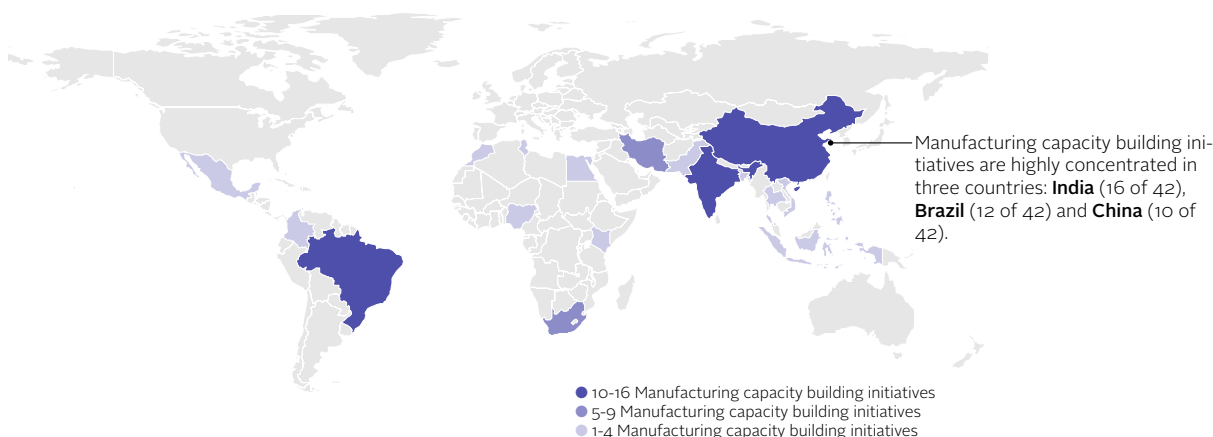
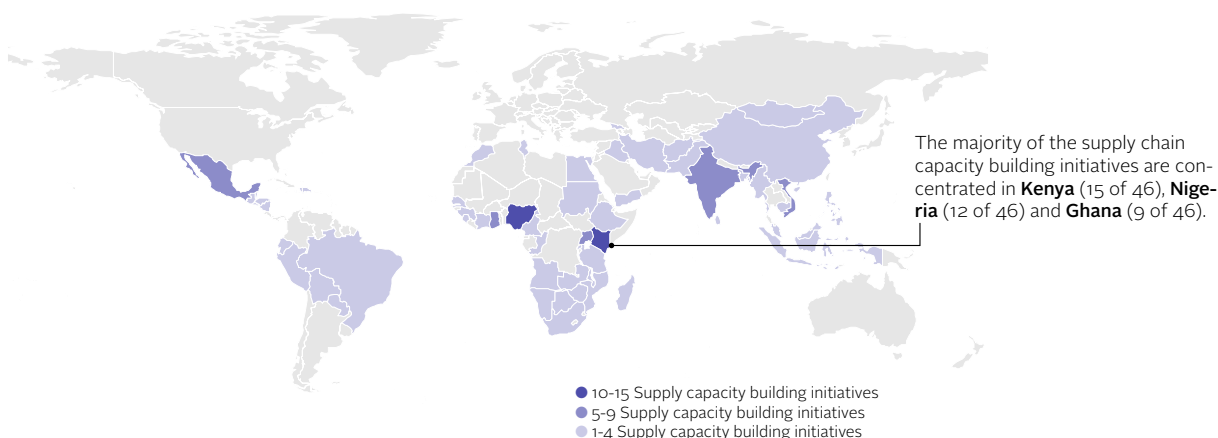


FIGURE 73. Where do companies focus their supply chain capacity building initiatives?



Building Active Pharmaceutical Ingredient (API) capacity in Africa

JOHNSON & JOHNSON

What: In response to the set priority of strengthening national supply chain management systems by the South African Development Community's (SADC) Pharmaceutical Program, Johnson & Johnson has supported the building of active pharmaceutical ingredient (API) manufacturing capacity of third-party manufacturers in Africa.

How: Noted as a strategic priority, the company works with local suppliers and manufacturers to build their knowledge, expertise and technical and managerial support needed to become a sustainable and reliable local API supplier.

Improving last-mile supply in the Democratic Republic of the Congo

PFIZER

What: Provides financial support to VillageReach to implement the Next Generation Supply Chain Initiative in the Sankuru province of the Democratic Republic of the Congo (DRC), which has low immunisation coverage and has seen resurgence of epidemics of poliomyelitis, measles and yellow fever. Only an estimated 60% of the vaccine posts in the DRC have the vaccines required in the country's immunisation schedule available.

How: The initiative aims to develop a new and optimised supply chain system that will improve the availability of vaccines at the last mile and reduce stockouts, strengthen the leadership and skills of health officers and frontline workers, support the implementation of streamlined distribution through the new logistics system and build a culture of data use to enable evidence-based continuous improvement. This initiative is supporting the government's Essential National Drug Supply System (SNAME) Strategic Plan, improving storage and distribution conditions for health products to last mile beneficiaries.

Opportunity for companies to expand efforts to sub-Saharan Africa

While manufacturing initiatives are concentrated in countries where companies generally have a manufacturing base (i.e. China, India, Brazil), supply chain capacity building initiatives are not concentrated in the same geographic areas. Moreover, a relatively large proportion of the supply chain capacity building initiatives are taking place in sub-Saharan Africa. Companies are encouraged to make provisions for both the quality of products and the availability by supporting supply chain skills and knowledge to ensure agile and strong supply chains in low- and middle-income countries, including the prevention of substandard and falsified products.

Countries covered by access strategies (see page 70) and efforts to ensure continuous supply are also the same countries covered by supply and manufacturing capacity building initiatives, generally emerging markets like Brazil, China and India as well as South Africa and Kenya.

Companies should expand their capacity building initiatives to additional countries where they have operational presence, including LICs.

With the majority of the manufacturing capacity building initiatives concentrated in just three countries, companies are encouraged to expand their activity to sub-Saharan Africa where there is, in general, a less established manufacturing infrastructure in place. A total of eight initiatives took place in Sub-Saharan Africa, of which the majority took place in South Africa (5), followed by Kenya (2) and Nigeria (1).

With the exception of initiatives in Mexico and Brazil and one initiative — Novartis' CML Path to care, supporting supply chains to ensure access to donated products for the treatment of chronic myeloid leukaemia — targeting multiple countries, Latin American countries are left out from the supply chain and manufacturing capacity building activities reported in the Index.

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- 2 World Health Organization. Substandard and falsified medical products. <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>. Accessed December 23, 2020.

HEALTH SYSTEM STRENGTHENING

How do companies overcome gaps in local health systems?

Some of the biggest challenges to access to medicine in low- and middle-income countries are gaps in local pharmaceutical and health systems. Poor infrastructure and patchy healthcare services cause inaccurate or late diagnosis, inappropriate treatment and a loss in follow-up, in addition to too few healthcare facilities to meet demand. While health systems are the primary responsibility of governments, product development and delivery are at the core of the pharmaceutical companies' responsibilities. Therefore, companies can provide local governments and healthcare organisations with support in product delivery as they often have the know-how, resources and strategic incentives to help fill these gaps.

The motivation to help build strong health systems in low- and middle-income countries can also be linked to the potential for building strong, established markets. When health systems are solid, healthcare professionals can more appropriately detect and treat conditions, which can

ultimately lead to an increase in product demand. Health system strengthening initiatives can, therefore, be a potential win-win investment in the longer term – though, this commercial interest is also precisely the reason why conflicts of interest need to be managed appropriately.

Why quality of initiatives matters

Company-led initiatives aiming to strengthen local health systems need to be held to high standards to ensure company activities are both responsible and impactful. Companies can build capacity outside the pharmaceutical value chain of R&D, manufacturing, pharmacovigilance and the supply chain, with a focus on prevention, education, diagnosis and/or treatment — providing certain criteria are met: the initiatives are carried out with appropriate partners and in alignment with local needs, they are guided by clear goals and objectives, the outcomes are monitored and measured and any conflicts of interests are managed carefully.

What the Index measures?

To better assess the quality of company health system strengthening initiatives, the Index assessed a sample of initiatives against the following criteria:

- takes place in a country in scope of the Index and during the period of analysis;
- addresses local needs priorities and/or skill gaps;
- is carried out in partnership with relevant stakeholders;
- has processes in place to mitigate or prevent conflict of interest;
- is guided by clear, measurable goals or objectives;
- measures or plans to measure outcomes.

Companies were invited to submit a maximum of five health system strengthening initiatives for analysis. The Index assessed whether initiatives have governance structures and long terms goals in place through, for example, integration in the local health system. These are known as Good Practice Standards. See Appendix IV for more information.

How companies perform overall

In general companies are performing well in this area, with all companies engaging in health system strengthening. Specifically, there has been an increase in measuring the outcomes of the company initiatives. In 2021, the outcomes of 82 initiatives were measured or planned to be measured, compared to 40 in 2018. Furthermore, companies are more transparent about the outcomes as a significant proportion is publicly disclosed. These two aspects are important for health system strengthening as they can ensure accountability, bolster the quality of the initiative, allow for recognising barriers and exemplify best practices.

How many health system strengthening initiatives did the Index assess?

The Index examined 82 initiatives from 20 companies that meet the inclusion criteria for this analysis. Of these, 70% (60 of 82) of initiatives meet all Good Practice Standards. Companies mostly develop solutions that are sustainable by

working with local authorities. A total of 18 companies report working with the respective national/regional health authorities to align the project with the government's priorities and/or to integrate the programme or the project deliverables (e.g. guidelines, training curricula) into local health services.

FIGURE 74: How many health system strengthening initiatives meet all the standards for good practice

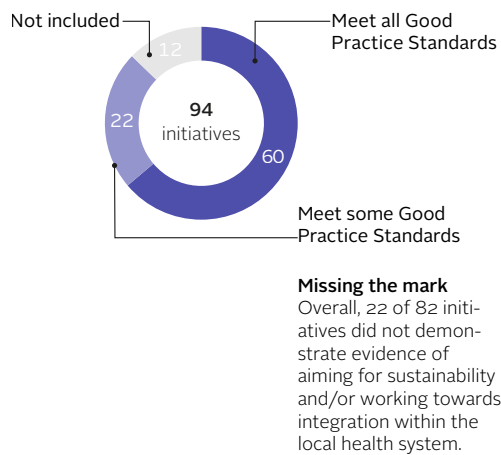
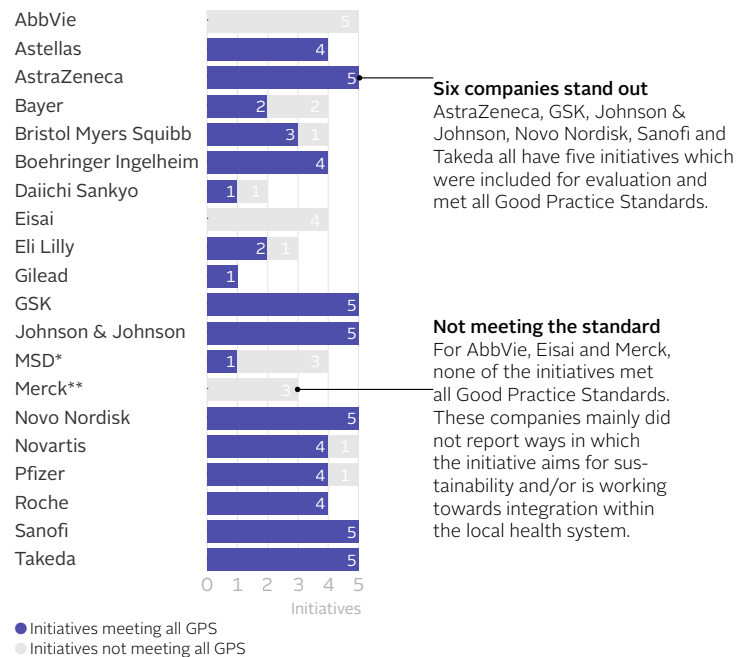


FIGURE 75. Which companies stand out for their health system strengthening initiatives?



Aligning stakeholders towards a shared agenda

NOVARTIS & THE AFYA DUMU 'END TO END CARE MODEL'

What: Three counties in Kenya participate in this programme, identifying facilities and community volunteers, collaborating on screening, education and utilising data to evaluate population health. The aim is to increase early diagnosis, treatment and follow-up rates for NCDs.
How: This programme ensures the training of caregivers and empowers nurses to initiate basic treatment. It provides a process and framework ensuring proper execution. It aims to empower patients and health providers to coordinate care and data across the patient journey. The digital health-based model aims to reduce costs by leveraging data to support allocation decisions based on disease burden. The programme started in late 2018 and is expected to screen approximately 200,000 individuals.

How one company aims for sustainability

NOVO NORDISK AND THE WORLD DIABETES FOUNDATION (WDF)

What: Founded and supported by Novo Nordisk, the WDF has supported over 500 projects in 116 countries with the majority of them in scope of the Index.
How: To ensure its sustainability, WDF-supported projects are locally owned, co-funded, focus on the retention of healthcare professionals and community workers and work together with local health authorities to address systematic barriers. To train and retain staff, project staff are given the possibility to be trained at so-called centres of excellence in therapeutic areas of relevance to the individual projects, including, for example, prevention of foot amputations. Furthermore, the projects are formally handed over and equipment is transferred when a project comes to an end.

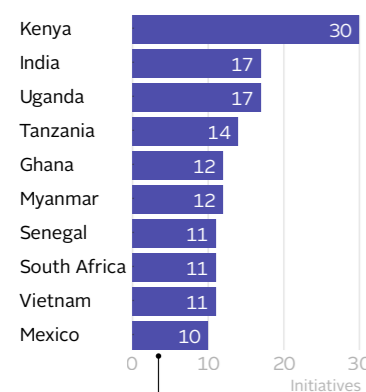
*Merck & Co., Inc., Kenilworth, NJ USA
**Merck KGaA, Darmstadt, Germany

What do the health system strengthening initiatives look like?

Most initiatives take a disease-specific approach, focusing activities on a predetermined set of diseases in which the company has products and expertise.

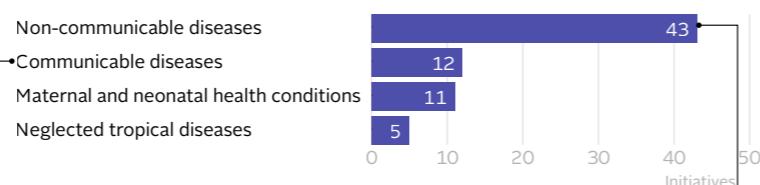
FIGURE 76. The focus of companies' health system strengthening initiatives

Top 10 countries in scope covered by an initiative



25 countries in scope are not covered at all, including small nations islands and countries in Latin America, Asia and sub-Saharan Africa that are home to a total of over 55 million people. What is more, initiatives are often limited to cities, provinces or counties. Once proved effective, companies should consider scaling up their initiatives both within and outside the country of activity.

Disease focus of companies' initiatives

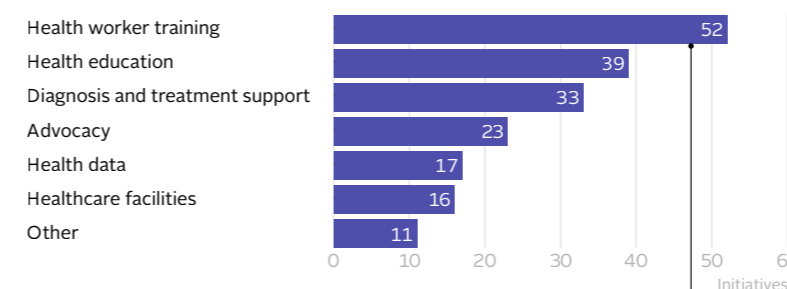


Initiatives that focus on communicable diseases predominantly target HIV (8 of 12).

The majority of NCD initiatives address diabetes care (16 of 43) and cancer (15 of 43) focusing on prevention and diagnosis. Most diabetes and cancer products (including screening, diagnostic and treatment products) require advanced facilities for administration, meaning that the knowledge and expertise of the pharmaceutical companies is particularly high in demand. For instance, Pfizer aimed to bring its expertise to Peru with a targeted cancer care programme in

collaboration with the organisation PATH. Its 'Scaling up Breast Cancer Services' programme aimed to improve the provision of breast cancer services in Peru by increasing community awareness of risks and preventative, improving the early detection and diagnosis and through training of healthcare workers along the continuum of care. In 2018, the programme resulted in 13,116 women undergoing a clinical breast examination.

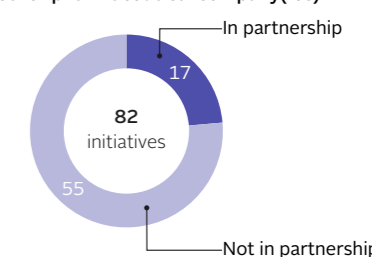
Initiative activity



Training of healthcare workers is the most reported activity
Initiatives include online courses, such as Sanofi's e-diabete and e-pediatric programmes, reaching approximately 100,000 healthcare professionals annually, as well as in-person training like GSK's Front-line Health Worker initiative, which has trained a total of 100,000 community health workers. Notably, in early 2020, Last Mile Health, Living Goods, The Audacious Project and the Bill and Melinda Gates Foundation partnered with the companies

Eli Lilly, GSK, Johnson & Johnson, Novartis and Pfizer in the Health Worker Training Initiative. The initiative aims to increase access to community-based healthcare for 1.7 million people in up to six countries in sub-Saharan Africa by, among other activities, supporting the training and deployment of 2,500 digitally enabled community health workers by 2022. Importantly, companies involved in healthcare training activities, should proactively mitigate conflicts of interest.

Initiatives carried out in partnership with other pharmaceutical company(ies)



Scaling-up to reach more people

ASTRAZENECA AND THE YOUNG HEALTH PROGRAMME
What: The YHP was co-founded in 2010 by AstraZeneca in partnership with Johns Hopkins Bloomberg School of Public Health and Plan International. UNICEF joined in 2019.
Reach: Since 2018, activities have expanded from Brazil, China, India, Indonesia and Kenya to include Colombia, Egypt, Mexico, Myanmar and Vietnam. YHP also expands their activities across various regions. In China, more than 40 activities have taken place in 25 different cities across China, reaching nearly 6,000 children. AstraZeneca has committed to extending their support until at least 2025.

Examples of patient and healthcare reach

NCDs

SANOI AND MY CHILD MATTER

Since 2006, Sanofi's My Child Matter programme is active in 42 countries across Africa, Asia and Latin America. It aims to address the barriers that prevent the improvement of paediatric cancer survival outcomes, including insufficient diagnosis and care and lack of surgeons and radiotherapy. Sanofi is supporting the African School of Paediatric Oncology Initiative, which aims to increase the pool of paediatric oncology professionals in French-speaking countries of Africa.

Reach: More than 25,000 professionals have been trained and more than 85,000 children have been taken into care.

Communicable diseases

GSK AND COMIC RELIEF

The Fighting Malaria partnership between GSK and Comic Relief worked with the London School of Hygiene and Tropical Medicine to address barriers in national malaria control programmes by improving data gathering and analysis and helping to increase funding for malaria control.
Reach: GSK reports 1,497,000 patients have accessed malaria services. E.g., in Myanmar, Malaria Consortium extended the roles of malaria volunteers to incorporate integrated Community Case Management (ICCM) so volunteers can safely detect and treat diarrhoea and pneumonia in children, along with testing and treatment for malaria.

Neglected tropical diseases

ABBVIE AND MAP INTERNATIONAL

Since 2014, AbbVie has partnered with MAP international to combat Chagas diseases in Bolivia. The programme takes a community-based approach to Chagas disease prevention and management, focusing on community health worker training, health education, housing improvement for vector control and diagnosis and treatment support.
Reach: Between 2015 and 2017 MAP's Chagas programme in Bolivia, supported by AbbVie, reached more than 30,000 individuals, trained 500 health workers and 400 community members and screened nearly 7,500 people for the disease.

Maternal health conditions

ASTELLAS AND THE FISTULA FOUNDATION

The UNFPA estimates 3,000 new cases of obstetric fistula occur annually in Kenya, of which the majority go untreated.¹ Since 2014, Astellas supported the ACTION ON FISTULA™ programme led by the Fistula Foundation in Kenya. The programme centres around four areas: (1) community outreach through radio; (2) surgeons and community health worker training; (3) building collaborative network of fistula hospitals by sharing resources and referrals; and (4) provision of screening, surgery and post-operative care.
Reach: Since 2014, the programme has reached over 330,000 people and resulted in more than 6,000 women receiving treatment.

Monitoring outcomes: commitments vs action

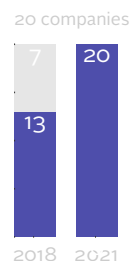
Stand-out efforts for measuring outcomes include working with third-party organisations and universities to measure outcomes. For example, various companies work with the London School of Hygiene and Tropical Medicine to that end. This includes MSD for their MSD for Mothers programme, Novo Nordisk for their Partnering for Change – Chronic Care in Humanitarian Crises initiative and Pfizer’s Healthy Families, Healthy Futures initiative, which aims to improve access to immunisation and family planning products and services.

The reported outcomes show an increase in awareness, diagnosis and treatment uptake as well as healthcare worker knowledge and the quality of healthcare facilities. For example, MSD for Mothers, a USD 500 million initiative, has reportedly resulted in 139,000 trained healthcare workers, enabling 9.2 million women to experience healthier pregnancies and safer childbirth, 35 million people with improved access to healthcare and 15 million people with improved access to medicine across 48 countries.

Sharing outcomes

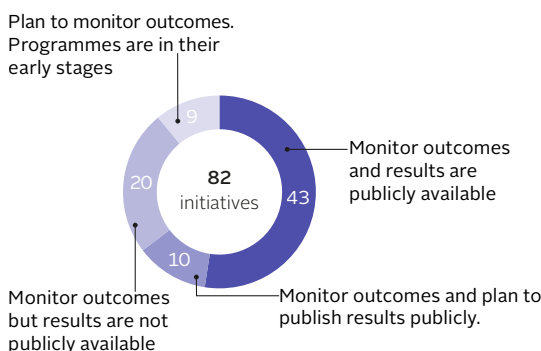
Initiatives that share the outcomes are disclosed either on the company/partner websites, through academic articles, at conferences and/or on platforms such as Access Observatory, a public platform for reporting on access to medicine programmes. None of the companies publicly discloses the outcomes of all their evaluated initiatives. Companies are encouraged to partner with organisations that measure outcomes, expand their outcomes measurement activities to initiatives for which they do not yet do so. Furthermore, they should accelerate their commitment to publicly disclosing the outcomes of their health system strengthening initiatives, sharing data on people reached, public health outcomes and best practices.

In 2021, all 20 companies take steps to measure outcomes compared to 13 in



Outcomes can show a change in:
 Awareness
 Diagnosis
 Treatment uptake
 Training

FIGURE 77. For more than 50% of the initiatives (43 of 82) outcomes are publicly disclosed.



How the Index defines outputs, outcomes and impact

Outputs: Outputs measure the direct deliverable of an activity. This is usually a quantitative deliverable. For example, 500 healthcare workers trained in diagnosis of breast cancer.

Outcomes: Outcomes measure the result of the activity, which is the direct result of the output. For examples, as a result of the 500 trained healthcare workers, 6000 women received screening and 400 women were early diagnosed with breast cancer, compared to 3000 and 50 before the intervention.

Impact: Impact measures the (lasting) effect of the activity on health systems. This can be both qualitative and quantitative. With an increase in early screening and early diagnosis, the breast cancer related mortality rate has decreased and the quality of life of women diagnosed with breast cancer increased within the geographic scope of the initiative.

Stand-out effort to measure outcomes

TAKEDA

How: For Takeda’s Blueprint for Innovative Healthcare Access programme, the company has partnered with Duke University Innovations in Healthcare and Broadreach to design an outcome measurement framework which was validated by key stakeholders and experts and aligns with Access Observatory. Data collection is conducted by partners responsible for the respective activities. The outcomes have been published on the Access Observatory website.

Outcomes: Among the outcomes of the first six months of the programme, Takeda reports that 500 healthcare workers have been trained to educate households on NCDs, 7,000 people have been reached through oral communication channels, 4,000 women have been screened for cancer and over 175 people are receiving treatment. There has also been a reported 65% change in healthcare worker knowledge, assessed through a written, oral or observational assessment that they undergo before and after the training.

Higher uptake of impact evaluations needed

While companies have demonstrated increased efforts to go beyond measuring output by measuring the outcomes of their health system strengthening initiatives, they can perform better in the area of impact evaluation. 22 initiatives by ten companies (AbbVie, AstraZeneca, GSK, Johnson & Johnson, MSD, Novo Nordisk, Roche, Sanofi, Takeda) show that the company, their partner or external evaluators measured or plan to measure the impact of their activities. GSK leads in this area, demonstrating efforts to measure impact for all five initiatives included for eval-

uation. For example, GSK's Positive Action initiative, supporting communities affected by HIV and AIDS, has partnered with over 200 organisations globally. While already having a strong monitoring and evaluation policy in place for its grantees, requiring them to measure outcomes, GSK has expanded this to include impact in early 2020. Grantees will be asked to report on pre-determined key performance indicators, which are part of an overarching impact measurement framework. The impact framework is publicly available.

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- 1 UNFPA. 2019 Annual Report; 2020. https://kenya.unfpa.org/sites/default/files/pub-pdf/annual_report_2019_kenya_o.pdf . Accessed December 22, 2020.

Best Practices

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine. Best practices are not new, they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness
- Sustainability
- Replicability
- Alignment with external standards/ stakeholder expectations

The 2021 Access to Medicine Index identified 23 best practices from 15 companies: four in Governance of Access, five in Research & Development and 14 in Product Delivery.

GOVERNANCE OF ACCESS - BEST PRACTICE HIGHLIGHTS

The companies demonstrating best practice in Governance of Access are proactive in implementing solid company-wide compliance controls and audits to reduce corruption risk across their business operations, including third-party collaborations.

Board-level committees are directly responsible for promoting and rewarding the effective access strategies for their portfolio, ensuring that the access to medicine mindset starts at the top level and is embedded into their business decisions, even in their employee performance reviews.

In addition, companies performing strongly in Governance of Access are actively engaged in measuring the progress and outcomes of their access to medicine initiatives in low- and middle-income countries. This, in turn, enables them to establish systematic frameworks to evaluate their long-term impact on patient populations and national health systems, alike. Particular attention is paid to increasing access to innovative medicines in sub-Saharan Africa, home to a considerable number of underserved communities.

RESEARCH & DEVELOPMENT - BEST PRACTICE HIGHLIGHTS

Companies acknowledge that access plans need to be elaborated in the early stages of their health products' clinical development to ensure equitable and broad patient access. Top-performing companies establish concrete access planning frameworks and processes which are implemented across their pipelines, both in house and collaborative. Such frameworks consider, among others, affordability and therapeutic needs, while the access strategies include voluntary licensing, WHO prequalification, tiered pricing and patient assistance programmes. Equally important is companies'

intention to safeguard and secure access to investigational treatments for clinical trial participants after the end of trials. Remarkable is the focus on the voluntary licensing of the paediatric formulation of dolutegravir (DTG), which broadens and accelerates access for the paediatric patients living with HIV, and the income- and country-tailored approach to offering the dengue vaccine.

PRODUCT DELIVERY - BEST PRACTICE HIGHLIGHTS

Equitable pricing strategies are at the heart of patient-oriented business operations. Top-performing companies consider affordability and continuous supply to increase patient reach at all levels of the income pyramid. They enter into supranational procurement agreements and develop patient assistance programmes (PAP) to provide personalised, income-tailored support based on intra-country pricing solutions and economic conditions.

As part of their health system strengthening initiatives, high-performing companies focus on educating and training health workers, raising public awareness and collaborating with local stakeholders. Mental disorders, cervical cancer, stroke, HIV/AIDS and non-communicable diseases are prioritised in their agenda due to the high incidence rates in certain countries and regions.

Lastly, donations are a strong asset in product delivery to broaden patients' access to medicine. Companies engaging in structured donation programmes to eliminate, eradicate or control the Neglected Tropical Diseases go beyond the WHO-determined goals to donate their products indefinitely and to larger patient populations.

Compliance controls against corruption

ASTELLAS, ASTRAZENECA, GSK, JOHNSON & JOHNSON, NOVARTIS, NOVO NORDISK, SANOFI, TAKEDA

Location: Globally

Focus: N/A

Action: Reducing the risk of corrupt acts by enforcing a set of control mechanisms

Aim: To ensure compliance with laws, regulations and company standards on ethical marketing and anti-corruption

Corruption and fraud threaten to undermine global health and access to medicine. In global health, some USD 7.35 trillion was spent worldwide on health service provision in 2013, with a loss of 6.19% (USD 455 billion) attributable to fraud, corruption or errors.¹ Today's true scope and cost of global health corruption are unknown, but these figures suggest significant impacts on access to medicine among vulnerable people. In addition, research from the World Health Organization (WHO) indicates that corrupt activities in the health sector (such as diverting resources from healthcare systems) risk damaging progress toward meeting the 2030 Sustainable Development Goals and Universal Health Coverage targets.²

Gaps in transparency and accountability within pharmaceutical companies can increase risks of undue influence and other abuses occurring. This may be exacerbated in low- and middle-income countries which may be more likely to have weaker regulatory or judicial controls and health systems than higher income countries.³

Compliance controls to reduce risks

The Access to Medicine Index looks for companies to implement compliance controls to mitigate risks in low- and middle-income countries operations and avoid undermining governance efforts on improving access to medicine. Eight companies demonstrate best practice in this area and in their overall approach to corruption: Astellas, AstraZeneca, GSK, Johnson & Johnson, Novartis, Novo Nordisk, Sanofi and Takeda.

Controls address the risk of non-compliance with laws and standards of conduct; fraud-specific and country-specific risk assessments; live monitoring to ensure continuous compliance; conduct of audits (internal, external and including third parties) in countries where the company operates; and formal processes (such as training or contractual agreements) to ensure third-party compliance with company standards. All eight companies have comprehensive processes to manage corruption-related risks, comply with laws and regulations in countries in scope and report reliably on financials.

Use of external tools

The companies that demonstrate best practice vary in how they mitigate the risks of corrupt activity. Some report using external tools, with three relying on findings from the Transparency International (TI) Corruption Perceptions Index. This independent tool uses insights from experts and business executives to score and rank countries based on the levels of corruption perceived in public sectors. Johnson & Johnson, for example, uses the Transparency International Corruption Perceptions Index to review corruption levels as part of its annual assessments to evaluate fraud risks in its operations. Novo Nordisk's risk assessments are also informed by multiple data sources including the TI Index. For Sanofi, the TI Index helps to inform auditing; TI Index findings enable the company to set and assess country risk profiles and thus determine the frequency of audits.

Compliance across the board

By implementing every component of compliance control, these eight companies recognise the extent to which corruption poses a threat to public health and access to medicine. Together, they demonstrate how pharmaceutical companies can seek to limit misconduct by enforcing stringent compliance processes across operations (i.e., in the areas of ethical marketing, anti-corruption and clinical trials), and among third parties.

All companies in scope have auditing mechanisms. By strengthening compliance controls further, more companies can focus on mitigating the risk of non-compliant or corrupt activities occurring in the low- and middle-income countries in which they operate.

¹ Genovese L, Edwards D. Why It Matters: Pharmaceutical Compliance, Anti-corruption and Access to Medicine; 2017. https://accesstomedicinefoundation.org/media/uploads/downloads/5bc5edf40595e_Compliance_Anti-corruption_Access-to-Medicine_Why_It_Matters_L_Genovese_D_Edwards.pdf. Accessed December 22, 2020.

² Transparency International. The Ignored Pandemic – Transparency International Health Initiative <http://ti-health.org/wp-content/uploads/2019/03/IgnoredPandemic-WEB-v2.pdf>. Accessed December 22, 2020.

³ World Health Organization. Integrating a Focus on Anti-Corruption, Transparency and Accountability in Health Systems Assessments; 2018. <https://apps.who.int/iris/bitstream/handle/10665/310991/9789241515177-eng.pdf>. Accessed October 21, 2020.

Promoting access: Senior staff incentives for access strategy effectiveness

GSK, NOVARTIS, PFIZER, TAKEDA

Location: Global

Focus: N/A

Action: Establishing senior-level responsibility and incentives for access to medicine

Aim: To reinforce governance of access through incentive structures

Access-to-medicine goals are one step closer to being accomplished when, among others, senior management executives within pharmaceutical companies engage in and are responsible for such strategies. GSK, Novartis, Pfizer and Takeda offer leading examples of best practice in governance of access as they establish long-term incentives for top-level managers, maintaining, thus, access to medicine as a pillar of their business operations. These companies have board-level committees that take direct responsibility for access strategies.

At **GSK**, long-term incentives programmes for senior management link access-related objectives to its global health strategy for its CEO and others. The CEO's personal access-related objectives relate to malaria, tuberculosis and paediatric HIV programmes, as do objectives for senior executives and regional and in-country managers in countries in scope of the Index. In 2020, for example, some objectives for GSK in-country and regional managers (e.g. the South Africa country manager) related to supporting global health, vaccines and HIV access initiatives (the latter being under the joint venture of ViiV Healthcare). Performance is measured against these objectives, with incentives awarded accordingly.

Novartis, recognised as a strong performer in access management in 2018, continues to exemplify this approach. It embeds its access principles into governance structures and applies access thinking to its core business at the highest level. Long-term financial incentives programmes for senior staff include specific access-related objectives for its CEO in line with a performance plan. Annual objectives are linked to variable compensation and the company publishes information on how its CEO's performance-related pay is based on strategic objectives such as building trust with society (including access to healthcare and environmental, social and corporate governance).

Since 2019, **Novartis** has set its managers specific incentive-related targets for access to medicine and global health. Balanced scorecards, measuring the performance of

executive committee members, include dates by which numbers of patients reached in low- and middle-income countries should be increased with innovative drugs and strategic brands. One example of access-related objectives for regional managers comprises targets linked to patient reach, set for the Kenya-based head of the company's new sub-Saharan Africa business unit.

At **Pfizer**, there is direct board-level responsibility for access. Pfizer's CEO has incentives based on access targets linked to its Purpose Blueprint strategy, which aims at accelerating patient impact. Takeda's CEO has performance-based key performance indicators (KPIs), including access to medicine as a corporate strategic issue. As access is part of corporate KPIs, the CEO, the company executive team and the regional and in-country managers (for its Growth and Emerging Markets units) have access-related incentives.

Focus on measurable objectives needed

Five other companies (AstraZeneca, Bayer, Daiichi Sankyo, Novo Nordisk, Sanofi) demonstrate good practice by incorporating sustainability and social targets, which include access to healthcare initiatives, into their CEO objectives. Yet, they show less information on measurable objectives and how these incentives specifically focus on the achievement of their access-to-medicine strategy.

Evaluating the long-term effects of access initiatives on healthcare systems and patients

GSK, MSD, NOVARTIS, SANOFI, TAKEDA

Location: Low- and middle-income countries

Focus: N/A

Action: Implementing impact assessment frameworks after measuring the access-to-medicine outcomes

Aim: To consistently evaluate the long-term effect of their access initiatives on national healthcare systems and patients

As companies work to improve access to medicine in low- and middle-income countries, they need to understand “what works” and ensure initiatives are effective so that they demonstrate and build on progress. Stakeholders such as governments, NGOs and communities increasingly expect pharmaceutical companies to set measurable goals and targets for access initiatives. Nevertheless, to make progress sustainable, companies must also measure long-term effects on healthcare systems and populations. Five companies demonstrate best practice in this area: GSK, Sanofi, MSD, Novartis and Takeda.

GSK and Sanofi: strong on partnerships

GSK measures long-term effects through its community investment partnerships with Save the Children (child mortality), Comic Relief (malaria) and Positive Action and Fast Track Cities (both HIV). With Save the Children, it measures and reports on impacts in multiple access programmes. With Comic Relief, it has metrics to evaluate how it strengthens health systems in countries in sub-Saharan Africa and the Greater Mekong region (e.g. Cambodia and Myanmar) where malaria is endemic. GSK is also developing an impact assessment dashboard to evaluate initiatives across the board.

Sanofi works with external partners to measure and publish information about long-term impacts of its access-related projects. One example is a study published in *The Lancet Oncology* (2018) on Sanofi Espoir Foundation’s cancer care My Child Matters programme in low- and middle-income countries. Another is a three-year research partnership with the Institute of Epidemiology and Tropical Neurology (France) to evaluate not just outcomes but also long-term impacts of an initiative in Armenia, Madagascar and Myanmar (three countries in scope of the Index) to increase access to mental health care.

MSD: focus on maternal health

MSD is unique in reporting a focus on maternal health. It measures impacts of MSD for Mothers, an initiative to address

maternal mortality rates and support pregnant women. Its Evidence for Impact research compendium (2018) outlined how research can facilitate action on maternal mortality. Partnerships include that with London School of Hygiene and Tropical Medicine, whose demographic health survey helped MSD understand where women seek family planning services. Knowledge of preferences has helped the company develop tools to ensure women get access to contraception and tailor programmes to improve health.

Novartis: an alternative approach

Novartis takes a highly systematic approach. For several years, it has worked to develop, test and apply a new methodology to measure societal impact in financial, environmental and social (FES) terms. Through ‘social impact valuation’, Novartis has calculated the outcomes of multiple innovative products in its portfolio across 117 countries. By consistently evaluating value, it aims to understand how to build trust with society. Measuring and evaluating impact is also helping Novartis to tailor access initiatives and make them more cost-effective. Research involves assessing societal needs (for example, indicators such as wages in places where it operates) to improve access to medicine and strengthen systems.

Takeda: creating a framework

Takeda is partnering with US-based Duke University to develop the Access to Health Impact Measurement Framework. Through this, it plans to measure company strategy and programmes by continuously assessing and responding to patients’ needs and monitoring impacts on healthcare systems. Goals for the framework include using it to identify complementary programmes and areas for deeper collaboration, and more efficient and effective deployment of resources. Takeda’s stated ambition is to implement the framework across its healthcare sectors to create one consistent tool to measure impact enabling improvement in patients’ lives. Now testing the framework, the company aims to launch this and make it publicly available by 2021.

Tailored strategy to reach more patients in sub-Saharan Africa

NOVARTIS

Location: Sub-Saharan Africa

Focus: Various high-burden diseases; innovative medicines

Action: Embedding a comprehensive access-to-medicine strategy into the overall strategy

Aim: To expand access for underserved communities in sub-Saharan Africa

Novartis is the only company in scope of the Index to explicitly tailor an access-to-medicine strategy to countries facing a high burden of disease. In fact, it commits itself to expanding access to innovative medicines in sub-Saharan Africa (SSA), a part of the world it highlights as being home to the largest underserved patient population.

Why is SSA important?

While a quarter of the world's disease burden is in Africa, just 3% of health workers are based there and the entire continent accounts for less than 1% of the world's health expenditure.¹ In terms of access to medicine, there are continent-wide gaps to address, but SSA faces a particularly high burden of disease.

To increase access to innovative medicines across its portfolio for these patients, Novartis launched a new strategy in November 2019. Novartis will build on its established activities to treat diseases in scope of the Index, including malaria, cancer, sickle cell disease and cardiovascular conditions. With established social business models in Africa, aligned with the Novartis Principles, the company highlights its choice to move away from financial metrics to focus more on what can drive access to innovative medicines and strengthen health systems across the region. A new SSA business unit will look at tiered pricing models, affordability strategies, scaling social business models and competitiveness in tenders, with the aim of increasing inclusivity and extending the ability of patients across the income spectrum to access Novartis's products.

For Novartis, innovative medicines include both newly approved products and those defined as novel (where novel biologic molecules or new technologies are used in clinical trials, for example). Under the strategy, which is overseen at board committee level and with no time limit, the company notes it will work to increase access by improving technologies. It will also boost trial capabilities and accelerate regulatory and administrative processes to lessen time elapsed between development, approval and availability of new medicines. Through its Access Principles it seeks to integrate all

access strategies systematically, from research through to global delivery.

In aspiring to be a partner of choice for governments and NGOs, helping to strengthen healthcare systems for the long term, Novartis is also deploying new technologies to provide the benefits of innovation to SSA countries. Recently, for example, it became part of a public-private partnership with the government of Ghana and Sickle Cell Foundation of Ghana to address sickle cell disease.

¹ Mash R, Howe A, Olayemi O, et al. Reflections on family medicine and primary health-care in sub-Saharan Africa. *BMJ Global Health* 2018;3:e000662.

RESEARCH & DEVELOPMENT

Industry shift toward systematic access planning during R&D

ASTRAZENECA, GSK, JOHNSON & JOHNSON, MERCK,
NOVARTIS, PFIZER, SANOFI, TAKEDA

Location: Global

Focus: All diseases and patient populations

Action: Eight companies adopt systematic access planning processes

Aim: To ensure all products have access plans at launch

Pharmaceutical companies need to plan ahead to ensure new products are rapidly accessible and affordable once they become available. Eight companies are taking the lead in developing structured approaches for pairing each R&D project with a plan to achieve this aim soon after the first global launch. The following approaches are the most comprehensive, although no company yet has access plans for all their late-stage projects.

AstraZeneca has strengthened its approach to access planning during R&D. Access plans are integrated ahead of resource allocation for Phase II/III development and apply to all R&D projects. Formal access planning is part of the company's Access to Healthcare framework and considers such factors as licensing, registration, tiered and differential pricing strategies, early access programmes, patient assistance programmes, royalty-free licensing, pricing transparency and innovative reimbursement models.

GSK's approach is applicable to all R&D projects in its pipeline and considers a variety of access planning strategies, including pricing strategies, IP approaches, product registration strategies, WHO prequalification, out-licensing and systematic or case-by-case access plans. Such approaches are also driven by global health priorities established externally by organisations such as the World Health Organization (WHO) and are guided by global health threats, product type, therapeutic area, development model pursued, target population and geographic scope. Notably, GSK leads in developing a systematic approach to access planning for its late-stage R&D, with 80% of said projects supported by an access plan.

Johnson & Johnson is committed to assessing the affordability of all R&D assets in its pipeline. The company follows a structured approach, developing access and pricing strategies at Phase II of clinical development. These strategies are grounded in Janssen Access and Pricing Principles and include access and affordability considerations across developed markets, middle-income and lower-middle income markets and least developed settings. These access strategies take several factors into account, such as the unmet medical

need in a market, relevant price comparisons, the cost burden of the disease and the affordability of the medicine consistent with the gross national income per capita.

Merck has an approach to systematically establish access plans for all its R&D projects developed in-house and in partnership. The development and implementation of access plans for R&D are grounded in the company's overall approach to access and pricing. To ensure sustainable access to products for vulnerable populations, Merck considers access throughout development and generally begins to introduce access plans into its projects in Phase II or earlier. These plans are informed by, among other factors, the targeted disease indication and the needs of patients in the relevant country.

Novartis has an approach to systematically develop and implement access plans for all its R&D projects. Furthermore, it states it will aim for all innovative drug programs to have the access planning process underway during Phase II. It considers access planning for both in-house and collaborative R&D projects. Novartis' approach is described in its Novartis Access Principles which consist of three key principles: needs-based R&D, medicine affordability (i.e. tiered pricing, managed entry agreements, outcome-based pricing and non-exclusive voluntary licensing) and health system strengthening.

Sanofi has improved its approach to planning for access during R&D, with a structured access planning framework now encompassing all projects in its pipeline. Planning for access starts at Phase II of clinical development and applies to both in-house and collaborative R&D projects. This approach is outlined in Sanofi's Access Blueprint which covers all innovative, patent-protected healthcare product types, including collaborative R&D projects. The company aims to price products equitably, with a focus on affordability and patients' ability to pay as well as access strategies such as tiered pricing, patient assistance programmes and donations. During later stages, country-level access plans are developed in emerging countries that detail in-country access strategies and tactics.

Pfizer has expanded its access planning processes from vaccines to all R&D projects for diseases in scope. The company's newly launched Global Pricing and Access Strategy also stipulates that access planning for all products begins at least two years prior to launch. Furthermore, access plans include guidance on equitable pricing, innovative arrangements and other approaches to support broad access and affordability.

Takeda has an approach to systematically plan for access for all R&D projects in its pipeline. Access principles are considered in Takeda's Asset Strategy and access planning starts from early clinical development (pre-Phase II development). For each project, the company considers factors such as registration planning, non-exclusive voluntary licensing, patent waivers, equitable pricing, sufficient supply, WHO prequalification, product donations, access through clinical trials and expanded access programmes.

GSK reinforces access to a paediatric HIV medicine

GSK

Location: Globally

Focus: paediatric HIV; dolutegravir

Action: Developing access plans for a new HIV medicine while still in clinical development

Aim: To establish an equitable pricing strategy for a broader patient reach

In collaboration with ViiV Healthcare (a global HIV specialist company majority-owned by GSK, with Pfizer and Shionogi Limited as shareholders), GSK has a strong access plan for the HIV/AIDS medicine dolutegravir (DTG) for paediatric patients, which recently received market approval. Under the voluntary licensing policy, ViiV Healthcare enables generic manufacturers to manufacture and sell versions of paediatric DTG royalty-free in all least developed, low-income, lower middle-income and sub-Saharan African countries and in some upper middle-income countries.

The paediatric DTG formulation is offered under 15 non-exclusive, royalty-free voluntary licences – one licence directly agreed with a generic medicine manufacturer and the other 14 manufacturers as sub-licensees of the agreement with the Medicines Patent Pool (MPP). As a result, they can develop, manufacture and supply the paediatric formulation to a territory covering regions where 99% of all children with HIV live.

Action on the paediatric formulation

ViiV Healthcare formed a public-private partnership with the Clinton Health Access Initiative (CHAI), funded by Unitaid.

Two generic medicine manufacturers which hold paediatric dolutegravir sub-licences from the MPP, Mylan Laboratories Limited (Mylan) and Macleods Pharmaceuticals Limited (Macleods), have been provided with the technical expertise of ViiV Healthcare and a financial incentive from Unitaid via CHAI to accelerate the development, registration, manufacture and supply. The partnership aims to improve the availability of paediatric DTG formulations in resource-limited settings.

In addition, ViiV Healthcare plans a registration strategy and it plans to submit the 5 mg dispersible tablet for WHO pre-qualification. Furthermore, ViiV Healthcare is funding a major collaborative research study (ODYSSEY) with the

Paediatric European Network for Treatment of AIDS (PENTA) Foundation. This will evaluate the role of DTG-based treatment as a first- and second-line therapy for children and adolescents with HIV.

Clinical trial participants retain access to investigational treatments

NOVARTIS

Location: Globally

Focus: All diseases and patient populations

Action: Providing clinical trial participants with continued access to investigational treatments

Aim: To reinforce clinical trial patients' access to medicine

In 2018 Novartis was acknowledged for its exemplary post-trial access (PTA) policy. Today Novartis continues to ensure post-trial access to all patients who complete a Novartis-sponsored confirmatory superiority clinical trial or a trial of any phase investigating a serious or life-threatening disease.

This applies to all patients regardless of the severity of the disease, availability of alternative therapies or geographical location. As required or permitted by local legislation, the responsibility to provide post-trial access should last for as long as there is evidence of clinical benefit for the patient or until other criteria are met: i) the Investigator discontinues treatment, ii) the benefit-risk profile of the product in that indication is no longer positive, iii) the product becomes available after product launch and subsequent reimbursement, where applicable or iv) if a marketing application or reimbursement of an investigational product is rejected in a region/country for the indication under study.

Reinforcing post-trial access mechanisms

Novartis has continued to strengthen and expand its commitment to post-trial access through several activities. The company has updated its internal guidance on PTA and developed a suite of tools, materials, and training to aid clinical teams' decision-making on post-trial access. Reinforced by a strong commitment from leadership to the updated guidelines, Novartis affirms early PTA planning in all in-scope studies. As part of this approach, Novartis considers a range of post-trial access mechanisms, including blinded extension studies, open-label extension studies, roll-over-extension programmes and Post-Study-Drug Supply (outside of a clinical trial setting), where permitted by local laws and regulations.

The company has also introduced governance/escalation mechanisms for post-trial access, including a Consultation Board to provide guidance to global, regional and local teams on PTA. As regards the affordability for broader populations to treatments after registration, launch and reimbursement in countries where trials are conducted, the approaches described above are complemented by the

activities implemented through application of the Novartis Access Principles. Affordability is a pillar of those principles to systematically integrating access strategies across Novartis's portfolio.

Planning ahead for access to the dengue vaccine

TAKEDA

Location: Globally

Focus: TAK-003

Action: Developing access planning at an early clinical development stage

Aim: To develop tailored access plans for a broader patient reach

With a structured approach to developing access plans as early in clinical development as in pre-Phase II, Takeda demonstrates best practice in access planning for its R&D pipeline. For each R&D project, Takeda considers registration, non-exclusive voluntary licensing, patent waivers, equitable pricing, sufficiency of supply, WHO prequalification, product donations, access through clinical trials and an expanded access programme.

In least developed countries and low-income countries (LICs), Takeda reports that it neither files patents nor enforces them, while it makes patent information available to the public upon request and participates in the Pat-INFORMED database. Where necessary, it supports voluntary licences and non-assertion declarations or clauses to improve patient access to medicines. It can consider granting licences to manufacturers under appropriate terms that can provide patients with low-cost access to their medicines on a selective basis.

Low- and middle-income countries prioritised for the dengue vaccine

Takeda has strong project-specific access plans for some late-stage R&D projects. One such project is its dengue vaccine (TAK-003). Takeda intends to file for WHO prequalification for TAK-003 immediately after first regulatory approval. It has also initiated a vaccine distribution and logistics readiness (VD&L) project and is setting up a robust, flexible, sustainable, compliant and temperature-controlled global distribution network.

Takeda will launch the product with a primary focus on countries with the highest unmet medical need, mainly low- and middle-income countries. To allow faster access, it will strive to implement a global filing strategy, targeting countries with a high patient need and suitable health system infrastructures in parallel to a first major reference country approval.

In middle-income countries where dengue is endemic, Takeda aims to expand access to its vaccine for two different

population segments. One access approach for broader patient populations involves sustainable initiatives (supplemented by a financial sustainability model) to help patients who cannot afford the full vaccine price and are not covered by any government programmes. A second access approach, for vulnerable populations, involves the development of partnerships and programmes to create access for underserved communities which cannot afford to pay for healthcare.

Beyond the dengue vaccine

Takeda states its aim to ensure the vaccine programmes are sustainable and is working on expanded access programmes through partnerships with institutions, funding organisations and NGOs. The company is also exploring access programmes for its products that treat life-threatening diseases such as cancer, planning to make these more swiftly available to patients.

Equipping and training local institutions and scientists

TAKEDA, MERCK

Location: Mali, India, Vietnam, the Philippines, Ethiopia, Kenya, Uganda, Tanzania, Namibia, Madagascar, Zimbabwe, Mozambique, eSwatini, Cameroon, Nigeria, Benin, Togo, Ghana, Democratic Republic of Congo, Republic of Congo, Armenia, Ukraine, Paraguay, Ecuador, Colombia, Guatemala, Haiti, Dominican Republic, Mexico, South Africa, Malawi, Peru, Zambia

The US-based NGO Seeding Labs is helping to strengthen research capacity in low- and middle-income countries through its instrumental access programme (IAP). The programme offers an accessible way to build local R&D capacity and make positive impact.

In the countries where it works, the IAP aligns its objectives with those of governments and research institutions. It aims to identify gaps in research capacity and communicate these in a streamlined way to stakeholders through an online platform. By determining what researchers need to be successful and providing fit-for-purpose scientific equipment to support such projects, the IAP helps to build country and institutional research capacity. It also offers scientific and technical training and mentoring to enable recipients to address local challenges effectively and teach future generations.

Through IAP, Seeding Labs has provided equipment to more than 2,000 researchers across 36 countries, working on drug discovery, infectious diseases, cancer, diabetes, genetic disorders and other areas. More than 1,800 postgraduate students have used IAP equipment and each year at least 26,000 undergraduate students take courses that rely on IAP-donated equipment.

Four pharmaceutical companies (Takeda, Merck [via MilliporeSigma], Sanofi and Eisai) have partnered with Seeding Labs in the programme. With a strong commitment to monitoring and evaluation, the IAP meets all Good Practice Standards, setting clear goals and objectives, aligning them with those of institutions and the local health system and measuring outcomes.

Taking the IAP initiative one step further

Takeda and Merck's engagement with the IAP, in particular, is a best practice as they have expanded their commitment to, and involvement in, the programme beyond donating equipment. They offer relevant training and mentoring on the use of the equipment as well as specific therapeutic research knowledge. Both companies have integrated IAP

Focus: N/A

Action: Providing local universities and researchers with equipment and mentoring

Aim: To strengthen research capacity in the fight against emerging global diseases

commitments into their internal R&D activities and expanded their geographic scope to include more countries in scope of the Index.

By adding the training and mentoring component, both Takeda and Merck are enabling R&D employees to share scientific and technical expertise and experience in specific therapeutic research areas with local universities and researchers who receive equipment. Takeda's R&D scientists, for example, respond to training and mentoring needs identified by Seeding Labs after equipment is set up.

Sustainable impact in the Dominican Republic

Remarkably, the partnership of Takeda and Merck with Seeding Labs has come a long way in the Dominican Republic. IAP equipment was used to launch the nation's first research centre focused on infectious diseases, which has subsequently attracted international funding and attention for its work on HIV and AIDS prevention and Zika virus as well as receiving certification to process COVID-19 diagnostic tests.

Following the example of Takeda and Merck, other pharmaceutical companies are encouraged to expand involvement by sharing skills and knowledge as part of their engagement activities in R&D.

HIV treatment supplied at cost price to public HIV and international donor programmes

GSK

Location: Least developed countries, low-income countries and all sub-Saharan African countries

Focus: dolutegravir (Tivicay®); HIV/AIDS

Action: Broadening access to an HIV/AIDS treatment

Aim: To introduce equitable access strategies in diverse countries

Equitable access strategies are a crucial element of product delivery. Pharmaceutical companies need to increase their patient reach ensuring that patients from all income levels have access to life-saving health products, particularly first-line treatments.

GSK demonstrates best practice with an inclusive access strategy that takes affordability into account. Through its joint venture with ViiV Healthcare, it has entered into supranational procurement agreements through which eligible countries can obtain dolutegravir (Tivicay®), an antiretroviral therapy for HIV/AIDS. GSK offers this at cost price (covering manufacturing and distribution costs only) to public HIV programmes and international donor agency programmes (e.g. US President's Emergency Plan for AIDS Relief (PEPFAR) initiative) in all least developed countries, low-income countries and all sub-Saharan African countries. By doing so, GSK is expanding access to this first-line therapy until generic formulations become available.

Supplying a middle-income country

On a related action, an equitable pricing strategy has allowed ViiV Healthcare to increase coverage in middle-income countries not eligible to procure dolutegravir (Tivicay®) as part of its supranational offer. For instance, a flexible pricing policy has enabled ViiV Healthcare to agree a high-volume, low-cost supply of the medicine with the Brazilian Ministry of Health. By 2019, Tivicay® had become Brazil's leading HIV therapy, with a third of the 900,000 people living with the condition using this medicine. This access strategy is further supported on the ground through ongoing access-related initiatives such as "Positive Action" which enables HIV testing.

Expanding accessibility through MPP

ViiV Healthcare is a specialist HIV company, majority-owned by GSK, with Pfizer and Shionogi Limited as shareholders. In 2014, ViiV Healthcare signed two non-exclusive voluntary licensing agreements with the Medicines Patent Pool (MPP), allowing generic medicine manufacturers to produce and sell

single and combination versions in countries with the highest HIV burden. Currently, 18 companies are licensed to manufacture versions of Tivicay® (including a newly developed fixed-dose combination) in 95 countries for adults and 121 countries for children globally. In November 2020, MPP and ViiV Healthcare signed a new voluntary licensing agreement to enable greater access for dolutegravir-based regimens (adult formulation) in certain upper-middle-income countries (UMICs). This new licensing agreement includes Azerbaijan, Belarus, Kazakhstan and Malaysia.

Increasing patient access to TB and HIV/AIDS treatments

JOHNSON & JOHNSON

Location: Sub-Saharan Africa (SSA) and Least Developed Countries (LDCs); Globally

Focus: bedaquiline (Sirturo®); darunavir (Prezista®)

Action: Broadening access to TB and HIV medicines

Aim: To apply equitable access strategies for high-burden diseases

Johnson & Johnson is a leading example in equitable access strategies, with an inclusive access strategy for two of its products that treat high-burden diseases, namely tuberculosis (TB) and HIV/AIDS. In fact, Johnson & Johnson goes one step further to supply its products to South Africa under terms similar to the ones it offers in supranational agreements, although South Africa procures those treatments outside of them.

Tuberculosis

The Global Drug Facility (GDF) for tuberculosis, established in 2001 and administered by the World Health Organization, ensures that national TB control programmes have uninterrupted access to high-quality medicines by providing direct procurement services and securing competitive prices. In collaboration with the GDF, Johnson & Johnson offers its recommended six-month TB treatment course of bedaquiline (Sirturo®) to more than 135 eligible countries for a not-for-profit price of USD 400 per course of treatment, which was reduced to USD 340 in July 2020.

The company recognises the disproportionate burden of disease in resource-limited settings together with its product's potential to improve outcomes for patients with multidrug-resistant tuberculosis (MDR-TB). Johnson & Johnson also extends similar pricing terms to a country that does not benefit from the GDF's supranational procurement assistance. In August 2018, South Africa announced it would move to all-oral second-line drug therapy for MDR-TB. Since then, the company has offered the country its six-month INN (Sirturo®) course at a price level in line with the one set forth in the supranational agreement (not-for-profit price).

HIV/AIDS

For sub-Saharan African and least developed countries, Johnson & Johnson sets a 'special effort' price for its HIV/AIDS product darunavir (Prezista®). To set this price, the company uses an inter-country equitable pricing framework that considers the economic conditions and disease burden

of each country, together with its public health need for the product. The company evaluates countries by gross national income per capita at purchasing power parity (GNI PPP) and measures severity of disease burden across countries. It also considers impact of the disease on economies, the proportion of a country's population paying out of pocket for healthcare or lacking access to health insurance and demographic factors such as income levels.

The 'special effort' price enables distributors to make a fair profit while keeping the price sufficiently low to ensure maximum coverage. Chemonics International, a supranational procurement organisation, benefits from this price to procure darunavir. The company extends similar terms to South Africa, a country directly procuring the treatment. Johnson & Johnson has also issued a non-assertion declaration for this product in sub-Saharan Africa and least developed countries, allowing generic medicine manufacturers to enter the market.

Affordability ‘mindset’ applied to diverse health products

NOVARTIS

Location: Globally

Focus: Multiple products

Action: Applying access strategies to supranationally procured, healthcare-administered and self-administered products

Aim: To offer sustainable equitable pricing strategies for maximum patient reach

Equitable pricing strategies can play a significant part in increasing access to medicine. The Index looks for companies to focus on the needs of local populations and integrate access strategies into the delivery of their health products. In line with this objective, Novartis has established the Novartis Access Principles, which entail innovative pricing, refocusing research and development based on society's healthcare needs and supporting approaches to strengthen healthcare systems.

Supranationally procured products

Through Sandoz, its generic division, Novartis is increasing access to three important tuberculosis (TB) medicines (pyrazinamide/ethambutol/rifampicin/isoniazid [Rimstar 4-FDC®], rifampicin/isoniazid [Rimactazid®] and clofazimine [Lamprene®]) through supranational procurement agreements. The Global Drug Facility (GDF) was established to ensure uninterrupted access to high-quality anti-TB drugs for national TB control programmes. Each year, Sandoz meets with the GDF to understand price and supply challenges and expectations, taking account of the previous tender's awarded price, competitor price points, manufacturing costs and currency fluctuations as it sets its own price point. The company extends similar pricing terms to Senegal, Angola and South Africa, three countries to which it directly supplies some of these TB treatments.

Healthcare practitioner-administered products

The Index looks for companies to consider how their access strategies can be tailored to increase the reach of medicines administered by healthcare professionals. The Index expects companies to look at both public sector agencies (such as national authorities and public insurance) and private sector entities (private insurance and the 'out of pocket' patient market) when considering 'ability to pay'. For these, specific access challenges may exist in low- and middle-income countries.

In India, Novartis has addressed such challenges by working

with its in-country partner Cipla to launch an emerging market branded version of omalizumab (Xolair®), a treatment for asthma to serve different income strata, in parallel to the original brand to improve affordability. The emerging market brand was launched at 10% of the original brand price. The company also takes into account the challenges to access diagnostics for asthma and negotiated with a diagnostics company to obtain spirometry tests in bulk at a discounted rate. It passes on this discount to the government and out-of-pocket patients. By doing so, it increases product reach for this innovative asthma treatment and strengthens the health system diagnostic capacity.

Self-administered products – Emerging market brand strategy

Novartis demonstrates best practice in how it applies its access strategy to several self-administered products. This type of products, typically treating non-communicable disease such as diabetes, heart diseases and cancer, is vital to the patient but may not be prioritised by governments or the global health community. To address affordability of self-administered products in three countries (Mexico, Philippines, India), the company, in line with Novartis Access Principles, makes available Emerging Market Brands (EMB), which are generally priced at significantly lower price than the global average for the original brand.

In Mexico, to treat migraine, Novartis has launched an emerging market brand for erenumab (Aimovig®). This aims to increase affordability and access in the public sector and ensure affordability for individuals who pay for this medicine themselves. For the latter, the company has a patient support programme (PSP) based on data from a National institute of Statistics and Geography survey of national income and expenses and on market research into ability and willingness to pay. This allows Novartis to set accurate thresholds to differentiate prices.

