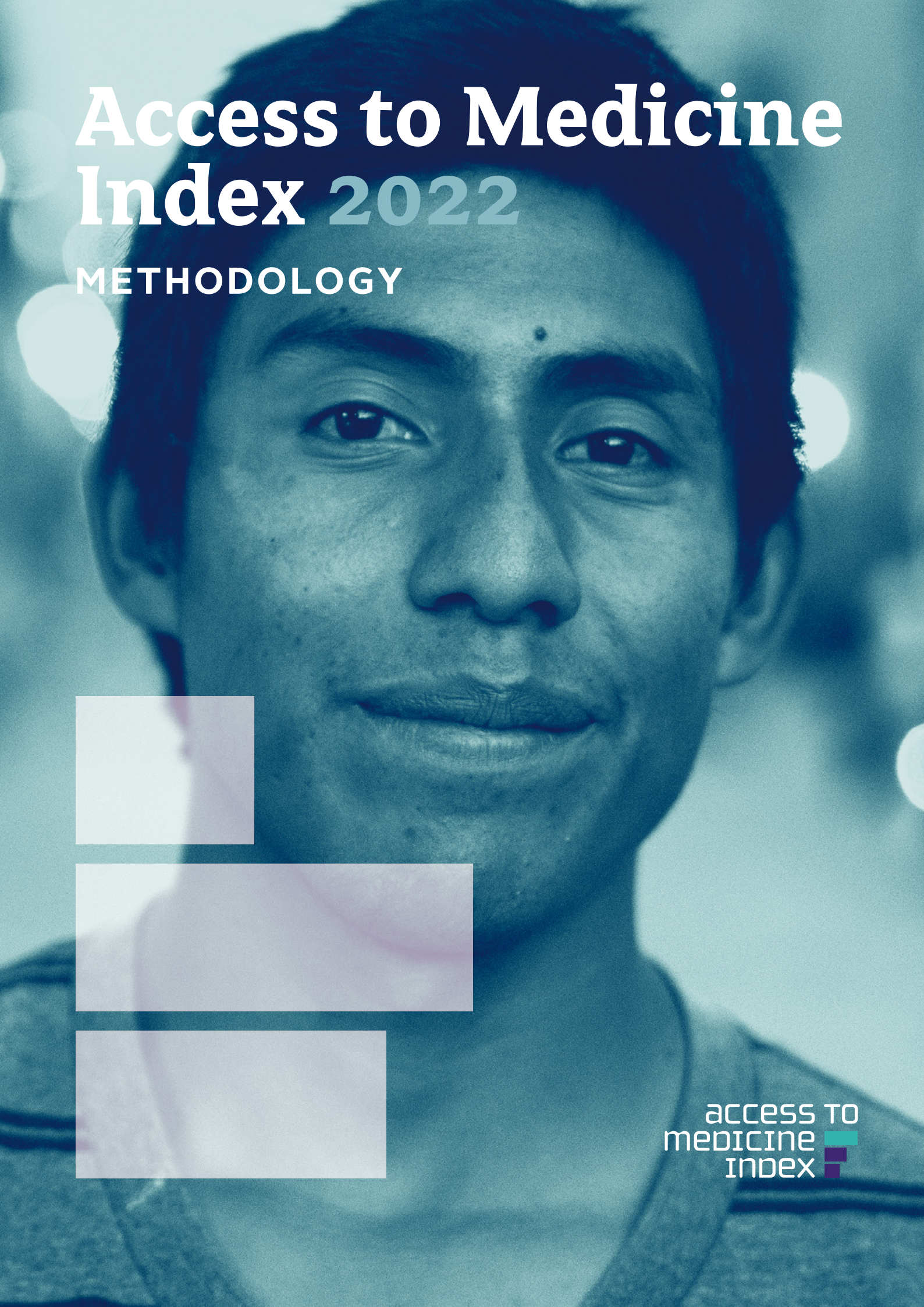

Access to Medicine Index 2022

METHODOLOGY

access to medicine index

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We would like to thank the many other experts who contributed their views to the development of this methodology (see page 39).

ACCESS TO MEDICINE FOUNDATION

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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Momentum for improving access must not be lost

The Covid-19 pandemic has exposed where the biggest fault-lines are in global access to medicine, and how much more must be done to fix them. But it has also been a period of innovation and partnership, with the pharmaceutical industry showing just how quickly it can move to address a health-care crisis. More widely, the pandemic has created a greater awareness of unequal access to healthcare and health products faced by people all over the world. I fear that these chronic issues will never go away if we do not harness this momentum – and act now.

In so many ways, the corporate and public sectors have stepped up since the pandemic began, developing new vaccines at unprecedented speeds while also tackling severe strains to public health services. Yet we have still left the poorest populations last in line. Healthcare systems and medical supply chains in lower-income countries have faced the biggest stresses, while the global distribution of vaccines has been far from equitable. There is much to celebrate, but also much to improve.

Our current Access to Medicine Index came out in January 2021, and my team continues to use the data and the conclusions from the report to facilitate real change within the pharmaceutical industry. The team has also now begun work towards the 2022 Access to Medicine Index, and this Methodology Report – which sets out the framework for the next Index – is a major milestone along that path.

The 2022 Access to Medicine Index will evaluate the work of 20 of the world's largest pharmaceutical countries, assessing their efforts in addressing access to medicine in 108 low- and middle-income countries, whose populations have long endured limited access to new or essential products.

This will be the eighth edition of the Index, which was first published in 2008. It has a central role in ensuring that the best of the industry thrives, highlighting best practice and showing where more can – and should – be done. The Index closely examines difficult issues like pricing, supply security, and reaching vulnerable populations. While Covid-19 is certainly within the scope of our analysis, this Index covers a total of 83 diseases and takes an in-depth look at access to medicine to provide a clear picture of where we now stand.

Previous indexes have shown worryingly short R&D pipelines for Emerging Infectious Diseases. In addition, not enough was being done to ensure affordability and access for the most vulnerable populations. So, as we look to the future, I ask: has the pharmaceutical industry truly learned from this pandemic, or has Covid-19 won in setting back progress? The Index will illuminate the answers to these questions. The impetus must not be lost.

Jayasree K. Iyer
Executive Director
Access to Medicine Foundation

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About this report

This report sets out the methodology for the 2022 Access to Medicine Index, including its framework, scopes, priority topics and indicators. It captures society's expectations of pharmaceutical companies regarding access to medicine in low- and middle-income countries (LMICs). Using this methodology, the next Index will assess progress by 20 of the world's largest pharmaceutical companies in making medicines, vaccines, diagnostics and other health products more accessible in LMICs. The Index is published every two years.

ANALYTICAL FRAMEWORK FOR THE 2022 ACCESS TO MEDICINE INDEX

Towards 2030
The UN has called for a decade of action in order to achieve the Sustainable Development Goals (SDGs) and universal health coverage (UHC) by 2030, and the clock has already begun to tick. To reach that milestone, pharmaceutical companies have a central role to play in developing the treatments needed by the more than 80% of the global population who live in LMICs, and in improving products' availability across socioeconomic divides. The findings of the 2022 Index will help illuminate where progress is already being made, and where action is still required.

Continuity of framework enables clear trend analysis
Each Access to Medicine Index is the result of a two-year process that begins with a review of the Index methodology. Ahead of the previous Index, a comprehensive methodology review was carried out in 2019 which resulted in a tighter analytical framework with a greater focus on the pharmaceutical industry's core responsibilities on access (such as R&D, affordability, and intellectual property management).

In this cycle, for the upcoming eighth Access to Medicine Index, a more targeted approach was taken when it came to reviewing the framework. A variety of experts were consulted to introduce refinements to the methodological framework, only where needed. This continuity within the methodology will facilitate clearer comparisons with data and information from the previous Index, enabling more nuanced trend analysis.

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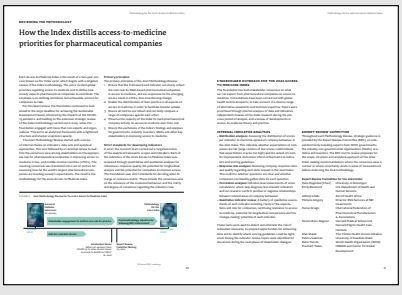
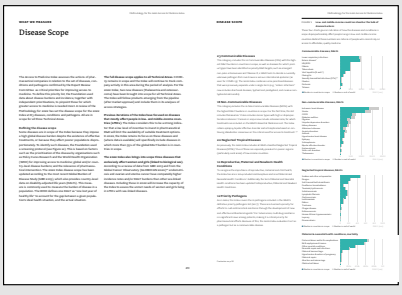

How the Index distills access-to-medicine priorities for pharmaceutical companies


2022 Index to put greater focus on measuring outcomes


Disease Scope


Geographic Scope

EXECUTIVE SUMMARY

A vision for 2030: how this Index will shift pharma company practice

This report sets out the analytical framework for the next Access to Medicine Index, the longest-running assessment of pharmaceutical industry action to improve access to medicine. It builds on the previous Index methodology, which was published in March 2020 when the world was waking up to the threat of COVID-19.

Governments, philanthropic foundations and multi-lateral agencies pivoted quickly to devote funding and resources to the pandemic. The private sector also responded vigorously, ramping up programmes to develop new vaccines, diagnostics and treatments, while working to minimise disruption to supply chains. The COVID-19 pandemic has provided a case study for the role played by the pharmaceutical industry in developing and delivering health products, and exposed the vast and complex network of supply chains and logistics that factories, clinics and pharmacies depend upon.

The UN has called for a decade of action to achieve its Sustainable Development Goals (SDGs) and universal health coverage (UHC) by 2030. The pandemic is demonstrating in real time how access to medicine can be achieved – or blocked. Even though vaccines now exist that could end the pandemic, price, patents, and national stockpiling are among the factors that influence which populations are served first.

The tough lessons from the pandemic should provide a wake-up call for changing the way healthcare is delivered. Yet there is a clear risk that the world could soon return to 'business as usual' when it comes to delivering access to medicine.

Fall-out continues from the pandemic

Furthermore, the COVID-19 pandemic is not over; action is still required to curb this pandemic and prepare for the future by building strong and responsive health systems. The COVID-19 pandemic has triggered far-reaching consequences for global health, disrupting a vast range of programmes designed to increase access to medicine. Screening and treatment for tuberculosis, malaria and HIV/AIDS have been interrupted; so have programmes and activities that target neglected tropical diseases (NTDs) and sexual and reproductive health. Such disruptions can have a ripple effect on development gains: for example, by putting women and girls at risk of unwanted pregnancies and impacting their ability to attend school, join the workforce and help provide for their families. Millions more children have gone without timely vaccinations since the pandemic began. The shortages of medicines caused by disruptions to supply chains also affect those living with non-communicable diseases, including diabetes and cancer. These groups are especially dependent on receiving a steady supply of treatment.

The pandemic has also reduced access to medicine in more indirect ways. With the closure of health facilities and restrictions on travel, many pregnant women have lost access to the obstetric and/or neonatal treatments they may require. This puts them at grave risk, and jeopardises gains made over the past decade in maternal and infant mortality rates.

FIG 1 **Companies in scope of the 2022 Access to Medicine Index**

Company Name	Country	Market cap 2020 (bn USD)
AbbVie Inc	USA	186,681
Astellas Pharma Inc	JPN	31,067
AstraZeneca plc	GBR	135,160
Bayer AG	DEU	63,404
Boehringer Ingelheim GmbH	DEU	n/a
Bristol Myers Squibb Co	USA	136,580
Daiichi Sankyo Co, Ltd	JPN	60,019
Eisai Co, Ltd	JPN	20,849
Eli Lilly & Co	USA	195,068
Gilead Sciences Inc	USA	80,940
GlaxoSmithKline plc	GBR	86,525
Johnson & Johnson	USA	433,237
Merck & Co, Inc	USA	190,309
Merck KGaA	DEU	73,652
Novartis AG	CHE	201,943
Novo Nordisk A/S	DNK	172,363
Pfizer Inc	USA	192,793
Roche Holding AG	CHE	292,984
Sanofi	FRA	118,723
Takeda Pharmaceutical Co, Ltd	JPN	55,422

A vision for 2030

To achieve the SDGs and UHC by 2030 despite the impact of COVID-19, the pharmaceutical industry must complete a shift in how it addresses access to medicine. Namely, it must approach access to medicine systematically and at scale, ensuring that healthcare products are delivered to the right people via initiatives tailored to local needs and health systems.

This has been confirmed in 2021 by the Access to Medicine Foundation through its stakeholder dialogue, which it holds every two years to verify the consensus view on pharma's core role in improving access to medicine. A key step in the methodology review for the next Access to Medicine Index, this latest dialogue builds on the extensive strategic review carried out in 2019, when the Foundation engaged with more than 100 experts and organisations. This led to an analytical framework with a tightened structure and sharper analytical capacity.

Each Access to Medicine Index assesses 20 of the world's largest R&D-based pharmaceutical companies on their actions to improve access to medicine for people living in the low- and middle-income countries measured by the Index, which are home to more than 80% of all people alive today. It examines companies on their policies and practices in strategy, compliance, R&D, pricing and product delivery. The 20 companies in scope account for more than half of global pharmaceutical revenue. Considering their pipelines, portfolios, resources and global reach, these companies have a unique capacity to develop the health products that people in LMICs need, and to improve the availability of these products across socioeconomic divides.

What changes are we working to achieve?

To achieve the SDGs and UHC by 2030 despite the impact of COVID-19, the pharmaceutical industry must complete a shift in how it addresses access to medicine:

Governance of Access by 2030

- Access-to-medicine is fully integrated into commercial strategy, including oversight, incentives and accountability from HQ to in-country operations.
- Results of access initiatives are monitored and shared publicly.
- Business is conducted in an ethical and responsible manner.

