Antimicrobial Resistance Benchmark 2026

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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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FOREWORD

Tilting the battle against superbugs in humanity's favour

The need for new antibiotics has never been greater. Without significant change, antimicrobial resistance (AMR) will cause a devastating rise in deaths from preventable infections over the next two decades, with vulnerable populations living in poorer countries hit the hardest.

This fourth edition of the AMR Benchmark highlights the scale of the challenge and presents concrete examples of positive actions that can be taken by pharmaceutical companies. It identifies some grounds for hope, including recent regulatory approvals for three antibiotics with innovative characteristics and several promising products in late-stage development. These advances show it is possible to tilt the battle against superbugs in humanity's favour. Overall, however, the research & development (R&D) pipeline remains worryingly thin, and industry investment has lost momentum.

In evaluating industry performance, our approach focuses on those areas where companies have a clear responsibility in the AMR fight: R&D, Responsible Manufacturing and Appropriate Access & Stewardship. With drug resistance now the biggest single threat to healthcare worldwide, a decisive step up in commitments in all three fields is urgently needed.

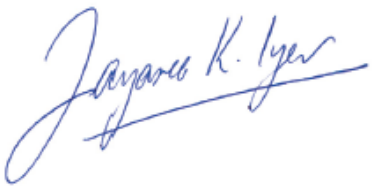
It is particularly concerning that the number of pipeline projects from large research-based pharmaceutical companies has shrunk by 35% over the past five years, with just three big players continuing to invest in innovative antimicrobial R&D. Smaller biotech firms have stepped in to fill some of the gaps, but they are constrained by limited access to capital and a lack of global reach.

The scarcity of projects in development makes it vital that medicines which do reach the market are accessible to the people who need them most – especially in low- and middle-income countries (LMICs), where serious access gaps persist. A handful of late-stage clinical development projects targeting drug-resistant urinary tract, intra-abdominal and respiratory infections could save many thousands of lives every year if access plans make them available to people in LMICs, who face the highest burden of drug resistance.

At present, the availability of antibiotics in LMICs is often woefully inadequate, especially when it comes to products for children. As a result, patients too often receive suboptimal treatments that are not up to the job, allowing resistance to develop. Against this backdrop, the modest improvement in product registrations seen since the last Benchmark report is encouraging. This could be a springboard to making far better use of lifesaving medicines in future.

There is no time to lose. More than one million people die each year as a direct result of drug-resistant infections, while AMR contributes to over four million deaths in total. By 2050, direct and indirect deaths are projected to rise to nearly two million and more than eight million, respectively.

This report sets out what must be done to minimise the threat by ensuring the sustainable development, supply and appropriate use of antibiotics for the benefit of the entire world. The necessary steps – from strengthening the R&D pipeline to improving product registration and antibiotic stewardship – are well known. What is needed now is more comprehensive action across the board. It is up to all stakeholders to deliver.



Jayasree K. Iyer
Chief Executive Officer
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Table of Contents

Executive Summary

Since the World Health Organization (WHO) declared antimicrobial resistance (AMR) a global health threat in 2014, significant progress has been made in raising awareness and mobilising global efforts to combat AMR. However, there is a long road ahead in curbing this threat, with more people dying due to AMR and lack of access to antimicrobials than from HIV/AIDS and malaria and these numbers still expected to rise. For people living in low- and middle-income countries (LMICs), where the burden of infectious diseases is disproportionally high, the combined impact of limited access to antimicrobials and rising drug resistance is devastating. But AMR is not an insurmountable challenge.

Since 2018, the AMR Benchmark has been tracking how pharmaceutical companies active in the antimicrobials space have taken action to combat drug resistance and ensure appropriate access to their products in LMICs. Not only can this protect people around the world from superbugs but, in the context of AMR, keeping effective antibiotics available to patients and healthcare systems also allows for the continued introduction of innovation in therapeutic areas like surgery and oncology.

By examining company efforts, this fourth iteration of the Benchmark sheds light on progress and reveals where the most urgent action is needed to save lives.

What does the Benchmark measure?

The 2026 AMR Benchmark Report evaluated the efforts of 25 pharmaceutical companies, comprised of seven large research-based companies, ten generic medicine manufacturers and eight small- and medium-sized enterprises (SMEs). The inclusion of these SMEs reflects these players' immense importance in stepping up antimicrobial research and development (R&D) while the exodus of large research-based companies in this space continues. However, with substantially less capital, in-house expertise and global commercial presence, SMEs face an even more challenging scientific and commercial journey in bringing antimicrobials to market. A reality made manifest by Pulmocide's January 2026 termination of its Phase II trial for opelconazole. This was the company's sole pipeline project analysed, leading to Pulmocide's removal from the 2026 AMR Benchmark Report. It was initially in scope among SMEs in the 2026 AMR Benchmark Methodology.*

In addition to assessing company pipelines and access and stewardship plans in the Research & Development (R&D) area of its analysis, the Benchmark also looks at what companies are doing to address AMR across their marketed products across Responsible Manufacturing and Appropriate Access & Stewardship.

Large research-based companies are assessed across R&D, Responsible Manufacturing and Appropriate Access & Stewardship. Generic medicine manufacturers are assessed in Responsible Manufacturing and Appropriate Access & Stewardship. SMEs are only assessed in R&D.

7 LARGE INNOVATIVE PHARMACEUTICAL COMPANIES

- GSK plc
- Johnson & Johnson
- Merck & Co, Inc
- Otsuka Pharmaceutical Co, Ltd
- Pfizer Inc
- Sanofi
- Shionogi & Co, Ltd

10 GENERIC MEDICINE MANUFACTURERS

- Abbott Laboratories Ltd
- Alkem Laboratories Ltd
- Aurobindo Pharma Ltd
- Cipla Ltd
- Fresenius Kabi AG
- Hikma Pharmaceuticals plc
- Sandoz
- Sun Pharmaceutical Industries Ltd
- Teva Pharmaceutical Industries Ltd
- Viatris Inc

8 SMALL- AND MEDIUM-SIZED ENTERPRISES

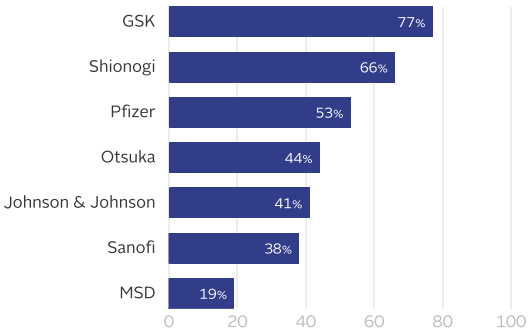
- Basilea Pharmaceutica AG
- BioVersys AG
- Evopoint Biosciencs Co, Ltd
- F2G Ltd
- Innoviva, Inc
- Iterum Therapeutics plc
- TenNor Therapeutics Ltd
- Venatorx Pharmaceuticals, Inc.

** After the period of analysis of the Benchmark, the Global Antibiotic Research and Development Partnership (GARDP) and Venatorx (an SME) announced the termination of their collaboration agreement on cefepime–taniborbactam, one of the two projects from Venatorx that were analysed in the Benchmark.*

How does industry fare in AMR and access?

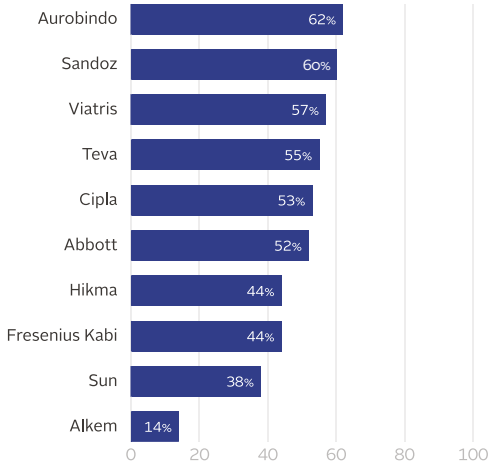
Overall, the Benchmark identifies hopeful spots of progress from companies still engaged in the antimicrobial space, but industry-wide efforts are being outpaced by drug resistance. The decrease in antimicrobial R&D is particularly concerning, especially for children. There are a handful of promising projects in late-stage development that target drug-resistant urinary tract, intra-abdominal and respiratory infections that could save many thousands of lives every year if they are made available in LMICs. However, even the availability of existing antimicrobials is lacking across LMICs. Far more comprehensive actions are now needed across the board to transform the fight against AMR.

GSK mantains lead, Shionogi makes biggest leap forward, but significant opportunities for industry action remain



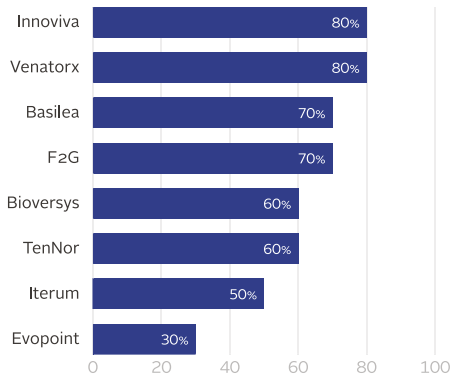
LARGE RESEARCH-BASED COMPANIES
GSK remains the leading company compared with peers, performing consistently well across all areas, leading in R&D and Appropriate Access & Stewardship, and demonstrating strong performance in Responsible Manufacturing. Pfizer, the former joint leader in 2021, has been outpaced by Shionogi, which has demonstrated stronger performance across all areas. Performance across companies remains mixed.

Aurobindo remains top performer, but overall slowdown in industry efforts



GENERIC MEDICINE MANUFACTURERS
Aurobindo remains the leading company compared with peers, leading in Responsible Manufacturing, and standing out for registering its off- patent products. It is followed closely by Sandoz (newly assessed), Viatris and Teva. Cipla and Abbott perform above the middle mark, demonstrating mixed strengths across the Research Areas.

AMR Benchmark's new evaluation of SMEs reflects their central role in antimicrobial R&D



SMALL- AND MEDIUM- SIZED ENTERPRISES (SMEs)
These companies are only assessed in R&D. Although they are assessed on the same grounds as large research-based companies – targeted pathogens, pipeline innovation and access and stewardship planning – they are not comparatively measured against these companies. All eight SMEs perform strongly in targeting 'high'- and 'priority'-pathogens with their pipeline projects – and six companies are also developing projects that meet innovation criteria.

Industry trends

RESEARCH & DEVELOPMENT

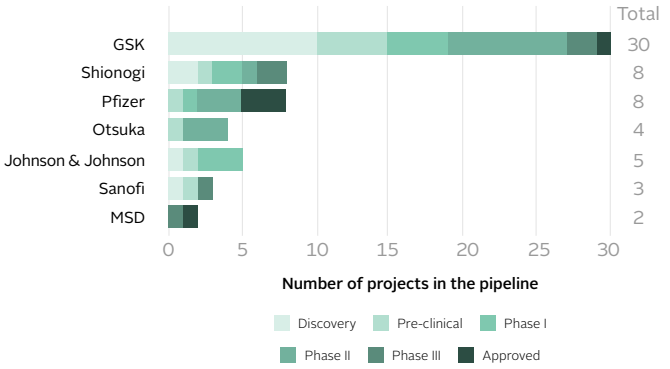
The Benchmark findings reflect the realities of the antimicrobial development landscape. There is a continued contraction of the pipelines among the seven large research-based companies assessed, with a 35% decline in the number of projects in development in the past five years. This makes the current efforts of companies still engaged in this space all the more vital.

Encouragingly, as set out in the Key Finding on R&D, there are seven innovative projects in late-stage development that can already have a significant impact against drug-resistant infections. These projects originate from three large research-based companies – **GSK, Otsuka** and **Shionogi** – and four SMEs – **BioVersys, F2G, Innoviva** and **Venatorx**. Three recent regulatory approvals among these projects demonstrate how important even a handful of advances are.

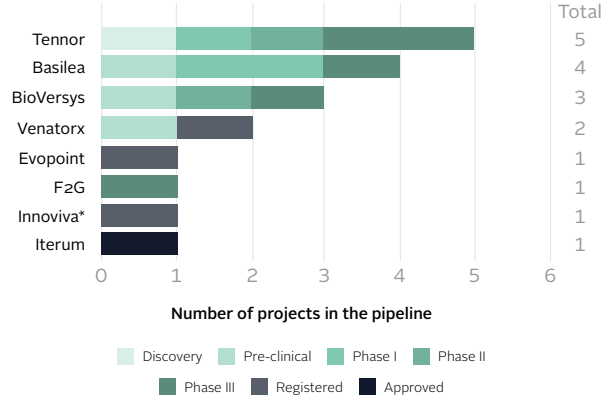
Despite these promising projects, development of antimicrobials with innovative characteristics that can overcome resistance where older drugs fail, remains sparse. **GSK, Otsuka** and **Shionogi** are the only large research-based companies among the seven assessed still actively pursuing this. The pipelines of the other four large research-based companies – **Johnson & Johnson, MSD, Pfizer** and **Sanofi** – focus on either vaccines and/ or adaptive R&D which offer primarily expanded indications or incremental improvements, but no new preventive or therapeutic options.

Of the large research-based companies analysed, **GSK** has by far the largest antimicrobial pipeline, with 30 projects in development. These span both preventive vaccines and antibacterial therapeutics and include three innovative candidates. **Shionogi** and **Pfizer** follow, with eight projects each. Critically, the **eight SMEs** are driving innovation for critical- and high-priority pathogens – as highlighted in a Best Practice.

Large research-based companies



Small- and medium-sized enterprises

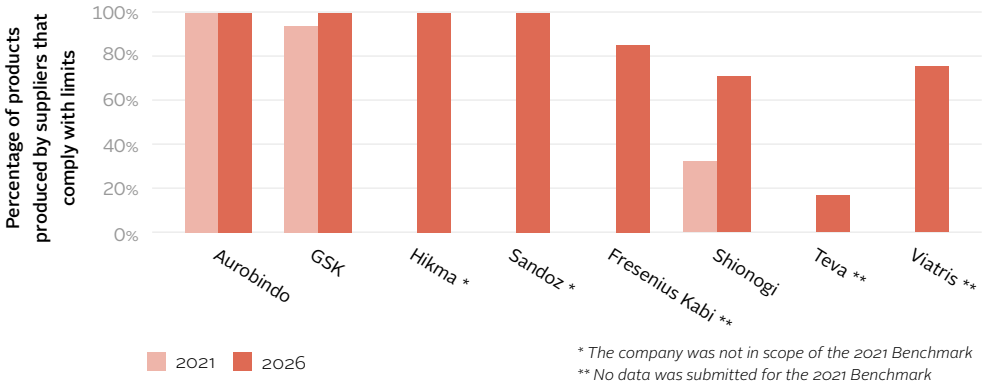


** Innoviva's pipeline project was approved after the period of analysis for the 2026 AMR Benchmark concluded.*

RESPONSIBLE MANUFACTURING

There has been a notable shift in companies working towards ensuring compliance with antibiotic discharge limits across their supply chains – at both their own and suppliers' manufacturing sites. Given the increased recognition of the impact that antibiotic manufacturing waste has on AMR, people and the environment, it is positive to see wider actions from some companies when it comes to their suppliers – as highlighted in a Key Finding and Best Practice. Notably, **Aurobindo, GSK** and **Sandoz** stand out for achieving 100% compliance in receiving waters for all products manufactured both in-house and at their supplier sites, demonstrating end-to-end control of environmental and AMR risks across their supply chains.