When patients enrol in the programme through a prescribing physician, an external party completes a socioeconomic

evaluation to determine how many vials of the product an individual can afford during the course of a year. Novartis then provides the balance to cover full treatment. Patients also use an app to record migraine diaries and help physicians monitor outcomes. Novartis estimates an additional 24 million people gain access.

Novartis has also launched an emerging market brand for Aimovig® in the Philippines, with a sophisticated PSP that takes into account affordability in public and private sectors. It has also engaged a variety of stakeholders to strengthen the system to manage migraine disease, initially focusing on the workplace.

Novartis applies the same EMB in India to address affordability for two other products in its portfolio sacubitril/valsartan (Entresto®) for the treatment of ischaemic heart disease and ribociclib (Kisqali®) for the treatment of breast cancer.

Novartis Access and a new business model in sub-Saharan Africa

Novartis Access (NA), a programme for non-communicable diseases (NCDs), comprises a portfolio of 15 products aligned for the treatment of 4 main diseases: cardiovascular, respiratory, cancer and diabetes. All medicines are branded in a dedicated pack with the Novartis Access logo indicating the active ingredient rather than the original brand name. The commitment by Novartis is to offer the products to governmental programmes in low-income countries (LICs) and LMICs primarily at prices of USD 1 per month and per treatment. At the end of 2019, Novartis took a new approach in sub-Saharan Africa (SSA). The SSA unit aims to maximise patient reach across the full income pyramid by focusing on tiered pricing models, competitiveness in tenders and scaling social business models as well as affordability strategies.

Uganda falls under the company's new sub-Saharan business model and benefits from availability of two anti-diabetes medicines in differentiated packs (original brand and NA branded) and prices, offered according to an income pyramid, the NA NCD programme and portfolio in Uganda is aligned

with the local government's agenda. Where a patient's income comes at the top of the pyramid, Novartis offers vildagliptin (Galvus®) and vildagliptin/metformin (Galvus-met®) for a competitive, higher price. Where income is at the bottom level and patients procure medicines in private market, the company offers NA vildagliptin at a lower tailored price. It also trains pharmacists to enhance their capacity to allocate the most suitable medicine pack to the right patient. Novartis is working with the Joint Medical Store (a local faith-based not-for-profit distributor) to build an entry into the Ugandan market and reach the lower income patients directly with lower-priced medicine in the private sector.

Income-tailored solutions for two self-administered cancer treatments

PFIZER

Location: Philippines (for crizotinib); India and Mexico (for palbociclib)

Focus: crizotinib (Xalkori®) for lung cancer and Palbociclib (Ibrance®) for breast cancer

Action: Launching a patient assistance programme for cancer medicines

Aim: To implement equitable access strategies for self-administered products

With 2 billion people estimated to lack regular access to essential medicines, access cannot currently be described as equitable. Varied barriers include mostly different pricing practices, inadequate health systems and gaps in funding and regulation processes. Recognising that only a small number of patients in some low- and middle-income countries can afford its cancer medicines, Pfizer has worked with governments and other stakeholders to develop sophisticated patient assistance programmes (PAPs) that take into consideration all income levels.

Pfizer exemplifies best practice in offering equitable solutions to patients living with cancer. It has implemented income-tailored solutions for two of its products: crizotinib (Xalkori®), which treats lung cancer, and palbociclib (Ibrance®), for the treatment of breast cancer. By developing a patient affordability model, the company has increased access to these self-administered oncology products in certain countries.

Philippines

In the Philippines, less than 2% of the patients in the private sector could afford to pay the list price for crizotinib (Xalkori®). To increase patient reach to 20% and access to full course of treatment, Pfizer analysed cost impacts according to length of treatment and used the information to create an affordability model. This fed into the design of its PAP (INSPIRE), which offers different pricing segments through capping and personalised discounts ranging from approximately 25% to 60% based on patient's ability to pay/income. The capping programme was included based on the observation that patients on Xalkori® treatment stayed on therapy for a limited time due to affordability barriers and/or treatment costs. Working with the Max Foundation, which partners with clinicians and hospitals, Pfizer also has a programme to provide medicines free of charge for patients with no other possibility of access.

India

In India, just 2% of the private sector patients can afford palbociclib (marketed as Ibrance®/Palbace®) at the list price for breast cancer treatment. To increase affordability, Pfizer now makes this available through an assistance programme that caps payments to a set number of cycles of product per patient. Medicine is then provided free of charge if the patient remains eligible. Where patients still find it difficult to make monthly payments, the programme enables a reduction in the number of paid monthly cycles or payments over a longer period. Additionally, the programme PayEase provides loans to eligible patients and guarantors to help them cover the cost of the monthly treatments before the product is offered free of charge. Finally, for patients whose income falls below the poverty limit in India, Pfizer provides all products free of charge.

Mexico

In Mexico, also for palbociclib (Ibrance®), Pfizer has addressed affordability challenges in both public and private sectors: It provides the medicine to all patients treated in public institutions at the same price. For patients with private health insurance Pfizer offers tiered discounts based on the remaining coverage of their insurance. For patients who pay for medicine themselves, Pfizer (a) makes the medicine available at public price for patients who attend public hospitals or are referred from hospital patient associations and (b) offers free goods with a purchase of a set number of paid packs to patients based on their socioeconomic status. More free medicines are given to those with greater affordability issues.

Income-tailored pricing for a healthcare practitioner-administered cancer medicine

TAKEDA

Location: Globally; Thailand

Focus: brentuximab vedotin (Adcetris®)

Action: Launching an equitable affordability-based model for all patients

Aim: To offer sustainable equitable pricing strategies

Establishing equitable pricing strategies is solely one part of the product delivery equation. Such strategies need to be sustainable in the long term for both the pharmaceutical companies and the patients to ensure maximum patient reach across the income pyramid. Takeda demonstrates best practice in intra-country tiered pricing strategy, addressing accessibility and affordability on a patient-by-patient basis.

Through a patient assistance programme (PAP) initiated in 2017, Takeda considers all population segments in upper-middle income countries (UMIC), low- and middle-income countries (LMIC) and low-income countries (LIC) to ensure broad affordability of its health products. The company first focused on brentuximab vedotin (Adcetris®), an oncology medicine for lymphoma, with Thailand offering an inclusive, comprehensive example of Takeda's intra-country pricing approach.

Via a collaborative, affordability-based model, Takeda and its partners align themselves on local needs in Thailand to enable eligible patients to benefit from their prescribed course of treatment. To be eligible for the PAP, patients need to be prescribed brentuximab vedotin (Adcetris®) for a locally approved indication and be unable to pay for the cost of their prescribed course of treatment. Together with the physician, patients complete, sign and submit a single application form to a third-party organisation, Axios. Once the application is submitted, patients participate in an independent and confidential, means-based assessment using a validated Patient Financial Eligibility Tool (PFET)¹ designed and administered by Axios to determine the amount of support needed by patients to pay for their prescribed course of treatment.

The PFET has been developed specifically for developing country settings. It assesses three factors, namely standard of living, income and assets to help ensure the results are accurate, particularly in countries where income cannot be solely relied on to determine affordability. Furthermore, the PFET is a versatile tool that can be adapted to each country's economic context to assess patient ability to contribute to their medication costs.

Takeda's PAPs also provide personalised patient support through the independent party Axios, including ongoing follow-up from programme staff to ensure patients adhere to their treatment plan and their physician's recommendations, thus improving the quality of care and efficacy of the treatment. Takeda and Axios take various steps to maintain impartiality and avoid any conflicts of interest, including monthly evaluation and programme data reports, day-to-day management, product requirement forecasting and communication support for physicians and patients, alike. Takeda reports its intention to implement this sustainable equitable pricing approach in all countries where there are no developed healthcare systems and there is limited reimbursement for medical expenses.

¹ Saba J, Audureau E, Bizé M, Koloshuk B, Ladner J. Development and Validation of a Multilateral Index to Determine Economic Status in Developing Countries: The Patient Financial Eligibility Tool (PFET). *Popul Health Manag.* 2013;16(2):82-89. doi:10.1089/pop.2012.0049

Rapid reporting of substandard and falsified medicinal products

ASTELLAS, ASTRAZENECA, GSK, EISAI, NOVARTIS, TAKEDA

Location: Globally

Focus: All diseases and patient populations

Action: Promptly reporting substandard and falsified (SF) medicinal products

Aim: To address the public health risk of SF medicines

The World Health Organization (WHO) estimates that in low- and middle-income countries, one in every 10 medicinal products is substandard or falsified (SF).¹ WHO reports anti-malarial treatments as part of the most commonly found SF products in sub-Saharan Africa, with approximately 60% of the treatments circulating in the region potentially being SF, consequently leading to an estimate of 116,000 deaths per year.² This incidence of SF medicinal products represents a substantial threat to public health and the Index expects pharmaceutical companies to promptly report cases to national authorities and/or notify WHO's global surveillance and monitoring system.

Companies ought to have policies in place to report any confirmed cases of SF medicines to the relevant health authorities in countries in scope as promptly as possible to mitigate the health risks. WHO, after validating and identifying the risk to public health, can then issue a rapid alert to warn states and populations and encourage increased vigilance and adequate regulatory action.³

Where laboratory analysis is required for confirmation, a company's policy should require reporting of cases as soon as possible and, following confirmation, within 10 business days. In the case of a SF medicine that needs only visual inspection for confirmation (such as the wrong packaging or batch number), it is good practice to commit to a shorter timeframe for reporting.

GSK's expedited reporting system

Of six companies leading in this area, GSK stands out as its policy to report SF medicine has the quickest reporting timeframe with a maximum period of five days. It also applies the shortest timeframe of reporting in a consistent way, using the same process across all countries including those in scope of the Index. Its policy enables it to report

to regulatory authorities, ministries of health and WHO and to quickly respond and take direct action in urgent situations where there is a significant risk of patient harm (for example, by withdrawing a product from market).

Public health factors taken into account

Five other companies, namely Astellas, AstraZeneca, Eisai, Novartis and Takeda, have policies in place to report SF cases to the relevant health authorities and/or WHO in less than 10 days. Each provides evidence of a policy to report SF medicine within a comparatively short timeframe. Astellas, AstraZeneca, Eisai and Takeda distinguish and differentiate cases that need only visual inspection for confirmation, while Novartis reports relying on packaging data verification and packaging testing. All demonstrate a policy based on public health considerations, allowing faster reporting to health authorities and quicker withdrawal of the potentially harmful SF medicine. One company in scope, Johnson & Johnson, also aims at reporting within five days, based on patient risk; however more details are not available. Novartis provides examples of robust collaborations with international and local authorities. In Egypt, it supports the local ministry of health to identify and tackle the circulation of falsified ophthalmology products and reports cases to the WHO. It has also worked with the Colombian government to tackle an illegal network manufacturing falsified medicine for patients needing critical care.

¹ World Health Organization. Substandard and falsified medical products. <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>. Accessed December 23, 2020.

² Medicines for Malaria Venture. Are fake drugs hampering the fight against malaria? <https://www.mmv.org/newsroom/publications/are-fake-drugs-hampering-fight-against-malaria>. Accessed December 14, 2020.

³ World Health Organization. Medical Product Alerts – Background.. 2017. <http://www.who.int/medicines/regulation/ssffc/medical-products/en/>. Accessed December 18, 2020.

Full on-patent portfolio for HIV/AIDS and viral hepatitis (HCV) now under voluntary licences

GILEAD

Location: Globally

Focus: HIV/AIDS and viral hepatitis (HCV)

Action: Non-exclusive voluntary licensing agreements for HIV/AIDS and viral hepatitis (HCV)

Aim: To enable generic medicine manufacturers to enter low- and middle-income countries

Since 2016, the Index has recognised Gilead for its leading, proactive approach to licensing, which helps speed the entry of generic medicines into the countries in scope. Previously, the company demonstrated best practice by voluntarily licensing its entire in-scope portfolio of on-patent products. Still with the most non-exclusive voluntary licences for patented products, Gilead continues to lead the way, having licensed its entire patented portfolio for HIV/AIDS and viral hepatitis (HBV/HCV). Other companies demonstrating good practice in this area include AbbVie, Bristol Myers Squibb, GSK [via ViiV Healthcare], Johnson & Johnson and MSD.

By issuing non-exclusive voluntary licences for patented medicines, rights-holding pharmaceutical companies enable other manufacturers to develop generic versions, fostering, thus, competition and supporting supply. This helps make drugs more affordable and broadens patient access. Gilead also publicly reports on the low- and middle-income countries where it has filed for registration and whether filings are successful. More than 90 countries in scope are included in the majority of Gilead's agreements, with all licences covering all sub-Saharan countries in scope. Many of its licensed products appear on the WHO Essential Medicines List (EML) and are regarded as first-line treatments with a high public health value.

HIV/AIDS

In 2011, Gilead became the first company and private sector partner to negotiate licences with the Medicines Patent Pool (MPP), a United Nations-backed public health organisation that works to increase access to lifesaving medicine in low- and middle-income countries. Since then, with the MPP, it has agreed multiple licences for HIV/AIDS treatment, including for bicitegravir, cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide and tenofovir disoproxil fumarate. Nine out of ten people living with HIV/AIDS in low- and middle-income countries are in countries covered by these licences.¹

Hepatitis C

Gilead is also the first company to work directly with generic medicine manufacturers to agree licences for its products to treat hepatitis C (HCV). This disease affects an estimated 71 million people worldwide and complications cause some 400,000 deaths each year.²

To license its products sofosbuvir, ledipasvir, velpatasvir and voxilaprevir, Gilead has signed agreements with 14 generic medicine manufacturers to manufacture products for use in 105 countries globally, including 90 countries in scope of the Index. Terms of these bilateral licences are comparable with those for MPP licences for HIV/AIDS in their transparency and geographic breadth.

In licensing for both HIV/AIDS and HCV products, Gilead also demonstrates best practice by planning for and agreeing licensing terms prior to gaining first global approval from the US Food and Drugs Administration (FDA) and the European Medicines Agency (EMA) for the majority of compounds licensed.

¹ Medicines Patent Pool. Licences. <https://medicinespatentpool.org/progress-achievements/licences/>. Accessed December 18, 2020.

² World Health Organization. Hepatitis C in the WHO European Region.; 2017. <https://ecdc.europa.eu>. Accessed December 18, 2020.

Product donations to continue until neglected tropical diseases are eliminated

EISAI, GSK, MERCK, MSD, SANOFI

Location: Globally

Focus: schistosomiasis; river blindness (onchocerciasis); lymphatic filariasis (LF); Human African Trypanosomiasis (HAT)

Action: Donating medicines indefinitely and/or beyond WHO-determined populations

In 2018, the Index recognised the public commitment of several companies (Bayer, Eisai, GSK, MSD and Merck) to structured donation programmes as best practice aiming to control, eliminate or eradicate neglected tropical diseases (NTDs).

In 2020, five companies, namely GSK, Eisai, MSD, Merck and Sanofi, demonstrate best practice in product donations to tackle the devastating impact of NTDs. These companies have made a public commitment to donating medicines for an indefinite period of time until elimination or control of these diseases in endemic countries. Some have expanded their donations to include more patient populations beyond the WHO-set patient milestones. By doing so, they provide millions of patients, even in the furthest regions, with access to life-saving medicine.

Indefinite medicine supply until NTD elimination or control
Driven by the World Health Organization (WHO) Roadmap on NTDs and in partnership with WHO, pharmaceutical companies are responding to the global health risk posed by certain NTDs which are endemic in up to 42 countries in scope of the Index.

Lymphatic filariasis (LF) has drawn particular attention from three pharmaceutical companies as it still threatens 893 million people in 49 countries worldwide. Since 2013, Eisai is publicly committed to its programme in partnership with WHO that aims to eliminate LF by donating diethylcarbamazine citrate (DEC) in endemic countries until the end of LF. GSK is partaking in WHO's annual mass drug administration programme to stop the spread of infection by donating its anti-parasitic medicine albendazole (Zentel®). The programme aims to alleviate suffering and prevent further disability in patients with LF. In addition, MSD has been working for more than 20 years to eliminate LF as part of its major donation initiative. Although not committed to an indefinite supply of medicine, the company publicly pledged to donate its product until 2020 to contribute to the disease elimination goals.

MSD has also targeted river blindness (onchocerciasis), which threatens the health of more than 200 million people globally. The company has dedicated itself to eliminating this

Aim: To fight neglected tropical diseases (NTDs)

disease through an unlimited supply of its medicine ivermectin (Mectizan®) beyond the WHO timeline goal to meet the treatment needs.

Schistosomiasis (bilharzia) affects the lives of at least 290 million people around the world. Since 2007, Merck has been donating praziquantel (Cesol®) to fight schistosomiasis. The Merck Schistosomiasis Elimination Programme (MSEP) began in 2007 in collaboration with WHO, primarily targeting school-aged children in Africa. This age group is most at risk of developing severe morbidity in adult life without access to treatment. In 2012, the company scaled up its commitment tenfold by agreeing to provide up to 250 million tablets each year until it reaches its goal of overcoming the disease.

Sanofi has a programme in partnership with WHO to eliminate Human African Trypanosomiasis (HAT) by donating pentamidine (Pentacarinat®), eflornithine (Ornidyl®), melarsoprol (Arsobal®) and fexinidazole (Fexinidazole Winthrop®) since 2001. This company, too, has made a public commitment to provide indefinite supplies of treatment until the disease is eliminated.

Expanding access to more patient populations

GSK has expanded its donation programme beyond the LF-related goals set in WHO's roadmap on NTDs: it has pledged to make its anti-parasitic product available to any validated member state that identifies areas of continuing transmission through recrudescence and to any untreated areas where transmission jeopardises elimination.

Further to the actions of Merck on an indefinite supply of its schistosomiasis treatment, the company renewed its collaboration with WHO in 2019, signing a new memorandum of understanding. This outlined new efforts to expand the target population to include all age groups by ensuring efficient use of tablets and redistributing unused supplies.

Finally, MSD expanded its donation programme to include those in remote areas through a community-directed approach. The company goes further with its community-directed treatment approach to improve mass-treatment programmes in remote areas, by introducing add-on services in communities where health services are limited.

Equipping health systems for the fight against non-communicable diseases

ASTRAZENECA

Location: Globally

Focus: Non-communicable diseases (NCDs)

Action: Implementing three multi-country initiatives

Aim: To assist adolescent patients, patients with lung diseases and patients with high blood pressure

AstraZeneca runs three multi-country initiatives focusing on non-communicable diseases (NCDs): the Young Health Programme, the Healthy Lung Initiative and Healthy Heart Africa. AstraZeneca demonstrates best practice as all three initiatives meet all Good Practice Standards: they are guided by measurable goals and objectives, have good governance structures, work according to local needs, mitigate conflicts of interest, measure outcomes and aim for integration within local health systems.

AstraZeneca co-designs activities with its local partners and health authorities. It is also partnering with academic institutions to measure the impact of its initiatives and continues to expand its three initiatives across countries and partnerships.

Young Health Programme (YHP)

YHP focuses on educating young people to reduce premature deaths caused by non-communicable diseases (i.e. cardiovascular and respiratory diseases, cancer, diabetes, mental health conditions), raising awareness specifically around the harmful use of tobacco and alcohol, physical inactivity, unhealthy diet and exposure to air pollution.

Since 2010, when AstraZeneca founded YHP with Johns Hopkins Bloomberg School of Public Health and Plan International, its programmes have reached more than four million young people. The initiative invests in community-based health programmes delivered by more than 30 partner organisations. Each local programme includes youth-led participatory research, conducting community surveys and site visits and engaging key stakeholders and opinion formers. Local partners measure outcomes and make evaluations publicly available.

Having established programmes in Brazil, China, India, Indonesia and Kenya, YHP has expanded its work to additional countries in scope of the Index, including Colombia, Egypt, Mexico, Myanmar and Vietnam. AstraZeneca has committed to funding YHP until 2025 with USD 35m and intends to deliver community-based behaviour change programming in at least ten low- and middle-income countries. Since launch, the programme has reached over four million young people with health information. In 2020, the initiative also partnered with UNICEF to expand advocacy practices and support programming to reach more than five million young people in the next six years, training 1,000 youth advocates.

Healthy Lung Initiative

This initiative targets people with respiratory and lung diseases, with a focus on asthma and chronic obstructive pulmonary disease (COPD). It started in 2017 in Asia and now also operates in Mexico. Many patients receive inadequate or incorrect care because of a growing prevalence of respiratory diseases, low public awareness, poorly coordinated systems and a lack of knowledge among clinicians and decision-makers. The Healthy Lung Initiative aims to improve access to treatment and improve its quality.

To that end, it helps to increase awareness and education, enable earlier diagnosis through partnerships, improve treatment through better protocols and connectivity and more comprehensive training and improve management of diseases. The initiative aims to establish standards of care in line with international best practice and to support health system capacity building.

Currently, the Healthy Lung Initiative has 65 active partnerships. It has reportedly enabled more than 800,000 people to receive a diagnosis of respiratory disease and has supported the creation of more than 1,150 respiratory centres. In addition, more than 100,000 patients have received training and education about their treatment. The Healthy Lung Initiative is now conducting research to demonstrate its outcomes, with an agreement to transfer work to local health systems if certain criteria are met.

Healthy Heart Africa (HHA)

HHA started in Kenya in 2014, with a range of partners (e.g. US President's Emergency Plan for AIDS Relief (PEPFAR)) testing models across the country's relatively fragmented healthcare system. The aim was to identify what worked and scale up, both in that country and across the region. Since 2016, HHA expanded its activities to four additional countries: Ethiopia, Tanzania, Ghana and Uganda. Aiming to help 10 million people with high blood pressure across Africa by 2025, it hopes to contribute to the WHO target of reducing hypertension by a quarter.

HHA has already screened nearly 15 million people and has identified more than 2.6 million as living with high blood pressure. It has also activated 780 healthcare facilities and trained more than 7,200 healthcare workers to provide hypertension education, screening and treatment services, providing care at the lower levels of healthcare systems. In addition, it is helping to secure supply chains for low-cost, high-quality originator antihypertensive medicines.

Initiative against stroke expands to 38 countries

BOEHRINGER INGELHEIM

Location: Globally

Focus: Stroke

Action: Implementing stroke care guidelines

Aim: To improve stroke care across the world

Globally, 70% of strokes and nearly 90% of stroke-related deaths and disability-adjusted life years occur in low- and middle-income countries.¹ A major factor contributing to the disease burden is the lack of sufficient infrastructure (e.g. optimised stroke units and “stroke-ready” hospitals) in these countries.

In 2016, Boehringer Ingelheim launched the Angels Initiative to support and strengthen healthcare systems for the benefit of stroke patients. With partners including the European Stroke Organisation, World Stroke Organisation, Stroke Alliance for Europe and other national stroke societies, companies and health institutions, the initiative collaborates with multidisciplinary stroke teams in nearly 4,000 hospitals, helping doctors, nurses and emergency medical services to improve their stroke diagnosis and treatment.

The role of the Angels

The so-called Angels consultants work in hospitals to help establish or improve the stroke patient pathway: the focus is on standardising processes, educating to close gaps, building practitioner communities and establishing quality monitoring. By promoting strategic planning of acute stroke care, the initiative is contributing to building coverage, coordinating networks and optimising emergency services links to stroke units.

Overall, the Angels Initiative aims to reduce treatment delays, increase guideline-led treatment and provide patients with the best possible care, the ultimate goal being to create a worldwide network of stroke-ready hospitals. In 200 “Angels” hospitals that adopted training simulation exercises, for example, door-to-treatment time for stroke patients fell by an average of 25 minutes.

Meeting all Good Practice Standards

The Angels Initiative meets all Good Practice Standards: it addresses local needs and priorities, has good governance structures, is guided by measurable goals and publicly shares its progress. Outcomes of activities are measured closely

prompting the company to identify the most effective practices. Finally, Boehringer Ingelheim demonstrates best practice in scalability. Since 2018, the Angels Initiative has added 12 low- and middle-income countries, including Armenia, Cambodia, the Democratic Republic of Congo, Ecuador, Kenya, Paraguay, Uzbekistan and Vietnam, operating now in 38 countries in scope of the Index.

¹ Johnson W, Onuma O, Owolabi M, Sachdev S. Stroke: a global response is needed. Bull World Health Organ. 2016;94(9):634-634A. doi:10.2471/BLT.16.181636

Extensive initiative to improve child healthcare

GSK

Location: Globally

Focus: Maternal and child health

Action: Developing medicines, training healthcare workers and increasing vaccination

Aim: To prevent one million preventable child deaths

In 2013, GSK partnered with Save the Children in a long-term strategic initiative to pave the way for access to medicine and help save the lives of a million children under the age of five. Their initial collaboration was extended in 2018 to continue until the end of 2023. The partnership continues to strive to make long-term impact and create sustainable solutions.

Overall, the partnership focuses on maternal and child health and addresses such issues as inequity, malnutrition, disease and empowerment. It oversees a wide range of projects in liaison with the national health ministries and GSK contributes by donating child-friendly medicines and vaccines, among other activities. The partnership also seeks to strengthen health systems by, for example, investing in training for healthcare workers, improving vaccination coverage in hard-to-reach areas and working with local partners to strengthen the supply chain.

Outcomes and impact

Between 2013 and 2019, the partnership reached nearly three million children under the age of five. It has treated 282,921 cases of malaria, pneumonia and diarrhoea, fully vaccinated 118,057 children and supported more than 15,000 community health workers.

In 2018, the Index recognised this partnership as a best practice. GSK remains exemplary in meeting all Good Practice Standards – among others, strong governance structure, understanding of local needs, integration and transparency. It also demonstrates scalability having expanded its geographic scope to a total of 31 countries in scope of the Index. Projects include Colombia, Indonesia and Mozambique, a new partnership in Nigeria with University College London and Nigerian university UCH Ibadan and the continued deployment of an outcome and impact assessment framework.

Many of the partnership projects measure their outcomes and impact by partnering with academic institutions and research organisations. In Nigeria, for example, University College London and the Nigerian university UCH Ibadan have facilitated a needs assessment and situational analysis

to understand specific local needs and to identify factors that prevent the reduction of pneumonia-led mortality. This research was published in a peer-reviewed journal¹ and GSK reports a commitment to ensuring the outcomes of the initiative are published.

¹ Murphy T. Tackling Pediatric Pneumonia in Nigeria – an Evidence-based Approach to Programming. *Pediatric Pulmonology*. 2021;55(S1):S1-S112.

Reducing HIV infections among adolescent girls and young women in South Africa

JOHNSON & JOHNSON

Location: South Africa

Focus: Adolescent girls and young women

Action: Introducing a youth-led peer-to-peer HIV prevention programme

Aim: To reduce HIV infections among adolescent girls and young women

In sub-Saharan Africa, three-quarters of new HIV infections among adolescents occur in adolescent girls and young women (AGYW).¹ In 2014, to counter this growing challenge, the US President's Emergency Plan for AIDS Relief (PEPFAR) launched DREAMS, a public-private partnership which addresses factors that amplify this group's vulnerability to the virus. It aims to help AGYW become Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS). Companies including Gilead, GSK/ViiV Healthcare and Johnson & Johnson joined DREAMS, which the Index acknowledged in 2018 as an innovative practice.

Johnson & Johnson has gone further, exemplifying best practice through a project it launched in South Africa that year. Interviews with AGYW in several African countries made clear it was necessary for them to be directly involved in their own empowerment. As a result, Johnson & Johnson partnered with UNFPA South Africa to establish a youth-led peer-to-peer initiative known as DREAMS Thina Abantu Abasha (DTAA), which means “we the youth” in Zulu. Like DREAMS, DTAA aims to deepen understanding of the challenges AGYW face, develop sustainable solutions to empower them to remain HIV free and reduce HIV infections overall.

The role and activities of DTAA

The DTAA youth leadership team designs and directs its own activities. Since launch, DTAA has reached more than 1.4 million AGYW with modules in the three areas that comprise major factors in preventing HIV spread: i) leadership, ii) employability and iii) sexual and reproductive health resources. It delivers these modules through interactions such as face-to-face sessions in schools and community facilities, radio “edutainment” (broadcasts on university and community radio stations) and community social media.

This Johnson & Johnson initiative meets all Good Practice Standards: it fulfils specific local needs, has set clear, measurable goals, uses strong governance structures and processes to mitigate conflicts of interest and is measuring its outcomes and the impact of activities.

Specifically, DTAA has developed its own monitoring and evaluation model to measure outputs and outcomes requesting all participants to complete pre- and post-programme evaluation forms. In 2019, a qualitative evaluation involving nearly 700 participants measured impact on behaviours. This found that 88% of sexually active participants aged 19-24 years (60% of the total cohort) indicated using modern contraception methods and 64% indicated using condoms as a result of programme participation. Additionally, 100% of sexually active participants aged 19-24 years reported they were tested for HIV as a result of program participation.

An alternative to PrEP treatment

While not having any pre-exposure prophylaxis (PrEP) products approved, Johnson & Johnson aims to prevent HIV infections through this alternative route. Its global public health division continues to engage local stakeholders to ensure it understands how to deliver meaningfully on the DTAA mandate and how to engage people locally for successful implementation. Johnson & Johnson also reports on its commitment to ensure that young people remain at the centre of the DTAA initiative.

¹ UNAIDS. Women and Girls and HIV; 2018. https://www.unaids.org/sites/default/files/media_asset/women_girls_hiv_en.pdf

Leadership development to improve cervical cancer prevention and care

ROCHE

Location: India, Tanzania, Uganda

Focus: Cervical cancer

Action: Preventing cervical cancer through leadership development

Aim: To combat cervical cancer

Named after the Kiswahili word for “the way”, NJIA is a leadership development programme in Tanzania aimed at preventing cervical cancer. Tanzania has the highest reported number of cervical cancer cases, which is the most common cause of cancer in women aged between 15 and 44, resulting in the death of nearly 7,000 women every year.¹

To address this, Roche, with their partner Pepal, initiated the NJIA Leadership Development Programme in Tanzania’s Kagera region (higher incidence of cervical cancer) in 2015. The programme aims to develop solutions collaboratively to develop leadership capacities and drive innovation in the face of situational and resource constraints, increasing disease awareness and access to screening and treatment. The programme draws on partnerships between companies, the ministry of health, NGOs and academic institutions to train local health leaders. Additionally, Roche has supported governments to integrate best practices from the NJIA programme into strategic plans at state and national levels. For example, leadership development is now a strategic objective in Tanzania’s updated national strategic plan for cervical cancer prevention and control for the next five years.

In 2019, NJIA was expanded to India, where more women die from cervical cancer than in any other country. Approximately 96,000 new cases and 60,000 deaths (a quarter of the global total) are registered here each year.² NJIA works in Uttar Pradesh state, where 15% of the deaths occur.

The twofold role of NJIA

NJIA has two distinct components: leadership skill development and cross-sector innovation. Roche joins government employees and officials, NGOs and local health stakeholders and other corporate peers in cohorts of 30. Each is put through a leadership experience that helps drive innovation in resource-constrained settings. Solving urgent challenges on the ground, participants enhance agility, strengthen inclusive behaviours, identify root causes of cervical cancer issues, apply problem-solving processes and create ‘early wins’ in

cervical cancer prevention solution testing, leveraging peer-to-peer networks.

NJIA presence in three countries

Currently running in three countries, Tanzania, Uganda and India, NJIA is a scaled-up initiative which aims to create engagement across cultures and sectors making measurable differences. In Tanzania, NJIA-trained health workers have screened nearly 7,000 women for cervical cancer since 2015, which indicates an increase of at least an average of 519% compared to the five years before the program started, with 288 treated for pre-cancerous lesions. In the Kagera region, 1,371 women have been vaccinated against the related HPV virus. In India, awareness materials have been distributed to more than 8,000 people, and four gynaecologists are now trained to perform low-cost screening. One district hospital in India has seen a 6% rise in screenings over three months. NJIA has also been instrumental in promoting a government-led screening campaign, and materials for community health workers are enabling communities to see impacts of the disease and understand why screening is needed.

¹ Bruni L, Albero G, Serrano B, Mena M, Gómez D, Muñoz J, de Bosch FX SS. Human Papillomavirus and related diseases report. 2018;(December).

² Bruni L, Albero G, Serrano B, Mena M, Gómez D, Muñoz J, Bosch FX, de Sanjosé S. ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre). Human Papillomavirus and Related Diseases in India. Summary Report 17 June 2019. <https://hpvcentre.net/statistics/reports/IND.pdf>. Accessed January 18, 2021

Fight Against Stigma programme breaks barriers to mental health care

SANOFI

Location: Armenia, Bolivia, Cameroon, Guatemala, Madagascar, Mali, Myanmar, South Africa

Focus: Mental health and epilepsy

Action: Training health workers, raising public awareness, educating patients

Aim: To improve access to and quality of mental healthcare

Across the world, nearly 800 million experience a mental health disorder such as depression, schizophrenia, anxiety or a bipolar disorder.¹ A further 50 million people have epilepsy.² Discrimination and stigmatisation prevents many of these individuals from getting the care they need. In low- and middle-income countries, other barriers to treatment include lack of training and insufficient resources. Where effective treatment does exist in these countries, up to 85% of those with mental health disorders and epilepsy do not receive this.³

In 2008, Sanofi established the Fight Against Stigma (FAST) programme to improve access to care for people in low- and middle-income countries with mental health disorders or epilepsy. With the World Association of Social Psychiatry (WASP), it has launched initiatives in more than 20 countries across Africa, Asia and South America, of which eight are in scope of the Index.

FAST works to reinforce mental health capacity in low- and middle-income countries by training primary healthcare providers, raising public awareness and educating patients and their families. Its programmes run for a specified period of time and through these, FAST seeks to change attitudes and practices. It works to ensure sustainability by engaging with local health authorities, experts, patient associations, NGOs and other partners.

Patient outcomes and impact

Since FAST began, more than 132,000 people with mental illness or epilepsy have been diagnosed and/or treated. In addition, more than three million have been reached through awareness and educational activities and more than 10,000 healthcare workers have been trained, with general practitioners (GPs) increasing their knowledge of mental health. In Mali, for example, where FAST has operated since July 2018, 19 GPs attended 10 days of face-to-face training workshops. Eight became trainers themselves. In the 18 months to December 2019, these trained GPs have diagnosed and managed 1,841 new patients.

Sanofi demonstrates best practice in this initiative as it

meets the Good Practice Standards. It publicly discloses its FAST outcomes and works with the national ministries of health to enable the latter to integrate training into national mental health and epilepsy programmes for continuing professional development (CPD). For the FAST access initiatives it has concluded in Madagascar, Myanmar and Armenia, it is undertaking scientific evaluations through a three-year partnership with the Institute of Epidemiology and Tropical Neurology (University of Limoges) to measure its impact. Sanofi also expands FAST to new countries on a continuous basis, making it a scalable initiative.

- 1 Ritchie H, Roser M. Our World in Data: Mental Health. 2018. <https://ourworldindata.org/mental-health>. Accessed January 18, 2021.
- 2 World Health Organization. Key Facts: Mental Health. 20 June 2019. <https://www.who.int/news-room/fact-sheets/detail/epilepsy>. Accessed January 18, 2021
- 3 World Health Organization. Mental Health Action Plan: 2013-2020. <https://www.who.int/publications/i/item/9789241506021> Accessed January 18, 2021

Company Report Cards

The 2021 Access to Medicine Index includes a set of 20 company report cards, that provide the most detailed overviews of each company's performance. Companies are all different in the way they operate, where they operate, and in their portfolio of investigational and marketed products. Each Report Card includes a summary of the company's strengths and weaknesses, drivers behind changes in its ranking, as well as any best and innovative practices. The report cards are divided into six sections:

PERFORMANCE

Explanation of the company's position in the 2021 Index and a summary of its access-to-medicine performance. Performance is broken down into Technical Areas and it describes the key drivers behind any movement, and the main areas where it scores well or poorly compared to peers.

CHANGES SINCE 2018

Update on where the company's access-to-medicine performance has changed most notably since the 2018 Index. It includes new or expanded commitments, strategies, activities and programmes.

OPPORTUNITIES

Tailored opportunities for the company to improve access to medicine, taking account of its R&D pipeline, product portfolio, current equitable pricing strategies and approach to IP management, among other factors.

SALES & OPERATIONS

General description of the company's operations, recent mergers & acquisitions, revenue per region and geographical reach.

PORTFOLIO & PIPELINE

Analysis of the company's portfolio of marketed products and pipeline of R&D projects that fall within the scope of the Index. This section looks at the size and focus of the company's portfolio and pipeline, whether the company has products that are considered first-line or are on the WHO Model List of Essential Medicines and whether it is conducting priority R&D and planning for access during development.

PERFORMANCE BY TECHNICAL AREA

Overview of the company's performance in each Technical Area measured by the Index. The report card performance points have been structured to be comparable between companies, while still describing the company's individual programmes, initiatives and approach.

| RANK | SCORE |
|-----------|-------------|
| 17 | 1.73 |
| 17 (2018) | |

AbbVie Inc

Stock Exchange: New York Stock Exchange • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: 47,000

PERFORMANCE IN THE 2021 INDEX

17th place. AbbVie performs poorly in two of the three Technical Areas, with weak performance in access strategies and capacity building but a stronger performance in R&D and access planning for priority diseases. It also shows comparatively poor performance in responsible promotional practices and limited evidence in compliance controls.

Governance of Access: 17th place. AbbVie performs poorly in this area. The company does not have a clear access-to-medicine strategy with measurable objectives and a business rationale. It conducts internal and external audits but does not demonstrate other components of compliance controls looked for by the Index.

Research & Development: 12th place. AbbVie has an average performance in this area. Despite the lack of an access planning process during R&D or a post-trial access policy, the company has an average-sized priority R&D pipeline compared to peers with the majority of late-stage projects covered by an access plan.

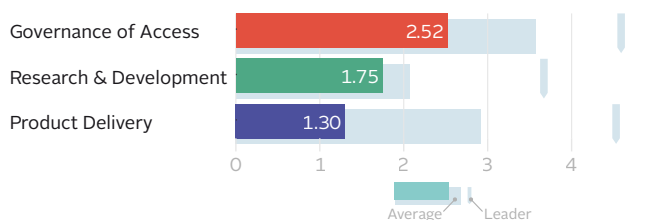
OPPORTUNITIES FOR ABBVIE

Organise governance of access. AbbVie can establish an access strategy that is integrated within its corporate business strategy. Such strategy should apply to all therapeutic areas in which it operates with managerial and executive incentives linked to it. The governance can also include responsible business practices.

Increase product delivery building on its IP approach. AbbVie, with a voluntary licence for glecaprevir/pibrentasvir (Mavyret®) and a non-assert declaration for lopinavir/ritonavir (Aluvia®/Kaletra®), can increase the patient reach for these treatments. It can expand this licence to high-burden hepatitis C countries such as Brazil, China, India, Mexico, Thailand and Uzbekistan. For lopinavir/ritonavir it can publicly disclose the non-assert declaration.

Expand access planning to in-house R&D projects. AbbVie has access plans in place for R&D projects it develops in access-oriented partnerships for certain disease areas such as malaria. It can update the process to develop access plans for all R&D projects from phase II onwards, for all diseases. It can develop access plans for Mavyret® (recently approved for paediatric use in hepatitis C), elagolix (recently approved for treatment of pain associated with endometriosis) and ABT-165 (first-in-class therapeutic for patients with solid tumors).

How score was achieved



Product Delivery: 17th place. AbbVie performs poorly in this area. Access strategies were identified for a few of its products. The company did not disclose, either publicly or to the Index, engagement in any inclusive business models. The company has entered into voluntary licence agreements for two compounds, enabling generic supply in 79 countries and issued a non-assert declaration for two other compounds. It engages in multiple health system strengthening initiatives, but evidence lacks on governance structures and sustainability.

CHANGE SINCE THE 2018 INDEX

- Issued a non-assert declaration for lopinavir/ritonavir (Aluvia®/Kaletra®).
- Signed a royalty-free voluntary licensing agreement via the Medicines Patent Pool (MPP) for glecaprevir/pibrentasvir, a pangenotypic regimen for hepatitis C.
- Committed USD 5 million via the COVID-19 Community Resilience Fund directed towards 26 non-profit organisations to support healthcare workers and underserved communities.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, AbbVie declined to submit data to the Access to Medicine Index.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

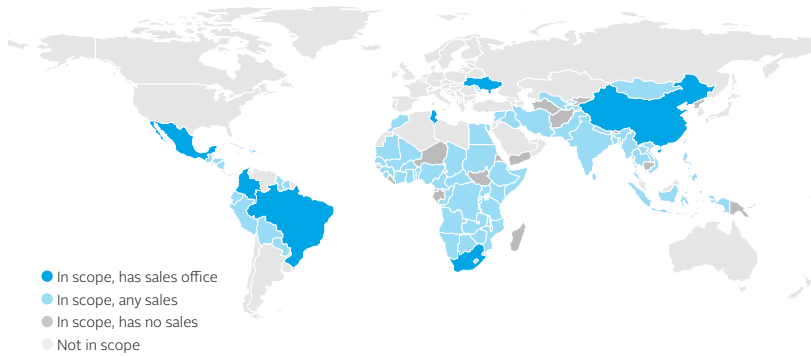
Business segments: Pharmaceutical products
Therapeutic areas: Immunology; Haematological oncology; Aesthetics; Neuroscience; Eye care; Women's health; Virology
Product categories: Innovative medicines
M&A news: Completed acquisition of Allergan (aesthetics, neuroscience, eye care) in May 2020 for USD 63 billion; acquired Mavupharma (oncology) in 2019.

AbbVie's products are sold in 77 out of 106 countries in scope. AbbVie has sales offices in 7 countries, sells via suppliers in 46 countries and via pooled procurement in 24 additional countries.

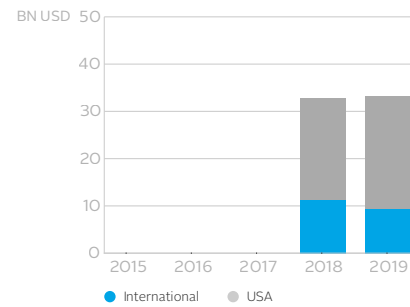
Net revenue by segment (2019) – USD

| | |
|-------------------------|-----------|
| Pharmaceutical products | 33.266 bn |
| Total | 33.266 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

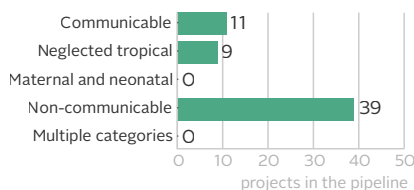
PIPELINE for diseases and countries in scope

AbbVie has a total of 59 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 20 projects. The other 39 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (4 projects). Most of AbbVie's priority projects are in the discovery stage. Of the projects targeting other diseases in scope, the focus is on oncology (34). 18 R&D projects are in late-stage development that target either a priority disease (8) or address a public health need in LMICs (10)*. Evidence of access planning was reported for 28% of these projects: 5 targeting a priority disease and none addressing a public health need in LMICs.

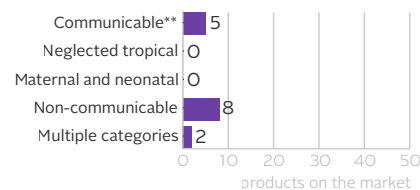
PORTFOLIO as selected for analysis by the Index

AbbVie has 15 medicines in scope, 9 of which are on patent. 60% of these medicines (9) are on WHO's EML. The off-patent medicines target mainly non-communicable diseases such as hypertensive heart disease (3), while one other product targets endometriosis. The on-patent medicines mainly target HIV (2) and hepatitis C (3). In addition, two products are for oncology, one is for preterm birth complications and one other product targets endometriosis. Access strategies were analysed for 11 products on AbbVie's portfolio – supranationally procured (2) or nationally procured HCP-administered (4) and self-administered products (5).

59 projects in the pipeline



15 products* as selected for analysis by the Index†**



Breakdown of projects#

TylAMac, advanced from Phase I to Phase II, a potential therapy for filarial diseases, in collaboration with DNDi.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 0 | 1 | 5 | 0 | 3 | 9 | 5 |
| Addresses needs of LMICs* | 0 | 9 | 5 | 3 | 2 | 19 | 0 |
| Other projects in scope | 0 | 12 | 6 | 0 | 1 | 19 | 0 |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 4 | 5 | 0 | 0 | 9 |
| off patent | 5 | 1 | 0 | 0 | 6 |
| Vaccines | 0 | 0 | 0 | 0 | 0 |
| Diagnostics | 0 | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

***AbbVie acquired Allergan in May 2020. The Allergan products have not been included in the analysis.
 † Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown

of the criteria.
 #Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

AbbVie Inc

GOVERNANCE OF ACCESS

RANK 17

SCORE 2.52

Does not have a clear access-to-medicine strategy with measurable objectives. Unlike most of its peers, AbbVie does not have a clear strategy integrated within its overall corporate strategy. It has a general commitment to access to medicine. The highest responsibility for access lies directly with the board, with its Public Policy committee responsible for corporate responsibility aspects, including access.

Does not provide evidence of financial or non-financial access-related incentives at the managerial level.

AbbVie performs relatively poorly here. It does not demonstrate evidence of having access-related incentives for senior executives or in-country managers.

Publicly discloses outcomes of a subset of its access-to-medicine activities. AbbVie performs well in

transparency regarding access activities. It discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example through the IFPMA Global Health Progress platform.

Performs comparatively poorly in responsible promotional practices. AbbVie's sales agents are solely incentivised on sales volume targets. The company does not disclose the level at which sales incentives are set. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities) unless required by local regulations, nor does it disclose a policy limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. AbbVie performs below average, with evidence of some of the components looked for by the Index: audits (both internal and external) and formal processes to ensure third-party compliance with company standards. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment.

Does not publicly support the Doha Declaration on TRIPS and Public Health. AbbVie does not publicly share any support of or statement on the Doha Declaration on TRIPS and Public Health. There is no evidence of a policy to dissent from industry association positions.

RESEARCH & DEVELOPMENT

RANK 12

SCORE 1.75

No structured process for access planning reported. AbbVie does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

Average size priority R&D pipeline compared to peers, with access plans in place for 63% of the late-stage candidates. AbbVie has 20 projects, including eight late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including malaria, viral hepatitis (B and C) and coronavirus diseases. Of AbbVie's eight late-stage candidates targeting a priority product gap, there is evidence of an access plan for five of them. These plans are applied through

access-oriented partnerships with product development partnerships (PDPs) and focus on affordability and availability.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for any of the late-stage projects. In this analysis, AbbVie has ten late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope. Most target cancer.

No public disclosure of post-trial access policy. AbbVie

does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants, nor did it disclose such a policy to the Index.

One R&D capacity building initiative included for evaluation. AbbVie performs below average in this area, with one initiative included for evaluation. AbbVie's initiative, providing scholarships to students attending the Asian University for Women (AUW), was identified for selection based on publicly available information and was also included in the 2018 Index. The initiative did not meet all Good Practice Standards†, as no public information on a governance structure and clear goals and objectives could be identified.

PRODUCT DELIVERY

RANK 17

SCORE 1.30

Lacks a public commitment on enforcing patents in countries in scope. AbbVie does not have a public policy that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, AbbVie publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Does not report newly shared IP assets with third-party researchers beyond existing agreements. AbbVie has existing agreements with, for example, product development partnerships like the Drugs for Neglected Diseases

initiative (DNDi) and the TB Alliance. During the period of analysis, beyond the existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Uses licensing and non-assert declarations to enable generic supply. The company has a non-exclusive voluntary licensing agreement in place for two compounds. Its licence for glecaprevir/pibrentasvir (Mavyret®), a treatment for hepatitis C, encompasses 79 countries, including 52 middle-income countries in scope. Following the outbreak of the Covid-19 pandemic, it has issued a non-assert declaration for two compounds in scope, lopinavir/ritonavir (Aluvia®/Kaletra®), previously covered by a licence.

Filed to register some new products in the majority of high burden countries. AbbVie has filed 12% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, lopinavir/ritonavir (Aluvia®/Kaletra®) for HIV/AIDS has been filed for registration/registered in eight high burden countries in scope, including Malawi, Namibia and Zambia.

Has access strategies for its supranationally procured products in scope for this analysis. AbbVie performs below average in securing access for products procured supranationally.‡ For the two products assessed in this category, the Index drew on public information about strategies both in countries eligible for supply from such procurers and in at least one country not eligible for such supply. For example, the company has equitable pricing strategies

130 ‡ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

and a licence for lopinavir/ritonavir (Aluvia®/Kaletra®) for non-eligible Global Fund countries. Information demonstrating patient reach through these approaches is not available.

Has access strategies for only one healthcare-practitioner-administered product in scope of this analysis. AbbVie performs poorly in this area. Examples of access strategies which consider affordability in LMICs and LICs are publicly available for one of the four products assessed. It makes efforts to reach additional patients through donations. AbbVie donated 2,500 vials of beractant (Survanta®) for the prevention of respiratory distress syndrome in premature newborns in Kosovo and 500 vials in India. However, no information was publicly available about access strategies and patient reach for the other three products.

Has few access strategies for self-administered products for some countries in scope of this analysis. AbbVie performs poorly in this area. Examples of access strategies which consider affordability in LMICs and LICs are publicly available for one of the five products assessed. It makes efforts to reach additional patients through equitable pricing strategies and licensing. For example, in LMICs and LICs in Africa for ombitasvir/paritaprevir/ritonavir (Technivie®) the company applies inter-country pricing strategies. However, no information was publicly available about the reach of such initiatives, and examples of access strategies for three out of five products.

No manufacturing capacity building initiatives included for evaluation. AbbVie has no initiatives included for analysis aimed at building manufacturing capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building manufacturing capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

No supply chain capacity building initiatives included for evaluation. AbbVie has no initiatives included for analysis aimed at building supply chain capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building supply chain capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

Five health system strengthening initiatives included for evaluation. AbbVie performs below average in this area. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index. Five initiatives that met all criteria for inclusion were found based on publicly available information: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. However, no information on governance structure and long-term sustainability could be identified. For example, since 2000 AbbVie partners with Baylor College of Medicine International Pediatric AIDS Initiative (BIPAI) to support the Kamuzu Central Hospital (KCH) in Malawi, reportedly reducing childhood cancer and blood disorder deaths from 90% at the start of the programme to 50%.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, AbbVie performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon. No initiatives were disclosed to the Index and no initiatives were found following a review of publicly available data.

Multiple mechanisms identified to ensure continuous supply in countries in scope of the Index. AbbVie performs well in this area, taking multiple steps to ensure the continuous supply of its medicines in countries in scope of the Index. The company reported to have a supply chain planning program in place, more details of which are under confidentiality.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope. AbbVie previously demonstrated evidence of reporting SF medicines to relevant regulatory authorities and WHO Rapid Alert, on a case-by-case basis. It does not disclose, publicly or to the Index, evidence, that it requires reporting to occur within the timeframe of 10 days looked for by the Index, nor does it distinguish time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end user. AbbVie has a public policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. AbbVie is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in other structured donation programmes such as the programme whereby it has been donating beractant (Survanta®) for infant respiratory distress syndrome to six countries since 2013 and 2015 through Americares and Direct Relief, respectively.

§ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

| RANK | SCORE |
|-----------|-------------|
| 14 | 2.33 |
| 19 (2018) | |

Astellas Pharma Inc

Stock Exchange: Tokyo Stock Exchange • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 16,243

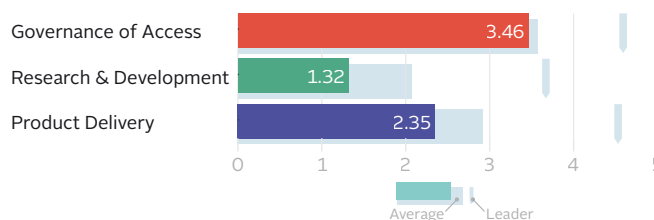
PERFORMANCE IN THE 2021 INDEX

14th place. Astellas has an average performance. It shows a strong performance in its approach to compliance controls and health system strengthening, but has a small priority R&D pipeline and a few access plans. Its equitable pricing approach is average.

Governance of Access: 9th place. Astellas is a middle-performing company in this area. It has a robust set of compliance controls in place, but lacks a clear access-to-medicine strategy with measurable objectives and a business rationale.

Research & Development: 14th place. Astellas performs below average in this area. It applies a structured process to developing access plans during R&D. However, it has a small-sized priority R&D pipeline compared to peers and does not engage in R&D capacity building.

How score was achieved



Product Delivery: 14th place. Astellas performs less well in this area. It applies access strategies to some of its products in some countries in scope and engages in multiple strong health system strengthening initiatives, but no supply chain and manufacturing capacity building initiatives were included for analysis.

OPPORTUNITIES FOR ASTELLAS

Consolidate its approach to access to medicine into an overall strategy integrated within its core business. Astellas can build an access strategy that is integrated within its corporate business strategy based on its public position on Access to Health. Such strategy should apply to all therapeutic areas in which the company is involved.

Apply newly established access planning process to all R&D projects. Astellas newly established an access planning process for all late-stage R&D projects for diseases in scope, but it has specific access plans in place for some late-stage projects. These plans are in partnerships or focus on registration. The company can expand its access plans to all late-stage R&D projects in the pipeline, such as zolbetuximab for cancer and micafungin (Micamine®) for neonatal infections and can include product delivery in low- and middle-income countries.

Strengthen post-trial access policy. Astellas can strengthen its post-trial access policy by allowing for continued affordable access to treatments for patients that take part in clinical trials following the close of these trials.

Expand access to innovative medicines for NCDs in more low- and middle-income countries. The company can increase affordability and supply through equitable pricing and/or non-exclusive voluntary licensing to products such as gilteritinib (Xospata®) for leukaemia and ipragliflozin (Suglat®) for diabetes.

CHANGE SINCE THE 2018 INDEX

- Newly demonstrates access-related incentives in place for senior level executives.
- Astellas Global Health Foundation provided support for NTDs with the END Fund in the Democratic Republic of Congo, from October 2019 to September 2020.
- Astellas Global Health Foundation provided a two-year grant to UNICEF Mothers and Babies in Good Care Initiative from December 2019.
- ACTION ON FISTULA™ supported by Astellas in 2019 increased number of programme outreach partners and exceeded targets set to 2020, performing 6,223 surgeries.
- Is creating a corporate-wide access to medicine strategy for 2021.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals
Therapeutic areas: Urology; Oncology; Immunology

Product categories: Innovative medicines

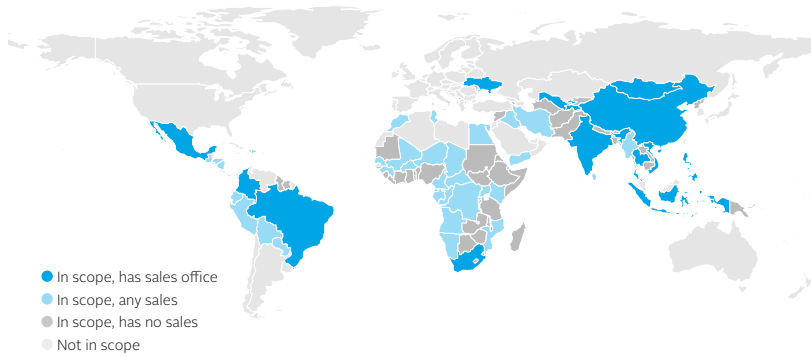
M&A news: In 2020, Astellas acquired Audentes (gene therapy), Nanna Therapeutics (rare diseases) and Iota Biosciences (bioelectronics); acquired Xyphos Biosciences (oncology) in 2019 and Potenza (oncology) in December 2018.

The Astellas products are sold in 49 out of 106 countries in scope. Astellas has sales offices in 14 countries and sells via suppliers in 35 additional countries.

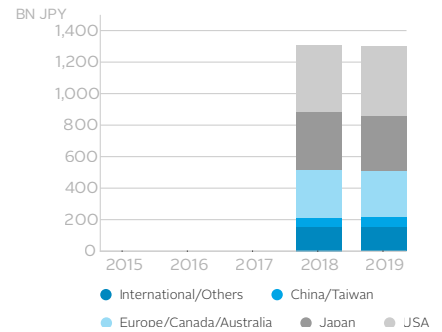
Revenue by segment (2019) – JPY

| | |
|-----------------|---------------------|
| Pharmaceuticals | 1,300.843 bn |
| Total | 1,300.843 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

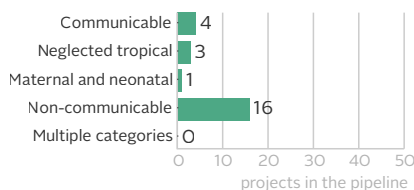
PIPELINE for diseases and countries in scope

Astellas has a total of 24 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 6 projects. The other 18 R&D projects target other diseases in scope. Projects targeting priority diseases include schistosomiasis and Chagas disease. Of note is the paediatric formulation (children aged < 6 years) of praziquantel (Phase III). Of projects targeting other diseases in scope, the focus is on oncology (14 projects). 9 R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (7). Evidence of access planning was in place for 33% of these projects: 1 targeting a priority disease and 2 addressing a public health need in LMICs.

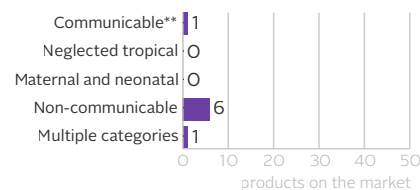
PORTFOLIO as selected for analysis by the Index

Astellas has 8 medicines in scope, 7 of which are on patent. 38% of these medicines (3) are on WHO's EML. The off-patent medicine targets oncology. The on-patent medicines mainly target oncology (3). In addition, one product targets diabetes, one targets diarrhoeal diseases and one is an antifungal medicine. Access strategies were analysed for all 7 products on Astellas' portfolio – nationally procured HCP-administered (3) and self-administered products (4).

24 projects in the pipeline



8 products as selected for analysis by the Index†



Breakdown of projects*

Paediatric formulation (children aged < 6 years) of praziquantel for treatment of schistosomiasis.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 0 | 0 | 1 | 1 | 0 | 2 | 1 |
| Addresses needs of LMICs* | 0 | 2 | 1 | 2 | 4 | 9 | 2 |
| Other projects in scope | 0 | 4 | 4 | 0 | 1 | 9 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 2 | 5 | | | 7 |
| off patent | 1 | 0 | | | 1 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

† Product included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Astellas Pharma Inc

GOVERNANCE OF ACCESS

RANK 9

SCORE 3.46

Does not have a clear access-to-medicine strategy with measurable objectives. Unlike most of its peers, Astellas does not have a clear strategy integrated within its overall corporate strategy. It has a general commitment to improve access to medicine, embedded within its public position on Access to Health. The highest responsibility for access lies indirectly with the board, with the Corporate Social Responsibility committee overseeing social activities, including access.

Provides evidence of financial access-related incentives at the executive level. Although Astellas does not have an access-to-medicine strategy, it incentivises some senior executives to perform on certain access-related factors with financial rewards. The CEO also has access-related incentives linked to its remuneration plan. Astellas does not, however, have such incentives in place for in-country or regional managers.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Astellas performs well in transparency of access activities. It publicly discloses commitments, including contributing to the achievement of SDG3, its measurable goals, objectives, and targets for improving access to medicine in countries in scope. It shares outcomes of a subset of its access activities, for example its ACTION ON FISTULA™ initiative.

Has an average performance in responsible promotional practices. Astellas' sales agents are not solely incentivised on sales volume targets. The company, however, sets sales incentives at the individual level for agents. Astellas does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities) unless required by local regulations, nor does it disclose a policy limiting such transfers.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Astellas performs strongly here, demonstrating all components looked for by the Index: Fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties.

Publicly supports the Doha Declaration on TRIPS and Public Health. Astellas publicly shares support of the Doha Declaration on TRIPS and Public Health with regard to the Least Developed Countries. It expresses reservations on the use of compulsory licensing and states that it does not believe IP protection is a primary factor in limiting access to health. It does not have a policy to dissent from industry association positions.

RESEARCH & DEVELOPMENT

RANK 14

SCORE 1.32

Access planning processes encompass all projects in pipeline. Astellas has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope and includes both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 50% of the late-stage candidates. Astellas has six projects, including two late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including schistosomiasis and Chagas disease. Of Astellas's two late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This plan is in partnership with the Pediatric Praziquantel Consortium,

which includes the registration and access and delivery of paediatric praziquantel.

Some projects address a public health need in LMICs*, with 29% of these projects covered by access plans. In this analysis, Astellas has seven late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Astellas provides evidence of access plans for two of these projects. These plans focus on registration in LMICs.

Public policy to ensure post-trial access; commits itself to registering trialed products. Astellas has a public policy for ensuring post-trial access to treatments for clinical trials participants. This policy covers a subset of clinical trial participants, including participants with a life-threatening condition, but does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Astellas performs poorly in this area. The company submitted two R&D capacity building initiatives, but none met all criteria for inclusion.

PRODUCT DELIVERY

RANK 14

SCORE 2.35

Public commitment not to enforce patents in countries in scope. Astellas publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Astellas publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Does not report newly shared IP assets with third-party researchers beyond existing agreements. Astellas reported current agreements with product development

partnerships such as the Medicines for Malaria Venture (MMV) and TB Alliance. During the period of analysis, beyond the existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No use of non-assert or licensing arrangements. Astellas does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of high burden countries. Astellas has filed 17% of its most recently registered products in more than half of the rele-

vant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease).

No supranationally procured products. Astellas has no products eligible for scoring in this indicator.

Has access strategies for the majority of health-care-practitioner-administered products in scope of this analysis. Astellas performs below average in this area compared to other companies. The company provides examples of access strategies which consider affordability countries of all assessed income levels (UMIC, LMIC, LIC) for one out of the three products assessed. It makes efforts to reach additional patients using equitable pricing strategies. The company is able to provide evidence of how patient

reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope for this analysis. Astellas has an average performance in this area compared to other companies. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the four products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies. Astellas is able to provide evidence of how patient reach has been increased through the approaches used.