Research & Development by 2030

- Pharmaceutical R&D responds to the needs of people in low- and middle-income countries.
- Companies' access plans for registration, supply and affordability are systematically developed during R&D, from at least Phase II of clinical development.

Product Delivery by 2030

- Access is prioritised for products viewed as essential to public health, particularly where there are few manufacturers.
- New products are quickly and widely registered in low-and middle-income countries.
- LMICs can rely on a steady and sufficient supply of quality products.
- Payers and patients can afford the health products they need, including people at the base of the income pyramid.
- Alternative manufacturers are enabled to supply quality products, competing on price, to countries where patent-holding companies do not plan to supply directly.
- Health systems are supported through partnerships including local stakeholders and in line with local needs.

How the Index drives change

As a tool to drive change, the Index identifies best practice, tracks progress and shows where critical action is needed to improve access to medicine. It evaluates companies in areas where they have the biggest potential and responsibility to make change, and identifies what is working where and why, in order to provide blueprints to expand good practice. By ranking companies every two years, it spurs them to compete and collaborate on priority access-to-medicine topics. It shows which companies are leading the way, as better performers rise in the ranking.

The next Index will be published in 2022. It will cover:

- 20 of the world's largest pharmaceutical companies;
- 31 metrics covering the core role for pharma on access to medicine in strategy, compliance, R&D, pricing and product delivery;
- 108 low- and middle-income countries (LMICs) where better access to medicine is most urgently needed; and
- 83 diseases, conditions and pathogens that disproportionately impact people in LMICs.

KEY ANALYTICAL THEMES FOR 2022

- **Progress toward the SDGs and UHC.** The methodology review introduced discrete refinements to the analytical framework while maintaining consistency with previous analytical approaches. Indicators have been modified to ensure like-for-like comparisons are more precise. As a result, the 2022 Index will continue to track progress, while making more sensitive comparisons of how pharmaceutical companies use their access approaches in different markets and territories around the world.

- **Pandemic preparedness and response**. The previous Index, published in January 2021, found that most pathogens posing pandemic concerns were unaddressed by R&D. In 2022, the Index will assess whether this has changed, as part of a broader assessment of the industry's level of pandemic preparedness. Importantly, it will also examine companies' agility in ramping up manufacturing and deployment to make COVID-19 products available to all countries, and particularly, assessing pricing and supply commitments, identifying best practices and exploring where and how the industry fell short.

- **Continuous supply.** Pharmaceutical companies are newly conscious of how quickly demand for new products can surge. The 2022 Index will assess the measures companies are putting in place to respond to urgent need, including through partnerships and/or by sharing technology with smaller companies, generic medicine manufacturers and research institutes. It will also assess the measures companies took to ensure the supply of existing health products and protect pre-existing access commitments.

ANALYTICAL FRAMEWORK FOR THE 2022 ACCESS TO MEDICINE INDEX

3 TECHNICAL AREAS	14 PRIORITY TOPICS	Indicators per topic
A GOVERNANCE OF ACCESS 15%	Responsible business practices	4
	Governance and strategy	3
B RESEARCH & DEVELOPMENT 30%	Access planning	3
	Product development	3
	Building R&D capacity	1
C PRODUCT DELIVERY 55%	Equitable access strategies	3
	Intellectual property strategy	3
	Quality and supply	3
	Licensing quality	2
	Product donations	2
	Registration	1
	Inclusive business models	1
	Local manufacturing	1
	Health systems strengthening	1

The 2022 Access to Medicine Index
Methodology 2021

The Access to Medicine Index is the product of a two-year cycle known as the Index cycle, which starts with a review of the Index methodology. The aim of the review is to distill global priorities regarding access to medicine and define how society expects pharmaceutical companies to contribute.

In this section:

REVIEWING THE METHODOLOGY
The 2022 Methodology Review started with a series of internal checks on indicators, data sets and analytical approaches. This was followed by an external review to confirm the consensus view among stakeholders on where pharmaceutical companies should take action in the coming decade.

STAKEHOLDER CONSENSUS
To achieve the SDGs and UHC by 2030 despite the impact of COVID-19, the pharmaceutical industry must complete a shift in how it addresses access to medicine. Namely, it must approach access to medicine systematically and at scale, ensuring that healthcare products are delivered to the right people via initiatives tailored to local needs and health systems. This has been confirmed in 2021 by the Access to Medicine Foundation through its stakeholder dialogue, which it holds every two years to verify the consensus view on pharma's core role in improving access to medicine.

ANALYTICAL FRAMEWORK
The 2022 Access to Medicine Index is based on a refined analytical framework of three Technical Areas, and 14 priority topics for corporate activity.

The analytical framework comprises 31 indicators grouped into three Technical Areas:
1. Governance of Access
2. Research & Development
3. Product Delivery

REVIEWING THE METHODOLOGY

How the Index distills access-to-medicine priorities for pharmaceutical companies

Each Access to Medicine Index is the result of a two-year process known as the 'Index cycle', which begins with a targeted review of the Index methodology. The aim is to distil global priorities regarding access to medicine and to define how society expects pharmaceutical companies to contribute. The emphasis is on defining ambitious, but achievable, actions for companies to take.

For this latest review, the Foundation continued to look ahead to the 2030 deadline for achieving the Sustainable Development Goals, informed by the impacts of the COVID-19 pandemic and building on the extensive strategic review of the Index methodology carried out in 2019, when the Foundation engaged with more than 100 experts and organisations. This led to an analytical framework with a tightened structure and sharper analytical capacity.

The 2021 Methodology Review started with a series of internal checks on indicators, data sets and analytical approaches. This was followed by an external review to reaffirm the consensus view among stakeholders on the appropriate role for pharmaceutical companies in improving access to medicine in low- and middle-income countries (LMICs). The resulting consensus was translated into a set of metrics for assessing how far the world's largest pharmaceutical companies are meeting society's expectations. The result is the methodology for the 2022 Access to Medicine Index.

Primary principles

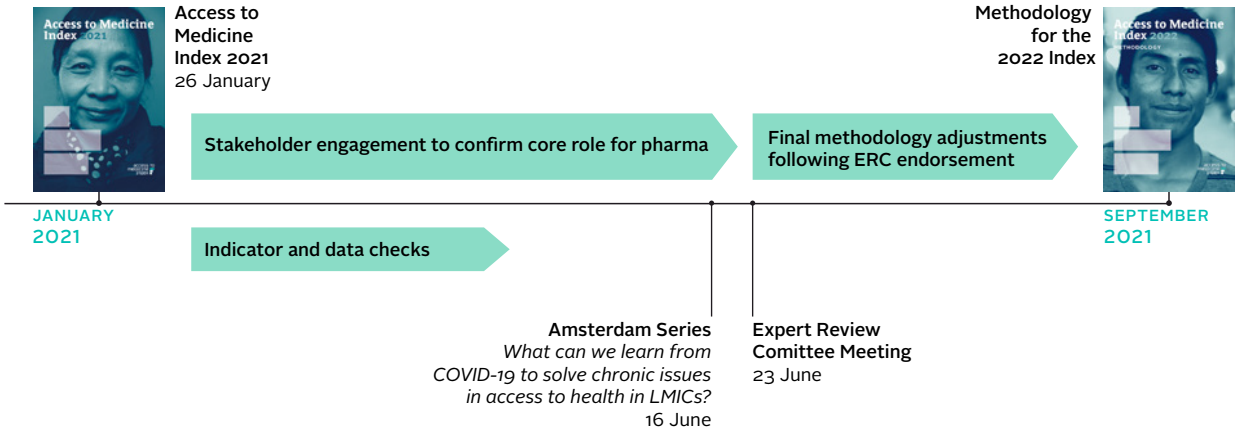
The primary principles of the 2021 Methodology Review:

1 Ensure that the framework and indicator set clearly reflect the core role for R&D-based pharmaceutical companies in access to medicine, and are responsive to the emerging access needs in LMICs, thus incentivising change;
2 Enable the identification of best practice in all aspects of access to medicine in order to facilitate broader uptake;
3 Ensure all metrics are robust and can fairly compare a range of companies against each other;
4 Preserve the capacity of the Index to track pharmaceutical company activity on access to medicine over time; and
5 Ensure the usefulness of the Index's findings and analyses for governments, industry, investors, NGOs and other key stakeholders in improving access to medicine.

Strict standards for developing indicators

In 2021, the research team carried out a targeted review of the analytical framework, scopes and indicators. Each of the indicators of the 2022 Access to Medicine Index was reviewed through quantitative and qualitative analyses for robustness, response quality, the potential for longitudinal analysis and the potential for companies to improve access. The Foundation uses strict standards for deciding when to merge or remove a metric. These include the consensus view on the relevance of the measured behaviour, and the clarity and degree of consensus regarding the industry's role.

FIGURE 2 **2021 Methodology Review for the 2022 Access to Medicine Index**



*At time of ERC meetings

STAKEHOLDER OUTREACH FOR THE 2022 ACCESS TO MEDICINE INDEX

The Foundation has built stakeholder consensus on what we can expect from pharmaceutical companies on access to medicine. As in previous years, consultations have been carried out with global health technical experts to ensure a diverse range of viewpoints and technical expertise are incorporated. This included global health donors, international organisations, investors, low- and middle-income country governments and regulators, NGOs, pharmaceutical industry organisations, product development partnerships (PDPs) and research and academic institutions. The Foundation also engaged with companies evaluated in the Index.

INTERNAL INDICATOR ANALYSES

- **Distribution analyses**: Assessing the distribution of scores per indicator to check the spread of company behaviour in the 2021 Index. This indicates whether expectations of companies are fair (large clusters of low scores could indicate that expectations may be too high) and the extent of room for improvement. Outcomes inform refinements to indicators and scoring guidelines.
- **Response rate analyses:** Assessing company response rates and quality regarding each data request in the 2021 Index. This confirms whether questions are clear and whether companies can feasibly gather data for each question.
- **Correlation analyses:** Indicator-level assessments of score correlations, which help diagnose less relevant indicators and can reveal or confirm positive or negative relationships between related areas of company behaviour.
- **Qualitative indicator review:** A battery of qualitative assessments of each indicator including clarity of the expectations and role for companies, continuing relevance to access to medicine, potential for longitudinal comparisons and the 'change-making' potential of each indicator.

These tests were used to detect and eliminate the risk of redundant measures, to pinpoint opportunities for enhancing data and to identify where scoring guidelines could be tightened. During the indicator review, topics were identified for discussion during the next phase of stakeholder dialogue.

EXPERT REVIEW COMMITTEE

Throughout each Methodology Review, strategic guidance is provided by the Expert Review Committee (ERC), an independent body including experts from WHO, governments, the industry, non-governmental organisations (NGOs), academia and investors. The ERC met to review proposals for the scope, structure and analytical approach of the 2022 Index, making recommendations where the consensus view is unclear or where uncertainty exists in areas of measurement, before endorsing the final methodology.

Expert Review Committee for the 2022 Index

Hans Hogerzeil (Chair)	University of Groningen
Emily Bleimund	U.S. Department of Health and Human Services
Githinji Gitahi	Amref Health Africa
Michela Gregory	Director, ESG Services at NEI Investments
Fumie Griego	International Federation of Pharmaceutical Manufacturers & Associations
Martha Gyansa-Lutterodt	Ministry of Health, Ghana
Dennis Ross-Degnan	Harvard Medical School and Harvard Pilgrim Health Care Institute
Alan Staple	The Clinton Health Access Initiative
Fatima Suleman	University of KwaZulu-Natal
Klara Tisocki	World Health Organization (WHO)
Prashant Yadav	INSEAD and Center for Global Development

ANALYTICAL FRAMEWORK

2022 Index to put greater focus on measuring outcomes

With more than 10 years of methodological development, the Index has evolved its framework and indicators through extensive dialogue between stakeholders. The result is a set of ambitious yet achievable expectations for the behaviour of pharmaceutical companies in improving access to medicine. The Methodology for the 2022 Index is based on a tight analytical framework of three Technical Areas, and on 14 priority topics for corporate activity. In each area, the policies and practices of pharmaceutical companies are measured by indicators that correspond to the core role they can play to improve access. As previously, this role centres on the creation and equitable delivery of health products while ensuring responsible business practice and appropriate management of access.

Analytical focus for 2022

The analytical framework for 2022 has a tight structure, with 31 indicators grouped into three Technical Areas:

1 Governance of Access
2 Research & Development
3 Product Delivery

For the 2022 Index, analytical criteria for each indicator have been refined to ensure like-for-like comparison. This could relate, for example, to the approaches of companies in similar country contexts and/or where external market incentives (such as pooled procurement mechanisms) resemble each other. This change will enable the 2022 Index to make a more nuanced comparison of access approaches deployed by companies in different markets and territories.

Three Technical Areas

Stakeholders have confirmed three key areas (Technical Areas) in which pharmaceutical companies have responsibility and ability to influence access to medicine in low- and middle-income countries (LMICs). The Technical Areas are divided into 14 priority topics. The Index weights each one according to its perceived importance in improving access to medicine.

31 indicators

The Index's methodological framework for 2022 streamlines the identification and confirmation of best practices and practices that, over the past decade, have proven to be successful, scalable and accepted by governments and other stakeholders. This streamlining reflects the global health community's emphasis on access programmes that can achieve both scale and sustainability.

Since the last iteration of the Index (2021), its number of indicators has dropped from 33 to 31. Some have been refined, either to tailor a metric more closely to stakeholders' expectations of company behaviour, or to improve elements such as data capture, comparison of companies or associated analyses. In addition, indicators may have been merged or removed in accordance with their relevance to access and/or the industry's role. All indicators for the 2022 Index are listed from page 28 onwards.

