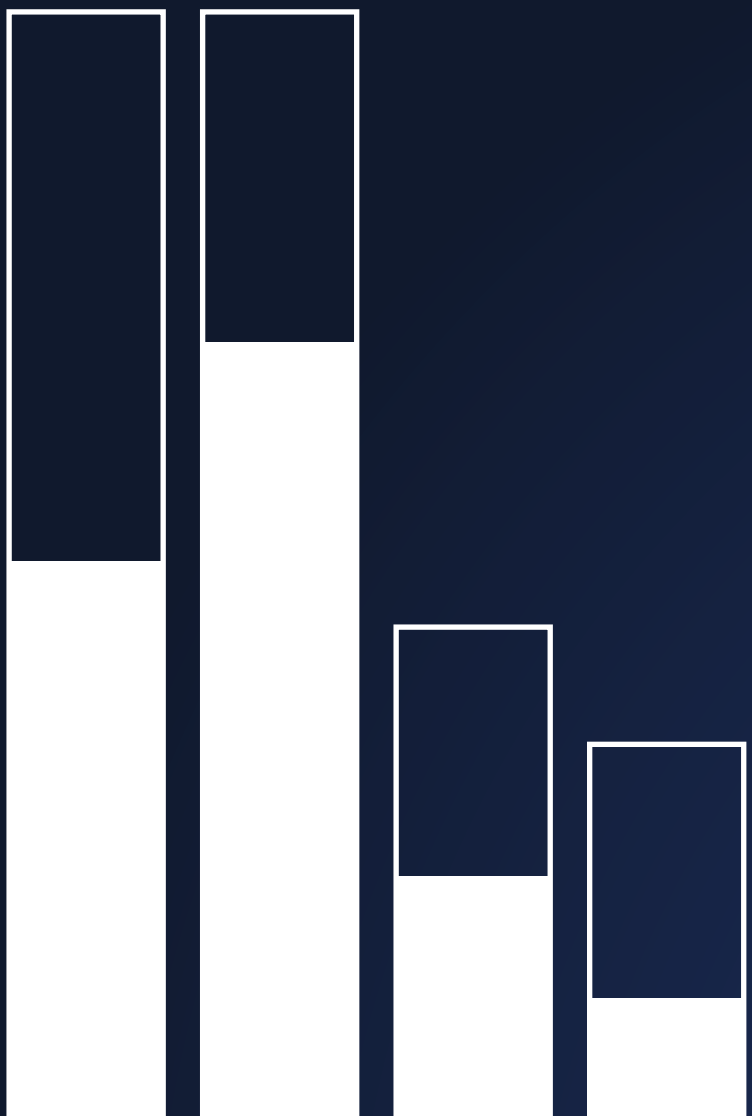
Antimicrobial Resistance Benchmark Opportunities

COMPANY PROGRESS SINCE 2021

NOVEMBER 2023



access to medicine FOUNDATION

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The Access to Medicine Foundation is an independent non-profit organisation that seeks to transform the healthcare ecosystem by motivating and mobilising companies to expand access to their essential healthcare products in low- and middle-income countries.

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INTRODUCTION

Turning the tide against antimicrobial resistance

When the Access to Medicine Foundation released the first Antimicrobial Resistance (AMR) Benchmark in 2018, drug resistance was already on the rise and spreading fast, with the World Health Organization (WHO) officially classifying it as one of world's top ten health threats in 2019.[1] At the time, projections suggested that annual deaths from AMR could escalate to 10 million by 2050.[2]

Today, AMR is already claiming the lives of at least 1.27 million people each year.[3] If its spread is not curbed, we could reach, if not surpass, previous predictions far sooner than we thought. Worryingly, it is also becoming increasingly clear that climate change impacts AMR, with rising temperatures, for example, accelerating the burden of infectious diseases.[4] Drastic and urgent action is needed if we are to combat the drivers of drug resistance, protect the planet and prevent the unnecessary loss of lives.

AMR knows no boundaries or borders, but the reality is the lives of people in low- and middle-income countries (LMICs) are most at risk. Tragically, people living in these countries face a 50% higher chance of dying from AMR than people living in high-income countries.[3,5]

While AMR is a complex global issue that must be tackled through collaborative, coordinated actions from global health stakeholders, we cannot turn the tide against drug resistance without action from pharmaceutical companies. Not only do they have the power to improve appropriate access to effective and safe antimicrobial products, including lifesaving antibiotics, but they operate on several fronts where some of the drivers of AMR risk can be curbed.

Driving progress

To enable progress, the Access to Medicine Foundation sets "Opportunities" for individual companies to pursue – a groundbreaking, practical and proven approach to moving companies in the right direction on critical access-to-medicine priorities.

Across three iterations of the AMR Benchmark (2018, 2020, and 2021), the Foundation has pinpointed specific actions each major company in scope can take to combat drug resistance and ensure appropriate access to antimicrobials. Beyond tracking and evaluating these companies' efforts, the Foundation actively engages with companies on how to drive change – guiding and encouraging them to move forward.

The Foundation's research has shown that good practice has become more common, specifically in access planning in research and development (R&D) to make new medicines available in LMICs, as well as in the steps taken to curb the release of antibacterial waste into the environment.[6]

While every positive step is critical, more transformative actions are urgently needed.

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17 **Companies were given Opportunities in the 2021 AMR Benchmark.**
These are:

8 **Research-based pharmaceutical companies**
GSK, Johnson & Johnson, MSD, Novartis*, Otsuka, Pfizer, Sanofi, Shionogi

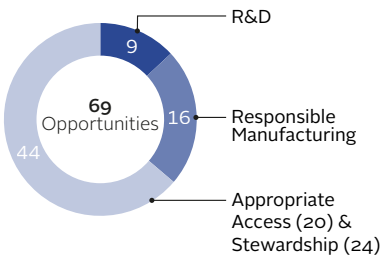
9 **Generic medicine manufacturers**
Abbott, Alkem, Aurobindo, Cipla, Fresenius Kabi, Hainan Hailing, Sun Pharma, Teva, Viatris

*Since the publication of the 2021 AMR Benchmark, Novartis has completed a 100% spin-off of its generics and biosimilars business, Sandoz. On 4 October 2023, Sandoz became an independently listed company. This report provides updates on Opportunities identified in Novartis's 2021 Benchmark Report Card, looking at progress over the two-year period and incorporating information about both Sandoz and Novartis.

To stimulate large-scale change, the Foundation identified key Opportunities for the 17 companies evaluated in the 2021 AMR Benchmark, which included eight leading research-based pharmaceutical companies and nine generic medicine manufacturers (see figure on p.3). These tailored Opportunities, included within each company's 2021 Report Card, provided calls-to-action, encouraging companies to do more to curb AMR and improve access to antimicrobial products in LMICs.

Now, in 2023, this report provides a vital update on the progress achieved by these 17 companies in response to these Opportunities. Tracking the progress companies have made over the last two years provides an important touchpoint for determining where successful steps are being taken and how the Foundation's work has contributed to such progress. It also provides key insights as to where companies have not yet taken sufficient action, showing them where they can focus their resources. At the same time, this can also point to systemic challenges that continue to hinder progress, providing other global health stakeholders with valuable insights they can use to support companies.

Opportunities are split across the Benchmark's 3 Research Areas



17 companies, 69 targeted Opportunities for tackling AMR

Companies are all different in the way they operate, where they operate, and in their portfolio of investigational and marketed products, which is why the Foundation set out tailored Opportunities for each company, accounting for R&D pipelines (where applicable), product portfolios, and other factors. By doing this, the aim was to provide companies with clear, practical and feasible ways in which they can each maximise their contributions to successfully improving access and addressing AMR.

The Benchmark evaluates companies in areas where they have the greatest opportunity and responsibility to limit AMR; specifically, R&D, managing antibacterial manufacturing waste, and ensuring appropriate access to – and responsible stewardship of – antimicrobial medicines. A total of 69 Opportunities were identified across these areas in the 2021 Report Cards of the 17 companies (see figure).

Using data submitted by companies and information from the public domain, the Foundation conducted an analysis of whether there has been progress on each Opportunity.

The industry analysis in this report reveals collective trends, both in terms of action and inaction, shedding light on the factors that have influenced the extent of progress achieved thus far – and where more action is required from companies.

INDUSTRY ANALYSIS

How have companies responded to their Opportunities?

- For Opportunities related to access, some progress can be seen – especially in expanding product registration and engaging in long-term initiatives to boost availability and affordability.
- Despite a handful of acquisitions to expand R&D pipelines, R&D projects targeting priority pathogens and urgent AMR threats are still lacking.
- Some positive examples of progress on Opportunities to limit AMR risk from manufacturing, yet minimal movement to increase public disclosure.
- No progress on Opportunities to delink bonuses from sales volume; some progress on improving surveillance disclosure and mitigating conflicts of interest.

RESEARCH & DEVELOPMENT

Few companies show progress on expanding R&D pipeline

With the current arsenal of antibiotics and antifungals losing its effectiveness due to AMR, new treatments are drastically needed. Five companies were presented with Opportunities that highlighted how they could expand the breadth of their pipelines to include more antimicrobial R&D projects targeting priority pathogens and urgent AMR threats. So far, two companies – Pfizer and Shionogi – have demonstrated progress, while Novartis, Otsuka and Sanofi have not. Both companies that demonstrated progress have added projects to their pipelines via acquisitions or strategic partnerships.

Given that small- and medium-sized enterprises (SMEs) struggle to survive the financial 'valleys of death' of the drug development process while carrying out 75% of antibacterial and antifungal R&D, acquisitions like those undertaken by Pfizer and Shionogi play a pivotal role in sustaining innovation and ensuring global access to these crucial developments.[7]

Pfizer, through an acquisition, added SPR206 to its pipeline and progressed three existing candidates to later stages of development. SPR206, an investigational intravenously (IV)-administered polymyxin product candidate, is ready to enter Phase II and targets multidrug-resistant (MDR) gram-negative bacterial infections. MDR gram-negative bacterial infections, such as pneumonia, meningitis, bloodstream infections, and surgical site infections, are predominantly found in hospitals, and are resistant to multiple antibiotics. Developing products that can target these infections effectively will protect patients.