No manufacturing capacity building initiatives included for evaluation. Astellas performs poorly in this area. The company submitted two initiatives aimed at building manufacturing capacity, but none met all criteria for inclusion.

No supply chain capacity building initiatives included for evaluation. Astellas performs poorly in this area. The company submitted one initiative aimed at building supply chain capacity, which did not meet all criteria for inclusion.

Four health system strengthening initiatives meet all Good Practice Standards. Astellas performs above average in this area. The company submitted the maximum of five initiatives, of which four were included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a clear governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- UNICEF Mothers and Babies in Good Care Initiative in the Dominican Republic, which started in 2019.
- ACTION ON FISTULA™; improving care for women with obstetric fistula in Kenya. Since its inception in 2014, more than 6,000 women have been treated through the initiative.

Has not engaged in the development and implementation of inclusive business models. Compared to its peers, Astellas performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon.

The company has some mechanisms in place to ensure continuous supply in countries in scope of the Index. Astellas shows average performance in this area, disclosing some strategies to ensure the continuous supply in countries in the scope of the Index. Astellas has safety stock regulations in place but did not report on policies to mitigate API shortages.

Has a policy for reporting falsified medicines in countries in scope in less than 10 days. Astellas has a policy for reporting falsified medicines within 10 days, to national health authorities and WHO Rapid Alert, but applies a separate process to substandard medicines. It can distinguish time frames for reporting for cases which only require visual inspection by experts to be confirmed and are not contingent upon laboratory analysis.

Donates in response to an expressed need and monitors delivery. Astellas donates medicines in response to an

expressed need and it monitors the delivery. Further details are provided under basis of confidentiality.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Astellas is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible.

| RANK | SCORE |
|----------|-------|
| 7 | 3.30 |
| 9 (2018) | |

AstraZeneca plc

Stock Exchange: London Stock Exchange • Ticker: AZN • HQ: Cambridge, UK • Employees: 70,600

PERFORMANCE IN THE 2021 INDEX

7th place. AstraZeneca takes a place among the top ten companies of the Index. It shows a strong performance in governance and compliance and health system strengthening, but has a small-sized priority R&D pipeline with few access plans.

Governance of Access: 3rd place. AstraZeneca shows a strong performance in this area with an access-to-medicine strategy that is integrated within the overall corporate strategy and a robust set of compliance controls in place.

Research & Development: 6th place. AstraZeneca performs well in this area with a structured process to develop access plans during R&D. It commits itself to registering trialed products but has a small-sized priority R&D pipeline with a few late-stage projects covered by access plans.

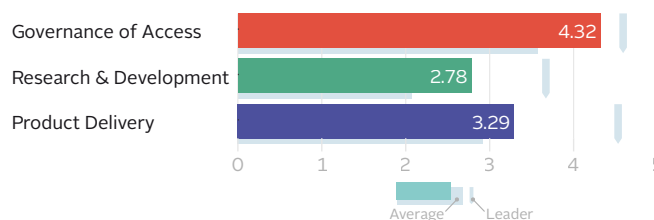
OPPORTUNITIES FOR ASTRAZENECA

Bring equitable pricing initiatives to scale. In the frame of the Healthy Heart Africa (HHA) initiative, the company identifies different levels of ability to pay and affordability in markets. In Kenya it offers reduced prices for products in its HHA portfolio to public market and faith-based sector utilising input from local stakeholders and NGO partners. Additional price reductions were implemented for patients in informal settlements where communities are typically very low income/migrant populations who generally pay out of pocket for healthcare. AstraZeneca can consider expanding the pricing model of Healthy Heart Africa to other countries in Sub-Saharan Africa not part of the programme yet and it can be scaled to more therapeutical areas such as diabetes and oncology.

Apply access planning process to all R&D projects. AstraZeneca has a structured process in place to develop access plans during R&D for all diseases in scope starting in Phase II of clinical development. It has specific access plans for some late-stage projects. These plans focus on registration. The company can expand its access plans to all late-stage R&D projects in the pipeline and can include more elements of product delivery, such as equitable pricing and licensing, in its plans. It can for example develop an access plan for suvratomumab for *S. aureus* and expand the access plan for nirsevimab for RSV.

Increase access to diabetes portfolio. By increasing affordability and supply through equitable pricing and/or non-exclusive voluntary licensing, AstraZeneca can expand access to diabetes medicines in its portfolio such as dapagliflozin (Farxiga/Forxiga®), dapagliflozin/metformin (Xigduo®), saxagliptin/dapagliflozin (Qtern®) and saxagliptin/dapagliflozin/metformin (Qternmet XR®). The company has some access strategies in UMICs and LMICs and it can expand further to countries with high burden of diabetes such as Mexico, Myanmar, Sri Lanka and Lesotho.

How score was achieved



Product Delivery: 6th place. AstraZeneca performs well in this area, with access strategies in place for certain products and markets. It has shared unpublished preclinical data for drug discovery and engages in multiple strong health system strengthening initiatives, but did not demonstrate evidence of inclusive business models with expectations to reach financial sustainability, as looked for by the Index.

CHANGE SINCE THE 2018 INDEX

- Launched an interactive tool, the Transparency Map, to share global data on sustainability topics, including access to healthcare.
- Expanded Healthy Lung initiative beyond Asia to eight countries in scope of the Index, including Mexico, Colombia and Egypt.
- Expanded Healthy Heart Africa to two new countries, Ghana and Uganda.
- Engaged in new ways of sharing IP, a public access Next Generation Sequencing Microbial Surveillance Toolbox for viral and bacterial genomes and an Open Innovation Program with unpublished, preclinical data sets shared ad hoc with research organisations.
- Started Project Heart Beats in December 2019, a collaborative initiative for acute coronary syndrome (ACS) in India.
- Expanded Young Health programme from five to nine countries in scope of the Index, with plans to develop initiatives in three more countries in partnership with UNICEF.
- New collaboration with Vietnam National Cancer Hospital to enhance cancer research capabilities.
- Launched Brazil Health Innovation Hub (InovaHC) in September 2019.
- Launched the Take CaRe of Me pilot in four Index countries in 2020, to improve end-to-end management of type 2 diabetes.
- Joined the COVID-19 Therapeutics Accelerator.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals

Therapeutic areas: Oncology; Cardiovascular, Renal & Metabolism; Respiratory & Immunology
Product categories: Innovative medicines

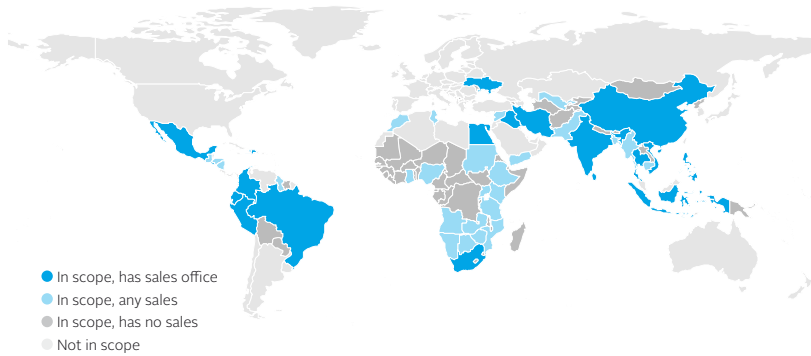
M&A news: Announced in December 2020 to acquire Alexion for USD 39 billion.

AstraZeneca's products are sold in 48 out of 106 countries in scope. AstraZeneca has sales offices in 19 countries and sells via suppliers in 29 additional countries.

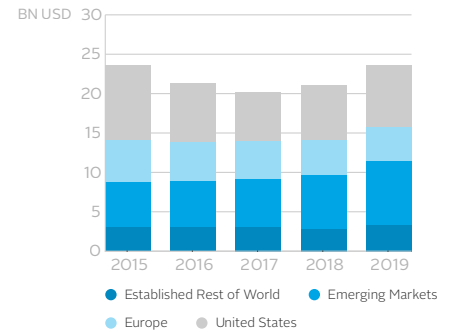
Total revenue in USD

| | |
|---------------------------------|------------------|
| Pharmaceuticals | 24.384 bn |
| Total Revenue by Segment | 24.384 bn |

Sales in countries in scope



Product sales in USD



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

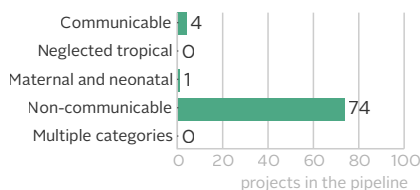
PIPELINE for diseases and countries in scope

AstraZeneca has a total of 79 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 4 projects. Remarkably, however, AstraZeneca has the third largest pipeline. The other 75 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on COVID-19 (3 projects). Of the projects targeting other diseases in scope, the focus is on oncology (42). 46 R&D projects are in late-stage development that target either a priority disease (4) or address a public health need in LMICs (42).^{*} Evidence of access planning was in place for 28% of these projects: 1 targeting a priority disease and 12 addressing a public health need in LMICs.

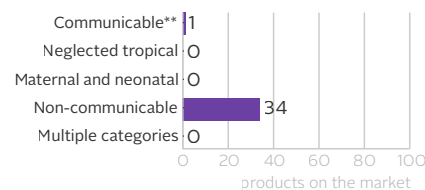
PORTFOLIO as selected for analysis by the Index

AstraZeneca has 34 medicines in scope, 26 of which are on patent, and 1 vaccine. 29% of these medicines and vaccines (10) are on WHO's EML. The off-patent medicines target non-communicable diseases (NCDs) such as cardiovascular diseases (4) and pulmonary diseases (4). The on-patent medicines target NCDs such as diabetes (8), pulmonary diseases (6) and oncology (9). The company's preventative vaccine targets the influenza virus. Access strategies were analysed for 9 products on AstraZeneca's portfolio – nationally procured HCP-administered (4) and self-administered products (5).

79 projects in the pipeline



35 products as selected for analysis by the Index[†]



Breakdown of projects[#]

Nirsevimab a monoclonal antibody in collaboration with Sanofi, aims to provide prophylaxis for respiratory syncytial virus in infants with a single injection.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 0 | 0 | 2 | 2 | 0 | 4 | 1 |
| Addresses needs of LMICs [*] | 0 | 8 | 20 | 13 | 9 | 50 | 12 |
| Other projects in scope | 0 | 11 | 5 | 6 | 3 | 25 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 4 | 22 | | | 26 |
| off patent | 5 | 3 | | | 8 |
| Vaccines | 1 | 0 | | | 1 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clin-

ical phase of development were included for this analysis.
^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

[†] Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

AstraZeneca plc

GOVERNANCE OF ACCESS

RANK 3

SCORE 4.32

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. AstraZeneca performs strongly. It has an access to healthcare strategy integrated within its core business, beyond philanthropy. The strategy covers all therapeutic areas the company is involved in. The highest responsibility for access lies directly with the board, with a Board of Directors member responsible for sustainability, including access to healthcare.

Provides evidence of financial and non-financial access-related incentives at the executive level.

AstraZeneca performs strongly. It incentivises select senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to its ESG performance, including targets on access initiatives such as Healthy Heart Africa, for tackling hypertension and cardiovascular disease.

Publicly discloses outcomes of its access-to-medicine activities. AstraZeneca performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access to healthcare activities, including tackling hypertension in Africa with Healthy Heart Africa, for example in its Sustainability Data Summary.

Performs above average in responsible promotional practices.

AstraZeneca's sales agents are not solely incentivised on sales volume targets. More details on how the company addresses sales incentives for agents are unavailable. AstraZeneca does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities) unless required by local regulations, but has policies on third party engagement, which can limit compensation and govern contributions and other items to HCPs under certain circumstances.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. AstraZeneca performs strongly, demonstrating all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, internal audits (in partnership with external experts, in the majority of countries where it operates and covering select third parties) and has formal processes to ensure compliance with company standards by third parties.

Publicly supports the Doha Declaration on TRIPS and Public Health.

AstraZeneca publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely on the use of compulsory licensing. There is no evidence of a policy, but the company states that it can dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

RANK 6

SCORE 2.78

Access planning processes encompass all projects in pipeline. AstraZeneca has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, AstraZeneca begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and its collaborative R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 25% of the late-stage candidates.

AstraZeneca has four projects in its pipeline, which are all late-stage candidates and target a priority product gap. The company focuses mostly on coronaviral diseases. Of AstraZeneca's four late-stage candidates targeting a priority product gap, there is evidence of access plans for one. This plan for AZD1222 COVID-19 vaccine includes manufacturing, procurement and distribution agreements with CEPI and Gavi and a licensing agreement with Serum Institute of India (SII) to supply one billion doses for LMICs.

Many projects address a public health need in LMICs*, with 29% of the late-stage projects covered by access plans.

In this analysis, AstraZeneca has 42 late-stage R&D projects in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. AstraZeneca provides evidence of access plans for 12 of these projects. These access plans prioritise registration in countries in scope.

Policy to ensure post-trial access; commits itself to registering trialed products.

AstraZeneca has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. It covers a subset of clinical trial participants who have a serious condition and no alternative treatments are available. Once a product is approved, AstraZeneca commits itself to registering it in all countries where clinical trials for

the product have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

Two R&D capacity building initiatives meet all Good Practice Standards.

AstraZeneca performs above average in this area. The company submitted four initiatives aimed at building R&D capacity in Index countries, of which three were included for analysis and two met all Good Practice Standards.† These initiatives include:

- AstraZeneca partnership with Hospital das Clínicas of the University of São Paulo Medical School to create InovaHC, a Health Innovation Hub within the Hospital das Clínicas.
- Advancing oncology research capability and capacity in Vietnam.

For one initiative, the Wuxi International Life Science Innovation Campus, AstraZeneca did not sufficiently demonstrate that the goals are aligned with its partner institutes.

PRODUCT DELIVERY

RANK 6

SCORE 3.29

Public commitment not to enforce patents in countries in scope. AstraZeneca publicly pledges to neither file for nor enforce patents. This commitment applies to any least developed countries and low-income countries and in a subset of lower-middle income countries and upper-middle income countries.

Publicly discloses detailed information on patent status.

AstraZeneca publicly discloses on its website information relating to the status of its patents for almost all products in scope. This includes: brand name, nature of the patent, patent number, expiry date and jurisdiction.

Shares some IP assets with third-party researchers.

AstraZeneca has newly shared some IP assets with

third-party researchers developing products for diseases in scope. This includes many IP assets shared via AstraZeneca's Open Innovation Program and with the research institution University Medical Center (UMC) Utrecht. Assets shared include unpublished preclinical stage data for drug discovery. †

† Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiative

goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

No use of non-assert or licensing arrangements.

AstraZeneca does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of high burden countries. AstraZeneca has filed 20% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, durvalumab (Imfinzi®), indicated for bladder and lung cancer, has been filed for registration/registered in nine high burden countries in scope, including Colombia and Peru.

No supranationally procured products. AstraZeneca has no products eligible for scoring in this indicator.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. AstraZeneca has average performance in this area compare to other companies. The company provides examples of access strategies which consider affordability for UMICs and LMICs for three out of the four products assessed. It falls short to provide example for a LMIC and a LICs for the other product. It makes efforts to reach additional patients using equitable pricing strategies. For example, in Mexico, for durvalumab (Imfinzi®), a treatment for bladder and lung cancer, the company applies equitable pricing strategy to list the product on the national list of essential medicine and has a patient assistance programme to increase access, while strengthening the health system via healthcare practitioner trainings. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. AstraZeneca has average performance in this area compare to other companies. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. For the other products, it falls short to provide example in LMICs and/or LICs. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in Kenya, for felodipine (Plendil®), the company offers a lower price in the public sector and faith based facilities as part of the healthy heart Africa programme. Additional reductions are implemented for patients in informal settlements where communities are typically low income/migrant populations who generally pay out of pocket for healthcare. The products reached nearly 70,000 patients.

One manufacturing capacity building initiative included for evaluation. AstraZeneca performs below average in this area. The company submitted two initiatives, of which one met all criteria for inclusion. The initiative, which ended in 2019, aimed to expand access to innovative medicines through training on quality standards and the transfer of pharmaceutical production technology in Iran. It did not meet all Good Practice Standards[§] as it did not demonstrate how it is guided by clear goals and objectives or that outcomes are being measured.

No supply chain capacity building initiatives included for evaluation. AstraZeneca performs poorly in this area. The company submitted two initiatives aimed at building supply chain capacity, but none were included for analysis as they did not meet all criteria for inclusion.

Five health system strengthening initiatives meet all Good Practice Standards. AstraZeneca is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a clear governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- The Healthy Lung initiative, improving access to and quality of respiratory disease care. Since its launch in Asia, there has been a reported 23% uptake increase in respiratory screenings.
- Healthy Heart Africa (HHA), tackling hypertension and the increasing burden of Cardiovascular Disease across Africa. To date, HHA has conducted approximately 14.9 million blood pressure screenings, trained over 7,200 health-care workers and supported more than 800 healthcare facilities to provide hypertension services.

Has not engaged in the development and implementation of inclusive business models as looked for by the Index during the period of analysis. Although it performs well in other areas, AstraZeneca performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long term horizon. Four initiatives were submitted, but did not meet the Index criteria.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. AstraZeneca performs well in this area, taking multiple steps to ensure the continuous supply of its medicine in Index countries. In UMICs, AstraZeneca forecasts demand, while in LDCs this is done through local distributors that report to AstraZeneca's regional commercial organisation. AstraZeneca is running an Export Simplification project in 30 countries in scope of the Index by aggregating demand of these markets onto one central distribution hub in Europe. For all markets, the company has Business Continuity Plans in place for major brands and reviews the global variability in demand and supply to ensure sufficient safety stocks. AstraZeneca did not report which products this include.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days.

AstraZeneca performs strongly in this area. It has a policy for reporting SF medicines to national health authorities within 5 days. It distinguishes time frames for reporting for cases which only require visual inspection to be confirmed, aiming at reporting within 3 working days when packaging is sufficient to assess the case.

Donates in response to an expressed need and monitors delivery to end user. AstraZeneca has a policy in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors the delivery until the

end user. For example, it donated AMP Rapid Test SARS-COV-2 IgG/IgM to Egypt in 2020 in response to the COVID-19 pandemic.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. AstraZeneca is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Cambodia Breast Cancer initiative whereby it has been donating anastrozole (Arimidex®) and fulvestrant (Faslodex®) to Cambodia since 2008.

§ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives;

measures outcomes; has long term aim/ aims for sustainability.
|| AstraZeneca joined the COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates

Foundation, Wellcome and Mastercard after the period of the analysis ended (31 May 2020).

| RANK | SCORE |
|-----------|-------------|
| 13 | 2.63 |
| 16 (2018) | |

Bayer AG

Stock Exchange: Frankfurt Stock Exchange • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 103,824

PERFORMANCE IN THE 2021 INDEX

13th place. Bayer has an average performance. It delivers a strong approach to filing its new products for registration, but has a small-sized R&D priority pipeline and no structured process for access planning. Its approach to governance and compliance is average.

Governance of Access: 8th place. Bayer has an average performance in this area. It implements an access-to-medicine strategy with a business rationale and discloses outcomes of some of its access-to-medicine activities. The company has some compliance controls in place, but lacks evidence of a continuous system to monitor compliance across its activities.

Research & Development: 17th place. Bayer falls to the lower ranks in R&D. The company features a small-sized R&D priority pipeline compared to peers and does not have a structured process to develop access plans during R&D. A few of its late-stage R&D projects are covered by access plans.

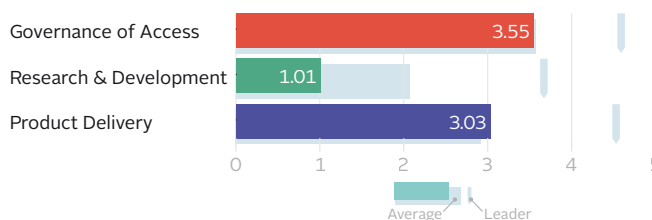
OPPORTUNITIES FOR BAYER

Expand access to more products. Bayer offers certain contraceptives for procurement through UNFPA for eligible countries and offers the same terms and price to non-eligible countries for ethinylestradiol/levonorgestrel/ferrous fumarate (Microgynon® ED Fe/Microgynon® Fe). Bayer can apply the same strategy in non-eligible countries for norethisterone enantate (Noristerat®). Furthermore, Bayer can apply equitable pricing strategies for contraceptives that are not procured through UNFPA: drospirenone/ethinylestradiol (Yasmin®), Estradiol valerate/dienogest (Qlaira®/Natazia®) or estradiol valerate/norethisterone enantate (Norigynon®), specifically in countries with a low contraceptive prevalence rate such as Angola, Gambia, Guinea and Mauritania. Outside contraceptives, Bayer can expand affordable access to on patent EML products such as rivaroxaban (Xarelto®) for the prevention of stroke.

Develop an access planning process and access plans for all R&D projects. Bayer can develop a formal access planning process and accordingly develop access plans for all Phase II projects, such as levonorgestrel/indomethacin (a combination intrauterine device). Bayer can also further strengthen its recently updated post-trial access policy by committing to filing the product for registration in countries where clinical trials take place, while ensuring affordability.

Commit to donating until NTD elimination and control goals. In partnership with the WHO since 2002, Bayer has worked to eliminate African Sleeping Sickness (HAT) and to control Chagas disease in Latin America by donating suramin (Germanin®) and nifurtimox (Lampit®) until 2021. Bayer can extend its public commitment indefinitely until elimination of HAT and control of Chagas disease in Latin America.

How score was achieved



Product Delivery: 11th place. Bayer has an average performance in this area. It has filed to register the majority of its new products in the majority of high-burden countries. The company has access strategies for some of its products and for some countries in scope and is able to provide evidence of how patient reach has been increased through the approaches used.

CHANGE SINCE THE 2018 INDEX

- Created a new external sustainability council to contribute to Bayer innovation, mindset and strategy as from May 2020.
- Disclosed a new commitment not to enforce or file for patents in all LICs.
- Joined Pat-INFORMED, publishing patent statuses for products in their portfolio.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Joined the COVID-19 Therapeutics Accelerator.
- Started a new two-year partnership in January 2020 with Living Goods to train Community Health Workers on family planning and neonatal care in rural Uganda.
- Established a new partnership with PATH for malaria and COVID-19 in Southern Senegal.
- Newly partnered with the UN Foundation for malaria eradication by donating Fludora® Fusion for vector control in Haiti.
- Has a new collaboration with John Hopkins University for The Challenge Initiative platform to enable governments in countries in scope of the Index to scale up family planning approaches for poorer populations in urban areas.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Crop Science; Pharmaceuticals; Consumer Health
Therapeutic areas: Cancer; Cardiovascular and kidney diseases; Eye conditions; Haemophilia; Contraception
Product categories: Innovative medicines
M&A news: Divested Bayer Animal Health to Elanco in August 2019 for USD 7.6 billion; acquired BlueRock (neurology) and Century (oncology) in 2019; announced acquisition of

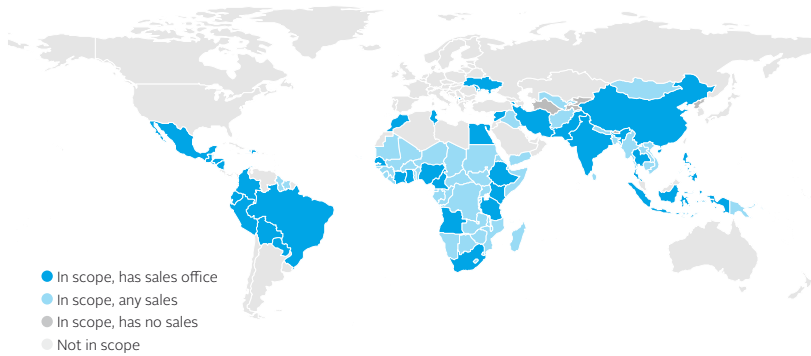
KaNdy Therapeutics (women's healthcare) and of Asklepios BioPharmaceutical (gene therapies) in 2020.

Bayer Pharma's products are sold in 92 out of 106 countries in scope. Bayer Pharma has sales offices in 37 countries, sells via suppliers in 7 countries and via pooled procurement into 48 additional countries.

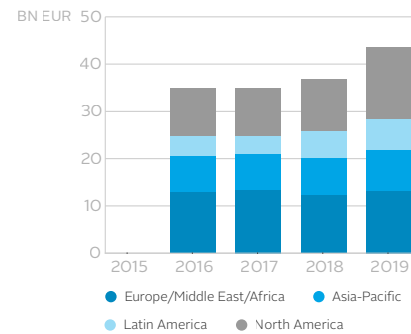
Net sales by segment (2019) – EUR

| | |
|-----------------|------------------|
| Crop Science | 19.832 bn |
| Pharmaceuticals | 17.962 bn |
| Consumer Health | 5.462 bn |
| Reconciliation | 0.289 bn |
| Total | 43.545 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

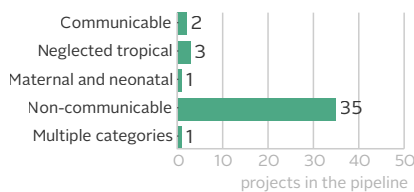
PIPELINE for diseases and countries in scope

Bayer has a total of 42 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 7 projects. The other 35 R&D projects target other diseases in scope. Of the projects targeting priority diseases the focus is on Chagas disease (2 projects). Of the projects targeting other diseases in scope the focus is on oncology (18). 17 R&D projects are in late-stage development that target either a priority disease (6) or address a public health need in LMICs (11).^{*} Evidence of access planning was in place for 24% of these projects: 3 targeting a priority disease and 1 addressing a public health need in LMICs.

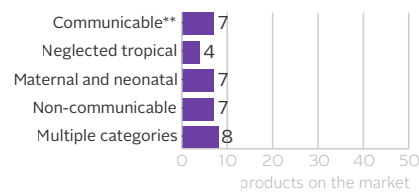
PORTFOLIO as selected for analysis by the Index

Bayer has 21 medicines and contraceptives in scope, 11 of which are on patent. 67% of these medicines and contraceptives (14) are on WHO's EML. In addition, the company markets 12 vector control products. The off-patent medicines target mainly neglected tropical diseases (NTD), such as schistosomiasis, Chagas and Human African Trypanosomiasis. One medicine targets malaria. The on-patent medicines mainly target non-communicable diseases, such as oncology (5), cardiovascular disease and endometriosis. Additionally, one medicine targets bacterial infections. Bayer has eight contraceptives in scope. The vector control products target malaria, dengue, Chikungunya and Zika. Access strategies were analysed for 11 products on Bayer's portfolio – supranationally procured (4) or nationally procured HCP-administered (2) and self-administered products (5).

42 projects in the pipeline



33 products as selected for analysis by the Index[†]



Breakdown of projects[#]

Levonorgestrel/indomethacin releasing intrauterine system for contraception.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 0 | 0 | 3 | 2 | 1 | 6 | 3 |
| Addresses needs of LMICs [*] | 0 | 13 | 6 | 3 | 2 | 24 | 1 |
| Other projects in scope | 0 | 4 | 3 | 4 | 0 | 11 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|----------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 6 | 5 | | | 11 |
| off patent | 8 | 2 | | | 10 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other ^{***} | | | | 12 | 12 |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

^{***}Other includes vector control products. See Appendix I for definitions.
[†]Product included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Bayer AG

GOVERNANCE OF ACCESS

RANK 8

SCORE 3.55

Has an access-to-medicine strategy with measurable objectives and a business rationale. Bayer has an average performance. It has an access strategy aiming at increasing the societal impact of their business activities. The strategy covers some therapeutic areas in which the company is involved, mainly focusing on women's health and access to contraceptives. The highest responsibility for access lies directly with the board, with the Chief Sustainability Officer.

Provides evidence of financial and non-financial access-related incentives at the executive level. Bayer performs strongly in this area. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to sustainability goals.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Bayer performs well in

transparency regarding access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example through the IFPMA Global Health Progress platform.

Has an average performance in responsible promotional practices. Bayer's sales agents are not solely incentivised on sales volume targets. Bayer sets sales incentives at the individual level for agents. Except for Ukraine where it discloses to EFPIA^{||}, the company does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), nor does it disclose a policy approach limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bayer has an average performance, demonstrating some of the components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes in place to ensure third-party compliance with company standards. It does not, however, have a continuous system to monitor activities.

Publicly supports the Doha Declaration on TRIPS and Public Health. Bayer publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions; that is, compulsory licenses are considered a last resort. It states that it can dissent from industry association positions on IP.

RESEARCH & DEVELOPMENT

RANK 17

SCORE 1.01

No structured process for access planning reported. Bayer does not have a structured process in place to develop access plans during R&D. The company does not have a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 50% of the late-stage candidates. Bayer has seven projects, including six late-stage candidates, in its pipeline that target a priority product gap. The company focuses mostly on Chagas disease. Of Bayer's six late-stage candidates targeting a priority product gap, there is evidence of an access plan for three. These plans range from registration to a partnership with DNDi. A notable example is the paediatric nifurtimox (Lampit[®]). Registration in additional endemic high dis-

ease-burden countries is planned for this project.

Many projects address a public health need in LMICs*, with one of the late-stage projects covered by access plans. In this analysis, Bayer has 11 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Bayer provides evidence of access plans for one of these projects, which is darolutamide (Nubeqa[®]), indicated for prostate cancer. Registration in LMICs with subsequent access plans are planned.

Public policy to ensure post-trial access; no stated commitment to registering trialled products. Bayer has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a severely debilitating or life-threatening disease. Bayer does not state a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

No R&D capacity building initiatives included for evaluation. Bayer performs low in this indicator. The company submitted four initiatives aimed at building R&D capacity, but none met all criteria for inclusion.

PRODUCT DELIVERY

RANK 11

SCORE 3.03

Public commitment not to enforce patents in countries in scope. Bayer publicly pledges to neither file for nor enforce patents. This commitment applies in low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Bayer discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares few IP assets with third-party researchers. Bayer has newly shared two IP assets with third-party research-

ers developing products for diseases in scope. It shares the assets with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard, as well as with the Medicines for Malaria Venture (MMV). Assets shared include molecule libraries.

No use of non-assert or licensing arrangements. Bayer does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope.

Filed to register the majority of its new products in the majority of high burden countries. Bayer has filed 63% of its most recently registered products in more than half of

the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, the oncology medicine regorafenib (Stivarga[®]) has been filed for registration/registered in seven high burden countries in scope.

Has access strategies for some supranationally procured products in scope of this analysis. Bayer has average performance in securing access for products procured supranationally.[‡] For three of the four products assessed in this category, it demonstrated strategies both in countries eligible for supply from such procurers and also in at least one country not eligible for such supply. For example, the company offers the same terms in Iraq for the oral con-

142 || Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

‡ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

traceptive pill; Microgynon® ED Fe; as they do in UNFPA-eligible countries. For the remaining products there was no evidence of equitable pricing strategies in non-eligible countries.

Has access strategies for the healthcare practitioner-administered products in scope of this analysis.

Bayer performs below average in this area. It provides weak examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the two products assessed. The company makes efforts to reach additional patients through donations. For example, in Brazil, it donated 33,000 contraceptive LNG IUS implants to increase access, while strengthening the health system via healthcare practitioner trainings. Bayer is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope for this analysis.

Bayer has average performance in this area. It shows some strength in access strategies in UMICs, though not in LMICs and LICs. The company applies access strategies which consider ability to pay/affordability for UMICs in three out of the five products assessed. It makes efforts to reach additional patients through equitable pricing strategies. For example, in China, they reduced the price of sorafenib (Nexavar®) and regorafenib (Stivarga®), two oncology medicines, to be listed on the reimbursement list and increase access for patient. After sorafenib was listed for reimbursement, the patient number increased from 8,000 in 2017 to about 19,000 in 2019. Bayer is able to provide evidence of how patient reach has been increased through the approaches used.

One manufacturing capacity building initiative included for evaluation. Bayer performs below average in this indicator. Bayer submitted two initiatives. One initiative, supporting Contract Manufacturing Organisations in addressing PSCI and Environment, Health and Safety gaps, met all criteria for inclusion but not all Good Practice Standards[§] as Bayer did not sufficiently demonstrate how the initiative aims for sustainability and is measuring outcomes.

Two supply chain capacity building initiative meet all Good Practice Standards. Bayer performs average on this indicator. Bayer submitted four initiatives, of which two initiatives met all criteria for inclusion and all Good Practice Standards.[§] For example, Bayer participates in a programme by the Global Family Planning Visibility and Analytics Network of the Reproductive Health Supplies Coalition, developing a coordination structure to prevent stock-outs of reproductive health supplies piloted in Malawi and Nigeria.

Two health system strengthening initiatives meet all Good Practice Standards. Bayer performs above average in this indicator, with four health system strengthening initiatives that met all criteria for inclusion: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. Two initiatives met all Good Practice Standards, including an NCD care programme in Ghana and The Challenge Initiative, which enables governments to scale up high-impact family planning approaches. For Bayer's other two initiatives, a partnership with PATH to eliminate malaria and fight COVID-19 in Senegal and a

partnership with Living Goods in Uganda to train community health workers on family planning and neonatal care, Bayer did not provide sufficient evidence on having a good governance structure in place.

Has engaged in the development and implementation of new inclusive business models. Compared to peers, Bayer performs well when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has newly developed four models: iBreast exam on breast cancer, partnership with BISA on digital health, partnership with Access Afya on the COVID-19 response, MUTTI (mPharma) on cardiovascular diseases.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Bayer performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. In addition to multiple processes to align demand forecasting and supply, Bayer has a 'stock-out situation notification procedure' in case of temporary shortage, which covers all products in its portfolio. During supply shortages, Bayer reports implementing the fair share principle, prioritising supply on the basis of medical needs status and ensuring that supply commitments to Global Healthcare Programmes are prioritised over commercial products. Bayer reported implementing this process in 2019 for two contraceptives, oral levonorgestrel/ethinylestradiol (Microgynon®) and injectable norethisterone enantate (Noristerat®), ensuring supply through USAID and/or the UNFPA.

Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Bayer performs well here. It has a policy for reporting SF medicines to national health authorities within 7 days for the most severe risk category. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end user. Bayer has a policy in place to ensure ad hoc donations are carried out only in response to an expressed need and it monitors the delivery until the end user. For example, it donated chloroquine (Resochin®) to 27 countries in 2020 in response to the COVID-19 pandemic.

Publicly commits itself to achieving elimination, eradication or control goals in its structured donation programme. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Bayer publicly commits itself to controlling Chagas disease and eliminating Human African Trypanosomiasis by donating nifurtimox (Lampit®) and suramin (Germanin®) from 2002 to 2021.

§ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 12 | 2.84 |
| 14 (2018) | |

Boehringer Ingelheim GmbH

Stock Exchange: n.a. • Ticker: n.a. • HQ: Ingelheim am Rhein, Germany • Employees: 51,015

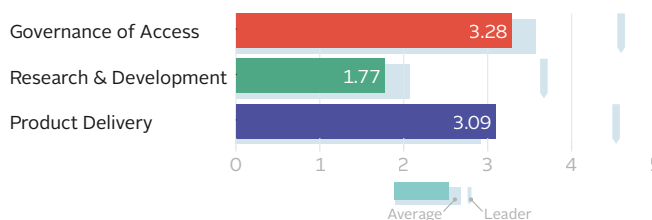
PERFORMANCE IN THE 2021 INDEX

12th place. Overall, Boehringer Ingelheim is a middle-performing company. It shows a strong performance in its access approach for specific products and markets but the company has a small-sized priority R&D pipeline with no late-stage candidates.

Governance of Access: 10th place. Boehringer Ingelheim is a middle-performing company in this area. Its access-to-medicine strategy is clearly linked to its business model, but it lacks access-related incentives for senior executives or in-country managers.

Research & Development: 11th place. Boehringer Ingelheim is a middle-performing company in this area. It has some R&D projects that address a public health need in LMICs, with the majority covered by an access plan. Yet, the company has a small-sized priority R&D pipeline compared to peers with no projects in late-stage development and does not engage in R&D capacity building.

How score was achieved



Product Delivery: 9th place. Boehringer Ingelheim performs average in this area. It newly shared some IP assets with third-party researchers. It has access strategies in place for some of its products in countries of all assessed income levels. Yet, there is no evidence of new products in scope filed for registration in the majority of high-burden countries. The company engages in some strong health system strengthening initiatives and has engaged in the development and implementation of multiple new inclusive business models.

OPPORTUNITIES FOR BOEHRINGER INGELHEIM

Develop access-oriented incentive structures. Boehringer Ingelheim has an access-to-medicine strategy, integrated within its overall corporate strategy. It can develop financial and non-financial access incentives for executives and in-country managers. Furthermore, it can review sales incentive structures to adopt a balanced scorecard approach consistently, thus ensuring that sales agents are not solely incentivised on sales volume targets.

Follow peers in publicly disclosing patent status. Boehringer Ingelheim can disclose patent information publicly to meet the actions of all other 19 companies in scope of the Index that currently disclose patent information for small molecules in scope via the Pat-INFORMED platform or via their own channels.

Improve access to patented products on WHO EML. Boehringer Ingelheim engages in equitable pricing for some its products. The company has in total six patented products which are on the 2019 WHO Model List of Essential Medicines (WHO EML). The company can further prioritise expanding access to these products, such as dabigatran (Pradaxa®) for the prevention of stroke and afatinib dimaleate (Giotrif®/Gilotrif®) first line treatment for metastatic non-small cell lung cancer, and patented medicines for type 2 diabetes mellitus that are not on WHO EML, such as empagliflozin (Jardiance®), empagliflozin/linagliptin (Glyxambi®) and empagliflozin/metformin (Synjardy®), by increasing affordability and supply using mechanisms such as equitable pricing and/or non-exclusive voluntary licensing in countries in scope.

CHANGE SINCE THE 2018 INDEX

- Announced partnership with Defeat-NCD to tackle the premature death, sickness, disability, and associated social and economic impacts from non-communicable diseases.
- Formed a Sub-Saharan operating unit, partnering with local distributors, provides guidance on logistical management and supports with knowledge on Good Distribution Practice (GDP) training and auditing to improve distribution.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Engaged in new ways to share IP via a new programme, opnMe: providing free access to compounds and their associated properties for research in areas, such as hepatitis, malaria, HCV, HIV, non-communicable diseases (NCDs) and via the Covid-19 Therapeutics Accelerator.
- Launched a new initiative in Kenya as part of the In Reach Initiative with AMPATH, 'Kuza Afya' for cardiovascular disease, hyper-tension and diabetes community health screening and referrals.
- Launched a new initiative in Kenya as part of In Reach Africa initiative with PharmAccess to use mobile technology to address awareness and access barriers in hypertension and diabetes.
- Launched a new pilot programme in Pakistan in collaboration with the OIE to eliminate rabies by donating the vaccine Rabisin® and dogs identification collars.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Human pharmaceuticals; Animal Health; Biopharmaceutical contract manufacturing
Therapeutic areas: Respiratory diseases; Cardiovascular and metabolic diseases; Oncology; Central nervous system diseases; Ophthalmology (retina health), Inflammation, Emerging areas (infectious diseases)
Product categories: Innovative medicines; Animal health; Biosimilars.

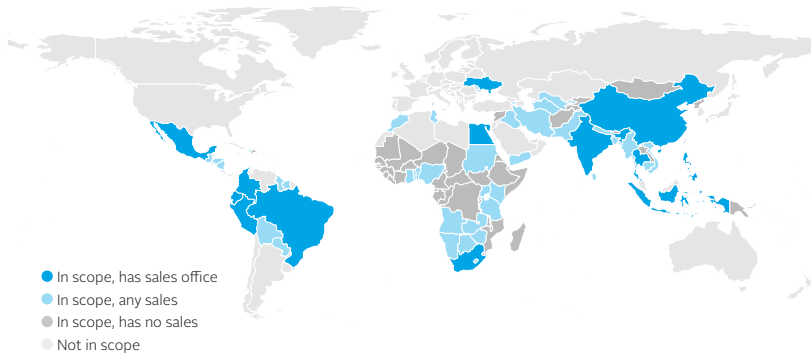
M&A news: Acquired AMAL Therapeutics (oncology) in 2019; acquired the preclinical pipeline of Northern Biologics (oncology) and NBE-Therapeutics (oncology) in 2020.

Boehringer Ingelheim's products are sold in 53 out of 106 countries in scope. Boehringer Ingelheim has sales offices in 13 countries, sells via suppliers in 36 countries and via pooled procurement into 4 additional countries.

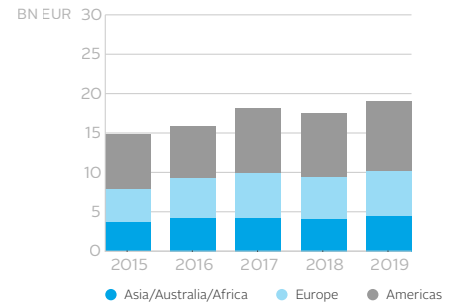
Net sales by segment (2019) – EUR

| | |
|--|------------------|
| Human Pharmaceuticals | 13.961 bn |
| Animal Health | 4.035 bn |
| Biopharmaceutical Contract Manufacturing | 0.786 bn |
| Other sales | 0.041 bn |
| Discontinued operations | 0.174 bn |
| Total | 18.997 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Boehringer Ingelheim has a total of 43 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 6 projects. The other 37 R&D projects target other diseases in scope. The projects targeting priority diseases include tuberculosis (2 projects). Of the projects targeting other diseases in scope, the focus is on kidney diseases (4), diabetes (4) and oncology (19).

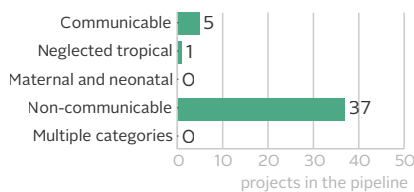
Boehringer Ingelheim has no projects in late-stage development targeting a priority disease. 9 R&D projects are in late-stage development that address a public health need in LMICs.* Evidence of access planning was in place for 89% of these projects.

PORTFOLIO as selected for analysis by the Index

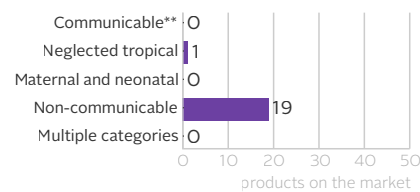
Boehringer Ingelheim has 19 medicines in scope, 12 of which are on patent. 58% of these medicines (11) are on WHO's EML. In addition the company markets 1 vector control product. The off-patent medicines target non-communicable diseases (NCDs) such as pulmonary diseases (3), cardiovascular diseases (3) and diabetes. The on-patent medicines target NCDs such as diabetes (5), pulmonary diseases (3), cardiovascular diseases (3) and oncology. The vector control product targets rabies.

Access strategies were analysed for 8 products on Boehringer Ingelheim's portfolio – supranationally procured (1) or nationally procured HCP-administered (2) and self-administered products (5).

43 projects in the pipeline



20 products as selected for analysis by the Index†



Breakdown of projects#

Xentuzumab a humanized immunoglobulin G (IgG) 1 monoclonal antibody targeting breast cancer.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| Addresses needs of LMICs* | 0 | 0 | 6 | 2 | 1 | 9 | 8 |
| Other projects in scope | 0 | 27 | 0 | 0 | 1 | 28 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 6 | 6 | | | 12 |
| off patent | 5 | 2 | | | 7 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other*** | | | | 1 | 1 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

***Other includes vector control product. See Appendix I for definitions.
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Boehringer Ingelheim GmbH

GOVERNANCE OF ACCESS

RANK 10

SCORE 3.28

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Boehringer Ingelheim performs strongly. It has an Access to Healthcare Approach, including both human and animal health. The strategy covers all therapeutic areas in which the company is involved, namely the non-communicable diseases (NCDs). The highest responsibility for access lies directly with the board, with the Access to Healthcare Steering committee.

Does not provide evidence of financial or non-financial access-related incentives at the managerial level. Although it has a clear access strategy, Boehringer Ingelheim performs relatively poorly here. It does not demonstrate evidence of having access-related incentives for senior executives or in-country managers.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Boehringer Ingelheim performs well in transparency of access activities. It publicly

discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example the Making More Health initiatives and through the IFPMA Global Health Progress platform.

Performs comparatively poorly in responsible promotional practices. Boehringer Ingelheim's sales agents are solely incentivised on sales volume targets. The company sets incentives based on sales targets at the individual level for agents. Except for Ukraine where it discloses to EFPIA^{||}, the company does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Boehringer Ingelheim has an average performance, demonstrating some of the components looked for by the Index: fraud-specific risk assessment, audits (both internal and external, covering third parties and in all countries where it operates), country risk-based assessments and formal processes to ensure third-party compliance with company standards. It does not, however, demonstrate sufficient evidence of a continuous system to monitor activities.

Publicly supports the Doha Declaration on TRIPS and Public Health. Boehringer Ingelheim publicly shares support of the Doha Declaration on TRIPS and Public Health. It views the Declaration as a mechanism offering more juridical certainty to countries which may intend to use the system. It can dissent from industry association positions, when such a case presents itself.

RESEARCH & DEVELOPMENT

RANK 11

SCORE 1.77

Access planning processes for some R&D projects for diseases in scope.

A small-sized priority R&D pipeline compared to peers, with no late-stage priority R&D candidates. Boehringer Ingelheim has six projects but no late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including tuberculosis. As no late-stage candidates targeting a priority product gap are in the pipeline, there is no evidence of any access plans.

Some projects address a public health need in LMICs*, with 89% of these projects covered by access plans. In this analysis, Boehringer Ingelheim has nine late-stage

R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Boehringer Ingelheim provides evidence of access plans for eight of these projects.

Public policy to ensure post-trial access; commits itself to registering trialed products. Boehringer Ingelheim has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a life-threat-

ening condition. Once a product is approved, Boehringer Ingelheim commits itself to registering it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Boehringer Ingelheim performs poorly in this indicator. The company submitted five initiatives aimed at building R&D capacity, but none were included for analysis as they did not meet the inclusion criteria.

PRODUCT DELIVERY

RANK 9

SCORE 3.09

Public commitment not to enforce patents in countries in scope. Boehringer Ingelheim publicly commits to neither file for nor enforce patents. This commitment applies to most Least Developed Countries in scope and low-income countries in scope and in a subset of lower and upper middle-income countries in scope.

Does not publicly disclose information on patent statuses. Unlike all its peers, Boehringer Ingelheim does not disclose the patent status of its products for diseases and countries in scope.

Shares some IP assets with third-party researchers. Compared to its peers, Boehringer Ingelheim has newly shared some IP assets with third-party researchers devel-

oping products for diseases in scope. This includes initiatives such as the opnMe program and the COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries.

No use of non-assert or licensing arrangements. Boehringer Ingelheim does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Boehringer Ingelheim did not disclose evidence of filing any of its most recently registered products in more than half of the top 10

high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, dabigatran etexilate (Pradaxa[®]) for stroke prevention, is registered/has been filed for registration in 38 countries in scope, including Haiti and Botswana.

Has access strategies for all supranationally procured products in scope for this analysis. Boehringer Ingelheim performs above average in securing access for its only product evaluated which is procured supranationally.[†] The company reports equitable pricing strategies and donates the veterinary rabies vaccine Rabisin[®] for non-eligible World Organization for Animal Health countries.

^{||} Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare professionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Boehringer Ingelheim performs well in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for the two products concerned. It makes efforts to reach additional patients through the use of equitable pricing strategies. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. Boehringer Ingelheim has average performance in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for three out of the five products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Two manufacturing capacity building initiatives included for evaluation. Boehringer Ingelheim performs below average in this indicator. Boehringer Ingelheim submitted the maximum of five initiatives, of which two met all criteria for inclusion. The initiatives, which support Contract Manufacturing Organisations to meet global quality regulations and requirements, did not meet all the Good Practice Standards[§] as the company could not sufficiently demonstrate how the initiatives aim for sustainability.

Four supply chain capacity building initiatives included for evaluation. Boehringer Ingelheim performs below average in this indicator. Boehringer Ingelheim submitted the maximum of five initiatives, of which four met all criteria for inclusion. The initiatives include training on Good Distribution Practices for storage, specifically cold and deep-frozen storage. None of the initiatives submitted by the company met all Good Practice Standards[§], as the company did not provide sufficient evidence on having clear goals and objectives and long-term aims.

Four health system strengthening initiatives meet all Good Practice Standards. Boehringer Ingelheim performs above average in this indicator, with four health system strengthening initiatives that were included for analysis and meet all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- The Angels initiative aims to improve and expand stroke care, at present in 103 countries, of which 38 are in scope of the Index. The initiative has reportedly reached over 35,000 healthcare professionals treating an estimated 3.3 million patients in registered hospitals.
- The Kuzu Afya initiative, a cardiovascular disease management programme in partnership with AMPATH, has screened over 70,000 patients in rural western Kenya and trained 50 healthcare professionals.

Has engaged in the development and implementation of new inclusive business models. Boehringer Ingelheim performs above average when it comes to implementing scalable inclusive business models that aim to meet the

access needs of populations at the base of the pyramid in countries in scope. It has contributed to multiple new models focused on NCD care, including Akiba ya Roho for informal settlements, and partnerships with social entrepreneurs, including Healthy Entrepreneurs, Chronic Drugs Medical Scheme, Jacaranda Maternity and Yako Medical.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Boehringer Ingelheim performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. For example, for handling shortages or stock-outs, the company reports that it has a notification and communication procedure that applies to all countries where they have presence and products on the market. This also includes some Least Developed Countries.

Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Boehringer Ingelheim has a policy for reporting SF medicines to national regulatory authorities within 7 days. It does not, however, distinguish reporting time frames for cases which only require visual inspection to be confirmed. If visual inspection of packaging is sufficient, the reporting timeline might be shorter, but this is not a standard procedure.

Donates in response to an expressed need and monitors delivery to end user. Boehringer Ingelheim has a policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user. For example, it donated essential medicine to three countries in 2018-2019 to the Supporting Healthy Mothers project.

Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programme. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Boehringer Ingelheim publicly commits itself to eliminating rabies by donating the rabies vaccine or medicine, Rabisin[®], from 2019 to 2030 in Pakistan as a pilot.

‡ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

§ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 19 | 1.55 |
| 15 (2018) | |

Bristol Myers Squibb Co

Stock Exchange: New York Stock Exchange • Ticker: BMJ • HQ: New York City, New York, United States • Employees: 30,000

PERFORMANCE IN THE 2021 INDEX

19th place. Bristol Myers Squibb is in the lower ranks across all Technical Areas, with weak performance, for example, in R&D in addition to a lack of evidence of access strategies. The company performs poorly in responsible promotional practices.

Governance of Access: 15th place. Bristol Myers Squibb performs below average in this area. While having an access-to-medicine strategy with measurable goals, the company performs poorly in the area of responsible promotional practices.

Research & Development: 16th place. Bristol Myers Squibb performs below average in R&D. The company commits to registering trialled products, but does not have a structured access planning process nor does it disclose evidence of access plans for late-stage projects that address a public health need in LMICs.

OPPORTUNITIES FOR BRISTOL MYERS SQUIBB

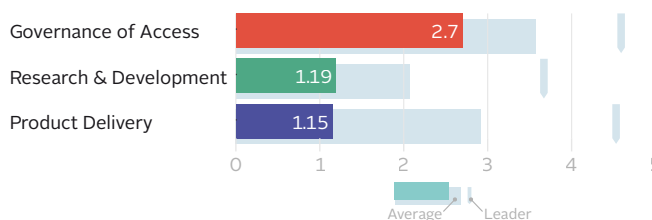
Strengthen governance of access to medicine. Bristol Myers Squibb can integrate its access strategy within its corporate business strategy, thus ensuring that all therapeutic areas are covered. It can implement financial and non-financial incentives for its CEO and in-country managers, linked to the achievement of the strategy, similar to how some senior executives now have access-related incentives. Furthermore, it can review sales incentive structures to adopt a balanced scorecard approach consistently, thus not solely promoting sales volume targets in countries in scope of the Index.

Develop access planning process and access plans for all R&D projects. Bristol Myers Squibb can develop a formal access planning process and accordingly develop access plans for all projects in Phase II clinical development, especially for products addressing a public health need in low- and middle-income countries such as paediatric dasatinib (Sprycel®), nivolumab (Opdivo®) and pomalidomide (Pomalyst®) for multiple indications for cancer.

Strengthen post-trial access policy. Bristol Myers Squibb can strengthen its post-trial access policy to cover all patients who gain a clinical benefit from existing treatments, not just those with serious and/or life-threatening conditions. It can also commit to ensuring affordability of essential products following cessation of post-trial access.

Improve access to patented products on WHO EML. Bristol Myers Squibb has in total eight products on patent which are on the 2019 WHO Model List of Essential Medicines (WHO EML). The company can further prioritise expanding access to these products, such as dasatinib (Sprycel®), for imatinib-resistant chronic myeloid leukaemia and apixaban (Eliquis®) for ischaemic heart disease and management of stroke.

How score was achieved



Product Delivery: 19th place. Bristol Myers Squibb performs poorly in this area. Access strategies were identified for a few of its products. The company does not disclose, either publicly or to the Index, mechanisms to ensure continuous supply. It is engaged in health system strengthening in China and sub-Saharan Africa but no initiatives aimed at building manufacturing or supply chain capacity were included for analysis.

CHANGE SINCE THE 2018 INDEX

- Expanded collaborative agreement with the Max Foundation to provide dasatinib (Sprycel®) to reach 45% more cancer patients than the previous agreement and to support health system strengthening.
- Discontinued daclatasvir (Daklinza®) in countries where the product is no longer routinely used or when other options are available, and commits itself to not enforcing the patent for this product in these countries.
- Joined the COVID-19 Therapeutics Accelerator.
- Announced the termination of all R&D collaborations with product development partnerships on NTDs and AMR, while outlicensing part of its compound library to MMV and offering one-off donations to MMV and DNDI.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, Bristol Myers Squibb declined to submit data to the Access to Medicine Index.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Biopharmaceuticals
Therapeutic areas: Oncology; Haematology; Immunology; Cardiovascular diseases; Fibrotic disease
Product categories: Innovative medicines
M&A news: Acquired Celgene (cancer, immunology) in November 2019 for USD 74 billion and subsequently divested Otezla to Amgen; divested consumer health business UPSA to Taisho in 2019; acquired Forbuis (oncology, fibrosis) in August 2020 and MyoKardia (cardi-

ovascular diseases) in October 2020 for USD 13.1 billion.

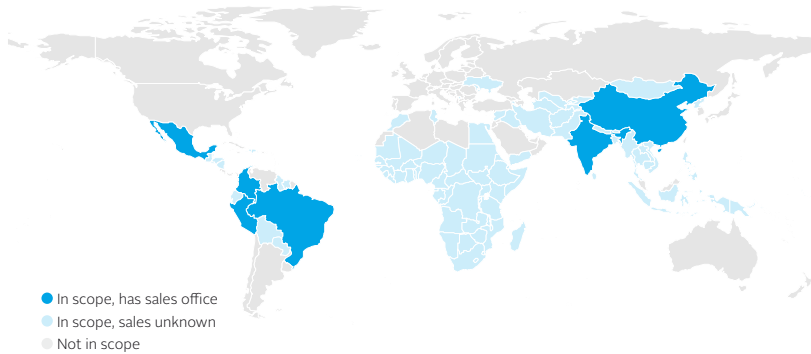
Bristol Myers Squibb's products are sold in 13* out of 106 countries in scope. Bristol Myers Squibb has sales offices in 6 countries and sells products via suppliers or pooled procurement in 7* countries.

*In 2018, Bristol Myers Squibb reported sales in 13 countries.

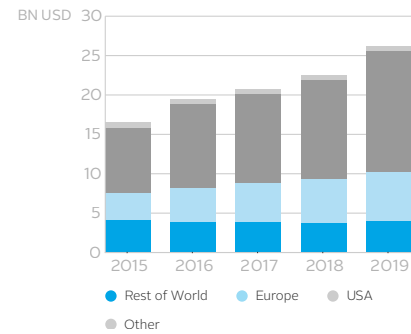
Revenue by segment (2019) – USD

| | |
|--------------------|-----------|
| Biopharmaceuticals | 26.145 bn |
| Total | 26.145 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Bristol Myers Squibb has a total of 63 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 11 projects. The other 52 R&D projects target other diseases in scope. The projects targeting priority diseases are for neglected tropical diseases such as leishmaniasis, Chagas disease and onchocerciasis. Of the projects targeting other diseases in scope, the focus is on oncology (46 projects).

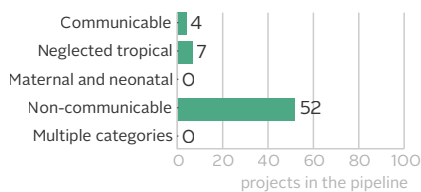
23 R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (21)*. Evidence of access planning was in place for 8.70% of these projects: 2 targeting a priority disease but none addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

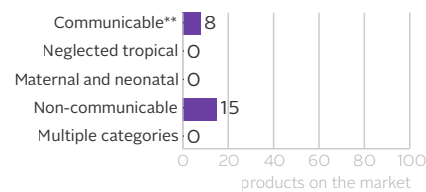
Bristol Myers Squibb has 23 medicines in scope, 18 of which are on patent. 52% of these medicines (12) are on WHO's EML. The off-patent medicines target mainly non-communicable diseases (NCDs) such as schizophrenia, cardiovascular diseases and sickle cell disease. One off-patent medicine is antifungal. The on-patent medicines mainly target NCDs, such as cancer (9), schizophrenia and cardiovascular diseases. In addition, 4 products target HIV and 3 products target hepatitis B and C.

Access strategies were analysed for 14 products on the Bristol Myers Squibb's portfolio – supranationally procured (4) or nationally procured HCP-administered (5) and self-administered products (5).

63 projects in the pipeline



23 products as selected for analysis by the Index†



Breakdown of projects*

Opdivo (nivolumab) indicated for different types of cancer. This pipeline comprised mostly of projects targeting cancer.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 1 | 0 | 2 | 0 | 0 | 3 | 2 |
| Addresses needs of LMICs* | 0 | 18 | 7 | 11 | 3 | 39 | 0 |
| Other projects in scope | 0 | 6 | 3 | 4 | 0 | 13 | 0 |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 8 | 10 | 0 | 0 | 18 |
| off patent | 4 | 1 | 0 | 0 | 5 |
| Vaccines | 0 | 0 | 0 | 0 | 0 |
| Diagnostics | 0 | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clin-

ical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

† Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Bristol Myers Squibb Co

GOVERNANCE OF ACCESS

RANK 15

SCORE 2.70

Has an access-to-medicine strategy with measurable objectives and a business rationale. Bristol Myers Squibb has an average performance. It has an access strategy linked to sustainability goals, including its hepatitis C virus (HCV) Developing World Strategy. The strategy covers some of the therapeutic areas in which the company is involved, including HCV in LMICs. The highest responsibility for access lies indirectly with the board, at the executive level with its World Access Council.

Provides evidence of financial and non-financial access-related incentives at the executive level. Bristol Myers Squibb performs well. It incentivises its senior executives to take action on access to medicine with financial and non-financial rewards. It does not disclose, however, whether in-country managers or the CEO are also incentivised toward access goals.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Bristol Myers Squibb performs well in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example through the IFPMA Global Health Progress platform.

Performs comparatively poorly in responsible promotional practices. Bristol Myers Squibb does not disclose that its sales agents are not solely incentivised on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bristol Myers Squibb performs below average, with evidence of some of the components looked for by the Index: audits (both internal and external and in all countries where it operates) and formal processes to ensure compliance with company standards by third parties. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Bristol Myers Squibb does not publicly share any support of or statement on the Doha Declaration on TRIPS and Public Health. There is no evidence of a policy to dissent from industry association positions.

RESEARCH & DEVELOPMENT

RANK 16

SCORE 1.19

No structured process for access planning reported. Bristol Myers Squibb does not have a structured process in place to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place. Bristol Myers Squibb has 11 projects, including two late-stage candidates, in its pipeline that target a priority product gap. The company focuses on various priority areas, including leishmaniasis, Chagas disease and onchocerciasis. Evidence of an access plan accompanies both of Bristol Myers Squibb's late-stage candidates targeting a priority product gap. These plans prioritise affordability and availability and are run in partnership with non-profit organisations (i.e. The Leprosy Institute Nepal and The Aurum Institute NPC).

Many projects address a public health need in LMICs*. The company does not disclose evidence of access plans for late-stage projects. In this analysis, Bristol Myers Squibb has 21 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope. Most target cancer.

Public policy to ensure post-trial access; commits itself to registering trialed products. Bristol Myers Squibb has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a life-threatening condition and no other therapeutic options. Once a product is approved, Bristol Myers Squibb commits itself

to registering it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Bristol Myers Squibb has no initiatives included for analysis aimed at building R&D capacity in countries in scope of the Index. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building R&D capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

PRODUCT DELIVERY

RANK 19

SCORE 1.15

Lacks a public commitment not to enforce patents in countries in scope. Bristol Myers Squibb does not have a public policy that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Bristol Myers Squibb discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

In addition to the older assets, Bristol Myers Squibb newly shared one IP asset with third-party researchers developing products for diseases in scope during the period of analysis. During the period of analysis Bristol Myers Squibb has newly shared one IP asset with third-party researchers developing products for diseases in scope. It shares this asset with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. The asset shared is molecule libraries. The new agreement is in addition to previously agreed IP sharing agreement with the Drugs for Neglected Diseases initiative (DNDi).