KEY CHANGES IN 2022

- The Index will modify the weighting of its three Technical Areas, decreasing the weighting of Governance of Access to 15% (from 20%) and increasing Research & Development to 30% (from 25%).
- A shifting of weight between Technical Areas puts greater focus on indicators that measure outcomes, rather than those that measure policies and processes.
- The Index will include two new countries but maintains longstanding consistency in its geographic scope. This reflects the recent economic shifts and inequality issues which can hinder access in such countries.
- The 2022 Index newly includes osteosarcoma and thalassemia in its disease scope, based on stakeholder consensus and the disproportionate burden of these diseases in countries in scope.
- In assessing supply chains, the Index will look more closely at the process of technology transfer and put more emphasis on this area.

FIGURE 3 **Analytical Framework for the 2022 Access to Medicine Index**

The 2022 Access to Medicine Index analyses company behaviour using a framework of 31 indicators organised in three Technical Areas. In line with previous Index methodology reviews, the emphasis has increased on R&D and product delivery strategies such as pricing and licensing.

3 TECHNICAL AREAS	14 PRIORITY TOPICS	Indicators per topic
A GOVERNANCE OF ACCESS 15%	Responsible business practices	4
	Governance and strategy	3
B RESEARCH & DEVELOPMENT 30%	Access planning	3
	Product development	3
	Building R&D capacity	1
C PRODUCT DELIVERY 55%	Equitable access strategies	3
	Intellectual property strategy	3
	Quality and supply	3
	Licensing quality	2
	Product donations	2
	Registration	1
	Inclusive business models	1
	Local manufacturing	1
	Health systems strengthening	1

GOVERNANCE OF ACCESS 15%

To improve access to medicine both tangibly and sustainably, pharmaceutical companies must implement clear access strategies that focus on the long term. By enforcing rigorous standards of behaviour across their operations (including with third-party contractors), companies can mitigate the risk of practices that cause harm and undermine their efforts to improve access from occurring.

This Technical Area looks at how companies plan, govern and manage the achievement of their objectives for increasing access to medicine, and at how they apply processes to minimise the occurrence and risks of non-compliant and/or corrupt behaviour. It evaluates companies' strategies for access, considering whether these align with corporate strategies. It also looks at how companies measure and incentivise progress towards their objectives for access.

Changes in 2022

- The 2022 Index looks at access-related governance structures including monitoring and incentives for top-level staff.
- It assesses whether a company's strategies cover all therapeutic areas, which may yield a wider range of access initiatives for consideration.
- It examines companies' limit-setting policies around transfers of value likely to influence the behaviour of healthcare professionals (HCPs) in countries in scope (e.g., payments to attend and/or speak at events, to continue medical education and other non-monetary benefits).
- It looks at how companies monitor risks around non-compliance at the national level with laws and standards on ethical marketing, anti-corruption and clinical trial governance.

PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Governance & strategy	Indicator(s)
To ensure that they implement access strategies successfully, pharmaceutical companies must establish structures for governance and management. By assigning responsibility and offering incentives at the highest level, companies can increase the likelihood of prioritising, maintaining and achieving access-related objectives. Companies are expected to develop and implement a clear, long-term strategy to improve access to medicine. Such a strategy should not remain isolated from the main business of the company; it should seek to align with commercial concerns. Companies should share publicly their progress towards strategic goals. Considerations around access to medicine should not be limited to a few areas but incorporated systematically into all R&D projects and all commercialisation/market-access strategies, specifically in relation to LMICs.	GA1, GA2, GA3

Responsible business practices	
Corrupt behaviour and unethical marketing can have direct consequences for access to medicine, such as the misdirection of national health budgets and promotion of the irrational use of medicines. Pharmaceutical companies can limit misconduct by enforcing stringent compliance processes across their operations and with third parties, and by modifying how they incentivise sales agents and disclosing publicly how they engage with healthcare professionals. They can also implement policies to ensure they interact ethically with healthcare professionals, for example by setting limits on transfers of value (e.g., with fair market value assessments). The Index expects companies to have in place controls to mitigate the risk of non-compliance for their operations in LMICs; these should include monitoring and auditing processes. Companies should also be able to regulate the activities of contracted third parties. To assess the effectiveness of controls, the Index checks for negative rulings and/or settlements with regards to unethical marketing, corruption, anti-competitive behaviour (whether or not related to intellectual property) and clinical trial misconduct in LMICs. In accordance with their public standing, companies are expected to have IP policies that are conducive to the international consensus on public health.	GA4, GA5, GA6, GA7

For indicators and their full rationales, see p.28-29

RESEARCH & DEVELOPMENT 30%

Large research-based pharmaceutical companies play a significant role not only in developing new medicines and other life-saving products, but also in bringing them to market. Advance planning is needed to make new products rapidly available to people who need them, wherever they live. This Technical Area analyses in-house and collaborative R&D activity that aims to develop or adapt products for diseases, conditions and pathogens in scope of the Index, and in response to the needs of people living in low- and middle-income countries (LMICs). It also examines whether companies plan sufficiently during the development of their products to make sure those that are successful become swiftly accessible in LMICs.

Changes in 2022

- The Index will no longer use a standalone indicator to assess how companies consider post-trial access to investigational products. Instead, it will incorporate this assessment when considering R&D access planning as a whole.

PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Product development	Indicator(s)
Pharmaceutical companies have the capacity and expertise to develop and adapt products to address unmet public health needs in LMICs, where products are suitable for those populations. Companies can do this either in-house or in partnership. The Index maps companies' R&D activity against defined and published R&D priorities outlining where new, effective products are needed urgently: for example, for pathogens flagged as a priority due to antimicrobial resistance, or for neglected tropical diseases. R&D priorities include 'Disease X', a term used by the WHO to refer to currently unknown pathogens that could cause a serious international epidemic or pandemic. Regarding diseases for which R&D priorities have not yet been independently assessed (such as non-communicable diseases), the Index examines whether companies' projects take account of particular needs of people living in LMICs. Companies are also expected to disaggregate and disclose the resources they dedicate to such R&D.	RD1a, RD1b, RD4

Planning for access	
Planning for access helps pharmaceutical companies to ensure they take account of public health needs during product development. Such planning can help those in LMICs to gain access to products more rapidly and affordably following their market entry. When companies establish a structured process to develop access plans, this can help such planning become standard. Companies are expected to have in place plans for pipeline projects from (at least) Phase II clinical trials. These plans need to prioritise access planning for R&D projects that target defined R&D priorities, or which demonstrate clear value for patients in LMICs.	RD2, RD3a, RD3b

Building R&D capacity	
Pharmaceutical companies have the expertise and ability to support the development of skilled R&D sectors in LMICs. Companies can engage in relevant activities, such as technology transfers, to build local R&D capacity and support the development of research skills. In turn, this can enable local researchers to address relevant health needs and priorities.	RD6

For indicators and their full rationales, see p.30-31

PRODUCT DELIVERY 55%

The choices pharmaceutical companies make in delivering their products are a critical factor for countries striving to achieve universal health coverage.
As a first step, companies must register their products for sale where they are needed, so that these can be made swiftly available to populations in need. Companies can then deploy three main access strategies considered to have the biggest potential for impact on the supply and affordability of medicine: equitable pricing, responsible IP (intellectual property) management and product donations.

This Technical Area assesses how companies design their strategies and tailor their tools to boost access. Further, it captures how companies leverage their expertise and resources to address significant local barriers to access. Such barriers might include gaps in local healthcare infrastructure, poorly functioning supply chains, weak quality assurance systems and/or lack of skills.

Changes in 2022

- The indicators and analytical approaches in this Technical Area have been held largely constant, to facilitate trend analysis.
- This Technical Area covers registration, pricing, IP strategies, licensing, product donations, quality and supply, local aspects of manufacturing and strengthening of health systems. Combining these reflects a consensus view that these are interdependent aspects of product delivery.
- Three categories are used to assess how companies tailor access strategies to their products: (a) supranationally procured products such as vaccines; (b) healthcare practitioner-administered products and; (c) self-administered products.
- Indicator PP1: Access Strategies: Coverage will no longer be assessed by the Index, as it was not feasible to systematically estimate the number of patients reached and make fair comparisons between different products used for different indications.

PRIORITY TOPICS AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Registration	Indicator(s)
Registration is a key first step for products to become available to populations in need. The Index continues to look at how widely pharmaceutical companies file to register their newest products in countries in scope and make them available for patients' use in these countries. Companies are expected to prioritise registration in countries with high disease burden, and to aim for registration in LMICs within 12 months of first registration with either the EMA, FDA or JPMDA.	PR1

Equitable access strategies	
Equitable access means no one is left behind, with everyone in LMICs – including those at the base of the income pyramid – enabled to benefit from products. Companies are expected to apply access strategies to key products across LMICs, maximising the availability of these products to those with less income. Such strategies include pricing, non-exclusive licensing, product donations and technology transfer. When setting pricing strategies, companies are expected to aim for affordability, and to integrate into their pricing approach a payer's ability to pay for the product.	PP3, PP4, PP5

Intellectual property (IP) strategy	
Responsible, transparent management of intellectual property can stimulate research and development (R&D) by third-party researchers. Companies that choose not to develop their IP assets further can license these out to external researchers on access-oriented terms. For LMICs, responsible IP management can also facilitate the affordable supply of medicines and other health products by supporting the entry of generic pharmaceutical manufacturers into new markets and the decision-making of international procurers. Companies are expected to publish patent statuses and implement patent filing/enforcement policies to mitigate the risk that patent protections will limit R&D and product availability and affordability.	PPL1, PPL2, PPL3

Licensing quality	
Non-exclusive voluntary licensing supports the market entry of alternative manufacturers of patented products, in turn supporting more secure supply and enhancing affordability through stimulation of competition. Pharmaceutical companies are expected to engage in quality non-exclusive licensing (acting to quickly license newly registered products, or those still in development, on terms that promote access) and to ensure they disclose these agreements publicly.	PPL4, PPL5

For indicators and their full rationales, see p.32-37

PRODUCT DELIVERY 55%

	Indicator(s)
Product donations Product donations continue to play an important role in eliminating, eradicating and/or controlling some diseases that affect populations living in LMICs. For people living in poverty, donations may represent the only chance to get access to the treatment they need. Pharmaceutical companies supplying such products are expected to publicly commit to staying engaged until elimination, eradication and control goals are reached, and to expanding coverage of programmes where these can facilitate goal achievement. Companies also need to be able to respond rapidly to emergencies by making *ad hoc* product donations.	PP2a, PP2b
Inclusive business models To achieve universal health coverage, people in the lowest income brackets must also gain access to medicine. Inclusive business models are an important way to extend market-based access strategies to populations with limited ability to pay (people on the lower tiers of the income pyramid). Successful outcomes are more likely for inclusive business models which address capacity constraints, and for those with a long-term vision and goals, financial commitments and clear objectives.	PBM1
Quality and supply Inefficiencies and weaknesses in supply chains (whether in procurement processes, delivery logistics, storage or at other stages) can have a huge impact on the accessibility, availability and quality of medicines. To identify bottlenecks and improve capacity for good supply chain management into LMICs, pharmaceutical companies are expected to engage with relevant local partners. Substandard and falsified (SF) medicines represent a significant threat to public health. To mitigate this, companies are expected to report SF cases to national authorities and/or WHO Rapid Alert in a timely manner.	PQ1, PQ2, PCB2
Local manufacturing Making medicines locally can help to reduce costs and improve supply, but quality must be guaranteed. When pharmaceutical companies work with third-party manufacturers in LMICs, they can take steps to ensure local staff have the skills and technology necessary to meet the requirements of good manufacturing practices (GMP). By engaging more widely with other manufacturers and organisations such as universities, companies can bring broader value in terms of quality manufacturing to build local capacity beyond that needed for their own products and portfolios.	PCB1
Health system strengthening Robust health systems must be in place for products to be deployed, prescribed and administered safely and effectively. Such systems may include infrastructure, trained health professionals, diagnostic capacity, data management and the means to reduce stigma. For pharmaceutical companies these activities are not a central responsibility, but companies have both the expertise and the capacity to help strengthen local health systems. Initiatives need to be carried out with appropriate partners (aligning with local needs) and must manage conflicts of interest and monitor outcomes.	PCB3

For indicators and their full rationales, see p.32-37

What the Index measures

The Access to Medicine Index assesses pharmaceutical company policies and behaviour regarding specific diseases and product types across a specific geographic scope. The following pages set out the rationale for these analytical scopes and how they have been defined.

In this section:

COMPANY SCOPE
20 companies
- Selected based on a combination of market capitalisation and relevance of pipeline and portfolio for access to medicine

DISEASE SCOPE
83 diseases, conditions and pathogens
- 23 Communicable Diseases
- 18 Non-Communicable Diseases
- 20 Neglected Tropical Diseases
- 10 Maternal & Neonatal Health Conditions
- 12 Priority Pathogens

GEOGRAPHIC SCOPE
108 low- and middle-income countries

PRODUCT TYPE SCOPE
Medicines, microbicides, preventive vaccines, therapeutic vaccines, vector control products, platform technologies, diagnostics, contraceptive methods and devices

WHAT WE MEASURE

Company Scope

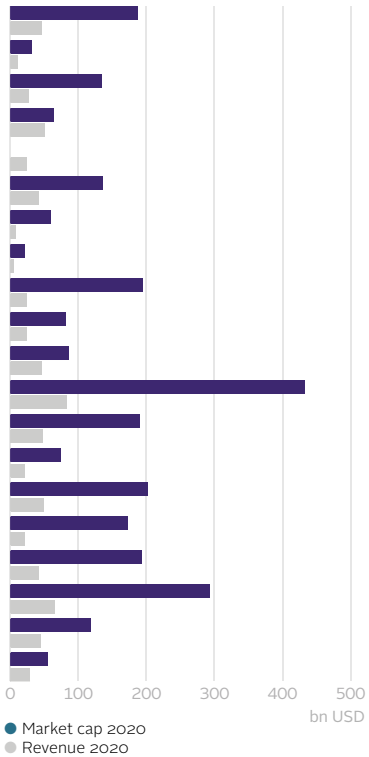
The Access to Medicine Index assesses 20 of the world's largest R&D-based pharmaceutical companies on their policies and practices to improve access to medicine for people living in low- and middle-income countries. Considering their pipelines, portfolios, resources and global reach, these companies have clear opportunities and a responsibility to address access.