Disclosure of supplier compliance has doubled since 2021

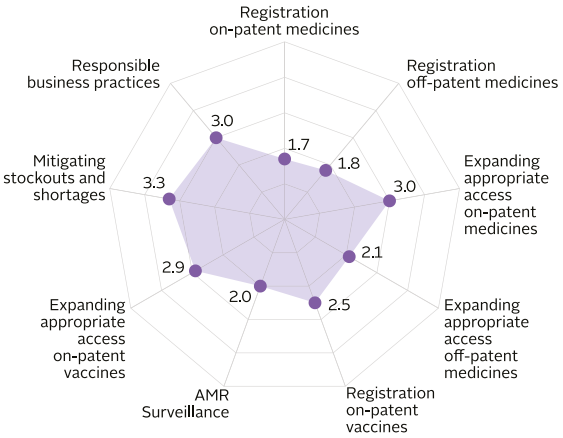


** The company was not in scope of the 2021 Benchmark*
*** No data was submitted for the 2021 Benchmark*

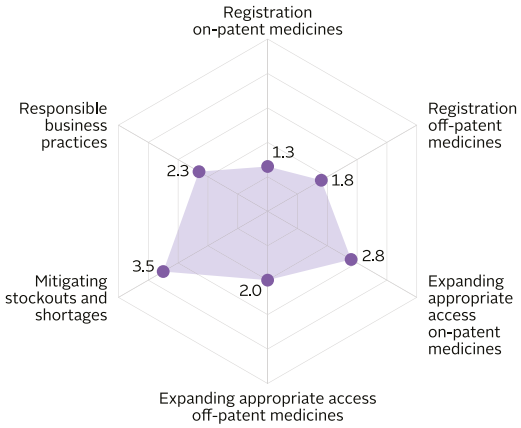
APPROPRIATE ACCESS & STEWARDSHIP

In the fight against AMR, access remains a central issue. On the one hand, patients must have access to the right antibiotics at the right time, no matter where they live. On the other hand, the overuse and misuse of antibiotics and antifungals remain the primary drivers of AMR. Striking a careful balance between access and stewardship is essential, with the Appropriate Access & Stewardship Research Area looking at how companies are navigating this – from product registration to the access and stewardship strategies they employ.

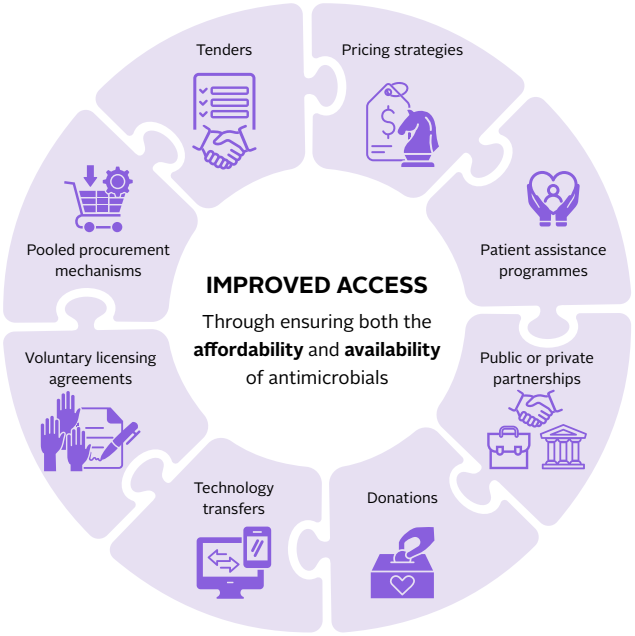
Large research-based companies perform strongest in mitigating stockouts and shortages, expanding appropriate access to their on-patent medicines and employing responsible business practices.



Generic medicine manufacturers stand out for mitigating stockouts and shortages and expanding appropriate access to their on-patent medicines.



Among the 146 products (including both on-patent and off-patent/generic antibacterials, antifungals and vaccines) assessed across the portfolios of the 17 large research-based companies and generic medicine manufacturers, just over half of these products are accompanied by access strategies, with national tenders emerging as the most common approach for supplying them in LMICs. However, access barriers are shaped by local contexts and take many forms, but all ultimately hinder the affordability and availability of medicines. Therefore, to improve access in these diverse settings, companies can develop tailored access strategies – beyond traditional tendering models – that take into consideration the realities of each country's patient population. This need is particularly relevant for innovative, on-patent antibacterial and antifungal medicines, which come with higher price tags.



The Benchmark identified examples of how companies are employing tailored strategies to address the affordability and availability of the lifesaving products they produce, including voluntary licensing agreements, tailored pricing strategies, technology transfers and participating in pooled procurement mechanisms. Given that only 44% of assessed products are covered by a tailored access strategy, applying such approaches more broadly, could enhance the accessibility of antibacterials, antifungals and vaccines in LMICs.

Overall, large research-based companies show modest performance for product registrations across the board. While product-level access and stewardship strategies are in place, gaps remain in patient reach tracking and company-wide stewardship policies. Generic medicine manufacturers also show modest performance in registering off-patent products, though there are positive signs for on-patent products and encouraging progress in access strategy coverage, with opportunities to further strengthen stewardship efforts.

The AMR Benchmark finds that gaps in access and innovation remain particularly acute for children. While generic medicine manufacturers perform somewhat better in systematically registering paediatric formulations in countries where adult formulations are already registered, across all companies assessed, none have registered child-friendly versions of their products in 17 sub-Saharan African countries, where access gaps are particularly severe.

Overall, more companies are implementing supplier diversification as a strategy to mitigate risks in the antibiotic supply chain – with nearly all generic producers assessed engaging in supplier diversification.

>> Read more detailed insights across the Thematic Analysis in the Benchmark on p.40 - 66.

4 KEY FINDINGS

1. Thin pipeline, high stakes: How are companies planning to expand access to vital, new antimicrobials?
2. Building a better antibiotic arsenal for children
3. Some companies take stronger action to curb AMR at manufacturing sites across their supply chains
4. Generic producers step up in tracking how many patients in LMICs receive lifesaving antimicrobials

RESEARCH & DEVELOPMENT

- The Benchmark identified seven new, innovative medicine projects in late-stage development by GSK, Otsuka, Shionogi, BioVersys, F2G, Innoviva and Venatorx. These target some of the deadliest drug-resistant pathogens disproportionately affecting people living in LMICs.
- Innoviva and Otsuka stand out for detailed, product-specific plans that explicitly address key access barriers in LMICs, including affordability, availability and supply.

PAEDIATRIC ACCESS

Among companies with paediatric formulations on the market, five – Aurobindo, GSK, Hikma, Sandoz and Teva – stand out by registering their paediatric formulations, on average, in more than 50% of the low- and middle-income countries where they register their other off-patent antimicrobials.

RESPONSIBLE MANUFACTURING

- Aurobindo, GSK and Sandoz stand out for reporting compliance with antibiotic waste limits for both in-house and supplier production of all their antimicrobial products.
- Companies reporting on supplier compliance has doubled since 2021 (4 to 8), with generic producers leading this improvement.

PATIENT REACH

- Sales volume remains the main measure for estimating patient reach among generic medicine manufacturers. However, four companies – Abbott, Hikma, Sandoz and Viatris – integrate additional data points for different antimicrobial products in their portfolios to more accurately track how many patients are being reached by these products in LMICs.
- Notably, Sandoz and Viatris are the only generic medicine manufacturers assessed by the Benchmark that do this across all of their medicines assessed.

>> Key Findings can be read in full on p.26 - 38.

5 Best Practices

Some Best Practices focus on a single company, while others draw on examples from several companies' efforts to curb the rise of AMR.

RESEARCH & DEVELOPMENT 1 BEST PRACTICE	RESPONSIBLE MANUFACTURING 1 BEST PRACTICE	APPROPRIATE ACCESS & STEWARDSHIP 3 BEST PRACTICES
• GSK sustains leadership in antimicrobial R&D, with SMEs driving innovation	• Six companies take hands-on approach to suppliers' wastewater management practices	• Aurobindo leads with a portfolio-wide approach to registration in East Africa • GSK and Sandoz raise the standard for reporting transfers of value • Four companies support diagnostic capacity to safeguard medicines against drug resistance

Best Practices are shared to accelerate adoption of similar practices by other companies, and to help raise the overall level of standard practice. Furthermore, recognising those companies trialling or scaling up valuable policies or initiatives is an important way of acknowledging companies that stand out from peers and are willing to risk new approaches to advance efforts.

>> Best Practices can be read in full on p.67 - 78.

The path forward

The 2026 AMR Benchmark highlights numerous strong examples – spanning strategies, products, and geographies – of company actions that effectively address AMR at different stages of the value chain. The challenge now is to develop and apply approaches across more products and across more countries to ensure efforts can be maximised to curb AMR and save lives. From R&D through manufacturing, to access and stewardship and measuring real-world patient reach, the Benchmark illustrates the potential for companies to develop more comprehensive approaches. However, industry efforts cannot advance at the pace and scale required without global and country-level reform – especially in procurement, financing and regulation.

Collaboration across the public and private sectors to combine resources, and industry know-how to drive innovation is also vital – especially in addressing the dearth in antimicrobial R&D. Given the high cost of bringing new products to market, antibiotic science is not keeping up with growing resistance, especially for gram-negative bacteria. As recent funding announcements by the Gates Foundation, the Novo Nordisk Foundation and Wellcome Trust demonstrate, collaborators are working to help support R&D but addressing the rate of innovation requires a more holistic approach. Until antibiotic discovery is funded at a scale that matches the threat posed by AMR, efforts will be reactive instead of proactive, costing money and lives. Governments and policymakers play a crucial role in shaping sustainable markets to support continued industry innovation and investment – without which global efforts to save people from drug resistant infections resistance cannot succeed.

Opportunities for companies to advance progress

Companies have already demonstrated success in addressing AMR across the pharmaceutical value chain, and these noteworthy examples provide a strong foundation to build on and drive further progress. By mapping their current efforts aimed at protecting people against drug resistance, pharmaceutical companies can better understand their strengths across the value chain and pinpoint the stages where their focus can have the most impact. Monitoring and reporting on these efforts not only helps to refine their own strategies but also provides valuable insights for other companies earlier in their AMR journey, fostering industry wide learning and progress.

25 Report Cards

Individual company Report Cards include tailored Opportunities for each of the 25 companies assessed in the 2026 AMR Benchmark. By pinpointing specific actions companies can take to make a positive impact in curbing AMR, these opportunities offer clear, practical and feasible ways in which companies can each maximise their efforts successfully. These Opportunities signal significant change-making potential for the company and are also valuable for investors and global health stakeholders as they engage with companies to drive change.

7
LARGE RESEARCH-BASED COMPANIES

10
GENERIC MEDICINE MANUFACTURERS

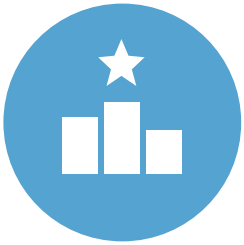
8
SMALL- AND MEDIUM-SIZED ENTERPRISES

>> Report Cards can be read in full on p.84 - 162.

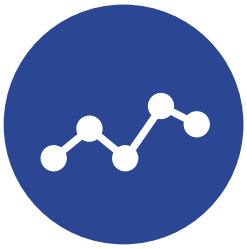
2026 AMR BENCHMARK

BENCHMARK IN FOCUS

COMPANY PERFORMANCE



INDUSTRY TRENDS



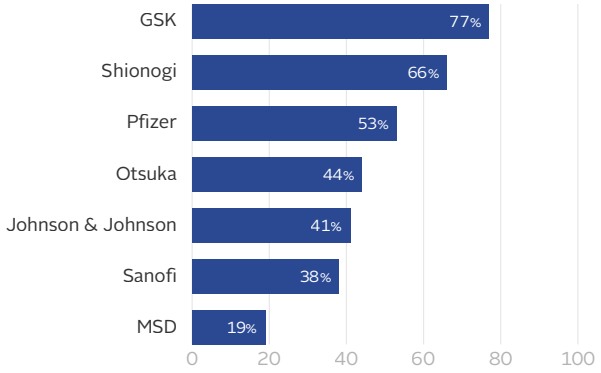
KEY FINDINGS

PERFORMANCE ACROSS LARGE RESEARCH-BASED COMPANIES

GSK maintains lead, Shionogi makes biggest leap forward, but industry-wide performance declines

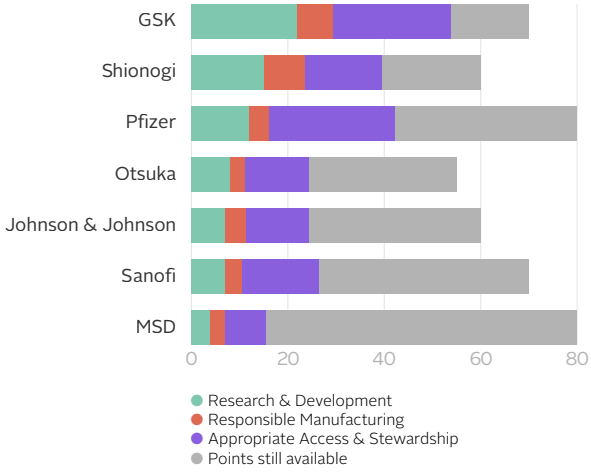
OVERALL PERFORMANCE – IN %

Compares each company's progress towards 100% of its maximum potential, depending on the number of indicators for which it is considered in the Benchmark's scope.



RESEARCH AREA PERFORMANCE – IN POINTS

Illustrates the points each company has achieved across Research Areas, as well as the remaining points available. Total possible points may differ between companies, depending on the number of indicators for which each company is in scope*.



The 2026 Antimicrobial Resistance (AMR) Benchmark evaluates how seven of the largest research-based pharmaceutical companies are tackling AMR through advancing the development, access and responsible use of lifesaving antimicrobials. While some companies have made progress in specific areas, overall performance has declined since 2021. GSK remains the leader, performing consistently well across all areas, leading in Research & Development (R&D) and Appropriate Access & Stewardship, and demonstrating strong performance in Responsible Manufacturing. Pfizer, the former joint leader in 2021, has been outpaced by Shionogi, which has demonstrated stronger performance across all areas. Performance across companies remains mixed, and no company is yet close to reaching its full potential, showing that there is still a long way to go in the fight against AMR.

▶ For more on industry performance, see Industry Trends on p.20.
▶ A detailed overview of each company's Benchmark performance is available in the individual Report Cards on p.84 - 162.

GSK is the overall leader and is the top company in R&D and Appropriate Access & Stewardship. Over the last five years, GSK has maintained the largest pipeline, with 30 projects targeting pathogens in scope (see Best Practice, p.69). In addition, it is more diverse compared to peers, with the most vaccines in development and the most projects addressing 'high'- or 'critical'-priority pathogens. GSK reports access and/or stewardship plans for all its late-stage projects, although some elements focus on overarching policies rather than concrete project-specific approaches. Moreover, it provides detailed access and stewardship strategies for its marketed products and is one of the few companies to transparently report transfers of value to healthcare practitioners across low- and middle-income countries (LMICs), as highlighted in the Best Practice on p.75. GSK also performs strongly in Responsible Manufacturing, with a comprehensive

*Due to these differences in the number of indicators, the total possible points – and therefore the denominators for overall percentage scores – differ per company. For a comprehensive list of the indicators and scoring eligibility by company, see Appendix II.

environmental risk management approach covering its own and suppliers' sites (see Best Practice, p.71).