Uses licensing to enable generic supply. Bristol Myers Squibb has non-exclusive voluntary licensing agreements in place for two compounds (for the diseases in scope). Its broadest licence, for atazanavir sulfate (Reyataz®), encompasses 96 countries, including 68 middle-income countries in scope. The company announced in March 2020 that the marketing authorisations for daclatasvir (Daklinza®) will be withdrawn or will be allowed to lapse in countries where the product is no longer routinely prescribed or where there are other therapeutic options available. Following the withdrawal/lapse of the marketing authorisation in each country, the patents will be allowed to lapse. In the interim period between the withdrawal/lapse of a market-

ing authorisation and the patent expiry, the company will not enforce its patents for daclatasvir in the country. This means that 11 more countries in scope (including Egypt, Arab Rep. and Moldova), not included in the licence territory will soon be able to procure from generic companies.

Filed to register some new products in the majority of high burden countries. Bristol Myers Squibb has filed 10% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, apixaban (Eliquis®) for stroke has been filed for registration/registered in six high burden countries in scope.

Has access strategies for some supranationally procured products in scope for this analysis. Bristol Myers Squibb performs below average in securing access for products procured supranationally.[‡] For one of the four products assessed in this category, evidence was publicly available that demonstrated strategies both in countries eligible for supply from such procurers and also in at least one non-eligible country. For example, the company applies equitable strategies, makes donations and has licences for the viral hepatitis medicine daclatasvir (Daklinza™) outside the Global Fund procurement. For the remaining products it usually lacks evidence of equitable pricing strategies in non-eligible countries and evidence of patient reach.

No evidence of access strategies for any of its health-care practitioner-administered products in scope of this analysis. Bristol Myers Squibb has not disclosed, either publicly or to the Index, access strategies for any of the products assessed by the Index in this category.

Has few access strategies for its self-administered products for some countries in scope of this analysis. Bristol Myers Squibb performs poorly in this area. For three out of the five products assessed, weak evidences of access strategies which consider ability to pay/affordability was publicly disclosed. The company makes efforts to reach additional patients through inter-country pricing strategies and donations. For example, in Paraguay and Cambodia it uses donations to increase access to dasatinib (Sprycel®), an oncology medicine. Information which demonstrates patient reach through these approaches is not available.

No manufacturing capacity building initiatives included for evaluation. Bristol Myers Squibb has no initiatives included for analysis aimed at building manufacturing capacity in countries in scope of the Index. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building manufacturing capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

No supply chain capacity building initiatives included for evaluation. Bristol Myers Squibb has no supply chain capacity building initiatives included for analysis. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building supply chain capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

Three health system strengthening initiatives meet all Good Practice Standards. Bristol Myers Squibb performs above average in this indicator, with four health system strengthening initiatives that were included for analysis: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. Three initiatives meet all Good Practice Standards, having a clear governance structure and long-term aims in place. The company's initiatives were identified on the basis of publicly available data. Examples include:

- Delivering Hope™, raising awareness on hepatitis B and C, informing health policy and building health worker capacity to address these diseases and promote prevention in India and China, reaching 700,000 people.
- Secure the Future®, implementing over 250 programmes in 22 countries in Africa since 1999, including a sustainable model for HIV care in partnership with UNAIDS, WHO and the Baylor International Pediatric AIDS Initiative (BIPAI), treating over 1 million children in Botswana, Lesotho, eSwatini, Uganda and Tanzania.

Has not engaged in the development and implementation of inclusive business models. Compared to its peers, Bristol Myers Squibb performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon. No initiatives were disclosed to the Index and no initiatives were found following a review of publicly available data.

Few mechanisms identified to improve supply chain efficiency in countries in scope of the Index. Bristol Myers Squibb performs less well than other companies in this area, disclosing limited information publicly on the steps it takes to ensure the continuous supply of its medicine in countries in scope of the Index. In 2018, the company reported having a demand planning system in place. No additional information on ensuring continuous supply was identified publicly by the Index.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended timeframe. Bristol Myers Squibb does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities.

Donates in response to an expressed need and monitors delivery to end user. Bristol Myers Squibb previously reported that it ensures ad hoc donations are carried out in response to an expressed need. Moreover, it monitors the delivery until the end user; however it is unclear whether this is defined as the patient.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Bristol Myers Squibb is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Max Access Solution programme where it donates dasatinib (Sprycel®) for leukaemia to 15 countries since 2017.

[‡] Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

| RANK | SCORE |
|-----------|-------------|
| 16 | 1.80 |
| 18 (2018) | |

Daiichi Sankyo Co, Ltd

Stock Exchange: Tokyo Stock Exchange • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 15,348

PERFORMANCE IN THE 2021 INDEX

16th place. Daiichi Sankyo is in the lower ranks across all Technical Areas, with weak performance in R&D. There is a lack of evidence of access strategies and it has a poor performance in responsible promotional practices.

Governance of Access: 16th place. Daiichi Sankyo performs poorly in this area. The company does not have a clear access-to-medicine strategy with measurable objectives and a business rationale. The company conducts internal and external audits but does not demonstrate other components of compliance controls looked for by the Index.

Research & Development: 20th place. Daiichi Sankyo performs poorly in this area. It has no structured process for the development of access plans during R&D and does not publicly disclose a post-trial access policy. It has 11 priority R&D projects in its pipeline but does not report access plans for its late-stage candidates.

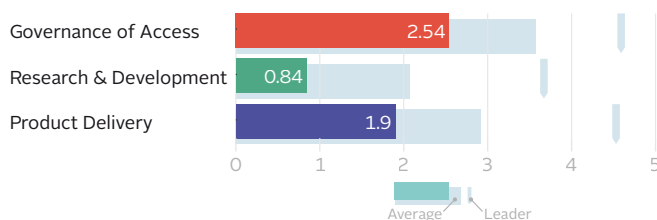
OPPORTUNITIES FOR DAIICHI SANKYO

Develop an access-to-medicine strategy and expand operations. Daiichi Sankyo can establish an access strategy that is integrated within its corporate business strategy building on its Group Policy on Access to Healthcare. Such a strategy can apply to all therapeutic areas in which it operates. It can also include risk mitigation of non-compliant or corrupt activities and a balanced scorecard approach for sales incentives, thus not solely promoting sales volumes as a performance target for its sales agents in countries in scope. In 2020 Daiichi Sankyo established a subsidiary in Vietnam, the fourth Index country where it now operates. It can expand operations to serve more countries in scope of the Index.

Develop an access planning process and access plans for all R&D projects. Daiichi Sankyo can develop a formal access planning process and accordingly develop access plans for all clinical Phase II projects, such as its diagnostic tests for Genoscholar®, its measles-mumps-rubella combination vaccine and for Valemetostat for leukaemia. Further, Daiichi Sankyo can develop and publish a post-trial access policy allowing for continued access to investigational treatments for clinical trial participants and can commit to registering the product in countries where clinical trials take place while ensuring affordability.

Improve access to patented products on WHO EML. Daiichi Sankyo has three patented products on patent which are on the 2019 WHO Model List of Essential Medicines (WHO EML). The company can further prioritise expanding access to these products, such as edoxaban (Lixiana®) for ischaemic heart disease and management of stroke and other blood clots, by increasing affordability and supply using mechanisms such as equitable pricing and/or non-exclusive voluntary licensing in countries in scope. The company should, e.g., take into account the different socio-economic levels and offer tailored pricing for different population segments.

How score was achieved



Product Delivery: 15th place. Daiichi Sankyo performs below average in this area. The company has a strong commitment not to enforce or file patents in the majority of the countries in scope (including LMICs and LICs). It applies a few access strategies to some of its products, yet only in upper-middle income countries. It does not perform well in capacity building, with four initiatives included across all fields, of which one meets all Good Practice Standards.

CHANGE SINCE THE 2018 INDEX

- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Launched a new initiative in Vietnam to promote the proper use of medicines with medication guiding tools through clinical pharmacists intervention from July 2019 to February 2020.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

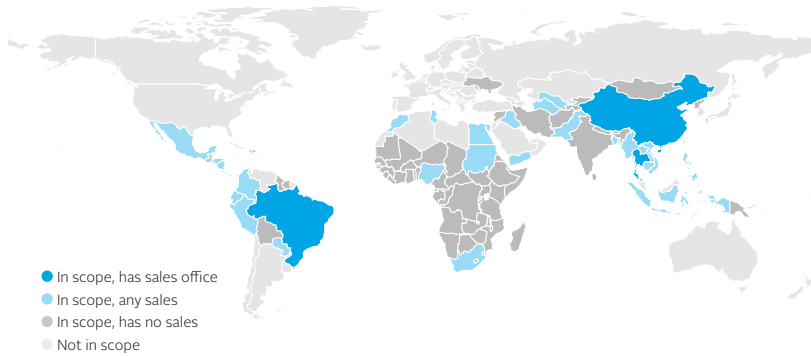
Business segments: Prescription drugs; Healthcare (OTC) products; Other
Therapeutic areas: Oncology; Genetic/Orphan Diseases; Inflammation/Immunology; Cardiorenal Diseases; Neurology; Vaccines
Product categories: Innovative medicines; Generic medicines; Vaccines; Consumer health
M&A news: None since publication of the 2018 Index.

Daiichi Sankyo's products are sold in 34 out of 106 countries in scope. Daiichi Sankyo has sales offices in 3 countries and sells via suppliers into 31 additional countries.

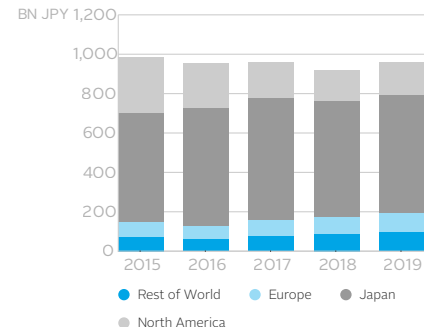
Revenue by segment (2019) – JPY

| | |
|---------------------------|-----------------|
| Prescription drugs | 911.3 bn |
| Healthcare (OTC) products | 68.4 bn |
| Other | 2.1 bn |
| Total | 981.8 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

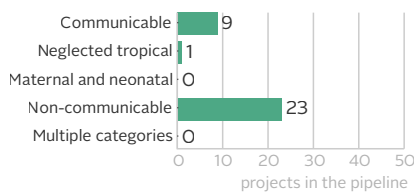
PIPELINE for diseases and countries in scope

Daiichi Sankyo has a total of 33 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 11 projects. The other 22 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on tuberculosis (4 projects). Of the projects targeting other diseases in scope, the focus is on oncology (18). 6 R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (5).^{*} No evidence of access planning was in place for any of these projects.

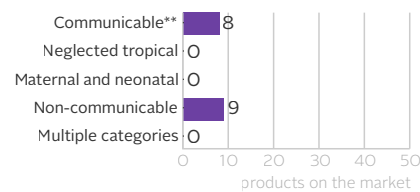
PORTFOLIO as selected for analysis by the Index

Daiichi Sankyo has 11 medicines in scope, 9 of which are on patent and 3 vaccines. 36% of these medicines (4) are on WHO's EML. In addition, the company markets 3 diagnostics. The off-patent medicines target ischaemic heart disease and lower respiratory tract infections. The on-patent medicines mainly target non-communicable diseases such as cardiovascular diseases (6), mental health and oncology. In addition, one medicine targets influenza. Daiichi Sankyo's preventative vaccines target pertussis and tetanus. The diagnostics in scope are for tuberculosis (3). Access strategies were analysed for 5 products on Daiichi Sankyo's portfolio – nationally procured self-administered products (5).

33 projects in the pipeline



17 products as selected for analysis by the Index[†]



Breakdown of projects^{*}

3 diagnostic Genoscholar[®] tests, in collaboration w. Nipro Corporation. To detect TB including pyrazinamide- and multidrug-resistant TB infections.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 1 | 0 | 0 | 1 | 0 | 2 | 0 |
| Addresses needs of LMICs [*] | 0 | 5 | 2 | 1 | 2 | 10 | 0 |
| Other projects in scope | 0 | 5 | 4 | 2 | 1 | 12 | 0 |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 3 | 6 | | | 9 |
| off patent | 1 | 1 | | | 2 |
| Vaccines | 3 | 0 | | | 3 |
| Diagnostics | | | 3 | | 3 |
| Other | | | | 0 | 0 |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

[†] Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria

drug development phases were not included in this breakdown.

#Projects in the discovery phases and/or other

Daiichi Sankyo Co, Ltd

GOVERNANCE OF ACCESS

RANK 16

SCORE 2.54

Does not have a clear access-to-medicine strategy with measurable objectives. Unlike most of its peers, Daiichi Sankyo does not have a clear strategy integrated within its overall corporate strategy. It has a general commitment to improve access to medicine, the Daiichi Sankyo Group Policy on Access to Healthcare. The highest responsibility for access is indirectly with the board, with its Global Management Committee discussing the access policy.

Provides evidence of financial and non-financial access-related incentives at the executive level. Although it performs poorly in access-to-medicine strategy, Daiichi Sankyo performs well here. It incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards, as part of their CSR goals. The CEO also has access-related incentives.

Does not publicly disclose outcomes of its access-to-medicine activities. Daiichi Sankyo performs below average in transparency regarding access initiatives. It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope, namely with its capacity building initiatives. It does not, however, share the outcomes of its access activities during the period of analysis.

Performs comparatively poorly in responsible promotional practices. Daiichi Sankyo's sales agents are solely incentivised on sales volume targets. The company does not disclose the level at which sales incentives are set. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Daiichi Sankyo performs below average, with evidence of some of the components looked for by the Index: audits (both internal and external) and it reports working on a compliance system for third parties it engages with in Brazil.

Publicly supports the Doha Declaration on TRIPS and Public Health. Daiichi Sankyo publicly shares a general statement on the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely it challenges the use of compulsory licensing, stating it should be carefully exercised. There is no evidence of a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

RANK 20

SCORE 0.84

No structured process for access planning reported. Daiichi Sankyo does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with no access plans in place. Daiichi Sankyo has 11 projects, including one late-stage candidate, in its pipeline that target a priority product gap. The company focuses mostly on tuberculosis. There is no evidence of an access plan for Daiichi Sankyo's late-stage candidate targeting a priority product gap.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for the late-stage projects. In this analysis, Daiichi Sankyo has five late-stage R&D projects in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs*. Primarily, these projects have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer.

No public disclosure of post-trial access policy. Daiichi Sankyo does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants, nor did it disclose such a policy to the Index.

No R&D capacity building initiatives included for evaluation. Daiichi Sankyo performs poorly in this area. Companies could submit a maximum of five initiatives in this area. The company reported no information to the Index about R&D capacity building in Index countries.

PRODUCT DELIVERY

RANK 15

SCORE 1.90

Public commitment not to enforce patents in countries in scope. Daiichi Sankyo commits publicly to neither file for nor enforce patents. This commitment applies in all least developed countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Daiichi Sankyo publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreement. Daiichi Sankyo reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases ini-

tiative (DNDi) and the Global Health Innovative Technology Fund. During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No use of non-assert or licensing arrangements. Daiichi Sankyo does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Daiichi Sankyo did not disclose evidence of filing any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, edoxaban (Lixiana®) for ischaemic heart disease and stroke is registered/has been filed for registration in twelve countries in scope including El

Salvador and Vietnam.

No supranationally procured products. Daiichi Sankyo has no products eligible for scoring in this indicator.

No healthcare-practitioner-administered products. Daiichi Sankyo has no products eligible for scoring in this indicator.

Has few access strategies for its self-administered products for some countries in scope for this analysis. Daiichi Sankyo performs poorly in this area. The company provides examples of access strategies which consider affordability only in UMICs for three out of the five products assessed. It makes efforts to reach additional patients through the use of both inter and intra country pricing strategy. For example, in Brazil it applies equitable pricing strategy for lurasidone hydrochloride (Latuda®), a treatment for bipolar affective disorder and schizophrenia

to reach 12,000 patients. The company provided evidence of patient reach through this approach. It falls short to provide example in LMICs or LICs for any of the product.

Two manufacturing capacity building initiative included for evaluation. Daiichi Sankyo performs below average in this area. The company submitted the maximum of five initiatives, of which two met all criteria for inclusion, including a technology transfer of prasugrel (Effient®) in China for the treatment of stroke and a collaboration with the Center for Research and Production of Vaccines and Biologicals (POLYVAC) in Vietnam for the manufacturing of a measles-rubella vaccine. The initiatives did not meet all Good Practice Standards[‡] as Daiichi Sankyo did not demonstrate that they were either guided by clear goals/objectives, aim for sustainability a long-term aims and are measuring outcomes in relation to manufacturing capacity.

No supply chain capacity building initiatives included for evaluation. Daiichi Sankyo performs poorly in this area, with no supply chain capacity building initiatives included for analysis. Companies could submit a maximum of five initiatives. The company reported no information to the Index about supply chain capacity building in Index countries.

One health system strengthening initiative meets all Good Practice Standards. Daiichi Sankyo has average performance in this area. The company submitted four health system strengthening initiatives, of which two were included for analysis. One initiative, clinical pharmacist intervention in Vietnam, promoting appropriate use of medicine through the development of medicine guidelines, met all Good Practice Standards: i.e. addresses local needs, has local partners, mitigates risk of conflict of interest, is guided by clear goals and objectives, (plans to) measure outcomes, has a governance structure in place and aims for sustainability/integration in the local health system. For the other initiative, Mobile Healthcare Field Clinical Services in Tanzania, which reportedly increased the measles immunisation ratio among infants from 78% to 96%, Daiichi Sankyo did not provide sufficient evidence on how the initiative aims for sustainability and/or integration in the local health system.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, Daiichi Sankyo performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon. It did not report on any initiative.

The company has some mechanisms in place to ensure continuous supply in countries in scope of the Index. Daiichi Sankyo has average performance in this area, disclosing some strategies to ensure the continuous supply in countries in the scope of the Index. The company provides evidence of having a Sales & Operations Planning process in place at the headquarter level, which is aimed at aligning demand and supply, covering some countries in scope of the Index. The company reports that a multiple supplier approach for key APIs has been implemented or is being considered for implementation. The company did not provide evidence of ensuring supply to Least Developed

Countries or communicating with governments on potential supply disruptions.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope. Daiichi Sankyo provides evidence of reporting SF medicines to relevant national health authorities, on a case-by-case basis. It does not, however, require reporting to occur within the time frame of ten days looked for by the Index, nor does it distinguish timeframes for reporting cases which only require visual inspection to be confirmed.

Donates in response to an expressed need, but does not monitor delivery to end user. Daiichi Sankyo reports that it ensures ad hoc donations are carried out in response to an expressed need. However, it is unclear if it monitors the delivery until the end user, though it selects partners with a secure and reliable monitoring system.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Daiichi Sankyo is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible.

‡ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 11 | 2.87 |
| 8 (2018) | |

Eisai Co, Ltd

Stock Exchange: Tokyo Stock Exchange • Ticker: 4523 • HQ: Tokyo, Japan • Employees: 10,998

PERFORMANCE IN THE 2021 INDEX

11th place. Eisai has an average performance across all technical areas of the Index. It shows a strong performance in its approach to structured donation programmes, but its performance in responsible business practices is average.

Governance of Access: 8th place. Eisai is a middle-performing company in this area. It has an access-to-medicine strategy that is clearly linked to a business rationale but is not embedded in its overall corporate strategy.

Research & Development: 10th place. Eisai has an average performance in this area. Half of its priority R&D projects are covered by an access plan, but none of the projects that address a public health need in LMICs are covered by an access plan.

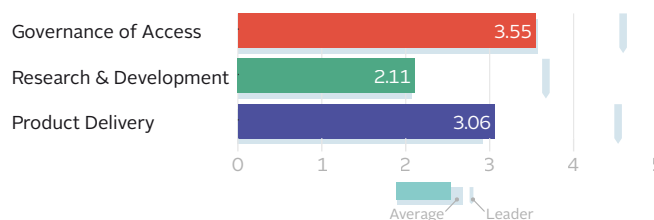
OPPORTUNITIES FOR EISAI

Expand registration for epilepsy medicines. Eisai has one of the largest patented antiepileptic portfolios in scope. Its antiepileptic perampanel (Fycompa®) is currently registered in one out of ten countries with highest epilepsy burden. It can file for registration for these antiepileptics, including rufinamide (Inovelon®), which is currently not registered in any of those countries, in all ten countries with highest epilepsy burden. These include countries such as Nigeria, Tajikistan, Angola, Mozambique.

Apply access planning process to all R&D projects. Eisai has a structured process in place that encompasses some projects in the pipeline and starting in Phase II of clinical development. It has specific access plans in place for some late-stage projects. These plans are for projects developed in partnership with DNDi. The company can expand its access plans to all late-stage R&D projects in the pipeline. It can develop access plans for lenvatinib (Lenvima®) (multiple indications) for treatment of cancer.

Expand access strategies to reach low-income country populations. Eisai deploys access strategies in Asian countries for different products such as eribulin (Halaven®) for breast cancer and donezepil (Aricept®) for Alzheimer's disease that consider affordability. These practices can be expanded to more low-income countries and other geographic regions with a high burden of breast cancer outside Asia, such as Ukraine, Armenia, Moldova and Morocco.

How score was achieved



Product Delivery: 10th place. Eisai has an average performance. The company has newly shared one IP asset with third-party researchers. It has access strategies in place for some of its products but these are mainly focused on middle-income countries. It applies multiple mechanisms to ensure continuous supply and has a strong structured donation programme to achieve elimination of lymphatic filariasis.

CHANGE SINCE THE 2018 INDEX

- Shares chemical libraries with the Global Antibiotic Research & Development Partnership (GARDP) to screen for novel compounds with antibacterial activity.
- Newly applies access planning process to all projects in R&D pipeline.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Reports fewer products falling under the commitment not to enforce or file for patents.
- Launched a new initiative in China via a partnership with JD Health on information on current care for people with Alzheimer's disease and caregivers.
- Supports the Association for Aid and Relief, Japan (AAR Japan) programme, in Sudan on awareness of early diagnosis and treatment among mycetoma patients and caregivers, in remote areas working with the Khartoum University Mycetoma Research Center (MRC).
- Joined the COVID-19 Therapeutics Accelerator.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

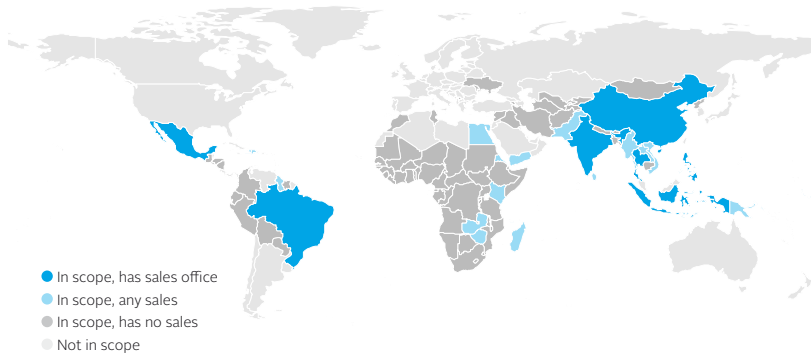
Business segments: Pharmaceutical business; Other business
Therapeutic areas: Neurology; Oncology
Product categories: Innovative medicines
M&A news: Divested its generic pharmaceutical subsidiary Elmed Eisai to Nichi-Iko in 2019.

Eisai's products are sold in 30 out of 106 countries in scope. Eisai has sales offices in 7 countries, sells via suppliers in 5 countries and via pooled procurement into 18 additional countries.

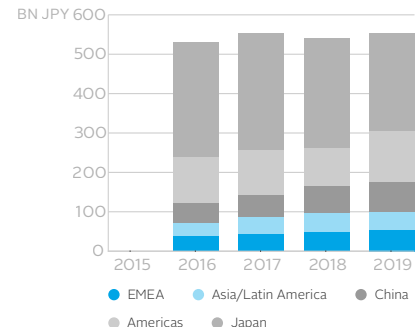
Revenue by segment (2019) – JPY

| | |
|-------------------------|-------------------|
| Pharmaceutical business | 577.267 bn |
| Other business | 118.355 bn |
| Total | 695.622 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

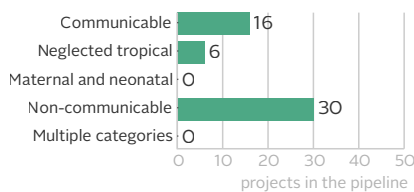
PIPELINE for diseases and countries in scope

Eisai has a total of 52 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 22 projects. Remarkably, over 40% of Eisai's R&D projects target priority diseases. The other 30 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (10 projects). Of the projects targeting other diseases in scope, the focus is on oncology (21). 13 R&D projects are in late-stage development that target either a priority disease (4) or address a public health need in LMICs (9).^{*} Evidence of access planning was in place for 15% of these projects: 2 targeting a priority disease but none addressing a public health need in LMICs.

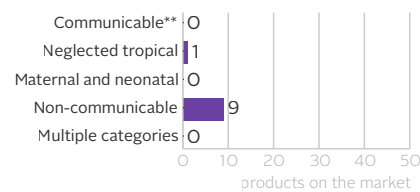
PORTFOLIO as selected for analysis by the Index

Eisai has 10 medicines in scope, 6 of which are on patent. 20% of these medicines (2) are on WHO's EML. The off-patent medicines (2) target mainly mental health. One product targets the neglected tropical disease lymphatic filariasis (LF) and one further product is for cardiovascular diseases. The on-patent medicines mainly target epilepsy (3) and oncology (2). In addition, one product is for Alzheimer's disease. Access strategies were analysed for 4 products on Eisai's portfolio – nationally procured HCP-administered (1) and self-administered products (3).

52 projects in the pipeline



10 products as selected for analysis by the Index⁺



Breakdown of projects[#]

Eritoran, previously examined as a potential therapy for severe sepsis, influenza and Ebola, is now being studied as a potential treatment for COVID-19

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 10 | 0 | 3 | 1 | 0 | 14 | 2 |
| Addresses needs of LMICs [*] | 0 | 5 | 2 | 3 | 4 | 14 | 0 |
| Other projects in scope | 0 | 8 | 4 | 3 | 0 | 15 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 0 | 6 | | | 6 |
| off patent | 2 | 2 | | | 4 |
| Vaccines | | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

⁺ Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Eisai Co, Ltd

GOVERNANCE OF ACCESS

RANK 8

SCORE 3.55

Has an access-to-medicine strategy with measurable objectives and a business rationale. Eisai has an average performance. It has an access strategy embedded in its human health care philosophy and states a commitment to long-term sustainable solutions including affordable pricing. The strategy covers some of the therapeutic areas in which the company is involved, including Alzheimer's disease and cancer. The highest responsibility for access lies indirectly with the board, namely with a senior executive.

Provides evidence of financial and non-financial access-related incentives at executive level. Eisai performs well here. It incentivises its in-country managers, including country-level corporate officers or regional managers, to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives, linked, for example, to initiatives aiming at eliminating neglected tropical diseases (NTDs).

Publicly discloses outcomes of a subset of its access-to-medicine activities. Eisai performs well in transparency regarding access activities. It discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope, related, for example, to its business plan EWAY 2025. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, including through the IFPMA Global Health Progress platform.

Has an average performance in responsible promotional practices. Eisai's sales agents are not solely incentivised on sales volume targets. The company does not disclose the level at which sales incentives are set. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), unless required by local regulations, nor does it disclose a policy limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eisai performs relatively well, demonstrating some of the components looked for by the Index: fraud-specific risk assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. It does not, however, demonstrate evidence of country risk-based assessments.

Publicly supports the Doha Declaration on TRIPS and Public Health. Eisai publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations, stating that Article 31bis covering the use of compulsory licence should be invoked under appropriate circumstances. It does not have a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

RANK 10

SCORE 2.11

Access planning processes encompass some projects in pipeline. Eisai has a structured process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects for diseases in scope. Eisai begins developing access plans for R&D projects in Phase II or earlier of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to peers, with access plans in place for 50% of the late-stage candidates. Eisai has 22 projects including four late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on malaria. Of Eisai's four late-stage candidates targeting a priority product gap, there is evidence of an access plan for two. These plans for (fosravuconazole) Nailin® are in partnership with DNDi.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for these projects. In this analysis, Eisai has nine late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer.

Policy to ensure post-trial access; commits itself to registering trialed products. Eisai has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. This policy

covers a subset of clinical trial participants on a case-by-case basis. Once a product is approved, Eisai commits itself to registering newly approved products in all countries where clinical trials for these products have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

Two R&D capacity building initiatives included for evaluation. Eisai performs below average in this indicator. The company submitted two initiatives aimed at building R&D capacity, which were both included for analysis but did not meet all Good Practice Standards.† For example, Eisai collaborates with scientists in Cameroon on drug discovery projects through WIPO Re:Search.

PRODUCT DELIVERY

RANK 10

SCORE 3.06

Public commitment not to enforce patents in countries in scope. Eisai publicly pledges to neither file for nor enforce patents. This commitment applies to Least Developed Countries and low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Eisai publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date, jurisdiction, publication number and publication date.

Shares some IP assets with third-party researchers.

Eisai has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes four IP assets shared with research institutions and the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries.

No use of non-assert or licensing arrangements. Eisai does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of

high burden countries. Eisai has filed 50% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, eribulin (Halaven®), for breast cancer has been filed for registration/registered in five high burden countries in scope, including Myanmar and Morocco.

No supranationally procured products. Eisai has no products eligible for scoring in this indicator.

Has access strategies for the healthcare practitioner-administered product in scope of this analysis. Eisai has average performance in this area. The company pro-

158 ‡ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

vided examples of access strategies which consider affordability in both an UMIC and a LMIC for the only product assessed. It makes efforts to reach additional patients using equitable pricing strategies. For example, in India, for eribulin (Halaven®), for breast cancer, the company applies intra-country pricing strategy through the patient assistant programme 'Hope to Her' where the co-payment is set at several tiers in accordance with the income level and health insurance availability of the patients, ranging from the full price to free of charge depending on the condition, while strengthening the health system via healthcare practitioner trainings. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope for this analysis. Eisai performs average in this area. The company provides examples of access strategies which consider affordability in both UMICs and LMICs for two of the three products assessed. It makes efforts to reach additional patients through equitable pricing strategies. For example, in Philippines, for the donezepil (Aricept®), a medicine for Alzheimer, the company participates in tenders, offers discount to senior citizens and has a patient assistance programme in place to increase affordability and access for patients. The company is able to provide evidence of how patient reach has been increased through the approaches used.

Two manufacturing capacity building initiative included for evaluation. Eisai performs below average in this area. The company submitted four initiatives, of which two met all criteria for inclusion. The initiatives, which included technology transfers of diethylcarbamazine (DEC) for the treatment of lymphatic filariasis in India and of cancer medicine eribulin (Halaven®), lenvatinib (Lenvima®) and antiepileptic drugs rufinamide (Inovelon®) and perampanel (Fycopma®) in Brazil and Mexico, did not meet all Good Practice Standards[§] as Eisai did not sufficiently demonstrate that outcomes are measured.

One supply chain capacity building initiative included for evaluation. Eisai performs below average in this area. The company submitted the maximum of five initiatives, of which one met all criteria for inclusion but not all Good Practice Standards.[§] Eisai participates in the NTD Supply Chain Forum, improving adequate supply of donated DEC tablets for the treatment of lymphatic filariasis to the WHO and the countries' Mass Drug Administration programmes. Eisai does not sufficiently demonstrate how the initiative aims for sustainability or that it is measuring outcomes.

Four health system strengthening initiatives included for evaluation. Eisai performs below average in this area. The company submitted the maximum of five initiatives, of which four met all criteria for inclusion: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. For example, since 2019 Eisai supports an educational mycetoma awareness programme in Sudan, which focuses on the importance of early diagnosis. Nearly 1500 people living in rural areas participated in the awareness activities and patients who are diagnosed as mycetoma received treatments and surgeries. None of the initiatives met all Good Practice Standards, as Eisai does not sufficiently demonstrate in what ways the initia-

tives aim for sustainability or integration in the local health system.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, Eisai performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Eisai performs well in this area, taking multiple steps to ensure the continuous supply of its medicine in countries in scope of the Index. Like other companies, Eisai works together with distribution partner DKSH to improve wider location access and product tracking information in South East Asia. For the distribution of DEC for the treatment of lymphatic filariasis, Eisai uses the NTDeliver system, sharing information with WHO and other pharmaceutical companies as well as the global health organisations which are taking important roles for the delivery to the community.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days.

Eisai has a policy for reporting SF medicines to national health authorities and WHO within 24 hours to 7 days. It distinguishes reporting time frames for cases which only require visual inspection to be confirmed based on the Risk evaluation committee.

Donates in response to an expressed need, but does not monitor delivery to end user. Eisai reports that it ensures ad hoc donations are carried out in response to an expressed need. However, it does not monitor the delivery until the end user as the monitoring system differs for each subsidiary company. For example, it donated medicines to Indonesia in 2018 in response to an earthquake and tsunami.

Publicly commits to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Eisai publicly commits itself to eliminating lymphatic filariasis by donating diethylcarbamazine citrate (DEC) in 24 countries in scope of the Index since 2013.

§ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 18 | 1.59 |
| 20 (2018) | |

Eli Lilly & Co

Stock Exchange: New York Stock Exchange • Ticker: LLY • HQ: Indianapolis, Indiana, United States • Employees: 35,074

PERFORMANCE IN THE 2021 INDEX

18th place. Eli Lilly is in the lower ranks across, with weak performances in all Technical Areas. The company features a comparatively small priority R&D pipeline and has no structured process for access planning during R&D.

Governance of Access: 13th place. Eli Lilly performs below average in this area. The company's Lilly 30x30 programme is an access-to-medicine strategy that covers some therapeutic areas. Yet, the company performs relatively poorly in responsible promotional practices with sales agents solely incentivised on sales volume targets and with no information publicly available on transfer of values to healthcare professionals in countries in scope.

Research & Development: 19th place. Eli Lilly falls to the lower ranks in R&D. It does not have a structured process for access planning during R&D. Only a few access plans for late-stage R&D projects are identified.

OPPORTUNITIES FOR ELI LILLY

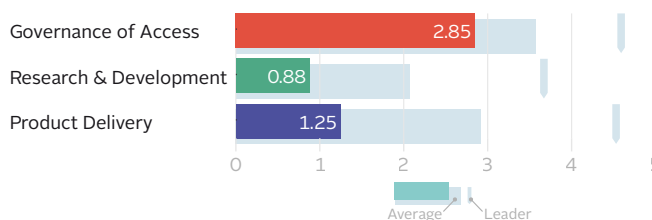
Improve transparency on access-to-medicine activities. Eli Lilly can improve transparency on its access-to-medicine activities by publicly disclosing progress and outcomes of such activities consistently, including through partners' platforms such as the IFPMA Global Health Progress. This applies to initiatives active during the period of analysis, namely its ongoing Lilly 30x30 programme in LMICs.

Develop an access planning process and access plans for all R&D projects. Eli Lilly can develop a formal access planning process and accordingly develop access plans for all clinical Phase II projects such as its diabetes projects nasal glucagon and tirzepatide (dual GIP and GLP-1 receptor agonist) in late-stage clinical development. Furthermore, Eli Lilly can update and publish a post-trial access policy allowing for continued access to investigational treatments for clinical trial participants and can commit to registering the product in countries where clinical trials take place while ensuring affordability.

Improve access to products on WHO EML. Eli Lilly has three products which are on the 2019 WHO Model List of Essential Medicines (WHO EML), for diabetes. The company can prioritise expanding access to these products by increasing affordability and supply through equitable pricing. The company should take into account the different socio-economic levels and offer tailored pricing for different population segments.

Expand operations and registration of medicines. Eli Lilly's most widely registered new product, dulaglutide (Trulicity®) for Type 2 diabetes mellitus, is registered in only seven countries in scope. The company now operates in fourteen countries in scope of the Index. It can expand operations to more countries and expand registration of new products such as dulaglutide (Trulicity®).

How score was achieved



Product Delivery: 18th place. Overall, Eli Lilly performs poorly. It does not disclose, either publicly or to the Index, access strategies for its products and has no manufacturing and supply chain capacity building initiatives, either. It is engaged in three health system strengthening initiatives that meet all Good Practice Standards.

CHANGE SINCE THE 2018 INDEX

- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Has a new Steering Committee since 2018, overseeing progress on Lilly 30x30 initiative.
- Disclosed a progress in patient reach through the 30x30 efforts.
- Entered into an agreement with the Bill and Melinda Gates Foundation to facilitate access to new therapeutic antibodies in LMICs and released Lilly's Principles of COVID-19 Antibody Therapy Pricing and Access.
- Joined the COVID-19 Therapeutics Accelerator.
- Partners with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four Pharmaceutical companies on Africa Health Worker Training Initiative.
- Supported its global health partner, AMPATH (the Academic Model Providing Access to Healthcare), with the expansion of its model to two more countries: Ghana and Mexico.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, Eli Lilly declined to submit data to the Access to Medicine Index.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segment: Human pharmaceutical products

Therapeutic areas: Diabetes and other endocrinology; Immunology; Neuroscience; Oncology.

Product categories: Innovative medicines.

M&A news: Spun off Elanco (Animal health) in 2019; acquired Loxo Oncology for USD 8 billion in 2019 and Dermira Inc. (immunology) in 2020 for approximately USD 1.1 billion in 2020. Announced the acquisition of Disarm

Therapeutics (axonal degeneration) in October 2020, for USD 135 million upfront and up to USD 1.225 billion in potential future milestones.

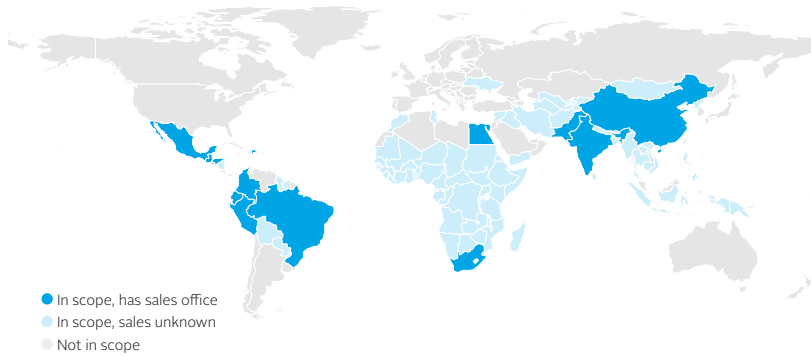
Eli Lilly's products are sold in 72* out of 106 countries in scope. Eli Lilly has sales offices in 14 countries and sells products via suppliers or pooled procurement in 68* countries.

*In 2016, Lilly reported sales in 72 countries.

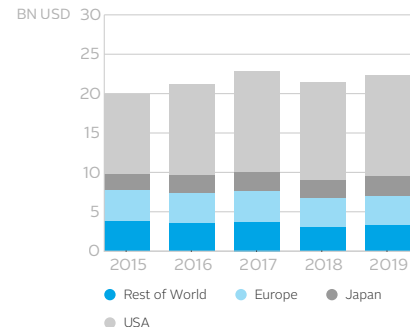
Revenue by segment (2019) – USD

| | |
|-------------------------------|----------|
| Human pharmaceutical products | 22.32 bn |
| Total | 22.32 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Eli Lilly has a total of 46 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 6 projects. The other 40 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on tuberculosis (3 projects) and COVID-19 (3). Of the projects targeting other diseases in scope, the focus is on oncology (15) and diabetes mellitus (14).

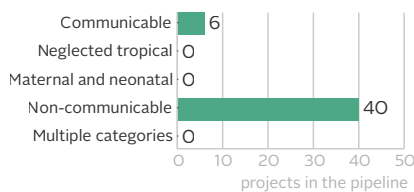
17 R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (14)*. Evidence of access planning was reported in these sections for 6% of these projects: 1 targeting a priority disease but none addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

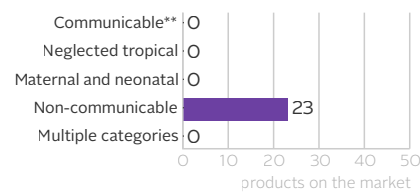
Eli Lilly has 23 medicines in scope, 15 of which are on patent. 13% of these medicines are on WHO's EML (3 products). The off-patent medicines target non-communicable diseases (NCDs) such as diabetes (5), cancer (1), cardiovascular diseases and mental health. The on-patent medicines target the NCDs diabetes (9), cancer (4) cardiovascular disease (1) and migraine (1).

Access strategies were analysed for 9 products on Eli Lilly's portfolio – nationally procured HCP-administered (4) and self-administered products (5).

46 projects in the pipeline



23 products as selected for analysis by the Index †



Breakdown of projects*

Nasal glucagon powder for severe hypoglycaemia in children (aged ≥ 4 years) and adults with diabetes.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 1 | 0 | 2 | 1 | 0 | 4 | 1 |
| Addresses needs of LMICs* | 0 | 15 | 3 | 3 | 8 | 29 | 0 |
| Other projects in scope | 0 | 5 | 2 | 1 | 3 | 11 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 0 | 15 | | | 15 |
| off patent | 3 | 5 | | | 8 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

† Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Eli Lilly & Co

GOVERNANCE OF ACCESS

RANK 13

SCORE 2.85

Has an access-to-medicine strategy with measurable objectives and a business rationale. Eli Lilly has an average performance. It has an access strategy, centred around the Lilly 30x30 programme, which goes beyond philanthropy. The strategy covers some of the therapeutic areas in which the company is involved, for example some non-communicable diseases (NCDs) including diabetes. While the board oversees access, the highest responsibility lies with the CEO and the executive team. A new Steering Committee oversees progress on Lilly 30x30.

Provides evidence of financial access-related incentives at the executive level. The CEO has access-related incentives linked to its ability to drive the 30x30 strategy and ensure progress. Eli Lilly does not disclose, however, whether senior executives and in-country managers are also incentivised toward access goals.

Does not publicly disclose outcomes of its access-to-medicine activities. Eli Lilly performs below average on transparency regarding access initiatives. It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope, also via the IFPMA Global Health Progress platform, namely with its Lilly 30x30 Programme initiatives. It does not, however, share the outcomes of its individual access activities during the period of analysis, but reports having reached 7.2 million patients in 2019, compared to 2015 through Lilly 30x30.

Performs comparatively poorly in responsible promotional practices. Eli Lilly does not disclose whether sales agents are incentivised on other measures than sales volume. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional

activities), unless required by local regulations or trade associations.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eli Lilly has an average performance, with evidence of some of the components looked for by the Index: A continuous system to monitor activities, audits and formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of fraud-specific risk assessment or country risk-based assessment.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Eli Lilly does not publicly share any support of or statement on the Doha Declaration on TRIPS and Public Health, but states that its position aligns with IFPMA. There is no evidence of a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

RANK 19

SCORE 0.88

No structured process for access planning reported. Eli Lilly does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 33% of the late-stage candidates. Eli Lilly has six projects including three late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on coronaviral diseases and tuberculosis. Of Eli Lilly's three late-stage candidates targeting a priority product gap, one has evidence of an access plan in place, which is for the TBA-7371 / DprE1 Inhibitor. This project runs in partnership with the TB alliance.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for the late-stage projects. In this analysis, Eli Lilly has 14 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer.

Public policy to ensure post-trial access; commits itself to registering trialed products. Eli Lilly has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants with a serious condition and no alternative treatments are available. Once a

product is approved, Eli Lilly commits itself to registering it in all countries where clinical trials for the product have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Eli Lilly has no initiatives included for analysis aimed at building supply chain capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building R&D capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

PRODUCT DELIVERY

RANK 18

SCORE 1.25

Public commitment not to enforce patents in countries in scope. Eli Lilly publicly pledges to neither file for nor enforce patents. This commitment applies to all Least Developed Countries.

Publicly discloses detailed information on patent status. Like most of its peers, Eli Lilly publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

In addition to the older assets, Eli Lilly newly shared one IP asset with third-party researchers developing products for diseases in scope during the period of analysis. During the period of analysis Eli Lilly newly shared one IP asset with third-party researchers developing products for diseases in scope. It shares this asset with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. The asset shared is molecule libraries. The new agreement is in addition to previously agreed IP sharing agreement with the product development partnership TB Alliance.

No use of non-assert or licensing arrangements. Eli Lilly does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Eli Lilly did not disclose evidence of filing any of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product dulaglutide (Trulicity®) for diabetes mellitus is reg-

istered in seven countries in scope, including El Salvador and India.

No supranationally procured products. Eli Lilly has no products eligible for scoring in this indicator.

No evidence of access strategies for any of its health-care practitioner-administered products in scope of this analysis. Eli Lilly has not disclosed, either publicly or to the Index, access strategies for any of the four products (three oncology medicines and a treatment for ischaemic heart disease) assessed by the Index in this category.

No evidence of access strategies for any of its self-administered products in scope for this analysis. Eli Lilly has not disclosed, either publicly or to the Index, access strategies for any of the five products, assessed by the Index in this category. Four products in this category are indicated for diabetes mellitus treatment.

No manufacturing capacity building initiatives included for evaluation. Eli Lilly has no initiatives included for analysis aimed at building manufacturing capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building manufacturing capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

No supply chain capacity building initiatives included for evaluation. Eli Lilly has no initiatives included for analysis aimed at building supply chain capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building supply chain capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

Two health system strengthening initiatives meet all Good Practice Standards. Eli Lilly has average performance in this area. The company reported no information to the Index about health system strengthening initiatives in countries in scope of the Index. Three initiatives were identified for selection based on publicly available information, of which two meet all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. These include:

- The HOPE Centre in South Africa, educating communities about diabetes mellitus and hypertension and providing clinical services. To date, 14,000 people have been screened.
- Health Worker Training Initiative, a multi-company partnership with Last Mile Health, Living Goods and the Bill & Melinda Gates Foundation, training and deploying 2,500 digitally enabled community health workers by 2022 in six sub-Saharan African countries.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, Eli Lilly performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon. No initiatives

were disclosed to the Index and no current status of any ongoing initiative was publicly available.

Some mechanisms identified to ensure continuous supply in countries in scope of the Index. Eli Lilly has average performance in this area, with limited information identified by the Index on the steps it takes to ensure the continuous supply of its medicine in countries in scope of the Index. Eli Lilly has policies and processes in place to align demand and supply, working together with local manufacturing and distribution sites. Eli Lilly reports having a global Product Shortage Prevention Strategy and a monitoring and reporting process for shortages in place. However, no details have been identified as to what these strategies and processes include.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended time frame. Eli Lilly does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities. It has a public policy on tackling counterfeit products.

Donates in response to an expressed need and monitors delivery to end user. Eli Lilly has a public policy in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors the delivery until the end user.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Eli Lilly is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, the company is engaged in other structured donation programmes, such as the Life for a Child programme where it donates insulin lispro, human insulin analogue (Humalog®) for Type 1 diabetes mellitus in 37 countries since 2009.

| RANK | SCORE |
|-----------|-------------|
| 14 | 2.33 |
| 13 (2018) | |

Gilead Sciences Inc

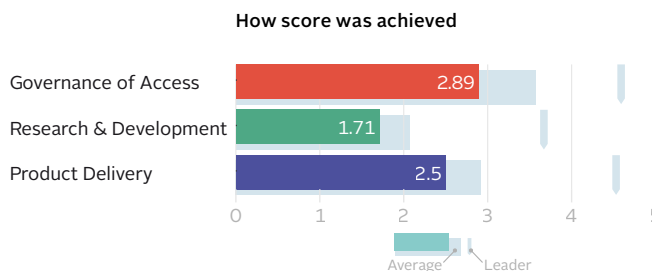
Stock Exchange: NASDAQ • Ticker: GILD • HQ: Foster City, California, United States • Employees: 12,000

PERFORMANCE IN THE 2021 INDEX

14th place. Gilead has an average overall performance. It performs strongly in financial access-related incentives but poorly in responsible promotional practices. The company has a small R&D pipeline with a few access plans, yet it strongly engages in licences to enable generic supply.

Governance of Access: 12th place. Gilead performs below average in this area. The company offers access-related incentives at the executive level, but discloses limited information in the area of responsible promotional practices.

Research & Development: 13th place. Gilead performs average in this area. The company has a structured process in place for access planning during R&D for some of its products but does not publicly disclose a post-trial access policy. It has a small-sized priority R&D portfolio compared to peers with one product covered by an access plan.



Product Delivery: 13th place. Gilead has an average performance in this area. The company filed to register some of its products in the majority of the high-burden countries, yet it implements strategies to improve access to only some of its products in some markets. The company performs strongly in licensing, with licences in place for ten marketed compounds.

OPPORTUNITIES FOR GILEAD

Manage the risk of misconduct and non-compliance in LMICs. Gilead can review sales incentive structures to adopt a balanced scorecard approach consistently, thus not solely promoting sales volumes as a performance target for its sales agents in LMICs. Furthermore, it can strengthen processes to mitigate the risk of non-compliant or corrupt activities occurring in Index countries by incorporating additional control mechanisms into its operations.

Expand registration filings of HIV products. Gilead can take steps to file its HIV products for registration in more high-burden countries, including products for which Gilead has entered into non-exclusive voluntary licensing agreements. The company has filed emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey®) in none of the top 10 high-burden countries, Biktarvy® and Genvoya® in only one of the top 10 high-burden countries and Descovy® in four out of those 10 countries. Additional countries the company can consider include Lesotho and Zimbabwe.

Apply access planning process to all R&D projects. Gilead has a structured process in place for access planning for R&D projects in Phase II for HIV, viral hepatitis and visceral leishmaniasis. It has specific access plans in place for some late-stage projects. The company can expand its access plans to all late-stage R&D projects, such as for lenacapavir a long-acting HIV-1 capsid inhibitor and projects targeting RSV and cancer. Furthermore, it can ensure that such products will be registered in countries where clinical trials take place and ensure affordable access to these products.

CHANGE SINCE THE 2018 INDEX

- Received WHO prequalification for sofosbuvir/velpatasvir (Epclusa®), the first treatment for hepatitis C, in February 2019.
- Joined Pat-INFORMED in 2018.
- Issued licences for remdesivir (Veklury®),*** a treatment for COVID-19, which received Emergency Use Authorisation by the FDA during the period of analysis, covering 127 countries, including technology transfer.
- Joined the COVID-19 Therapeutics Accelerator.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, Gilead declined to submit data to the Access to Medicine Index.

***Remdesivir (Veklury®) was not included in the product portfolio, FDA approved it for the treatment of COVID-19 after period of analysis (October 2019).

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segment: Innovative medicines
Therapeutic areas: Viral Diseases; Inflammatory Diseases; Oncology; Fibrotic Diseases
Product categories: Innovative medicines
M&A news: Acquired Forty Seven (oncology) for USD 4.9 billion, Immunomedics (oncology) for USD 20 billion and MYR GmbH (chronic hepatitis delta virus) for USD 1.4 billion in 2020.

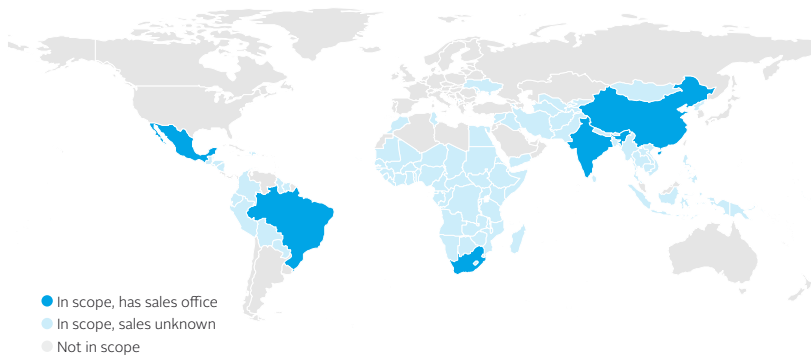
Gilead's products are sold in 32* out of 106 countries in scope. Gilead has sales offices in 5 countries and sells products via suppliers or pooled procurement in 27* countries.

*In 2018, Gilead reported sales in 32 countries.

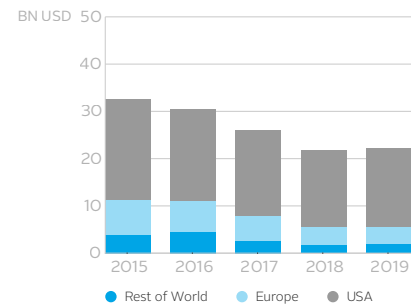
Revenue by segment (2019) – USD

| | |
|----------------------|-----------|
| Innovative medicines | 22.449 bn |
| Total | 22.449 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

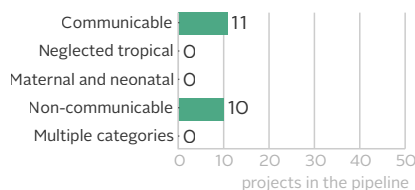
PIPELINE for diseases and countries in scope

Gilead has a total of 21 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 9 projects. Remarkably, these 9 priority projects make up almost half of Gilead's R&D projects. The other 12 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (5 projects). Of the projects targeting other diseases in scope, the focus is on oncology (9). 9 R&D projects are in late-stage development that target either a priority disease (6) or address a public health need in LMICs (3).^{*} Evidence of access planning was reported for 11% of these projects: 1 targeting a priority disease and none addressing a public health need in LMICs.

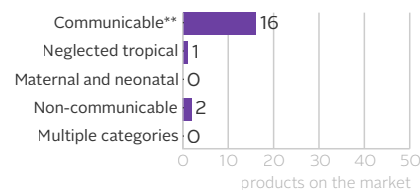
PORTFOLIO as selected for analysis by the Index

Gilead has 19 medicines in scope, 15 of which are on patent. 47% of these medicines (9) are on WHO's EML. The off-patent medicines target mainly communicable diseases, such as HIV, hepatitis B as well as neglected tropical diseases such as leishmaniasis. One other product targets cardiovascular diseases. The on-patent medicines mainly target viral infections: HIV (9), hepatitis B (1) and hepatitis C (4). One product targets cancer. Access strategies were analysed for 7 products on Gilead's portfolio – supranationally procured (4) or nationally procured self-administered products (3).

21 projects in the pipeline



19 products as selected for analysis by the Index*



Breakdown of projects#

Broadly neutralising antibody (bNAb) combination GS-5423 and GS-2872, a potential HIV cure

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 0 | 3 | 3 | 2 | 1 | 9 | 1 |
| Addresses needs of LMICs* | 0 | 2 | 2 | 1 | 0 | 5 | 0 |
| Other projects in scope | 0 | 3 | 4 | 0 | 0 | 7 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 6 | 9 | | | 15 |
| off patent | 3 | 1 | | | 4 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

† Products included in the analysis were selected

using a set of criteria determined by stakeholder consensus. See Appendix 1 for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Gilead Sciences Inc

GOVERNANCE OF ACCESS

RANK 12

SCORE 2.89

Has an access-to-medicine strategy with measurable objectives and a business rationale. Gilead has an average performance in this area. It has an access strategy based on partnerships and sees access as part of its corporate values. The strategy covers some of the therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Nominating and Corporate Governance Committee overseeing pricing and access issues.

Provides evidence of financial access-related incentives at the executive level. Gilead performs well here. The CEO has incentives, linked to its performance in expanding access to HCV products. The company does not disclose, however, whether senior executives and in-country managers are also incentivised toward access goals.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Gilead performs well in transparency regarding access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example through the IFPMA Global Health Progress platform.

Performs comparatively poorly in responsible promotional practices. Gilead's sales agents are solely incentivised on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It has an anti-bribery and anti-corruption policy, but does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities).

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Gilead performs below average, with evidence of some of the components looked for by the Index: audits (both internal and external, covering third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Gilead does not publicly share any support of or statement on the Doha Declaration on TRIPS and Public Health. There is no evidence of a policy to dissent from industry association positions.

RESEARCH & DEVELOPMENT

RANK 13

SCORE 1.71

Access planning processes encompass some projects in pipeline. Gilead has a structured process in place to develop access plans during R&D. The process is intended to be applied to some R&D projects for diseases in scope. In general, Gilead begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 17% of the late-stage candidates. Gilead has nine projects, including six late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on HIV/AIDS. Of Gilead's six late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This plan for the COVID-19 product remdesivir includes a non-exclusive

voluntary licensing agreement with several generic medicine manufacturers, a technology transfer of the Gilead manufacturing process. The licences are royalty-free until the WHO declares the end of the COVID-19 public health emergency of international concern or until a pharmaceutical product other than remdesivir or a vaccine is approved to treat or prevent COVID-19. The regulatory approval status of remdesivir varies by country.

Some projects address a public health need in LMICs*. The company does not disclose evidence of access plans for the late-stage projects. In this analysis, Gilead has three late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people

living in LMICs.* Primarily, these projects are first-in-class molecules. Most target cancer.

No public disclosure of post-trial access policy. Gilead does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants nor did it disclose such a policy to the Index.

Two R&D capacity building initiatives included for evaluation. Gilead performs below average in this indicator, with two R&D capacity building initiatives included for analysis. Gilead's initiatives were identified for selection based on publicly available information. The initiatives were also included in the 2018 Index.

PRODUCT DELIVERY

RANK 13

SCORE 2.50

Lacks a public commitment not to enforce patents in countries in scope. Gilead does not have a public policy that sets out its approach to filing or enforcing patents in low- and middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Gilead discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

One IP asset shared with third-party researchers. During the period of analysis Gilead newly shared one IP

asset with third-party researchers developing products for diseases in scope. It shares this asset with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. The asset shared is molecule libraries.

Uses licensing to enable generic supply. Gilead is the company with the highest number of licensing agreements. The company has non-exclusive voluntary licensing agreements in place for ten marketed compounds (for diseases in scope). Its broadest licences, for bicittegravir, cobicistat, emtricitabine, tenofovir alafenamide and tenofovir disoproxil fumarate encompass 91 countries in scope, including 64 middle-income countries in scope. It recently agreed on a licence for remdesivir (Veklury®), a treatment for COVID-

19* (*it received Emergency Use Authorisation by the FDA during period of analysis). It has not issued any non-assert declarations for products in scope.

Filed to register some new products in the majority of high burden countries. Gilead has filed 10% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For instance, sofosbuvir/ledipasvir (Harvoni®) for viral hepatitis (B and C) has been filed for registration/registered in five high burden countries in scope, including Egypt.

Has access strategies for all supranationally procured products in scope for this analysis. Gilead per-

‡ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

forms average in securing access for products procured supranationally. For the four products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers and also in at least one non-eligible country. However, no patient reach has been demonstrated for any of the products. For example, the company has equitable strategies, donations and licences for the HIV/AIDS medicine emtricitabine/tenofovir disoproxil fumarate (Truvada®) for non-eligible Global Fund countries.

No healthcare practitioner-administered products. Gilead has no products eligible for scoring in this indicator.

Has access strategies for some of its self-administered products for countries in scope for this analysis. Gilead performs average in this area. Examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) was found publicly for two of the three products assessed. The company makes efforts to reach additional patients through equitable pricing strategies and licensing. For example, in LICs, it uses flat pricing and non-exclusive voluntary licensing to increase access to hepatitis medicines sofosbuvir (Sovaldi®) and sofosbuvir/ledipasvir (Harvoni®). Information which demonstrates patient reach through these approaches is not available.

One manufacturing capacity building initiative meets all Good Practice Standards. Gilead performs below average in this indicator, with one manufacturing capacity building initiative included for analysis and meeting all Good Practice Standards.⁵ Gilead's initiative, which includes the technology transfers to manufacturers that hold a product licence through the MPP, was identified for selection based on publicly available information. The initiative was also included in the 2018 Index.

No supply chain capacity building initiatives included for evaluation. Gilead has no initiatives included for analysis aimed at building supply chain capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building supply chain capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

One health system strengthening initiative meets all Good Practice Standards. Gilead performs below average in this indicator, with one health system strengthening initiative included for analysis and meeting all Good Practice Standards: i.e., it addresses local needs, has local partners, mitigates risk of conflict of interest, is guided by clear goals and objectives, (plans to) measure outcomes, has a governance structure in place and aims for sustainability/integration in the local health system. Gilead's initiative, the Test-and-Treat Demonstration Project in Tanzania, was identified for selection based on publicly available information. The initiative aims to reach people living with HIV and provide them with care. To date, the initiative has screened 300,000 people and provided treatment to an estimate of 20,000 diagnosed people. The initiative was also included in the 2018 Index.

Has engaged in the development and implementation of a new inclusive business model. Gilead improved performance since 2018 when it comes to implement-

ing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has supported the Mobile Health Smiles Wallets model on digital health in partnership with PharmAccess, now continued with Access Afya.

Some mechanisms identified place to improve supply chain efficiency in countries in scope of the Index.

Gilead has an average performance in this area. It discloses little information publicly on the steps it takes to ensure the continuous supply of its medicines in countries in scope of the Index. In 2018, the company reported having a system in place to align demand and supply, including for some Least Developed Countries, with monthly forecasts for a 12-month period. Furthermore, the company reported holding a safety stock of unlabelled bottles to fill gaps during supply disruptions. No information steps taken to prevent API shortages was found publicly by the Index.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended time frame. Gilead does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to the relevant health authorities.

Donates in response to an expressed need, and monitors delivery. Gilead previously reported that it has a supply process in place to ensure ad hoc donations are carried out in response to an expressed need. Moreover, it monitors the delivery.

Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Gilead publicly commits itself to eliminating visceral leishmaniasis by donating amphotericin B liposome (AmBisome®) from 2011 to 2020 in six countries.

⁵ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; measures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|----------|-------------|
| 1 | 4.23 |
| 1 (2018) | |

GlaxoSmithKline plc

Stock Exchange: XLON • Ticker: GSK • HQ: Brentford, United Kingdom • Employees: 99,437

PERFORMANCE IN THE 2021 INDEX

1st place. GSK outpaces peers by building on a strong foundation of strategies applied to both R&D projects and products on the market. GSK leads in two of the three Technical Areas.

Governance of Access: 1st place. GSK leads in this area. It has a clear access-to-medicine strategy embedded in its overall corporate strategy, with access-related objectives tied to the CEO remuneration.