Shionogi expanded its pipeline by adding, through a strategic partnership, a novel oral antifungal therapy in Phase III to treat invasive aspergillosis and by acquiring two combination products in Phase I that target pathogens including carbapenem-resistant *A. baumannii*, *P. aeruginosa*, and *Enterbacterales*. These products, designed for both oral and IV administration, are based on xeruborbactam, a novel boronic acid ß-lactamase inhibitor.

When antibiotics are developed solely as an IV treatment, patients need to visit a hospital for administration of the medicine. By developing both an oral and an IV formulation in parallel, patients could potentially spend less time receiving treatment at a hospital; reduced bed occupancy could, in turn, also alleviate pressure on hospitals.

RESPONSIBLE MANUFACTURING

More companies are integrating AMR risk into their environmental risk strategies

When manufacturing lifesaving antibiotics, it is critical that AMR does not become an unintended side effect – which is why companies must manage their antibiotic waste responsibly.

In 2021, five out of the 17 companies in scope – Alkem, Fresenius Kabi, Hainan Hailing, Otsuka and Sun Pharma – did not specify any strategy to limit AMR risk

through responsible manufacturing. Since then, four of these companies have reported some progress, with the exception of Hainan Hailing, which has not demonstrated any significant progress in this area.

FIGURE 1 **Progress on Opportunity to limit AMR risk from manufacturing**

Of the 5 companies that did not previously specify any strategy to limit AMR risk through responsible manufacturing, 4 now report some progress.

Fresenius Kabi reports that it is in the process of fully implementing the manufacturing standards of the AMR Industry Alliance and reports that approximately one-third of all its own sites and half of its assessed suppliers now comply with discharge limits in the receiving environment. Otsuka has developed an analytical method to quantify the levels of delamanid, its sole product in scope of the AMR Benchmark, and has plans to measure discharge levels. While Sun Pharma and Alkem do not report on environmental risk-management strategies covering AMR, Alkem has publicly reported that it has implemented Zero Liquid Discharge (ZLD) – a treatment process in which the site does not discharge any water into the environment – across 64% of its manufacturing sites. Sun Pharma reports the use of ZLD systems at all 12 of its manufacturing sites.

These developments indicate a growing awareness and commitment among these companies to integrate responsible manufacturing practices that address AMR risk into their broader environmental strategies.

The AMR Industry Alliance is a coalition of companies and associations that aims to drive progress on AMR. In the absence of independent regulation targeting the AMR risk from antibiotic manufacturing, the Antibiotic Manufacturing Standard facilitated by BSI Standards Limited.[8]

In 2023, the Foundation published a report zeroing in on responsible manufacturing practices. It identifies examples of how some companies are developing and maintaining solutions that will help them limit their antibiotic waste more effectively. This report, which includes specific recommendations, can help guide companies to make further progress on their Opportunities.

Limited reporting on supplier compliance with discharge limits

While several companies show progress in their efforts to collaborate with suppliers to reduce AMR risk, only a few have disclosed the extent to which their suppliers adhere to discharge limits from antibiotic waste.

Pfizer reports that 86% of its 100-plus supplier sites are now compliant with discharge limits in the receiving environment (e.g., rivers and waterways). Similarly, Shionogi reports that 71% of its supplier sites are compliant, up from 33% in 2021.

Companies' submissions for this report outline the challenges associated with improving compliance among their suppliers, as there is currently no specific regulation stipulating permitted antibiotic waste release levels into the environment. While contractual provisions offer a solution, enforcing such contracts can be difficult, often due to limited alternative supplier options. Consequently, companies are taking proactive measures to support and assist their suppliers in addressing compliance challenges. For instance, Abbott supports suppliers by providing free wastewater analysis and logistics assistance.

If wastewater containing high levels of active pharmaceutical ingredients (APIs) is released into the environment, it poses a serious risk to human health, while also causing environmental harm.[10]

Public disclosure on managing antibiotic waste keeps falling short

Out of 17 companies, 16 were presented with the Opportunity to increase public disclosure on their AMR-focused manufacturing approaches. However, to date, none of the companies have disclosed audit results or antibacterial discharge levels of their own sites or those of their suppliers. The one example of progress comes from Viatris, which now publicly discloses that all its own manufacturing sites comply with certain discharge limits set by the AMR Industry Alliance.

APPROPRIATE ACCESS

Expanded registration of essential off-patent and/or generic medicines

To save patients' lives and curb AMR, it is crucial that every patient has access to

the right antibiotic or antifungal medicine at the right time. An important element of this is for companies to ensure that their older, off-patent and/or generic products are widely registered with national regulatory authorities, including in low- and middle-income countries (LMICs). Of the nine companies given the Opportunity to expand registration of such products, six – Abbott, Aurobindo, Cipla, Sanofi, Teva and Viatris – have made progress, to varying degrees. Viatris, for instance, filed six products listed on the 2023 WHO Model List of Essential Medicines (EML) in an average of two additional LMICs in scope. Teva reports that it has filed five of its essential medicines for registration in at least one additional LMIC.

The 2023 WHO EML presents essential medicines that should be available to every healthcare system. Of these medicines, 90% are already off-patent, offering huge potential for generic medicine manufacturers to expand access. In 2023, a first-of-its-kind report from the Foundation examined what five of the world's largest generic and biosimilar medicine manufacturers are doing to expand access to essential medicines – and provides tailored Opportunities for each company to bolster efforts.[11]

FIGURE 2 **Movement on expanding registration of critically-needed off-patent and/or generic products to more LMICs**

Of the 9 companies with an Opportunity to expand registration of off-patent and/or generic products, 6 have made some degree of progress.

Nonetheless, several companies expressed market viability concerns as a barrier to expand registration filings in LMICs. This includes tenders that predominantly take prices into account and not quality or environmental aspects. In addition, for in-licensed products, expanding registration can be constrained by contractual terms with licensors. Based on companies' submissions for this report, broader medicine registration in LMICs could be facilitated by clarity about demand, harmonised registration procedures and non-price tender criteria.

In a report published in 2022, the Foundation set out a wide range of strategies that are available to companies for overcoming such barriers and improving access appropriately and sustainably. The report includes six case studies showing what companies and their partners are already doing to expand appropriate access.[12]

Pfizer and Sanofi take steps to ensure access and availability in LMICs

Pfizer and Sanofi – which both had Opportunities in this area – have established global not-for-profit programmes to expand access to antibiotics and antifungals in LMICs. Both initiatives show a strong potential for securing sustainable access to medicines and vaccines in these countries.

Pfizer's Accord for a Healthier World initiative, launched in May 2022, was expanded in January 2023 and aims to offer individuals in 45 LMICs access to the company's complete portfolio of both on-patent and off-patent medicines and vaccines. This includes 4 antibacterial vaccines, 11 branded antibiotics and 4 branded antifungals, which the company has shared a commitment to provide on a not-for-profit basis. Sanofi's non-profit Global Health Unit, launched in 2021, aims to increase product availability in LMICs by supplying 30 essential medicines to 40 LMICs, including 2 antibiotics – metronidazole and rifampicin.

Efforts to enhance accessibility and affordability of MDR-TB products

All three companies – Johnson & Johnson, Otsuka and Viatris – with the specific Opportunity to expand access and improve affordability of multidrug-resistant tuberculosis (MDR-TB) products report progress on access strategies for MDR-TB medicines. These strategies include price reductions, extended shelf life, pooled procurement mechanisms and expanding registration in multiple LMICs.

The bacteria that cause MDR-TB are resistant to the two most potent TB drugs, making equitable access to MDR-TB products vital.[13]

Johnson & Johnson offered a reduced price of its six-month bedaquiline treatment course to the Stop TB Partnership's Global Drug Facility (GDF) and the countries GDF supplies. At USD 130, this marks a 55% reduction from the previous price, when the same treatment course was supplied to GDF at USD 289.[14] In June 2023, Johnson & Johnson granted the GDF appropriate licences, which allow GDF to purchase generic versions of bedaquiline for the majority of LMICs.[15] Moreover, after public pressure from organisations such as Unitaid, Johnson & Johnson announced in September 2023 that it will not enforce any of its patents for bedaquiline in all 134 LMICs.[16]

This allows generic competition in all LMICs, including those that do not procure bedaquiline via GDF.

Viatris has registered or submitted registration filings for pretomanid in four additional countries in scope. Collaborating with MedAccess and the TB Alliance, Viatris announced a 34% reduction in the price of pretomanid, ensuring it is now available at a maximum of USD 240 for a six-month treatment course.[17] Additionally, Viatris reports that the shelf life of pretomanid has been extended from 36 to 48 months, allowing for extended storage periods.

This also reduces the frequency of resupply, which optimises logistics and reduces waste.

Otsuka reports that since 2021, it has registered or submitted registration filings for delamanid in seven countries in scope and is initiating a technology transfer for its paediatric formulation of delamanid to Viatris in India, with a focus on improving affordability and accessibility. This is in addition to a completed technology transfer for the adult formulation.

Moreover, Teva also reports improving MDR-TB product availability by supplying linezolid and pyridoxine (a vitamin supplement used in tuberculosis regimens) to the Stop TB partnership in 2022.

Expanding access to cefiderocol through collaboration agreement

In 2022, Shionogi engaged with the Global Antibiotic Research & Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI) in a collaboration agreement to scale up global cefiderocol production and distribution, specifically to meet demand in LMICs.[18]

Ensuring widespread access to group antibiotic cefiderocol – a novel antibiotic effective against aerobic gram-negative bacteria – will bolster the treatment of patients' infections, such as complicated urinary tract infections (including pyelonephritis), for which limited treatment options currently exist.