Shionogi progresses in relation to peers, with the most innovative pipeline and the lead position in Responsible Manufacturing. The company is the second-best performing in R&D, with the joint second-largest pipeline (8 projects). Though still considerably smaller than GSK's, its pipeline is the most innovative. Notably, Shionogi leads in Responsible Manufacturing, managing AMR risks across its supply chain, demonstrating Best Practice in supporting its suppliers with managing antimicrobial waste (see p.71). It also stands out for transparency, publicly disclosing its AMR mitigation strategy, product compliance and the locations of its manufacturing sites.

Pfizer, previously joint leader with GSK, drops to third place and shows mid-range performance across all areas assessed by the Benchmark. While Pfizer, alongside Shionogi, has the second-largest pipeline among large research-based companies, its R&D pipeline targeting priority pathogens has declined from 13 to 8 projects, with no medicines meeting any of the World Health Organization's (WHO's) innovation criteria currently in development. It performs well in access and stewardship planning, with about half of its late-stage R&D projects supported by plans that focus on registration, equitable pricing and sustainable supply. It also does better than peers in registering on- and off-patent products and uses multiple strategies to expand access to its off-patent portfolio. The company performs well in AMR surveillance, and it also demonstrates Best Practice for supporting diagnostic capacity in LMICs (see p.77). In Responsible Manufacturing, it misses opportunities to transparently report details of its environmental risk management strategy.

Otsuka progresses relative to peers, with strong access and stewardship planning and improvement in Responsible Manufacturing. Its R&D pipeline has remained about the same size, with all four projects focused on the development of its innovative medicine quabodepistat. Otsuka stands out for its comprehensive access and stewardship plan for quabodepistat, which includes elements that address barriers to affordability, availability and supply in LMICs (see Key Finding on p.26). Notably, Otsuka's performance in Responsible Manufacturing has improved with the adoption of a waste management strategy, but the company still lags in publicly disclosing practices to minimise AMR risks and ecological impacts from antibacterial manufacturing at its own and suppliers' sites. Otsuka has a comprehensive access strategy, accompanied by some stewardship efforts, for its sole assessed product, delamanid (Deltyba®), part of one of the WHO-recommended DR-TB regimens. When it comes to stewardship, the company takes concrete steps to improve diagnostic capacity in LMICs (see Best Practice, p.77).

Johnson & Johnson's performance declines, scaling down significantly in antimicrobial R&D, but good performance in Appropriate Access & Stewardship. The company has sharply reduced its pipeline since 2021, with a 64% decrease in pipeline size after halting its infectious diseases and vaccine R&D. Most remaining R&D projects (5) focus on adaptations of its approved antituberculosis drug, bedaquiline. The company also no longer reports being engaged in surveillance efforts, with its previous surveillance programme for bedaquiline ending in 2019. It performs well on registration, with bedaquiline registered in 28 countries, and the paediatric version registered in 11 countries. Johnson & Johnson also demonstrates a comprehensive strategy to expand access to bedaquiline by supplying it through supranational procurement via the Stop TB Partnership's Global Drug Facility and tracking the number of patients reached. It also supports the development of diagnostic capacity in LMICs (see Best Practice, p.77). It is a mid-performing company in Responsible Manufacturing, outlining its AMR risk management strategy for its own and supplier sites, but it does not publicly disclose product compliance.

Sanofi shows significant decreases, with limited disclosure of actions to ensure appropriate Access & Stewardship and Responsible Manufacturing. Sanofi's already small pipeline declined by 50% since 2021, leaving just 3 projects in development that target pathogens in scope. It performs well in registering on-patent vaccines, with registrations in an average of 38 LMICs, and leverages supranational procurement mechanisms to expand access in LMICs. Its limited reporting on off-patent medicine registrations reduces transparency on wider access. The company also does not report any engagement in surveillance programmes. It has a basic environmental risk management strategy for its own and suppliers' sites, but transparency on how the strategy is applied across its supply chain and on discharge limit compliance outcomes can be improved.

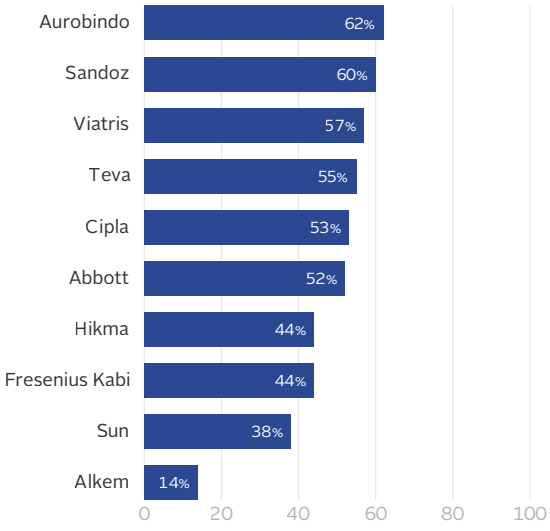
MSD lags its peers, showing low performance across all areas. MSD's pipeline has had the sharpest decline of all companies (85% since 2021). Its AMR pipeline is made up exclusively of two projects for its 21-valent conjugate pneumococcal vaccine, CAPVAXIVE®, which was approved for adults in 2024. Access plans for both projects are limited to registration commitments in countries where it conducts clinical trials. MSD has a basic environmental risk management strategy aimed at mitigating AMR at its own sites and those of its suppliers. MSD provides limited evidence of access and stewardship strategies for its innovative medicines and vaccines, although it does have general approach for pricing and stewardship for its antibacterial and antifungal medicines. It does not share any evidence of such strategies for its off-patent products. The company does not share data to the Benchmark beyond publicly available information.

PERFORMANCE ACROSS GENERIC MEDICINE MANUFACTURERS

Aurobindo remains top performer, but overall loss of industry momentum since 2021

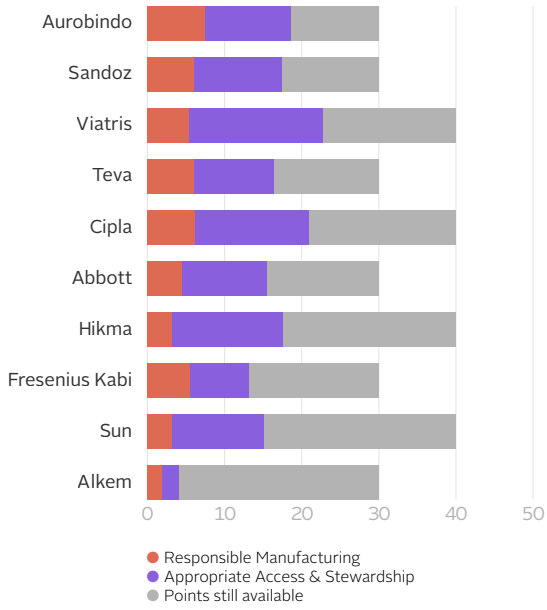
OVERALL PERFORMANCE – IN %

Compares each company's progress towards 100% of its maximum potential, depending on the number of indicators for which it is considered in the Benchmark's scope.



RESEARCH AREA PERFORMANCE – IN POINTS

Illustrates the points each company has achieved across Research Areas, as well as the remaining points available. Total possible points may differ between companies, depending on the number of indicators for which each company is in scope*.



The 2026 Antimicrobial Resistance (AMR) Benchmark assessed the actions of a core group of ten generic medicine manufacturers in tackling antimicrobial resistance (AMR). Aurobindo remains the leader, followed closely by Sandoz (newly assessed), Viatris and Teva. Cipla and Abbott perform above the middle mark, demonstrating mixed strengths across the Research Areas assessed. Critically, Aurobindo, the highest-performing company, reaches just over 60% of the Benchmark's maximum possible score. This loss of momentum among generic companies signals missed opportunities to strengthen industry-wide efforts.

▶ For more on industry performance, see Industry Trends on p.20.
▶ A detailed overview of each company's Benchmark performance is available in the individual Report Cards on p.84 - 162.

Aurobindo remains the top performer, leading in Responsible Manufacturing, and standing out for registering its off-patent products. Aurobindo leads in Responsible Manufacturing for strengthening transparency around its AMR mitigation strategy, while maintaining and ensuring compliance with clearly defined antibiotic discharge limits across its supply chain (see Best Practice, p.71). Aurobindo also stands out for registering its off-patent antimicrobial medicines analysed more widely than any of its peers. It also registers paediatric formulations in many of the same low- and middle-income countries (LMICs) where it markets other off-patent antibiotics (see Key Finding, p.30) and participates in the East African Community Medicine Harmonization Programme for all products assessed (see Best Practice, p.73). Furthermore, it is one of only six generic producers to provide a detailed methodology for calculating patient reach for specific antimicrobial products in LMICs (see Key Finding, p.36).

*Due to these differences in the number of indicators, the total possible points – and therefore the denominators for overall percentage scores – differ per company. For a comprehensive list of the indicators and scoring eligibility by company, see Appendix II.

Newly assessed Sandoz shows good practice across most areas, particularly in Responsible Manufacturing. **Sandoz** demonstrates good performance in Responsible Manufacturing, with a comprehensive environmental risk management strategy and full compliance with antibiotic discharge limits across its supply chain, aided by contractual provisions to ensure suppliers meet these limits as well (see Best Practice, p.71). It is also the best-performing company in terms of registering paediatric formulations, doing this for seven child-friendly antimicrobial formulations across 38 of the same countries where it registers the corresponding adult formulation (see Key Finding, p.30). As part of its sales strategy, Sandoz ensures that interactions with healthcare professionals are based on legitimate need and that any transfers of value are made at fair market value (see Best Practice, p.75).

Viatris and Teva perform at a moderate level, meeting just over half of the Benchmark criteria and demonstrating consistent efforts, with opportunities for further improvement.

Viatris leads in Appropriate Access & Stewardship slightly ahead of peers, showing a comprehensive strategy to prevent stockouts and ensure the availability of quality assured products. This includes supply planning with frequent updates to support agile operations, as well as a Rapid Response Advanced Planning System that enables daily sharing of information on demand, inventory and potential shortages across its global network. It also registers its on-patent medicines more broadly than its peers, covering an average of 13 LMICs, and has engaged in World Health Organization prequalification for some products to facilitate regulatory approvals.

Teva implements effective strategies to mitigate stockouts and ensure continuous supply of its antimicrobial products, including through efforts to pursue local sourcing of raw materials or finished products to increase the resilience of its antimicrobial supply. Teva demonstrates robust strategies to minimise AMR and environmental risks from antimicrobial manufacturing and is transparent in publishing information on how these risks are managed. It also stands out as the only generic company taking a holistic approach to promote appropriate use of its antimicrobials, addressing AMR risks through both its sales practices and its governance of interactions with healthcare professionals. Nonetheless, Teva has opportunities to advance strategies for expanding appropriate access to off-patent and generic antimicrobial medicines.

Abbott and Cipla perform in the low 50%-range point, with uneven performance across different areas.

After dropping from the leading spot in the 2021, **Cipla** has maintained its mid-tier position in 2026, though its overall performance decreased slightly. Cipla performs well in Responsible Manufacturing and has effective strategies to mitigate stockouts and ensure continuous supply. It also supports the development of diagnostic capacity in LMICs (see Best Practice, p.77). However, it misses opportunities to register both its on-patent and off-patent products more widely in LMICs, and in implementing strategies to ensure appropriate access to its on-patent products.

Abbott demonstrates good performance in supply management, implementing various strategies for keeping buffer stock of critical active pharmaceutical ingredients (APIs) and finished products – and implementing diversified sourcing strategies to increase supply chain resilience. It also takes a relatively comprehensive approach to sales practices, ensuring that any transfers of value to healthcare professionals are made at fair market value and are subject to limits. Furthermore, Abbott is the strongest performer in terms of access strategies, reporting the implementation of an access strategy for every product assessed by the Benchmark. The company also demonstrates strong participation in public tenders, bidding for six of the nine products assessed and being awarded the tender as the sole supplier for four of these six. Abbott's stewardship strategies could be strengthened, as they focus solely on responsible promotion and sales strategies and lack engagement in surveillance or diagnostic activities.

In Responsible Manufacturing, both **Cipla** and **Abbott** are among the companies providing hands-on support for suppliers, with Cipla running workshops on discharge level quantification and Abbott offering free wastewater analysis (see Best Practice, p.71).

Hikma, newly assessed by the Benchmark, and Fresenius Kabi perform below average but show strength in specific areas.

Hikma performs well in its access strategies for both on-patent and off-patent medicines, for example, as the sole supplier of amoxicillin-clavulanic acid in Jordan's national tender. It also stands out for implementing and monitoring these access strategies. However, there are opportunities to improve, including expanding registration of on-patent antibacterial and antifungal medicines, reinforcing responsible promotional practices and improving transparency around its strategy to mitigate AMR from manufacturing.

Fresenius Kabi performs well with its strategy to minimise AMR and environmental risks from antimicrobial manufacturing, but has opportunities to improve by transparently reporting details of this strategy. Notably, for the first time, it reports supplier compliance to the Benchmark, with 86% of all products manufactured by its suppliers meeting antibiotic discharge limits (see Key Finding, p.33). The company also does well in registering its off-patent medicines more widely than its peers, covering an average of 12 LMICs. There is room to improve its strategies for expanding access to off-patent and generic antibacterial

and antifungal medicines, as it currently only discloses a high-level strategy applied to its whole portfolio. It also performs strongly in mitigating inappropriate antimicrobial use, providing clear evidence of implementing a responsible sales model as its primary approach in sales practices (see Responsible Business Practices, p.59).

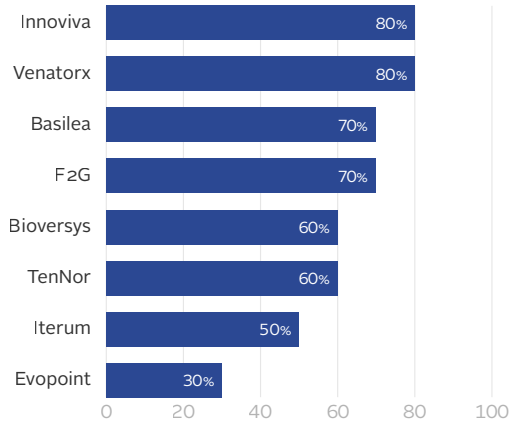
Sun Pharma underperforms across various areas of the Benchmark and drops slightly compared to 2021. It misses opportunities to expand registration of both on-patent and off-patent products in more LMICs, as well as to implement access and stewardship strategies for its assessed products. The company could also report on patient reach numbers more consistently for its products. While it has environmental risk management measures to mitigate AMR at its own manufacturing sites, it does not report reviewing antibiotic discharge limits at its supplier sites.

Alkem trails the group, with several opportunities for improvement across the Benchmark. Alkem continues to show limited transparency as it does not share – with the Benchmark or publicly – the data needed to assess its commitments to limiting AMR.