Research & Development: 1st place. GSK leads in this area. Its R&D pipeline consists of 25 late-stage priority R&D projects with the majority covered by access plans. It also performs well in R&D capacity building and has an access planning process that covers all projects in the pipeline.

OPPORTUNITIES FOR GSK

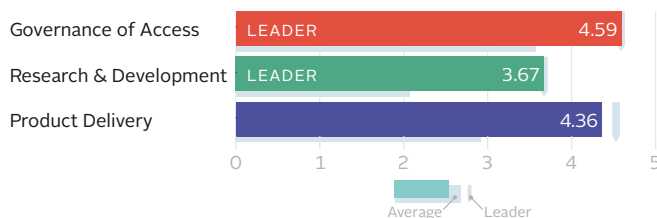
Expand depth and breadth of access planning. GSK has a process in place to develop access plans for all R&D projects in its pipeline. The company can plan for both registration and affordability as well as availability for all its late-stage R&D projects, such as GSK3902986A / GSK3536852A for Shigella. Further, it could strengthen its post-trial access policy to commit to registration and affordability in countries where it conducts clinical trials.

Apply access strategies in poorest countries. GSK has access strategies for nationally procured products, such as for mepolizumab (Nucala®), a treatment for asthma, and for umeclidinium bromide (Incruse®), a treatment for COPD. The company can scale these strategies to more LMICs and to LICs with high burden of pulmonary diseases, such as Central African Republic, Bangladesh, Myanmar and Nepal.

Expand manufacturing capacity building to sub-Saharan Africa. GSK performs well in manufacturing capacity building with initiatives in East and Southeast Asia (India, Pakistan, China, Thailand), Latin America (Mexico, Brazil) and northern Africa (Morocco, Egypt). It can expand its manufacturing capacity building to more geographic areas, including sub-Saharan African countries.

Expand albendazole donation to control soil-transmitted helminthiasis. Since 2011, GSK's albendazole (Zentel®) donation programme in partnership with WHO is aimed at controlling the soil-transmitted helminthiasis (STH) in at-risk populations (school-aged children). The company publicly committed to donating until 2020. GSK can extend its public commitment indefinitely until STH is controlled in at-risk populations.

How score was achieved



Product Delivery: 2nd place. GSK performs strongly in this area. It applies access strategies to the majority of its products and has the highest number of capacity building initiatives (i.e., manufacturing, supply and health system strengthening) meeting all Good Practice Standards. It filed to register some of its products in the majority of high-burden countries and has multiple mechanisms in place to ensure continuous supply.

CHANGE SINCE THE 2018 INDEX

- Pledged to ramp up HPV vaccine supply for Gavi-supported countries.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Joined the COVID-19 Therapeutics Accelerator.
- Engages in technology transfer and development support for paediatric formulations of dolutegravir.
- Set up a local protocol to ensure continued provision of dolutegravir (Tivicay®) to participants in clinical studies, in countries where local availability after market authorisation is uncertain.
- Partners with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four Pharmaceutical companies on Africa Health Worker Training Initiative.
- Supported the VNCV's Vietnam Paediatric Vaccine Supply Chain Initiative since July 2019.
- Expanded initiative STEP from 14 to 21 countries.
- Formed a supranational organisation service platform for supply planning, launches and route set-up for global health products for its pharmaceutical portfolio
- Licensed its tuberculosis (TB) vaccine candidate to the Gates MRI for development and use in low-income countries.
- Collaborates with WHO and PATH to implement the new RTS,S vaccine for malaria in three countries (Ghana, Kenya, Malawi).

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals; Vaccines; and Consumer Healthcare
Therapeutic areas: Pharmaceuticals: Respiratory, HIV, Immuno-inflammation, Oncology; Vaccines: Meningitis, Shingles, Influenza
Product categories: Innovative medicines, Vaccines, Consumer health products
M&A news: Combined consumer health business into a JV (68% stake) with Pfizer in 2019;

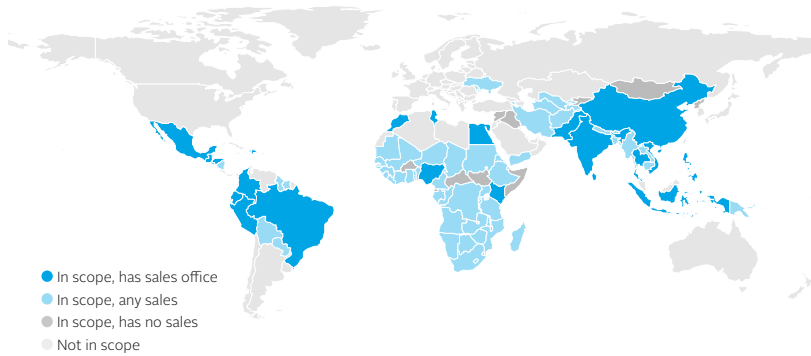
acquired Tesaro (oncology) for USD 5.1 billion in 2019.

GSK's products are sold in 89 out of 106 countries in scope. GSK has sales offices in 22 countries, sells via suppliers in 43 countries and via pooled procurement into 24 additional countries.

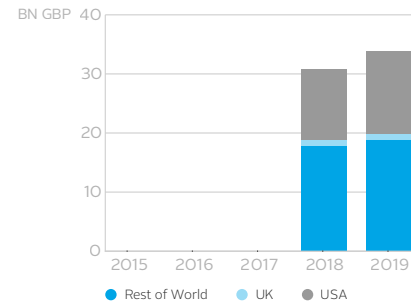
Turnover by segment (2019) – GBP

| | |
|---------------------------------|------------------|
| Pharmaceuticals | 17,554 bn |
| Vaccines | 7,157 bn |
| Consumer Healthcare | 8,995 bn |
| Corporate and other unallocated | 0.048 bn |
| Total | 33,754 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

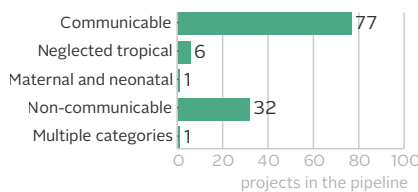
PIPELINE for diseases and countries in scope

GSK has a total of 117 R&D projects featuring the largest priority R&D pipeline compared to its peers: 81 projects. Remarkably, two thirds of GSK's total R&D projects target priority diseases. The other 36 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (16 projects) and COVID-19 (16). Of the projects targeting other diseases in scope, the focus is on oncology (22). 40 R&D projects are in late-stage development that target either a priority disease (25) or address a public health need in LMICs (15).^{*} Evidence of access planning was in place for 80% of these projects: 20 targeting a priority disease and 12 addressing a public health need in LMICs.

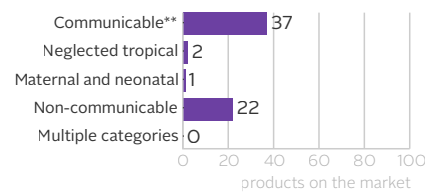
PORTFOLIO as selected for analysis by the Index

GSK has 39 medicines in scope, 21 of which are on patent, and 22 vaccines. 49% of these medicines (19) are on WHO's EML. In addition, the company markets 1 platform technology. The off-patent medicines target communicable diseases (CDs) (7) such as HIV (4) and hepatitis B (2); non-communicable diseases (NCDs) (9) such as mental health (3) and cardiovascular diseases (4); the neglected tropical disease leishmaniasis and neonatal sepsis and infections. The on-patent medicines target the CDs HIV (8) and malaria and NCDs such as pulmonary diseases (9) and mental health (1). GSK's preventative vaccines (22) target CDs such as meningitis (3) and rotavirus diarrhoea. The platform technology targets COVID-19. Access strategies were analysed for 12 products on GSK's portfolio – supranationally procured (5) or nationally procured HCP-administered (2) and self-administered products (5).

117 projects in the pipeline



62 products as selected for analysis by the Index[†]



Breakdown of projects[#]

ViiV Healthcare & Janssen's long-acting injectable formulation of cabotegravir and rilpivirine (Cabenuva). It is the first complete long-acting regimen for the treatment of HIV-1 infection in adults. The product is currently only approved in Canada.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 18 | 10 | 16 | 5 | 5 | 54 | 20 |
| Addresses needs of LMICs [*] | 0 | 14 | 6 | 4 | 5 | 29 | 12 |
| Other projects in scope | 0 | 3 | 2 | 1 | 0 | 6 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|----------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 6 | 15 | | | 21 |
| off patent | 13 | 5 | | | 18 |
| Vaccines | 22 | 0 | | | 22 |
| Diagnostics | | | 0 | | 0 |
| Other ^{***} | | | | 1 | 1 |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

^{***}Other includes a platform technologies. See Appendix I for definitions.

Appendix I for definitions.

[†] Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other

drug development phases were not included in this breakdown.

GlaxoSmithKline plc

GOVERNANCE OF ACCESS

RANK 1

SCORE 4.59

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. GSK performs strongly. It has a comprehensive access to medicines and vaccines strategy. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with its Corporate Responsibility Committee (CRC) which is responsible for global health and access strategies.

Provides evidence of financial and non-financial access-related incentives at the executive level. GSK performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives included in its annual bonus plan.

Publicly discloses outcomes of its access-to-medicine activities. GSK performs strongly in transparency regarding access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving

access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities for example with its ESG Performance Summary.

Performs above average in responsible promotional practices. For countries in scope GSK's sales agents are not solely incentivised on sales volume targets. In addition, GSK does not set sales incentives at the individual level for agents in these countries. It does not publicly disclose information related to transfers of values to health-care professionals in countries in scope, but it has a policy limiting such transfers, i.e. prohibiting payments for promotional activities in certain countries based on their scores in the Transparency International Corruption Perceptions Index.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. GSK performs strongly, demonstrating all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties.

Publicly supports the Doha Declaration on TRIPS and Public Health. GSK publicly shares support of the Doha Declaration on TRIPS and Public Health and acknowledges that the flexibilities can allow countries to address their public health needs. GSK has a policy to dissent from industry association positions on these, if it does not agree with a public policy position, it will not participate in related advocacy activity.

RESEARCH & DEVELOPMENT

RANK 1

SCORE 3.67

Access planning processes encompass all projects in pipeline. GSK has a structured process to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, GSK begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

GSK has the largest priority R&D pipeline compare to peers, with access plans in place for 80% of the late-stage candidates. GSK has 81 projects including 25 late-stage candidates in its pipeline that target a priority product gap. The company focuses mainly on HIV/AIDS and other infectious diseases. Of GSK's 25 late-stage candidates targeting a priority product gap, 20 have evidence of having an access plan in place. These plans range from commitments to ensure access; to product registration in several countries in scope; to equitable pricing strategies wherein prices are linked to the country's ability to pay (i.e. GNI per capita). GSK (as ViiV Healthcare) applies a non-profit pricing approach in lower-income countries, least-developed countries and sub-Saharan Africa for its antiretro-

virals products. ViiV Healthcare plans for a broad registration plan for this product and considers where appropriate, local manufacturing partnerships. Notably, ViiV Healthcare's paediatric dolutegravir dispersible is the first integrase inhibitor available as a dispersible tablet for oral suspension for children.

Many projects address a public health need in LMICs*, with 80% of the late-stage projects covered by access plans. In this analysis, GSK has 15 late-stage R&D projects in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules and/or clinical trials are conducted in countries in scope. Most target cancer. GSK provides evidence of access plans for 12 of these projects.

Public policy to ensure post-trial access; commits itself to registering trialed products. GSK has a publicly available policy for ensuring post-trial access to treatments for

clinical trial participants. This policy applies on a case-by-case basis. GSK does not conduct clinical trials in countries where, at the time of the trial, GSK knows it will not pursue registration and make the product available for use. The policy considers affordability for the wider population in the country where the trial(s) took place.

Four R&D capacity building initiatives meet all Good Practice Standards. GSK leads in this area. GSK submitted the maximum of five initiatives. Four initiatives met all criteria for inclusion and all Good Practice Standards:†

- Africa NCD Open Lab, providing funds and additional in-kind support for research into Non-Communicable Diseases in sub-Saharan Africa.
- Institute for Infectious Diseases and Public Health.
- Trust in Science, enabling scientific exchange with and supporting research organisations in Latin America and Asia.
- PENTA's EPIICAL Consortium, advancing the science of HIV remission in children for clinicians and researchers and enabling technology and expertise transfers.

PRODUCT DELIVERY

RANK 2

SCORE 4.36

Public commitment not to enforce patents in the majority of countries in scope. GSK publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, GSK discloses the patent

statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares some IP assets with third-party researchers.

During the period of analysis GSK has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes five IP assets shared with research institutions, including sets of target-specific compounds in discovery stage and molecule libraries. GSK also joined the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda

170 ‡ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability

Gates Foundation, Wellcome and Mastercard.

Uses licensing to enable generic supply. The company has two non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its adult licence for dolutegravir (Tivicay®) encompasses 91 countries in scope including 63 middle-income countries. Its paediatric licence for dolutegravir (Tivicay®) encompasses 102 countries in scope including 74 middle-income countries. It has not issued any non-assert declarations for products in scope.

Filed to register some new products in the majority of high burden countries. GSK has filed 30% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, dolutegravir (Tivicay®) for HIV/AIDS has been filed for registration/registered in 63 countries in scope, from which many with large populations of HIV patients such as South Africa, Mozambique, Tanzania and Zimbabwe.

Has access strategies for all supranationally procured products in scope of this analysis. GSK leads in securing access for products procured supranationally.[§] For the five products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers and also in at least one non-eligible country. For example, through its price freeze commitment GSK offers the same terms to former GAVI countries such as Angola for two vaccines: Cervarix®, a HPV vaccine, and Rotarix®, a rotavirus vaccine, as they do in GAVI-eligible countries.

Has access strategies for both of the healthcare practitioner administered products in scope of this analysis. GSK performs well in this area. The company provides examples of access strategies which consider affordability in UMICs and LMICs for the two products assessed in this category. It makes efforts to reach additional patients through equitable pricing strategy and patient assistance programmes. For example, in Colombia, for mepolizumab (Nucala®), a treatment for asthma, the company use equitable pricing strategies and implemented a patient support programme to increase access, while strengthening the health system by providing nurse home visits for patients. GSK forecasts that access to this medicine will have increased by 100% by the end of 2020. GSK is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. GSK performs above average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for two of the five products assessed. For the other products the company falls short to provide example for LMICs and/or LICs. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in Thailand, the company reduced the price of fluticasone propionate/salmeterol xinafoate (Seretide®), a treatment for asthma, for inclusion for reimbursement on the national list of essential medicines and launched a second discounted brand to increase affordability and access for patients. 380,000 patients access this medicine every year in Thailand. GSK is able to provide evidence of how patient

reach has been increased through the approaches used.

Four manufacturing capacity building initiatives meet all Good Practice Standards. GSK is a leader in this area, with five manufacturing capacity building initiatives included for analysis. GSK submitted the maximum of five, which all met all criteria for inclusion. Four initiatives met all Good Practice Standards.^{||} Examples include:

- Providing manufacturers of tafenoquine for the prevention treatment of malaria, in India with Environment, Health and Safety (EHS) risk and quality support.
- Technology transfer and development support for paediatric dispersible formulations of dolutegravir (Tivicay®) in India.

For the initiative 'Implementation of Child Resistant Senior Friendly packaging in India', GSK does not demonstrate that it is measuring outcomes.

Five supply chain capacity building initiatives meet all Good Practice Standards. GSK leads in this area with the highest number of initiatives that meet all Good Practice Standards.^{||} GSK submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards.^{||} Examples include:

- PULSE Volunteer Partnership, supporting CHAI in Sierra Leone to deliver a supply system that supports Sierra Leone's Free Healthcare Initiative.
- Nigeria Vaccines Supply and Cold Chain Integrity initiative, supporting the Murtala Muhammed International Airport in Lagos, Nigeria to maintain stable temperatures to ensure safe vaccine storage.

Five health system strengthening initiatives meet all Good Practice Standards. GSK is one of the leaders in this area. The company submitted the maximum of five initiatives, which all met the criteria for inclusion and all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- GSK and Save the Children partnership, reaching nearly 3 million children under the age of five between 2013 and 2018.
- Frontline Health Worker Programme, strengthening health infrastructure and improving access to healthcare in Least Developed Countries. Since 2010, GSK's investment has reportedly enabled the training of more than 100,000 health workers and reached over 16 million people in 44 countries.

Has engaged in the development and implementation of scaled up inclusive business models. GSK performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope of the Index. During the period of analysis, it has scaled up its Live Well social enterprise model aiming at building and supporting local distributor networks in Zambia.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. GSK performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in scope. For example, GSK manages global and regional

supply & demand hubs, overseeing forecasts of countries including some Least Developed Countries. GSK maintains a dual sourcing policy which supports supply of key medicines. In 2019, it set up a supranational organisation service platform to improve forecast accuracy and supply planning.

Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. GSK has a policy for reporting SF medicines to national health authorities and WHO within 5 days. It distinguishes reporting time frames for cases which only require visual inspection to be confirmed. In urgent situations where there is a significant risk of patient harm, the policy enables GSK to respond quickly.

Donates in response to an expressed need and monitors delivery to end user. GSK has a policy in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors how it is delivered the end user. For example, it donated antibacterial medicine in 2018 in response to the conflict in Syria.

Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programmes for NTDs. Two structured donation programmes for NTDs were included for analysis where elimination, eradication or control goals are possible. In one programme, GSK publicly commits itself to eliminating lymphatic filariasis by donating albendazole (Zentel®) in 39 Index countries since 1998.

§ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

|| Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|----------|-------------|
| 3 | 3.76 |
| 3 (2018) | |

Johnson & Johnson

Stock Exchange: New York Stock Exchange • Ticker: JNJ • HQ: New Brunswick, New Jersey, United States • Employees: 137,700

PERFORMANCE IN THE 2021 INDEX

3rd place. Johnson & Johnson takes a place among the top three companies of the Index. The company has a particularly strong performance in R&D, with a large-sized priority pipeline.

Governance of Access: 4th place. Johnson & Johnson performs strongly in this area. It has embedded access-to-medicine into its corporate strategy as part of the Global Public Health unit. The company has a robust set of compliance controls in place to safeguard its governance efforts.

Research & Development: 2nd place. Johnson & Johnson has a strong performance in this area with 16 late-stage priority R&D projects in its pipeline. The company leads in R&D capacity building and has an access planning process in place that covers all projects in the pipeline.

OPPORTUNITIES FOR JOHNSON & JOHNSON

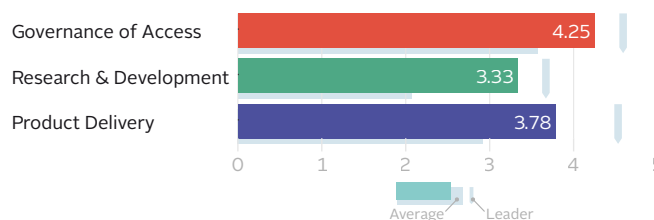
Expand supply chain process reviews to more countries. Johnson & Johnson's Global Public Health unit conducted supply chain process reviews in sub-Saharan African countries such as Kenya, Uganda and Nigeria for products it is responsible for such as HIV/AIDS medicines and vaccines. It can expand these supply chain reviews to more countries.

File patented HIV/AIDS medicines for registration in more countries. Johnson & Johnson's antiretrovirals darunavir/cobicistat (Prezcobix®/Rezosta®) and darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) can be filed for registration in the high-burden countries in scope of the Index such as Equatorial Guinea, Lesotho, Malawi, Mozambique, South Africa and Zimbabwe.

Apply access planning to more R&D projects and consider affordability. Johnson & Johnson has access plans in place for 79% of its late-stage R&D projects. It plans for filing for registration for most of these projects. The company can plan for both registration and affordability as well as availability for all its late-stage R&D projects, e.g. for hepatitis B virus and for daratumumab (Darzalex®) for cancer.

Expand access to patented products. Johnson & Johnson can apply further access strategies to expand access for more patients using equitable pricing and/or non-exclusive voluntary licensing for on-patent products for Type 2 diabetes mellitus (e.g. canagliflozin (Invokana®), canagliflozin/metformin (Vokanamet®/Invokamet®) and for MDR-TB, bedaquiline (Sirturo®).

How score was achieved



Product Delivery: 5th place. Johnson & Johnson performs well in this area. The company shares many IP assets with third-party researchers and leads in its approach to access strategies for supranationally procured products. The majority of its capacity building initiatives meet all Good Practice Standards.

CHANGE SINCE THE 2018 INDEX

- Expanded its mental health initiative in Rwanda and completed the first-ever mental health survey in the country.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Expands donation programme of mebendazole chewable (Vermox®, Vermox® Chewable) for children until 2025.
- Received FDA approval for bedaquiline (Sirturo®) paediatric formulation and EMA approval of their Ebola vaccine regimen composing the two doses (Zabdeno® and Mvabea®).
- Engaged in nine IP sharing agreements via WIPO research (NTDs), the Pan-TB (Project to Accelerate New Treatments for TB) and the COVID-19 Therapeutics Accelerator initiative.
- Expanded HIV drug-resistance mapping from the Democratic Republic of Congo (DRC) to Kenya with KEMRI.
- Supported the building of active pharmaceutical ingredient (API) capacity of third-party manufacturers in Africa, including exploring local drug substance manufacturing.
- Active partner in the Pandemic Cold Chain System Coalition.
- Collaborated with Stop TB to reduce the price and enact a volume-based free goods framework for bedaquiline (Sirturo®).
- Supported by the Johnson & Johnson Foundation, the company partnered with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four pharmaceutical companies on the Africa Health Worker Training Initiative.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Consumer Health; Pharmaceutical; Medical Devices
Therapeutic areas: Pharmaceutical: Immunology; Infectious Diseases; Neuroscience; Oncology; Cardiovascular and Metabolism; Pulmonary Hypertension
Product categories: Innovative medicines; Vaccines; Diagnostics; Consumer health products; Medical devices
M&A news: Acquired all rights to the investiga-

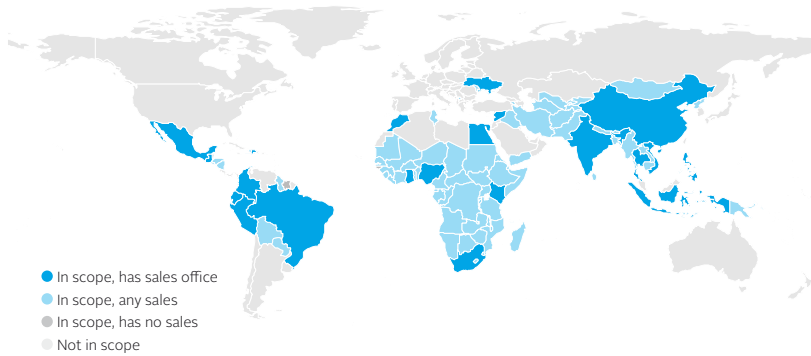
tional compound bermekimab (immunology) from XBiotech in Q1 2020; acquired Momenta (immune-mediated diseases) for USD 6.5 billion in Q4 2020.

Johnson & Johnson's pharmaceutical products are sold in 94 out of 106 countries in scope. Johnson & Johnson has sales offices in 21 countries, sells via suppliers in 60 countries and via pooled procurement into 13 additional countries.

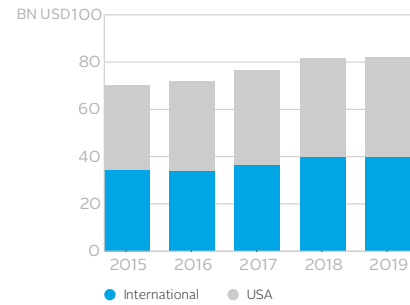
Sales by segment (2019) – USD

| | |
|-----------------|------------------|
| Pharmaceuticals | 42.198 bn |
| Medical Devices | 25.963 bn |
| Consumer Health | 13.898 bn |
| Total | 82.059 bn |

Sales in countries in scope



Sales by geographic region

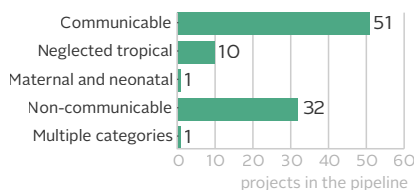


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Johnson & Johnson has a total of 95 R&D projects featuring a relatively large priority R&D pipeline compared to its peers: 51 projects. Remarkably, Johnson & Johnson has the second largest pipeline and more than half of its R&D projects target priority diseases. The other 44 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (10 projects). Of the projects targeting other diseases in scope, the focus is on oncology (17). 39 R&D projects are in late-stage development. Johnson & Johnson is involved in 16 projects, with 15 of them in its own pipeline and one driven by ViiV healthcare. These target either a priority disease (16) or address a public health need in LMICs (23).^{*} Evidence of access planning was in place for 79% of these projects: 10 targeting a priority disease and 21 addressing a public health need in LMICs.

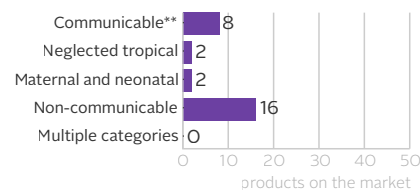
95 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Johnson & Johnson has 28 medicines and contraceptives in scope, 19 of which are on patent. 32% of these medicines (9) are on WHO's EML. The off-patent medicines target the neglected tropical diseases soil-transmitted helminthiasis and echinococcosis and the non-communicable diseases relating to cancer (3), mental health conditions and kidney diseases. The company also markets two off-patent contraceptive methods. The on-patent medicines mainly target HIV (7), cancer (5) and mental health (3). Furthermore, it targets diabetes (2), tuberculosis and Alzheimer's disease. Access strategies were analysed for 13 products on Johnson & Johnson's portfolio – supranationally procured (3) or nationally procured HCP-administered (5) and self-administered products (5).

28 products as selected for analysis by the Index[†]



Breakdown of projects[#]

ViiV Healthcare & Janssen's long-acting injectable formulation of cabotegravir and rilpivirine (Cabenuva). It is the first complete long-acting regimen for the treatment of HIV-1 infection in adults. The product is currently only approved in Canada.

COVID-19 vaccine candidate Ad26.COV2.S, progressing from preclinical to Phase III (during the period of analysis)

^{*}Targets established R&D priorities
^{*}Addresses needs of LMICs^{*}
^{*}Other projects in scope

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 9 | 8 | 10 | 2 | 4 | 33 | 10 |
| Addresses needs of LMICs [*] | 0 | 13 | 13 | 6 | 4 | 36 | 21 |
| Other projects in scope | 0 | 2 | 4 | 0 | 0 | 6 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 4 | 15 | | | 19 |
| off patent | 5 | 4 | | | 9 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clin-

ical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Johnson & Johnson

GOVERNANCE OF ACCESS

RANK 4

SCORE 4.25

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Johnson & Johnson performs strongly. It has an access strategy integrated within its overall corporate strategy. The strategy, embedded in its Global Public Health unit, covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Science, Technology & Sustainability Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level.

Johnson & Johnson performs well here. It incentivises its senior executives, including both Vice Chairpersons of the Executive Committee, and regional managers to take action on access to medicine with financial and non-financial rewards. There is limited evidence, however, that the CEO is also incentivised toward access goals.

Publicly discloses outcomes of its access-to-medicine activities. Johnson & Johnson performs strongly in transparency regarding access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities with its Health for Humanity 2020 Goals Progress Scorecard.

Has an average performance in responsible promotional practices.

Johnson & Johnson's sales agents are not solely incentivised on sales volume targets. The company, however, sets sales incentives at the individual level for agents. Except for Ukraine where it discloses to EFPIA[‡] and some countries where it is required by local regulations, it does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities). However, it reports not using sales and marketing representatives for some products related to diseases in scope, such as HIV medicines.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Johnson & Johnson performs strongly, demonstrating all the components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards.

Publicly supports international agreements. Johnson & Johnson states that it is a member of, and supports, industry associations that advocate for strong IP systems, but that it employs flexible IP approaches that further its Global Public Health objectives. It expresses reservations on compulsory licensing, namely that it should be limited to certain circumstances when alternatives are exhausted. It can dissent from industry association positions.

RESEARCH & DEVELOPMENT

RANK 2

SCORE 3.33

Access planning processes encompass all projects in pipeline. Johnson & Johnson has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, Johnson & Johnson begins developing access plans for R&D projects in Phase II of clinical development. The process is for both in-house and collaborative R&D projects.

A large-sized priority R&D pipeline compared to peers, with access plans in place for 67% of the late-stage candidates. Johnson & Johnson has 51 projects including 15 late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on HIV/AIDS. Of Johnson & Johnson's 15 late-stage candidates targeting a priority product gap, ten have evidence of having an access plan in place. These plans range from commitments to register product in several countries in scope to equity-based tiered pricing strategies for some projects. Note, if the development of the investigational Janssen preventative HIV vaccine is successful, the company plans to implement a global access strategy.

Many projects address a public health need in LMICs*, with 91% of the late-stage projects covered by access plans. In this analysis, Johnson & Johnson has 23 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. Johnson & Johnson provides evidence of access plans for 21 of these projects. In general these access plans focus on registration plans in LMICs. The 23 projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope and/or are first-in-class molecules. Most target asthma and cancer.

Public policy to ensure post-trial access; commits itself to registering trialed products. Johnson & Johnson has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a severe or life-threatening condition. In general, once a product is initially approved, Johnson & Johnson commits to submit applications for product registration in countries where the clinical trials for the product have taken place. This policy does not consider

affordability for the wider population in the country where the trial(s) took place.

Five R&D capacity building initiatives meet all Good Practice Standards. Johnson & Johnson leads in this area.

The company submitted the maximum of five initiatives, which were all included for analysis and met all the Good Practice Standards.[§] The initiatives all target R&D capacity building in sub-Saharan Africa, predominantly focusing on communicable diseases such as HIV, TB and malaria:

- The Johnson & Johnson Global Public Health R&D Fellowship Program for African scientists and doctors.
- The Ugandan Academy for Health Innovation and Impact, which has been running since 2015.
- UMURINZI, working the Rwanda Biomedical Centre (RBC) of the Rwanda Ministry of Health to deliver the Ebola vaccine regime, supporting Clinical trial management and Good clinical practices.
- Strengthening HIV resistance mapping in Kenya and the DRC.
- Visiting Scientist Program and Mentorship Program at the University of Cape Town (UCT) Drug Discovery and Development Center (H3D).

PRODUCT DELIVERY

RANK 5

SCORE 3.78

Public commitment not to enforce patents in countries in scope. Johnson & Johnson publicly pledges not to enforce patents on darunavir (Prezista®). This commitment applies in sub-Saharan Africa and in Least Developed Countries.

Publicly discloses detailed information on patent status. Like most of its peers, Johnson & Johnson discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about pat-

ents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Johnson & Johnson has newly

‡ Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

§ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

shared many IP assets with third-party researchers developing products for diseases in scope. This includes nine IP assets shared with research institutions and the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries and performing assay for drug discovery.

Uses licensing to enable generic supply. Johnson & Johnson has a non-exclusive voluntary licensing agreement for one compound (for diseases in scope). Its licence, which is for rilpivirine (Edurant®), encompasses 89 countries including 62 middle-income countries in scope. It has also issued a non-assert declaration for one patented compound in scope, darunavir (Prezista®).

Filed to register some new products in the majority of high burden countries. Johnson & Johnson has filed 20% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, the oncology medicine ibrutinib (Imbruvica®) has been filed for registrations/registered in, among others, six high-burden countries in scope.

Has access strategies for all supranationally procured products in scope for this analysis. Johnson & Johnson leads in securing access for products procured supranationally.¶ For the three products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers, and also in at least one country not eligible for such supply. For example, Johnson & Johnson offers similar terms in South Africa for tuberculosis medicine Sirturo® as it does for eligible countries procuring through Stop TB Partnership's Global Drug Facility.

Has access strategies for the majority of health-care practitioner-administered products in scope of this analysis. Johnson & Johnson performs above average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. The company makes efforts to reach additional patients using equitable pricing strategies. For example, in India, for the schizophrenia treatment paliperidone palmitate (Invega®), it applies tiered pricing, participates in tenders and has a Patient Access Programme which provides financial support to patient to increase access, while strengthening the health system by raising awareness around schizophrenia. Johnson & Johnson is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope for this analysis. Johnson & Johnson performs on average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategy and licensing. For example, in Kenya, for the oncology medicine Abiraterone acetate (Zytiga®), the company uses a tiered pricing strategy and provides additional support through patient assistance programs to address affordability and access for patients. Johnson & Johnson is able to provide evidence of how

patient reach has been increased through the approaches used.

Two manufacturing capacity building initiatives meet all Good Practice Standards. Johnson & Johnson performs well in this indicator, with five manufacturing capacity building initiatives included for analysis. Johnson & Johnson submitted the maximum of five and all met inclusion criteria. Two initiatives met all Good Practice Standards,¶ including a technology transfer programme in China for darunavir (Prezista®) for the treatment of HIV, which started in 2018. For three initiatives, Johnson & Johnson does not demonstrate that it is measuring outcomes.

Four supply chain capacity building initiatives meet all Good Practice Standards. Johnson & Johnson performs well in this indicator, with five supply chain capacity building initiatives included for analysis. Johnson & Johnson submitted the maximum of five initiatives, which met all criteria for inclusion. Four initiatives met all Good Practice Standards.¶ Examples include:

- Last Mile Health Medical Drone Project, using medical drones to overcome geographical barriers to deliver antiretroviral therapy for the treatment of HIV.
- Africa Resource Centre Secondments, enabling company employees to offer their expertise to improve public sector supply chain capabilities in South Africa and Kenya.

For the J&J STAR programme, a six-month training course for supply chain professionals, Johnson & Johnson does not sufficiently demonstrate how it aims for sustainability.

Five health system strengthening initiatives meet all Good Practice Standards. Johnson & Johnson is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- DREAMS, Thina Abantu Abasha, a youth-led peer-to-peer initiative aimed at reducing HIV infections in adolescent girls and young women in South Africa.
- In collaboration with the government of Rwanda, Johnson & Johnson co-developed and launched the first remote training system in the country, training over 48,000 community healthcare workers in 2019 on recognising mental illness and the referral process.

Has engaged in the development and implementation of new inclusive business models. Johnson & Johnson improved performance since 2018 when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. In 2019, the company launched Johnson & Johnson Impact Ventures, supported by the Johnson & Johnson Foundation, including the development of two new models: partnership with Jacaranda maternity and partnership with Southlake Medical Center Kenya on access to primary and secondary healthcare.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Johnson & Johnson performs well in this area, disclosing multiple strategies to ensure continuous supply in

countries in the scope of the Index. For example, based on the insights from the Sales & Operations Planning process, the company takes various measures to ensure continuous supply, including holding sufficient safety stocks and dual/multiple sourcing of supply and inventory. In 2019, Johnson & Johnson redesigned the distribution network of their HIV portfolio, reportedly enhancing demand forecasting and last mile distribution.

Has a procedure for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Johnson & Johnson has a procedure for reporting SF medicines to national health authorities within 5 days. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed. However, it reports that its aims at reporting within 2 days if the case presents a direct and serious or life-threatening risk to patient or healthcare professional.

Donates in response to an expressed need, and monitors delivery to end user. Johnson & Johnson has a process in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors the delivery until the end user. For example, it donated darunavir/cobicistat (Rezolsta®) for HIV/AIDS to the Ivory Coast in 2020 to project HOPE worldwide.

Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Johnson & Johnson publicly commits itself to controlling soil-transmitted helminthiasis by donating mebendazole (Vermox®) from 2006 to 2025 in 33 countries.

¶ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

¶ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 15 | 1.88 |
| 12 (2018) | |

Merck & Co, Inc

Stock Exchange: New York Stock Exchange • Ticker: MRK • HQ: Kenilworth, New Jersey, United States • Employees: 71,000

PERFORMANCE IN THE 2021 INDEX

15th place. Merck & Co, Inc (MSD) performs below average across all Technical Areas, with a weak performance in planning for access during R&D. There is a lack of evidence of access strategies and a poor performance in responsible promotional practices compared to peers.

Governance of Access: 14th place. MSD performs below average in this area. While having an access-to-medicine strategy with measurable objectives integrated within its overall corporate strategy, the company comparatively performs poorly in the area of responsible promotional practices.

Research & Development: 15th place. MSD performs below average in R&D. The company commits to registering trialled products, but does not have a process for access planning during R&D nor does it disclose any evidence of access plans for late-stage projects that address a public health need in LMICs.

OPPORTUNITIES FOR MSD

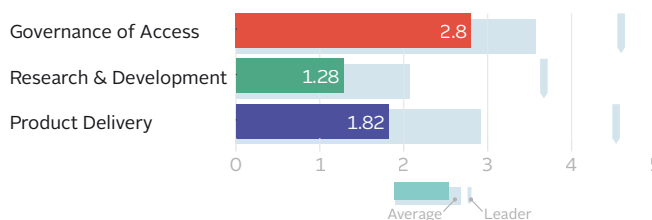
Link incentive structures to access-to-medicine strategy. MSD has an access-to-medicine strategy, guided by its Access to Health Statement of Guiding Principles. Financial and non-financial incentives for senior executives, the CEO and in-country managers can be linked to it. Furthermore, it can review sales incentive structures for sales agents to adopt a balanced scorecard approach consistently, thus not solely promoting sales volume targets in countries in scope.

Expand access to patented medicines on EML. MSD agreed a licence for paediatric raltegravir (Isentress®); one generic company is manufacturing this product under this agreement. The company can further expand access in high-burden countries, by expanding registration and affordability. The company could prioritise increasing access to more on patent EML products, such as pembrolizumab (Keytruda®) and to further patented medicines considered for future inclusion, such as ertugliflozin (Steglatro®) for diabetes mellitus and doravirine (Pifeltro®) for HIV/AIDS.

Develop access planning process and access plans for all R&D projects. MSD can establish a formal access planning process and develop access plans for all clinical projects in Phase II and beyond, such as for gefapixant for endometriosis-related pain, tedizolid (Sivextro®) for S. pneumoniae and MK-8591 (islatravir) a pre-exposure prophylaxis (PrEP) to prevent HIV infection.

Improve transparency on access strategies at a product level. MSD can improve transparency on the access strategies it develops for marketed products, including information about how it reaches patients at the bottom of the income pyramid and a number of patients reached. Furthermore, it can disclose how it plans to reach patients in countries in scope with R&D projects in late-stage development.

How score was achieved



Product Delivery: 16th place. MSD performs below average in this area. It has an access strategy for one product and only in upper-middle income countries. It is engaged in the development and implementation of one inclusive business model in Kenya and engages in some health system strengthening initiatives of which one meets all Good Practice Standards.

CHANGE SINCE THE 2018 INDEX

- Obtained FDA approval and WHO prequalification for Ebola vaccine (Ervebo®) in November 2019.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Joined Bill and Melinda Gates Foundation on industry collaboration to address product development and delivery challenges related to COVID-19 and future pandemics.
- Pledged to ramp up HPV vaccine supply availability for Gavi-supported countries.
- As part of a broader refresh of its Access to Health Guiding Principles, the company set new KPIs on number of countries with affordability solutions initiated and number of patents filed in low-income countries (LICs)
- Entered into a non-exclusive voluntary licensing agreement with two generic medicine manufacturers for HIV/AIDS treatment doravirine in September 2020. The agreement covers 86 countries, including all sub-Saharan African countries.
- Collaborates with the Bill & Melinda Gates Foundation on the Phase 3 study investigating islatravir as an once-monthly oral pre-exposure prophylaxis (PrEP) treatment option for adolescent and adult women at high risk for acquiring HIV-1 infection in sub-Saharan Africa.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, MSD declined to submit data to the Access to Medicine Index.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals; Animal Health; Other Revenues

Therapeutic areas: Pharmaceuticals: Oncology; Vaccines; Hospital acute care; Immunology; Virology; Cardiovascular; Diabetes; Women's health

Product categories: Innovative medicines; Vaccines; Animal health; Biosimilars

M&A news: In 2020 MSD acquired Themis, including the COVID-19 vaccine candidate, for USD 2.7 billion it acquired ArQule (oncology, rare diseases) and it acquired Oncolmmune

(cancer, auto-immune diseases); acquired Immune Design (infectious diseases), Peloton Therapeutics (oncology), Tilos Therapeutics (oncology) and Calporta Therapeutics (neuroscience) in 2019.

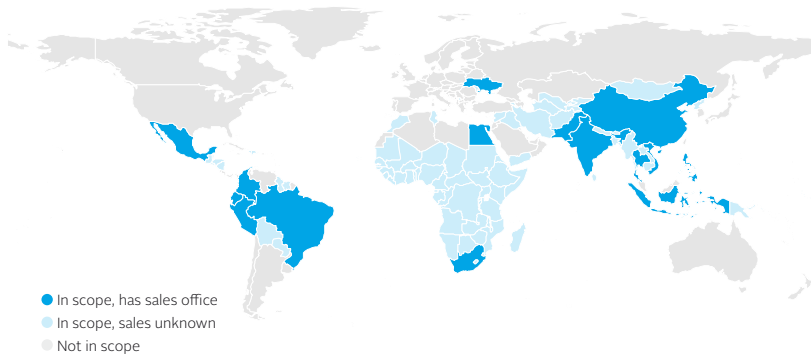
MSD products are sold in 81* out of 106 countries in scope. MSD has sales offices in 15 countries and sells products via suppliers or pooled procurement in 66* countries.

*In 2016, MSD reported sales in 81 countries.

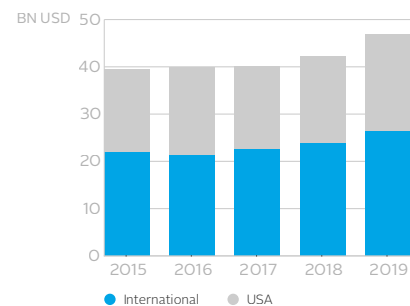
Sales by segment (2019) – USD

| | |
|-----------------|------------------|
| Pharmaceuticals | 41.751 bn |
| Animal Health | 4.393 bn |
| Other revenues | 0.696 bn |
| Total | 46.840 bn |

Sales in countries in scope



Sales by geographic region



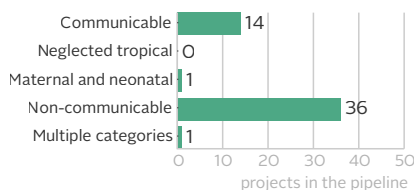
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

MSD has a total of 52 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 13 projects. The other 39 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (5 projects) and lower respiratory tract infections (5). Of the projects targeting other diseases in scope, the focus is on oncology (34).

33 R&D projects are in late-stage development that target either a priority disease (9) or address a public health need in LMICs (24).^{*} Evidence of access planning was reported in these sections for 3% of these projects: 1 targeting a priority disease, but none addressing a public health need in LMICs.

52 projects in the pipeline



Breakdown of projects[#]

MK-8591 (islatravir) a pre-exposure prophylaxis (PrEP) to prevent HIV infection. The product is in development as an oral formulation (Phase II) and an implant for long-lasting PrEP (Phase I)

The Merck & Co, Inc pipeline includes one of the two currently approved Ebola vaccines, Ervebo (rVSV-ZEBOV).

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 2 | 2 | 1 | 3 | 5 | 13 | 1 |
| Addresses needs of LMICs [*] | 0 | 1 | 12 | 7 | 5 | 25 | 0 |
| Other projects in scope | 0 | 3 | 7 | 2 | 2 | 14 | |

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

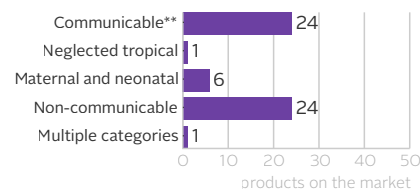
^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

PORTFOLIO as selected for analysis by the Index

MSD has 43 medicines and contraceptives in scope, 26 of which are on patent, and 12 vaccines. 35% of these medicines and contraceptives (15) are on WHO's EML. In addition, the company markets 1 vector control product. The off-patent medicines target communicable diseases (CDs) (2) such as hepatitis C and non-communicable diseases (NCDs) (11) such as cardiovascular diseases (4). The on-patent medicines target CDs such as HIV (6) and NCDs such as diabetes (6) and cancer (3). MSD has six contraceptive methods and devices in scope. The company's preventative vaccines (11) target CDs such as HPV (2). The therapeutic vaccine targets bladder cancer. The vector control product targets rabies.

Access strategies were analysed for 15 products on MSD portfolio – supra-nationally procured (5) or nationally procured HCP-administered (5) and self-administered products (5).

56 products as selected for analysis by the Index †



Breakdown of products

| | WHO EML | Not-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 6 | 20 | | | 26 |
| off patent | 9 | 8 | | | 17 |
| Vaccines*** | 12 | 0 | | | 12 |
| Diagnostics | | | 0 | | 0 |
| Other† | | | | 1 | 1 |

^{***}Vaccines included in the analysis are both therapeutic and preventative

[†]Other includes a vector control product. See Appendix I for definitions.

[‡]Product included in the analysis were selected using a set of criteria determined by stakeholder

consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Merck & Co, Inc

GOVERNANCE OF ACCESS

RANK 14

SCORE 2.80

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. MSD performs well here. It has an access strategy, guided by its Access to Health Statement of Guiding Principles, which covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, namely with the Public Policy and Responsibility Council reporting to the Executive Committee.

Does not provide evidence of financial or non-financial access-related incentives at the managerial level. MSD performs comparatively poorly here. It does not disclose access-related incentives for senior executives or in-country managers.

Publicly discloses outcomes of its access-to-medicine activities. MSD performs strongly in transparency of access activities. It publicly discloses commitments, meas-

urable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, for example through its Corporate Social Responsibility report, and for its MSD for Mothers initiatives.

Performs comparatively poorly in responsible promotional practices. MSD does not disclose that its sales agents are not solely incentivised on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It has Guiding Principles for ethical business practices involving the medical and scientific community, but does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities).

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. MSD performs below average, with evidence of some of the components looked for by the Index: Audits (both internal and external, covering third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment.

Publicly supports the Doha Declaration on TRIPS and Public Health. MSD publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions. That is, it challenges the use of compulsory licensing, which it can respect only in very limited circumstances. There is no evidence of a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

RANK 15

SCORE 1.28

No evidence found of structured process for access planning. MSD did not disclose to the index a structured process in place to develop access plans during R&D. The process is intended to be applied to some R&D projects for diseases in scope. MSD did not disclose a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with evidence of access plans for 11% of the late-stage candidates. MSD has 13 projects, including nine late-stage candidates in its pipeline, that target a priority product gap. The company focuses mostly on HIV/AIDS. Of MSD's nine late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This plan for the newly registered Ebola vaccine Ervebo (rVSV-ZEBOV) includes WHO prequalification and registration in four

African countries (DRC, Burundi, Ghana and Zambia). There are plans to make the product available at the lowest possible access price in Gavi-eligible countries.

Many projects address a public health need in LMICs*. The company did not disclose any access plans for the late-stage projects. In this analysis, MSD has 24 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope. Most target cancer.

Public policy to ensure post-trial access; commits itself to registering trialed products. MSD has a policy for ensuring post-trial access to treatments for clinical trial

participants. This policy is applied on a case-by-case basis. Once a product is approved, MSD commits itself to registering it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. MSD has no initiatives included for analysis aimed at building R&D capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about R&D capacity building in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

PRODUCT DELIVERY

RANK 16

SCORE 1.82

Public commitment not to enforce patents in countries in scope. MSD publicly pledges to neither file for nor enforce patents. This commitment applies in low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, MSD discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction. Additionally, they self-disclosed US patent numbers for their whole US portfolio, vaccines and biologics.

In addition to the older assets, MSD newly shared one IP asset with third-party researchers. During the period of analysis MSD has newly shared one IP assets with third-party researchers developing products for diseases in scope. It shares this asset with the research institute Seattle Children's research Institute, via the WIPO Re:search collaboration. The asset shared includes performing assay and share advice about drug target structure for schistosomiasis. The new agreement is in addition to previously agreed IP sharing agreements with the research institute Butantan in Brazil.

Uses licensing to enable generic supply. MSD has a non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence for its paediatric formulation of raltegravir (Isentress®) encompasses 89 countries including 61 middle-income countries in scope. It has not issued any non-assert declarations for products in scope. Outside period of analysis, the company entered into a non-exclusive voluntary licensing agreement with two generic medicine manufacturers for HIV/AIDS treatment doravirine in September 2020. The agreement covers 86 countries, including all sub-Saharan African countries.

No evidence of new products in scope filed for registration in the majority of high burden countries. MSD did not disclose evidence of filing for any of its ten assessed products in more than half of the relevant top 10 high burden countries in scope (disease-specific subset of countries with the highest burden of disease). However, WHO prequalified the Ebola Zaire vaccine, Live (Ervebo®), in November 2019. It facilitated the registration of the vaccine in several African countries such as the Democratic Republic of Congo, Burundi, Ghana and Zambia. The company has also publicly disclosed the registration status for other products on their website.

Has access strategies for some supranationally procured products in scope of this analysis. MSD has an average performance in securing access for products procured supranationally.⁵ For four of the five products assessed in this category, examples of strategies both in countries eligible for supply from such procurers and in at least one non-eligible country were found publicly. For example, the company offers the same terms for the HPV vaccine Gardasil® in GAVI transitioning countries as it does in GAVI-eligible countries. Information which demonstrates patient reach through these approaches is not available.

No evidence of access strategies for any of its health-care practitioner-administered products in scope of this analysis. MSD has not disclosed, either publicly or to the Index, access strategies for any of the five products assessed by the Index in this category. The products are oncology treatments, antibiotics and a product targeting ischaemic heart disease.

Limited available evidence on access strategies for its self-administered products for countries in scope of the analysis. MSD performs poorly in this area. Examples of access strategies considering affordability in UMICs was found publicly for one out of the five products assessed. The company makes efforts to reach additional patients through the use of both inter- and intra-country pricing strategy. For example, in UMICs MSD offers discounts for contraceptives to organisations that serve women of all income levels, like Planned Parenthood affiliates. However, there was no public information about the reach of such initiatives or examples in LMICs and LICs.

No manufacturing capacity building initiatives included for evaluation. MSD has no initiatives included for analysis aimed at building manufacturing capacity in countries in scope of the Index. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about manufacturing capacity building in countries in scope of the Index. No initiatives were identified for selection based on publicly avail-

able information.

Three supply chain capacity building initiative meet all Good Practice Standards. MSD performs above average in this indicator, with three supply chain capacity building initiatives included for analysis and meeting all Good Practice Standards.¹¹ MSD's initiatives were identified for selection based on publicly available information. For example, MSD's Informed Push Model (IPM-3PL) implements an innovative supply chain model aimed at eliminating stockouts of contraceptives at health facilities in Senegal, which was recognised as a Best Practice in the 2018 Index.

One health system strengthening initiative meets all Good Practice Standards. MSD performs above average in this indicator, with four health system strengthening initiatives included for analysis: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. MSD's initiatives were identified for selection based on publicly available information. One initiative, MSD for Mothers, meets all Good Practice Standards, demonstrating a good governance structure and long-term aims. For the other four initiatives, such information could not be found publicly.

Has engaged in the development and implementation of new inclusive business models. MSD performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope of the Index. It has developed a model focused on maternal health: MomCare.

Few mechanisms identified to improve supply chain efficiency in countries in scope of the Index. MSD performs less well than other companies in this area, disclosing little information publicly on the steps it takes to ensure the continuous supply of its medicine in countries in scope of the Index. Few strategies were identified based on publicly available information, including the use of dual API sourcing for some of its supply nodes and markets.

Does not disclose a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended timeframe. MSD does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities. It has a public policy on tackling counterfeit products.

Donates in response to an expressed need and monitors delivery to end user. MSD publicly reports that it ensures ad hoc donations are carried out in response to an expressed need. Moreover, it monitors the delivery until the end user; however, it is unclear whether this is defined as the patient.

Publicly commits itself to the achievement of elimination, eradication or control goals in its structured donation programmes for NTDs. Two structured donation programmes for NTDs were included for analysis where elimination, eradication or control goals are possible. In one programme, MSD publicly commits itself to eliminating onchocerciasis (since 1987) and lymphatic filariasis (from 1998 to 2020) by donating ivermectin (Mectizan®) in 27 countries.

⁵ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

¹¹ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|----------|-------------|
| 8 | 3.09 |
| 4 (2018) | |

Merck KGaA

Stock Exchange: Frankfurt Stock Exchange • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 57,036

PERFORMANCE IN THE 2021 INDEX

8th place. Merck KGaA (Merck) has an average performance. It shows a strong performance in planning for access and transparency of access activities, publicly disclosing its commitment and outcomes. The company leads in sharing intellectual property, yet its equitable access approach for specific products and markets is below average.

Governance of Access: 7th place. Merck has an average performance in this area. It has an access-to-medicine strategy and publicly discloses commitments and outcomes of its related activities. While having compliance controls in place, it demonstrates limited evidence of how it monitors these controls.

Research & Development: 5th place. Merck performs well in this area. The company's late-stage priority R&D projects are covered by an access plan. It has a structured process in place to develop access plans during R&D, commits itself to registering trialed products and engages in R&D capacity building activities.

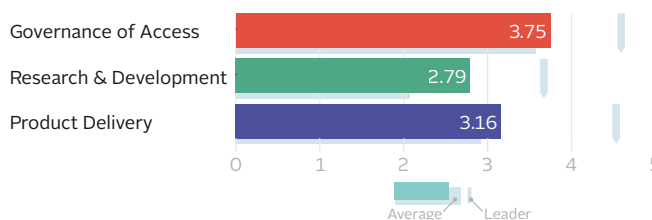
OPPORTUNITIES FOR MERCK

Plan for expansion of vaccine manufacturing initiative. Merck started a pilot in Kenya, the Merck Africa Vaccine Initiative (MAVI), to develop integrated solutions to deploy innovative manufacturing technologies that enable local vaccine manufacturing across Africa. The company can start planning the expansion of the initiative once the pilot proves successful.

Expand access to cancer treatment avelumab (Bavencio®). Merck can file avelumab (Bavencio®) for registration in more high-burden countries such as Ukraine, Egypt and Mali. Furthermore, the company can expand equitable access strategies for avelumab to lower-middle income countries and low-income countries. By applying an equitable pricing strategy in countries that have the capacity to administer this drug, Merck can help reduce inequity in access to cancer treatment.

Apply access planning to more R&D projects and consider affordability. Merck applies access plans to 33% of its late-stage R&D projects. These plans range from registration commitments to equitable pricing strategies. Merck can plan for access for all late-stage R&D projects. The company can plan for both registration and affordability as well as availability for all its late-stage R&D projects, including new indications of its avelumab (Bavencio®), such as breast and brain cancer.

How score was achieved



Product Delivery: 8th place. Merck is a middle-performing company in this area. It shares many IP assets with third-party researchers and publicly pledges not to enforce patents. Yet, it performs below average in access strategies, with a strategy in place only for certain products and markets. The company has a strong approach to donations.

CHANGE SINCE THE 2018 INDEX

- Renewed partnership with WHO on praziquantel donation to Merck Schistosomiasis Elimination Program, targeting school-aged children.
- Merck Africa Vaccine Initiative (MAVI): Merck started a pilot in Kenya with the Government and a local investor as a proof of concept.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Engaged in ten new sharing IP arrangements, e.g. via WIPO research (NTDs), via the COVID-19 Therapeutics Accelerator initiative.
- Expanded PAVON initiative for mapping malaria from three to 11 countries.
- Started a new partnership with China Cardiovascular Association, Heart Failure Center Program, for diagnosis and treatment.
- Joined CAMP-N Supply Chain Technical Working Group for NCD medicines.
- Collaborates with local distributors on Access Delivery Mentorship in Tanzania.
- Publicly shares prerequisites for granting post-study access to investigational products in Position Statement on Post-Study Access.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Healthcare; Life Sciences; Performance Materials

Therapeutic areas: Oncology and Immunology; Neurology & Immunology; Fertility; General Medicine & Endocrinology

Product categories: Innovative medicines; Diagnostics; Medical devices

M&A news: Divested its Consumer Health business to Procter & Gamble in December 2018 for USD 3.4 billion; divested Allergopharma, its

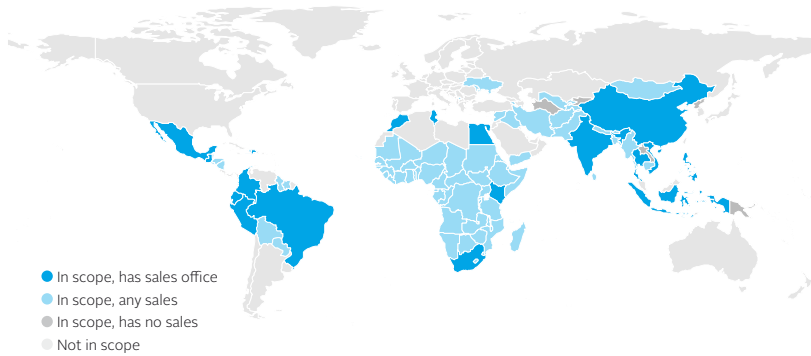
allergy business, to Dermapharm in March 2020.

Merck's products are sold in 93 out of 106 countries in scope. Merck has sales offices in 18 countries and sells via suppliers into 75 additional countries.

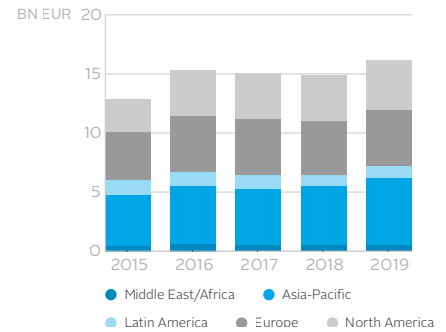
Net sales by segment (2019) – EUR

| | |
|-----------------------|------------------|
| Life Sciences | 6.864 bn |
| Healthcare | 6.714 bn |
| Performance Materials | 2.574 bn |
| Total | 16.152 bn |

Sales in countries in scope



Sales by geographic region



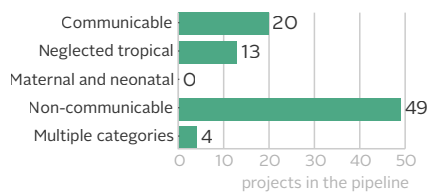
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Merck has a total of 86 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 35 projects. Remarkably, Merck has the fourth largest pipeline as almost 41% of its R&D projects target priority diseases. The other 51 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on schistosomiasis (14 projects). Of the projects targeting other diseases in scope, the focus is on oncology (44).

18 R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (16).^{*} Evidence of access planning was in place for 33% of these projects: 2 targeting a priority disease and 4 addressing a public health need in LMICs.

86 projects in the pipeline



Breakdown of projects[#]

Praziquantel paediatric formulation, an oral dispersible formulation developed by the Pediatric Praziquantel Consortium, led by Merck

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 1 | 3 | 1 | 1 | 0 | 6 | 2 |
| Addresses needs of LMICs [*] | 0 | 12 | 12 | 3 | 1 | 28 | 4 |
| Other projects in scope | 0 | 7 | 12 | 0 | 0 | 19 | |

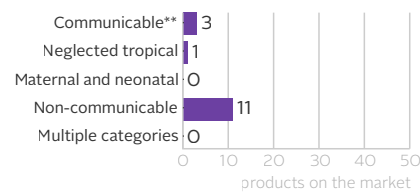
^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

PORTFOLIO as selected for analysis by the Index

Merck has 13 medicines in scope, 3 of which are on patent. 38% of these medicines (5) are on WHO's EML. In addition, the company markets 2 diagnostics. The off-patent medicines target mainly non-communicable diseases (NCDs): cardiovascular diseases (5), diabetes (2) and cancer. One medicine targets malaria and one targets schistosomiasis and other neglected tropical diseases (NTDs). The on-patent medicines target NCDs: oncology and diabetes. The diagnostics in scope are for HIV (2). Access strategies were analysed for 7 products on Merck's portfolio – nationally procured HCP-administered (2) and self-administered products (5).

15 products as selected for analysis by the Index[†]



Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 0 | 3 | | | 3 |
| off patent | 5 | 5 | | | 10 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 2 | | 2 |
| Other | | | | 0 | 0 |

[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Merck KGaA

GOVERNANCE OF ACCESS

RANK 7

SCORE 3.75

Has an access-to-medicine strategy with measurable objectives and a business rationale. Merck has an average performance. It has a Global Health strategy focused on availability, affordability, awareness and accessibility. The strategy covers some of the therapeutic areas in which the company is involved, including neglected tropical diseases (NTDs) and diabetes mellitus. The highest responsibility for access lies indirectly with the board, namely with the Head of Corporate Affairs.

Does not publicly disclose its approach to financial and non-financial access-related incentives at the executive level. Merck has an average performance. Merck discloses to the Index, but not publicly, whether it incentivises its in-country managers and senior executives to perform on access to medicine with financial and non-financial rewards. There is no publicly available evidence that the CEO is also incentivised toward access goals.

Publicly discloses outcomes of its access-to-medicine activities. Merck performs strongly in transparency of access activities. It publicly discloses commitments including on combating NCDs, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, for example through the IFPMA Global Health Progress platform.

Has an average performance in responsible promotional practices. Merck's sales agents are not solely incentivised on sales volume targets. More details on how the company addresses sales incentives for agents are unavailable. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), unless required by local regulations, e.g. in Brazil.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Merck performs relatively poorly,

demonstrating some of the components looked for by the Index: audits (both internal and external, covering third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards. It does not, however, demonstrate evidence of a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment. It reports having in-country compliance officers evaluating risks based on the business sector in all respective legal entities or departments.