As part of the collaboration agreement, Shionogi and GARDP signed a licensing agreement, providing GARDP the right to bring cefiderocol to market in 135 countries where access to cefiderocol has faced delays. In 2023, GARDP entered a non-exclusive sublicensing agreement with Orchid Pharma for the manufacturing of cefiderocol.[19] To spur the uptake of the product in LMICs, the agreement stipulates that Orchid Pharma will submit the product to WHO's medicines prequalification (PQ) programme.

STEWARDSHIP

Progress in data sharing and conflict of interest mitigation

Specific strategies by companies are needed to reduce the misuse and overuse of antibacterial and antifungal medicines. Critically, steps to strengthen responsible practices must be applied globally and committed to for the long term to ensure changes made are sustainable, and not transient.

In 2021, seven companies were presented with an Opportunity to share raw surveillance data, which can reveal areas where infection rates are rising and resistance is emerging. Since 2021, four of the companies – GSK, Johnson & Johnson, MSD and Shionogi – have seized the Opportunity by disclosing their raw data via Vivli's AMR Register. Sharing this information is key in tracking the emergence and spread of resistant pathogens, particularly when it covers countries without national surveillance efforts. For example, the data can be used to inform treatment guidelines used by doctors and can ensure appropriate prescribing of antibiotics.

7 **Companies with an Opportunity to share raw surveillance data.**

- **4** **Achieved this Opportunity by 2023**
  GSK, Johnson & Johnson, MSD, Shionogi
- **3** **Did not achieve this Opportunity by 2023**
  Novartis, Otsuka, Sanofi

Where companies contribute to educational activities for healthcare professionals on how best to manage the risk of AMR, they must proactively avoid conflicts of interest. The two companies with Opportunities in this area, Abbott and GSK, have both demonstrated progress by no longer using branded materials in any of their educational programmes.

However, limited to no progress has been observed by all 11 companies with an Opportunity to fully decouple sales bonuses from sales volumes. Fully decoupling sales bonuses from antibiotic sales volumes is key to reduce the risk of stimulating inappropriate prescribing. Although incentives can encourage employees to work towards achieving access-related goals, bonuses and rewards for sales representatives are commonly linked to sales volume. This can negatively affect access to medicine by increasing the risk of mis-selling or over-selling products.

11 **Companies with an Opportunity to fully decouple sales bonuses from sales volumes.**

- **0** **Achieved this Opportunity by 2023**
- **11** **Did not achieve this Opportunity by 2023**
  Abbott, Alkem, Cipla, GSK, Hainan Hailing, Johnson & Johnson, MSD, Novartis, Pfizer, Sun Pharma, Viatris

WHERE COMPANIES NEED TO MAKE A GREATER IMPACT

Since the previous Benchmark, companies have taken decisive action in certain areas – actions which will help hold back the rising tide of AMR. Yet, there are areas where this analysis also identifies little movement towards realising critical Opportunities. Concerted efforts are now needed by companies to help drastically curb drug resistance and prevent unnecessary loss of life.

Addressing AMR is a daunting task, but the Foundation has identified tangible, clear ways in which companies can take action against this global health threat. By focusing on critical gaps that remain, they can have a huge impact in turning the rising tide of drug resistance. The Foundation will continue to engage with pharmaceutical companies, monitor progress and encourage them to move forward.

Research & Development	There is still an urgent need for companies to deepen their investments and engagement in antibacterial and antifungal R&D, particularly for pathogens in the highest threat categories. Many people, particularly those living in LMICs, are at risk of drug resistant infections that currently have no cure – making the development of new, effective medicines vital to saving lives.
Responsible Manufacturing	Collaboration with suppliers to ensure compliance with discharge limits throughout the supply chain is imperative. By being more involved in supporting their suppliers, companies can have a wider impact on reducing the AMR risks associated with the release of antibiotic waste. Companies need to provide clearer information on how much of their antibiotic manufacturing waste ends up in the environment, and how they are monitoring supplier compliance. This will not only allow for greater accountability across the supply chain, but it can provide valuable insights into where potential AMR risks from manufacturing are located, and where better practices are needed.
Appropriate Access & Stewardship	While some companies have taken commendable steps by introducing global access programmes and expanding product registrations, significant gaps in adopting access strategies for antibacterials and antifungals, especially for essential off-patent ones, still exist. Companies can utilise tools already available to them - such as equitable pricing policies, patient assistance programmes and technology transfers - for these medicines to reach more vulnerable populations in LMICs. In addition, to ensure access is provided in an appropriate way, companies can step away from sales incentives that stimulate the overselling of antibiotics and antifungals.

Progress on Opportunities: company updates

This section of the report goes company-by-company, looking at the 17 companies analysed in the 2021 Antimicrobial Resistance Benchmark and whether they have made progress on the Opportunities highlighted in their respective 2021 Report Cards.

The company updates feature the 2021 Opportunities in the left-hand column, with updates in the right-hand column. To see each company's full 2021 Report Card for more context and information, please follow the links on the first page of every company's progress update, or see the Access to Medicine Foundation website to look across all 17 companies.

8 large research-based pharmaceutical companies

- GSK plc
- Johnson & Johnson
- Merck & Co, Inc (MSD)
- Novartis AG
- Otsuka Pharmaceutical Co, Ltd
- Pfizer Inc
- Sanofi
- Shionogi & Co, Ltd

9 generic medicine manufacturers

- Abbott Laboratories
- Alkem Laboratories Ltd
- Aurobindo Pharma Ltd
- Cipla Ltd
- Fresenius Kabi AG
- Hainan Hailing Chemipharma Corp Ltd
- Sun Pharmaceutical Industries Ltd
- Teva Pharmaceutical Industries Ltd
- Viatris Inc

GSK plc

▶ **Read GSK's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand and tailor access and stewardship plans for critical late-stage R&D projects. As a leader in antibacterial and antifungal R&D with the largest pipeline, GSK can further strengthen their company-wide policies and project-specific plans to ensure new medicines are swiftly available to those in critical need but also to prevent excessive use. GSK maintains policies and plans for their late-stage R&D projects and can make plans more wide-reaching and timely. As an example, for its vaccine Bexsero, that is in phase III targeting *N. gonorrhaeae*, GSK can define the access countries where it plans to file for registration, based on burden of disease and where resistance for *N. gonorrhaeae* is highest and where it considers ability-to-pay in its pricing strategy. In addition, GSK can expand its stewardship plans for its medicine R&D projects through more comprehensive surveillance activities by covering more priority pathogens and countries, as well as re-evaluating its sales practices for when these medicines reach the market to safeguard them from overuse and misuse.	GSK adheres to a structured process to develop access plans for all R&D projects in Phase II and beyond. The company is implementing an evaluation process to systematically determine which late-stage pipeline projects can bring benefits to lower-income countries. In the context of AMR, GSK commits to exploring additional indications for antibiotics under development. For its vaccine Bexsero, targeting meningitis B, GSK has access plans in place in Thailand. Third-party clinical trials around the world, including Thailand, are ongoing to assess Bexsero's cross-protective effect against *N. gonorrhaeae*. Furthermore, GSK continues to commit to developing new surveillance programmes that will cover the antibiotic R&D projects in late-stage development.
Increase public disclosure on environmental risk management. GSK publishes information on some of the components of its environmental risk-management strategy including compliance percentages of its own and suppliers' sites with discharge limits. While it reports 100% compliance at its own sites, it can disclose more information to provide clear evidence of its progress publicly. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency. GSK can also apply limits directly in effluent to fully mitigate AMR risk.	GSK maintains its practice of publicly sharing some aspects of its environmental risk management strategy. GSK publicly reports that in 2022 all its own sites and 98% of its antibiotic manufacturing supplier sites were in compliance with discharge targets outlined by the AMR Industry Alliance. However, the company does not publicly disclose results of product-specific audits, encompassing antibacterial discharge levels for its own sites and suppliers' sites. Additionally, GSK does not disclose the names and locations of its suppliers.
Comprehensively mitigate COI for educational programmes. GSK organises medical education programmes for healthcare professionals on responsible use of antimicrobial medicines. It ensures that branded materials are not used in most educational programmes. It can ensure that this is applied in all educational programmes.	GSK continues to be involved in educational stewardship activities, while reporting comprehensive conflict of interest mitigation across all organised activities. The company maintains a practice of excluding product branded materials for any education programme centred on the responsible use of antimicrobial medicines.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Fully decouple incentives for sales agents from sales volumes. GSK links part of its sales agents' incentives to sales volumes of antibacterial and antifungal medicines. It can fully decouple incentives for sales agents from sales volumes again.	GSK does not fully decouple incentives for sales agents from sales volumes. Instead, sales agents are deployed to promote its antibacterial and antifungal medicines, with sales incentives partially decoupled from sales volumes. GSK maintains a capped compensation ratio of 75% fixed and 25% variable pay for primary care sales agents, including those selling the company's anti-infectives portfolio.
Publicly share raw data from surveillance programme. GSK runs the multinational Survey of Antibiotic Resistance (SOAR) programme, which is focused on community-acquired respiratory-tract infections. It can publicly share raw data from this surveillance programme, following through on clear commitments to share this with the University of Washington (as part of the GRAM project) and on the AMR Register.	GSK has shared the anonymised raw data from the multinational Survey of Antibiotic Resistance (SOAR) programme to the AMR Register, an initiative by Vivli. As with all datasets available on AMR Register, the dataset is available for researchers to access after submitting a request, which is then subjected to a review by Vivli and the relevant company before data is shared. GSK extended this data-sharing commitment from the SOAR programme to the 2022 Global Research on Antimicrobial Resistance (GRAM) report, which included single drug-resistance profiles.