PERFORMANCE ACROSS SMALL- AND MEDIUM-SIZED ENTERPRISES

AMR Benchmark's new evaluation of SMEs reflects their central role in antimicrobial R&D

OVERALL PERFORMANCE – IN %



The 2026 Antimicrobial Resistance (AMR) Benchmark newly evaluates how eight of small- and medium- enterprises (SMEs) are tackling AMR through **Research & Development (R&D)**. These companies are only assessed in R&D. Although they are assessed on the same grounds as large research-based companies – targeted pathogens, pipeline innovation and access and stewardship planning – they are not comparatively measured against these companies. All eight SMEs perform strongly in targeting 'high'- and 'priority'-pathogens with their pipeline projects – and six companies are also developing innovative projects (see Best Practice, p.69). However, performance in access and stewardship planning is mixed. While some companies stand out for having robust plans in place, others lack both access and/or stewardship provisions.

▶ For more on SME performance, see Industry Trends on p.20.
▶ A detailed overview of each company's Benchmark performance is available in the individual Report Cards on p.84 - 162.

Venatorx and Innoviva stand out for strong performance in access and stewardship planning.

Venatorx and **Innoviva** perform strongly among SMEs. Both of Venatorx's pipeline candidates target 'critical'-priority pathogens and meet at least one of the World Health Organization's (WHO's) four innovation criteria. **Innoviva's** sole pipeline candidate, zoliflodacin – which was approved for uncomplicated gonorrhoea after the analysis period for the 2026 AMR Benchmark concluded – targets a 'high'- priority pathogen and meets three of four WHO innovation criteria.

Venatorx and **Innoviva** stand out for their strong access and stewardship plans for their late-stage candidates, which were both developed in partnership with the Global Antibiotic Research and Development Partnership (GARDP). **Venatorx** has a comprehensive access and stewardship plan for cefepime-taniborbactam,* which is currently undergoing regulatory review for serious urinary tract infections and hospital-acquired pneumonia. **Innoviva** has a robust plan for zoliflodacin that addresses availability, affordability and supply barriers in low- and middle-income countries (LMICs), alongside stewardship plans to strengthen AMR surveillance.

Basilea, F2G, BioVersys and TenNor perform well, each demonstrating strengths in different areas.

Four companies – **Basiliea**, **F2G**, **BioVersys** and **TenNor** – are all advancing projects that address 'high'- and/or 'critical'-priority pathogens, aiming to address urgent AMR threats.

*After the period of analysis of the Benchmark, GARDP and Venatorx announced the termination of their collaboration agreement on cefepime–taniborbactam.

These companies perform well, with strengths in some areas but room for improvement in others.

Basiliea, with four different antibacterial and antifungal candidates in development, has one of the most diverse pipelines among SMEs, with all of its clinical-stage candidates classified as innovative. However, it misses opportunities in the Benchmark's assessment of access and stewardship planning because, as a development-only company, it does not develop access plans for its projects, though it does participate in surveillance efforts.

F2G's sole pipeline candidate, olorofim – in development for invasive Aspergillosis, which is a severe fungal infection – is considered innovative, meeting all of WHO's innovation criteria. It performs well in access and stewardship planning, with a plan for olorofim that addresses availability and supply through a licensing agreement with Shionogi. However, concrete details, including affordability considerations, remain unclear.

Both of **BioVersys'** clinical-stage candidates are classified as innovative: one by meeting WHO's innovation criteria, while the other meets the Benchmark's 'other' innovation criterion due to its novel indication and formulation targeting a 'critical'-priority pathogen. However, BioVersys currently lacks access and stewardship plans for its late-stage projects. Meanwhile, **TenNor** has the largest pipeline among its peers, with five projects in development. However, none are categorised as innovative. It performs moderately in access and stewardship planning; while plans are in place, they remain limited in depth and breadth.

Iterum offers a unique innovation put lags in access planning.

Iterum's sole pipeline candidate, sulopenem etzadroxil and probenecid (ORLYNVAH®) targets a 'critical'-priority pathogen. Although it does not meet WHO innovation criteria, it meets the 'other' innovation criterion, set by the Benchmark, whereby a project has features that may strengthen real-world utility in LMICs. Specifically, its product (ORLYNVAH®), approved in 2024, marks the first oral option in the penem class, enabling outpatient treatment of uncomplicated urinary tract infections.

While **Iterum** does not currently have an access plan in place for LMICs, it does have a stewardship plan in place that includes provisions for diagnostic support, appropriate use and surveillance.

Evopoint lags with no innovative candidates or access and stewardship plans.

Evopoint has opportunities to strengthen its overall performance. Although its sole pipeline project, funobactam, targets both 'high'- and 'critical'- priority pathogens, it does not meet any of the four WHO innovation criteria – nor does it meet the Benchmark's additional criterion for innovative real-world utility in LMICs. Additionally, the company currently lacks access and stewardship planning, with no plans currently in place to address access and stewardship of funobactam in LMICs.

INDUSTRY TRENDS

Glimmers of progress, but drug resistance is outpacing industry-wide efforts

Five years since the release of the 2021 Antimicrobial Resistance (AMR) Benchmark, this new iteration evaluates a cross-section of the pharmaceutical industry, ranging from large research-based companies to generic medicine manufacturers to small- and medium-sized enterprises (SMEs),* focusing on areas where they have a clear responsibility to help address AMR. In evaluating efforts across three Research Areas – Research & Development, Responsible Manufacturing and Appropriate Access & Stewardship – findings from the 2026 AMR Benchmark reveal where companies perform strongly and where progress needs to be accelerated in tackling AMR. Overall industry trends reveal some hopeful spots of progress from companies, but more comprehensive efforts are needed across the board. Further insights across Key Findings, Thematic Analyses and Best Practices showcase several other notable trends that provide valuable context and highlight broader patterns emerging from the Benchmark's analysis of company actions to address AMR.

RESEARCH & DEVELOPMENT

Findings reflect realities of antimicrobial development landscape

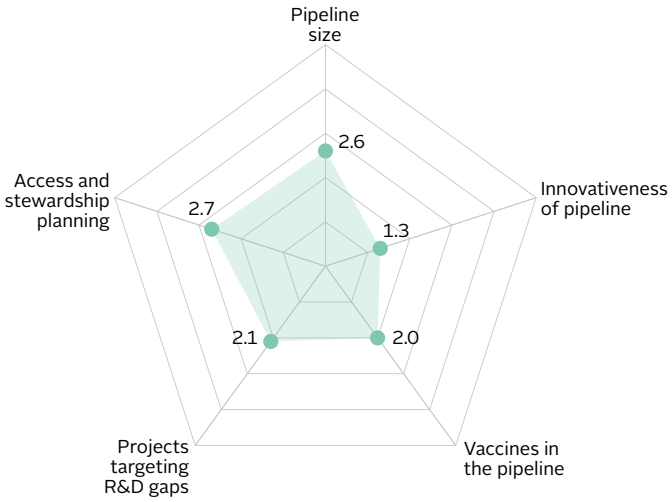
▶ **Sustained drop in activity from large research-based pharmaceutical companies**

When compared to the previous 2021 Benchmark, there has been a 35% decrease in the number of **pipeline projects** in development from large research-based pharmaceutical companies. All companies have had considerable pipeline contractions. **GSK** remains the outlier – maintaining a pipeline of 30 candidates spanning both preventive vaccines and anti-bacterial therapeutics, including three **innovative candidates** (see Best Practice, p.69). Conversely, **MSD** and **Johnson & Johnson** have had the largest decreases in pipeline sizes (85% and 64% respectively); with the latter ceasing its vaccines and infectious disease R&D in 2023. Consequently, only three companies – **GSK**, **Otsuka** and **Shionogi** – are continuing to invest in innovative antimicrobial R&D; other companies have only a small number of projects in development, primarily focused on vaccine programmes and/or adaptive R&D of existing medicines.

Performance across **access and stewardship planning** is mixed. While most pipeline candidates (83%) in development have some measure **of access and/or stewardship plans** in place, the quality of plans varies considerably. In general, there is a focus on high-level commitments or overarching policies, often lacking concrete actionable plans. However, for some innovative candidates, companies have developed access and stewardship plans to ensure appropriate use that explicitly address availability, affordability and supply in LMICs (see Key Finding, p.26 and Research & Development, p.40).

Companies assessed: 15	
7 large research-based pharmaceutical companies	8 small- and medium-sized enterprises (SMEs)

FIGURE 1 **Large research-based companies' performance across R&D**



*Nine small- and medium-sized enterprises (SMEs) were originally part of the company scope for the 2026 AMR Benchmark Methodology. However, in January 2026, Pulmocide announced the termination of its Phase II trial for opelconazole. This was the company's sole pipeline project analysed, leading to Pulmocide's removal from the 2026 AMR Benchmark Report. As such, eight SMEs are included in the final assessment.

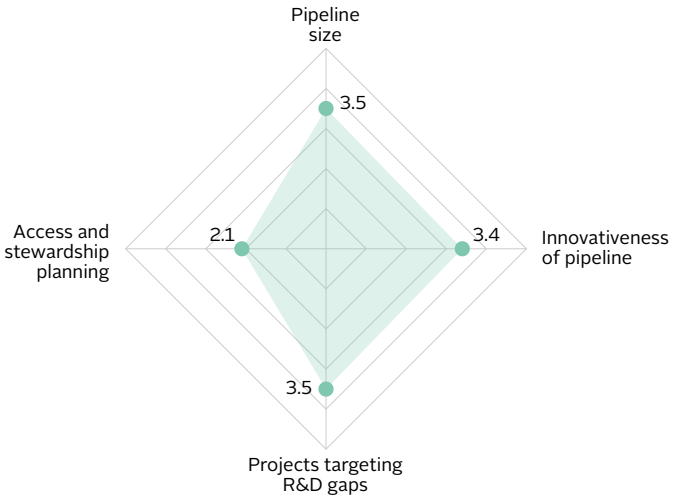
▶ Small- and medium-sized enterprises fill the gap

The eight **small- and medium-sized enterprises** (SMEs), newly assessed in the 2026 Benchmark, are driving innovation for **critical- and high-priority pathogens**. Six of these eight companies have innovative medicines in their pipeline (see Best Practice, p.69).

Collectively, these companies have been filling gaps left by the withdrawal of large research-based companies and lead in the development of medicines for resistant fungal infections (see Antifungal Spotlight, p.43). Although the total number of innovative candidates (15) – across both company types – is still worryingly low, SMEs are punching above their weight relative to large research-based companies. This is despite having substantially less capital, in-house expertise and global commercial presence – all while navigating the same challenging scientific and commercial conditions to bring antimicrobials to market.

Performance for **access and stewardship planning** is also mixed across SMEs; 36% have no access or stewardship plans in place. However, some candidates have notable plans that simultaneously address barriers to availability, affordability and supply – especially through leveraging partnerships – to scale appropriate access in LMICs with high unmet needs (see Key Finding, p.26 and Research & Development, p.40).

FIGURE 2 **Small- and medium-sized enterprises' performance across R&D**



▶ Overall scarcity of innovation threatens future treatment options

Across the entire antimicrobial pipeline of both SMEs and large research-based companies, limited activity and scarce innovation have revealed shortcomings in both the quantity and quality of new candidates – signalling an imminent scarcity of effective treatment options for resistant infections. There have been some positive developments, with regulatory approvals for three antibiotics with innovative characteristics – developed by **GSK**, **Innoviva*** and **Iterum**, respectively. Additionally, **MSD** has had one vaccine approval and **Pfizer** has secured three new approvals – one new antibiotic and paediatric label extensions for two existing medicines. However, the downward trend in pipeline activity suggests that the rate of innovation is not enough to outpace growing resistance.

Fixing the broken business model for antimicrobials

In response to the lack of commercial incentives for antimicrobial R&D, governments in high-income countries have been trialling 'pull incentives' to stimulate innovation and combat AMR. A leading example is the UK's National Health Service (NHS), which in May 2024 formally adopted a Netflix-style subscription model that pays fixed annual fees to pharmaceutical companies for access to certain new antimicrobials, encouraging development while decoupling revenue from sales volume.[1] This has the dual benefit of guaranteeing a return on investment for companies to sustain R&D, while also aligning with stewardship efforts to prevent overuse of antimicrobials and safeguarding them for future use. Under this model, drugs such as Pfizer's ceftazidime-avibactam and Shionogi's cefiderocol have been evaluated and are being made available through the NHS as part of long-term contracts. Meanwhile, other regions are considering different approaches. In December 2025, the European Union reached a provisional agreement to introduce a 'transferable exclusivity voucher' system, which would allow companies to extend the market protection of other successful drugs as a reward for developing new antibiotics.[2] Collectively, these initiatives signal to pharmaceutical companies that innovation is commercially supported, and their expansion to other countries should be monitored as means to protect public health in the fight as AMR; both as a viable/lucrative option for companies to generate revenue and sustain R&D and by ensuring availability of critical antimicrobials for drug-resistant infections.

*Innoviva's zoliflodacin was approved after the period of analysis for the 2026 AMR Benchmark concluded.

References:

1. Duddy, C. (2024, September 18). "Netflix" for antimicrobials: The Antimicrobial Products Subscription Model. House of Commons Library. https://commonslibrary.parliament.uk/netflix-for-antimicrobials-the-antimicrobial-products-subscription-model/

2. European Parliament. (2025, December 11). Deal on comprehensive reform of EU pharmaceutical legislation. European Parliament. https://www.europarl.europa.eu/news/en/press-room/20251209IPR32110/deal-on-comprehensive-reform-of-eu-pharmaceutical-legislation

RESPONSIBLE MANUFACTURING

Notable steps to limit AMR risk from manufacturing across the supply chain

The 2026 AMR Benchmark assessed whether antibiotic discharge limits are being quantified and met at both company-owned and suppliers' manufacturing sites – preferably for individual antimicrobial products. The previous Benchmark only assessed whether companies were quantifying these limits. This shift – reinforced by growing political attention to responsible manufacturing and the publication of the World Health Organization's (WHO's) independent guidance on wastewater and solid waste – is intended to encourage companies to track and safeguard against resistance risks associated with the manufacturing of each product individually.

Ensuring full supply-chain compliance – and transparently disclosing this – is critical for responsible manufacturing, as it allows stakeholders to verify robust controls, identify risks and drive consistent industry-wide standards.

Of the 17 companies assessed in **Responsible Manufacturing**, ten share details on whether their in-house antibiotic production meets discharge limits. Notably, the number of companies reporting supplier compliance with discharge limits has doubled from four to eight since 2021 (see Key Finding, p.33).

Currently, all companies that do report compliance (at both their own and suppliers' sites) do so only for waste that has already been discharged into waterways. No company currently complies with limits at end-of-pipe (i.e., directly in wastewater before it is released into the environment), as recommended by WHO.

▶ Only two large research-based companies stand out

GSK is the only large research-based company that reports 100% compliance across its entire antimicrobial supply chain (i.e., at both its own sites and suppliers' sites). **Shionogi** reports 100% compliance at its own sites but only reports 73% compliance at supplier sites. However, it is the level of detail and transparency of Shionogi's disclosure that makes it the top performer in **Responsible Manufacturing**. The company discloses product-specific compliance, with country-level locations of all manufacturing sites across its supply chain. Other companies lag in publicly reporting levels of compliance achieved.

Companies assessed: 17	
7 large research-based pharmaceutical companies	10 generic medicine manufacturers

▶ Generic producers show improvement with compliance reporting and supplier engagement

Companies demonstrate good performance and transparency, with five reporting 100% compliance at their own sites and eight disclosing compliance information. More generic companies are also reporting on supplier compliance, with six disclosing compliance data compared to only one in the previous Benchmark (see Key Finding, p.33).