Publicly supports the Doha Declaration on TRIPS and Public Health. Merck publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on the implementation of its provisions. That is, it highlights compulsory licensing as a risk of undermining innovation. There is no evidence of a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

RANK 5

SCORE 2.79

Access planning processes encompass all projects in pipeline. Merck has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, Merck begins developing access plans for R&D projects in Phase II or earlier of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to its peers, with access plans in place. Merck has 35 projects including two late-stage candidates in its pipeline that target a priority product gap. The company focuses mainly on schistosomiasis. There is evidence of access plans for both Merck's late-stage candidates, which are two different praziquantel formulations. The access plan for the praziquantel paediatric formulation includes a commitment for WHO prequalification, priority registration in high burden African countries and non-exclusive licenses in agreement with the Pediatric Praziquantel Consortium partners to generics or local drug manufacturers in endemic countries.

Many projects address a public health need in LMICs*, with 25% of the late-stage projects covered by access plans. In this analysis, Merck has 16 late-stage R&D projects that target a disease and/or product gap not yet designated as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Merck provides evidence of access plans for four of these projects. These plans range from registration commitments to equitable pricing strategies for some projects. Notable is a combination therapy with bintrafusp alfa, a potential first-in-class TGF-beta receptor 1 inhibitor, to treat gallbladder cancer. The company commits itself to registering the product in four countries in scope and applying a pricing strategy based on ability to pay.

Public policy to ensure post-trial access; commits itself to registering trialed products. Merck has a policy for ensuring post-trial access to treatments for clinical trial

participants. This policy covers a subset of clinical trial participants who have a life-threatening, chronic or seriously disabling illness. Once a product is approved, Merck commits itself to registering it in all countries where clinical trials for the product have taken place. The policy states that it takes into account local affordability in any given country. Details of which are not available.

Two R&D capacity building initiatives meet all Good Practice Standards. Merck performs above average in this indicator. Five initiatives were included for analysis. Two initiatives met all Good Practice Standards[‡]:

- Merck's collaboration with Makerere University's in Uganda, focusing on antimicrobial resistance research and building national infection control programme capacity by training medical students at the National Referral and Training Hospital, the Mulago Hospital.
- Partnership with Seeding Labs for the Instrumental Access Programme, providing equipment and training to scientists and universities in LMICs.

PRODUCT DELIVERY

RANK 8

SCORE 3.16

Public commitment not to enforce patents in countries in scope. Merck publicly pledges to neither file for nor enforce patents. This commitment applies to all Least Developed Countries and low-income countries as well as in a subset of lower-middle income countries and upper-middle income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Merck publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Merck has shared many IP assets with third-party researchers developing products for diseases in scope. This includes ten IP assets shared with research institutions and drug discovery initiatives, such as COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard.

182 ‡ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

Assets shared include molecule libraries and sets of target-specific compounds for drug discovery.

No use of non-assert or licensing arrangements. Merck does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of high burden countries. Merck has filed 20% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, cetuximab (Erbix[®]) for colorectal cancer has been filed for registration/registered in six high burden countries in scope, including Thailand and Moldova.

No supranationally procured products. Merck has no products eligible for scoring in this indicator.

Has access strategies for some healthcare practitioner-administered products in scope of this analysis.

Merck performs below average in this area. The company provides examples of access strategies which consider affordability countries of all assessed income levels (UMIC, LMIC, LIC) for one of the two products assessed. The company makes efforts to reach additional patients using equitable pricing strategies. For example, in China, for cetuximab (Erbix[®]), a treatment for colorectal cancer, it applies equitable pricing strategy to list the product on the national reimbursement drug list, and previously offered a patient assistance programme to reduce co-pay for low income patients to increase affordability and access. Merck is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. Merck performs below average in this area. The company provides examples of access strategies which consider affordability countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. For the other products, it falls short providing example in one or two of the countries type. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in South Africa, for bisoprolol (Concor[®]), the company participates in tenders in the public sectors and has a 'clone' strategy, where they offer price reduction for the clone Betacor[®] to list it on all payer formularies to increase access for low-income patients. Merck is able to provide evidence of how patient reach has been increased through the approaches used.

One manufacturing capacity building initiative meets all Good Practice Standards. Merck has an average performance in this area. The company submitted the maximum of five initiatives, which all met all the criteria for inclusion. One initiative met all Good Practice Standards.[§] For this initiative, Merck aims to create manufacturing process robustness by enabling its Contract Manufacturing Organisations to deal with quality issues in a proactive manner through the implementation of a 'Continuous and On-going Process Verification' roll-out in six countries in scope of the Index.

One supply chain capacity building initiative meets all Good Practice Standards. Merck has an average performance in this area. The company submitted the maximum of five initiatives, of which two met all criteria for inclusion. The access delivery mentorship programme in Tanzania met all Good Practice Standards.[§] The programme provides four local distributors with supply chain and delivery support to strengthen last-mile delivery,

Three health system strengthening initiatives included for evaluation. Merck performs below average in this area. The company submitted the maximum of five initiatives, of which three met all criteria for inclusion: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives and (plan to) measure outcomes. The initiatives did not meet all Good Practice Standards. For example, Merck's aims to enhance integrated disease management for women's health in Cameroon through, amongst others, HPV screening, HIV screening, FGS diagnosis, precision mapping of schistosomiasis endemic areas and health worker training. However, Merck did not sufficiently demonstrate how it aims for sustainability.

Has engaged in the development and implementation of a scaled up inclusive business model. Merck performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has scaled up its model Curafa, supporting primary healthcare in Kenya. The programme is now facilitated by Access Afya.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Merck performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. The company has a process in place to align demand and supply at the country, regional and global level. Merck keeps safety stock of finished goods, inventory of semi-finished products and has a dual sourcing policy in place. In Yemen, the company has set up a new logistical route to overcome supply challenges and ensure product availability while preserving quality.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope. Merck provides evidence of reporting SF medicines to the relevant national health authorities, on a case-by-case basis. It does not, however, require reporting to occur within the timeframe of ten days looked for by the Index, nor does it distinguish reporting time frames for cases which only require visual inspection to be confirmed. It looks at the ICH standards of 15 days for serious cases or 90 for non-serious cases.

Donates in response to an expressed need and monitors delivery to end user. Merck has a policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user. For example, it donated metformin (Glucophage[®]) for diabetes mellitus in 2019 in response to natural disasters and/or emergency situations in nine countries.

Publicly commits to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Merck publicly commits itself to eliminating schistosomiasis by donating praziquantel (Cesol[®]) in 42 countries since 2007.

§ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|----------|-------------|
| 2 | 4.18 |
| 2 (2018) | |

Novartis AG

Stock Exchange: SIX Swiss Exchange • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 103,914

PERFORMANCE IN THE 2021 INDEX

2nd place. Novartis is a leading company. The company has a strong performance in all three Technical Areas of the Index, leading in its approach to Product Delivery.

Governance of Access: 2nd place. It has embedded access to medicine into its corporate strategy under the Novartis Access Principles. The company has access-related incentives for the CEO and a robust set of compliance controls.

Research & Development: 3rd place. Novartis performs strongly in this area. It has an access planning process in place that covers all projects in the pipeline. It is the only company that both commits to post-trial access to all clinical trial participants and considers post-trial affordability in countries in scope. The company has nine late-stage priority R&D projects in the pipeline, with two-thirds covered by comprehensive access plans.

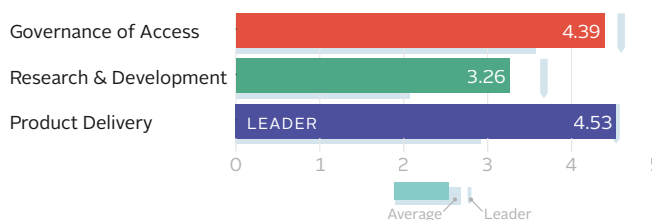
OPPORTUNITIES FOR NOVARTIS

Expand technology transfers to other geographic areas. Novartis reports three technology transfers to build manufacturing capacity, including one for biosimilars. Capacity building is focused on middle-income countries such as Brazil and Pakistan. The company can expand its technology transfer initiatives to low-income countries, including those in sub-Saharan Africa.

Implement an access planning process across all late-stage R&D projects. In its Novartis Access Principles, the company commits to planning for access for all late-stage R&D projects from Phase II onwards. The company can implement project-specific access and registration plans as well as access strategies addressing affordability for all late-stage R&D projects, e.g. for asthma and cancer.

Improve access to patented products on WHO EML. In the countries in scope, Novartis can further expand access to patented products listed on the 2019 WHO List of Essential Medicines such as nilotinib (Tasigna®) by increasing affordability and supply through voluntary licensing and equitable pricing strategies. Countries such as Vanuatu, Myanmar, Laos, Philippines, Ecuador, Bolivia, El Salvador, Ukraine can be considered.

How score was achieved



Product Delivery: 1st place. Novartis leads in this area. Leading consistently across access strategies, it is the only company that applies equitable access strategies in low-income countries (LICs) for all its products. It has newly shared thirteen IP assets and leads in this area. The company engages in all areas of capacity building and performs strongly in implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope.

CHANGE SINCE THE 2018 INDEX

- Launched new strategy to reach more patients in sub-Saharan Africa (SSA) across its portfolio.
- Newly commits itself to patient access targets in low- and middle-income countries, reinforced via sustainability-linked bond.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Partners with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four Pharmaceutical companies on Africa Health Worker Training Initiative
- Engages in new IP sharing via WIPO Research (TB, Chagas and malaria), the COVID-19 Therapeutics Accelerator, IMI call 21 project institutions, DNDi and MMV.
- Started Afya Dumu (End to End Care Model, Kenya) working with Kenya County governments to improve clinical outcomes in chronic diseases through community awareness, building capacity of healthcare providers, product access and improved supply chain management.
- Has new technology transfer agreements with Indian manufacturers for TB products and products falling under the Healthy Family programme and with Chinese manufacturer for Kymriah® for cancer.
- Partners with the government of Brazil on 10-year technology transfer of biosimilars with initial focus on rituximab.
- Collaborates with West African Centre for Cell Biology of Infectious Pathogens (WACCBIP) to improve research capabilities.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Innovative Medicines; Sandoz
Therapeutic areas: Oncology; Ophthalmology; Neuroscience; Immunology, Hepatology and Dermatology; Respiratory; Cardiovascular, Renal and Metabolism; Anti-infectives (Sandoz)
Product categories: Innovative medicines; Generic medicines; Biosimilars
M&A news: In 2019, Novartis acquired The Medicines Company for USD 9.7 billion and the

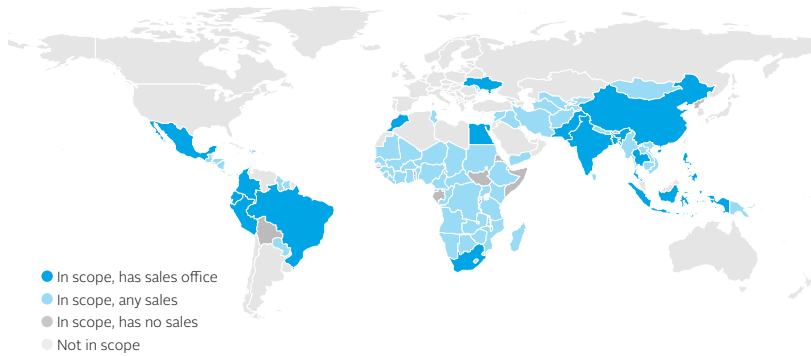
eye care business of Takeda for USD 3.4 billion. Spun off Alcon, its eye care business, in April 2019.

Novartis' products are sold in 83 out of 106 countries in scope. Novartis has sales offices in 16 countries, sells via suppliers in 57 countries and via pooled procurement in 10 additional countries.

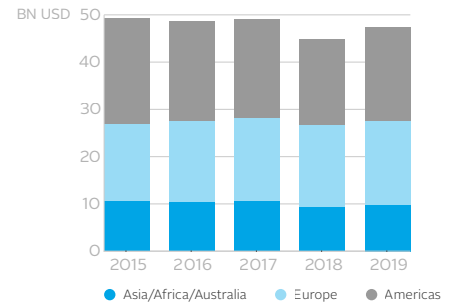
Net sales by segment (2019) – USD

| | |
|----------------------|------------------|
| Innovative Medicines | 37.714 bn |
| Sandoz | 9.731 bn |
| Total | 47.445 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Novartis has a total of 60 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 21 projects. Remarkably, more than one third of the Novartis total R&D projects target priority diseases. The other 39 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (9 projects) and COVID-19 (5). Of the projects targeting other diseases in scope, the focus is on asthma (4) and oncology (23).

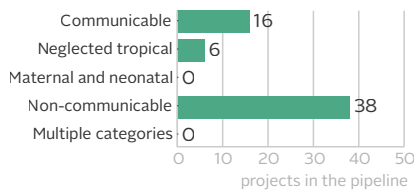
28 R&D projects are in late-stage development that target either a priority disease (9) or address a specific need in LMICs (19)*. Evidence of access planning was in place for 57% of these projects: 6 targeting a priority disease and 10 addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

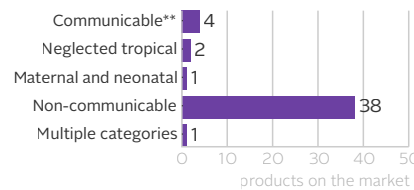
Novartis has 46 medicines in scope, 24 of which are on patent. 52% of these medicines (24) are on WHO's EML. The off-patent medicines target mainly non-communicable diseases (NCDs) (15) such as cardiovascular diseases (6) and cancer (3). Four products target communicable diseases such as tuberculosis (3) and malaria. Two further products target the neglected tropical diseases (NTDs) leprosy and food-borne trematodiasis. One further product targets maternal haemorrhage. The on-patent medicines mainly target NCDs such as cancer (11) and pulmonary diseases (4). One further medicine targets hepatitis B.

Access strategies were analysed for 13 products on the Novartis portfolio – supranationally procured (4) or nationally procured HCP-administered (4) and self-administered products (5).

60 projects in the pipeline



46 products as selected for analysis by the Index†



Breakdown of projects*

KAF156/lumefantrine is the first compound to progress into clinical development from the novel imidazolo-piperazine class of antimalarial molecules (partnership with MMV)

Crizanlizumab (Adakveo) a targeted therapy to treat patients with sickle cell disease.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 4 | 1 | 4 | 4 | 0 | 13 | 6 |
| Addresses needs of LMICs* | 0 | 11 | 13 | 5 | 2 | 31 | 10 |
| Other projects in scope | 0 | 7 | 1 | 0 | 0 | 8 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 4 | 20 | | | 24 |
| off patent | 20 | 2 | | | 22 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

1 product for sickle cell disease

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Novartis AG

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.39

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novartis performs strongly. It has an access strategy embedded in the Novartis Access Principles and a new tailored approach for sub-Saharan Africa. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Governance, Nomination and Corporate Responsibilities Committee.

Provides evidence of financial and non-financial access-related incentives at executive level. Novartis performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives included in their performance targets.

Publicly discloses outcomes of its access-to-medicine

activities. Novartis performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, namely the progress of its Access Principles initiatives, in various channels e.g. its annual report.

Has an average performance in responsible promotional practices. Novartis' sales agents are not solely incentivised on sales volume targets. The company sets sales incentives at the individual level for agents. Except for Ukraine where it reports to EFPIA[†] and other cases where it is required by law, Novartis does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novartis performs strongly, demonstrating all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards.

Publicly supports the Doha Declaration on TRIPS and Public Health. Novartis publicly shares explicit support of the Doha Declaration on TRIPS and Public Health without expressing reservations on the appropriate use of its flexibilities, including compulsory licences, parallel imports, Bolar provisions, exemptions for Least Developed Countries (LDCs). It has a statement of independence to dissent from industry association positions on IP.

RESEARCH & DEVELOPMENT

RANK 3

SCORE 3.26

Access planning processes encompass all projects in pipeline. Novartis has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, Novartis begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to peers, with access plans in place for 67% of the late-stage candidates. Novartis has 21 projects, including nine late-stage candidates in its pipeline, that target a priority product gap. Of the projects targeting priority diseases, the focus is on malaria (9 projects) and COVID-19 (5). Of the Novartis nine late-stage candidates targeting a priority product gap, six have an access plan. These plans are mostly applied through access-oriented partnerships with PDPs and focus on affordability and availability.

Many projects address a public health need in LMICs*, with 53% of the late-stage projects covered by access plans. In this analysis, Novartis has 19 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules, e.g. for asthma. Novartis provides evidence of access plans for ten of these projects. These access strategies across the portfolio include commitments to register products in countries in scope and to strive to take equitable pricing strategies in to account for some projects (i.e. income levels, local affordability barriers). Notable, is Egaten® (triclabendazole) to control fascioliasis. This product will continue to be donated to more than 40 eligible countries through the WHO.

Public policy to ensure post-trial access; commits itself to registering trialed products. Novartis has a public policy for ensuring post-trial access to treatments for clinical trial participants. The policy covers all clinical trial participants. Once a product is approved, Novartis commits itself to registering it in all countries where clinical trials for the product have taken place. The policy considers affordability for the wider population in the country where the trial(s) took place.

One R&D capacity building initiative meets all Good Practice Standards. Performs above average in this indicator. Novartis submitted the maximum of five initiatives and four met all criteria for inclusion. One initiative, the Memorandum of Understanding (MoU) with the South African Department of Science and Technology (DST) and South African Medical Research Council (SAMRC), met all Good Practice Standards.[§] For Novartis' Scientific Exchange Programs, the company does not demonstrate how it aims for long-term impact on local R&D capacity.

PRODUCT DELIVERY

RANK 1

SCORE 4.53

Public commitment not to enforce patents in countries in scope. Novartis publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries, low-income countries and a subset of lower middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Novartis discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically

updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Novartis has newly shared many IP assets with third-party researchers developing products for diseases in scope. This includes thirteen IP assets shared with research institutions and drug discovery initiatives such as COVID-19 Therapeutics Accelerator launched

by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries.

No use of non-assert or licensing arrangements. Novartis does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of

† Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

§ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

high burden countries. Novartis has filed 10% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, sacubitril/valsartan (Entresto®) for ischaemic heart disease has been filed for registration/registered in six high burden countries in scope, including Moldova and Morocco.

Has access strategies for all supranationally procured products in scope of this analysis. Novartis leads in securing access for products procured supranationally.[¶] For the four products assessed in this category, it demonstrated strategies both in countries eligible for supply from such procurers and also in at least one non-eligible country. For example, the company offers the same terms in South Africa for the tuberculosis medicine Lamprone® as they do in Global Drug Facility eligible countries.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Novartis leads in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for three of the four products assessed. Novartis makes efforts to reach additional patients using equitable pricing strategies. For example, in India, for omalizumab (Xolair®), a treatment for asthma, the company uses tenders and launched an emerging market brand offered at discount price to increase access, while strengthening the health system by increasing affordability and accessibility to spirometry tests. Novartis is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for the majority of self-administered products in scope of this analysis. Novartis leads in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for the five products assessed. Novartis makes efforts to reach additional patients using both inter- and intra-country equitable pricing strategies. For example, in Uganda, part of the new sub-Saharan business model, the company offers different packs of vildagliptin depending on income level. For the top of the income pyramid, vildagliptin (Galvus®) and vildagliptin/metformin (Galvus-met®) are offered at a higher price. For the base of the pyramid and in the lower-income private market 'Novartis Access' Vildagliptin is offered at a lower price. 400 patients gained access to this treatment since 2019 in Uganda. Novartis is able to provide evidence of how patient reach has been increased through the approaches used.

Three manufacturing capacity building initiatives meet all Good Practice Standards. Novartis performs above average in this area. Novartis submitted the maximum of five initiatives, of which four met all criteria for inclusion. Three initiatives, technology transfers of a wide range of products India, Iran and Pakistan and biosimilars in Brazil, met all Good Practice Standards.[¶]

Three supply chain capacity building initiatives meet all Good Practice Standards. Novartis performs well in this area. Novartis submitted the maximum of five initiatives and all met all criteria for inclusion. Three initiatives met all Good Practice Standards.[¶] Examples include:
- Authentifield by Novartis, enabling mobile and fast detec-

tion of counterfeit medicines in 12 countries in scope of the Index.

- Drone delivery partnerships with Zipline and Linex in Ghana and Brazil, respectively, enabling faster supply to harder-to-reach areas. In Ghana, Zipline reaches 12 million people across the country.

For the two other initiatives, which include demand and supply planning with the WHO for donated leprosy medicine and workshops on standardised supply chain processes for distribution partners in sub-Saharan Africa, Novartis did not sufficiently demonstrate how they aim for sustainability.

Four health system strengthening initiatives meet all Good Practice Standards. Novartis is one of the leading companies. The company submitted the maximum of five initiatives and all met all criteria for inclusion and all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, through the Afya Dumu /'End to End Care Model', Novartis aims to screen 200,000 people and improve clinical outcomes for cancer and diabetes through early diagnosis, early treatment and proper follow-up.

Has engaged in the development and implementation of new and scaled up inclusive business models. Novartis performs strongly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has scaled up its models Novartis Access on non-communicable disease (NCD) care and Healthy Family creating health camps and contributed to one new: the Novartis Africa Sickle Cell Disease Flagship programme.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Novartis performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. The Novartis process to align demand and supply is applied globally in countries where Novartis has an affiliate of distributor, including in 31 Least Developed Countries. The Novartis Supply Risk Management framework is regularly reviewed and updated, which can be followed by measures such as increased safety stocks, pandemic preparedness plans and the implementation of dual API sourcing strategies.

Has a policy for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Novartis has a policy for reporting SF medicines to both national health authorities and WHO, within 7 days. Novartis authentication relies on packaging data verification, packaging testing (i.e. security features) and/or product testing whichever can be performed the fastest. The policy classifies incidents following categories according to their degree of severity, which may enable faster action.

Donates in response to an expressed need, but does not monitor delivery to end user. Novartis has a policy in place to ensure ad hoc donations are carried out in response to an expressed need; however, it does not monitor the delivery until the end user.

Publicly commits to the achievement of elimination,

eradication or control goals in its structured donation programmes for NTDs. Two structured donation programmes for NTDs were included for analysis where elimination, eradication or control goals are possible. In one programme, Novartis publicly commits itself to eliminating leprosy by donating the MDT Combi clofazimine/dapsone/rifampicine (Lamprone®/Rimactane®/Dapsone®) from 2000 to 2020 in 74 countries. Moreover, it is engaged in another structured donation programme: the Max Access Solution programme whereby it has been donating imatinib (Glivec®) and nilotinib (Tasigna®) for leukaemia and gastrointestinal stromal tumours in 33 countries since 2002.

¶ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

¶ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 10 | 2.96 |
| 6 (2018) | |

Novo Nordisk A/S

Stock Exchange: Copenhagen Stock Exchange • Ticker: NOVO B • HQ: Bagsværd, Denmark • Employees: 43,258

PERFORMANCE IN THE 2021 INDEX

10th place. Novo Nordisk is a middle-performing company. It shows a strong performance in access strategies for its products in specific markets and launched the Defeat Diabetes Strategy, but has a small R&D pipeline with no priority projects.

Governance of Access: 5th place. Novo Nordisk performs well in this area. It has an access-to-medicine strategy integrated within the overall corporate strategy and publicly discloses the outcomes of its access-to-medicine activities.

Research & Development: 18th place. Novo Nordisk performs poorly in this area. The company does not have a structured process for access planning during R&D and does not engage in R&D capacity building initiatives. It has a small-sized R&D pipeline compared to its peers; no priority projects.

OPPORTUNITIES FOR NOVO NORDISK

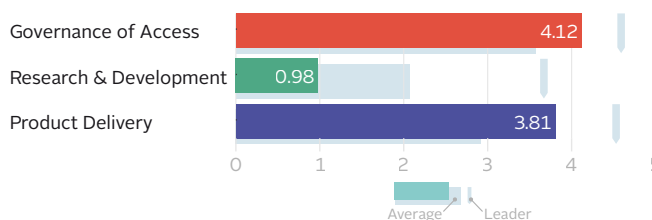
Continue to expand capacity building for vulnerable populations. Novo Nordisk's Changing Diabetes in Children (CDiC) initiative is active in 14 LDCs, LICs and LMICs in Asia and sub-Saharan Africa and was extended to 2030. It can scale up to additional countries, for example, in Latin America. It has scaled up its Base of the Pyramid model addressing diabetes-related access issues including awareness and health infrastructures in Kenya, Ghana, Nigeria, Senegal and Morocco. Novo Nordisk can apply this model in more countries with a high burden of diabetes and populations at the base of the pyramid such as Swaziland and Sri Lanka.

Expand access to innovative products. Novo Nordisk has an equitable pricing strategy, the 'Access to Insulin Commitment', that applies to recombinant human insulins for all LDCs, other LICs and MICs with large low-income populations. It can also apply equitable pricing strategies in LDCs and LICs to analogue insulins, such as insulin degludec (Tresiba®), and to other innovative anti-diabetic medicines such as liraglutide (Victoza®). Furthermore, it can expand filing for registration to most recently introduced products such as semaglutide injection (Ozempic®) and oral (Rybelsus®) and insulin aspart + niacinamide (Fiasp®).

Develop an access planning process and access plans for all R&D projects.

Novo Nordisk can develop a formal access planning process and accordingly develop access plans for all clinical Phase II projects, especially for products addressing a public health need in low- and middle-income countries such as its once-weekly basal insulin analogue, and ensure a stronger access plan for oral semaglutide (Rybelsus®) that includes affordability.

How score was achieved



Product Delivery: 4th place. Novo Nordisk performs above average in this area. The company demonstrates engagement in high-quality initiatives in all fields of capacity building, i.e. manufacturing, supply chain and health system strengthening. It has access strategies for its products and multiple mechanisms to ensure continuous supply for some countries in scope. Yet, there is no evidence of new products filed for registration in the majority of high-burden countries and the company does not share IP assets with third-parties.

CHANGE SINCE THE 2018 INDEX

- Launched the Defeat Diabetes Strategy.
- Strengthened its Access to Insulin Commitment to include 76 low- and middle-income countries and lowered the price ceiling of human insulin to USD 3.00 per human insulin vial.
- Extended Changing Diabetes in Children initiative to 2030.
- Extended Partnering for Change to support the efforts of ICRC and the Danish Red Cross to provide access to NCD care for the populations they serve.
- Increased capacity, with the formation of a Sustainable Supply Chain team, to supply insulin products to humanitarian organisations on preferential terms until at least 2030.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Donates via WHO insulin and glucagon for diabetes mellitus for use in 50 low- and middle-income countries in response to COVID-19.
- Partners with the Coalition for Access to NCD Medicines and Products to develop a demand forecasting tool.
- Set up an insulin production line in Iran.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

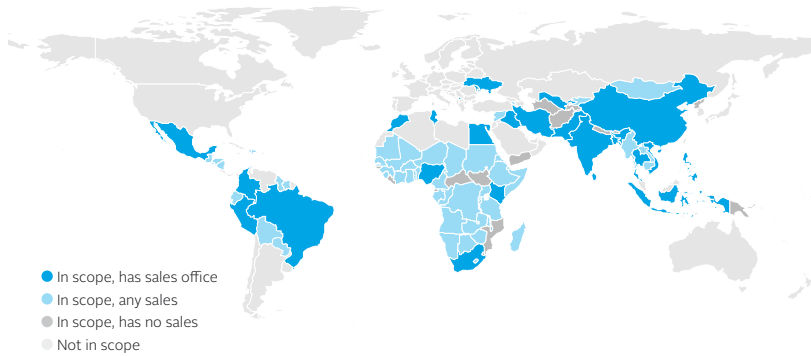
Business segments: Diabetes and Obesity care; Biopharm
Therapeutic areas: Diabetes; Obesity; Haemophilia, Growth disorders and Hormone replacement therapy.
Product categories: Innovative medicines
M&A news: Acquired Emisphere Technologies (drug delivery) for USD 1.35 billion.

Novo Nordisk's products are sold in 81 out of 106 countries in scope. Novo Nordisk has sales offices in 25 countries and sells via suppliers in 56 additional countries.

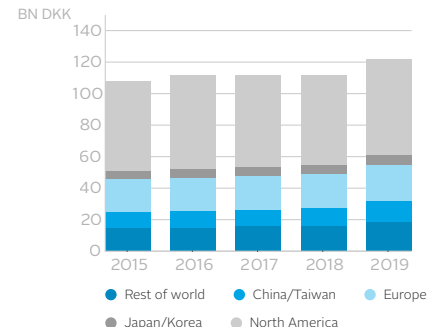
Net sales by segment (2019) – DKK

| | |
|---------------------------|-------------------|
| Diabetes and Obesity care | 102.840 bn |
| Biopharm | 19.181 bn |
| Total | 122.021 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

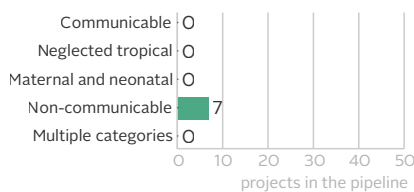
PIPELINE for diseases and countries in scope

Novo Nordisk has the smallest pipeline compared to its peers with 7 R&D projects targeting other diseases in scope (no priority R&D pipeline). The focus of these projects is on diabetes (5 projects). One project targets sickle cell disease and one is for ischaemic heart disease. 3 R&D projects are in late-stage development that address a public health need in LMICs.* Evidence of access planning was in place for 33% of these projects (1).

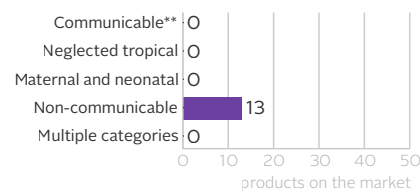
PORTFOLIO as selected for analysis by the Index

Novo Nordisk has 13 medicines in scope, 8 of which are on patent. 15% of these medicines (2) are on WHO's EML. All medicines in the off-patent portfolio target diabetes and are insulins (4) and glucagon. The medicines in the on-patent portfolio target diabetes, as well. Novo Nordisk has insulins (5) and GLP1 agonists (3) on its on-patent portfolio. Access strategies were analysed for 5 products on Novo Nordisk's portfolio – nationally procured self-administered products (5).

7 projects in the pipeline



13 products as selected for analysis by the Index*



Breakdown of projects#

Eclipse (EPL01 + decitabine + tetrahydrouridine) is an oral formulation of a potential disease-modifying treatment for sickle cell disease

Semaglutide is the first oral GLP-1 treatment for Type 2 diabetes mellitus. Does not require refrigerated storage.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | | | | | | | |
| Addresses needs of LMICs* | 0 | 2 | 2 | 0 | 1 | 5 | 1 |
| Other projects in scope | 0 | 2 | 0 | 0 | 0 | 2 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 0 | 8 | | | 8 |
| off patent | 2 | 3 | | | 5 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clin-

ical phase of development were included for this analysis.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Novo Nordisk A/S

GOVERNANCE OF ACCESS

RANK 5

SCORE 4.12

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novo Nordisk performs strongly. The Defeat Diabetes strategy, focused on prevention, innovation, access and affordability, covers all therapeutic areas in which the company is involved for diseases in scope. The highest responsibility for access lies directly with the board, namely with the CEO, under the supervision of the Board of Directors.

Provides evidence of financial and non-financial access-related incentives at the executive level. Novo Nordisk also performs strongly here. It incentivises its senior executives and in-country leaders for delivering on its access to care objectives. The CEO also has access-related incentives, linked to long-term social targets.

Publicly discloses outcomes of its access-to-medicine activities. Novo Nordisk performs strongly in transparency of access activities. It publicly discloses commitments

including Access to Insulin, measurable goals, objectives and targets for improving access in countries in scope. It consistently shares outcomes of its access-to-medicine activities, including on the number people treated with insulin based on targets set and for its Changing Diabetes in Children programme.

Has an average performance in responsible promotional practices. Novo Nordisk's sales agents are not solely incentivised on sales volume targets. The company sets sales incentives at the individual level for agents. Novo Nordisk does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), unless required by local regulations or industry association commitments e.g. in Brazil and in the Philippines.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novo Nordisk performs strongly here, demonstrating all components looked for by the Index: Fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties.

Publicly supports international agreements. Novo Nordisk states that health emergencies requiring exceptions to IP rights can and should be accommodated under the international legal framework. It expresses reservations on the use of compulsory licensing. It states that its positions are generally aligned with its industry associations.

RESEARCH & DEVELOPMENT

RANK 18

SCORE 0.98

No structured process for access planning disclosed. Novo Nordisk does not have a structured process in place to develop access plans during R&D. The company did not disclose a structured timeline for the development of access plans for its R&D projects.

Novo Nordisk has no priority R&D projects in its pipeline. The company's R&D projects focus mostly on diabetes mellitus (Type 1 and 2).

Some projects address a public health need in LMICs*, with 33% of the late-stage projects covered by access plans. In this analysis, Novo Nordisk has three late-stage

R&D projects that target a disease and/or product gap not yet designated as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target diabetes mellitus. Novo Nordisk provides evidence of access plans for one of these projects.

Public policy to ensure post-trial access; commits itself to registering trialed products. Novo Nordisk has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical

trial participants on a case-by-case basis. Once a product is approved, Novo Nordisk commits to seek registration in all countries where clinical trials for the product have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Novo Nordisk performs poorly in this area. The company submitted two R&D capacity building initiatives, but none met all criteria for inclusion.

PRODUCT DELIVERY

RANK 4

SCORE 3.81

Public commitment not to enforce patents in countries in scope. Novo Nordisk publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and low-income countries.

Publicly discloses detailed information on patent status. Novo Nordisk both publicly discloses on its website the patent statuses for biologics and for small molecules in scope via the Pat-INFORMED database. Novo Nordisk's disclosure includes detailed information about patents, including expiry date, patent number and jurisdiction.

Does not share IP assets with third-party researchers. Novo Nordisk reports no instances where it shares IP assets with third-party researchers developing products for diseases in scope during the period of analysis.

No use of non-assert or licensing arrangements. Novo Nordisk does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Novo Nordisk did not disclose evidence of filing any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, insulin human (rDNA) (Actrapid®) for diabetes mellitus is registered/has been filed for registration in 76 countries in scope, including Guyana and Central African Republic.

No supranationally procured products. Novo Nordisk has no products eligible for scoring in this indicator.

No healthcare practitioner-administered products. Novo Nordisk has no products eligible for scoring in this indicator.

Has access strategies for its self-administered products for some countries in scope of this analysis. Novo Nordisk performs above average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for three of the five products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies and donation. For example, in Kenya, the human insulin (rDNA) (Actrapid®) is covered by the Access to Insulin Commitment, an inter- and intra-country equitable pricing strategy. The company guarantees a price ceiling of 3 USD per vial under this the commitment. Novo Nordisk also runs a programme that

covers capacity building, patient education and provision of insulin at a low price in faith-based health facilities for patients at the base of the economic pyramid. In addition, the company donates human insulin for children with Type 1 diabetes mellitus through the Changing Diabetes® in Children programme. Novo Nordisk is able to provide evidence of how patient reach has been increased.

Two manufacturing capacity building initiatives meet all Good Practice Standards. Novo Nordisk has an average performance in this area. The company submitted two initiatives, which were both included for analysis and met all Good Practice Standards.† Both initiatives support partner manufacturing sites in India and Bangladesh in meeting Good Manufacturing Practice (GMP) standards, the qualification of equipment and the validation of manufacturing processes.

Three supply chain capacity building initiatives meet all Good Practice Standards. Novo Nordisk performs above average in this area. The company submitted four initiatives, which all met all criteria for inclusion. Three of them met all Good Practice Standards.‡ Examples include:

- The Defeat-NCD Partnership, strengthening the supply and procurement of non-communicable disease (NCD) treatments.
- The Base of the Pyramid, improving diabetes care for people living at the base of the economic pyramid in Kenya

For the partnership initiative with the Africa Resource Centre in Kenya to support the National AIDS and STD Control Program, Novo Nordisk did not sufficiently demonstrate how the initiative aims for sustainability.

Five health system strengthening initiatives meet all Good Practice Standards. Novo Nordisk is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, have defined goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, the Changing Diabetes in Children (CDiC) initiative aims to improve diabetes care for children by establishing clinics for Type 1 diabetes care, training healthcare workers, supporting patient education and donating free-of-charge human insulin. To date, the initiative has established 208 clinics in 14 countries, enrolled over 26,500 children and has been extended until 2030.

Has engaged in the development and implementation of a scaled up inclusive business model. Novo Nordisk performs well when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has scaled up its model Base of the Pyramid addressing diabetes-related access issues including awareness and health infrastructures in five African countries.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Novo Nordisk performs well in this area, disclosing multiple strategies to ensure the continuous supply in countries in the scope of the Index. In January 2020, Novo Nordisk rolled out a new demand planning platform 'Demand Planning 4 Future', which covers all markets and

products and includes both commercial sales and humanitarian organisations sales. In February 2020, Novo Nordisk started a mapping project in 15 sub-Saharan African countries and India, identifying key agents in the value chain with the aim to improve processes and enhance availability.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days.

Novo Nordisk has a policy for reporting SF medicines to the relevant health authorities, including the FDA, within 7 days. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need, and monitors delivery to end user. Novo Nordisk has a policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user. For example, it donated insulin and glucagon for diabetes mellitus to at least 50 countries in 2020 in response to the COVID-19 pandemic.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Novo Nordisk is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Changing Diabetes in Children programme where it donates human insulin (Actrapid®, Insulatard® and Mixtard®) to 14 countries since 2009.

† Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 4 | 3.65 |
| 11 (2018) | |

Pfizer Inc

Stock Exchange: New York Stock Exchange • Ticker: PFE • HQ: New York City, New York, United States • Employees: 88,300

PERFORMANCE IN THE 2021 INDEX

4th place. Pfizer performs strongly and is now in the top five of the Index. The company performs strongly in access strategies and capacity building as well as access planning during R&D.

Governance of Access: 5th place. Pfizer performs well in this area. It has embedded access to medicine into its corporate strategy, under the Purpose Blueprint, with CEO remuneration linked to access performance. The company has some compliance controls in place, yet lacks evidence of a continuous system to monitor activities.

Research & Development: 7th place. Pfizer performs above average in this area. Its performance in planning for access is better than in previous years, with a structured access planning process during R&D applied to all its projects in the pipeline. The majority of its late-stage R&D projects is covered by an access plan.

OPPORTUNITIES FOR PFIZER

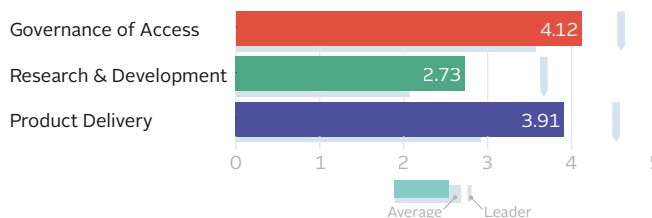
Improve access to key antibiotics. Pfizer could improve access to antibiotics such as ceftazidime/avibactam (Zavicefta®) and ceftaroline (Zinforo®) through equitable pricing strategies and filing for registration in more countries where the burden of lower respiratory tract infections is high such as Nigeria, Niger, Guinea, Burkina Faso, Sierra Leone, Somalia and Afghanistan.

Expand post-trial access policy. Pfizer can expand its post-trial access policy to include all patients who have received a clinical benefit from an investigational treatment and not on a case-by-case basis. Furthermore, the company can ensure product affordability.

Expand equitable pricing strategies to include more countries and products. Pfizer applies equitable pricing strategies for healthcare practitioner-administered products in UMICs and LMICs, but does not report implementing such strategies in LICs. For example, Pfizer applies a pricing segmentation strategy for palbociclib (Ibrance®) in Mexico and India through a patient assistance programme which assesses patients' ability to pay and socio-economic status and offers tailored solutions (tiered discount, cap payments, free goods). Pfizer can expand this strategy to more countries, including LICs, and to more products.

Improve access plans for R&D projects during development. Currently, Pfizer has access plans in place for 67% of late stage priority projects and 70% of projects identified as having a clear public health benefit in LMICs have access plans. These plans range from plans to register products to considering equitable pricing strategies for some projects. It can expand access planning to more late-stage R&D projects such as the vaccines for meningococcal infections and for meningitis.

How score was achieved



Product Delivery: 3rd place. Pfizer performs strongly in this area. The company has access strategies in place for the majority of its products and shares many IP assets with third-party researchers. The company engages in all areas of capacity building, with the majority of its initiatives meeting all Good Practice Standards.

CHANGE SINCE THE 2018 INDEX

- Issued a non-exclusive voluntary licence for sutezolid via the Medicines Patent Pool (MPP), including access to investigational study data and results for new tuberculosis (TB) regimens.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Completed sustainability bond whose proceeds are used for social (e.g. for COVID-19 and AMR) and environmental projects.
- Reviewed its access approach via a roadmap to align access to corporate strategy and improve patient impact, the Purpose Blueprint.
- Engaged in eight IP sharing agreements, e.g. on malaria and TB via research institutions and via the COVID-19 Therapeutics Accelerator.
- Partners with Wellcome and governments of Ghana, Kenya, Malawi and Uganda to launch the Surveillance Partnership to Improve Data for Action on Antimicrobial Resistance (SPIDAAR).
- Partners with Last Mile Health and Living Goods on Africa Health Worker Training initiative.
- Expanded access planning during development from vaccines to all products and launched a Global Pricing and Access Strategy that requires access planning for all products to commence two years pre-launch.
- Supported training via P4B Program for Counterfeit Medicine in three countries.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Biopharma

Therapeutic areas: Oncology; Inflammation & Immunology; Rare Disease; Hospital; Vaccines; Internal Medicine

Product categories: Innovative medicines; Generic medicines; Biosimilars; Vaccines

M&A news: In November 2020, completed the transaction to spin off its Upjohn Business and combined it with Mylan N.V. to form Viatrix Inc. Combined its consumer health business into a

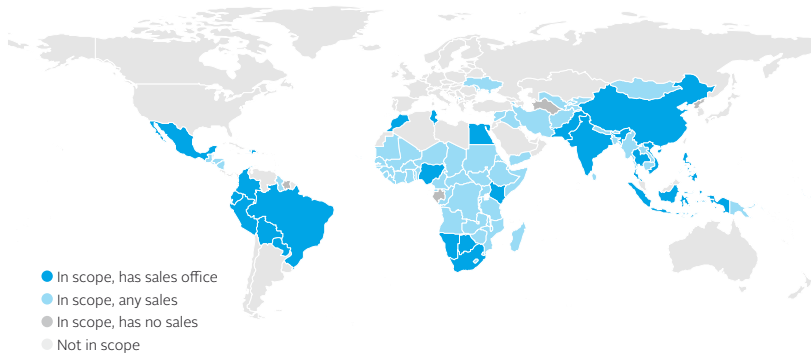
JV (32% stake) with GSK in 2019. Acquired Array (oncology) for 11.4 billion USD and Theracon (rare diseases) in 2019.

Pfizer's products are sold in 95 out of 106 countries in scope. Pfizer has sales offices in 23 countries, sells via suppliers in 28 countries and sells via pooled procurement into 44 additional countries.

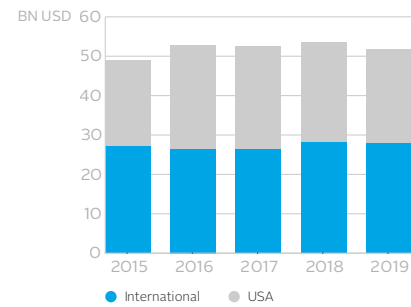
Revenue by segment (2019) – USD

| | |
|---|------------------|
| Biopharma | 39.419 bn |
| Upjohn | 10.233 bn |
| Consumer Health (through July 31, 2019) | 2.098 bn |
| Total | 51.750 bn |

Sales in countries in scope



Sales by geographic region



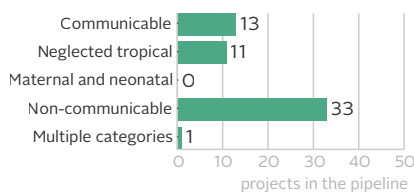
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Pfizer has a total of 58 R&D projects in scope featuring an average-sized priority R&D pipeline compared to its peers: 22 projects. Remarkably, more than one third of Pfizer's R&D projects target priority diseases. The other 36 R&D projects target other diseases in scope. Of the projects targeting priority diseases the focus is on lower respiratory tract infections (6 projects). Of the projects targeting other diseases in scope, the focus is on oncology (28).

16 R&D projects are in late-stage development that target either a priority disease (6) or address a public health need in LMICs (10)*. Evidence of access planning was in place for 69% of these projects: 4 targeting a priority disease and 7 addressing a public health need in LMICs.

58 projects in the pipeline



Pfizer works with BioNTech on BNT162, a preventive COVID-19 vaccine. This project progressed from Phase I to Phase III during the period of analysis.

Breakdown of projects*

| | Group B <i>Streptococcus</i> vaccine progressed from Phase I to Phase II. | | | | | Total | W. access plans |
|------------------------------------|---|---------|---------|---------|----------|-------|-----------------|
| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | | |
| Targets established R&D priorities | 10 | 1 | 3 | 3 | 0 | 17 | 4 |
| Addresses needs of LMICs* | 0 | 8 | 3 | 3 | 4 | 18 | 7 |
| Other projects in scope | 0 | 8 | 7 | 1 | 0 | 16 | |

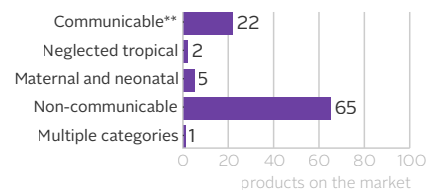
*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

PORTFOLIO as selected for analysis by the Index

Pfizer has 90 medicines and contraceptives in scope, 23 of which are on patent, and 5 vaccines. 61% of these medicines and contraceptives are on WHO's EML (55). The off-patent medicines target mainly non-communicable diseases (NCDs) (49) such as cancer (26). Thirteen products target communicable diseases (CDs) such as tuberculosis (5). Three further products target the neglected tropical diseases soil-transmitted helminthiasis (2) and leishmaniasis. One further medicine targets maternal haemorrhage. The on-patent medicines mainly target NCDs such as cancer (13). In addition, five medicines target CDs such as lower respiratory tract infections (3) and HIV (2). Pfizer has four contraceptives in scope. Pfizer's preventative vaccines (5) target the CDs meningitis (4) and pneumonia. Access strategies were analysed for 14 products on Pfizer's portfolio – supra-nationally procured (4) or nationally procured HCP-administered (5) and self-administered products (5).

95 products as selected for analysis by the Index †



Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 5 | 18 | | | 23 |
| off patent | 50 | 17 | | | 67 |
| Vaccines | 5 | 0 | | | 5 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Pfizer Inc

GOVERNANCE OF ACCESS

RANK 5

SCORE 4.12

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Pfizer performs strongly. It has an access strategy integrated within its Purpose Blueprint. The strategy covers all therapeutic areas in which the company is involved, including rare diseases. The highest responsibility for access lies directly with the board, namely with the Corporate Governance and Sustainability Committee. It also established the Global Health Partnerships Business Unit.

Provides evidence of financial and non-financial access-related incentives at executive the level. Pfizer performs strongly. It incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to the Purpose Blueprint goals, including improving access through partnerships.

Publicly discloses outcomes of its access-to-medicine activities. Pfizer performs strongly in transparency of access activities. It publicly discloses its commitment to global public health, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, including its progress on SDG3-related targets.

Has an average performance in responsible promotional practices. Pfizer's sales agents are not solely incentivised on sales volume targets, but behavioural components are also incorporated in their objectives. The company does not set incentives at the individual colleague level. It has a global policy on interactions with healthcare professionals, but does not publicly disclose information related to transfers of values to HCPs in countries in scope (e.g. payments for attending events or promotional activities), unless required by local regulations.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Pfizer has an average performance, demonstrating some of the components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, audits (both internal and external, covering third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards. It does not, however, demonstrate evidence of a continuous system to monitor activities, but has adopted a compliance monitoring & analytics approach in a selected number of countries in scope.

Publicly supports the Doha Declaration on TRIPS and Public Health. Pfizer publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely on the use of compulsory licensing. It may not always agree with its industry association positions on these and it states that participation does not necessarily mean agreement.

RESEARCH & DEVELOPMENT

RANK 7

SCORE 2.73

Access planning processes encompass all projects in pipeline. Pfizer has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 67% of the late-stage candidates. Pfizer has 22 projects including six late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on lower respiratory tract infections. Of Pfizer's seven late-stage candidates targeting a priority product gap, four have evidence of having an access plan in place. These plans range from plans to register products in Gavi-eligible countries and countries in scope, to considering equitable pricing strategies. Notable, is the development of the preventive group B streptococcus vaccine for neonatal sepsis in partnership with BMGF. Pending the achievement of development milestones, Pfizer intends to seek WHO pre-qualification to facilitate access in LMICs (inclusive of GAVI countries) and would

explore pricing mechanisms and manufacturing options to ensure sufficient supply.

Many projects address a public health need in LMICs*, with 70% of the late-stage projects covered by access plans. In this analysis, Pfizer has ten late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope. Most target cancer. Pfizer provides evidence of access plans for seven of these projects. These plans include commitments to register product in countries in scope and equitable pricing strategies for most of the projects.

Public policy to ensure post-trial access; commits itself to registering trialed products. Pfizer has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial par-

ticipants who have a serious condition and the availability of alternative treatments. Once a product is approved, Pfizer commits itself to registering it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place. Company reports that this may be addressed in specific situations.

Three R&D capacity building initiatives included for evaluation. Pfizer has an average performance in this area. The company submitted the maximum of five initiatives, of which three were included for analysis. None of the initiatives meet all Good Practice Standards.† For example, for the partnership with the Indian Council of Medical Research (ICMR) on Antimicrobial Resistance, Pfizer does not demonstrate evidence of measuring the outcomes of the partnership.

PRODUCT DELIVERY

RANK 3

SCORE 3.91

Public commitment not to enforce patents in countries in scope. Pfizer newly publicly pledges not to enforce patents in least developed countries.

Publicly discloses detailed information on patent status. Like most of its peers, Pfizer publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. It discloses the patent status of its entire small molecule on patent portfolio. This information

is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Pfizer has newly shared many IP assets with third-party researchers developing products for diseases in scope. This includes eight IP assets shared with WIPO Re:Search collaborations and compounds for screen-

ing in the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include compounds for screening.

Makes ARV patents available for licensing on pro-access terms. Pfizer (as ViiV Healthcare[§]) has made dolutegravir for the treatment of HIV available for non-exclusive voluntary licensing. Pfizer has signed a licensing agree-

194 ‡ Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

ment directly with the Medicines Patent Pool (MPP) for sunitinib, an investigational medicine for the treatment of tuberculosis.

No evidence of new products in scope filed for registration in the majority of high burden countries. Pfizer did not disclose evidence of filing any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, palbociclib (Ibrance®) for breast cancer is registered in 31 countries in scope.

Has access strategies for all supranationally procured products in scope for this analysis. Pfizer performs above average in securing access for its products procured supranationally.[§] For the four products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers and in at least one non-eligible country.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Pfizer has an average performance in this area. The company provides examples of access strategies which consider affordability in both UMICs and LMICs for the five products assessed. The company falls short at providing examples for LICs. It makes efforts to reach additional patients using equitable pricing strategies. For example, in Nigeria, for a portfolio of oncology medicines, since 2017, the company, and its local partners Worldwide Commercial Ventures Limited and EMGE Resources, have an agreement with the Clinton Health Access Initiative and the American Cancer Society to increase affordability and access of those products, while simplifying the distribution system. Pfizer forecasts that in the year 2021 approximately 2000 patients in Nigeria will benefit from this program. Pfizer is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for the majority of self-administered products in scope of this analysis. Pfizer leads in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for three of the five products assessed. It makes efforts to reach additional patients using both inter- and intra- country equitable pricing strategies and donations. Pfizer is able to provide evidence of how patient reach has been increased through the approaches used.

Three manufacturing capacity building initiatives meet all Good Practice Standards. Pfizer performs above average in this area. The company submitted the maximum of five initiatives, of which four met all criteria for inclusion. Three initiatives met all Good Practice Standards.[¶] The initiatives reflect Pfizer's work with contract manufacturing organisations (CMO) to build capacity in the areas of dosage form manufacturing, Good Manufacturing Practices (GMP) and Environment, Health and Safety (EHS) compliance. For its work with CMOs in Egypt on meeting GMPs, Pfizer did not demonstrate how it aimed for sustainability.

Four supply chain capacity building initiatives meet all Good Practice Standards. Pfizer performs above average in this area. The company submitted the maximum of five initiatives, which all met all criteria for inclusion. Four initia-

tives met all Good Practice Standards.[¶] Examples include:
- P4B Program, training 683 pharmacists in Nigeria, Kenya and Ghana on counterfeit medicine.
- Vaccine Visibility System, tackling vaccine supply chain management challenges in the Gambia through a 2D bar-coding open-source inventory management system. For this programme, Pfizer has partnered with PATH to conduct an impact assessment.
For one initiative, training distributors in Ghana on replenishment planning, Pfizer did not demonstrate in what ways the initiative aims for sustainability.

Four health system strengthening initiatives meet all Good Practice Standards. Pfizer performs well in this area. The company submitted the maximum of five initiatives, which were all included for analysis and four initiatives met all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, since 2016 it has trained 30 public health nurses and 139 midwives in Ghana with skills to screen newborns for sickle cell disease. For the Healthy Families, Health Futures initiative, Pfizer has partnered with the London School of Hygiene and Tropical Medicine to evaluate outcomes on access to immunisation and family planning products and services in five sub-Saharan African countries, of which the results are publicly available. For one initiative, the Global Health Fellows Program, Pfizer could not demonstrate how it aimed for sustainability/integration in the local health system.

Has not engaged in the development and implementation of inclusive business models. Compared to its peers, Pfizer performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Pfizer performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in scope. The company has a system in place to align demand and supply, providing monthly demand forecasts on the next 24-36 months. Where Pfizer has no presence, the company works together with supranational partners including UNICEF, Gavi and the Gates Foundation to forecast and manage supply. Pfizer's standard processes include maintaining buffer stock for each stock keeping unit and internal API production.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope. Pfizer has a policy for reporting SF medicines to the relevant national health authorities, but does not specify time frames. Pfizer reports that it follows locally mandated time frames. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end user. Pfizer reports that it ensures ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user. For example, it donated amlodipine besylate/atorvastatin calcium

(Caduet®) for hypertension to Uganda in 2019 in response to a humanitarian crisis.

Publicly commits itself to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Pfizer publicly commits itself to eliminating trachoma by donating azithromycin (Zithromax®) from 1998 to 2025 in 29 countries. Moreover, it is engaged in another structured donation programme: the Max Access Solution programme whereby it has been donating axitinib (Inlyta®), bosutinib (Bosulif®), crizotinib (Xalkori®) and temsirolimus (Torisel®) for cancer in 22 countries since 2015.

§ Pfizer holds a 13.5% stake of Viiv Healthcare.

¶ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

¶ Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|-----------|-------------|
| 9 | 3.07 |
| 10 (2018) | |

Roche

Stock Exchange: SIX Swiss Exchange • Ticker: ROG • HQ: Basel, Switzerland • Employees: 97,735

PERFORMANCE IN THE 2021 INDEX

9th place. Roche has an average performance. The company performs well in filing for registration and transparency of access activities, publicly disclosing its commitment and outcomes, but performs less strongly in R&D.

Governance of Access: 6th place. Roche performs well in this area. It has an access-to-medicine strategy integrated into its corporate strategy and publicly discloses commitments and outcomes of its access-to-medicine activities. The company provides access-related incentives at the executive level, but not for the CEO.

Research & Development: 9th place. Roche's performance is average in this area. The company has a structured process to develop access plans during R&D for all projects in the pipeline. Yet, it has a small R&D priority pipeline compared to peers and few of its late-stage projects that address a public health need in LMICs are covered by an access plan.

OPPORTUNITIES FOR ROCHE

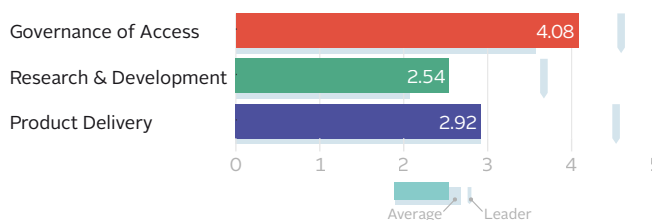
Expand access strategies for oncology products to LICs. Roche has six on-patent medicines listed on the 2019 WHO Model List of Essential Medicines (WHO EML), including erlotinib (Tarceva®) and trastuzumab (Herceptin®), two first line treatments for lung and breast cancer, whose incidence is the highest in countries in scope, using mechanisms such as voluntary licenses. Roche implemented an intra-country pricing strategy for erlotinib (Tarceva®) in Peru. Roche could apply similar intra-country pricing strategies in LMICs with high burden of lung cancer such as Vietnam, Moldova, Tunisia and Myanmar. For healthcare practitioner-administered oncology treatments, Roche could apply access strategies in those countries where the cancer burden is growing.

Expand technology transfer initiatives to other geographic areas, including sub-Saharan Africa. Roche could expand the geographic scope of its technology transfers beyond China and Brazil.

Expand the Global Access Program to include Covid-19. The Global Access Program was launched in 2014 in partnership with UNAIDS, CHAI, PEPFAR and the Global Fund to facilitate access to viral load testing. Roche could include diagnostics for SARS-CoV-2 in this programme to facilitate access to testing in countries in scope.

Expand access planning to include equitable pricing and apply to all R&D projects. Roche has an access plan in place for its one late-stage priority R&D project and for 21% of R&D projects identified as having a clear public health benefit in countries in scope. These plans prioritise filing for registration and a differential pricing strategy for some products. Roche should apply its access planning process (e.g. registration and tiered pricing strategies) to all late-stage R&D projects, especially its diagnostics such as malaria diagnostics and HPV diagnostics.

How score was achieved



Product Delivery: 12th place. Roche is a middle-performing company in this area. The company provides evidence of access strategies, but they are focused on middle-income countries. It registered some of its new products in the majority of high burden countries. Although engaged in capacity building initiatives, most initiatives did not meet all Good Practice Standards.

CHANGE SINCE THE 2018 INDEX

- Developed and launched a tracking tool, the Roche Access Index, to measure progress on global patient access.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Joined the COVID-19 Therapeutics Accelerator.
- Partners with Gusun, China to produce biotech products locally with first product bevacizumab (Avastin®).
- Established new partnerships on supply chain (cold chain) and training programmes with governments of Kenya and Sudan.
- Expanded NJIA aimed at leadership development for cervical cancer to include India.
- Develops centres of excellence in selected sites focused on the African patient access and representation in key clinical trials for oncology, haemophilia and neurology.
- Expanded the Global Access Program beyond HIV to include tuberculosis, hepatitis B and C and human papillomavirus (HPV).

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals; Diagnostics
Therapeutic areas: Oncology; Immunology; Neuroscience; Ophthalmology; Haemophilia A; Infectious diseases; Diabetes care
Product categories: Innovative medicines; Diagnostics
M&A news: Acquired Spark Therapeutics (gene therapy) for USD 4.3 billion in 2019; acquired Promedior (fibrotic diseases), Stratos Genomics

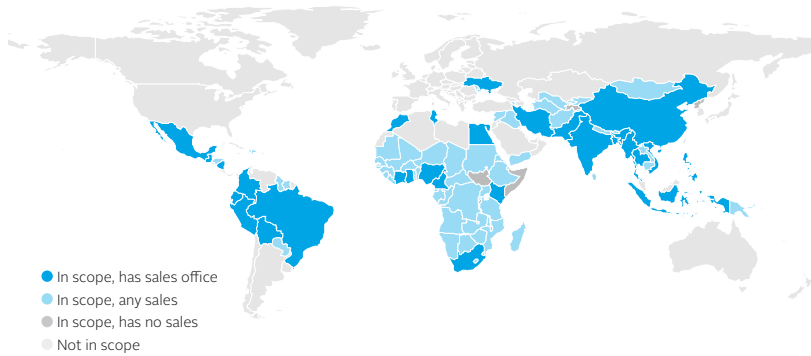
(diagnostics) and Inflazome (inflammatory diseases) in 2020.

Roche's products are sold in 96 out of 106 LMICs in scope. Roche has sales offices in 28 countries and sells via suppliers into 68 additional countries.

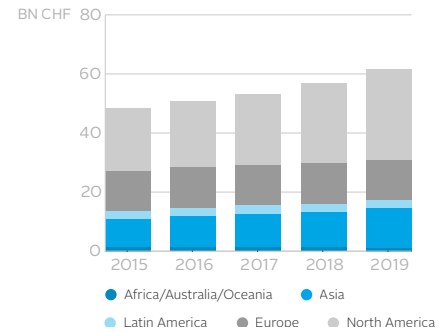
Sales by segment (2019) – CHF

| | |
|-----------------|------------------|
| Pharmaceuticals | 48.516 bn |
| Diagnostics | 12.950 bn |
| Total | 61.466 bn |

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

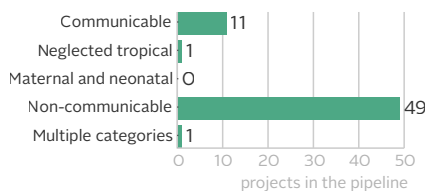
PIPELINE for diseases and countries in scope

Roche has a total of 62 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 12 projects. The other 50 R&D projects target other diseases in scope. In total, 15 of the 62 projects are diagnostic R&D projects. Of the projects targeting priority diseases, including five diagnostic projects, the therapeutic focus is on hepatitis B (6 projects). Of the projects targeting other diseases in scope, the focus is on oncology (33). 20 R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (19).^{*} Evidence of access planning was in place for 25% of these projects: 1 targeting a priority disease and 4 addressing a public health need in LMICs.