Companies are selected based on their market capitalisation and revenue, and the relevance of their product portfolios and pipelines for the diseases and countries covered by the Index. Following a review of these criteria, the 2022 Index will evaluate the same 20 companies as in 2022, facilitating trend analysis.

The largest R&D-based companies were identified through a company market capitalisation and revenue analysis, which also took mergers, acquisitions and divestments into account. Their pipelines and portfolios were then mapped against diseases in the scope of the Index and the R&D needs of people living in countries in scope. Companies that qualified for analysis based on size could be disqualified for having fewer relevant products and R&D projects than companies of similar size. 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.

FIGURE 4 **Companies in scope of the 2022 Access to Medicine Index**

Company Name	Stock Exchange	Country	Ticker	Revenue, 2020 (bn USD)*	Market cap** (bn USD)***
AbbVie Inc	New York	USA	ABBV	45,804	186,681
Astellas Pharma Inc	Tokyo	JPN	4503	11,338	31,067
AstraZeneca plc	London	GBR	AZN	26,617	135,160
Bayer AG	Xetra Germany	DEU	BAYN	50,849	63,404
Boehringer Ingelheim GmbH	n/a	DEU	n/a	24,032	n/a
Bristol Myers Squibb Co	New York	USA	BMY	42,518	136,580
Daiichi Sankyo Co, Ltd	Tokyo	JPN	4568	8,734	60,019
Eisai Co, Ltd	Tokyo	JPN	4523	5,861	20,849
Eli Lilly & Co	New York	USA	LLY	24,540	195,068
Gilead Sciences Inc	NASDAQ	USA	GILD	24,642	80,940
GlaxoSmithKline plc	London	GBR	GSK	46,297	86,525
Johnson & Johnson	New York	USA	JNJ	82,584	433,237
Merck & Co, Inc	New York	USA	MRK	47,994	190,309
Merck KGaA	Xetra Germany	DEU	MRK	21,536	73,652
Novartis AG	Swiss Exchange	CHE	NOVN	48,659	201,943
Novo Nordisk A/S	Copenhagen	DNK	NOVO B	20,955	172,363
Pfizer Inc	New York	USA	PFE	41,908	192,793
Roche Holding AG	Swiss Exchange	CHE	ROG	66,049	292,984
Sanofi	Euronext Paris	FRA	SAN	44,267	118,723
Takeda Pharmaceutical Co, Ltd	Tokyo	JPN	4502	29,016	55,422



* Exchange rates on 31 December 2020, from oanda.com. For Yen, exchange rate is as of 31 March 2021.
** Market cap on 18 February 2021, from Bloomberg terminal
*** Exchange rates on 18 February 2021, from oanda.com

WHAT WE MEASURE

Disease Scope

The Access to Medicine Index assesses the actions of pharmaceutical companies in relation to the set of diseases, conditions and pathogens confirmed by the Expert Review Committee as critical priorities for improving access to medicine. To define this priority list, the Foundation used data about disease burdens and incidence, together with independent prioritisations, to pinpoint those for which greater access to medicine is needed most. A review of the Methodology for 2022 has set the disease scope for the 2022 Index at 83 diseases, conditions and pathogens. All are in scope for all three Technical Areas.

Defining the disease scope

Some diseases are in scope of the Index because they impose a high global disease burden despite the existence of effective treatments, or because they affect poorer populations disproportionately. To identify such diseases, the Foundation used a screening protocol (see Table 1). This is based on factors such as: the prioritisation of the disease by organisations such as Policy Cures Research and the World Health Organization (WHO) for improving access to medicine; global and/or country-level disease burdens; and the relevance of pharmaceutical intervention. The 2022 Index disease scope has been updated according to the most recent Global Burden of Disease Study (GBD 2019)[1], which also provides country-level data on disability-adjusted life years (DALYs). This measure is commonly used to measure the burden of disease in a population. The WHO defines one DALY as "one lost year of healthy life" to account for the gap between a given population's ideal health situation, and the actual situation.

The full disease scope applies to all Technical Areas. COVID-19 remains in scope and the Index will continue to track company activity in this area during the period of analysis. For the 2022 Index, two new diseases (thalassemia and osteosarcoma) have been brought into scope for all Technical Areas. The Index will follow products emerging from the pipeline (after market approval) and include them in its analyses of access strategies.

Previous iterations of the Index have focused on diseases that mostly affect people in low- and middle-income countries (LMICs). The Index considers this to be a strong indicator that a low level of incentive to invest in pharmaceutical R&D will limit the availability of suitable treatment options. In 2022, the Index retains its focus on these diseases and (where data is available) will specifically include diseases in which more than 95% of the global DALY burden is in countries in scope.[1]

Three diseases that exclusively affect women and girls (linked to biological sex) remain in scope for the 2022 Index. According to a review of data from GBD 2019 and from the Global Cancer Observatory (GLOBOCAN 2020),[1,2] endometriosis and ovarian and uterine cancer have comparably higher incidence rates and/or DALY burdens than other sex-linked diseases. Their inclusion in the disease scope increases the capacity of the Index to assess the unmet needs of women and girls living in LMICs with sex-linked diseases.

DISEASE SCOPE

23 Communicable Diseases

This category includes the 10 Communicable Diseases (CDs) with the highest DALY burdens in countries in scope[1], as well as diseases for which product gaps have been identified as priority R&D targets, such as emergent non-polio enteroviruses and 'Disease X', a WHO term to denote a currently unknown pathogen that could cause a serious international epidemic (as seen for COVID-19). The 2022 Index combines some prioritised diseases that were previously separate under a single term (e.g., "enteric infections" now includes diarrhoeal diseases, typhoid and paratyphoid, and invasive non-typhoidal salmonella).

18 Non-Communicable Diseases

This category includes the 10 Non-Communicable Diseases (NCDs) with the highest DALY burdens in countries in scope. For the first time, this list includes thalassemia.[1] It also includes cancer types with high or disproportionate incidences.[2] Cancers in scope now include osteosarcoma, for which treatments are included on the WHO's Essential Medicines List. The Index retains epilepsy, bipolar affective disorder and schizophrenia based on continuing stakeholder consensus on the critical need for access to treatment. [3,4]

20 Neglected Tropical Diseases

As previously, the 2022 Index includes all WHO-classified Neglected Tropical Diseases (NTDs).[5] Five of these are especially prevalent in poorer regions (particularly rural areas) of low-income countries.

10 Reproductive, Maternal and Newborn Health Conditions

To recognise the importance of reproductive, maternal and child health, the Index has since 2014 included contraceptives and nine Maternal and Neonatal Health Conditions. Additionally the term Maternal and Neonatal Health conditions has been updated to Reproductive, Maternal and Newborn Health Conditions.

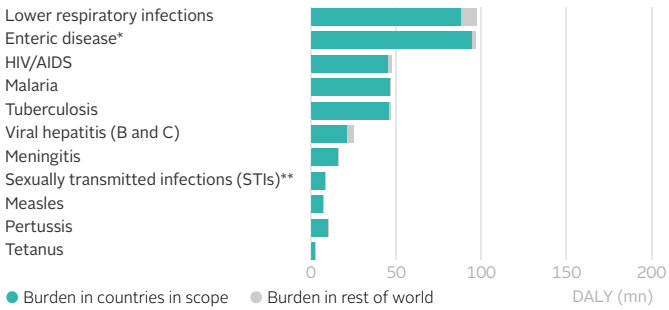
12 Priority Pathogens

As in 2020, the Index covers the 12 pathogens included in the WHO's definitive priority pathogens list (2017). These are deemed a priority for efforts to curb antimicrobial resistance through the development of new and effective antibacterial agents.[6] For tuberculosis, multidrug resistance is a significant issue among patients, making it a critical priority for pharmaceutical efforts. Because of this, the 2022 Index evaluates it not as a pathogen but as a communicable disease.

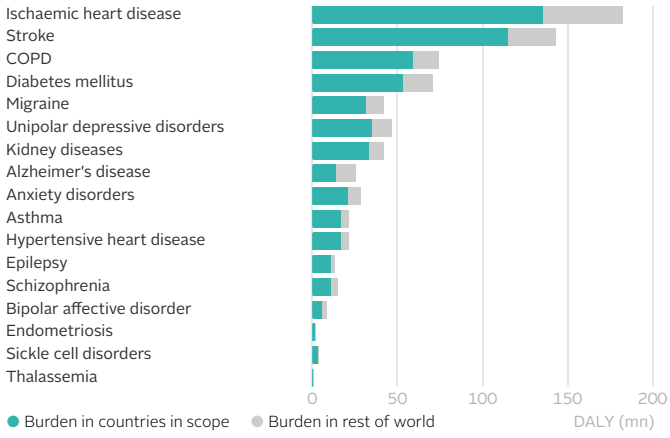
FIGURE 5 **Low- and middle-income countries shoulder the bulk of disease burdens**

These four charts give an indication of how the diseases and conditions in scope disproportionately affect people living in low- and middle-income countries. Behind these numbers are millions of people who cannot rely on access to affordable, quality medicine.

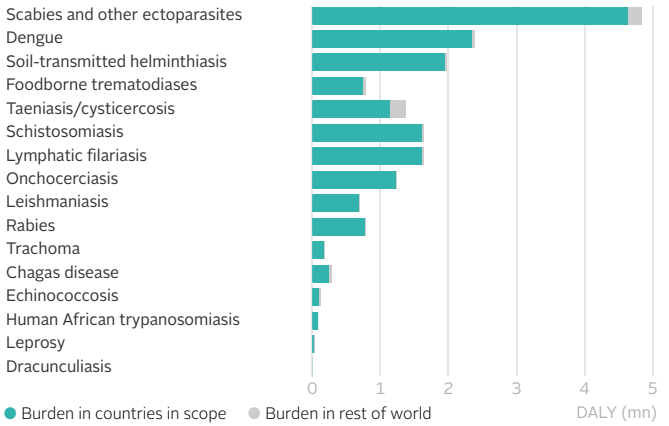
Communicable diseases, DALYs



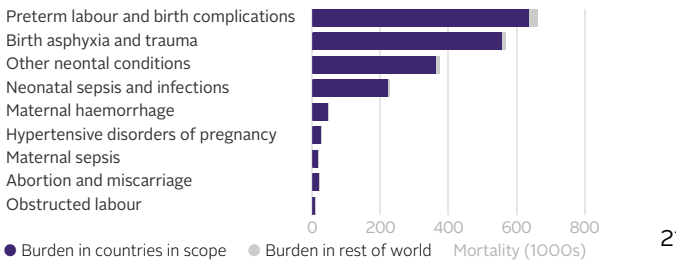
Non-communicable diseases, DALYs



Neglected tropical diseases, DALYs



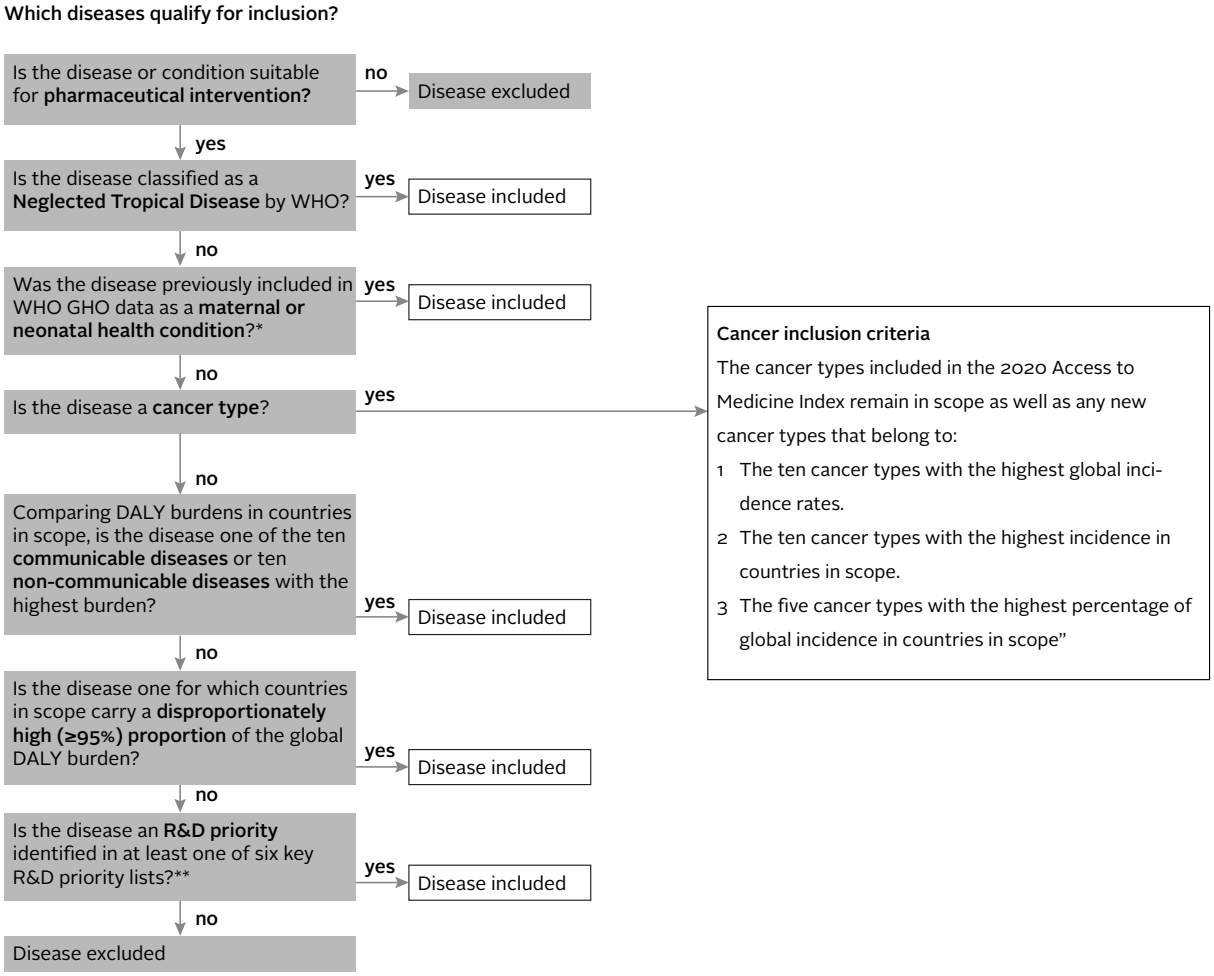
Maternal & neonatal health conditions, mortality



Footnotes on p.24

FIGURE 6 **Defining the disease scope - screening protocol**

The Access to Medicine Index analyses company practice in relation to a defined set of diseases, conditions and pathogens. These are identified as priorities for improving access to medicine using the protocol shown here.