Aurobindo is the highest performer in **Responsible Manufacturing**, publicly reporting complete compliance across its supply chain. **Sandoz** follows closely, also reporting complete compliance, but public disclosure of supplier site compliance information is lacking. **Notably**, **Abbott**, **Aurobindo**, **Cipla** and **Sandoz** all demonstrate more engagement to help suppliers meet discharge limits (see Best Practice, p.71).

FIGURE 3 **Large research-based companies' performance across Responsible Manufacturing**

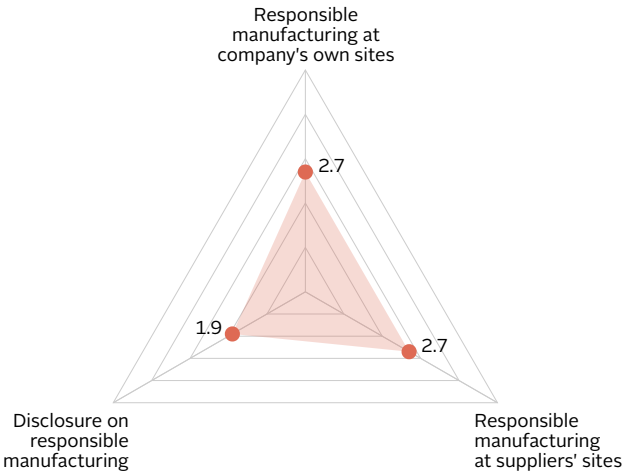
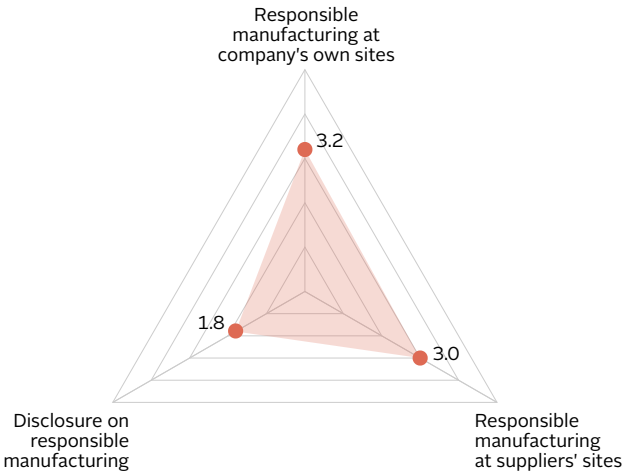


FIGURE 4 **Generic medicine manufacturers' performance across Responsible Manufacturing**



A noteworthy example of progress since the previous Benchmark is **Alkem**. Although it has consistently lagged in implementing an environmental risk management strategy specifically aimed at mitigating AMR, the company recently initiated a gap assessment with BSI Kitemark™ to evaluate antibacterial waste practices at one of its sites.

APPROPRIATE ACCESS & STEWARDSHIP

Large research-based companies

▶ Modest performance across the board for product registrations, with gaps in paediatric registrations

Many large research-based companies have been downsizing their antimicrobial portfolios, with some cutting them by as much as half since 2021. Across all these product types assessed by the 2026 AMR Benchmark, companies systematically prioritise registrations in upper- and lower-middle-income countries over low-income countries. This is especially the case for vaccines, reflecting a continued focus on emerging markets rather than in areas of greatest unmet need.

Despite 11 low- and middle-income countries (LMICs) being added to the geographic scope of the Benchmark since 2021, the level of product registrations has not widened over the last five years. In fact, registrations remain thin across all product categories, with registrations in an average* of just 24 of the 113 countries in scope.

However, some on-patent medicines evaluated in 2021 – for example, cefiderocol, ceftazidime-avibactam and delamanid – are now registered in a few more countries, leading to an increase in the average* number of registrations across all on-patent medicines from 11 to 16 countries. Overall performance is thus still low here. On-patent vaccines remain most widely registered, averaging* 29 countries, reflecting dynamics such as international procurement and broader target populations. At an average* of 23 countries, registrations of off-patent medicines fall between these categories.

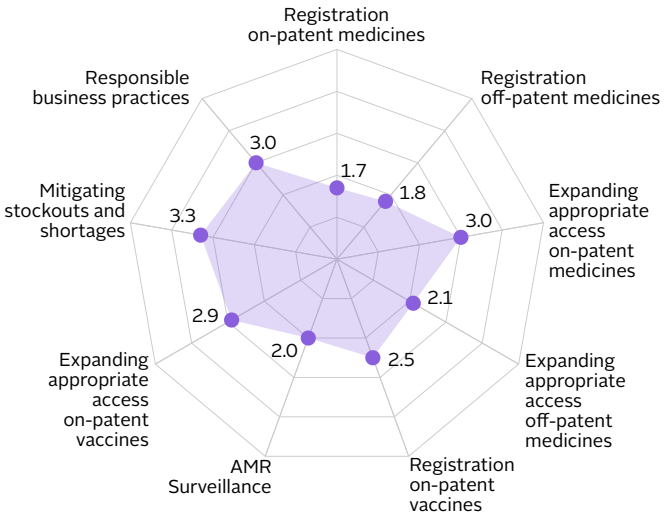
Overall, registrations of off-patent medicines remain stagnant across companies, with some discontinuing some of the products that were included in the 2021 Benchmark. Against this backdrop, only **Pfizer** stands out for significantly increasing its registrations across off-patent medicines from an average* of 17 countries to 29.

Among off-patent medicines, Access antibiotics are registered most widely – across 78 countries in scope. Reserve antibiotics and antituberculosis medicines are registered significantly less – across 33 countries and 31 countries, respectively. While prioritising Access antibiotics is necessary, as first-line treatments need to be available everywhere, the limited registration of Reserve antibiotics is concerning, particularly given the disproportionate burden of AMR in LMICs.

Companies assessed: 17

7 large research-based pharmaceutical companies	10 generic medicine manufacturers

FIGURE 5 **Large research-based companies' performance across Appropriate Access & Stewardship**



Paediatric formulations, which are mainly assessed for off-patent Access and Watch antibiotics, are not systematically registered in the same countries where the corresponding adult formulations are registered, creating a clear access gap for children – even for essential first-line treatments (see Key Finding, p.30).

▶ Product-level access and stewardship strategies are established, but gaps remain in patient reach tracking and company-level stewardship policies

The 2026 Benchmark adopted a more integrated approach to appropriate access and stewardship, incorporating a new assessment of product-specific stewardship strategies and a new patient reach component, to evaluate the effectiveness of the access strategies employed by companies.

*All average numbers are based on the products for which companies disclosed registration data to the 2026 AMR Benchmark. Products from non-submitting companies have been excluded. Products are considered for the product category as per the 2026 AMR Benchmark scope.

Encouragingly, of the 47 products assessed across the portfolios of companies, only one – an on-patent vaccine – lacked any form of access strategy. All other products were supported by either a general access strategy or a tailored approach, designed specifically for the product, the country context, or both. Tailored access strategies are more common than general ones, covering around 65% of medicines (both on and off-patent) and 53% of on-patent vaccines.

Companies show considerable variation in both the transparency and completeness of their patient reach measuring and reporting. Of the seven companies assessed, four disclose details on their methodologies and patient reach figures for at least some products, and only two of these four do so for all assessed products.

Stewardship coverage is highest for on-patent medicines: all of them have a stewardship strategy in place. This is encouraging, as five of the eight are Reserve antibiotics, which require more stringent stewardship. However, only two of these five Reserve antibiotics have product-specific strategies, while the remaining three are only supported by general, high-level measures. Off-patent medicines have less consistent stewardship coverage (73%); among the products that do have coverage, general strategies (58%) are slightly more common than tailored strategies (42%). Most of these strategies – whether general or tailored – focus primarily on responsible promotion and sales strategies, as assessed in Responsible Business Practices.

Since 2021, there has been no significant progress in companies' efforts to implement sales practices that disincentivise the overselling of their antimicrobial medicines. However, in newly assessing governance of interactions with healthcare professionals (HCPs), the Benchmark finds that all companies, except **MSD**, perform well. **Otsuka**, **Pfizer**, **Sanofi** and **Shionogi** stand out for clearly addressing stewardship across both sales practices and their governance of interactions with HCPs (see Responsible Business Practices, p.59).

Pfizer and **Shionogi** are also among the four companies currently actively engaged in AMR surveillance, with **GSK** and **MSD** being the other two. While the number of programmes these companies engage in has fluctuated since 2021, the Benchmark notes increased coordination across efforts (see AMR Surveillance, p.64). **Johnson & Johnson** and **Sanofi** discontinued their surveillance efforts since 2021.

▶ Efforts to ensure continuous supply can be strengthened

Large researched-based companies continue implementing diverse strategies to mitigate shortages and stockouts and to ensure continuous supply. Notably, some companies are increasingly engaging in supplier diversification to strengthen supply chain resilience (see Supply, p.53). **Shionogi** is the top performer and is among the four companies in this group that reports sharing demand forecasts with country-level stakeholders. This is a drop from 2021, where all companies reported sharing data with external stakeholders, highlighting the need for greater engagement in bilateral data sharing. All seven companies report maintaining buffer stocks of their products – up from six out of eight companies in 2021. However, wider adoption of automated inventory systems is still needed, with only four companies using them (see Supply, p.53).

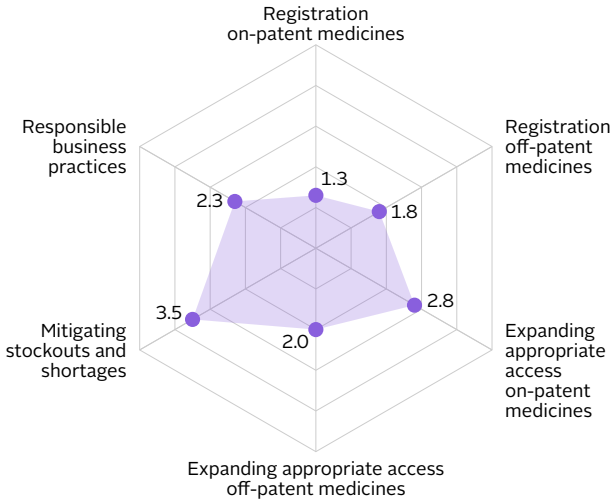
Generic medicine manufacturers

▶ Low performance in off-patent product registrations but bright spots for on-patent

Off-patent medicines form the core business model for generic producers, but since 2021 there has been no significant progress in the number of registrations across LMICs. Overall, these medicines are only registered in nine of the 113 countries in scope on average*. Only Fresenius Kabi slightly increased its average number of registrations across the products selected for analysis, while other generic medicine manufacturers either stagnated or even regressed. Aurobindo remains the leader, registering its off-patent medicines most widely – 19 countries in scope on average* (see Best Practice, p.73).

Overall, among off-patent medicines, Access antibiotics are fairly widely registered – across 75 countries in scope. Watch antibiotics and antituberculosis medicines are registered across 68 and 38 countries in scope, respectively, signalling a gap for treatments that can be effective against drug-resistant infections. Reserve antibiotics are registered across only 23 countries, making these last-resort treatments sparse.

FIGURE 6 **Generic medicine manufacturers' performance across Appropriate Access & Stewardship**



*All average numbers are based on the products for which companies disclosed registration data to the 2026 AMR Benchmark. Products from non-submitting companies have been excluded. Products are considered for the product category as per the 2026 AMR Benchmark scope.

Despite not registering off-patent medicines widely, at least four companies do register off-patent paediatric formulations of their products in a large proportion of the countries they already register other products in, with **Sandoz** leading here (see Key Finding, p.30). Across the board, generic medicine manufacturers register paediatric formulations in about half of the countries they register in.

More on-patent medicines are included across the antimicrobial portfolios of companies assessed, but this now includes **Hikma's** portfolio, which is newly evaluated in the Benchmark (increasing the number of companies from nine to ten since 2021). The increase in on-patent medicines can have a direct impact on availability – and potentially affordability – of newer medicines in LMICs. However, registrations of on-patent medicines are low, with an average* of just six countries and a primary focus on India. This can be attributed to companies being bound by licensing terms and agreements or the territories for which they acquired the commercialisation rights.

Viatris does stand out for registering its on-patent medicine pretomanid in eight additional countries since 2021. While pretomanid is supplied via The Stop TB Partnership's Global Drug Facility (GDF), registering it widely with national regulatory authorities remains important for enabling broader access, including routine procurement outside of GDF procurement channels, and integration into national treatment guidelines. Although **Cipla** has global rights for its on-patent Reserve antibiotic plazomicin, the company has not registered in any additional countries in scope since 2021.

▶ Encouraging steps in access strategy coverage and supplier diversification, but stewardship efforts lag

The 2026 Benchmark adopted a more integrated approach to appropriate access and stewardship, incorporating a new assessment of product-specific stewardship strategies and a new patient reach component, to evaluate the effectiveness of the access strategies employed by companies.

All eight on-patent medicines assessed among generic producers are covered by access strategies, and notably, 62% are tailored approaches. Among off-patent medicines, the vast majority (84%) have access strategies in place, with only 16% lacking any form of strategy. However, unlike on-patent medicines, generic medicines are more likely to have general rather than tailored access strategies, with this being the case for 60% of strategies. For examples of how tailored strategies can address access barriers in LMICs, see Access Strategies on p.49.

Patient reach can provide a temperature check on the effectiveness of access strategies, with the Benchmark assessing generic producers on this for the first time. Encouragingly, six out of the ten companies track patient reach across nearly all assessed antibiotics and antifungals (see Key Finding, p.36).

Stewardship coverage is notably lower than access strategy coverage for both on-patent and off-patent medicines. Around 40% of medicines, on- and off-patent, lack a stewardship strategy of any form. For on-patent medicines, those with a stewardship strategy are more likely to have a product-specific approach (80%) than general stewardship practices (20%), reflecting a proactive approach to safeguarding new medicines from the threat of resistance. Conversely, for off-patent medicines, stewardship strategies are more often general (80%) than product specific (20%).

Performance among generic medicine manufacturers in addressing the appropriate use of antibiotics in their business practices is uneven. Their business model, which relies on volume rather than high margins, is often more conducive to mitigating the overselling of individual products. Some companies do take additional measures to mitigate this risk, contributing to good performance in this area. However, their performance on governing interactions with HCPs is weaker, with nearly half of the companies not incorporating specific provisions in their public policies that can help to ensure such interactions remain ethical. Teva is the only company to include clear principles to address appropriate use across its business practices (see Responsible Business Practices, p.59).

Despite not being evaluated on AMR surveillance, a small number of generic medicine manufacturers continue to report engagement here. While this mostly reflects post-marketing surveillance requirements, **Sandoz** stands out for doing this beyond such mandates (see AMR Surveillance, p.64).

▶ Nearly all generic producers engage in supplier diversification

Generic medicine manufacturers newly demonstrate the use of upstream strategies to mitigate stockouts and shortages of quality-assured products, such as supplier diversification. Nine of the ten companies are actively pursuing local sourcing of raw materials or finished products in LMICs, which can help mitigate potential supply disruptions. **Abbott** and **Viatris** lead here, sourcing from multiple local suppliers for their key antimicrobials (see Supply, p.53). To complement local sourcing in LMICs, all companies, except **Alkem**, report conducting routine Good Manufacturing Practice audits for their suppliers. However, additional quality assurance measures when sourcing from countries with evolving regulatory systems is still lacking across the board.