Johnson & Johnson

▶ **Read Johnson & Johnson's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Diversify access plans for late-stage R&D projects. Johnson & Johnson has one medicine and one vaccine in late-stage development. It can improve access to these new products, by developing plans for registration, affordability and sustainable supply. For example, for their phase III vaccine, ExPEC9V, Johnson & Johnson can define the access countries where they will file for registration, based on burden of disease, and where it considers ability-to-pay in its pricing strategy. Johnson & Johnson can also engage with external partners with the expertise to help boost availability of the vaccine in relevant territories once approved.	Clinical trials for the ExPEC9V vaccine candidate are actively recruiting participants, including in two low- and middle-income countries (LMICs): China and Thailand. In October 2023, Johnson & Johnson announced a development and commercialisation agreement with Sanofi for the candidate. It is too early for the companies to disclose access plans for the ExPEC9V vaccine candidate.
Ensure compliance with antibacterial discharge limits at own sites and suppliers by tracking and publicly disclosing progress and results. Johnson & Johnson reports to set limits and to quantify the discharge levels at its own sites and suppliers' sites. To provide clear evidence of its progress, it can track compliance at all sites and publicly disclose the results. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.	Johnson & Johnson continues to report implementing the AMR Industry Alliance's Antibiotic Manufacturing Standard. However, based on public information, it is unclear how many of its own and supplier sites are compliant with discharge limits. Similar to 2021, Johnson & Johnson does not publicly disclose individual audit results containing antibacterial discharge levels for both its own sites and suppliers' sites. Furthermore, the company does not disclose the names and locations of its suppliers.
Expand reach of bedaquiline (Sirturo) for eligible MDR-TB patients. Johnson & Johnson has continued to reach more patients with MDR-TB through tenders, patient assistance programmes, access price settings and public or private partnerships. It can further apply these mechanisms to expand access and ensure diagnosed patients are treated, especially in countries where gaps remain between diagnosis of MDR-TB and treatment.	Johnson & Johnson continues to expand access to bedaquiline (Sirturo®) for multidrug-resistant tuberculosis (MDR-TB) patients. By the end of 2020, Johnson & Johnson had provided more than 317,000 courses of bedaquiline cumulatively to patients in 144 countries, including all 30 high-burden MDR-TB countries. By September 2023, this number has more than doubled to a total of 745,000 courses of bedaquiline, provided to patients in 159 countries, including all 30 high-burden MDR-TB countries. Three out of four MDR-TB patients on treatment globally are receiving all-oral bedaquiline-containing regimens. The majority of bedaquiline courses have been supplied via the supranational agreement with the Stop TB Partnership's Global Drug Facility (GDF). In 2023, there were three key developments affecting access to bedaquiline in LMICs. 1) In June 2023, Johnson & Johnson granted GDF appropriate licences which allows GDF to purchase generic versions of bedaquiline for the majority of LMICs. 2) In August 2023, GDF announced that Johnson & Johnson, through a competitive tender process, offered GDF and the countries it supplies a 55% price reduction for Johnson & Johnson's 6-month bedaquiline treatment course, supplying it at USD 130 per course.3) In September 2023, Johnson & Johnson publicly reported that it will not enforce any of its patents for bedaquiline in 134 LMICs.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Fully decouple incentives for sales agents from sales volumes. Johnson & Johnson does not promote bedaquiline (Sirturo) in most countries. Johnson & Johnson can apply the practice of not promoting this product globally. Further, it can fully decouple incentives for sales agents from sales volumes of all antibacterial and antifungal medicines.	Johnson & Johnson reports not deploying sales agents for bedaquiline, except in one country. However, globally, for other antibiotics and antifungals, sales agents may be deployed. Sales agents' annual performance evaluation encompasses both financial and non-financial goals, and their incentives are not solely based on sales volume targets.
Publicly share raw data from surveillance programme. Johnson & Johnson runs the multinational Drug Resistance Emergence Assessment in MDR-TB (DREAM) programme, which is focused on resistance against bedaquiline (Sirturo). It can publicly share raw data from this surveillance programme, anonymised and in a freely accessible format.	Johnson & Johnson has shared the anonymised raw data from the bedaquiline DREAM programme with the AMR Register, an initiative by Vivli. As with all datasets available on AMR Register, the dataset is available for researchers to access after submitting a request, which is then subjected to a review by Vivli and the relevant company before data are shared. Johnson & Johnson had also published aggregated results of the programme in a peer-reviewed, open-access journal.

Merck & Co, Inc (MSD)

▶ **Read MSD's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Develop and disclose project-specific plans to improve access and stewardship for R&D projects in late-stage development. MSD reports a commitment to expand access through broad registration, including in LMICs, and supports appropriate and responsible use of their antibacterial medicines. MSD can develop project-specific access and stewardship plans for all its late-stage R&D projects. For example, for its *S. pneumoniae* vaccine V116 it can commit to fast registration in countries with the highest burden of disease, and develop a pricing strategy that considers the ability to pay of target populations in those countries.	Merck & Co, Inc (MSD) did not report any updates on this Opportunity. Additionally, the company does not report any project-specific access and stewardship plans for its late-stage antibacterial or antifungal R&D projects including the *S. pneumoniae* vaccine V116 currently in Phase III of clinical development.
Expand its environmental risk-management strategy to suppliers and ensure compliance at all sites with antibacterial discharge limits by tracking and publicly disclosing progress and results. MSD reports to set limits and to quantify the discharge levels at its own sites. It can extend this practice to suppliers' sites and track compliance of both own and suppliers' sites with discharge limits and publicly disclose the results. To provide clear evidence of its progress, it can publicly report compliance at all sites. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.	MSD continues to disclose implementing the AMR Industry Alliance guidelines at its own and supplier sites. The company does not report any developments on the number of its own and supplier sites that comply with discharge limits. Similar to 2021, MSD does not publicly disclose audit results containing antibacterial discharge levels for both its own sites and suppliers' sites. Furthermore, the company does not disclose the names and locations of its suppliers.
Expand registration of medicines and vaccines to more access countries. MSD reports that ceftolozane/tazobactam (Zerbaxa®) was filed for registration in 25 access countries. It can file its antibacterial and antifungal medicines and vaccines (e.g. Zinplava™, Recarbio™ and Pneumovax 23) in more countries, including low-income countries, with a high burden of disease. It can improve disclosure on where its medicines are registered and made available.	MSD did not report any progress on this Opportunity. The company sought and secured inclusion of ceftolozane/tazobactam (Zerbaxa®) in the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML) as a Reserve antibiotic. This antibiotic is effective against multi-drug resistant bacteria, including difficult-to-treat infections caused by carbapenem resistant *Pseudomonas aeruginosa*.
Fully decouple incentives for sales agents from sales volumes. MSD runs a pilot in the UK, in which it fully decouples incentives for sales agents from sales volumes of antibacterial medicines sold in UK hospitals. It can expand this practice to all countries it operates in and to all antibacterial and antifungal medicines.	MSD did not report any progress on this Opportunity.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Publicly share raw data from surveillance programmes. MSD runs multiple AMR surveillance programmes. It can publicly share raw data from these surveillance programmes: SMART, PACTS and STAR - anonymised and in a freely accessible format. Additionally, either MSD or the managing partners can publicly share raw data from the CANWARD and BSAC surveillance programmes.	MSD has shared the anonymised raw data from the SMART surveillance programme to the AMR Register, an initiative by Vivli. As with all datasets available on AMR Register, the dataset is available for researchers to access after submitting a request, which is then subjected to a review by Vivli and the relevant company before data is shared. MSD extended this data-sharing commitment from the SMART programme to the 2022 Global Research on Antimicrobial Resistance (GRAM) report, which included single drug-resistance profiles. Data from the two other surveillance programmes MSD runs, have not been shared with the AMR Register, nor has the company reported public disclosure of the raw data from these programmes.

Novartis AG

▶ **Read Novartis's full 2021 AMR Benchmark Report Card online for additional information and context.**

Since the publication of the 2021 AMR Benchmark, Novartis has completed a 100% spin-off of its generics and biosimilars business, Sandoz. On 4 October 2023, Sandoz became an independently listed company. This report provides updates on opportunities identified in Novartis's 2021 Benchmark Report Card, looking at progress over the two-year period and incorporating information about both Sandoz and Novartis.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Engage in antibacterial and antifungal R&D including medicines and vaccines against priority pathogens. Novartis contributes to the AMR Action Fund, a joint venture that aims to bring 2-4 new antibiotics to the market by 2030 and has a partnership with GARDP to provide antibiotic formulations accessible for children with drug-resistant infections. Novartis can engage in in-house R&D, through acquisition or collaboration with other companies, or by joining existing public private partnerships, to target resistant pathogens for which R&D is limited, such as *Campylobacter spp.* and *H. pylori*.	Novartis did not report any progress on this Opportunity, referring to its earlier contributions to the AMR Action Fund.
Ensure compliance to antibacterial discharge limits at suppliers sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Novartis can expand its requirements to quantify discharge levels as it does for its own sites to all its suppliers' sites and track compliance with set limits. It can publicly disclose the results including the discharge levels. The company currently publishes information on compliance at own sites with pharmaceutical limits that include, but is not specific to, antibacterials. Novartis can also apply limits directly in effluent to fully mitigate AMR risk.	Novartis continues to report implementing the AMR Industry Alliance guidelines. The company publicly reports that, in 2022, it engaged with over 100 priority suppliers to assess their discharge levels against the standards of the AMR Industry Alliance. However, Novartis does not report any developments on the number of its own and supplier sites that are compliant with discharge limits. Similar to 2021, Novartis does not publicly disclose audit results containing antibacterial discharge levels for both its own sites and suppliers' sites. Furthermore, the company does not disclose the names and locations of its suppliers.
Expand registration and ensure availability of antibacterial and antifungal medicines. Novartis can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as daptomycin and tigecycline, to more countries, including low-income countries, with a high burden of disease.	Novartis did not report any progress related to expanding the registration of its antibiotics and antifungals to additional countries in scope of the Benchmark. In 2022, Sandoz announced plans to invest EUR 50M to increase manufacturing capacity for finished dosage form penicillins at its manufacturing site in Kundl, Austria. This brings the total investment in Sandoz's antibiotics manufacturing network in Europe to over EUR 250M. However, the extent to which this expansion will increase availability of penicillins in countries in scope is unclear.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Fully decouple incentives for sales agents from sales volumes. In Novartis' limited promotional activities directed at health-care professionals, it links part of its sales agents' incentives to sales volumes of antibacterial and antifungal medicines. It can fully decouple such incentives for sales agents.	Novartis did not report any progress on this Opportunity.
Publicly share raw data from surveillance programme. Novartis supports the national Diagnostics of Central Nervous System Bacterial Infections (KOROUN) programme, which is managed by the Polish National Medicines Institute. Either Novartis or the managing partner can publicly share raw data from this surveillance programme.	Sandoz continues to support the KOROUN surveillance programme. However, Novartis did not report updates in regard to publicly sharing the raw data from this programme. In 2022, Sandoz announced an AMR surveillance programme in collaboration with Ares, a subsidiary of OpGen Inc,. However, Novartis did not report any updates in regard to publicly sharing the raw data from this programme.