Exceptions: Bipolar affective disorder, epilepsy, hypertensive heart disease, schizophrenia and alzheimer's disease were in scope for the 2021 Index and have been retained due to, e.g., the continuing need for better access to treatment. Endometriosis and ovarian and uterine cancer have also been retained to reflect a greater focus on sex-linked barriers to access. Furthermore osteosarcoma has been included as it is the most common primary malignant bone tumor in children and young adults (ref 1.)

* As listed in the WHO methods and data sources for global burden of disease estimates 2000-2019

** R&D priority lists: Policy Cures Research G-FINDER neglected disease, emerging infectious diseases and reproductive health areas; WHO R&D Blueprint; WHO Initiative for Vaccine Research; WHO priority pathogen list.

TABLE 1 **List of diseases, conditions and pathogens included in the 2022 Access to Medicine Index**

	Rationale for inclusion				
Communicable Diseases	Top 10 DALY burden in countries in scope	≥95% disease burden in countries in scope	WHO-identified NTD or MNH condition	R&D priority*	Stakeholder consensus**
Arenaviral haemorrhagic fevers (Lassa fever)				●	
Bunyaviral diseases				●	
Coronaviral diseases				●	
Enteric diseases	●	●		●	
Diphtheria		●			
Disease X***				●	
Emergent non-polio enteroviruses				●	
Filoviral diseases		●		●	
Henipaviral diseases				●	
HIV/AIDS	●	●		●	
Leptospirosis				●	
Lower respiratory infections	●			●	
Malaria	●	●		●	
Measles	●	●			
Meningitis	●	●		●	
Pertussis	●	●			
Rheumatic fever				●	
Sexually transmitted infections (STIs)†	●	●		●	
Tetanus		●			
Tuberculosis	●			●	
Viral hepatitis (B and C)	●	●		●	
Yellow fever		●			
Zika				●	
Non-Communicable Diseases					
Alzheimer's disease					●
Anxiety disorders	●				
Asthma	●				
Bipolar disorder					●
Cancer‡				●	●
Chronic obstructive pulmonary disease (COPD)	●				
Diabetes mellitus	●				
Endometriosis					●
Epilepsy					●
Hypertensive heart disease	●				●
Ischaemic heart disease	●				
Kidney diseases	●				
Migraine	●				
Schizophrenia					●
Thalassemia		●			●
Sickle cell disease		●			
Stroke	●				
Unipolar depressive disorders	●				

	Rationale for inclusion				
Neglected Tropical Diseases	Top ten DALY burden in countries in scope	≥95% disease burden in countries in scope	WHO-identified NTD or MNH condition	R&D priority*	Stakeholder consensus**
Buruli ulcer			●	●	
Chagas disease			●	●	
Dengue and Chikungunya		●	●	●	
Dracunculiasis		●	●		
Echinococcosis			●		
Food-borne trematodiases		●	●		
Human African Trypanosomiasis		●	●	●	
Leishmaniasis		●	●	●	
Leprosy		●	●	●	
Lymphatic filariasis		●	●	●	
Mycetoma, chromoblastomycosis and other deep mycoses			●	●	
Onchocerciasis		●	●	●	
Rabies		●	●		
Scabies and other ectoparasites		●	●	●	
Schistosomiasis		●	●	●	
Snakebite envenoming		●	●	●	
Soil-transmitted helminthiasis		●	●	●	
Taeniasis/cysticercosis			●	●	
Trachoma		●	●	●	
Yaws		●	●		
Reproductive, Maternal and Newborn Health Conditions					
Birth asphyxia and birth trauma		●	●		
Contraceptive methods			●	●	
Hypertensive disorders of pregnancy		●	●	●	
Abortion and miscarriage§		●	●		
Maternal haemorrhage		●	●	●	
Maternal sepsis		●	●		
Neonatal sepsis and infections		●	●		
Obstructed labour		●	●		
Other neonatal conditions		●	●		
Preterm birth complications		●	●		

Priority pathogens||

Acinetobacter baumannii (carbapenem-resistant)
Campylobacter spp. (fluoroquinolone-resistant)
Enterobacteriaceae (carbapenem-resistant, 3rd generation cephalosporin-resistant)
Enterococcus faecium (vancomycin-resistant)
Haemophilus influenzae (ampicillin-resistant)
Helicobacter pylori (clarithromycin-resistant)
Neisseria gonorrhoeae (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)
Pseudomonas aeruginosa (carbapenem-resistant)
Salmonella spp. (fluoroquinolone-resistant)
Shigella spp. (fluoroquinolone-resistant)
Staphylococcus aureus (methicillin-resistant, vancomycin-intermediate and vancomycin-resistant)
Streptococcus pneumoniae (penicillin-non-susceptible)

Green text = newly in scope for the 2022 Index

Exclusions: none in 2021

* Diseases, conditions and pathogens indicated as R&D priorities on identified lists published by Policy Cures Research and WHO.

** These diseases have been retained or added due to specific access barriers, amongst other reasons, as identified in stakeholder engagement.

*** Disease X is defined by WHO as a pathogen currently unknown to cause human disease that could cause a serious international epidemic.

† Excludes HIV/AIDS.

‡ Includes 18 cancer types. See Cancer Inclusion Appendix for more details.

§ Listed as 'Abortion' in previous Indices.

|| Collectively, these will be referred to as communicable diseases in the 2021 Access to Medicine Index as 'Other prioritised antibacterial-resistant infections'.

WHAT WE MEASURE

Geographic Scope

The Access to Medicine Index measures the actions of pharmaceutical companies in places where there is an urgent need for better access to medicine. Three criteria have been used to select countries for the 2022 Index (geographic scope): (1) countries' level of income (gross national income (GNI) per capita); (2) level of development, and; (3) scale and scope of inequality. Assessments for each country were based on data from the World Bank, the United Nations Development Programme (UNDP) and the United Nations Economic and Social Council (ECOSOC).

The 2022 Index has a geographic scope that covers 108 countries. Two new countries have been added for the 2022 Index (Algeria and Venezuela). The rest have been in scope since 2018. With its two previous iterations covering the same 106 countries, the Index can draw on the benefits of consistency and capacity in tracking the progress of pharmaceutical companies and their impacts in countries that face development and inequality-related constraints in access to medicine.

DEFINING THE GEOGRAPHIC SCOPE

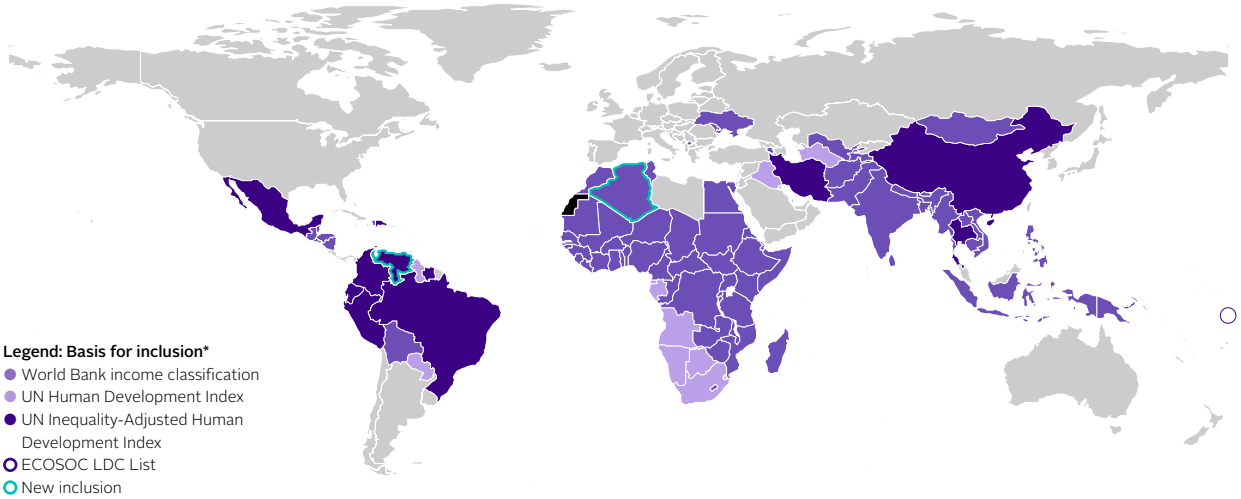
Step 1: Include all countries classified (according to World Bank data) as low income or lower-middle income;[7]

Step 2: Include all countries defined (according to the UNDP's Human Development Index) as having low or medium human development;[8]

Step 3: Include all high-development countries with a high inequality-adjusted HDI ratio (HiHDI) as defined by the UN Inequality-Adjusted Human Development Index[8] (this enables the Index to track higher-income countries with significant levels of inequality); and

Step 4: Include all Least Developed Countries (LDCs) as defined by ECOSOC.[9]

FIGURE 7 **Countries included in the 2022 Access to Medicine Index – 108 Countries**



* The latest country income and development classifications are available through the World Bank and UNDP data.

Due to scaling, countries may not be visible on the map (e.g., Tuvalu)

TABLE 2 **List of countries included in the 2022 Access to Medicine Index – 108 countries***

East Asia & Pacific	
Cambodia	LMIC
China	HiHDI
Indonesia	LMIC
Kiribati	LMIC
Korea, Dem. People's Rep.	LIC
Lao PDR	LMIC
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LMIC
Papua New Guinea	LMIC
Philippines	LMIC
Samoa	LMIC
Solomon Islands	LMIC
Thailand	HiHDI
Timor-Leste	LMIC
Tonga	LMIC
Tuvalu	LDC
Vanuatu	LMIC
Vietnam	LMIC

Europe & Central Asia	
Armenia	LMIC
Kosovo	LMIC
Kyrgyz Republic	LMIC
Moldova	LMIC
Tajikistan	LMIC
Turkmenistan	MHDC
Ukraine	LMIC
Uzbekistan	LMIC

Latin America & Caribbean	
Belize	HiHDI
Bolivia	LMIC
Brazil	HiHDI
Colombia	HiHDI
Dominican Republic	HiHDI
Ecuador	HiHDI
El Salvador	LMIC
Guatemala	LMIC
Guyana	MHDC
Haiti	LIC
Honduras	LMIC
Mexico	HiHDI
Nicaragua	LMIC
Paraguay	MHDC
Peru	HiHDI
Suriname	HiHDI
Venezuela	HiHDI

Middle East & North Africa	
Algeria	LMIC
Djibouti	LMIC
Egypt, Arab Rep.	LMIC
Iran	HiHDI
Iraq	MHDC
Morocco	LMIC
Palestine, State of/ West Bank Gaza	LMIC
Syrian Arab Republic	LMIC
Tunisia	LMIC
Yemen, Rep.	LMIC

South Asia	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
India	LMIC
Maldives	HiHDI
Nepal	LIC
Pakistan	LMIC
Sri Lanka	LMIC

Sub-Saharan Africa	
Angola	LHDC
Benin	LIC
Botswana	MHDC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cameroon	LMIC
Central African Republic	LIC
Chad	LIC
Comoros	LIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	MHDC
Eritrea	LIC
Ethiopia	LIC
Gabon	MHDC
Gambia, The	LIC
Ghana	LMIC
Guinea	LIC
Guinea-Bissau	LIC
Kenya	LMIC
Lesotho	LMIC
Liberia	LIC
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
Mozambique	LIC
Namibia	MHDC
Niger	LIC
Nigeria	LMIC
Rwanda	LIC
São Tomé and Principe	LMIC
Senegal	LIC
Sierra Leone	LIC
Somalia	LIC
South Africa	MHDC
South Sudan	LIC
Sudan	LMIC
Swaziland/Eswatini	LMIC
Tanzania	LIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LIC

LIC	Low income country World Bank income classifications
LMIC	Lower-middle income country World Bank income classifications
LDC	Least Developed Country ECOSOC LDC List
LHDC	Low Human Development Country UN Human Development Index
MHDC	Medium Human Development Country UN Human Development Index
HiHDI	High Human Development Country with high inequality UN Inequality-Adjusted Human Development Index

* These include 106 countries assessed in the 2021 Access to Medicine Index, with two new countries in scope, that are Algeria and Venezuela. The latest country income and development classifications are available through the World Bank and UNDP data.