*All average numbers are based on the products for which companies disclosed registration data to the 2026 AMR Benchmark. Products from non-submitting companies have been excluded. Products are considered for the product category as per the 2026 AMR Benchmark scope.

KEY FINDING 1 | RESEARCH & DEVELOPMENT

Thin pipeline, high stakes: How are companies planning to expand access to vital, new antimicrobials?

- The antimicrobial pipeline continues to shrink, with a 35% decrease in the number of pipeline projects from large research-based pharmaceutical companies assessed by the Benchmark in the past five years.
- Amid this declining pipeline, the 2026 AMR Benchmark identified seven new, innovative medicine projects in late-stage development by GSK, Otsuka, Shionogi, BioVersys, F2G, Innoviva and Venatorx.* These target some of the deadliest drug-resistant pathogens disproportionately affecting people living in low-and middle-income countries (LMICs).
- While companies demonstrate strong elements in their access planning, Innoviva and Otsuka stand out for detailed, product-specific plans that explicitly address key access barriers in LMICs, including affordability, availability and supply.

Superbugs do not respect borders, and they are putting lives everywhere at risk. But for people in low- and middle-income countries (LMICs), where infectious diseases already hit hardest, this danger is not a distant threat; it is daily life. Infants, children and other vulnerable groups face the highest stakes, especially in countries on the frontlines of drug resistance.[1] In addition to having limited access to basic antimicrobials, patients in these settings cannot access the newer treatments that could save them from deadly, drug-resistant infections – leaving them exposed at best, and at worst, without a fighting chance.

As antimicrobial research and development (R&D) continues to decline, people are being left with fewer drugs that can treat resistant infections. Since the publication of the 2021 Antimicrobial Resistance (AMR) Benchmark, for instance, there has been a 35% decrease (92 projects to 60) in the number of pipeline candidates from large research-based pharmaceutical companies assessed (see Figure 1 alongside).

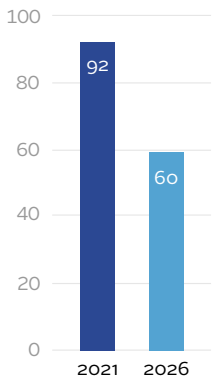
This low number of promising projects makes it vital to ensure that any hopeful new medicine projects in development that successfully make it to market reach the patients who need them most, especially in LMICs where access gaps remain persistent.

Access to these medicines could tip the scales for millions

Of the 78 projects assessed, seven are especially notable: they target critical- and high-priority pathogens in need of new treatments, exhibit genuine innovation[2] with potential to overcome resistance, and are already in late-stage development (Phase II or later) with access plans in place. Together, these features position them for future availability in LMICs if they successfully reach the market.

These products originate from both large research-based companies GSK, Otsuka, Shionogi and small- and medium-sized enterprises BioVersys, F2G, Innoviva, Venatorx – and have the potential to significantly impact patients in LMICs (see infographic on next page).

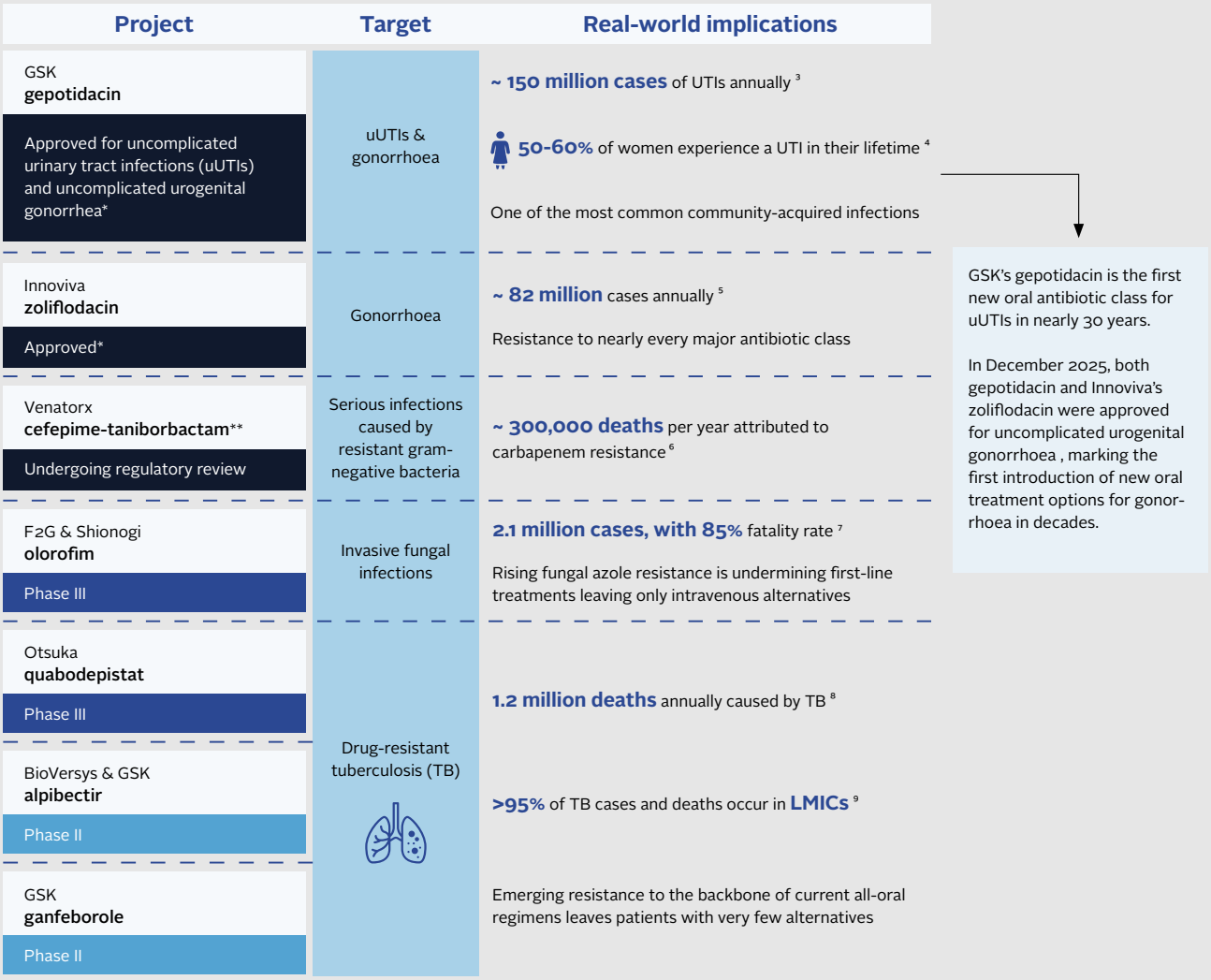
FIGURE 1 **The antimicrobial pipeline continues to shrink**
The number of projects in the pipeline of large research-based pharmaceutical companies assessed by the AMR Benchmark has declined by 35% from 2021 to 2026.



** After the period of analysis of the Benchmark, the Global Antibiotic Research and Development Partnership (GARDP) and Venatorx announced the termination of their collaboration agreement on cefepime–taniborbactam.*

PROMISING MEDICINES CAN CURB DEADLY RESISTANT INFECTIONS IN BOTH HOSPITALS AND COMMUNITIES

The seven projects identified by the Benchmark target both hospital- and community-acquired infections that currently put millions of lives at risk, especially in low- and middle-income countries. By ensuring comprehensive access and stewardship plans are in place before these medicines are available on the market, companies can strike the right balance between ensuring access for all patients who need these medicines and minimising the risk of resistance.



** In 2025, gepotidacin was approved for uncomplicated urinary tract infections (uUTIs) and gonorrhoea, and zoliflodacin was approved for gonorrhoea. However, both were assessed as pipeline projects, as they were still in development during the period of analysis for the 2026 AMR Benchmark.*

*** After the period of analysis of the Benchmark, the Global Antibiotic Research and Development Partnership (GARDP) and Venatorx announced the termination of their collaboration agreement on cefepime–taniborbactam.*

Notably, three projects target multidrug-resistant tuberculosis (MDR-TB). Although MDR-TB has been virtually eradicated in high-income countries, it remains a severe and ongoing public health crisis in LMICs, with only two in five patients able to access appropriate treatment.[8] However, the impact of all these potential new drugs will only be realised if the current access plans linked to them are put into practice by companies.

▶ Some companies demonstrate strong elements in access plans, but scale and scope are still limited

Realising the public health benefit and ensuring appropriate access to these innovations in LMICs is contingent on a shared responsibility: both from companies through their access planning and the implementation of National Action Plans (NAPs) from governments. However, companies can help immensely

by weaving in measures into their access plans that can tackle the most critical access challenges in LMICs, such as regulatory barriers and supply chain barriers. Additionally, ensuring that antimicrobials remain accessible and affordable to those who need them most is critical, yet this goal must be balanced with predictable, sustainable returns – which is challenging due to the need to limit antimicrobial use. Governments, in collaboration with companies, can work to develop and implement novel incentive models, which guarantee revenue to sustain R&D investment. In parallel, companies can focus on implementing equitable pricing strategies tailored to ensure fair access across diverse markets. To ensure appropriate use of these drugs, companies and governments can implement stewardship provisions – such as data-sharing arrangements and availability of appropriate diagnostics – to safeguard the efficacy of antimicrobial medicines.

To this end, as set out in the accompanying table, the Benchmark assessed the breadth and depth of the access plans for the seven projects, based on whether companies are specifically considering availability, affordability and continuous supply of these breakthrough treatments in LMICs.

TABLE 1 **How comprehensive are the access plans for these breakthrough medicines?**

The depth and specificity of the access plans across the seven projects vary, with only two companies – Innoviva and Otsuka – providing concrete evidence of addressing availability, affordability and continuous supply (beyond high-level policies and commitments) for their specific projects in low-and middle-income countries.

	Availability	Affordability	Continuous supply
Examples of how companies plan for access	• Registrations (incl. collaborative registration mechanisms) • Early access programmes • Post-trial access commitments	• Price ceilings/controls • Detailed equitable pricing plans (beyond broad commitments)	• Market research • Pooled procurement mechanisms • Demand forecasting • Manufacturing practices
gepotidacin GSK	●	●	●
cefepime-taniborbactam* Venatorx	●	●	●
zoliflodacin Innoviva	●	●	●
olorofim F2G & Shionogi	●	●	●
quabodepistat Otsuka	●	●	●
alpibectir BioVersys & GSK	●	●	●
ganfeborole GSK	●	●	●

** After the period of analysis of the Benchmark, the Global Antibiotic Research and Development Partnership (GARDP) and Venatorx announced the termination of their collaboration agreement on cefepime–taniborbactam.*

Overall, access plans for the seven projects focus on availability of the medicines in LMICs. While these efforts are encouraging, the depth and specificity of access plans still vary significantly across companies. Only Innoviva and Otsuka collectively and pre-emptively address some of the most critical access barriers of availability, affordability and supply in LMICs through detailed plans at a project-specific level. Partnerships are key for driving innovation in antimicrobial R&D, with both Innoviva and Venatorx collaborating with the Global Antibiotic Research and Development Partnership (GARDP), an organisation that integrates equitable access in LMICs and appropriate use worldwide into its plans.

Without comprehensive, early, appropriate and tailored access planning across the board, the potential impact of these breakthrough innovations will not be realised. With these treatments so close to reaching the market, the current gaps in access planning could leave millions in LMICs with delayed treatment – or no access at all. With treatment options for resistant infections becoming increasingly limited – or non-existent – and superbugs only increasing, the consequences of missing the opportunity to reach people with these new treatments will be devastating.

Some companies plan for stewardship in parallel with access

For five of the seven projects (gepotidacin, cefepime-taniborbactam, zoliflodacin, olorofim and quabodepistat), companies included project-specific measures in their plans.

Such a targeted approach is essential, because stewardship challenges are not uniform across pathogens, products or healthcare settings. Moreover, stewardship planning is particularly critical for last-resort antimicrobials and those used to treat multi drug-resistant infections. (Also see Research & Development on p.47 for the various elements companies employ in their stewardship plans).

With so few new medicines on the horizon, safeguarding their efficacy with stewardship strategies will go a long way to ensuring these lifesaving treatments are not at risk of AMR. However, access must be secured first, with stewardship hard-wired into the access plans that will make these game-changing treatments available and affordable to those who need them, when they need them.

WHAT NEXT?

Given the critically thin pipeline of new antimicrobials targeting priority pathogens – and the public health potential of new developments – it is more vital than ever that pharmaceutical companies start integrating early access considerations during R&D.

- Companies must scale up their current access plans, moving beyond high-level plans to actionable commitments that include clear registration pathways and pricing models that balance sustainable returns with affordable access. By tailoring these plans to specific products and countries, companies can maximise their impact on public health.
- In addition to universal availability of their products for those who need it, companies must work alongside governments – with robust AMR policies – to ensure stewardship measures are in place to safeguard appropriate use.

KEY FINDING 2 | PAEDIATRIC ACCESS

Building a better antibiotic arsenal for children

- Access gaps in paediatric antimicrobials persist, evidenced by a sparse research and development pipeline and limited availability of medicines already on the market.
- Only 13% of antimicrobial pipeline projects belonging to companies assessed by the AMR Benchmark are developed for children under five, leaving delays in paediatric approvals, even for existing antibiotics.
- Among these companies with paediatric formulations on the market, five – Aurobindo, GSK, Hikma, Sandoz and Teva – stand out by registering their paediatric formulations, on average, in more than 50% of the low- and middle-income countries where they register their other off-patent antimicrobials.
- Despite this, gaps in access are prominent in 17 sub-Saharan African countries, where no child-friendly versions of any of these products have been registered by any of the companies assessed by the Benchmark.

Right now, there simply are not enough child-friendly formulations to treat bacterial infections. Even among World Health Organization (WHO)-recommended Access, Watch, and Reserve antibiotics, many lack age-appropriate formulations or doses.[1] Overall, of all new antibiotics introduced since 2000, only 10% carry a paediatric label.[2] This gap is particularly pronounced for antibiotics used to treat drug-resistant infections – such as neonatal sepsis caused by hard-to-treat gram-negative bacteria.[3] Developing safe and appropriate dosage forms for children – especially neonates, who require very small doses – remains a challenge. In cases where child-friendly antimicrobials exist, gaps in access mean that they are not always readily available to those who need them in low- and middle-income countries (LMICs).