Otsuka Pharmaceutical Co, Ltd

▶ **Read Otsuka's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand breadth of R&D pipeline into more pathogens. Despite being the smallest of the large R&D-based companies assessed in the AMR Benchmark, Otsuka optimises its resources and has achieved remarkable expertise in tuberculosis R&D, being one of the main investors in TB R&D worldwide. Otsuka can now redirect this expertise and invest in innovative in-house R&D to target resistant pathogens for which R&D is limited, such as *Campylobacter spp.* and *H. pylori*, through acquisition or collaboration with other companies, or by joining existing public private partnerships.	Otsuka did not report progress on this Opportunity, referring to its current focus on tuberculosis (TB) R&D.
Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Otsuka reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. The company can develop an AMR strategy for its own manufacturing sites, the sites of suppliers and external private waste-treatment plants, based on the guidelines of the AMR Industry Alliance, of which Otsuka is a member. This includes setting limits and quantifying discharge levels to track compliance. Moreover, Otsuka can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR.	Otsuka reports that it has completed the development of an analytical method to quantify the levels of delamanid in wastewater. As a follow-up, Otsuka plans to quantify discharge levels to confirm if the existing wastewater treatment setup maintains delamanid concentration below discharge limits.
Ensure availability and affordability of delamanid (Deltyba). Otsuka can expand the availability of delamanid (Deltyba) by filing for registration in more access countries, including through its voluntary licensing agreement with Viatris, in particular in the 30 countries with the highest MDR-TB burden identified by the WHO.	Otsuka reports that since 2021, Deltyba® is newly registered in three countries in scope of the Benchmark – Brazil, Morocco and Uzbekistan. Additionally, Otsuka has also filed for registration in four countries in scope – Malaysia, Mexico, Thailand and Vietnam. To increase affordability and accessibility, Otsuka has completed a full technology transfer for its 50mg delamanid formulation to Viatris in India. In addition, Otsuka has initiated a technology transfer of delamanid's paediatric formulation. Furthermore, Otsuka reports a commitment to ensure a continuous supply of delamanid's paediatric formulation to the Stop TB Partnership's Global Drug Facility (GDF).
Engage in AMR surveillance activities. Otsuka is not active in AMR surveillance activities. It can engage in AMR surveillance programmes through setting up (in-house) programmes or by funding established programmes run by research organisations. Additionally, Otsuka should publicly share raw data collected from the programme.	Otsuka reports plans to set up surveillance activities in at least two countries in scope. However, Otsuka does not report when these surveillance activities will commence. The company reports that future surveillance results will be submitted for publication in open access journals.

Pfizer Inc

▶ **Read Pfizer's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Fully decouple incentives for sales agents from sales volumes. Pfizer fully decouples incentives for sales agents from sales volumes of antibacterial medicines in the UK. It can expand this practice to all countries it operates in and to all antibacterial and antifungal medicines.	Pfizer plans to continue its practice of decoupling incentives for sales agents from sales volume in the countries where newer access and reimbursement models are implemented, such as the 'subscription model' used in the United Kingdom. In countries where it doesn't decouple incentives for sales agents from sales volume, the company implemented a partial decoupling of financial incentives from sales volumes. In Brazil, sales agents were completely replaced by company representatives whose role and financial incentives are fully decoupled from sales volumes.
Expand breadth of R&D pipeline into more pathogens. Pfizer has the largest late-stage clinical pipeline compared to peers in the AMR Benchmark. It has made a series of acquisitions of small biotech companies to increase the size of its pipeline. Pfizer can expand the focus of its pipeline to target resistant pathogens for which R&D is limited, such as *Campylobacter spp.* and *H. pylori*.	Pfizer entered into a licensing agreement that encompasses commercial rights globally, with the exception of Asia and the United States, for SPR206, an investigational IV-administered polymyxin product candidate targeting MDR gram-negative bacterial infections in hospital settings. Meanwhile, the company has completed the Phase I trial for its oral antibacterial combination ceftibuten-avibactam prodrug, a potential treatment option for infections caused by MDR Enterobacterales. Pfizer is considering opportunities to continue the development of its *Clostridioides difficile* vaccine (PF-06425090), following non-attainment of its pre-specified primary endpoint of preventing primary *C. difficile* infection (CDI). Additionally, Pfizer's maternal vaccine candidate for prevention of Group B Streptococcus infection in infants is set to enter Phase III in the latter half of 2023. In September 2022, the Bill & Melinda Gates Foundation announced a USD 100 million grant to help support this candidate's development into Phase III, and if successfully developed and licensed, its future accessibility in lower-income countries. Pfizer's pipeline also previously included fosmanogepix, an antifungal, which completed Phase II of development. In November 2023, Basilea Pharmaceutica announced it had acquired this treatment candidate.
Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Pfizer tracks the compliance of all own sites with set discharge limits. It can also track such compliance of all its suppliers' sites since Pfizer reports all suppliers have quantified discharge levels and it can publicly disclose the results. The company currently publishes information on compliance of own and suppliers' sites with the guidelines of the AMR Industry Alliance but it is unclear whether this includes compliance to discharge limits.	Pfizer reports that over 100 antibiotic supplier sites (approximately 86%) have met voluntary discharge limits in the receiving environment. The company is committed to working with its antibiotic suppliers to achieve discharge limits by the end of 2025. Additionally, Pfizer reports it is actively working with the remaining approximately 14% of suppliers to support them in meeting discharge limits. Similar to 2021, Pfizer does not publicly disclose audit results containing antibacterial discharge levels for both its own sites and suppliers' sites. Furthermore, the company does not disclose the names and locations of its suppliers.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
Expand registration of Trumenba and NeisVac-C. Pfizer can file its vaccines Trumenba and NeisVac-C for registration in more countries, including low-income countries with a high burden of disease.	Pfizer reports that Trumenba received regulatory approval in one additional low- and middle-income country (LMIC). Although no progress is reported for NeisVac-C, the company reports it has filed Nimenrix, its other meningococcal vaccine, for registration in eight LMICs since 2021. Additionally, Cresemba, an antifungal, has been registered in eight additional LMICs. Zavicefta, a Reserve antibiotic listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML), has been registered in six additional LMICs and filed for registration in one additional LMIC.
Expand accessibility of its antibacterial and antifungal medicines in access countries. Pfizer can implement new programmes and partnerships to expand access to its antibacterial and antifungal medicines in access countries while demonstrating how it improves the availability and affordability of its medicines, including in low-income countries. For example, it can expand access to Zavicefta® and Zinforo® in Sub-Saharan Africa while taking ability-to-pay into account.	Pfizer reports that, as of May 2023, approximately 71,000 patients in LMICs have been treated with Cresemba, Zavicefta or Zinforo – already exceeding the total number treated with these medicines throughout the entirety of 2020 by 20,000, as reported in 2021. In 2023, Pfizer expanded its commitment to its Accord for a Healthier World initiative. This expansion provides individuals in 45 LMICs, 43 of which are in scope of the Benchmark, with access to Pfizer's full portfolio of on-patent and off-patent medicines and vaccines for which it has global rights, including 11 branded antibiotics and four branded antifungals, on a not-for-profit basis. Rwanda was the first country to receive deliveries of these branded products through the Accord, which included nine medicines and vaccines, including Zavicefta and Nimenrix. Pfizer reports it is currently expecting product orders, which include antibiotics and antifungals, from countries outside of Rwanda and expects to ship them in the latter half of 2023. In Ghana, Pfizer partnered with a local health-tech company to provide price discounts and microfinancing to patients, thereby improving the affordability of Zavicefta. Additionally, Pfizer was awarded a contract by UNICEF to supply 500,000 doses of Nimenrix for UNICEF's 2022 and 2023 emergency stockpile programme.