WHAT WE MEASURE

Product Type Scope

To capture the wide-ranging product types available to support the prevention, diagnosis and treatment of relevant conditions and diseases in countries covered by the Index, this scope is deliberately broad. In 2022, as in four previous iterations, the Index continues to include the same eight product types in scope, as described below.

Medicines
All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, 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 infection.

Preventive Vaccines
This covers vaccines intended to prevent infection.

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 intended for global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to 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 platforms, 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.

How the Index measures

The 2022 Access to Medicine Index assesses company behaviour using an analytical framework of 31 indicators organised in three Technical Areas. The following pages set out what each Technical Area measures and the rationale for each indicator.

In this section:

INDICATORS

A GOVERNANCE OF ACCESS 15%

2022 Indicator code	2022 Indicator	Change since 2021 (new/ retained/ modified)	Indicator rationale
GA1	**Governance structures and 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 (that is, 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.	**Retained** No change	Assigning responsibility for access to medicine in low- and middle- income countries at the highest level of a company increases the chance that access-related objectives are given attention, remain on track and are achieved. Access-related objectives and incentives encourage the CEO, senior management and in-country/regional managers to perform towards achieving access goals.
GA2	**Access-to-medicine strategy** The company has an access-to-medicine strategy and demonstrates that it is integrated within its corporate strategy. Well-integrated strategies extend across the company's portfolio and pipeline, for diseases within Index scope.	**Retained** The indicator covers how the company applies 'access thinking' across its products and therapeutic areas.	An access-to-medicine strategy integrated in the overall corporate strategy indicates that a company considers access to medicine in LMICs to be relevant for its long-term growth, creating more sustainability for access to medicine. The strategy should cover all products in the company's portfolio and all projects, particularly those deemed to be of significant public health importance.
GA3	**Public disclosure of access-to-medicine outcomes** The company has time-bound, measurable goals The company has time-bound, measurable goals and objectives for access to medicine. It publicly shares progress toward such goals and objectives (outcomes*). * Results achieved by a company's access-related activities. These can be short-term (such as an increased proportion of people with more knowledge about diseases, symptoms or treatments) and/or medium- to long-term (such as number of patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; and/or availability of medicines at outlets). Outcomes can also relate to a country's health system (such as the number of healthcare professionals trained).	**Retained** No change	Public reporting of such information informs external stakeholders about companies' activities and progress, and facilitates accountability.
GA4	**Responsible promotional practices** The company incentivises responsible sales practices (for example, by taking steps to decouple bonuses for sales agents* from sales volume targets only). Further, it has a policy limiting transfers of value** to healthcare professionals (HCPs) in countries in Index scope or volunteers to publicly disclose information about such transfers in countries in scope. The company also follows local disclosure requirements and has a clear (public) policy to ensure ethical interactions with such HCPs. *Including sales representative employees and third parties. **Transfers could include payments for attending and/or speaking at events, continuing medical education, promotional activities, or other non-monetary benefits directed at HCPs.	**Retained**	Decoupling sales agents' financial rewards from the volume of medicine they sell removes the incentive to oversell. This is not only important to stem the rise of antimicrobial resistance, but also to prevent scarce resources being diverted from health budgets. Public disclosure of transfers of value provides accountability regarding interactions between companies and healthcare professionals. Such disclosure can, for example, help to curb inappropriate incentives that can lead to irrational prescribing. Research shows that HCPs report often using promotion as a source of information about new drugs. It is important to foster responsible promotional practices to ensure appropriate and quality access to medicine.

GA5	**Compliance controls** The company demonstrates it has controls* (such as internal controls, risk-based country audits and formal processes applying to third parties) to mitigate the risk of non-compliance in its operations in LMICs; for example, in areas such as ethical marketing, anti-corruption and clinical trials. * The Index looks for compliance controls such as the following: fraud-specific risk assessment; auditing and review mechanisms; live/continuous monitoring system for compliance; country risk-based assessments; and processes to ensure third party compliance.	**Retained** The indicator assesses those compliance controls which correspond to the specific needs of LMICs.	Corruption can detract from access to medicine, so it is essential for companies to implement compliance controls to reduce this risk. Such controls aim to prevent non-compliant activities, which can negatively affect access by undermining confidence in the pharmaceutical sector, diverting scarce resources from health budgets, impacting prices and limiting the availability of medicines in the public sector.
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 scope of the Index during the past two years.	**Retained** No change	Breaches of codes/regulations/laws can undermine confidence in the pharmaceutical sector, divert scarce resources from health budgets, impact prices and limit the availability of medicines in the public sector. Such civil, criminal and regulatory infractions provide information about the quality of a company's compliance systems and responses to unethical or illegal behaviour. These cases take time to prosecute and settle, and therefore, though they might be historical in nature, they may reach settlement during the Index's period of analysis.
GA7	**Policies related to competition** There is evidence the company employs an intellectual property (IP) strategy conducive to creating access to medicine. This is in accordance with the rights of national governments to deploy IP systems flexibly, as defined by the international framework on IP (i.e., the Doha Declaration on the TRIPS Agreement and Public Health).	**Modified** IP-related anti-competitive behaviour* will be assessed alongside a company's publicly disclosed stance on the international framework on IP. The Index no longer assesses whether companies have a policy to dissent from industry association positions on IP. * For example, patenting products in Least Developed Countries, challenging patent waivers, adopting evergreening practices, lobbying against the usage of TRIPS flexibilities by governments of countries in Index scope (including through industry trade associations), and lobbying for strengthening of IP standards beyond TRIPS in countries in Index scope.	Where a company applies an IP strategy which does not operate in accordance with the international consensus on IP standards (through, for example, exerting pressure on governments not to incorporate TRIPS flexibilities within national legislation), there can be a knock-on negative impact for access to medicine in those countries. The Index looks for an absence of such incidents over two years.

INDICATORS

B RESEARCH & DEVELOPMENT 30%

2022 Indicator code	2022 Indicator	Change since 2021 (new/ retained/ modified)	Indicator rationale
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 innovative and adaptive R&D and in-house and collaborative R&D. *Currently, the Index categorises R&D priorities using lists from the WHO and Policy Cures Research.	**Retained** No change	Large research-based companies have the capacity through R&D to help address public health needs in low- and middle-income countries (LMICs) for identified priorities. They are well positioned to ensure that these products progress through the pipeline, even if there is little commercial incentive.
RD1b	**R&D pipeline: Other diseases** The company engages in the development of products that clearly address a public health need in LMICs beyond the R&D priorities identified by global health research organisations.* This includes innovative and adaptive R&D that, for example, addresses heat stability issues or ease of administration, or targets populations for which further studies/specific formulations are needed (such as for children, pregnant/lactating women, etc). *Currently, the Index categorises R&D priorities using lists from the WHO and Policy Cures Research.	**Retained** No change	Where the global health community has not formally identified gaps that should be prioritised (there is no priority list for NCDs, for example), companies can consider independently the development of innovative and adaptive products. These should clearly address a public health need in LMICs based on considerations including heat stability, use in special populations (such as among children and pregnant women) and the participation of patients from these countries in clinical trials.
RD2	**Planning for access: Framework** The company ensures it plans equitable access for all products it develops successfully (both in-house and collaboratively) for people in LMICs, and demonstrates a systematic approach to access for all R&D projects, which is applied from Phase II study onward.	**Retained** No change	By establishing a structured framework and approach to develop access plans for all product candidates (both in-house and collaborative R&D), a company increases the likelihood of developing long-term access plans as early in the process as possible.
RD3a	**Planning for access: Project-specific plans for prioritised diseases** The company ensures that all R&D projects for diseases prioritised by the WHO and Policy Cures Research are supported by detailed commitments and strategies to improve access to products in countries within the scope of the Index.	**Retained** No change	Advance access planning is particularly critical for R&D projects developed to address key product gaps relevant to patients in LMICs. Companies can ensure these products quickly reach the people who need them by planning for access during clinical development (starting from Phase II). To strengthen the potential for impacts on public health, the company's access plans should go beyond addressing registration to consider affordability and aspects such as supply.

RD3b	**Planning for access: Project-specific plans for other diseases** The company ensures that its R&D projects that address a public health need in LMICs beyond the R&D priorities identified by WHO and Policy Cures Research are supported by detailed plans to improve access to products in countries within the scope of the Index.	**Retain** No change	To ensure successful products can be made available swiftly and widely, R&D projects that target high-burden diseases in LMICs and address the needs of their populations require solid advance access planning. Companies can ensure these products are quick to reach the people who need them by planning for access during clinical development (starting from Phase II). To strengthen the potential for impacts on public health, the company's access plans should go beyond addressing registration to consider affordability and aspects such as supply.
RD4	**Disclosure of resources dedicated to R&D** The company publicly discloses the resources dedicated to its R&D activities conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.	**Retain** No change	Public disclosure of R&D investments can be used to identify and prioritise areas of limited financial investment for which a greater level of investment from public and private sectors may be needed. Such disclosure can contribute to build understanding about levels of investment needed to bring to market particular types of products from different therapeutic areas.
RD5	**Clinical trial conduct: Post-trial access** The company publicly commits to ensuring equitable post-trial access to investigative treatments tested in countries within the scope of the Index for treatment-eligible clinical trial participants living in these countries.	**Deleted** This indicator has been deleted: registration and affordability commitments following clinical trials are captured in indicators RD2 and RD3a/b.	Commitment to this principle helps ensure that access to investigational products can continue once the trial has ended (post-trial access) for trial participants and for the general population in which the trial was held. Public disclosure of this commitment enables accountability and understanding of a company's intended approach. Stakeholders agree that post-trial access is one of the key responsibilities of companies related to clinical trials, and they increasingly call for consideration of access in ways that extend beyond registration commitments.
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 standards of good practice* in countries in Index scope. *Such practice addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; has good governance structures in place for the partnership; supports or aligns its initiative goals with institutional goals; measures outcomes; and works toward long-term aims/sustainability.	**Retained** No change	For the development of medicines that can treat local diseases, meet local needs, and correspond to disease patterns in countries in scope, it is important to support local R&D. Companies need to be incentivised to take action for building local R&D capacity that goes beyond their own interests/portfolio. They have expertise in R&D that they can share locally.

INDICATORS

C PRODUCT DELIVERY 55%

2022 Indicator code	2022 Indicator	Change since 2021 (new/ retained/ modified)	Indicator rationale
PR1	**Registration** The company files to register its most recently launched products that target diseases in scope of the Index broadly, while taking the countries with the highest disease burdens into account.	Retained	Filing to register new products rapidly in low- and middle-income countries is a critical step to enable more widespread access in those countries. Recently launched products should ideally be filed for registration in countries in need within 12 months of the first global filing.
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. *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.	Retained	Donation programmes are a route to access to medicine for the poorest populations. When donations are made ad hoc in humanitarian situations (e.g., conflict, natural disasters, etc.), they should be made rapidly in response to expressed need.
PP2b	**Access strategies: Long-term donation programmes** The company engages in long-term, sustainable product donation programmes whose goals of elimination, eradication and control are possible and realistic. It publicly commits to the achievement of such goals.	Retained	Donation programmes can be a route to access to medicine for the poorest populations. They play a special role where there is very limited ability to pay and where a commitment is made to stay in the programme until elimination, eradication and control goals are achieved. Public disclosure of such a commitment is an important indicator of this will to remain active until goals are achieved.

PP3	**Supranationally procured products: Access strategies** The company applies access strategies to its supranationally procured products* and extends those strategies not only to countries graduating from these procurement agreements, but also to countries and populations which do not qualify for them. *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. Companies which do not market these products will not have this indicator applied.	**Retained**	For relevant products, this indicator evaluates whether or not companies engage with market-shaping and/or pooled procurement organisations such as UNICEF, Gavi, and the Global Fund. Importantly, it also assesses the extent to which companies consider comparative access to products for countries which do not qualify for such support.
PP4	**Healthcare practitioner-administered products: Access strategies** The company takes into consideration the ability of a country's reimbursement authority to pay and the demographic* characteristics of a country, in order to determine the 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 how 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. * 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.	**Retained**	Companies have an important role of supporting governments in achieving universal health coverage by improving the reach of products across the income pyramid. Companies should carefully determine ability to pay, taking into account socioeconomic factors which may determine different payers' abilities. Products which need the oversight of a healthcare practitioner for administration are likely to be more complex and require more sophisticated health systems for administration and ongoing care. Companies may therefore choose to also partner with public sector organisations to boost health system strength. Companies can choose to use a mix of strategies to maximise reach of their access approach: intra-country segmentation, licensing and donations. Successful strategies should be evidenced by an increase in patient numbers both to date and projected into the future.

2022 Indicator code	2022 Indicator	Change since 2021(new/ retained/ modified)	Indicator rationale
PP5	**Self-administered products: Access strategies** The company takes into consideration the ability of a country's reimbursement authority to pay and the demographic* characteristics of a country, in order to determine the 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 how 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. * 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.	**Retained**	Companies have an important role of supporting governments in achieving universal health coverage by improving the reach of products across the income pyramid. Companies should carefully determine ability to pay, taking into account socioeconomic factors which may determine different payers' abilities. Companies can choose to use a mix of strategies to maximise reach of their access approach: intra-country segmentation, licensing and donations. Successful strategies should be evidenced by an increase in patient numbers both to date and projected into the future.
PPL1	**Patent filing & enforcement** The company publicly commits to not filing for (or enforcing) patents relating to diseases in scope in least developed countries, low-income countries and in a subset of lower-middle income countries and upper-middle income countries.	**Retained**	Clarity about where patents are to be filed or will be enforced gives greater certainty to international drug procurers and generic medicine manufacturers when planning the manufacture and/or supply of generic products.
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.	**Retained**	Transparency is part of the social contract that underlies the patent system. When transparency is standard, this supports procurement agencies to make important decisions about which products to supply. Companies should deploy a transparent approach for all relevant therapeutic areas and product types.
PPL3	**IP sharing** The company provides evidence of sharing its intellectual capital (such as molecule libraries, patented compounds, processes and technologies) with research institutions and neglected disease drug discovery initiatives (such as WIPO Re:Search, Conserved Domains Database and Open Source Drug Discovery) which are developing products for diseases and countries in scope of the Index.	**Retained**	When a company shares its intellectual property on terms conducive to increasing access, this can accelerate research and development efforts and help to make new products available to populations in need in LMICs. Such potential for access is optimised when companies share their more valuable assets, such as those more likely to accelerate a product/s onto the market.