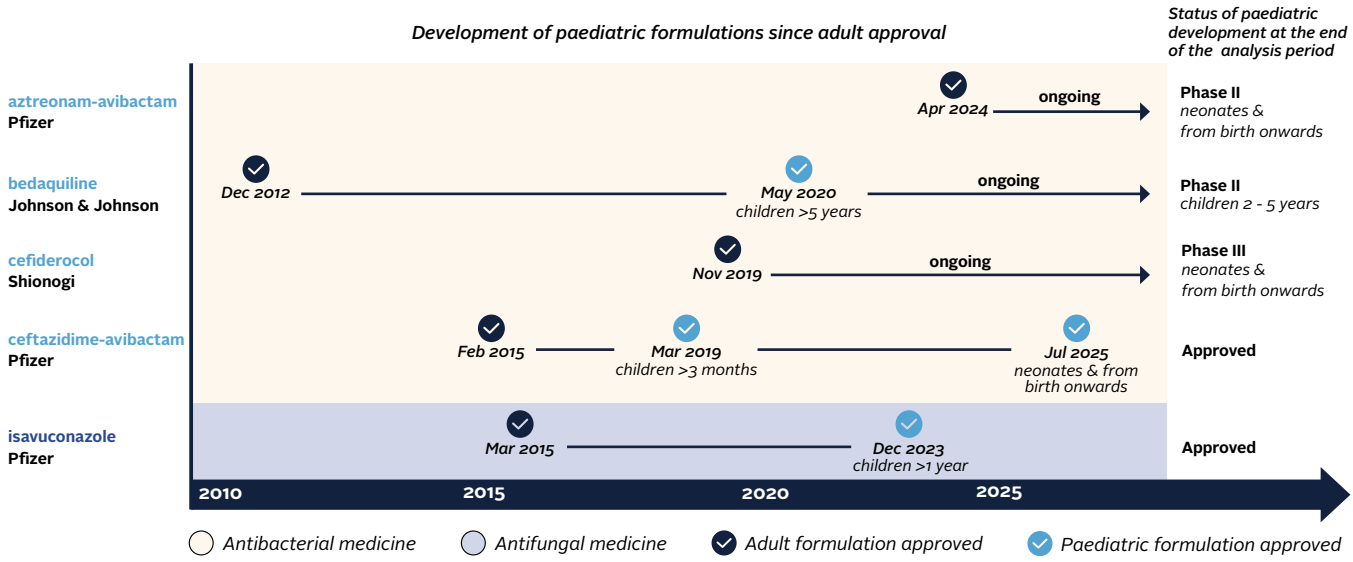
A two-fold approach is required to close gaps in both innovation and access: advancing neonatal and paediatric label extensions and dosage forms for existing antimicrobials and ensuring equitable access to those already available.

Innovation gap: With only five medicines in development for children under the age of five, speedy access is key

With antimicrobial resistance (AMR) rising, the efficacy of existing products is at risk. Yet, across the pipelines of the seven large research-based companies and eight small and medium-sized enterprises assessed, only five of the 39 projects targeting WHO-listed priority pathogens in clinical

FIGURE 1 **5 projects across companies pipelines also focus on children under 5**

The five projects are adaptations of existing, approved adult formulations. Two of the projects, isavuconazole and ceftazidime-avibactam, received approval for children under five during the period of analysis and other medicines are already approved for older children, but this process can take years.

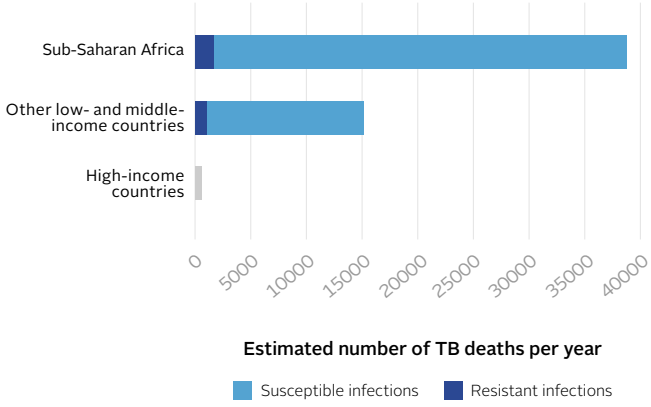


development are specifically designed to meet the needs of children under five.

Notably, two of these projects – Pfizer's antibiotic aztreonam-avibactam and Shionogi's cefiderocol – which both target serious, life-threatening multidrug-resistant gram-negative bacterial infections, are on WHO's Paediatric Drug Optimisation for Antibiotics (WHO PADO) list. This list highlights antibiotics for which the development of age-appropriate paediatric versions is much needed.[1] However, as seen in Figure 1 above, paediatric approvals – specifically for children under five – can take years.

These delays are, in part, attributable to the complexities of developing and marketing age-appropriate medicines, such as strict ethical and regulatory requirements. However, it is also crucial for companies and other stakeholders to ensure that paediatric developments – especially adaptations of existing, successful adult formulations – reach children with as little delay as possible. For example, Johnson & Johnson's anti-tuberculosis (TB) medicine, bedaquiline, is still being evaluated in children under five years of age (see Figure 1).

FIGURE 2 **80% of children who die from TB infections, live in sub-Saharan Africa**



[Source: IHME, 2024]

Although the drug was approved for adult use in 2012, the paediatric formulation for children over five was not approved until 2020, highlighting that, for almost ten years, children lacked access to an age-appropriate formulation of this critical treatment. For children living in sub-Saharan Africa, where the burden of TB is highest (as per Figure 2 above), access to treatments that can overcome drug-resistant TB is vital.

Early parallel development of adult and paediatric formulations, combined with proactive access planning, can help bridge delays and support timely availability. For its PADO-listed aztreonam-avibactam, for example, Pfizer is planning for access for young children, with Phase II trials initiated prior to product approval in 2024. Rising resistance against carbapenems, one of the few effective classes for treating drug-resistant infections in children, now already leaves about 19% of children without effective treatment options, putting them at high risk of death.[2] With its ability to treat carbapenem-resistant gram-negative infections, Pfizer's aztreonam-avibactam has the potential to offer a treatment option for children who are currently left without, including difficult cases of neonatal sepsis. Ensuring plans are in place to make aztreonam-avibactam available to children and neonates as quickly as possible can fill this gap and save lives.

Access gap: Registration can signal a gateway to access, but only a handful of companies register existing child-friendly antimicrobials widely in LMICs

Once a product is approved and exits the pipeline, registration is the first step a company can take to ensure availability. Although registration does not guarantee a product's availability, it signals a company's intent to make it commercially available and serves as a critical first step to initiating access. The Benchmark assessed 19 marketed antimicrobial medicines (18 antibiotics and 1 antifungal) across the portfolios of six large research-based pharmaceutical companies and eight generic medicine manufacturers,* all of which are included on WHO's Model List of Essential Medicines for children (EMLc) – which means they should be available and affordable everywhere.

▶ Five companies stand out

Overall, the 14 companies register paediatric formulations of antimicrobials in a combined total of 79 of the 113 countries covered by the Benchmark. Access antibiotics, such as amoxicillin and amoxicillin-clavulanic acid – both essential first-line treatments commonly used for the treatment of respiratory and urinary tract infections – are registered most widely (also see Industry Trends on p.20).

Of the 14 companies assessed, five – Aurobindo, GSK, Hikma, Sandoz and Teva – stand out by registering their paediatric formulations, on average, in more than 50% of the LMICs where they register their other off-patent antimicrobials. Generic producer Sandoz performs best in registering such child-friendly dosage forms, with paediatric versions of its antimicrobials registered in about 85% of the LMICs where it registers its off-patent antimicrobials.

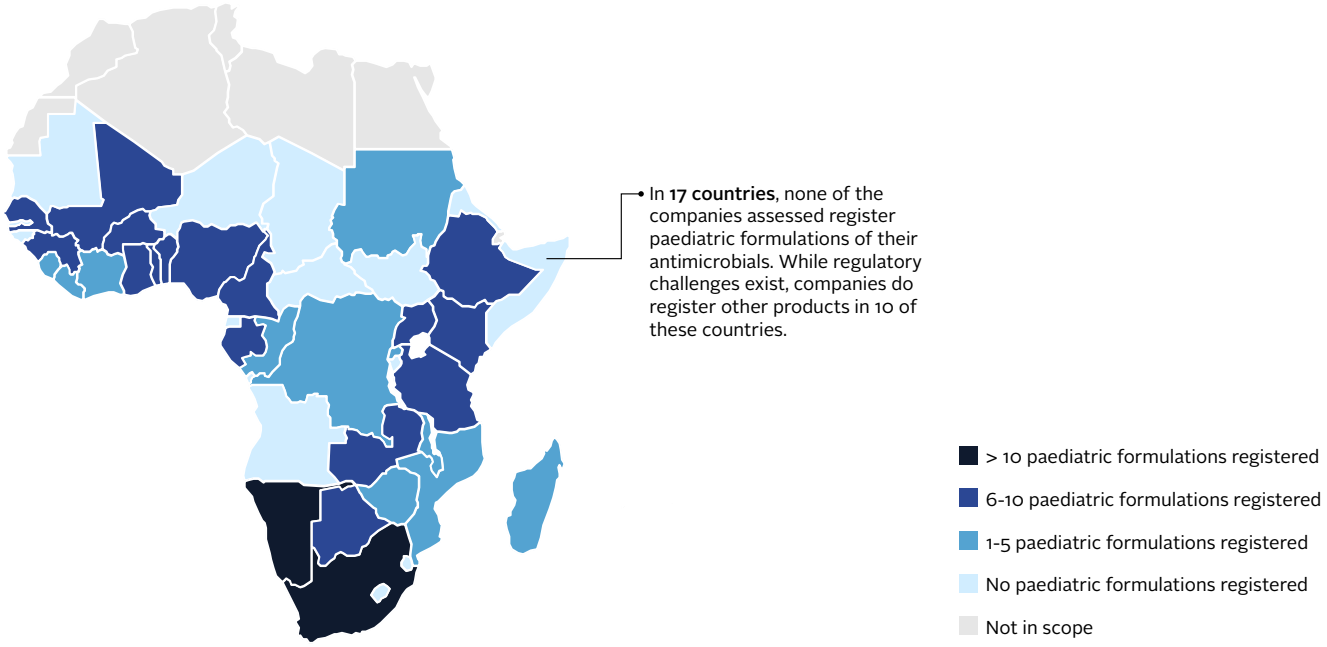
▶ Registration coverage in sub-Saharan Africa is sparse

Sandoz also stands out for registering its paediatric formulations across 14 of the 46 sub-Saharan African countries covered by the Benchmark. However, registrations of the 19 products across companies' portfolios are otherwise limited in this region, where the burden of infectious diseases – and its impact on children – is disproportionately high. In 17 countries, none of the companies assessed by the Benchmark register existing paediatric formulations of any of their antimicrobials (see Figure 3 on next page). Some of these countries lack National or Regional Regulatory Authorities, making registration unfeasible. However, in ten of these countries, companies already register adult formulations of their products, indicating that there is scope to do this for paediatric formulations in these ten countries as well.

Abbott, Fresenius Kabi and Shionogi were not assessed here, as specific paediatric formulations for the products selected for analysis could not be confirmed within their portfolios.

FIGURE 3 **Limited registrations of child-friendly antimicrobial products across sub-Saharan Africa****

Companies register a limited number of child-friendly antimicrobial products across the 46 sub-Saharan Africa countries covered by the Benchmark. The Benchmark assessed registrations of 19 different child-friendly dosage forms, all of which are on the World Health Organization's Model List of Essential Medicines for children.



***It is important to note that this registration data is based only on the seven pharmaceutical companies and ten generic producers assessed in the 2026 AMR Benchmark. It is possible that other companies register paediatric formulations in sub-Saharan Africa.*

South Africa and Namibia are the only sub-Saharan African countries where more than ten different types of paediatric formulations of antibiotics produced by the 14 companies are registered, with coverage in other countries being very patchy. For example, in only 11 countries are more than five products registered. When only a few antibiotics are registered, it limits treatment options, fuels resistance and leaves children vulnerable to otherwise treatable infections.

Given that the few paediatric antimicrobial products that are available are not registered as widely as needed, companies need to continue driving efforts to expand access to the drugs we already have. But, at the same time, new treatments are also urgently needed.

WHAT NEXT?

Close the innovation gap by prioritising paediatric R&D and planning for access:

- By initiating paediatric studies in parallel with adult development early on – once Phase I is completed or during early Phase II trials – companies can proactively conduct clinical trials to test the safety and efficacy of their products in children to avoid delays as much as possible. Prioritising paediatric formulations and dosing strategies early on, especially for diseases with high mortality rates in children under five, can also accelerate drug development.
- Companies can align their development efforts with WHO's Global Accelerator for Peadiatric Formulations Network (GAP-f) to ensure resources are channelled into the most urgent and impactful treatments as per GAP-f's PADO list.
- In parallel, companies should develop access plans from Phase II onwards to ensure that new pipeline projects become available without delay for paediatric populations in LMICs.

Close the access gap by expanding access to the paediatric products that already exist:

- To accelerate access to children, especially in LMICs, companies can ensure paediatric formulations of marketed antibiotics are registered widely in the countries where they are needed, and in the same countries as their corresponding adult products.
- Beyond registration, companies can utilise further access strategies to ensure that registered products actually reach the children who need them.

KEY FINDING 3 | RESPONSIBLE MANUFACTURING

Some companies take stronger action to curb AMR at manufacturing sites across their supply chains

- Across the 17 companies assessed, Aurobindo, GSK and Sandoz stand out for reporting compliance with antibiotic waste limits for both in-house and supplier production of all their antimicrobial products.
- Companies reporting on supplier compliance has doubled since 2021 (4 to 8), with generic producers leading this improvement. However, nine companies do not disclose details of supplier compliance at all.
- Currently, all waste limits are being measured and met in receiving waters, after dilution may have occurred. By doing this at 'end-of-pipe' before waste is released into the environment, antimicrobial resistance and environmental risk can be contained even further.

The global production of antibiotics can release waste into rivers and soil around manufacturing sites. When this waste is not properly controlled, it creates the perfect breeding ground for drug-resistant bacteria, threatening the very antibiotics we rely on to save lives. Ensuring antibiotic waste from manufacturing is managed responsibly is one of the ways in which pharmaceutical companies can limit antimicrobial resistance (AMR), while also protecting people and the environment.

The 2026 AMR Benchmark assessed seven large research-based companies and ten generic medicine manufacturers on how they ensure compliance with antibiotic discharge limits – both in-house and at supplier sites. Overall, there has been improvement in meeting limits once waste has been released into the environment. However, in line with measures recommended by the World Health Organization (WHO), ensuring compliance before waste is released into the environment would further help protect ecosystems and communities worldwide. Currently, none of the companies assessed by the Benchmark report doing this.

Seven companies meet waste targets in receiving waters for 100% of products manufactured in-house

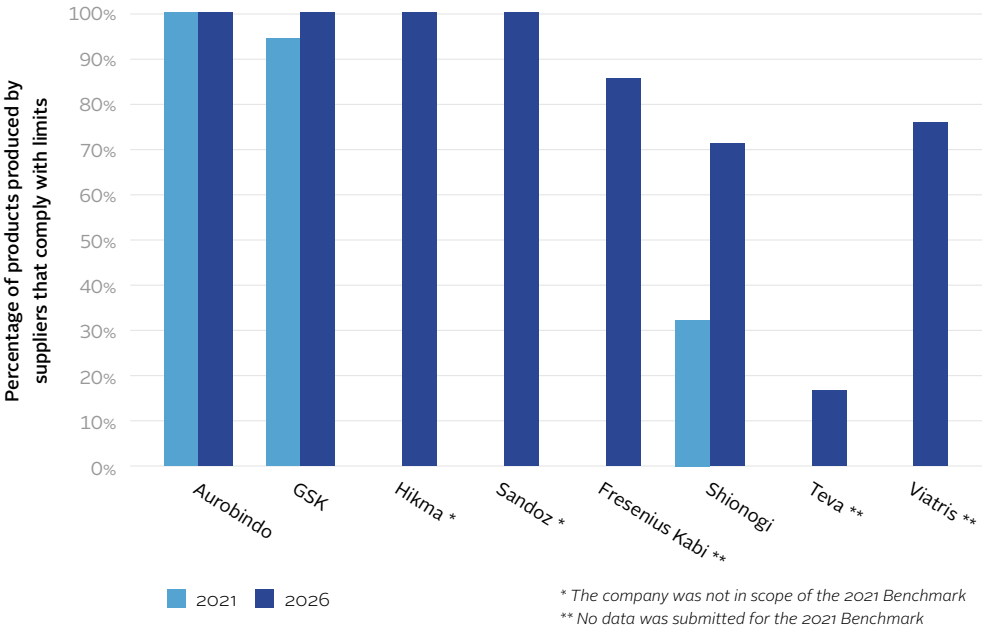
Given that companies have full control over their own manufacturing sites, meeting waste limits at direct operations is a baseline of expectation. Of the 17 companies assessed, ten share details on whether their in-house antibiotic production meets discharge limits. Notably, seven of these companies – Aurobindo, Cipla, GSK, Sandoz, Shionogi, Sun Pharma and Viatris – indicate 100% compliance in the receiving environment where waste is released for all antibiotics produced in-house.