Sanofi

▶ **Read Sanofi's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand breadth of R&D pipeline into more pathogens. Sanofi has antibacterial vaccines and medicines in late-stage clinical development that target, e.g., *S. pneumonia* and *M. tuberculosis*. Sanofi can expand the focus of its pipeline to target resistant pathogens for which R&D is limited, such as *Campylobacter spp.* and *H. pylori*. It can do so by investing in in-house R&D, through acquisition or collaboration with other companies, or by joining existing public private partnerships.	Sanofi has reported progress on its pipeline, with its conjugate pneumococcal vaccine candidate (SP0202) advancing to Phase III in 2024. In October 2023, Sanofi announced a development and commercialisation agreement with Johnson & Johnson for ExPEC9V, a vaccine candidate for extraintestinal pathogenic *E. coli*, currently in Phase III of clinical development. The company has further added vaccine projects to its R&D pipeline that target bacteria not included in the priority lists published by the US Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO). This includes a *Cutibacterium acnes* mRNA vaccine candidate moving to Phase I/II in 2023 and a chlamydia mRNA vaccine candidate moving to Phase I/II in 2024.
Expand and tailor access and stewardship plans for late-stage R&D projects. Sanofi has both vaccines and medicines in late-stage clinical development. It can improve access to these new products, by developing plans for registration, affordability and sustainable supply. For example, for their phase II vaccine, Skypac, Sanofi can develop equitable pricing plans that consider ability-to-pay and apply supply chain best practices including buffer and safety stocks and shortage mitigation strategies. In addition, Sanofi can expand its stewardship plans for its medicine R&D projects by getting involved in comprehensive surveillance activities resistance trends information to their products as well as other medicines often given alongside them in the long multidrug treatments required for this disease, and to do it in relevant geographical regions where limited evidence is available.	Sanofi's conjugate pneumococcal vaccine candidate (SP0202/Skypac) is currently undergoing review under Sanofi's Global Access Plan commitment. The company did not report any further progress on its late-stage R&D projects for bacteria that are included in the priority lists published by the CDC and WHO. Sanofi has acquired worldwide commercial rights to ExPEC9v from Johnson & Johnson. It is too early for Sanofi and Johnson & Johnson to disclose access plans for the ExPEC9V vaccine candidate.
Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Sanofi can quantify discharge levels at all suppliers' sites and track compliance with set limits, as it does at own sites, and publicly disclose the results. To provide clear evidence of its progress it can publicly report compliance at all sites. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.	Sanofi continues to report implementing the AMR Industry Alliance guidelines. The company publicly reports that 72% of its own manufacturing sites launched a programme to monitor, manage, and reduce pharmaceutical discharges. However, Sanofi does not report any developments on the number of its own and supplier sites that are compliant with voluntary discharge limits. Similar to 2021, Sanofi does not publicly disclose audit results that specify antibacterial discharge levels of its own sites and suppliers' sites. It also does not disclose the names and locations of its suppliers.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand registration of antibacterial and antifungal medicines. Sanofi can expand filing for registration of its off-patent antibiotics and antifungals listed on the 2021 WHO EML, such as colistin and fosfomycin, to more countries, including low-income countries, with a high burden of disease.	Sanofi did not report any specific developments regarding the registration filings of antibacterial and antifungal medicines. Sanofi reports that cefotaxime, ceftriaxone and colistin – all listed on the 2023 WHO Model List of Essential Medicines (EML) – are no longer part of the company's portfolio. To increase the availability of its products in LMICs, Sanofi launched its non-profit Global Health Unit in 2021. This initiative supplies 30 of its most essential medicines, including metronidazole (Access antibiotic listed on WHO EML 2023) and rifampicin (Watch antibiotic listed on WHO EML 2023), to 40 LMICs. Furthermore, the Impact® brand was launched in 2022 to provide standard care medicines on a non-profit basis to 40 LMICs.
Publicly share raw data from surveillance programme. Sanofi supports a national programme focused on *S. pneumoniae*, the Observatoires Régionaux du Pneumocoque (ORP) programme, managed by the National Reference Centre for Pneumococci (NRCP). Either Sanofi or the NRCP can publicly share raw data from this surveillance programme.	Sanofi reported it is no longer partnering with the Observatoires Régionaux du Pneumocoque (ORP) programme in France since the contract has expired.

Shionogi & Co, Ltd

▶ **Read Shionogi's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand breadth of R&D pipeline and depth of R&D access and stewardship plans. Shionogi has one of the most diverse pipelines across all large research-based companies in the AMR Benchmark. It can expand the focus of its pipeline to target resistant pathogens for which R&D is limited, such as *Campylobacter spp.* and *H. pylori*. For its recently approved cefiderocol (Fetroja/ Fetcroja), Shionogi engages with generic medicines manufacturers and access-related organisations such as GARDP and the Clinton Health Access Initiative to increase affordability and availability. Shionogi can intensify these engagements to reach more patients and countries. Shionogi can continue to build towards a comprehensive surveillance programme to ensure cefiderocol is not used excessively.	Shionogi has expanded the breadth of its AMR pipeline to include more pathogens. For olorofim (F901318), a novel oral antifungal therapy developed by F2G to treat invasive aspergillosis, the company will be conducting clinical trials and subsequent registration and commercialisation in Europe and Asia. This project is currently in Phase III of clinical development. In July 2023, Shionogi acquired Qpex, a company developing two combination products targeting resistant gram-negative pathogens. These products, designed for both oral and IV administration, are based on xeruborbactam, a novel boronic acid ß-lactamase inhibitor, and focus on pathogens like carbapenem-resistant *A. baumannii*, *P. aeruginosa*, and *Enterbacterales*. For more details about the collaboration progress between Shionogi, Global Antibiotic Research and Development Partnership (GARDP) and Clinton Health Action Initiative (CHAI) to ensure access and stewardship for cefiderocol, please refer to update below.
Expand registration to cefiderocol (Fetroja/ Fetcroja) in access countries. Shionogi can file cefiderocol (Fetroja/ Fetcroja) for registration in access countries. Further, to accelerate the availability of cefiderocol in access countries Shionogi can consider voluntary non-exclusive licensing, compassionate use programmes and public/private partnerships.	In June 2022, Shionogi, GARDP and CHAI engaged in a three-way collaboration agreement which aims to roll out cefiderocol, while ensuring quality assurance and appropriate use. This collaboration also strives to develop real-world best practices on how access can be achieved. Together with this collaboration agreement, Shionogi and GARDP signed a first-in-kind and publicly available license and technology transfer agreement for cefiderocol. This agreement encompasses the development, registration, manufacturing and commercialisation of the product. The license territory covers 135 countries including all low-income countries and most lower-middle and upper- middle income countries. To increase affordability, Shionogi has waived its cost recoupment fees on cefiderocol sales in low-income and lower middle-income countries. In September 2023, GARDP entered into a sublicensing agreement with Orchid Pharma for the manufacturing of cefiderocol. The sublicence agreement stipulates that Orchid Pharma will submit the product to the World Health Organization's (WHO) medicines prequalification (PQ) programme. In March 2023, the WHO PQ Unit published the first invitation to manufacturers of medicinal products for treatment of multi-drug resistant bacterial infections, to submit an Expression of Interest (EOI) for product evaluation of cefiderocol.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand adaptations to brochures and packaging to consider more patient needs. Shionogi adapts brochures to take account of paediatric use to support the appropriate use of cefcapene pivoxil (Flomox) by patients. It can further adapt its brochures and packaging of all antibacterial and antifungal medicines to consider local languages, literacy levels, environmental conditions and patient adherence to treatment.	Shionogi did not report any further adaptations to brochures and packaging for its marketed antibiotics.
Publicly share raw data from surveillance programmes. Shionogi runs the multinational SIDERO-WT programme, which is focused on resistance against antibacterials targeting Gram-negative bacteria. It can publicly share raw data from this surveillance programme, following through on commitments to share this with the AMR Register in 2021. Additionally, either Shionogi or the managing partners should publicly share raw data from the other surveillance programmes it is involved in.	Shionogi has shared the anonymised raw data from the SIDERO-WT programme to the AMR Register, an initiative by Vivli. As with all datasets available on AMR Register, the dataset is available for researchers to access after submitting a request, which is then subjected to a review by Vivli and the relevant company before data is shared. Data from the other four surveillance programmes Shionogi is involved in, have not been shared with the AMR Register, nor has the company reported public disclosure of the raw data from these programmes.

Abbott Laboratories

▶ **Read Abbott's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Request and review discharge levels of all suppliers and increase public disclosure on environmental risk management. Abbott can expand its environmental risk management requirements to all suppliers by fully implementing its supplier contract template which outlines specific provisions for AMR. Abbott currently requests and reviews discharge levels for only a subset of its suppliers. Abbott can also publicly disclose more information on how it manages environmental risk related to antibacterial manufacturing. It can publish information on its progress in implementing the strategy, the limits it sets, and the results of the audits of own and suppliers' sites including antibacterial discharge levels.	In 2021, Abbott introduced AMR provisions within the medicines business' template contract for its suppliers. These provisions require suppliers to implement liquid and solid waste management practices, adhere to antimicrobial discharge limits, and provide discharge level information upon request. Abbott publicly reports that the contract is being implemented with suppliers for its branded generic medicines business. In addition, support is provided to suppliers to cohere with the provisions. For example, since 2022, Abbott offers free wastewater analysis to all suppliers that exceed discharge limits based on mass balance quantifications. To identify high-risk suppliers for AMR, Abbott reports the use of a desktop assessment tool since 2023. This involves a questionnaire including questions on pharmaceuticals in the environment and AMR. It is unclear how many supplier sites out of the total are compliant with discharge limits. In the public domain, Abbott reports regularly quantifying antibiotic discharge levels against set discharge limits.
Expand registration and ensure availability of antibacterial and antifungal medicines. Abbott can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as gentamicin, itraconazole and tigecycline, to more countries, including low-income countries, with a high burden of disease. Further, it can expand equitable access in countries where medicines have been registered.	In India, Abbott has expanded registration for two Access antibiotics and two antifungals listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML). Similarly, in the Middle East, Turkey, Africa and Pakistan, Abbott has registered four Watch antibiotics listed on the same EML. Clarithromycin is the company's most widely filed antibiotic, with filings spanning 31 low-income countries and 55 lower-middle income countries, and market presence in the majority of them. Abbott highlights that registration expansion for in-licensed products can be constrained by contractual terms with licensors. Abbott did not report any developments pertaining to expanding access to its off-patent/generic antibacterials and antifungals.
Fully decouple incentives for sales agents from sales volumes. Abbott ran a pilot in India where it fully decoupled incentives for sales agents from sales volumes of an anti-infective for three months. It can expand this practice to more countries where it markets antibacterial and/or antifungal medicines and to more relevant products.	Abbott reports that its sales agents are incentivised for the sales of a basket of medicines that covers different therapeutic areas and includes antibacterial and antifungal medicines. Sales incentives are partially decoupled from sales volumes and, in India, are partially based on qualitative targets, including targets related to AMR risks. However, the specific percentage of variable pay or the level at which incentives are set is not disclosed.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
Comprehensively mitigate COI for educational programmes. Abbott organises medical education programmes for healthcare professionals on responsible use of antimicrobial medicines. It can ensure that branded materials are not used in any educational programmes, as is now the case for some.	Abbott continues to organise medical education programmes that focus on the responsible use of antimicrobial medicines for healthcare professionals, tailored to the needs of healthcare systems and in collaboration with appropriate partners across all regions where its medicines business operates. As of 2023, branded materials are no longer used in any educational programmes.