PPL4	**Licensing: Access-oriented terms** The company agrees access-oriented, transparent, non-exclusive voluntary licences which include clauses that facilitate the affordability and supply of quality products.	**Retained**	Access-oriented terms provide generic medicine manufacturers with additional flexibility (in manufacturing and/or distribution processes, for example) supporting them to optimise affordability and supply.
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	**Retained**	Including more countries in a licence will increase the potential for that licence to make an impact on public health. Often, the terms of voluntary licences exclude entire populations of middle-income countries. To increase access to medicine and potential benefits for public health, voluntary licences should include those populations with proven need.
PQ1	**Ensuring continuous supply** The company has mechanisms in place to improve supply chain efficiency and takes informed action to ensure uninterrupted supply and to make products available in sufficient quantities in a timely manner. Such mechanisms and actions are as follows: (a) The company has a system in place and works with relevant stakeholders (e.g. Government agencies, distributors, hospitals, warehouses, wholesalers or other relevant networks) to inform on issues that may affect the supply chain. (b) The company manages a buffer stock of relevant products and works with several API suppliers in place and/or produces in-house APIs to prevent shortages. (c) The company works to enhance local supply capacities and strengthen supply chains.* (d) The company transfers technology to regional manufacturers to improve manufacturing capacity and availability.* *Analysis is based on submission in PCB1 and PCB2.	**Modified** This indicator has been made to better capture actions taken by companies to ensure uninterrupted supply.	Ensuring continuous supply and preventing the risk of stock-outs means patients who need essential medicines can continue to access high-quality products.

PQ2	**Reporting substandard and falsified (SF) medicines** The company has a policy/procedure for reporting confirmed cases of substandard and falsified (SF) medicines in countries in scope to relevant stakeholders (national regulatory authorities and WHO Rapid Alert)* in a timely manner.** This prioritises the minimisation of harm to public health. . *Reporting to local regulatory authorities should take place regardless of whether local regulations require it. Reporting to WHO Rapid Alert is encouraged in all cases, particularly when local regulatory systems are weak and/or compromised. **The company provides evidence of a policy or approach to report confirmed cases of SF medicines as soon as possible and within 10 working days to local regulatory authorities and WHO Rapid Alert, when visual inspection (confirmation of mislabeling, confirmation of fake packaging) is sufficient to establish that product packaging is falsified. In cases where laboratory analysis is required for confirmation, the policy should require reporting of cases as soon as possible (and within 10 working days, once confirmation has taken place) to local regulatory authorities (and WHO Rapid Alert)	**Retained**	From a public health point of view, reporting to the relevant authority confirmed cases of SF medicines in a timely manner is important, as it allows authorities to quickly withdraw these from the market. SF medicines cause harm and death. Pharmaceutical companies have a responsibility to mitigate the risk of harm by sharing information with health authorities as rapidly as possible.
PCB1	**Capacity building in manufacturing** The company undertakes manufacturing capacity building initiatives with local manufacturers aimed at achieving international Good Manufacturing Practice (GMP). These initiatives meet good practice standards* in countries within the scope of the Index. *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	**Retained**	Companies have a role in supporting local manufacture outside of their own plants, contributing to the quality manufacture of other products locally. Local manufacturing can bring medicines more quickly to low- and middle-income country markets and simplify supply chains.
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 and public procurement, logistics and distribution agencies) that meet good practice standards* with the aim of improving the affordability, accessibility and quality of products, including products outside of its own portfolio. *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	**Retained**	An inefficient supply chain can significantly impact access to medicine. It can increase the risk of low quality, counterfeit medicines and stockouts. Companies have a role in supporting strong, resilient supply chains which also benefit products beyond their own portfolios.

PCB3	**Health system strengthening** Where no conflicts of interest exist, the company in partnership with local stakeholders undertakes health system strengthening initiatives that meet good practice standards* in countries in scope of the Index. Such initiatives work in a coordinated way with other parties, complementing the local health system, with outcomes clearly monitored. *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	**Retained**	While health systems are the primary responsibility of governments, companies can provide support. Well-functioning health systems promote better diagnosis, pharmacovigilance, disease surveillance and overall treatment. They are critical for sustainable access to medicine.
PBM1	**Inclusive business models** The company develops and implements scalable inclusive business models with long-term horizons that aim to meet the access needs of populations at the base of the pyramid* and/or of vulnerable populations** in countries in scope of the Index. *Sometimes referred to as the bottom level of the income pyramid or 'working poor', a term that designates roughly four billion people who live on USD $1-5 per day. **Vulnerable populations can include (but are not limited to) children, girls and women, LGBTQI+ people, people living with HIV and people living with mental health conditions.	**Retained** The Index covers models which address access issues for the lowest income tiers of populations (which may include other vulnerable populations); are implemented in-country, within the Index scope; are done in partnership (with support of local actors); present benefits for business and patients alike; demonstrate evidence of financial sustainability; (plan to) measure outcomes.	Inclusive business models aim to identify access constraints and remedy market inefficiencies within LMICs. They can create opportunities for business and populations at the base of the income pyramid. These models need a long-term horizon with the ultimate aim of being adopted by a country's national health system. Such models also provide value in targeting vulnerable populations who may not receive adequate attention from health systems.

Appendices

APPENDIX I CONTRIBUTORS TO THIS REPORT

Throughout the 2021 Methodology Review, many contributors have supported the Index Research Team. Strategic guidance was provided by the Expert Review Committee (ERC), a panel of independent experts from the WHO, governments, the industry, NGOs, academia and investors, among others. Recommendations on specific topics of the Index were provided by a wide range of specialists in different aspects of access to medicine. Experts from a variety of organisations (academic, non-governmental, multilateral) supported the development of the Methodology for the 2022 Access to Medicine Index with multiple viewpoints. Other stakeholder groups and individuals who are part of the Index engagement streams (companies, investors, and governments) have not been named, but have engaged through different ways. The Access to Medicine Foundation engaged with all 20 companies evaluated in the 2021 Index, and companies' staff from across their organisations provided feedback. We gratefully acknowledge all contributions. The following individuals agreed for their names to be publicly acknowledged:

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Acknowledgment in this report is not intended to imply endorsement of the Access to Medicine Index, its final methodology, the analysis or the results. Final decisions regarding the content of the Technical Areas and indicators are ultimately made by the Access to Medicine Foundation. Contributors engaged in a personal capacity, and their views may not necessarily reflect the views of all members of the stakeholder groups or the organisations they represent.

APPENDIX IIA DISEASES IN SCOPE FOR THE 2022 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 2022 Index has expanded from 82 to 83 diseases, conditions and pathogens. DALY burden and mortality data was collected from the Institute for Health Metrics and Evaluation's 2019 Global Burden of Disease study (GBD 2019) and are presented as totals for countries in scope and disaggregated by sex where possible. Incidence data for cancer types was collected from GLOBOCAN 2020.

TABLE 3 **Diseases, conditions and pathogens in scope of the 2022 Access to Medicine Index**

NON-COMMUNICABLE DISEASES (17)	**Total DALYs (Countries in scope)**	**% DALYs (female)**	**% DALYs (male)**
Alzheimer's disease	14091001	60	40
Anxiety disorders	21036967	61	39
Asthma	17205253	50	50
Bipolar affective disorder	5719253	51	49
Cancer*	DALY not applicable	N/A	N/A
Chronic obstructive pulmonary disease (COPD)	59324781	43	57
Diabetes mellitus	53331082	49	51
Endometriosis	1817717	100	0
Epilepsy	10894638	45	55
Hypertensive heart disease	16968658	52	48
Ischaemic heart disease	135566680	39	61
Kidney diseases	33377377	47	53
Migraine	32046243	62	38
Schizophrenia	11253865	46	54
Sickle cell disease	3353910	50	50
Stroke	115249723	45	55
Thalassemia	740243	47	53
Unipolar depressive disorders	35449935	61	39

CANCER TYPES IN SCOPE (18)*	**Total incidence (countries in scope)**	**% incidence (female)**	**% incidence (male)**
Bladder	206405	24	76
Brain, nervous system	188564	45	55
Breast	1205094	100	0
Cervical	492901	100	0
Colorectal	952245	44	56
Gallbladder	79290	65	35
Head and neck	626069	25	75
Kaposi sarcoma	25498	33	67
Leukaemia	260989	57	43
Liver	674563	29	71
Lung	1200632	33	67
Non-Hodgkin lymphoma	266902	43	57
Oesophageal	487416	33	67
Osteosarcoma	Incidence not available in GLOBOCAN 2020	N/A	N/A
Ovarian	192618	100	0
Prostate	488157	0	100
Stomach	720206	33	67
Thyroid	367564	76	24
Uterine	181414	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 2019	N/A	N/A
Coronaviral diseases	DALY not available in GBD 2019	N/A	N/A
Disease X	N/A	N/A	N/A
Enteric diseases	94517532	48	52
Diarrhoeal diseases	365622	48	52
Diphtheria	DALY not available in GBD 2019	N/A	N/A
Emergent non-polio enteroviruses	195394	54	46
Filoviral diseases***	DALY not available in GBD 2019	N/A	N/A
Henipaviral diseases	45381627	52	48
HIV/AIDS	DALY not available in GBD 2019	N/A	N/A
Leptospirosis	88246796	48	52
Lower respiratory infections	46424214	49	51
Malaria	6992861	49	51
Measles	16003241	45	55
Meningitis	N/A	N/A	N/A
Other prioritised antibacterial-resistant infections	10119037	54	46
Pertussis	DALY not available in GBD 2019	N/A	N/A
Rheumatic fever	8333009	49	51
Sexually transmitted infections (STIs)	2308625	45	55
Tetanus	46042666	37	63
Tuberculosis	21105821	28	72
Viral hepatitis (B and C)	287110	28	72
Yellow fever	257	45	55
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	245559	41	59
Dengue and chikungunya†	2348991	47	53
Dracunculiasis	1	54	46
Echinococcosis	98181	51	49
Foodborne trematodiases	747282	39	61
Human African trypanosomiasis	82612	48	52
Leishmaniasis	692709	42	58
Leprosy	28672	36	64
Lymphatic filariasis	1613533	19	81
Mycetoma, chromoblastomycosis and other deep mycoses	DALY not available in GBD 2017	N/A	N/A
Onchocerciasis	1230270	47	53
Rabies	780120	30	70
Scabies and other ectoparasites	4633065	49	51
Schistosomiasis	1614876	52	48
Snakebite envenoming	DALY not available in GBD 2017	N/A	N/A
Soil-transmitted helminthiasis	1945708	58	42
Taeniasis/cysticercosis‡	1150180	54	46
Trachoma	180125	52	48
Yaws	DALY not available in GBD 2017	N/A	N/A

REPRODUCTIVE, MATERNAL AND NEWBORN HEALTH (10)	**Total mortality (countries in scope)**
Birth asphyxia and birth trauma	558039
Contraceptive methods	Mortality not applicable
Hypertensive disorders of pregnancy	27429
Abortion and miscarriage	19365
Maternal haemorrhage	46117
Maternal sepsis	16699
Neonatal sepsis and infections	221229
Obstructed labour	10454
Other neonatal conditions	363225
Preterm birth complications	638178

* 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.

APPENDIX IIB CANCERS IN SCOPE FOR THE 2022 ACCESS TO MEDICINE INDEX

Cancer remains in scope for the 2022 Index, and the cancer types included are in scope for all Technical Areas. The 18 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 2020.

There are 19 cancer types in scope for the 2022 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 are combined as a single cancer type.

Osteosarcoma is newly in scope. Ovarian and uterine cancer remain in scope as they have comparably higher incidences compared to other sex-linked cancer types. As in the methodologies for the 2018 and 2021 Indices, 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 2022.

Cancer types in scope (19)	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 2022 Access to Medicine Index	Included following sex-linked cancer analysis
Bladder					
Brain, nervous system					
Breast	2261419	1205094			
Cervical	604127	492901	81%		
Colorectal	1931590	952245			
Gallbladder					
Head and neck*	931931	626069	87%**		
Kaposi sarcoma			74%		
Leukaemia					
Liver	905677	674563	81%		
Lung	2206771	1200632			
Non-Hodgkin lymphoma					
Oesophageal	604100	487416	80%		
Osteosarcoma				●	
Ovarian					●
Prostate	1414259	488157			
Stomach	1089103	720206			
Thyroid	586202	367564			
Uterine					●

* Includes all head and neck cancers defined by GLOBOCAN 2018.

** This percentage reflects the proportion of naso-pharynx cancer cases in countries in scope.

APPENDIX III 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.