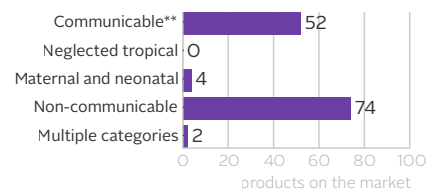
PORTFOLIO as selected for analysis by the Index

Roche has 27 medicines in scope, 19 of which are on patent. 48% of these medicines (13) are on WHO's EML. In addition, the company markets 93 diagnostics and 12 platform technologies. The off-patent medicines target both non-communicable diseases (NCDs) such as cardiovascular diseases (2) and cancer and communicable diseases (CDs) such as hepatitis C (2). The on-patent medicines mainly target cancer (13) and other NCDs. In addition, two products target CDs: HIV and lower respiratory tract infections. The diagnostics in scope are for NCDs such as diabetes (5) and cancer (37), for CDs such as viral hepatitis (18) and for maternal and neonatal health conditions such as maternal sepsis (3). The 12 platform technologies target both NCDs (4) such as cancer (2) and CDs (8) such as HIV (2). Access strategies were analysed for 13 products on Roche's portfolio – supranationally procured (4) or nationally procured HCP-administered (5) and self-administered products (4).

62 projects in the pipeline



132 products as selected for analysis by the Index †



Breakdown of projects[#]

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|---|--------------|---------|---------|---------|----------|-------|-----------------|
| Self-sampling kit for human papillomavirus (HPV). | | | | | | | |
| Targets established R&D priorities | 0 | 6 | 0 | 1 | 0 | 7 | 1 |
| Addresses needs of LMICs [*] | 0 | 11 | 7 | 9 | 3 | 30 | 4 |
| Other projects in scope | 0 | 9 | 3 | 0 | 5 | 17 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|----------------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 7 | 12 | | | 19 |
| off patent | 6 | 2 | | | 8 |
| Vaccines | 0 | 0 | | | 0 |
| Diagnostics ^{***} | | | 93 | | 93 |
| Other [†] | | | | 12 | 12 |

2 diagnostic tests for COVID-19
 Simplified blood-based screening test for Alzheimer disease

^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**} Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

^{***}Diagnostics for Covid-19 are not listed on the 2019 WHO Model List of Essential In Vitro Diagnostics
[†] Other includes platform technologies. See Appendix I for definitions.
[‡] Products included in the analysis were selected

using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.
[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Roche Holding AG

GOVERNANCE OF ACCESS

RANK 6

SCORE 4.08

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Roche performs strongly. It has a strategy focused on understanding local barriers to access. The strategy covers all therapeutic areas the company is involved in. The highest responsibility for access lies directly with the board, namely with the Corporate Governance and Sustainability Committee of the Board of Directors.

Provides evidence of financial and non-financial access-related incentives at the executive level. Roche performs well here. It incentivises its senior executives and in-country managers to take action on access to medicine as part of their annual bonus plan. There is no evidence, however, that the CEO is also incentivised toward access goals.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Roche performs well in transparency regarding access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example its Global Access Programme, and through the IFPMA Global Health Progress platform.

Has an average performance in responsible promotional practices. Roche's sales agents are not solely incentivised on sales volume targets. The company sets sales incentives at the individual level for agents. Roche has an internal tracking tool but does not publicly disclose information related to transfers of values to healthcare professionals (e.g. payments for attending events or promotional activities), unless required by local regulations.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Roche has an average performance, demonstrating some of the components looked for by the Index: country risk-based assessment, audits (both internal and external, covering third parties and in all countries where it operates), a continuous system to monitor activities and formal processes in place to ensure third-party compliance with company standards. It does not, however, have a fraud-specific risk assessment in place.

Publicly supports the Doha Declaration on TRIPS and Public Health. Roche publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely on the use of compulsory licensing. There is no evidence of a policy to dissent from industry association positions on IP.

RESEARCH & DEVELOPMENT

RANK 9

SCORE 2.54

Access planning processes encompass all projects in pipeline. Roche has a structured process in place to develop access plans on a case-by-case basis during R&D. In general, Roche begins developing access plans for R&D projects in Phase III of clinical development. The process is for both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to its peers, with access plans in place for one of the late-stage candidates. Roche has 12 projects including one late-stage candidate in its pipeline that target a priority product gap. The company focuses mostly on viral hepatitis (B and C). There is evidence of an access plan for Roche's late-stage candidate targeting a priority product gap. This plan for tocilizumab to treat COVID-19 includes plans to register the product, apply an equitable pricing approach whereby prices are linked to the country's ability to pay (i.e. GNI per capita) and increase sufficient supply.

Many projects address a public health need in LMICs*, with 21% of these projects covered by access plans. In this analysis, Roche has 19 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs*. Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Roche provides evidence of access plans for four of these projects. These plans prioritise registration in LMICs and a differentiated pricing strategy will be applied to some products.

Public policy to ensure post-trial access; commits itself to registering trialed products. Roche has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy applies on a case-by-case basis. Once a product is approved, Roche commits itself to registering it in all countries where clinical trials for the prod-

uct have taken place. This policy considers affordability for the wider population in the country where the trial(s) took place.

One R&D capacity building initiative meets all Good Practice Standards. Roche has an average performance in this indicator. The company submitted four initiatives, of which two were included for analysis. One initiative met all Good Practice Standards.[§] For this initiative, Roche is building clinical R&D capacity in clinical trial sites in seven sub-Saharan African countries, with a focus on site training and increasing African patient access to, and representation in, key clinical trials. The initiative takes place in South Africa, Ivory Coast, Tanzania, Ghana, Nigeria, Kenya and Uganda and areas of focus include oncology, haemophilia and neurology.

PRODUCT DELIVERY

RANK 12

SCORE 2.92

Public commitment not to enforce patents in countries in scope. Roche publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries and low-income countries. The company also does not file or enforce patents for any of its antiretroviral HIV medicines in sub-Saharan African countries.

Publicly discloses detailed information on patent status. Like most of its peers, Roche discloses the patent statuses for small molecules in scope via the Pat-

INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Does not report newly sharing IP assets with third-party researchers beyond existing agreements. Roche reported agreements with product development partnerships, such as the TB Alliance. During the period of analysis, beyond the existing agreements, the company reported no instances where it newly shares IP assets with

third party researchers developing products for diseases in scope.

No use of non-assert or licensing arrangements. Roche does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope.

Filed to register some new products in the majority of high burden countries. Roche has filed 30% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of coun-

198 § Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

tries with the highest burden of disease). For example, the oncology medicine atezolizumab (Tecentriq®) has been filed for registration/registered in 17 high burden countries in scope, including El Salvador and Myanmar.

Has access strategies for some supranationally procured products in scope for this analysis. Roche performs below average in securing access for products procured supranationally.^{||} The company did not provide examples of how access was secured for countries not eligible for supranational supply in three of the four products selected for analysis in this indicator. However, for valganciclovir (Valcyte®), all countries in scope are eligible to procure it supranationally through the Medicines Patent Pool supply agreement.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Roche performs above average in this area. The company provides examples of access strategies which consider affordability in both UMICs and LMICs for three of the five products assessed. It makes efforts to reach additional patients using patient assistance programmes. For example, in India, for the oncology medicine, atezolizumab (Tecentriq®), Roche applies intra-country pricing strategy through a patient assistance programme that assess patient income and reimbursement status and offers tailored payment schemes to increase access, while strengthening the health system by enhancing diagnostics capacity. The company increased access by 20% in 2020. Roche is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope of this analysis. Roche performs below average in this area. The company provides examples of access strategies which consider affordability in UMICs and LMICs for one of the four products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in Peru, for the oncology medicines portfolio, the company uses a staggered payment fee for private sector clinics. Roche is able to provide evidence of how patient reach has been increased through the approaches used.

Two manufacturing capacity building initiatives included for evaluation. Roche performs below average in this indicator. The company submitted the two initiatives, which both met all criteria for inclusion. The initiatives, which included technology transfers of biotechnology and biological products in China and Brazil, respectively, did not meet all Good Practice Standards[¶], as Roche did not sufficiently demonstrate that the initiative is measuring outcomes.

Four supply chain capacity building initiatives included for evaluation. Roche performs below average in this indicator. Roche submitted five initiatives, of which four met all criteria for inclusion. For example, through the Global Philanthropic Secondment Programme, Roche is sharing company and employee knowledge on supply chain and logistics management at the Namibia University of Science and Technology. None of the initiatives submitted by the company met all Good Practice Standards[¶], as Roche does not sufficiently demonstrate how the initiatives have long-term supply chain capacity aims.

Four health system strengthening initiatives meet all Good Practice Standards. Roche performs above average in this indicator. The company submitted the maximum of five initiatives, of which four were included for analysis and met all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, the NJIA initiative in Tanzania and India aims to enhance the prevention and early diagnosis of cervical cancer through leadership development amongst community health workers. Since its launch in 2015, NJIA-trained health workers have screened 6,972 eligible women in the Kagera region in Tanzania as part of NJIA activities, which indicates an increase of at least an average of 519% compared to the five years before the program started.

Has engaged in the development and implementation of scaled up inclusive business models. Roche performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has scaled up its Global Access Programme running in 82 countries (which aimed to provide better access to diagnostic testing for HIV/AIDS) to include other diseases: hepatitis B and C, human papillomavirus (HPV) and tuberculosis.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Roche performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in scope of the Index. For example, the API manufacturing of their core medicines is spread across different geographic regions to protect against local and/or regional incidents. To overcome challenges related to timely and accurate demand forecasts in hard-to-reach areas, Roche holds additional inventory at different supply chain tiers and decoupling points.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope. Roche has a policy for reporting SF medicines to relevant health authorities, but does not strictly specify the reporting timeframe. Roche, however, reports that it mostly occurs within 24h once a case is confirmed. It states that earlier reporting is possible with visual inspection, but does not specifically distinguish the reporting time frames of cases which only require visual inspection for confirmation.

Donates in response to an expressed need and monitors delivery to end user. Roche has a policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user; however, it is unclear whether this is defined as the patient. For example, it donated trimethoprim/sulfamethoxazole (Bactrim®) for a variety of bacterial infections to Mozambique in 2019 in response to cyclone Idai.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Roche is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible.

^{||} Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

[¶] Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|----------|-------------|
| 5 | 3.47 |
| 7 (2018) | |

Sanofi

Stock Exchange: Euronext Paris • Ticker: SAN • HQ: Paris, France • Employees: 100,409

PERFORMANCE IN THE 2021 INDEX

5th place. Sanofi takes a place among the top five companies of the Index. The company performs strongly in two of the Technical Areas, but has an average performance in Governance of Access.

Governance of Access: 11th place. Sanofi performs below average in this area. The company has an access-to-medicine strategy incorporated within its overall corporate strategy and a robust set of compliance controls, but was faced with a settlement of a breach during the period of analysis.

Research & Development: 4th place. Sanofi performs strongly in this area. Its R&D pipeline consists of ten late-stage priority R&D projects, with six of them covered by an access plan. The company has an access planning process that covers all projects in the pipeline and engages in some high-quality R&D capacity building initiatives.

OPPORTUNITIES FOR SANOFI

Review sales incentive structures. Sanofi could consider adopting a balanced scorecard approach consistently, thus not solely promoting sales volumes as a performance target for its sales agents in countries in scope of the Index.

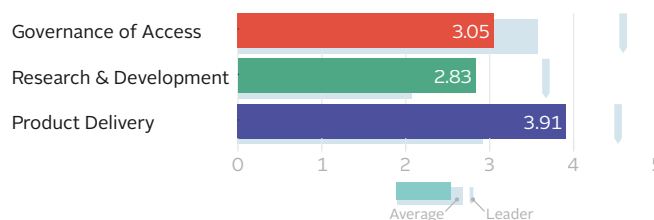
Disclose patent status of products. Sanofi has 80 products in scope, including 34 medicines on the 2019 WHO Model List of Essential Medicines (WHO EML). Sanofi can clearly show which products are on- and off-patent. Sanofi can improve standard of disclosure by including jurisdiction, patent number and expiry date. Sanofi can disclose patent information via the Pat-INFORMED platform or elect to self-disclose patent statuses.

Expand registration of dupilumab (Dupixent®) to more countries with a high burden of asthma. Sanofi could endeavour to register this product broadly in more asthma high-burden countries.

Expand access plans to R&D projects. Sanofi implements access plans (registration and WHO prequalification) to 60% of its late-stage priority R&D projects. The company can apply access plans to all late-stage R&D projects. Furthermore, Sanofi can include affordability and supply in its access plans. These plans can be based on an intra-country tiered pricing strategy. Specific examples include the respiratory syncytial virus vaccine for infants and nirsevimab, a respiratory syncytial virus monoclonal antibody.

Expand access to insulin in LICs. Sanofi is one of the three companies in scope that supply insulin. For insulin glargine (Lantus®), the company can apply equitable pricing strategies in low-income countries to improve access and affordability.

How score was achieved



Product Delivery: 3rd place. Sanofi performs strongly in this area. The company has access strategies in place for the majority of its products and leads in its approach to access strategies for supranationally procured products. The company has a strong approach to donations, monitoring delivery to end users and committing itself to achieving elimination. Yet, there is no evidence of new products in scope filed for registration in the majority of high-burden countries.

CHANGE SINCE THE 2018 INDEX

- New agreement with Unitaid and the Global Fund for reduced price of USD 15.00 per rifapentine treatment course for public sector use in 100 low- and middle-income countries.
- Publishes its post-trial access plan.
- Has multiple new initiatives for supply chain, vaccines capacity building and product packaging in Vietnam and India.
- Joined the COVID-19 Therapeutics Accelerator.
- Expanded Good Clinical Practice (GCP) training initiative from China to include South Africa.
- Newly discloses patent status information for its EML products.
- Newly incorporated access planning for the whole pipeline.
- Expanded FAST initiative on mental health to three more countries, Mali, Myanmar and South Africa.
- Signed two sustainability-linked revolving credit facilities with social (e.g. for polio) and environmental targets.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals; Consumer Healthcare; Vaccines
Therapeutic areas: Immunology; Rare Diseases; Rare Blood Disorders; Multiple Sclerosis / Neurology; Oncology; Diabetes; Cardiovascular; Vaccines
Product categories: Innovative medicines; Generic medicines; Vaccines; Consumer health products
M&A news: Acquired Synthorx (oncol-

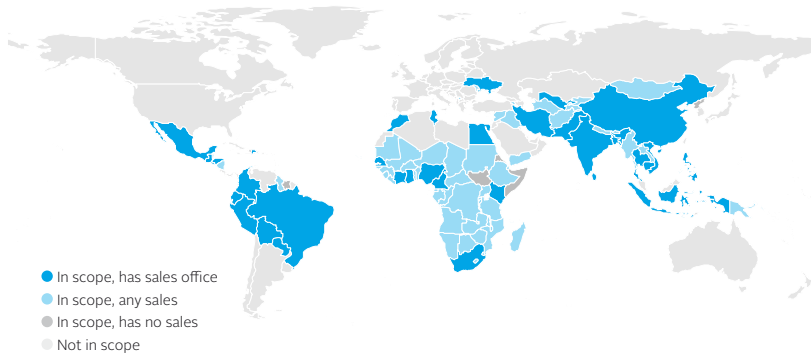
ogy) for USD 2.5 billion, Principia Biopharma (immune-mediated diseases) for USD 3.7 billion and Kiadis (immunotherapy) for USD 308 million in 2020.

Sanofi's products are sold in 92 out of 106 countries in scope. Sanofi has sales offices in 34 countries, sells via suppliers in 55 countries and via pooled procurement into 3 additional countries.

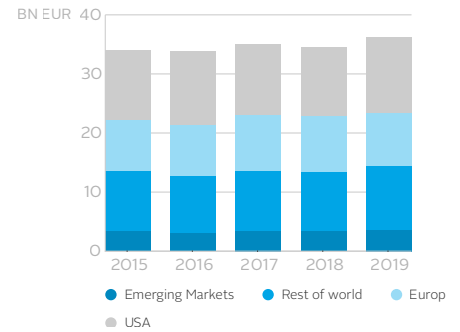
Net sales by segment (2019) – EUR

| | |
|---------------------------|------------------|
| Pharmaceuticals | 25.708 bn |
| Sanofi Pasteur (Vaccines) | 5.731 bn |
| Consumer Healthcare | 4.687 bn |
| Total | 36.126 bn |

Sales in countries in scope



Sales by geographic region

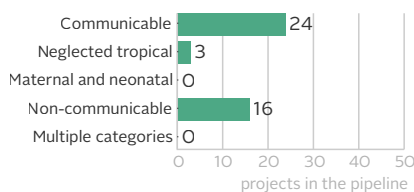


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Sanofi has a total of 43 R&D projects, featuring an average-sized priority R&D pipeline compared to its peers: 21 projects. Remarkably, the priority pipeline constitutes half of Sanofi's R&D projects. The other 22 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on lower respiratory tract infections (7 projects) and COVID-19. Of the projects targeting other diseases in scope, the focus is on oncology (9). 23 R&D projects are in late-stage development that target either a priority disease (10) or address a public health need in LMICs (13).^{*} Evidence of access planning was in place for 39% of these projects: 6 targeting a priority disease and 3 addressing a public health need in LMICs.

43 projects in the pipeline



Fexinidazole was developed in partnership with DNDi for treatment of *T.b. gambiense* and approved in the Democratic Republic of Congo in 2019

Breakdown of projects#

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 4 | 4 | 1 | 5 | 4 | 18 | 6 |
| Addresses needs of LMICs* | 0 | 4 | 5 | 7 | 1 | 17 | 3 |
| Other projects in scope | 0 | 2 | 1 | 0 | 1 | 4 | |

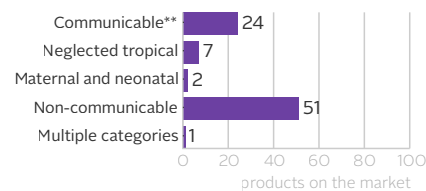
^{*}50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

^{**}Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

PORTFOLIO as selected for analysis by the Index

Sanofi has 65 medicines in scope (13 on patent) and 15 vaccines. 52% of these medicines (34) are on WHO's EML. The off-patent medicines target mainly non-communicable diseases (NCDs) (34) such as mental health (11), communicable diseases (CDs) such as tuberculosis (7) and malaria (3) and neglected tropical diseases (NTDs) such as Human African Trypanosomiasis (HAT) (3) and leishmaniasis. Furthermore, one product targets neonatal sepsis and one is for missed abortion. The on-patent medicines mainly target NCDs (12) such as diabetes (4). In addition, one patented medicine is for HAT (The fexinidazole (Fexinidazole Winthrop) patent expired in November 2020 after the period of analysis). The company's vaccines (15) target mainly CDs (13) such as meningitis (4) and two vaccines target the NTDs rabies and dengue. In addition, the company markets 4 platform technologies for diabetes. Access strategies were analysed for 14 products on Sanofi's portfolio – supranationally procured (5) or nationally procured HCP-administered (4) and self-administered products (5).

85 products as selected for analysis by the Index †



Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 1 | 12 | | | 13 |
| off patent | 33 | 20 | | | 53 |
| Vaccines | 15 | 0 | | | 15 |
| Diagnostics | | | 0 | | 0 |
| Other*** | | | | 4 | 4 |

^{***}Other includes platform technologies. See Appendix I for definitions.
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

[#]Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Sanofi

GOVERNANCE OF ACCESS

RANK 11

SCORE 3.05

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Sanofi performs strongly in this area. Its access to healthcare strategy is integrated in the activities of its three Global Business Units: Sanofi Pasteur, Sanofi Genzyme and General Medicines. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, namely with the Corporate Social Responsibility (CSR) committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Sanofi performs strongly in this area, too. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives based on CSR goals.

Publicly discloses outcomes of its access-to-medicine activities. Sanofi performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, with reporting on its Access to Healthcare programmes.

Has an average performance in responsible promotional practices. Sanofi's sales agents performance incentives are mostly sales driven. More details on how the company addresses sales incentives for agents are unavailable. It has a policy on service engagement with scientific experts, however, except for Ukraine where it discloses to EFPIA[‡], Sanofi does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities).

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Sanofi performs strongly, demonstrating all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards.

Publicly supports the Doha Declaration on TRIPS and Public Health. Sanofi publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, stating that compulsory licensing should only be used in extraordinary and very limited circumstances. It has a statement of independence to dissent from industry association positions on IP.

RESEARCH & DEVELOPMENT

RANK 4

SCORE 2.83

Access planning processes encompass all projects in pipeline. Sanofi has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, Sanofi begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 60% of the late-stage candidates. Sanofi has 21 projects, including ten late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including lower respiratory tract infections and coronaviral diseases. Of Sanofi's ten late-stage candidates targeting a priority product gap, there is evidence of an access plan for six. These plans prioritise WHO prequalification and registration in some countries in scope. Notable is the diphtheria, tetanus, pertussis, hepatitis B, polio and haemophilus influenzae Type b paediatric hexavalent vaccine (Shan 6), especially developed for lower income countries. Sanofi commits itself to WHO prequalification to ensure

access to GAVI countries and plans to register the product in some additional countries in scope.

Some projects address a public health need in LMICs*, with 23% of these projects covered by access plans. In this analysis, Sanofi has 13 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by the global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Sanofi provides evidence of access plans for three of these projects. These access plans prioritise registration in several UMICs and LMICs.

Public policy to ensure post-trial access; commits itself to registering trialed products. Sanofi has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a life-threatening condition. Once a product is approved, Sanofi commits itself to register-

ing it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place.

Two R&D capacity building initiatives meet all Good Practice Standards. Sanofi performs above average in this area. The company submitted the maximum of five initiatives, of which four met all criteria for inclusion and two met all Good Practice Standards.[§] Examples include:

- Seeding Labs Instrumental Access Program, providing equipment to scientists and universities in low- and middle-income countries.
- Sanofi Global Site Partnership, improving the capacity of clinical trial sites in order to increase efficiency from design to regulatory submission.

For two of its initiatives, Good Clinical Practice training in China and South Africa and the LIVE Master programme in vaccinology, Sanofi does not demonstrate evidence of measuring outcomes.

PRODUCT DELIVERY

RANK 3

SCORE 3.91

Publicly pledges not to enforce patents. Sanofi publicly pledges to neither file for nor enforce patents. This commitment applies in all least Developed and low-income countries and in a subset of lower-middle income countries and upper-middle income countries.

Publicly discloses detailed information on patent status. Sanofi publicly discloses on its website informa-

tion relating to the status of its patents for products on the WHO Model Lists of Essential Medicines. The only information disclosed is the patent status. No further information is publicly available.

Shares some IP assets with third-party researchers.

During the period of analysis Sanofi newly shared some IP assets with third-party researchers developing prod-

ucts for diseases in scope. This includes four IP assets shared with drug discovery initiatives, such as COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries and clinical-stage unpublished data.

[‡] Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

[§] Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

No use of non-assert or licensing arrangements. Sanofi does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope.

No evidence of new products in scope filed for registration in the majority of high burden countries. Sanofi did not disclose evidence of filing for any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, Toujeo® (insulin glargine) for diabetes mellitus is registered/has been filed for registration in 24 countries in scope, including Ecuador and Mexico.

Has access strategies for all supranationally procured products in scope for this analysis. Sanofi leads in securing access for products procured supranationally.^{||} For the five products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, the company offers the same terms to South Africa for rifapentine (Prifitin®) as they do for Unitaid-eligible countries.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Sanofi performs below average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for only one of the four products assessed. It makes efforts to reach additional patients through donations. For example, in Indonesia and Thailand, it participates in public-sector tenders to increase access to Verorab®, a rabies vaccine, while strengthening the health system via healthcare practitioner trainings and awareness raising campaigns. Between 265,000 and 375,000 patients per year access the vaccine in Thailand and 100,000 in Indonesia. Sanofi is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for some of its self-administered products for countries in scope of this analysis. Sanofi has an average performance in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. It makes efforts to reach additional patients through equitable pricing strategies and donations. For example, in Brazil, the company participates in state and municipality tenders and offer a patient support program to increase access to insulin glargine (Lantus®). Sanofi is able to provide evidence of how patient reach has been increased through the approaches used.

Four manufacturing capacity building initiatives meet all Good Practice Standards. Sanofi performs above average in this area. The company submitted the maximum of five initiatives, which were all included for analysis. Four initiatives met all Good Practice Standards[¶], including:

- Technology transfer of metronidazole (Flagyl®) for the treatment of bacterial infections to the manufacturer May & Baker in Lagos, Nigeria.
- Supporting a manufacturing site in India to meet Good Manufacturing Practices (GMP) standards.

Two supply chain capacity building initiatives meet all Good Practice Standards. Sanofi performs above average in this area. The company submitted five initiatives, which met all criteria for inclusion. Three of the five initiatives take place in Vietnam. Two initiatives met all Good Practice Standards.[¶] Both initiatives are aimed at improving vaccine supply in Vietnam by improving forecasting and cold chain distribution. For two of its initiatives, the cold chain management training in hospitals in India and pharmacies and supporting the Vietnamese manufacturer to expand its activities to include distribution, Sanofi only reports on measuring output but not outcomes.

Five health system strengthening initiatives meet all Good Practice Standards. Sanofi is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, through the Kids and Diabetes in Schools (KiDS) programme, Sanofi has raised awareness among approximately 189,000 children, 13,750 teachers and other school staff and more than 15,000 parents in 745 schools in nine countries, of which four are in scope of the Index.

Has contributed to the development and implementation of a new inclusive business model. Sanofi has improved performance since 2018 when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has contributed to the development of one new model: Ngao ya Afya, focused on non-communicable disease (NCD) care in Kenya.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Sanofi performs well in this indicator, disclosing multiple strategies to ensure continuous supply in countries in scope of the Index. For example, as part of their supply de-risking strategy the company has a system in place to ensure the availability of API. In addition to internal production of API, the company has a dual/multiple sourcing arrangement for their Established Products range. Sanofi has signed Rapid Supply Mechanisms with UNICEF and Gavi to ensure availability of their medicines in emergency situations.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days. Sanofi has a policy for reporting SF medicines to national health authorities or WHO within 7 days, with the Central Anti-Counterfeit Laboratory conducting the assessment. It does not, however, distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end user. Sanofi has a policy in place to ensure ad hoc donations are carried out in response to an expressed need. It monitors the delivery until the end user. For example, it donated ibuprofen/paracetamol and metformin for diabetes mellitus in 2019 in response to cyclone Vayu in three countries.

Publicly commits itself to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Sanofi publicly commits itself to eliminating Human African Trypanosomiasis by donating pentamidine (Pentacarinat®), eflornithine (Ornidyl®), melarsoprol (Arsobal®) and fexinidazole (Fexinidazole Winthrop®) in 21 countries since 2001.

^{||} Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.

[¶] Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

| RANK | SCORE |
|----------|-------------|
| 6 | 3.31 |
| 5 (2018) | |

Takeda Pharmaceutical Co, Ltd

Stock Exchange: Tokyo Stock Exchange • Ticker: 4502 • HQ: Tokyo, Japan • Employees: 49,578

PERFORMANCE IN THE 2021 INDEX

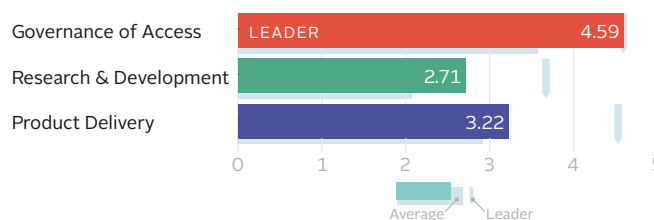
6th place. Takeda leads in Governance of Access, showing a strong performance in governance and compliance and health system strengthening. It has a small-sized priority R&D pipeline with a few late-stage candidates covered by an access plan.

Governance of Access: 1st place. Takeda leads in this area with a clear access-to-medicine strategy, embedded in its corporate strategy, and access-related incentives for the CEO.

Research & Development: 8th place. Takeda performs above average in this area. It has a small-sized priority R&D pipeline compared to peers with one late-stage project covered by a comprehensive access plan. It has an access planning process that encompasses all projects in pipeline. The company performs strongly in R&D capacity-building, with four initiatives meeting all Good Practice Standards.

Product Delivery: 7th place. Takeda has an above average performance in this area. It newly shared some IP assets with third party researchers. It has access strategies in place for

How score was achieved



some of its products in countries of all assessed income levels, yet there is no evidence of new products in scope filed for registration in the majority of high-burden countries. It applies a solid reporting policy to substandard and falsified medicines and discloses some strategies to ensure continuous supply in countries in scope. Yet, it does not provide evidence of ensuring continuous supply in the Least Developed Countries.

OPPORTUNITIES FOR TAKEDA

Strengthen registration approach. Takeda can register its products more broadly and take into account disease burden when looking to register its newest products, such as brentuximab vedotin (Adcetris®) for the treatment of non-Hodgkin's lymphoma, in countries in scope.

Establish project-specific access plans, particularly for NCDs. Takeda has access plans (registration and equitable pricing) for its one late-stage priority R&D project and for 57% of the late-stage R&D projects identified as having a clear public health benefit in countries in scope. Takeda demonstrates a strong access plan for its dengue vaccine candidate and can apply high quality access plans to all its late-stage R&D projects, such as pevonedistat for lung cancer, and TAK-607 for the complications of premature birth.

Expand price segmentation approach. Takeda developed a sophisticated Patient Assistance Tool to define intra-country pricing segmentation for some countries in scope. The company could apply this tool to more of its marketed products, such as brigatinib (Alunbrig®), in countries where the tool is already being applied for other products, and to more countries in scope with a high burden of lung cancer such as Vietnam, Myanmar and Moldova.

CHANGE SINCE THE 2018 INDEX

- Newly launched Blueprint for Innovative Healthcare Access, aimed at addressing access to treatment constraints for patients with non-communicable diseases (NCD), including supply chain management (in Kenya).
- Published a new Position on Access to Medicine with end-to-end access commitments.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Expanded partnership with Seeding Labs from 10 to 23 countries on the Instrumental Access Program (IAP) providing equipment and training.
- Partners with Last Mile Health to train community health workers in Malawi and Liberia.
- Shares chemical libraries to the Global Antibiotic Research & Development Partnership (GARDP) to screen for novel compounds with antibacterial activity.
- Partners with UNICEF to help strengthen health systems for children under five years and pregnant women in Angola, Guinea, Togo.

The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

SALES AND OPERATIONS

Business segments: Pharmaceuticals
Therapeutic areas: Gastroenterology; Rare Diseases; Plasma-derived therapies; Immunology; Oncology; Neuroscience
Product categories: Innovative medicines; Vaccines
M&A news: Completed acquisition of Shire (rare diseases) in 2019 for USD 62 billion. It divested its eye care business to Novartis in 2019 for USD 3.4 billion. Several primary care and OTC

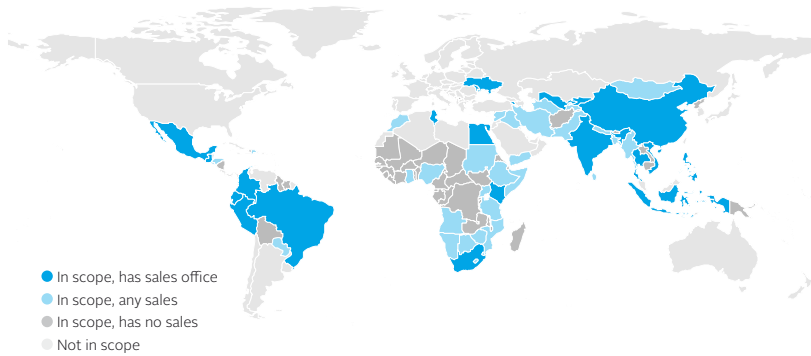
products were divested to different companies, including Stada, Acino, Hypera, Orifarm, Celltrion and Cheplapharm.

Takeda's products are sold in 53 out of 106 countries in scope. Takeda has sales offices in 21 countries, sells via suppliers in 21 countries and via pooled procurement into 11 additional countries.

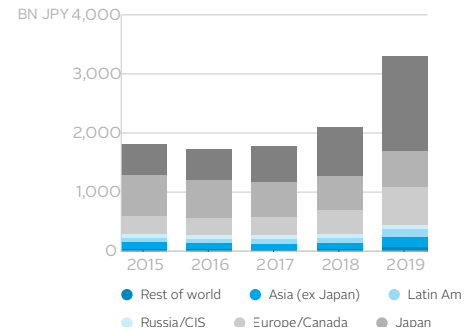
Revenue by segment (2019) – JPY

| | |
|-----------------|------------|
| Pharmaceuticals | 3,291.2 bn |
| Total | 3,291.2 bn |

Sales in countries in scope



Sales by geographic region



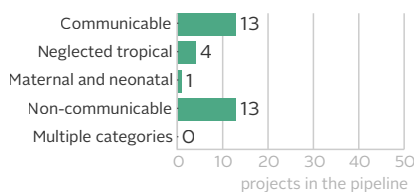
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Takeda has a total of 31 projects featuring an average-sized priority R&D pipeline compared to its peers: 16 projects. The other 15 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on communicable diseases, which includes a late-stage vaccine for dengue. Of the projects targeting other diseases in scope, the focus is on oncology (12).

8 R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (7).^{*} Evidence of access planning was in place for 63% of these projects: 1 targeting a priority disease and 4 addressing a public health need in LMICs.

31 projects in the pipeline

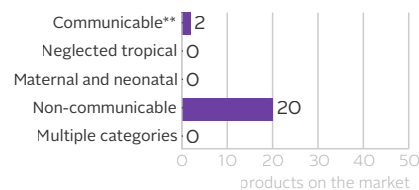


PORTFOLIO as selected for analysis by the Index

Takeda has 22 medicines in scope, 15 of which are on patent, and one vaccine. 19% of these medicines (4) are on WHO's EML. All six off-patent medicines target non-communicable diseases (NCDs) cardiovascular diseases (3), cancer, migraine and kidney diseases. The on-patent medicines mainly target NCDs (13) such as diabetes (6) and cancer (4), cardiovascular diseases (2), kidney diseases and mental health. In addition, one product targets lower respiratory tract infections. Takeda's preventative vaccine targets lower respiratory tract infections, as well.

Access strategies were analysed for 8 products on Takeda's portfolio – nationally procured HCP-administered (3) and self-administered products (5).

22 products as selected for analysis by the Index †



Breakdown of projects*

Takeda has the only project targeting preterm birth complications

Dengue vaccine (TAK-003) indicated for children and adolescents (4 to 16 years) has demonstrated immunogenicity against all four serotypes of the dengue virus.

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approval | Total | W. access plans |
|------------------------------------|--------------|---------|---------|---------|----------|-------|-----------------|
| Targets established R&D priorities | 8 | 3 | 0 | 1 | 0 | 12 | 1 |
| Addresses needs of LMICs* | 0 | 3 | 3 | 4 | 0 | 10 | 4 |
| Other projects in scope | 0 | 2 | 3 | 0 | 0 | 5 | |

Breakdown of products

| | WHO EML | Non-EML | WHO EDL | Other | Total |
|---------------------|---------|---------|---------|-------|-------|
| Medicines on patent | 1 | 14 | | | 15 |
| off patent | 4 | 2 | | | 6 |
| Vaccines | 1 | 0 | | | 1 |
| Diagnostics | | | 0 | | 0 |
| Other | | | | 0 | 0 |

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

#Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Takeda Pharmaceutical Co, Ltd

GOVERNANCE OF ACCESS

RANK 1

SCORE 4.59

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Takeda performs strongly in this area. The strategy, the Access to Medicines Vision aiming at increasing sustainable access of innovative medicines globally, covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the CEO.

Provides evidence of financial and non-financial access-related incentives at the executive level. Takeda performs strongly. It incentivises its senior executives and in-country managers in Growth and Emerging Markets units to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives.

Publicly discloses outcomes of its access-to-medicine activities. Takeda performs strongly in transparency of access activities. It publicly discloses commitments, meas-

urable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, including in its Access to Medicines progress report.

Performs above average in responsible promotional practices. Takeda's sales agents are not solely incentivised on sales volume targets. Takeda, however, sets sales incentives at the individual level for agents. Except for Ukraine where it discloses to EFPIA[†] and one Brazilian state with such regulatory requirement, it does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities). However, Takeda reports that it has standard operating procedures to control HCP engagement in all countries in scope.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Takeda performs strongly, demonstrating all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards.

Publicly supports the Doha Declaration on TRIPS and Public Health. Takeda publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions, namely it challenges the use of compulsory licensing, which it does not see as a sustainable solution. It states that it reserves itself the right to go further than the JPMA where it considers a need to increase access to medicine, in line with its corporate commitments.

RESEARCH & DEVELOPMENT

RANK 8

SCORE 2.71

Access planning processes encompass all projects in pipeline. Takeda has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope. In general, Takeda begins developing access plans for R&D projects in Phase II of clinical development. The process is for both its in-house and collaborative R&D projects.

A small-sized priority R&D pipeline compared to peers. Takeda has 16 projects, including one late-stage candidate, in its pipeline that target a priority product gap. Among these, the company has most projects for communicable diseases such as malaria. There is evidence of an access plan for Takeda's late-stage candidate targeting a priority product gap. This plan for a dengue vaccine (TAK003) includes a commitment to register the vaccine in dengue endemic areas, WHO prequalification, country tiered pricing strategies, and voluntary licenses.

Some projects address a public health need in LMICs*, with 57% of the late-stage projects covered by access plans. In this analysis, Takeda has seven late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules. Most target cancer. Takeda provides evidence of access plans for four of these projects. These plans prioritize registration in LMICs and equitable pricing for some projects.

Public policy to ensure post-trial access; commits itself to registering trialed products. Takeda has a policy for ensuring post-trial access to treatments for clinical trial participants, who meet criteria as defined in Takeda's Global Patient Access policy. Once a product is approved, Takeda commits itself to registering it in all countries where clinical trials for the product have taken place. This policy considers affordability for the wider population in

the country where the trial(s) took place.

Four R&D capacity building initiatives meets all Good Practice Standards. Takeda leads in this area. The company submitted the maximum of five initiatives, which all met all criteria for inclusion. Four initiatives met all the Good Practice Standards:[§]

- The African Consortium for Cancer Clinical Trials, strengthening cancer clinical trial and research capacity in low- and middle-income countries.
- Seeding Lab's Instrumental Access Program, providing training and equipment to scientists and universities in low- and middle-income countries.
- Mental Health Research and Care Delivery in low- and middle-income countries with Partners in Health.
- Cancer Research and Care Delivery in low- and middle-income countries with AMPATH Kenya, Foundation for Cancer Care Tanzania (FCCT) and Healthcare Partners for Access (HPA).

PRODUCT DELIVERY

RANK 7

SCORE 3.22

Public commitment not to enforce patents in countries in scope. Takeda publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, Takeda discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically

updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares some IP assets with third-party researchers. Compared to its peers, Takeda has newly shared some IP assets with third-party researchers developing products for diseases in scope. This includes five IP assets shared with research institutions, such as the Infectious Disease

Research Institute. Assets shared include molecule libraries and set of target-specific compounds at the discovery stage.

No use of non-assert or licensing arrangements. Takeda does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

[†] Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare pro-

fessionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

[§] Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initia-

tive goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

No evidence of new products in scope filed for registration in the majority of high burden countries. Takeda did not disclose evidence of filing any of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). One of its most widely registered products, Brentuximab vedotin (Adcetris®) for the treatment Non-Hodgkin Lymphoma, is registered/has been filed for registration in 17 countries in scope including two high burden countries; Tanzania and Uganda.

No supranationally procured products. Takeda has no products eligible for scoring in this indicator.

Has access strategies for the majority of health-care practitioner-administered products in scope of this analysis. Takeda is leading in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for two out of the three products assessed. It makes efforts to reach additional patients using tiered inter-country pricing strategies and intra-country pricing strategy through patient assistance programs. For example, in the Philippines, for the oncology medicine, brentuximab vedotin (Adcetris®), the company partners with Axios to offer a patient assistance programme that assesses patient income and offers tailored solutions to increase access, while strengthening the health system by strengthening diagnostics capacity. The company forecasts an increase of 200% in patient reach by the programme in the next 4 years. Takeda is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for some of its self-administered products for countries in scope of this analysis. Takeda performs on average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for two of the five products assessed. It makes efforts to reach additional patients through equitable pricing strategies and donations. For example, in Rwanda, Takeda applies an inter-country tiered pricing strategy and an approach to reduce distribution mark-ups to increase access to alogliptin (Nesina®) for patients across the income pyramid. The company is able to provide evidence of how patient reach has been increased through the approaches used.

One manufacturing capacity building initiative included for evaluation. Takeda performs below average in this indicator. The company submitted two initiatives, of which one initiative, a transfer of Takeda's measles and acellular pertussis vaccine technologies for the development of combination vaccines including diphtheria, tetanus and acellular pertussis (DTaP) and measles-rubella (MR) vaccine, met all criteria for inclusion but not all Good Practice Standards.^{||} Takeda did not demonstrate how the initiative aims for sustainability.

One supply chain capacity building initiative meets all Good Practice Standards. Takeda has an average performance in this area. The company submitted the three initiatives, of which one met the criteria for inclusion and all Good Practice Standards.^{||} Takeda's initiative aims to strengthen supply chain management in Meru County of Kenya, addressing data for decision making, coordination,

cash flow and capacity challenges.

Five health system strengthening initiatives meet all Good Practice Standards. Takeda is one of the leaders in this area. The company submitted the maximum of five initiatives, which all met all criteria for inclusion and all Good Practice Standards: i.e. they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:

- Partnership with Pan-African Heart Foundation and AMREF to provide chronic care programmes for diabetes mellitus and hypertension in Kenya. Since 2016, the initiative has screened over 200,000 people and trained more than 160 community health workers.
- Partnership with Last Mile Health to train community health workers in Malawi and Liberia, reportedly enabling nearly 200,000 women in Liberia to access family planning services since 2018.

Has engaged in the development and implementation of a new inclusive business model. Takeda has improved performance since 2018 when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. It has developed one new model: the Blueprint for Innovative Healthcare Access, focused on non-communicable disease (NCD) care for local communities in Kenya and Rwanda.

The company has some mechanisms in place to ensure continuous supply in countries in scope of the Index.

Takeda is a medium-performing company in this area, disclosing some strategies to ensure continuous supply in countries in scope. For example, in 2017 Takeda implemented a new end-to-end Sales & Operations Planning System, aligning demand forecasts with supply and assess safe stock levels. Takeda is currently implementing this process in all countries where the company operates, including 12 countries in scope of the Index. Takeda did not provide supporting evidence on ensuring supply in Least Developed Countries.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days.

Takeda has improved performance since 2018. It has a policy for reporting SF medicines to national health authorities and WHO within 7 days. It distinguishes reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need, but does not monitor delivery to end user.

Takeda has a policy in place to ensure ad hoc donations are carried out in response to an expressed need; however, it monitors the delivery until the recipient healthcare organisation, not the end user. For example, it donated human albumin (Flexbumin®) in February 2020 in response to the COVID-19 outbreak in China.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Takeda is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Max Access

Solution programme where it donates ponatinib (Iclusig®) for chronic myeloid leukaemia in 12 countries since 2015.

^{||} Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated partner, or works with external parties; guided by clear, measurable goals or objectives; meas-

ures outcomes; has long term aims/ aims for sustainability.

Appendices

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APPENDIX I

Key parameters for evaluation

PIPELINE AND PORTFOLIO

R&D pipeline and product portfolio inclusion process

Before inclusion for analysis, the Index team reviewed both marketed products and projects in companies' R&D pipelines. This review was to ensure they were within the scope of the 2021 Index and met relevant inclusion criteria.

Furthermore, they were verified and updated against public sources of information to ensure that the most up-to-date and accurate pipelines and portfolios were represented before scoring and analysis began. Public data could include pipeline and portfolio information found on company websites, in approvals from stringent regulatory authorities, the website clinicaltrials.gov and information on relevant product development partnership pipelines. Companies verified ongoing R&D projects and notified the Index team when a project had been divested or discontinued while also confirming each product in their portfolios. These final pipelines and product portfolios were then entered into the final datasheets sent to companies at the beginning of the data collection cycle.

Analysis criteria for R&D projects

For R&D projects the following inclusion criteria were utilised:

- Projects which target a disease, condition or pathogen within the disease scope of the Index and belong to a product type in scope (as detailed below) were included in the pipeline if they fell into one of the following categories:
 - Collaborative projects to which the company continued to actively contribute resources and expertise during the period of analysis.
 - All projects which target a priority R&D product gap identified by Policy Cures Research and/or WHO, regardless of stage of development.
 - Clinical-stage projects which do not target a priority R&D product gap identified by Policy Cures Research and/or WHO but do target a disease, condition or pathogen within the scope of the Index.

Cancer projects inclusion criteria

- For cancer projects, R&D projects were included only if they contained a chemical or biological entity that had not previously been approved for a given cancer type before the period of analysis. For example, if a medicine had been approved as monotherapy for one form of leukaemia before the period of analysis, further projects for the development of this medicine as a monotherapy for another form of leukaemia or in combination with a medicine that had also previously been approved for leukaemia were excluded.
- If a medicine that had previously been approved for a specific cancer type is being developed for the same cancer type, but in combination with a medicine that has not received an approval for treating this cancer type, the project was included. Where multiple projects were ongoing for a single cancer type and the medicine(s) had not yet been approved for this cancer type, the latest stage of development was included. Projects were pre-populated and clustered by multiple group indications if these indications were being examined as a group within the same clinical trial(s) (e.g., a Phase II trial of a medicine for patients with breast, lung and colorectal cancer was counted as one project for all three cancer types; if a new chemical or biological entity was being tested in a Phase II trial for breast cancer only and in a Phase II trial for colorectal cancer only, these projects were listed separately).

Product types in scope

This scope is deliberately broad in order to capture the wide-ranging product types available to support the prevention, diagnosis and treatment of relevant conditions and diseases in the 106 countries covered by the Access to Medicine Index. In 2021, the Index continues to use the same eight product types within the product scope, as in the last four iterations of the Access to Medicine Index.

Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease pro-

cess, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

Microbicides

These include topical microbicides specifically intended to prevent HIV.

Therapeutic Vaccines

This covers vaccines intended to treat infections.

Preventive Vaccines

This covers vaccines intended to prevent infections.

Diagnostics

This covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable, easier to use in the field).

Vector Control Products

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides which are intended for global public health use and specifically aim to inhibit and kill vectors that transmit diseases in scope of the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors associated with transmitting Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Contraceptive Methods & Devices

This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used to control contraception (e.g., condoms or diaphragms). It also includes combination products that deliver medicines (e.g., hormone-delivery contraceptive rings).

Platform Technologies

Only products that are specifically directed at meeting the needs of people living in the countries covered by the Index are included. These comprise, for example, general diagnostic plat-

forms, adjuvants, immunomodulators and delivery technologies and devices. Implants and platform technologies for reproductive health are also included in this category.

Platform technologies that have utility for accelerating the development of health products for 'Disease X', a term used by WHO to refer to currently unknown pathogens that could cause a serious international epidemic, are also included. These platform technologies have led to the rapid development of potential COVID-19 vaccine candidates.

Process for registered product inclusion

Registered products also went through a verification process. Products targeting a disease, condition or pathogen listed in the disease scope (based on information from regulatory authorities such as FDA and EMA) were included in the portfolio under several conditions:

- Medicines which are:
 - Patented
 - Listed on the 2019 WHO Model List of Essential Medicines (EML) AND where it was determined that companies had significant ability to shape the market, have a mean and/or median number of manufacturers <4.0 in a set of ten representative low- and middle-income countries (LMICs: Brazil, China, Egypt, India, Mexico, Morocco, Philippines, South Africa, Tunisia and Vietnam), per IQVIA MIDAS data OR
 - Not listed on the 2019 WHO Model List of Essential Medicines but listed as a first- or second-line treatment for a disease in scope by one of the five sets of guidelines (World Health Organization (WHO), Centers for Disease Control (CDC), National Institute for Health and Care Excellence (NICE), National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO)) used by the Index team AND where it was determined that companies had significant ability to shape the market.
- To determine where companies had significant ability to shape the market, the Index team used IQVIA MIDAS data. Market dominance was defined for products:
 - Which have a mean and/or median number of manufacturers <4.0 in a set of ten representative low- and middle-income countries (LMICs: Brazil, China, Egypt, India, Mexico, Morocco, Philippines, South Africa, Tunisia and Vietnam), per IQVIA MIDAS data OR
 - Where a listed company has >70% of the

market share in these countries by volume of sales, per IQVIA MIDAS data.

- Diagnostics which are listed on the 2019 WHO Model List of Essential In Vitro Diagnostics, with the addition of diagnostics for COVID-19.
- Vaccines, vector control products and platform technologies.

Determining patent status

Patent status for each product in scope of the Index was determined through a process of external research combined with verification from participating companies for the purpose of including or excluding products. This process was developed in consultation with experts from diverse constituencies. Patent status was first researched through the related regulatory authority websites (i.e South-African CIPC Intellectual Property database¹, the US FDA Orange Book², Health Canada³) and/or patent databases (MedsPaL⁴ and Pat-INFORMED⁵) and later verified with companies. The Index clarifies that for the patent status in South Africa, if the information was not available, the Index looked at the status in the US. and in some cases (e.g. for biologics) in Canada. Yet, it is not intended to be a presentation of patent rights worldwide nor does it capture all patents that might apply to a product. It is reasonable to assume that this Index may, therefore, underreport where patents are in place. It should only be used as a proxy description and cannot be used as an indication of patent status outside of South Africa and/or the US and Canada. In some instances, the patent status of a particular product was identified as off-patent in South Africa, the US or Canada but on-patent in other jurisdictions.

SCORING

Neutral scoring protocol

Neutral scoring is used to avoid double negative marking of a company for the lack of a policy, strategy, programme or initiative whose score has already been impacted negatively once and for which the company cannot meet the additional expectations. For example, when a company has no R&D priority projects in their pipeline, it is assessed for scoring in the relevant R&D indicator (RD1a). However, for the indicator relating to access plans for R&D priority projects (RD3a) a neutral score is applied, as the company has already been evaluated for not having R&D priority projects in the pipeline. Then a proxy measure was identified for that indicator. The proxy measure includes the average score

of the company across all indicators in the three Technical Areas. In 2021, neutral scoring was applied within the following areas: project-specific plans for prioritised diseases (RD3a), supra-nationally procured products: access strategies (PP3), healthcare practitioner-administered products: access strategies (PP4) and long-term donations (PP2b).

Scoring

Companies were assessed and scored by the Index in three Technical Areas: Governance of Access, Research & Development and Product Delivery, with each area composed of several indicators. Scoring was carried out based on data from a wide range of information sources including companies themselves, independent reports and databases or documents from WHO, other multilateral organisations and Non-Governmental Organisations. Public data sources, including information shared on company websites, in annual reports and through local health authorities, helped to triangulate data. Additional information retrieved from the US FDA Orange Book, Health Canada and the South African CIPC Intellectual Property database provided deeper insight and analysis pertaining to patent information. The Medicines Patent Pool's MedsPal and WIPO's Pat-INFORMED databases were also beneficial resources used for analysis. To determine approval and first registration, information from the European Medicines Agency, FDA and the Pharmaceutical Device Medical Devices Agency was employed. The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process beginning with scoring per company by the Technical Area analyst during the first round of the data collection period, followed by re-scoring after companies have provided further clarification in areas identified by the analyst. This was followed by verification by the Technical Area analyst, including an extensive quantitative and qualitative check of each indicator for each company. The research manager performs a quality assurance check on all scores to ensure consistency, with senior management performing a final spot-check. Each Technical Area analyst then cross-checked their Technical Area ranking, before the final ranking was cross-checked and verified by the research manager.

REVIEW PROCESS

Following clarification with companies, cross-check of company scores and consultation with experts, the Index team wrote the various sections of the Index report. The company report cards were fact checked by companies and confidential information was requested to be lifted for publication. Global health experts have provided reviews on each Technical Area analysed in the Index. Following internal review by the Foundation's management team, the entire Index was reviewed by the Chair of the Expert Review Committee (ERC), Professor Hans Hogerzeil.

METHODOLOGY LIMITATIONS

Limitations exist in every study of this design. Significant limitations specific to this study are discussed here. These and other methodological limitations will be reviewed for the 2022 Access to Medicine Index, as part of the 2021 multi-stakeholder Methodology Review process.

Disease, product scopes and country comparability

The outputs analysed in this study and the findings generated relate only to the geographical, disease, product and company scopes, as determined by the ERC during the methodology review process and as published in the Access to Medicine Index Methodology 2020. Although the Foundation recognises that all products, diseases, countries, access and product initiatives are not the same, in general in most Technical Areas in this study they are treated equally. For example, in R&D, nearly all compounds are treated equally if they meet the inclusion criteria, regardless of their mechanism of action or expected efficacy. In one indicator, RD1a in the R&D Technical Area projects are differentiated

based on whether they target priority product gaps, as defined by WHO^{6,7,8} and Policy Cures Research's G-FINDER tool.^{9,10,11} In indicator RD1b, where priorities have not been formally identified by the global health community, projects are differentiated based on specific evidence provided by companies of how an R&D need is being addressed. The Index used additional methods in other Technical Areas to correct for variations between products and countries within the scope of the Index. In filing for registration the Index used data from the Institute for Health Metrics and Evaluation's 2017 Global Burden of Disease¹² results to prioritise the top ten Index countries by DALY rate. These disease-specific subset of countries with the highest burden of disease were given credit in indicators PR1. In Access strategies, for indicators PP3, PP4 and PP5 a maximum of five products was evaluated per company. These products were identified using criteria such as either on patent or off patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

Longitudinal comparability

Comparability between companies over successive indices was not always possible or appropriate, especially for new areas of evaluation or where the scoring criteria of an indicator had been refined. During the period of analysis, where trend analysis was useful, the Index team compared raw data from past indices with raw data from 2020.

Company comparability

The objective of the Index is to produce a standardised relative ranking of the 20 companies' access-to-medicine performances. However, not

all companies are the same. Some have large portfolios and pipelines. Some have a comparatively narrow disease focus. Some have a comparatively narrow scope of country operations. Others have generic pharmaceuticals subsidiaries. Companies differ in size, geographical reach and capability for recording and reporting information. The Index uses various methods to correct for these variations between companies. In order to minimise the variability of information sourced from companies, all companies were provided with training on the data submission process and the datasheets were accompanied by help text to provide definitions and examples for Index jargon. In addition, a clarification round was carried out, giving companies an opportunity to provide additional data where there were gaps, inconsistencies or where clarifications were necessary.

In several indicators that measure quantitative elements, in general, the Index makes adjustments for company size. In the case of some R&D indicators in this Index, the company's pipeline size was used as an additional differentiator to group companies together, so that both large and small companies' performances were scored relative to peers of similar size. As outlined in the Access to Medicine Index Methodology 2020, companies that exclusively produce generic medicines are not eligible for inclusion as they have a distinctly different role to play in improving access to medicine.

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DISEASES IN SCOPE FOR THE 2021 ACCESS TO MEDICINE INDEX

Diseases are included based on their burden of disability-adjusted life years (DALYs) in countries in scope, WHO classifications and the relevance of pharmaceutical interventions. The disease scope for the 2021 Index has expanded from 77 to 82 diseases, conditions and pathogens. DALY burden and

mortality data was collected from the Institute for Health Metrics and Evaluation's 2017 Global Burden of Disease study (GBD 2017) and are presented as totals for countries in scope and disaggregated by sex where possible. Incidence data for cancer types was collected from GLOBOCAN 2018.

TABLE 3. Diseases, conditions and pathogens in scope of the 2021 Access to Medicine Index

| NON-COMMUNICABLE DISEASES (17) | Total DALYs (Countries in scope) | % DALYs (female) | % DALYs (male) |
|---|---|---------------------------------|-------------------------------|
| Alzheimer's disease | 16,877,547 | 60 | 40 |
| Anxiety disorders | 19,310,005 | 61 | 39 |
| Asthma | 19,115,654 | 50 | 50 |
| Bipolar affective disorder | 6,638,357 | 51 | 49 |
| Cancer* | DALY not applicable | N/A | N/A |
| Chronic obstructive pulmonary disease (COPD) | 65,609,411 | 47 | 53 |
| Diabetes mellitus | 51,453,359 | 49 | 51 |
| Endometriosis | 2,944,175 | 100 | 0 |
| Epilepsy | 12,487,825 | 46 | 54 |
| Hypertensive heart disease | 12,849,438 | 52 | 48 |
| Ischaemic heart disease | 125,559,544 | 38 | 62 |
| Kidney diseases | 28,817,082 | 47 | 53 |
| Migraine | 34,701,299 | 62 | 38 |
| Schizophrenia | 9,560,269 | 48 | 52 |
| Sickle cell disease | 2,980,127 | 48 | 52 |
| Stroke | 105,422,483 | 44 | 56 |
| Unipolar depressive disorders | 31,871,524 | 60 | 40 |
| CANCER TYPES IN SCOPE (18)* | Total incidence (countries in scope) | % incidence (female) | % incidence (male) |
| Bladder | 186,571 | 24 | 76 |
| Brain, nervous system | 177,529 | 45 | 55 |
| Breast | 1,078,400 | 100 | 0 |
| Cervical | 456,235 | 100 | 0 |
| Colorectal | 873,405 | 43 | 57 |
| Gallbladder | 128,360 | 58 | 42 |
| Head and neck | 585,568 | 25 | 75 |
| Kaposi sarcoma | 36,091 | 34 | 66 |
| Leukaemia | 243,713 | 43 | 57 |
| Liver | 629,658 | 28 | 72 |
| Lung | 1,117,600 | 33 | 67 |
| Non-Hodgkin lymphoma | 245,838 | 43 | 57 |
| Oesophageal | 459,664 | 32 | 68 |
| Ovarian | 172,934 | 100 | 0 |
| Prostate | 410,564 | 0 | 100 |
| Stomach | 680,465 | 33 | 67 |
| Thyroid | 321,687 | 76 | 24 |
| Uterine | 158,893 | 100 | 0 |
| COMMUNICABLE DISEASES (23 + 12 priority pathogens**) | Total DALYs (Countries in scope) | % DALYs (female) | % DALYs (male) |
| Arenaviral haemorrhagic fevers (Lassa fever) | DALY not available in GBD 2017 | N/A | N/A |
| Bunyaviral diseases | DALY not available in GBD 2017 | | 100 |
| Coronaviral diseases | DALY not available in GBD 2017 | N/A | N/A |

| | | | |
|--|--------------------------------|-----|-----|
| Disease X | N/A | N/A | N/A |
| Diarrhoeal diseases | 93,131,606 | 48 | 52 |
| Diphtheria | 298,033 | 48 | 52 |
| Emergent non-polio enteroviruses | DALY not available in GBD 2017 | N/A | N/A |
| Filoviral diseases*** | 503 | 37 | 63 |
| Henipaviral diseases | DALY not available in GBD 2017 | N/A | N/A |
| HIV/AIDS | 52,008,191 | 49 | 51 |
| Leptospirosis | DALY not available in GBD 2017 | N/A | N/A |
| Lower respiratory infections | 97,591,475 | 47 | 53 |
| Malaria | 45,001,032 | 47 | 53 |
| Measles | 8,119,059 | 50 | 50 |
| Meningitis | 19,903,199 | 46 | 54 |
| Other prioritised antibacterial-resistant infections | N/A | N/A | N/A |
| Pertussis | 7,917,655 | 56 | 44 |
| Rheumatic fever | DALY not available in GBD 2017 | N/A | N/A |
| Sexually transmitted infections (STIs) | 11,058,329 | 41 | 59 |
| Tetanus | 2,442,298 | 43 | 57 |
| Tuberculosis | 43,981,326 | 38 | 62 |
| Viral hepatitis (B and C) | 22,317,027 | 30 | 70 |
| Yellow fever | 310,869 | 29 | 71 |
| Zika | 1,700 | 48 | 52 |

| NEGLECTED TROPICAL DISEASES (20) | Total DALYs (Countries in scope) | % DALYs (female) | % DALYs (male) |
|--|---|-------------------------|-----------------------|
| Buruli ulcer | DALY not available in GBD 2017 | N/A | N/A |
| Chagas disease | 184,507 | 41 | 59 |
| Dengue and chikungunya [†] | 2,880,343 | 47 | 53 |
| Dracunculiasis | 1 | 55 | 45 |
| Echinococcosis | 79,542 | 52 | 48 |
| Foodborne trematodiasis | 1,650,536 | 40 | 60 |
| Human African trypanosomiasis | 78,985 | 47 | 53 |
| Leishmaniasis | 768,969 | 43 | 57 |
| Leprosy | 31,366 | 30 | 70 |
| Lymphatic filariasis | 1,361,196 | 19 | 81 |
| Mycetoma, chromoblastomycosis and other deep mycoses | DALY not available in GBD 2017 | N/A | N/A |
| Onchocerciasis | 1,342,282 | 46 | 54 |
| Rabies | 632,677 | 30 | 70 |
| Scabies and other ectoparasites | 4,228,505 | 50 | 50 |
| Schistosomiasis | 1,409,670 | 52 | 48 |
| Snakebite envenoming | DALY not available in GBD 2017 | N/A | N/A |
| Soil-transmitted helminthiasis | 1,878,838 | 53 | 47 |
| Taeniasis/cysticercosis [‡] | 1,394,465 | 58 | 42 |
| Trachoma | 299,003 | 60 | 40 |
| Yaws | DALY not available in GBD 2017 | N/A | N/A |

MATERNAL AND NEONATAL HEALTH CONDITIONS (10)

| | Total mortality (countries in scope) |
|-------------------------------------|---|
| Birth asphyxia and birth trauma | 520,507 |
| Contraceptive methods | Mortality not applicable |
| Hypertensive disorders of pregnancy | 28,748 |
| Maternal abortion and miscarriage | 16,859 |
| Maternal haemorrhage | 37,928 |
| Maternal sepsis | 20,782 |
| Neonatal sepsis and infections | 196,759 |
| Obstructed labour | 12,779 |
| Other neonatal conditions | 336,664 |
| Preterm birth complications | 612,925 |

* The 18 cancer types are collectively counted as one non-communicable disease.