Alkem Laboratories Ltd

▶ **Read Alkem's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Alkem reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. The company can develop an AMR strategy for its own manufacturing sites, the sites of suppliers and external private waste-treatment plants, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Moreover, Alkem can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.	For the first time, Alkem has publicly reported the implementation of Zero Liquid Discharge (ZLD) systems across 64% of its manufacturing sites. The company also publicly reports the city-level locations of its manufacturing sites, with 18 located in India and two in the United States. However, it remains unspecified which sites manufacture antibacterials and/or antifungals. In addition, Alkem does not report an AMR-specific environmental risk-management strategy.
Expand registration and ensure availability of antibacterial and antifungal medicines. Alkem can expand registration and ensure equitable access of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefotaxime and tigecycline, to more countries, including low-income countries, with a high burden of disease. It can improve transparency on where its medicines are registered and made available.	Alkem did not report any developments specific to this Opportunity.
Apply responsible sales practices for antibacterial and antifungal medicines. Alkem can apply responsible sales practices for antibacterial and antifungal medicines by not deploying sales agents. Alternatively, it can fully decouple incentives for sales agents from sales volumes of such medicine.	Alkem did not report any developments specific to this Opportunity.

Aurobindo Pharma Ltd

▶ **Read Aurobindo's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Increase public disclosure on environmental risk management. Aurobindo publishes information on some of the components of its general environmental risk-management strategy. It can publish more information on how it manages environmental risk related to antibiotic discharge into the environment to curb AMR. While Aurobindo reports that all its own sites are compliant with set limits, it can provide clear evidence by publicly disclosing its progress in implementing the strategy and by publishing the audit results of own and suppliers' sites, including antibacterial discharge levels if applicable.	Aurobindo publicly reports that it performed mass balance calculations for antibiotics and ensured compliance with discharge limits, in line with the AMR Industry Alliance guidelines. Additionally, the company publicly reports that some manufacturing sites have implemented Zero Liquid Discharge (ZLD) systems. While Aurobindo manufactures more than 99% of its API in-house, it publicly reports that suppliers have been asked to adopt the AMR Industry Alliance guidelines, including discharge targets.
Expand access and ensure adequate supply of antibacterial and antifungal medicines in more access countries. Aurobindo has a Day-1 generic policy by which it introduces a generic product as soon as the patent on a brand expires for the EU and USA. It can expand access to its generic antibiotics and antifungals listed on the 2021 WHO EML to more products and countries, allowing for generic options to be made available in access countries as soon as the originator's patent expires.	Aurobindo reports it has extended the reach of its antibiotic portfolio from 34 to 41 countries in Africa and Asia. The number of products offered in the antibiotic portfolio has increased from 20 to 25, encompassing products such as ciprofloxacin, azithromycin, ampicillin/sulbactam, piperacillin/tazobactam and ertapenem. The company has registered ertapenem in 15 countries, and filed for registration in seven additional countries across Africa, Latin America and Asia. In addition, Aurobindo reports its intention to manufacture and market antifungals such as liposomal amphotericin B and posaconazole in the near future.
Expand adaptations to brochures and packaging to consider more patient needs. In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Aurobindo adapts brochures to take account of local languages. It can further adapt its brochures and packaging to consider literacy levels, paediatric use, environmental conditions and patient adherence to treatment.	Aurobindo has reported filing for regulatory approval of bilingual packaging for its antibiotics in African countries. The company does not report details of any further packaging adaptations for its antibiotics.

Cipla Ltd

▶ **Read Cipla's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand environmental risk-management strategy to include suppliers and ensure compliance with limits. Cipla tracks compliance with discharge limits it set for its own manufacturing sites. It can quantify discharge levels at all suppliers' sites and track compliance with limits, and publicly disclose the results. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.	Cipla has conducted a workshop with suppliers on how to quantify discharge levels with mass balance calculations. To support its suppliers, Cipla reports it will conduct training and awareness sessions on a regular basis. Currently, it is unclear how many of the supplier sites have quantified discharge levels and are compliant with discharge limits. Cipla highlights that due to the absence of any regulations, ensuring supplier adherence to discharge limits poses challenges. In regard to its own manufacturing sites, Cipla reports that all ten of its sites are now compliant with discharge limits in the receiving environment – up from two sites in 2021. The company reports that Zero Liquid Discharge (ZLD) systems are applied at its manufacturing sites in Bommasandra, Goa, Indore, Kurkumbh, Sikkim and Virgonagar. In addition, Cipla eliminates the risk of AMR by not reusing recycled water from ZLD sites in horticulture and gardening.
Expand registration antibacterial medicines to more access countries and ensure adequate supply. Cipla can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as itraconazole and levofloxacin to more countries, including low-income countries and ensure adequate supply. To ensure adequate supply, Cipla can promote capacity building and technology transfer initiatives in access countries, to improve access to its medicines.	Cipla reports it has marketed ceftazidime/avibactam in India. In 2022, this antibiotic – also featured on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML) as a Reserve antibiotic – lost its exclusivity status and became a generic drug in India. In South Africa, Cipla has registered fosfomycin and nitrofurantoin, both listed on the 2023 WHO EML as Reserve and Access antibiotics respectively. While no specific initiatives are reported, Cipla states its intentions toward expanding access to plazomicin (Zemdri®) and ceftriaxone/sulbactam (Elores™) in low- and middle-income countries (LMICs). However, due to a lack of evidence-based indications for use or recommendations in high-quality international guidelines, WHO actively advises against the clinical use of ceftriaxone/sulbactam. The company does not report any updates on how it ensures an adequate supply of antibacterial medicines in LMICs.
Fully decouple incentives for sales agents from sales volumes. Cipla links part of its sales agents' incentives to sales volumes. It can fully decouple incentives for sales agents from sales volumes of antibacterial and antifungal medicines again.	Cipla did not report any developments specific to this Opportunity.

Fresenius Kabi AG

▶ **Read Fresenius Kabi's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Integrate AMR in environmental risk-management strategy and increase public disclosure. Fresenius Kabi reports an environmental risk management strategy that includes auditing processes and recently became a member of the AMR Industry Alliance. The company can integrate AMR in its strategy for its own manufacturing sites, the sites of suppliers and external private waste-treatment plants, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Moreover, Fresenius Kabi can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.	Fresenius Kabi publicly reports to be in the process of fully integrating the manufacturing standards of the AMR Industry Alliance into its environmental risk-management strategy. The company requires all its own sites to quantify discharge levels through mass balance calculations, with certain locations also conducting chemical analysis on wastewater samples. Fresenius Kabi reports that approximately one-third of its own manufacturing sites are compliant with discharge limits in the receiving environment. In instances where discharge limits are exceeded, investigation and improvement plans to reach compliance are developed. Additionally, the company publicly reports that, since 2021, it has introduced new methods and systems for treating wastewater, aiming to control discharge levels of antibiotics. Fresenius Kabi revised its Third-Party Code of Conduct (CoC) to specify that suppliers are expected to make reasonable efforts to meet discharge limits. The company is in the process of evaluating all its suppliers. Currently, approximately half of the company's assessed supplier sites are reported to be compliant with discharge limits in the receiving environment.
Expand availability and ensure continuous supply of antibacterial and antifungal medicines to more access countries. Fresenius Kabi expands access through direct selling contracts or tenders and reports a set of cost-containment measures. It also reports to ensure accurate demand planning and data sharing. Fresenius Kabi can ensure equitable access and adequate supply of its antibiotics and antifungals listed on the 2021 WHO EML in more access countries. For example, Fresenius Kabi can build on capacity or mitigate against shortages by working with several API suppliers.	Fresenius Kabi did not report any updates on expanding the availability of antibacterial and antifungal medicines in countries in scope of the Benchmark. The company expanded Active Pharmaceutical Ingredient (API) production capacity at its manufacturing site in Italy. Yet, the extent to which this has increased the availability in countries in scope remains unclear. Fresenius Kabi reports on several challenges it encounters in ensuring a continuous supply of essential medicines, including economic factors such as rising production costs, increasing environmental standards which require additional resources and European Union's legal proposals lacking incentives for strengthening the generics industry.
Expand registration of antibacterial and antifungal medicines. Fresenius Kabi reports developing generic IV formulations that are ready to launch directly after the patents of the branded products expire. It can apply this policy in access countries and register its antibiotics and antifungals listed on the 2021 WHO EML, (e.g. daptomycin and caspofungin), in more countries, including in low-income countries with a high burden of disease.	Fresenius Kabi reports it has received approvals for ten antibacterial medicines across seven low- and middle-income countries (LMICs) cumulatively. Among these, two products are listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML).