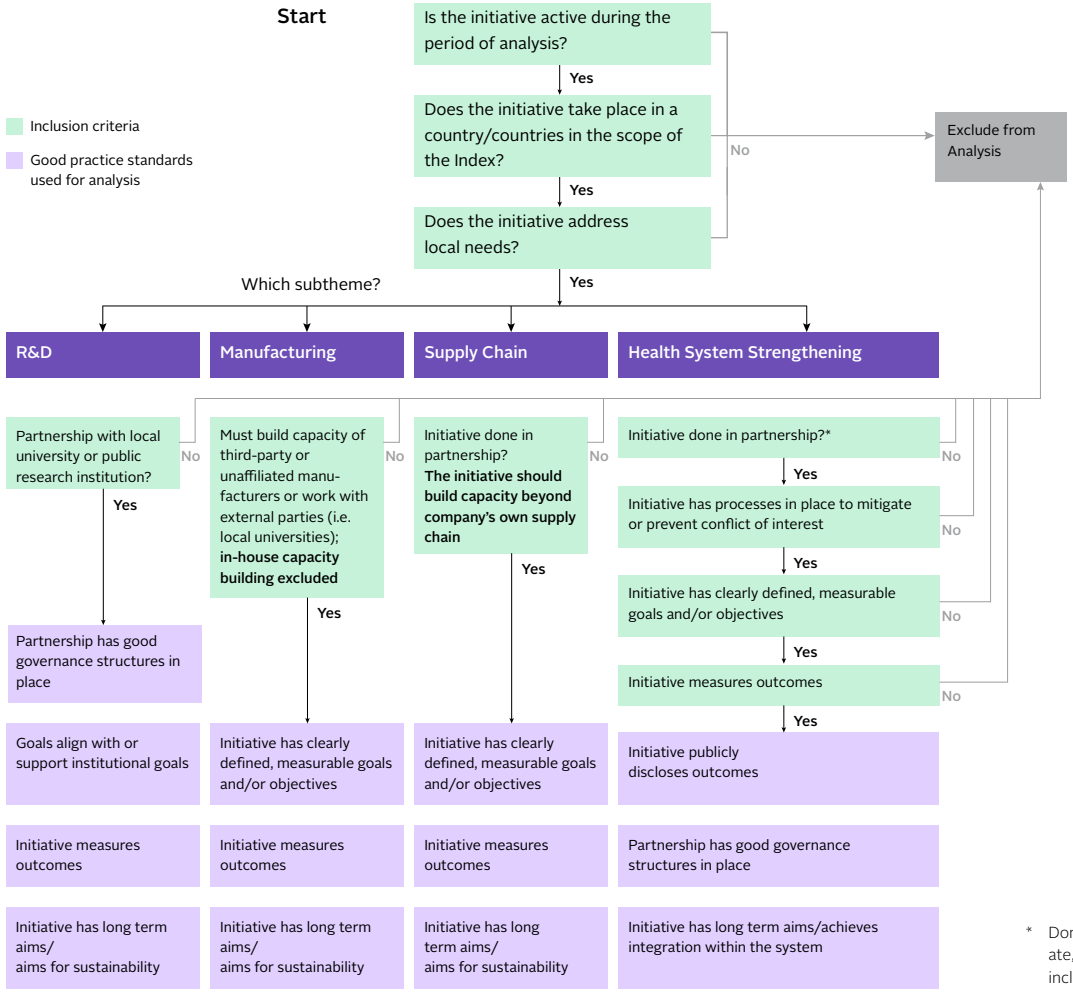
Good practice standards for initiatives:

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.



* Done with appropriate, relevant partners, including local partners

APPENDIX IV R&D PRIORITIES

TABLE 6 **Priority diseases, conditions and pathogens**

ATMI Disease	Specific disease target	Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (for reproductive health only)	Policy Cures Research G-FINDER neglected diseases	Policy Cures Research G-FINDER sexual & reproductive health	Policy Cures Research G-FINDER emerging infectious diseases	WHO R&D Blueprint	WHO Initiative for Vaccine Research	WHO Priority Pathogen List
Arenaviral haemorrhagic fevers (Lassa fever)		●	●	●	●						●	●		
Bunyaviral diseases	Crimean-Congo haemorrhagic fever	●	●	●	●		●				●	●		
	Rift Valley fever	●	●	●	●		●				●	●		
	Severe fever with thrombocytopenia syndrome (SFTS)	●	●	●	●		●				●			
	Other bunyaviral diseases	●	●	●	●		●				●			
Buruli ulcer		●	●		●				●					
Cancer	HPV-related cervical cancer	●	●	●	●	●		●		●				
Chagas disease		●	●	●	●		●		●					
Contraceptive methods		●	●	●				●		●				
Coronaviral diseases	Middle East respiratory syndrome coronavirus (MERS-CoV)		●	●	●		●				●	●		
	Severe acute respiratory syndrome (SARS)	●	●	●	●		●				●	●		
	Coronavirus disease 2019 (COVID-19)	●	●	●	●		●				●	●		
	Other highly pathogenic coronaviral diseases	●	●	●	●						●			
Dengue and Chikungunya	Chikungunya	●	●	●	●		●				●			
	Dengue	●	●	●	●		●		●				●	
Enteric diseases	Cholera	●	●	●	●				●					
	Cryptosporidiosis	●	●	●	●				●					
	Enterotoxigenic *E. coli* (ETEC) infections		●		●				●					
	Enteroaggregative *E. coli* (EAEC) infections		●		●				●					
	Giardiasis (lambliasis)				●				●					
	Rotaviral gastroenteritis		●						●					
	Shigellosis	●	●	●	●				●					
	Typhoid and paratyphoid fever (*S. typhi, S. paratyphi A*)	●	●	●	●				●					
	Non-typhoidal *S. enterica* (NTS)	●	●	●	●				●					
Emergent non-polio enteroviruses (including EV71, D68)		●	●	●	●						●			
Filoviral diseases	Ebola	●	●	●	●		●				●	●		
	Marburg	●	●	●	●		●				●	●		
	Other filoviral diseases	●	●	●	●		●				●			
Henipaviral diseases	Nipah	●	●	●	●		●				●	●		
	Other henipaviral diseases	●	●	●	●		●				●	●		
HIV/AIDS		●	●	●	●	●			●				●	

Human African trypanosomiasis		●	●	●	●		●		●					
Hypertensive disorders of pregnancy	Pre-eclampsia	●		●	●					●				
Leishmaniasis		●	●	●	●				●					
Leprosy		●	●	●	●				●					
Leptospirosis					●				●					
Lower respiratory infections	*S. pneumoniae*		●		●				●					
	Influenza		●										●	
	Respiratory syncytial virus (RSV)		●										●	
Lymphatic filariasis		●			●		●		●					
Malaria	*P. falciparum*	●	●	●	●		●		●				●	
	P. vivax	●	●	●	●		●		●				●	
Maternal haemorrhage	Postpartum haemorrhage	●						●		●				
Meningitis	*N. meningitidis*		●		●				●				●	
	Cryptococcal meningitis	●		●					●					
Mycetoma, chromoblastomycosis and other deep mycoses	Mycetoma	●			●				●					
Neonatal sepsis and infections	Group B *Streptococcus*		●										●	
Onchocerciasis		●	●		●		●		●					
Rheumatic fever			●						●				●	
Scabies			●		●				●					
Schistosomiasis		●	●	●	●		●		●					
Sexually transmitted infections (STIs)	Chlamydia		●	●	●					●				
	Gonorrhoea	●	●	●	●					●				
	HSV-2	●	●	●	●					●				
	HTLV-1	●	●	●	●					●				
	Syphilis	●	●	●	●					●				
	Other STIs	●	●	●	●					●				
Soil transmitted helminthiasis	Hookworm diseases	●	●						●					
	Strongyloidiasis	●	●		●				●					
	Trichuriasis	●							●					
	Ascariasis	●							●					
Snakebite envenoming		●		●	●				●					
Taeniasis/cysticercosis		●			●		●		●					
Trachoma			●		●				●					
Tuberculosis		●	●	●	●				●				●	
Viral hepatitis (B and C)	Hepatitis B	●		●	●				●					
	Hepatitis C	●	●		●				●					
Zika		●	●	●	●		●				●	●	●	
Disease X*												●		

Green text = priority R&D product gap newly in scope for the 2020 Index

● Gap identified
Definition: Product gap identified for the disease, condition or pathogen on one or more of the R&D priority lists

● Specific gap
Definition: Specific R&D need or product gap identified, e.g., for a new route of administration to be developed or specific serotypes to be targeted

● Included on priority R&D list

* 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.

TABLE 7 **Priority pathogens**

12 antibacterial-resistant pathogens remain in scope for the 2022 Access to Medicine Index. Pathogens on the WHO priority pathogen list are deemed by WHO as priority R&D targets for new and effective antibacterials active against the pathogens themselves and the diseases they cause. This WHO priority pathogen list does not define specific products needed.

Other prioritised antibacterial-resistant infections	Policy Cures Research G-FINDER neglected diseases	Policy Cures Research G-FINDER sexual & reproductive health	Policy Cures Research G-FINDER emerging infectious diseases	WHO R&D Blueprint	WHO Initiative for Vaccine Research gaps	WHO Priority Pathogen List
Acinetobacter baumannii (carbapenem-resistant)						●
Campylobacter spp. (fluoroquinolone-resistant)						●
Enterobacteriaceae (carbapenem-resistant, 3rd generation cephalosporin-resistant)	●					●
Enterococcus faecium (vancomycin-resistant)						●
Haemophilus influenzae (ampicillin-resistant)						●
Helicobacter pylori (clarithromycin-resistant)						●
Neisseria gonorrhoeae (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)		●				●
Pseudomonas aeruginosa (carbapenem-resistant)						●
Salmonella spp. (fluoroquinolone-resistant)	●					●
Shigella spp. (fluoroquinolone-resistant)	●					●
Staphylococcus aureus (methicillin-resistant, vancomycin-intermediate and vancomycin-resistant)						●
Streptococcus pneumoniae (penicillin-non-susceptible)	●					●

● Included on priority R&D list

APPENDIX V ENSURING THE METHODOLOGY CONSIDERS ISSUES OF SEX AND GENDER

To be effective in creating access to medicine and health products, companies must recognise and address in their approaches those barriers to access that lie beyond affordability, supply and health system strength. Barriers may relate to differences in socioeconomic status and to the prevalence of diseases in certain geographic locations, but some barriers are rooted in the sex and gender of patients. Among cisgender women and girls, for example, one report found that up to 58% of those in low- and middle-income countries (LMICs) cannot access or use the medicine they need. Fear of side effects and other health concerns may be factors, but so may the preferences of their male partners.[1]

Sex and gender are important in how diseases present and how disease burdens are distributed. Females in countries included in scope of the Index carry approximately 60% of the DALY (disability-adjusted life year) burden for anxiety and depressive disorders[2] (although males are less likely to disclose mental health problems to primary care providers, with corresponding underreporting and undertreatment).[3] Males carry approximately 60% of the DALY burden for stroke and heart disease.[2] Certain vulnerable populations have higher rates of HIV infections and experience considerable stigma: these include transgender women, female sex workers and cisgender men who have sex with men.[4,5]

Social and cultural stigmas present enormous barriers for people to access the medicines they need. While governments and local organisations familiar with cultural and social norms must address these barriers, pharmaceutical companies can play a key role in partnerships to support the development and integration of inclusive business models. These need to be set up with a long-term outlook, one that appreciates the varying vulnerabilities of a range of patient groups.

In 2022, the Index aims to ensure that it fully considers those access challenges that pertain to sex and gender. Experts emphasise the need to approach methodological matters in a manner that is neither gender-blind (for example, aggregating burden without considering disproportionate gender-based burden or discrimination) nor gender-unequal (that is, considering needs that apply only to one gender). The effects of the COVID-19 pandemic have brought such issues into sharper focus: disrupted access to modern contraceptive methods, for example, is affecting females disproportionately and differently in certain settings.[6]

According to the consensus view of the role pharmaceutical companies should play in addressing these issues, it is vital that companies ensure adequate representation and consideration of sex and gender in clinical trial cohorts and product development. Such consideration might lead to (a) greater representation of female, transgender and vulnerable populations in clinical trials, and thereby to more suitable products for those populations; (b) greater focus on the safety and efficacy of medicines in pregnant or lactating women; (c) a focus during product development of sex- or gender-linked comorbidities relating to the disease/condition in question; and/or (d) information about the presence or absence of drug-drug interactions with contraceptives.

Reflecting on these points, the Foundation has examined sex-disaggregated DALY burden data to consider the inclusion of additional diseases or conditions. Most for which the burden is disproportionately (more than 70%) high for either males or females, such as maternal health conditions, are already included in the disease scope. Some, such as road injuries and sexual violence, are not suitable as candidates for specific pharmaceutical intervention. However, assessment of the incidence of sex-linked cancer types (both globally and in countries in scope) previously led the Index to include uterine and ovarian cancer, as these appear far more frequently than other sex-linked cancers (such as testicular, vulval, penile and vaginal). For 2022, the Index keeps these two cancer types in scope.[7] Breast, cervical and prostate cancer types remain included in the disease scope on the basis of other criteria (see page 23).

Furthermore, to examine how companies address access barriers that relate to stigma, the 2022 Index evaluates inclusive business models that target populations at the base of the income pyramid. These may include vulnerable populations such as cisgender women and girls, and those who are part of LGBTQI+ communities. For all R&D projects the Index examines, it considers whether companies include vulnerable populations in clinical trials.

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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 provisions: 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, technology transfer or 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
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 across its operations in low- and middle-income countries.
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.

Fair market value assessment
Working definition, used for analysis
Fair market value assessments define the appropriateness of payments made to healthcare professionals. These provide structure to ensure ethical interactions between the pharmaceutical industry and HCPs they engaged with.

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
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 partnership, 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). Outcomes can also reflect on the country health system (e.g., number of healthcare professionals trained).

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 2022 Index, the time period for which data will be analysed covers company activities which must be ongoing between 1 June 2020 and 31 May 2022, as this is the cycle of the Index. Projects that have ended before 1 June 2020 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 healthcare 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, members of the LGBTQI+ community, people living with HIV, etc.

APPENDIX VII REFERENCES

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