** Collectively, these will be referred to as communicable diseases in the 2021

Access to Medicine Index as 'Other prioritised antibacterial-resistant infections'.

***Includes DALY burden for Ebola only.

[†] Includes DALY burden for dengue only.

[‡] Includes DALY burden for cysticercosis only.

CANCERS IN SCOPE FOR THE 2021 ACCESS TO MEDICINE INDEX

Cancer remains in scope for the 2021 Index, and the cancer types included are in scope for all Technical Areas. The 17 cancer types in scope for the 2018 Index have been retained and supplemented with new cancer types based on high incidence both globally and in countries in the scope of the Index, using data from GLOBOCAN 2018.

There are 18 cancer types in scope for the 2021 Index, including 15 which were originally in scope for the R&D Technical Area of the 2018 Index based on high incidence. Head and neck cancers have been combined as a single cancer type for this Index.

Thyroid cancer is newly in scope as the cancer type with the tenth highest incidence globally and in countries in scope. Ovarian and uterine cancer were added as they have comparably higher incidences compared to other sex-linked cancer types.

As in the 2018 Index, products for the management of pain and supportive treatments (for e.g., antiemetics) will not be included.

TABLE 4. Cancer types in scope and basis for inclusion

Three main criteria were used to include cancer types in the previous Index for the R&D Technical Area. These cancer types were retained and supplemented with additional cancer types that met an updated set of criteria, or which had a comparably high incidence amongst sex-linked cancer types. The resulting 18 cancer types are in scope for all Technical Areas in 2021.

| Cancer types in scope (18) | Ten cancer types with highest global incidence rates | Ten cancer types with highest incidence in countries in scope | Five cancer types where countries in scope account for highest % of global incidence | Included in 2018 Access to Medicine Index | Included following sex-linked cancer analysis |
|----------------------------|--|---|--|---|---|
| Bladder | | | | ● | |
| Brain, nervous system | | | | ● | |
| Breast | 2,088,849 | 1,078,400 | | ● | |
| Cervical | 569,847 | 456,235 | 80% | ● | |
| Colorectal | 1,849,518 | 873,405 | | ● | |
| Gallbladder | | | | ● | |
| Head and neck* | 887,659 | 585,568 | 87%** | ● | |
| Kaposi sarcoma | | | 86% | ● | |
| Leukaemia | | | | ● | |
| Liver | 841,080 | 629,658 | 75% | ● | |
| Lung | 2,093,876 | 1,117,600 | | ● | |
| Non-Hodgkin lymphoma | | | | ● | |
| Oesophageal | 572,034 | 459,664 | 80% | ● | |
| Ovarian | | | | | ● |
| Prostate | 1,276,106 | 410,564 | | ● | |
| Stomach | 1,033,701 | 680,465 | | ● | |
| Thyroid | 567,233 | 321,687 | | | |
| Uterine | | | | | ● |

* Includes all head and neck cancers defined by GLOBOCAN 2018.

** This percentage reflects the proportion of nasopharynx cancer cases in countries in scope.

APPENDIX II

Indicators and scoring guidelines

A GOVERNANCE OF ACCESS 20%

Indicator

GA1 Governance structures & incentives

The company has a governance system that includes direct board-level responsibility and accountability for its access-to-medicine initiatives. To facilitate effective implementation of the strategy, senior management (i.e., CEO and/or senior executives) and in-country operational managers have access-to-medicine objectives and incentives to reward the effective delivery of initiatives that improve access to medicine in countries and for diseases within the Index scope.

- 5 The company has a board member or board-level committee directly responsible for its access-to-medicine approach. Its CEO and/or senior executives have (long-term) access-related objectives and incentives. Its regional and/or in-country managers also have objectives and incentives to improve access in countries in scope of the Index
- 4 The company has a board member or board-level committee (directly or indirectly) responsible for its access-to-medicine approach. There is evidence of access-related incentives in place at an executive or managerial level (for senior management or regional/in-country managers in countries in scope of the Index.
- 3 The company has a board member or board-level committee responsible for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level.
- 2 The company has an executive manager or executive committee, that directly reports to a board member or to a board-level committee, responsible for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level in countries in scope of the Index.
- o The company has no board or executive level responsibility for its access-to-medicine approach.

GA2 Access-to-medicine strategy

The company has an access-to-medicine strategy and demonstrates that it is integrated within its corporate strategy. The strategy extends across the company's portfolio and pipeline, within the Index scope.

- 5 The company has a clear access-to-medicine strategy with evidence of alignment with corporate/business strategy. It includes measurable objectives to improve access to medicine. The company demonstrates evidence that the strategy is integrated through the application of it across the company's portfolio and pipeline, within the Index scope.
- 3 The company has an access-to-medicine strategy with a business rationale.

- 1 The company has commitments to improve access to medicine but does not have an access-to-medicine strategy.
- o The company neither has access-to-medicine strategy, nor has commitments for improving access to medicine.

GA3 Public disclosure of access-to-medicine outcomes

The company has time-bound measurable objectives, goals and targets related to improving access to medicine in countries in scope of the Index.* It publicly shares progress against such objectives, goals and targets (i.e. outcomes**).

- 5 The company publicly discloses its commitments to access to medicine, alongside targets, measurable goals, objectives, and outcomes** (or plans to report outcomes when available) related to improving access to medicine.
- 4 The company publicly discloses its commitments to access to medicine, alongside targets, measurable goals, objectives and outcomes (or plans to report outcomes when available) for a subset of access to medicine initiatives related to improving access to medicine.
- 3 The company publicly discloses its commitment to access to medicine, targets, and measurable goals, objectives related to improving access to medicine.
- 1 The company publicly discloses commitments related to improving access to medicine.
- o The company does not publicly disclose any of the above information.

GA4 Responsible promotional practices

The company mitigates the risk of unethical sales practice (e.g. by decoupling bonuses for sales agents from sales volumes only). Further, it takes a voluntary approach to publicly disclose information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope (e.g. payments for attending and/or speaking at events, continuing medical education, promotional activities, or other non-monetary values directed at HCPs).

- 5 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope. Sales agent incentives not driven exclusively by sales volume targets. Instead, the company has adopted a balanced scorecard approach to reward sales agents' performances.

- 4 The company has a policy which limits/bans transfers of values to HCPs in certain circumstances, for certain products in the Index scope, in countries in the Index scope. Sales agent incentives not driven exclusively by sales volume targets. Instead, the company has adopted a balance scorecard approach to reward sales agents' performances.
- 3 The company demonstrates evidence that it has adopted a balanced scorecard approach to reward sales agents' performances.
- o The company makes no disclosure regarding its approach to transfers of values to HCPs. Its incentives for sales agents are based solely on sales volume targets.

GA5 Compliance Controls

The company demonstrates that it has robust controls in place to mitigate the risk of non-compliance in its operations in countries in scope of the Index (i.e. in the areas of ethical marketing, anti-corruption, and clinical trials), which include the following components:

- a) fraud-specific risk assessment;
 - b) country risk-based assessment;
 - c) a live/continuous monitoring system for compliance (other than auditing);
 - d) auditing and review mechanisms, which involve the use of both internal and external resources, apply to all third parties and all countries where it has operations, based on risk assessment
 - e) formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries in scope of the Index.
- 5 The company has all of the above-mentioned elements in place.
 - 3 The company has at least 3 of the above-mentioned elements in place.
 - 2 The company has at least 2 of the above-mentioned elements in place.
 - 1 The company has 1 of the above-mentioned elements in place
 - o The company does not have any of the above-mentioned elements in place or does not disclose information.

GA6 Incidence of breaches

The company has not been found to be the subject of negative legal rulings or settled cases for unethical marketing practices/ corrupt practices/ anti-competitive practices / misconduct in clinical trials in countries within the scope of the Index during the past two years.

- 5 The company has not been the subject of any settlements for criminal, civil or regulatory infractions in countries within the scope of the Index during the past two years (pending cases, allegations and cases under appeal are not included).
- 3 The company has not been the subject of any criminal or civil infractions in countries within the scope of the Index, but has been the subject of one breach of a code of practice in one of the countries within the scope of the Index.
- 2 The company has been the subject of more than one breach of a code of practice in countries within the scope of the Index.
- o The company has been the subject of at least one negative ruling or settlement in a country within the scope of the Index, over the period of analysis.

GA7 Trade policy: IP and access to medicine

The company publicly discloses its support of the policy flexibilities intended to protect public health confirmed by the Doha Declaration on TRIPS and Public Health. Further, the company employs an intellectual property (IP) strategy that is conducive to access to medicine, operating in accordance with the international consensus on IP standards as it pertains to public health, confirmed by the Doha Declaration. This is evidenced by an absence of IP-related anti-competitive practices in relation to access to medicine in countries in scope.

- 5 The company publicly discloses support for the Doha Declaration and the usage of TRIPS flexibilities. There is no evidence-based information that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.
- 3 The company publicly discloses general support for the Doha Declaration and the usage of TRIPS flexibilities, though reservations on its provisions can be expressed. However, it has been involved in one IP-related anti-competitive practice* via industry associations
- 2 The company has been involved in one IP-related anti-competitive practice* via industry associations, but has a policy for dissent from industry association positions.
- 1 The company has been involved in IP-related anti-competitive practice* via industry associations and has no clear policy for dissent from industry association positions.
- o The company has been directly involved in anti-competitive IP-related practices*

*Patenting in Least Developed Countries, lobbying against the usage of TRIPS flexibilities by country governments within the Index scope (including through trade associations), lobbying for strengthening of IP standards beyond TRIPS in countries within the scope of the Index.

B RESEARCH & DEVELOPMENT 25%

Indicator

RD1A R&D pipeline: Prioritised diseases

The company engages in the development of products that target priority product gaps identified by global health research organisations*. This includes both innovative and adaptive R&D and both in-house and collaborative R&D.

- 5-1 The total size of each company's 'priority R&D' pipeline within the scope of the Index that targets an externally established R&D gap from Policy Cures Research and/or WHO, scaled across all companies and scored.
- o The company has no projects within the scope of the Index in its research pipeline for which it targets specific needs in countries in scope as defined by Policy Cures Research and/or WHO.

*Currently, R&D priorities are categorised using lists from WHO and Policy Cures Research.

RD1B R&D Pipeline: Other diseases

The company engages in the development of products that address a clear public health need in low- and middle-income countries beyond the R&D priorities identified by global health research organisations*. This includes innovative and adaptive R&D that addresses, for example, heat stability issues and targets populations for which further studies/specific formulations are needed (such as children and pregnant women, etc.) as determined by stakeholder consensus.

- 5-1 The total size of each company's pipeline that does not target externally established R&D gaps from Policy Cures Research and/or WHO but meets stakeholder-informed criteria of possessing product characteristics or target populations that are highly relevant to patients living in countries in scope, scaled across all companies and scored.
- o The company has no projects in its research pipeline within the scope of the Index that meets stakeholder-informed criteria of possessing product characteristics or target populations that are highly relevant to patients living in countries in scope

RD2 Planning for access: Structured framework

The company has a process through which equitable access is planned for products successfully developed both in-house and collaboratively.

- 5 The company has a structured process in place and commits to developing access plans during clinical development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations. Access plans are developed as early in the product development process as possible with clear timelines.

- 3 The company has a structured process in place to develop access plans during development for a subset of its R&D projects targeting diseases and countries within the scope of the Index. The process includes consideration of different provisions for different product types, disease targets and target populations. Access plans are developed as early in the product development process as possible with clear timelines.
- 2 The company has a structured process in place to develop access plans during development for a subset of its R&D projects targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations.
- 1 The company has a general process in place to include access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.
- o The company has no processes in place in this area or applies access planning on an ad-hoc basis.

RD3A Planning for access: Project-specific plans for prioritised diseases

The company provides evidence that its R&D projects for diseases prioritised by WHO and the Policy Cures Research are supported by detailed commitments and strategies to improve access to products in countries within the scope of the Index.

- 5-1 The company's late-stage R&D projects that meet externally defined priorities identified by Policy Cures Research and/or WHO are assessed on the breadth and depth of access plans in place for these projects, scaled across all companies and scored (i.e. group companies together, so that both large and small companies' performances were scored relative to peers of similar size). The following elements were analysed: availability, affordability, the breadth of the access plans (covering more than five countries) and other supplementary access components such as sufficient supply and donation programmes.
- o The company provides no evidence of access plans for any late-stage R&D projects that meet externally established priorities within the scope of the Index nor does it provide evidence of any partnerships with access-oriented organisations for these projects.

RD3B Planning for access: Project-specific plans for other diseases

The company provides evidence that its R&D projects for diseases not prioritised by WHO and the Policy Cures Research are supported by detailed plans to improve access to products in countries within the scope of the Index.

- 5-1 The company's late-stage R&D projects that do not meet externally established R&D priorities but do meet stakeholder-informed criteria of a clear relevance to patients in countries in scope are assessed on the breadth and depth of access plans in place for these projects, scaled across all companies and scored (i.e. group companies together, so that both large and small companies' performances were scored relative to peers of similar size). The following elements were analysed: availability, affordability, the breadth of the access plans (covering more than five countries) and other supplementary access components such as sufficient supply and donation programmes.
- o The company provides no evidence of access plans for any late-stage R&D projects that do not meet externally defined priorities but do meet stakeholder-informed criteria of a clear relevance to patients in countries in scope. Nor does it provide evidence of any partnerships with access-oriented organisations for these projects.

RD4 Disclosure of resources dedicated to R&D

The company publicly discloses the resources dedicated to its R&D activities which are conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.

- 5 The company publicly discloses its R&D investments, disaggregated at least the following levels: disease, project and development phase.
- 2 The company publicly discloses its R&D investments disaggregated to some degree: disease category, product type, aggregated phase of development (e.g., clinical versus pre-clinical), acquisition, licensing costs, etc.
- 1 The company does not publicly disclose R&D investment data that has been disaggregated at any level. The company voluntarily discloses disaggregated R&D investment data to organisations that present anonymised aggregate data for global health purposes, such as Policy Cures Research.
- o The company does not publicly disclose R&D investment data that has been disaggregated at any level and does not contribute data to Policy Cures Research.

RD5 Clinical trial conduct: Post-trial access

- 5 The company has a publicly available policy on post-trial access that is aligned with the Declaration of Helsinki and includes a commitment to provide investigational treatments to all clinical trial participants who gain benefits from the treatment, where legally appropriate until the treatment is locally available and accessible. This commitment includes steps to register and considers affordability through reimbursement and access mechanisms in all countries where clinical trials have taken place.
- 4 The company has a publicly available policy on post-trial access that is aligned with the Declaration of Helsinki and includes a commitment to provide investigational treatments to all clinical trial participants who gain benefits from the treatment, where legally appropriate until the treatment is locally available and accessible. This commitment includes steps to register in all countries where clinical trials have taken place.

- 3 The company has a public policy on post-trial access that is aligned with the Declaration of Helsinki and includes a commitment to provide investigational treatments to a subset of clinical trial participants where clinically and legally appropriate until the treatment is locally available. This commitment includes steps to register in all countries where clinical trials have taken place.
- 2 The company has an internal policy on post-trial access that is aligned with the Declaration of Helsinki and includes a commitment to provide investigational treatments to a subset of clinical trial participants where clinically and legally appropriate until the treatment is locally available. This commitment includes steps to register in all countries where clinical trials have taken place.
- 1 The company has an internal policy on post-trial access that is aligned with the Declaration of Helsinki. The company does not make a commitment to register approved treatments in all countries where clinical trials have taken place.
- o The company has no policies in this area.

RD6 Capacity building in R&D

The company increases local capacity for health research (including clinical trial capacity) and product development by undertaking R&D capacity building initiatives in partnership with local universities and public sector research organisations that meet Good Practice Standards* in countries within the scope of the Index.

- 5 The company provided evidence of five R&D capacity building initiatives in partnership which address local needs and at least three initiatives met all additional Good Practice Standards.
- 4 The company provided evidence of three R&D capacity building initiatives, which all meet all additional Good Practice Standards OR the company provided evidence of four R&D capacity building initiatives of which at least two meet all additional Good Practice Standards OR the company provided evidence of five R&D capacity building initiatives of which two meet all additional Good Practice Standards.
- 3 The company provided evidence of one R&D capacity building initiative, which all meets all additional Good Practice Standards OR the company provided evidence of two R&D capacity building initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of three R&D capacity building initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of four or five R&D capacity building initiatives of which one meets all additional Good Practice Standards.
- 2 The company provided evidence of at least two R&D capacity building initiatives, of which none meet all additional Good Practice Standards.
- 1 The company provided evidence of one R&D capacity building initiative in partnership which address local needs but does not meet all additional Good Practice Standards.
- o The company did not provide any examples of R&D capacity building initiatives in partnership which met local needs in Index countries during the period of analysis.

*Good Practice Standards: Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiative goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.

C PRODUCT DELIVERY 55%

Indicator

PR1 Registration

The company rapidly files to register its most recently launched products* targeting diseases within the scope of Index in countries within scope that have the highest disease burden.

5 Companies with newer products** that target diseases within the scope of the Index: all of its newer products** are filed for registration within 12 months of first global approval in majority of countries with the highest disease burden and all of its older products*** are filed for registration or are registered in the majority of countries with the highest disease burden within the scope of the Index when compared to peers.

1-4 Companies with newer products** that target diseases within the scope of the Index: X amount of its products are filed for registration or are registered in X amount of countries within the scope of the Index when compared to peers. Companies with older products*** that target diseases within the scope of the Index: X amount of its older products*** are filed for registration or are registered in the X amount of the countries with the highest disease burden within the scope of the Index when compared to peers.

o The company provides no evidence of filing to register any of its in-scope products that target diseases in the Index scope in any countries in scope.

*Most recently launched refers to the date the product was first approved to be marketed anywhere globally. The Index analyses information for up to 10 of the company's most recently launched products, depending on the size of the company's portfolio.

**Newer product refers to the product that was first approved to be marketed in last 5 years anywhere globally, that targets diseases within scope.

***Older product refers to the product that was first approved to be marketed between last 5 to 20 years anywhere globally, that targets diseases within scope.

PP1 Access strategies: Coverage*

The company applies access strategies which aim to maximise patient reach across the selected products (e.g., equitable pricing strategies, voluntary licensing, non-assert declarations, donation programmes) in the greatest proportion of countries within the Index scope.

* PP1 was deleted as comparisons were not possible with the data quality.

PP2A Access strategies: Ad hoc donations

The company has public policies and supply processes in place to ensure ad hoc donations* are carried out rapidly in response to expressed need.

5 The company meets all of the following criteria with respect to ad-hoc donations: a) it has a policies/agreements/supply processes in place to ensure all of its ad-hoc donations are carried out rapidly in response to expressed needs; b) Company or its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user.

2,5 The company meets one of the following criteria with respect to ad-hoc donations: a) it has a policies/agreements/supply processes in place to ensure all of its ad-hoc donations are carried out rapidly in response to expressed needs; b) Company or its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user.

o The company meets none of the following criteria with respect to ad-hoc donations: a) it has a policies/agreements/supply processes in place to ensure all of its ad-hoc donations are carried out rapidly in response to expressed needs; b) Company or its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user.

* A gift of products for which there is no clear, defined long term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

PP2B Access strategies: Long-term donation programmes

The company engages in long-term, sustainable product donation programmes where elimination, eradication and control goals are possible, and publicly commits to the achievement of such goals.

5 The company publicly commits to remain engaged in long term donation programmes for the achievement of elimination, eradication, or control goals with no time limit and has commitments which extends beyond stated goals.

4 The company publicly commits to remain engaged in at least one long term donation programmes until the achievement of elimination, eradication, or control goals, either with no time limit, or takes steps to expand programme beyond stated goals.

3 The company publicly commits to engage in long term donation programmes to support elimination, eradication, or control goals for a time-limited period.

1 The company is engaged in donation programmes which support elimination, eradication or control but makes no public commitment regarding this engagement.

NB Companies without structured donation programmes receive a neutral score. Moreover, companies with structured donation programmes that have no elimination, eradication, or control goals also receive a neutral score.

PP3 Access Strategies: Supranational products

The company applies access strategies to the products it holds which are supranationally procured*, through engaging with international procurers, advanced market commitments etc., and extends those strategies to countries graduating from development assistance or countries who do not qualify for such assistance.

5 Companies with supranationally procured products within the scope of the Index that targets the diseases in supranational mechanisms: For all of its relevant products that are supplied through supranational mechanisms, the company meets all of the following criteria with respect to access strategies: a) it applies equitable pricing strategies, takes into account affordability and demonstrates the applied use of demographic and economic factors considered in determining the ex-manufacturer price per program; b) it applies access strategies to the countries which does not qualify for assistance from these mechanisms, or are/have graduated from these programs; c) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

1-4 Companies with supranationally procured products within the scope of the Index that targets the diseases in supranational mechanisms: For subset of its relevant products that are supplied through supranational mechanisms, the company meets X number of the following criteria with respect to access strategies: a) it applies equitable pricing strategies, takes into account affordability and demonstrates the applied use of demographic and economic factors considered in determining the ex-manufacturer price per program; b) it applies access strategies to the countries which does not qualify for assistance from these mechanisms, or are/have graduated from these programs; c) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

- o Companies with supranationally procured products within the scope of the Index that targets the diseases in supranational mechanisms: The company meets none of the following criteria for its relevant products that are supplied through supranational mechanisms : a) it applies equitable pricing strategies, takes into account affordability and demonstrates the applied use of demographic and economic factors considered in determining the ex-manufacturer price per program; b) it applies access strategies to the countries which does not qualify for assistance from these mechanisms, or are/have graduated from these programs; c) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

* Products for which international procurement, advanced market commitments or market-shaping facilities exist. These products include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria and other neglected tropical diseases. Companies which do not market these products will not have this indicator applied to them.

For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on patent or of patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

PP4 Access Strategies: Health Care Practitioner-administered Products

The company takes into consideration both the ability-to-pay of the reimbursement authority and the demographics* characteristics of a country in order to determine ability-to-pay of different segments of the country's population, aiming to increase reach for their healthcare practitioner-administered products** across the income pyramid.

This is evidenced by:

- a) an approach which demonstrates how pricing strategies incorporate factors which determine payer's ability to pay for different segments of the population (e.g. patients paying out of pocket) and non-pricing initiatives (i.e. patient assistance programmes, donations, voluntary licensing) complement those pricing strategies to maximise reach, and
- b) evidence of how the approach has increased the patient number since the product was introduced, and
- c) plans to increase patient numbers for the following X years.

5 Companies with healthcare practitioner-administered products within the scope of the Index that have equitable access strategies: For all of its selected healthcare practitioner-administered products, the company meets all of the following criteria in all selected countries with respect to access strategies: a) it applies pricing strategies, takes into account the ability to pay of available payer types within different segments of the population; b) it provides evidence for the demographic characteristics taken into account in making socioeconomic and pharmaco-economic analysis considering the budget impact of the product on the health care budget of the payer; c) it applies non-pricing initiatives complement pricing strategies to maximize reach across the different segments of the population; d) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

1-4 Companies with healthcare practitioner-administered products within the scope of the Index that have equitable access strategies: For a subset of its selected healthcare practitioner-administered products, the company meets X number of the following criteria in X number of selected countries with respect to access strategies: a) it applies pricing strategies, takes into account the ability to pay of available payer types within different segments of the population; b) it provides evidence for the demographic characteristics taken into account in making socioeconomic and pharmaco-economic analysis considering the budget impact of the product on the health care budget of the payer; c) it applies non-pricing initiatives complement pricing strategies to maximize reach across the different segments of the population; d) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

o Companies with healthcare practitioner-administered products within the scope of the Index that have equitable access strategies. The company meets none of the following criteria for its relevant products in countries in scope with respect to access strategies.

* The characteristics of a population such as age, sex, income level, education level, employment, etc.

** Products that often require either hospital administration of the product or the attention of a skilled healthcare professional during administration. Companies which do not market these products will not have this indicator applied to them. For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on patent or off patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

PP5 Access Strategies: Self-administered products

The company takes into consideration both the ability-to-pay of the reimbursement authority and the demographics* characteristics of a country in order to determine ability-to-pay of different segments of the country's population, aiming to increase reach for their self-administered products** across the income pyramid.

This is evidenced by:

- a) an approach which demonstrates how pricing strategies incorporate factors which determine payer's ability to pay for different segments of the population (e.g. patients paying out of pocket) and non-pricing initiatives (i.e. patient assistance programs, donations, voluntary licensing) complement those pricing strategies to maximize reach, and
- b) evidence of how the approach has increased the patient number since the product was introduced, and
- c) plans to increase patient numbers for the following X years.

5 Companies with self-administered products within the scope of the Index that have equitable access strategies: For all of its selected self-administered products, the company meets all of the following criteria in all selected countries with respect to access strategies: a) it applies pricing strategies, takes into account the ability to pay of available payer types within different segments of the population; b) it provides evidence for the demographic characteristics taken into account in making socioeconomic and pharmaco-economic analysis considering the budget impact of the product on the health care budget of the payer; c) it applies non-pricing initiatives complement pricing strategies to maximize reach across the different segments of the population; d) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

1-4 Companies with self-administered products within the scope of the Index that have equitable access strategies: For a subset of its selected self-administered products, the company meets X number of the following criteria in X number of selected countries with respect to access strategies: a) it applies pricing strategies, takes into account the ability to pay of available payer types within different segments of the population; b) it provides evidence for the demographic characteristics taken into account in making socioeconomic and pharmaco-economic analysis considering the budget impact of the product on the health care budget of the payer; c) it applies non-pricing initiatives complement pricing strategies to maximize reach across the different segments of the population; d) it provides evidence which shows how this approach has increased or is planned to increase access to the product for more patients in the countries covered by these programs.

- o Companies with self-administered products within the scope of the Index that have equitable access strategies: The company meets none of the following criteria for its relevant products in countries in scope with respect to access strategies.

* The characteristics of a population such as age, sex, income level, education level, employment, etc.

**Self-administered products are defined as those products which are easier to administer by the individual patient, and that are not necessarily prioritised by governments or by the global health community (typically treatments for other non-communicable diseases, such as diabetes, stroke, hypertension and heart disease). Companies who do not market these products will not have this indicator applied. For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on patent or of patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

PPL1 Patent filing & enforcement

The company publicly commits to not filing for or enforcing patents related to diseases within the Index scope in Least Developed Countries, low-income countries, and a subset of lower-middle income countries and upper-middle income countries.

- 5 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products for diseases in the Index scope in all LDCs, LICs, and a subset of LMICs and UMICs. Least Developed Countries, low-income countries, and a subset of lower-middle income countries and upper-middle income countries.
 - 4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in the Index scope in a subset of Least Developed Countries, low-income countries, and a subset of lower-middle income countries.
 - 3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in the Index scope in all Least Developed Countries and/or all low-income countries.
 - 2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in the Index scope in a specific region or regions (e.g., Least Developed Countries, sub-Saharan Africa, etc.)
- o The company makes no commitment in this area.

PPL2 Patent status disclosure

The company publicly discloses the patent status of its products for diseases relevant to the Index, in countries within the Index scope.

- 5 The company publicly discloses the patent status for all or a subset of products in their portfolio, including on-patent products, within the Index scope in countries within the scope of the Index. This information is updated periodically and the standard of transparency achieved is analogous to or greater than that set out by the US FDA's Orange Book*.

- 4 The company publicly discloses the patent status for a subset of products, including on-patent products, in the Index scope in all countries within the scope of the Index. This information is updated periodically but the standard of transparency achieved falls short of that set out by the US FDA's Orange Book.

2.5 The company publicly discloses patent status for some products within the Index scope patent status information for its products in the Index scope in countries in the Index scope, but this information is provided for a subset of products and/or countries. There is no evidence that this information is updated periodically and/or that the standard of transparency achieved is less than that set out by the US FDA's Orange Book.

- o The company makes no public disclosure in this area.

* The FDA Orange Book includes product patent data, patent number and expiry date.

PPL3 IP Sharing

The company provides evidence of sharing its intellectual capital (e.g., molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g., WIPO Re: Search, Conserved Domain Database (CDD), Open Source Drug Discovery (OSDD)) that develop products for diseases relevant to the Index on terms conducive to access to medicine for countries within the scope of the Index.

- 5-2 The agreements that each company has made during the period of analysis to share its intellectual capital with research institutions or drug discovery initiatives on terms which promote access to resulting products in countries relevant to the Index are weighted, added together, scaled across all companies and scored.
 - 1 The company has previously made available its intellectual capital with research institutions or drug discovery initiatives on terms which promote access to resulting products in countries relevant to the Index prior to the period of analysis and those agreements remain valid.
- o The company does not provide evidence of sharing its intellectual property according to the above criteria.

PPL4 Access-oriented quality licensing*

The company agrees access-oriented, transparent non-exclusive voluntary licences which include clauses that facilitate affordability and supply of quality products.

*This indicator was not scored as a minority of companies have licences eligible for assessment under this indicator.

PPL5 Licensing: Geographic scope*

The company includes a broad range of countries within the geographic scope of its licences, including middle-income countries outside of sub-Saharan Africa with high burdens of disease.

*This indicator was not scored as a minority of companies have licences eligible for assessment under this indicator.

PQ1 Ensuring continuous supply

The company has processes in place to improve supply chain efficiency for all its product within the Index scope, making efforts to understand product distribution and demand behaviour in countries in the scope of the Index beyond first product hand-off, takes informed action to ensure uninterrupted supply and making products available in sufficient quantities in a timely manner. This process includes the following elements:

- a) has an established forecasting/information systems to manage its supply chain
 - b) manages a safety stock of relevant products
 - c) works with several API suppliers to prevent shortages
 - d) communicates plans with governmental agencies, regulators, purchasers, hospitals and other relevant stakeholders to align demand and supply
 - e) works with other collaborators on managing stockouts and shortages
 - f) ensures supply in at least one Least Developed Country.
- 5 The company has all of the above-mentioned elements in place.
 - 3 The company has some of the above-mentioned elements in place.
 - 1 The company provides evidence of having a demand/supply planning system in place (a) but does not provide evidence of this process or how it is targeting any of the other elements (b-f).
- o The company does not have any of the above-mentioned elements in place or does not disclose information.

PQ2 Reporting substandard and falsified medicines

The company has a policy/protocol for reporting substandard and falsified (SF) medicines in countries within the scope of the Index that specifies timeframes for reporting to relevant stakeholders (i.e., national regulatory authorities and WHO Rapid Alert).

- 5 The company provides evidence of a policy or approach to report confirmed cases of SF medicines as soon as possible and within ten working days to WHO Rapid Alert and local regulatory authorities, when visual inspection (e.g. confirmation of mislabeling, confirmation of fake packaging) is sufficient to establish that the product packaging is falsified. In cases where laboratory analysis is required for confirmation of substandard or falsified medicines, the policy should require reporting of cases of SF medicines as soon as possible and within ten working days once this confirmation has taken place to WHO Rapid Alert and/or local regulatory authorities.
- 4 The company provides evidence of a policy or approach to reporting confirmed SF cases to WHO Rapid Alert and/or local regulatory authorities within ten days of the confirmation in countries within the scope of the Index.
- 2 The company provides evidence/examples to the Index of reporting cases of SF medicines on a case-by-case basis, in countries within the scope of the Index, to relevant authorities, OR provides evidence of policy or approach for addressing falsified and/or substandard medicines in countries within the scope of the Index.

- o The company does not provide evidence of such a policy or approach or provide examples of reporting SF medicines.

PCB1 Capacity building in manufacturing

The company undertakes manufacturing capacity building initiatives with local manufacturers. These initiatives meet Good Practice Standards* in countries within the scope of the Index.

- 5 The company provided evidence of five manufacturing capacity building initiatives in partnership which address local needs, and at least three initiatives met all additional Good Practice Standards, i.e. are guided by clear goals and measurable objectives, measures progress or outcomes, aims for sustainability & long-term impact.
 - 4 The company provided evidence of three manufacturing capacity building initiatives, which all meet all additional Good Practice Standards OR the company provided evidence of four manufacturing capacity building initiatives of which at least two meet all additional Good Practice Standards OR the company provided evidence of five manufacturing capacity building initiatives of which two meet all additional Good Practice Standards.
 - 3 The company provided evidence of one manufacturing capacity building initiative, which all meets all additional Good Practice Standards OR the company provided evidence of two manufacturing capacity building initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of three manufacturing capacity building initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of four or five manufacturing capacity building initiatives of which one meets all additional Good Practice Standards.
 - 2 The company provided evidence of two manufacturing capacity building initiatives in partnership which address local needs but they do not meet all additional Good Practice Standards.
 - 1 The company provided evidence of one manufacturing capacity building initiative in partnership which addresses local needs but does not meet all additional Good Practice Standards.
- o The company did not provide any examples of manufacturing capacity building initiatives in partnership which met local needs in Index countries during the period of analysis.

*Addresses local needs, priorities and/or skills gaps; builds capacity of third-party or unaffiliated manufacturers, or works with external parties; guided by clear, measurable goals or objectives; measures outcomes; has long term aims/aims for sustainability.

PCB2 Capacity building in supply chain management

The company undertakes supply chain capacity building initiatives in countries within the scope of the Index in partnership with local stakeholders (e.g., ministries of health, procurement, logistics and distribution agencies) that meet Good Practice Standards* with the aim of improving the affordability, accessibility and quality of products.

- 5 The company provided evidence of five supply chain capacity building initiatives in partnership which address local needs, and at least three initiatives met all additional Good Practice Standards, i.e. are guided by clear goals and measurable objectives, measures progress or outcomes, aims for sustainability & long-term impact.
 - 4 The company provided evidence of three supply chain capacity building initiatives, which all meet all additional Good Practice Standards OR the company provided evidence of four supply chain capacity building initiatives of which at least two meet all additional Good Practice Standards OR the company provided evidence of five supply chain capacity building initiatives of which two meet all additional Good Practice Standards.
 - 3 The company provided evidence of one supply chain capacity building initiative, which all meets all additional Good Practice Standards OR the company provided evidence of two supply chain capacity building initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of three supply chain capacity building initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of four or five supply chain capacity building initiatives of which one meets all additional Good Practice Standards.
 - 2 The company provided evidence of two supply chain capacity building initiatives in partnership which address local needs but they do not meet all additional Good Practice Standards.
 - 1 The company provided evidence of one supply chain capacity building initiative in partnership which addresses local needs but does not meet all additional Good Practice Standards.
 - o The company did not provide any examples of supply chain capacity building initiatives in partnership which met local needs in Index countries during the period of analysis.
- 3 The company provided evidence of one health system strengthening initiative, which all meets all additional Good Practice Standards OR the company provided evidence of two health system strengthening initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of three health system strengthening initiatives of which at least one meets all additional Good Practice Standards OR the company provided evidence of four or five health system strengthening initiatives of which one meets all additional Good Practice Standards.
 - 2 The company provided evidence of two health system strengthening initiatives in partnership which address local needs but they do not meet all additional Good Practice Standards.
 - 1 The company provided evidence of one health system strengthening initiative in partnership which addresses local needs but does not meet all additional Good Practice Standards.
 - o The company did not provide any examples of health system strengthening initiatives in partnership which met local needs in Index countries during the period of analysis.

*Addresses local needs, priorities and/or skills gaps; is carried out in partnership with relevant stakeholders; has good governance structures in place; has processes in place to mitigate or prevent conflict of interest; is guided by clear, measurable goals or objectives; measures outcomes; publicly discloses outcomes; has long term aims/achieves integration within the system.

*Addresses local needs, priorities and/or skills gaps; is carried out in partnership with relevant stakeholders; is guided by clear, measurable goals or objectives; measures outcomes; has long term aims/aims for sustainability

PCB3 Health System Strengthening

The company undertakes health system strengthening initiatives in partnership with local stakeholders (where there is no conflict of interest) that meet Good Practice Standards* in countries within the scope of the Index. Such initiatives should work in a coordinated way with other parties, complementing the local health system, with outcomes clearly monitored.

- 5 The company provided evidence of five health system strengthening initiatives in partnership which address local needs, and at least three initiatives met all additional Good Practice Standards
- 4 The company provided evidence of three health system strengthening initiatives, which all meet all additional Good Practice Standards OR the company provided evidence of four health system strengthening initiatives of which at least two meet all additional Good Practice Standards OR the company provided evidence of five health system strengthening initiatives of which two meet all additional Good Practice Standards.

PBM1 Inclusive business models

The company has contributed to the development and implementation of scalable inclusive business models that aim to meet the access needs of populations at the base of the income pyramid* (which may include vulnerable populations**) in countries within the Index scope, with a long-term horizon.

- 5 The company has contributed to the development of inclusive business models that improve access, with a focus on the needs of populations at the base of the pyramid (which may include vulnerable populations) and has scaled up one or multiple models measured in previous Indices. There is evidence of, or projections for, financial sustainability of these business models.
- 4 The company has scaled up one or more existing inclusive business models that improve access, with a focus on the needs of populations at the base of the pyramid (which may include vulnerable populations). There is evidence of, or projections for financial sustainability.
- 3 The company has contributed to the development of an inclusive business model that improves access, with a focus on the needs of populations at the base of the pyramid and (which may include vulnerable populations). There is evidence of, or projections for, the model's financial sustainability.
- 2 The company has contributed to the development of an inclusive business model that improves access, with a focus on the needs of populations at the base of the pyramid (which may include vulnerable populations). However, information shared on the model's financial sustainability is limited.
- o No inclusive business models identified in this area.

The 2021 Access to Medicine Index indicator weights

| Technical area | Indicator | Description | % |
|-------------------------------|-----------------------------|--|--|
| Governance of Access 20% | GA1 | Governance structures & incentives | 3.78 |
| | GA2 | Access-to-medicine strategy | 1.80 |
| | GA3 | Public disclosure of access-to-medicine outcomes | 2.27 |
| | GA4 | Responsible promotional practices | 2.73 |
| | GA5 | Compliance controls | 2.73 |
| | GA6 | Incidence of breaches | 3.99 |
| | GA7 | Trade policy: IP and access to medicine | 2.72 |
| Research & Development 25% | RD1a | R&D pipeline: Prioritised diseases | 4.40 |
| | RD1b | R&D pipeline: Other diseases | 3.30 |
| | RD2 | Planning for access: Framework | 2.75 |
| | RD3a | Planning for access: Project-specific plans for prioritised diseases | 2.20 |
| | RD3b | Planning for access: Project-specific plans for other diseases | 2.20 |
| | RD4 | Disclosure of resources dedicated to R&D | 5.50 |
| | RD5 | Clinical trial conduct: Post-trial access | 1.10 |
| | RD6 | Capacity building in R&D | 3.57 |
| Product Delivery 55% | PR1 | Registration | 5.60 |
| | PP1 | Access strategies: Coverage | This indicator was deleted as comparisons were not possible with the data quality |
| | PP2a | Access strategies: Ad hoc donation | 1.86 |
| | PP2b | Access strategies: Long-term donation programmes | 4.18 |
| | PP3 | Supranationally procured products: Access strategies | 6.70 |
| | PP4 | Healthcare practitioner-administered products: Access strategies | 6.70 |
| | PP5 | Self-administered products: Access strategies | 6.70 |
| | PPL1 | Patent filing & enforcement | 2.15 |
| | PPL2 | Patent status disclosure | 1.60 |
| | PPL3 | IP sharing | 1.26 |
| | PPL4 | Licensing: Access-oriented terms | This indicator was not scored as a minority of companies have licences eligible for assessment under this indicator. |
| | PPL5 | Licensing: Geographic scope | This indicator was not scored as a minority of companies have licences eligible for assessment under this indicator |
| | PQ1 | Ensuring continuous supply | 2.58 |
| | PQ2 | Reporting falsified and substandard medicines | 2.68 |
| | PCB1 | Capacity building in manufacturing | 3.58 |
| | PCB2 | Capacity building in supply chain management | 3.58 |
| PCB3 | Health system strengthening | 4.40 | |
| PBM1 | Inclusive business models | 1.43 | |

APPENDIX III

Identifying best practices

The diffusion of best practices is one of the Access to Medicine Index's mechanisms for supporting the pharmaceutical industry in achieving greater access to medicine. Similarly, recognising those companies trialling or scaling up innovative unique-in-industry policies or initiatives is an important way of acknowledging those companies prepared to stand out from peers and to risk new approaches.

BEST PRACTICES

Best practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best practices are not new practices – they have already been conceived of, applied and proven to meet at least some of the following criteria:

- Sustainability;
- Replicability;
- Alignment with external standards/stakeholder expectations; and
- Proven effectiveness.

In different areas of analysis (for example, in Research & Development vs. in Governance of Access) how a best practice is identified may be different. A best practice need not be unique amongst companies. A best practice might be an example of a 'gold standard' of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations. Best practices should be considered as the exemplar of positive practices in the corresponding research area in comparison to those of the other companies that submitted data within the current period of analysis. These best practices are identified based on evidence of progress submitted in the data collection period and verified with public information and through consultation with experts, where appropriate.

PROCESS

To determine which of the company's practices would be highlighted as best practice, the Foundation's research team evaluated all aspects of company practices, compiling those that met the criteria used for the purpose of scoring with additional standards for each Technical Area, where necessary. Practices that met these outlined criteria were reviewed and finalised by the Foundation's senior management with additional input from experts in the corresponding field, when required.

APPENDIX IV

The Good Practice Standards framework for capacity building

This framework has been developed to convey stakeholders' expectations for good practice in capacity building. The framework is tailored for four subthemes of capacity building included in the Index and is comprised of six standards. All company initiatives are measured against this framework.

Good Practice Standards for initiatives:

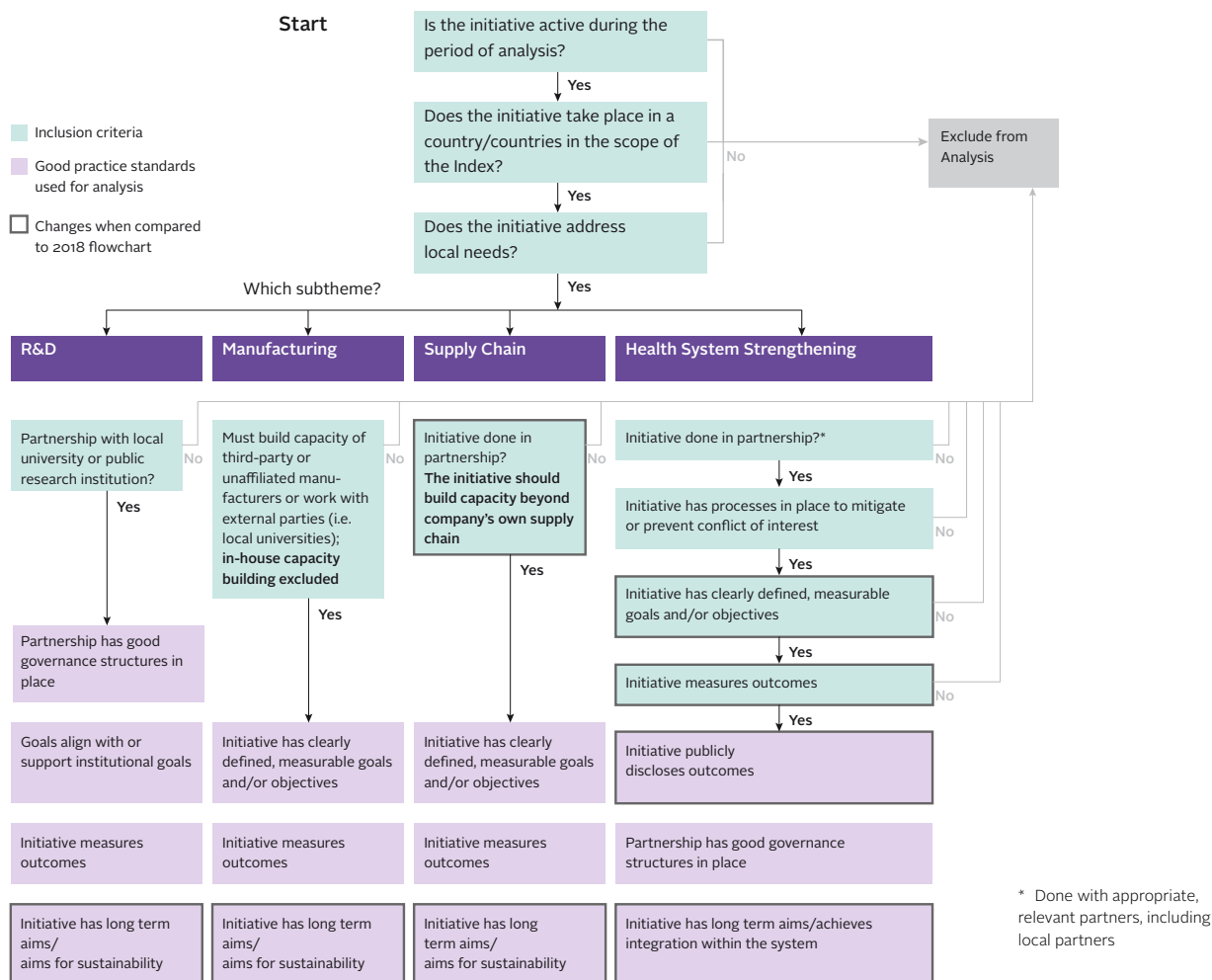
- 1 Addresses local needs, priorities and/or skills gaps
- 2 Carried out in partnership with relevant stakeholders
- 3 Has good governance structures in place (including for mitigating or preventing conflicts of interest)
- 4 Guided by clear, measurable goals or objectives
- 5 Includes regular monitoring, evaluation and public sharing of approaches, progress and learnings
- 6 Has long term aims or achieves integration within the health system

There are three basic criteria that all initiatives must meet: 1) be active during the period of analysis, 2) take place in a country/countries in scope of the Index and 3) address a clearly defined local need. Initiatives in all subthemes are expected to be done in partnership, save in manufacturing where there may be a direct engagement with contracted third-party manufacturers. Health system strengthening initiatives must also have processes in place to prevent conflict of interest; have clearly defined, measurable goals and/or objectives; and measure outcomes in order to be eligible. Initiatives are excluded if they do not meet all inclusion criteria, with excluded initiatives not being considered for scoring or further analysis. Initiatives that meet all inclusion criteria are assessed against the remaining Good Practice Standards.

TABLE 5. Capacity building initiative flowchart

The chart provides a guide to the criteria by which submitted company initiatives are included for analysis in the Index and the criteria by which they are analysed. The chart is broken down by subtheme/area of capacity

building. The expectations from stakeholders vary slightly for each area based on the nature of the activities which typically fall within that area. This chart was developed as a tool for companies to guide them in selection of their five initiatives per area during the data collection process.



APPENDIX V

Guide to Report Cards

The Guide to Report Cards provides a description of each section of the Report Cards for the 2021 Access to Medicine Index.

| Section | Description | Source |
|---|---|--|
| General information (heading) | Stock exchange ticker(s) Location of Headquarters Number of employees (as FTE) | Annual reports and/or the company's website |
| Performance in the 2021 Index (text) | This section explains the company's position in the 2021 Index, while summarising its access-to-medicine performance. It covers: <ul style="list-style-type: none"> • Drivers behind its ranking, including a breakdown of performance for the three technical areas assessed by the Index. • Main areas where the company scores well or poorly compared to peers. | Index analysis |
| How score was achieved (graph) | This graph shows the company's scores in each of the Index's three Technical Areas, benchmarked against the industry average and the leader's score in each area. The company's overall score is calculated using a weighted combination of these scores. | Index analysis |
| Opportunities (text) | This section outlines tailored opportunities for the company to improve access to medicine, taking account of company-specific characteristics, business models, strategies, policies and practices, such as its access-to-medicine strategy, compliance system, R&D pipeline, product portfolio, equitable pricing strategies and approach to IP management, as captured in the 2021 Index. | Index analysis |
| Change since the 2018 Index (text) | This section provides an update of the company's access-to-medicine performance since the 2018 Index. It covers: <ul style="list-style-type: none"> • New commitments • New, expanded or unchanged strategies, activities and programmes • Areas in which the company continues to perform particularly strongly or poorly • Interesting developments, initiatives or activities that can influence access to medicine • Notable new developments that have influenced its performance in the Index. | Index analysis |
| Sales and Operations (text) | This section provides a general description of the company's operations globally, including changes in its business (such as acquisitions or divestments) over the period of analysis. Product categories are standardised across companies. | Annual reports, company website, press releases and other news sources |
| Sales by segment (table) | This figure shows the breakdown of the company's 2019 net sales/revenue/turnover by business segment. Depending on how the company reports this figure may vary. | Company financial statements |
| Sales in countries in scope (figure) | This figure shows the countries in scope in which the company has sales. | Raw data submission to the Index |
| Sales by geographical region (graph) | This figure shows a geographic breakdown of the company's gross or net sales/revenue/turnover over the last two to five years. Sales are broken down into the geographic distribution reported by the company is used. | Company financial statements |
| Sample of pipeline and portfolio assessed by the Index | This section describes the company's portfolio of products and pipeline of R&D projects that fall within the scope of the Index, including details on the number of registered products and R&D projects (this relative to peers) per disease category, e.g., communicable diseases or neglected tropical diseases and the main therapeutic areas. | N/a |

| | | |
|---|---|--|
| <p>Pipeline for diseases and countries in scope (text)</p> | <p>The company's R&D pipeline is described on the following factors: proportion of the pipeline projects targeting R&D priorities, as defined by G-FINDER, proportion of priority and non-priority R&D projects with public health value to low- and middle-income countries in late-stage development, and other projects. In addition, the pipeline section describes the percentage of late-stage development projects with access plans (see below definition).</p> <p>Inclusion criteria for R&D projects: Project was ongoing during the period of analysis</p> <p>Innovative R&D is defined as the development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides.</p> <ul style="list-style-type: none"> • Innovative R&D for medicines and vaccines: All early-stage projects targeting priority R&D are included (all disease categories). All late-stage projects targeting communicable diseases and neglected tropical diseases are included. Late-stage projects targeting non-communicable diseases and maternal and neonatal health conditions are included. • Adaptive R&D is defined as the adaptation of existing/registered NCEs, NBEs or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides to address an unmet need in the countries within scope, for example, new demographic segments (e.g., infants/children, pregnant women), environmental conditions (e.g., heat-stable formulations) or new formulations (e.g., fixed-dose combinations). • R&D for other product types (e.g. diagnostics, platform technologies): projects are included if the R&D is directed at meeting unmet needs of populations in countries in scope of the Index. <p>Access plans are measures put in place to ensure future affordability and availability of successful investigational products. Access plans can take many forms, including patent waivers, voluntary licensing, supply commitments, registration targets, donation programmes and affordable pricing strategies.</p> <p>Note that in some cases this section may refer to products approved during the period of analysis that do not appear in the pipeline figures below. This is due to differences in the inclusion criteria for analysis of products and R&D projects.</p> | <p>Data source for the R&D pipeline is products submitted by the company for scoring and analysis in the Index</p> |
| <p>Portfolio as selected for analysis by the Index</p> | <p>The product portfolio section indicates the number of medicines on patent and number of medicines included on the WHO Model List of Essential Medicines (2019).</p> <p>Inclusion criteria for products:</p> <ul style="list-style-type: none"> • Product indications were verified via regulatory authorities (FDA, EMA and PMDA). • Medicines with no specific indication for a disease in scope were excluded from analysis. • All registered products that meet inclusion criteria were included, regardless of whether registration and sales has/have not occurred in countries within the scope of the Index. • New products which were approved by FDA, EMA or PMDA during the period of analysis and meet inclusion criteria were included. | <p>Data sources for the product portfolio are products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMEA, PMDA, and the company's website</p> |
| <p>Pipeline projects per disease category (graph)</p> | <p>This figure shows company's pipeline projects broken down by disease categories. This covers medicines (including microbicides), vaccines, diagnostics, vector control products and platform technologies R&D projects. The disease category 'Multiple categories' includes projects targeting multiple diseases within scope and covering multiple disease categories (e.g. broad spectrum antibiotics, steroids). Contraceptive methods and devices are included under maternal and neonatal health conditions.</p> | <p>Index analysis of products submitted by the company for scoring and analysis in the Index</p> |

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| Breakdown of pipeline projects (graph) | This figure shows all relevant innovative pipeline projects in preclinical and clinical development. In addition, relevant market approvals granted within the period of analysis are shown. The data is displayed per projects targeting R&D priorities, non-priority R&D with value to low- and middle-income countries and other project in scope. | Index analysis of products submitted by the company for scoring and analysis in the Index |
| Products per disease category (graph) | This figure shows the total number of products in the company's portfolio within the disease scope of the Index, broken down by disease categories. This covers medicines (including microbicides, contraceptive methods and devices), vaccines, diagnostics, vector-control products and platform technologies. The disease category 'Multiple categories' includes medicines that are indicated for multiple diseases within scope and cover multiple disease categories (e.g. broad spectrum antibiotics, steroids). Contraceptive methods and devices are included under maternal and neonatal health conditions. | Products submitted by the company for scoring and analysis in the Index as well as any registered products identified on the FDA, EMEA, PMDA, and the company's website |
| Breakdown of products (graph) | This figure shows the total number of the company's products within the scope of the Index, broken down by type of products: medicines, vaccines, diagnostics and others. In addition, the figure indicates number of on-patent and off-patent medicines as well as those on the WHO Model List of Essential Medicines (2019). Other includes control vector products and platform technologies. Contraceptive methods and devices are included under medicine. | Products submitted by the company for scoring and analysis in the Index as well as any registered products identified on the FDA, EMEA, PMDA, and the company's website |
| Performance by technical area (text) | This section summarises company performance per Technical Area. Each Technical Area section includes a description of: The company's position in the Technical Area sub-ranking The main areas within the Technical Area where the company scores well or poorly The main areas where the company has significantly changed its performance compared to Index 2018. New developments that have influenced performance in the Technical Area. | Index analysis |

APPENDIX VI

Definitions

Access plans

Working definition, used for analysis

Plans to ensure that public health needs are taken into consideration during R&D. Access plans can be developed in-house or in collaboration and include commitments and strategies as well as more concrete access plans: agreed-upon measures typically developed in partnership to enforce accountability. These plans facilitate availability, accessibility and affordability for patients in countries within the scope of the Index (e.g., registration commitments, equitable pricing strategies, sufficient supply commitments, non-exclusivity in specified territories, waiving patent rights, royalty-free provisions and applying for WHO prequalification).

Access initiatives

Working definition, used for analysis

An access initiative - within the context of the Access to Medicine Index - is an initiative a company is involved in which seeks to address access to medicine constraints in low- and middle-income countries. This may or may not be in partnership with others, and may or may not involve improving access to specific pharmaceutical products. Where access initiatives relate to products, it may be either an equitable pricing strategy, a non-exclusive voluntary licensing approach or a structured donation programme. Examples of access initiatives which do not involve products include, for e.g., awareness-raising activities in health system strengthening. Where products are involved in an access initiative, this will be clearly identified within the text of the Access to Medicine Index report.

Access-to-medicine strategy

Working definition, used for analysis

A strategy specifically intended to improve access to medicine, that

includes all the typical elements of a strategy (a clear rationale, targets, objectives and expected outcomes). In low- and middle-income countries where the company operates, the strategy may apply to a defined set of diseases, products or therapeutic areas, or to the whole pipeline and portfolio.

Ad hoc donation programmes

Working definition, used for analysis

A gift of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on the explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

Adaptive product R&D

Working definition, used for analysis

The adaptation of existing/registered New Chemical Entities (NCEs), New Biological Entities (NBEs) or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products, microbicides or other health products that may address an unmet need in countries in scope, e.g., new demographic segments (e.g., infants/children, pregnant women), environmental conditions (e.g., heat-resistant formulations) or new formulations (e.g., oral formulations).

Affordability

Working definition, used for analysis

A measure of the payer's ability to pay for a product (whether or not they are the end user). The Index takes this into account when assessing pricing strategies for relevant products. Pharmaceutical companies use many different criteria to assess affordability.

Base of the income pyramid

The base of the income pyramid, also referred to sometimes as the working poor, designates the four billion people living on an average of USD 1-5 per day.

Compliance controls

Working definition, used for analysis

Compliance controls evaluated in the Index are processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour of the company's employees and, if applicable, the third parties the company formally engages with.

These processes include:

- Fraud-specific risk assessment to pro-actively identify vulnerabilities for fraud and actual cases;
- Auditing and review mechanisms conducted by external, independent specialists, applying to third parties in all countries the company is operating;
- A live/continuous monitoring system for compliance, other than financial auditing, to continuously monitor activities to detect discrepancies;
- Country risk-based assessments to identify vulnerabilities for non-compliant or corrupt activities in countries in scope where the company is operating; and
- Processes to ensure third party compliance (including e.g., contractual agreements, training on codes of conduct).

Budget impact

Working definition, used for analysis

An estimated measure of the cost of treatment with a given therapy for a given number of patients in a specific population.

Conflict of interest

A conflict of interest is the conflict that arises when the commercial interests of a company are potentially at odds with

the interests of the partnership, the partner (i.e., local stakeholders), or the health and well-being of the population the partnership intends to help.

Demographic factors

Working definition, used for analysis

Characteristics of a population such as age, sex, income level, education level, employment, etc.

Equitable pricing strategy

Working definition, used for analysis

A targeted pricing strategy which aims at improving access to medicine for those in need by taking the abilities to pay of individuals and healthcare systems into account in a manner that is locally appropriate.

Ethical marketing

Promotional activities that are aimed at the general public, patients, healthcare professionals/students and opinion leaders in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.

Falsified medicine

Medical products that deliberately/fraudulently misrepresent their identity, composition or source. [Definition from WHO, 2017]

Good governance structures

Working definition, used for analysis

Good governance structures include three components: 1) the structures put in place which establish clear roles, responsibilities and decision making structures; 2) the systems of communications whereby information is regularly conveyed to all concerned; and 3) the transparency and accountability for processes, decisions and outcomes of initiatives.

Good Practice Standards

Working definition, used for analysis

A set of six standards that encompass good practice in capacity building initiatives. These standards form a framework used for the assessment of company capacity building initiatives. The standards include: working in partner-

ship, having good governance structures in place, addressing local needs, having clear goals and objectives, measuring outcomes and having long-term aims or achieving integration in the system.

Healthcare practitioner-administered products

Working definition, used for analysis

Products that typically require either hospital administration of the product or the continued attention of a skilled healthcare professional for administration, such as an intravenously administered oncology medicine.

Innovative product R&D

Working definition, used for analysis

The development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventive vaccines, diagnostics, vector control products and microbicides which have not previously been approved for use.

National reimbursement authority

Working definition, used for analysis

Governmental bodies with the authority to control, approve and determine pricing and reimbursement of medicinal products in a country.

Non-exclusive voluntary licences

Working definition, used for analysis

Non-exclusive voluntary licences are defined as the licences which enable - on a non-exclusive basis, and according to the terms of the licence agreed - the manufacture and supply of generic versions of patented medicines by other manufacturers.

Non-pricing initiatives

Working definition, used for analysis

Actions taken to increase the number of patients reached through access methods other than price. Non-pricing initiatives applied may include, but are not limited to, non-exclusive voluntary licensing, donations partnering with governments, patient assistance programmes and non-assert declarations.

Outcomes

Working definition, used for analysis

Outcomes are the results achieved by a company's access-related activities. These can include short-term (e.g., an increased proportion of people with more knowledge on diseases, symptoms or treatments) and/or medium- to long-term outcomes (e.g., patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; availability of medicines at outlets).

Patient Assistance Programmes

Working definition, used for analysis

Patient assistance programmes are defined as programmes initiated by pharmaceutical companies which provide financial assistance or free-of-charge medicines for a defined patient population with limited ability to pay.

Period of analysis

For the 2020 Index, the time period for which data will be analysed covers company activities which must be ongoing between 1 June 2018 and 31 May 2020, as this is the cycle of the Index. Projects that have ended before 1 June 2018 are not included.

Post-trial access

The continued provision of treatment to clinical trial participants who still require an intervention following the close of the clinical trials in which they participated.

Priority R&D

Working definition, used for analysis

R&D that addresses product gaps that are needed by people living in low- and middle-income countries due to ineffective, maladaptive or non-existent products for certain diseases, conditions and pathogens in the scope of the Index. These product gaps are defined as being those listed in a series of six priority lists developed by WHO and Policy Cures Research, an independent research group.

Private sector

Working definition, used for analysis

Private sector refers to payer types

such as private insurance and patients paying out of pocket.

Self-administered products

Working definition, used for analysis

Self-administered products are defined as those products which patients can typically take or administer to themselves without needing a skilled health-care worker for regular usage. These products may or may not be prioritised by governments or by the global health community (e.g., treatments for non-communicable diseases such as diabetes, stroke and heart disease).

Substandard medical products

Also called 'out of specification', these are authorized medical products that fail to meet either their quality standards or specifications, or both.

[Definition from WHO, 2017]

Supranationally procured products

Working definition, used for analysis

Products for which international pooled

procurement, advance market commitments, market-shaping facilities and significant public funding and donor support exist. These products include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria and neglected tropical diseases.

Structured donation programmes

Working definition, used for analysis

A gift of products for which a defined strategy exists as to the type, volume and destination of donated products. Structured donation programmes are long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate or eradicate a disease.

Vulnerable populations

Working definition, used for analysis

Vulnerable populations represent people at greater risk of facing stigma and additional barriers to access due to social, economic or health considerations. These can include, but are not limited to, children, girls and women, men who have sex with men, people living with HIV, etc.

APPENDIX VII

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APPENDIX VIII**Acknowledgements**

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