Hainan Hailing Chemipharma Corp Ltd

▶ **Read Hainan Hailing's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Hainan Hailing reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. The company can develop an AMR strategy for its own manufacturing sites, the sites of suppliers and external private waste-treatment plants, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Moreover, Hainan Hailing can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.	Hainan Hailing did not report any progress on this Opportunity.
Expand registration and ensure availability of antibacterial and antifungal medicines. Hainan Hailing can expand registration and ensure equitable access of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefepime and ceftazidime, to more countries, including low-income countries. It can improve transparency on where its medicines are registered and made available.	Hainan Hailing did not report any progress on this Opportunity.
Apply responsible sales practices for antibacterial and antifungal medicines. Hainan Hailing can apply responsible sales practices for antibacterial and antifungal medicines by not deploying sales agents. Alternatively, it can fully decouple incentives for sales agents from sales volumes of such medicines.	Hainan Hailing did not report any progress on this Opportunity.

Sun Pharmaceutical Industries Ltd

▶ **Read Sun Pharma's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Sun Pharma reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. It reports having one owned manufacturing site, which employs Zero Liquid Discharge (ZLD) treatment processes. The company can develop an AMR strategy for its own site and suppliers, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Sun Pharma can publish information on how it manages environmental risk related to antibacterial manufacturing. The company publishes limited information about this.	Sun Pharma reports a correction to the information contained in the 2021 Benchmark regarding its number of antibiotic manufacturing sites. Sun Pharma reports that antibiotics are manufactured at four active pharmaceutical ingredient (API) manufacturing sites and eight formulation sites. All 12 sites are reported to be Zero Liquid Discharge (ZLD) sites, implying that no liquid is discharged into the environment from these facilities. However, it remains unclear whether recycled water is reused for gardening and horticulture. Sun Pharma has initiated a process to measure antibiotic levels in wastewater to verify discharge limit compliance. The company did not demonstrate any progress on increasing public disclosure concerning its environmental risk management. In 2022, Sun Pharma faced penalties from the Punjab Pollution Control Board due to discharge of untreated wastewater from its Toansa site into the environment. In a separate case, the National Green Tribunal asked Sun Pharma to pay compensation for releasing untreated wastewater from its Madhuranthagam's site, despite being labelled as a ZLD site. In both instances, it's unclear whether wastewater containing antibiotics was discharged.
Expand availability and ensure continuous supply of antibacterial and antifungal medicines to more access countries. Sun Pharma can ensure equitable access and adequate supply of its antibiotics and antifungals listed on the 2021 WHO EML (e.g. the antifungal itraconazole and the reserve antibiotic tigecycline) in more access countries. For example, Sun Pharma can ensure accurate demand planning and data sharing, build on capacity or mitigate against shortages by working with several API suppliers.	Sun Pharma reports it has increased access to anti-infectives in nine African countries with varying product counts, including Benin (6), Gabon (5), Togo (5), Burkina Faso (4), Mali (2), Niger (2), Chad (2), Mauritania (1). The company also reports it has registered or filed for registration at least one product in 64 low- and middle-income countries (LMICs). Yet, it is unclear whether these products include antibacterial and antifungal medicines listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML), along with the strategies employed to ensure availability and affordability in the mentioned African countries. To ensure accurate demand planning, Sun Pharma reports forecasting 6-12 months in advance and closely monitoring buffer stocks.
Apply responsible sales practices for antibacterial and antifungal medicines. Sun Pharma can apply responsible sales practices for antibacterial and antifungal medicines by not deploying sales agents. Alternatively, it can fully decouple incentives for sales agents from sales volumes of such medicines.	Sun Pharma did not report any progress on this Opportunity.

Teva Pharmaceuticals Industries Ltd

▶ **Read Teva's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Teva can set limits and quantify discharge levels to track compliance at all suppliers' sites, as it does at its own sites, and publicly disclose the results. Teva reports the goal to audit half of all supplier sites by end of 2030. Teva can also publish information on how it manages environmental risk related to antibacterial manufacturing. The company currently publishes limited information.	Teva has continued its efforts to achieve compliance with discharge limits for antibiotic waste. It reports that all 33 of its own sites were assessed in 2022 and 21 (64%) sites are compliant with discharge limits in the receiving environment. This is an improvement from 2021, when 10 (31%) of its own sites were reported as compliant. Teva also publicly discloses this information in the public domain. Teva reports it has communicated its expectations to follow the AMR Industry Alliance standards to 50 of its approximately 140 priority suppliers. In 2023, Teva has rolled out a questionnaire to suppliers to determine the status of their compliance with discharge limits.
Expand registration of antibacterial and antifungal medicines. Teva can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefalexin, colistin and nystatin, to more countries, including low-income countries.	Since 2021, Teva reports that it has filed antibacterial and antifungal medicines, listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML), for registration in five additional low and middle-income countries (LMICs). These include azithromycin, fosfomycin, fluconazole, caspofungin and terbinafine. However, the company highlights expanding registration for in-licensed products can be constrained by contract terms with each licensor.
Ensure continuous supply of antibacterial and antifungal medicines. Teva mitigates against shortage risks, e.g., by maintaining a flexible safety stock management process and keeping buffer stocks. It can implement several strategies to mitigate against shortage risks in access countries, e.g., build local manufacturing capacity and transfer technology into access countries.	Teva reports that it supplies antibiotics to 57 markets, including 21 LMICs. Almost 80% of the expected antibiotic sales volume for 2023 is reported to be manufactured in-house. Teva reports that it has supplied 438,830 doses of antibiotics to address national shortages in South Africa. Additionally, the company reports supplying linezolid and pyridoxine (a vitamin supplement used in tuberculosis regimens) through tenders to the Stop TB partnership in 2022. Furthermore, in 2022, Teva reports its donations exceeded 25 million doses of antibiotics, valued at over USD 56 million, to various countries around the world, the majority of which are LMICs. Additionally, over 3.2 million doses of antibiotics were donated to the Ukrainian relief effort in 2022.

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Expand adaptations to brochures and packaging to consider more patient needs. In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Teva adapts brochures to take account of local languages. It can further adapt its brochures and packaging to consider literacy levels, paediatric use, environmental conditions and patient adherence to treatment.	Teva reports continuing to insert information leaflets in four languages in its antibiotic packaging, with aims to extend this practice to more countries. On packaging of certain products, Teva includes information on the importance of appropriate use of antibiotics. The company also reports implementing tamper-proof packaging in response to global serialisation regulations.

Viatris Inc

▶ **Read Viatris's full 2021 AMR Benchmark Report Card online for additional information and context.**

2021 OPPORTUNITY **What was the Opportunity shared in the AMR Benchmark?**	2023 UPDATE **What progress has been made on this Opportunity?**
Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Viatris can set limits and quantify discharge levels to track compliance at all suppliers' sites and it can publicly disclose the results. Viatris can also publish information on how it manages environmental risk related to antibacterial manufacturing. To provide clear evidence of its progress it can publicly report compliance at all sites. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.	Viatris continues to report that all its own manufacturing sites are compliant with discharge limits in the receiving environment. Viatris also publicly discloses this information. In addition, Viatris publicly reports that it has adopted the AMR Industry Alliance's Antibiotic Manufacturing Standard to manage AMR risk from antibacterial manufacturing. The company publicly reports that 15 supplier sites have been audited against the AMR Industry Alliance guidelines through 2022.
Improve accessibility of pretomanid (Dovprela) and delamanid (Deltyba). Viatris filed delamanid (Deltyba) and pretomanid (Dovprela) for registration in seven and 23 access countries. It can expand the availability of these MDR-TB treatments by filing for registration in more access countries, in particular the countries with a high burden of MDR-TB identified by the WHO, where it has commercialisation rights. Accessibility can be improved through public/private partnerships, patient assistance programmes and donations.	Viatris has registered, or has filed for registration, delamanid (Deltyba®) and pretomanid (Dovprela) in six and 27 countries in scope of the Benchmark respectively, in comparison to seven and 23 countries recorded in 2021. Collaborating with MedAccess and the TB Alliance in 2022, Viatris announced an agreement to reduce the price of pretomanid by 34%. As a result, the maximum price of pretomanid charged by Viatris came down to USD 240 per six-month treatment course. As a result of the price reduction, it is projected that globally an additional 36,000 patients can be treated successfully, and 31,000 adverse events can be averted. Furthermore, Viatris reports that the shelf life of pretomanid has been extended from 36 months to 48 months, allowing for longer storage periods, reducing the frequency of resupply and allowing for optimised logistics and reduced waste. Pretomanid is newly included in the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML) for treatment of multidrug-resistant or rifampicin-resistant tuberculosis.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
Expand registration of generic antibacterial and antifungal medicines. Viatris can expand registration of its generic antibiotics and antifungals listed on the 2021 WHO EML, such as linezolid, polymyxin B, and amphotericin b, to more countries, including low-income countries.	Since 2021, Viatris has increased the number of filed registrations for amoxicillin, amoxicillin/clavulanic acid, isoniazid, linezolid, vancomycin and flucytosine in multiple countries within scope of the AMR Benchmark. Since 2021, these products – all listed on the WHO EML 2023 – are on average filed in two additional countries in scope. Among these, filed registrations for linezolid have increased the most, from two countries by 2021 to 13 countries by 2023.
Fully decouple incentives for sales agents from sales volumes. Viatris does not promote pretomanid (Dovprela) and flucytosine. Viatris can expand this practice to all antibacterial and antifungal medicines. Alternatively, it can fully decouple incentives for sales agents from sales volumes of all antibacterial and antifungal medicines.	Viatris reports that in many low- and middle-income countries (LMICs) it sells directly to distributors, and that in these countries, it does not deploy sales agents. The company did not disclose an update on sales incentives in countries where it deploys sales agents for antibacterial and antifungal medicines.
Adapt brochures and packaging. In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Viatris can adapt its brochures and packaging to consider local languages, literacy levels, paediatric use, environmental conditions and patient adherence to treatment.	For its generic medicines, Viatris reports it does not adapt brochures and packaging for its antibacterial and antifungal medicines. For pretomanid, Viatris reports inserting information leaflets in the regulatorily required languages and four additional languages (English, French, Spanish, and Russian), unless one of those four is the regulatory authority language.

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