> "Aurobindo, Cipla, GSK, Sandoz, Shionogi, Sun Pharma and Viatris indicate 100% compliance in the receiving environment where waste is released for all antibiotics produced in-house."

Number of companies reporting on supplier compliance has doubled since the 2021 Benchmark, with generic producers making biggest leap forward

By controlling impacts across their supply chains, and not just within their own facilities, companies can prevent the creation of resistance hotspots linked to manufacturing. Encouragingly, the Benchmark finds that the number of companies reporting on supplier compliance has doubled from four to eight since 2021. Aurobindo, GSK, Hikma, Sandoz, Fresenius Kabi, Shionogi, Viatris and Teva share details on whether suppliers they contract for antibiotic production are compliant with waste targets in the receiving environment (see Figure 1). Aside from Teva, these companies all exceed the industry average of 40%[1] of products manufactured by suppliers that comply with discharge limits.

FIGURE 1 **Disclosure of supplier compliance has doubled since 2021, with high levels of compliance achieved**



The improvement among generic companies is strongest, with six now reporting supplier compliance, compared to just one in 2021. This progress is a critical development, as the ten generic companies assessed account for nearly one-fifth of global antimicrobial sales, making their practices instrumental in minimising manufacturing-related AMR risks. Notably, generic producer Fresenius Kabi, which has not previously reported supplier compliance to the Benchmark, now reports that 86% of all products manufactured by its suppliers meet safe discharge limits in the receiving environment (i.e., rivers and waterways). As an important producer of sterile injectable antibiotics, which often require more water-intensive manufacturing than other types of antibiotics, ensuring proper wastewater management is critical.

▶ **Aurobindo, GSK and Sandoz stand out for 100% compliance across their supply chains**

Aurobindo, GSK and Sandoz achieve 100% compliance in receiving waters for all products manufactured both in-house and at their supplier sites, demonstrating end-to-end control of environmental and AMR risks across their supply chains. Notably, both GSK and Sandoz achieve this across a vast network of external suppliers, demonstrating that achieving compliance at scale across supply chains is attainable.

How are companies ensuring supplier compliance?

Companies employ a range of approaches to ensure their suppliers meet waste targets. Most companies (11/17) conduct supplier audits to monitor whether discharge limits are being met – and also request suppliers to implement Corrective and Preventive Action plans (CAPA plans) when waste levels are too high. Seven companies – Abbott, Aurobindo, GSK, Sandoz, Pfizer, Teva and Shionogi – do this through contractual provisions that expect supplier compliance with discharge limits. Six companies also demonstrate actively engaging their suppliers in complying with these discharge limits. Abbott, Aurobindo, Cipla, GSK, Sandoz and Shionogi do this by, for example, guiding suppliers on quantifying discharge levels, how to adjust waste management processes and offering free wastewater analysis. By engaging and educating suppliers, these companies are actively helping them achieve compliance. (Also see Best Practice on p.71 for more detailed examples.) Notably, Aurobindo, GSK and Sandoz report 100% supplier compliance, indicating that a more hands-on approach can help yield demonstrable results.

Industry-wide efforts must accelerate, with progress needed where it matters most: at the source

The growing global recognition that antibiotic waste drives resistance is leading to stricter expectations from stakeholders. As a result, governments and buyers, both in high-income countries but also in countries with large manufacturing hubs such as China and India, are tightening rules and introducing new mechanisms for regulators to better monitor antibiotic residues in wastewater.[2]

Despite the voluntary efforts – and improvements – from some companies, seven do not report on compliance at their direct operations, and nine do not share details on compliance by suppliers. At the moment, all companies that do report compliance only assess compliance in receiving waters, as per AMR Alliance Antibiotic Manufacturing Standard. No company currently measures discharge directly at end-of-pipe according to WHO 'Stringent' guidelines, which would better indicate how responsibly a site manages waste and limits AMR risk.

WHAT NEXT? 

It is encouraging to see the steps companies are taking with their suppliers to ensure the responsible management of antibiotic waste across the supply chain, but it is vital that higher levels of compliance in the supply chain are achieved by more companies across the board. Not only will this have a significant impact on curbing AMR and protecting people, but it will set companies up for sustainable business amid rising expectations from stakeholders.

- By being transparent on how compliance is assessed and what the actual discharge levels are, companies can offer much-needed insights into the relationship between wastewater management and AMR while also meeting expectations from stakeholders.
- Companies can work towards expanding and strengthening contractual obligations for their suppliers, while also supporting them by sharing knowledge, resources, expertise and analytical capabilities. Better external auditing and reporting of compliance across the industry, including manufacturers not currently assessed by the Benchmark, will also be important to ensure consistent compliance.
- By adopting WHO's 'Stringent' wastewater management guidance and supporting suppliers to do the same, companies can cut antibiotic pollution at the source, directly slowing the rise of AMR and driving lasting industry-wide change.
- Stakeholders, such as regulators, procurers, investors and licence partners can further implement waste standards that ensure compliance across the supply chain. For example, legislators can set basic requirements on waste practices while procurers can reward companies that adhere to WHO's stringent guidance.

KEY FINDING 4 | PATIENT REACH

Generic producers step up in tracking how many patients in LMICs receive lifesaving antimicrobials

- For the first time, the AMR Benchmark assessed the approaches used by generic medicine manufacturers to track and monitor patient reach – with six of the ten companies doing this across almost all their antibiotic and antifungal products analysed.
- Sales volume remains the main measure for estimating patient reach, but four companies – Abbott, Hikma, Sandoz and Viatris – integrate additional data points for different antimicrobial products in their portfolios to more accurately track how many patients are being reached by these products in low- and middle-income countries.
- Notably, Sandoz and Viatris are the only companies assessed by the Benchmark that do this across all of their medicines assessed.

Generic medicine manufacturers produce the vast majority of the world's antibiotics and antifungals, and their role is especially critical in low- and middle-income countries (LMICs). With many innovator companies exiting or scaling back their antimicrobial research and development (R&D) and portfolios in recent years, the world has become increasingly reliant on existing, off-patent generic antibiotics to treat both common and serious infections. Because of their scale, local presence and participation in national or hospital tenders to supply at lower prices, these manufacturers are uniquely positioned to enable access to these lifesaving medicines to large patient populations, while also helping preserve their effectiveness.

To do so, however, companies need a granular picture of where their lifesaving treatments are used, how they are used and how many patients they truly reach. This is especially important for antibiotic and antifungal (antimicrobial) products. Unlike other medicines, higher sales volumes do not necessarily indicate improved patient outcomes, as drug resistance is fuelled by overuse and misuse. Conversely, limited access results in untreated infections, suboptimal therapies and increased numbers of deaths. By systematically tracking patient reach across their portfolios – and integrating these insights into their access and stewardship strategies – companies can pinpoint gaps in access and identify areas of potential overuse that heighten the risk of antimicrobial resistance (AMR). Patient reach data can also help target registration, supply and stewardship efforts where they are most urgently needed.

The 2021 AMR Benchmark already reported on the total numbers of patients being reached with antimicrobials, but the ways in which companies determined these numbers (i.e., their patient reach methodologies) were not assessed. This iteration of the Benchmark – which analysed seven large research-based pharmaceutical companies and ten generic medicine manufacturers – provides the first assessment of the methodologies companies use to calculate patient reach for the antimicrobials in their portfolios.

Six generic producers take promising steps to measure patient reach, but further action is needed

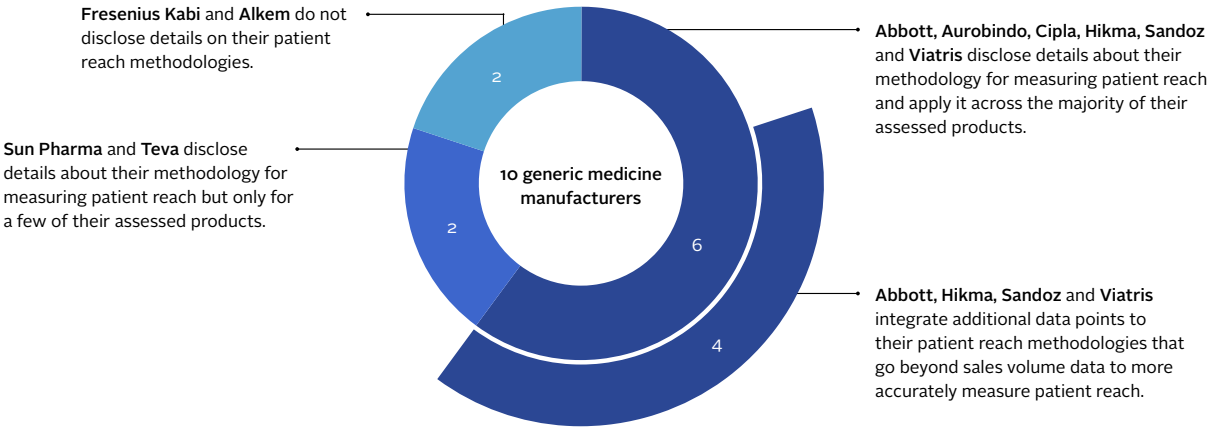
Among the companies assessed, six generic medicine manufacturers – Abbott, Aurobindo, Cipla Hikma, Sandoz and Viatris – stand out for providing details on how they calculate patient reach in LMICs across almost all of their antibiotic and antifungal products analysed (see Figure 1 on next page).

Tenders are commonly used by procurers, particularly in LMICs, to purchase large volumes of off-patent medicines at lower prices (also see Access Strategies on p.49). Therefore, it is not surprising for companies to estimate patient reach using sales and purchasing data.

However, the Benchmark finds that Abbott, Hikma, Sandoz and Viatris all consider additional factors beyond global sales data in their patient reach approaches to better estimate the number of patients receiving their antimicrobial medicines in specific countries. Although Aurobindo and Cipla only use sales volumes to track patient reach, both companies do this on an individual product and country level.

FIGURE 1 **Breakdown of how the ten generic producers assessed in the 2026 AMR Benchmark measure patient reach**

Of the ten companies assessed, six consistently track patient reach across almost all of their antibiotic and antifungal products analysed. Abbott, Hikma, Sandoz and Viatris stand out for incorporating additional data points into their methodologies, yielding more accurate estimates.



Sandoz and Viatris lead by consistently applying a strong patient reach methodology across all products

Not only do Sandoz and Viatris go beyond sales volume to estimate their patient reach, but they are also the only two companies assessed by the Benchmark that effectively measure patient reach across all their assessed medicines.

Sandoz does this by adjusting its sales data based on the defined daily doses and treatment duration of each medicine, which can help provide a clearer picture of how many patients have actually received these medicines. This is important because, even in high-income countries, incomplete treatment and inappropriate antibiotic use remain major drivers of resistance. Although the data was provided under a non-disclosure agreement (NDA), Sandoz was able to share disaggregated, country-level patient reach estimates for all nine medicines.

Viatris uses sales volume data and estimated per-patient usage, which is based on treatment dose, duration and adherence. While also provided under an NDA, Viatris does share disaggregated patient reach data at the country level* for its products as well.

By calculating patient reach data at the country level, pharmaceutical companies gain a better understanding of usage patterns. This enables them to tailor their product portfolios, including formulations and dosages they offer, to specific regions and patient populations, ensuring therapies are more effective and better aligned with patient needs.

Abbott and Hikma have strong patient reach approaches that could be applied more widely to their other products

Abbott and Hikma also consider additional factors beyond sales data in their patient reach approaches. However, neither company has yet applied these methodologies across its entire antimicrobial portfolio to systematically calculate product-level patient reach estimates.

Unlike most companies that rely on internal sales data, Abbott uses real-world sales data sourced from IQVIA. This data is compared to a country's population to get an indication of patient reach and then adjusted for three additional factors: treatment duration, patient adherence and disease prevalence. While Abbott's patient reach methodology is strong, patient reach estimates are currently available only at the portfolio level, not for individual products. Hence, for the nine off-patent/generic products assessed, Abbott did not report patient reach estimates employing this approach. However, the company provided disaggregated, country-level sales volume for most products (6 out of 9).

While Hikma only provided patient reach estimates for 5 of 11 products assessed, the company's approach aims to better reflect the actual number of patients receiving treatment, specifically by accounting for treatment duration. For example, Hikma estimates that with one of the antifungal medicines in its portfolio – fluconazole – it has reached 360,000 patients in India. For the remaining six products assessed, Hikma provided disaggregated, country-level sales volume instead.

**Viatris provided the number of patients reached at the country level for all products assessed except one, tobramycin, for which only the global number of patients reached was provided, as it had only recently been launched in a country in scope of the Benchmark.*

It is encouraging that Abbott and Hikma are tracking patient reach beyond sales data for some products, but applying this across all of their antibiotics and antifungals will be key to identifying access gaps and promoting appropriate use.

Aurobindo and Cipla move in the right direction by sharing concrete, product-level sales volume data for all of their assessed products

Although Aurobindo and Cipla only use sales volumes to track patient reach, both companies do this on an individual product and country level, providing a more accurate baseline for patient reach estimates than global sales volume reporting does.

Aurobindo consistently tracks sales volumes at both the individual product and country levels and transparently reports this data to the Benchmark for all eight off-patent/generic medicines from its portfolio selected for analysis. For example, Aurobindo reports selling approximately 15 million doses of amoxicillin to Vietnam and one million doses of amoxicillin-clavulanic acid to Nepal, respectively. Similarly, Cipla consistently tracks and transparently reports sales volumes at both the individual product and country levels for all 12 medicines in its portfolio selected for analysis, two of which are on-patent antibiotics. For the on-patent antibacterial medicine cefepime-enmetazobactam (CIPENMET and Esblocip), Cipla reports selling a total of 162,338 units directly to hospitals in India.

WHAT NEXT?

It is critical for companies to apply patient reach methodologies that go beyond sales volume reporting across their entire portfolios. In addition, companies should implement these methodologies and track patient reach at the individual country and product level. This is especially important in supporting more responsible access and stewardship of antimicrobials everywhere by ensuring these lifesaving medicines are used where they are truly needed, in the right quantities – safeguarding patients and reducing the global spread of drug resistance.

It is vital that:

- Companies use more accurate patient reach and usage estimates internally to inform their access strategies and drive more targeted applications for tenders in LMICs so that their lifesaving treatments can be brought to people living in countries with the highest burden of disease.
- With antimicrobial products, the goal should not just be to reach as many people as possible. The number of patients reached should match the actual medical need in specific countries. Because different antibiotics are used for different purposes, internal company incentives should focus on proper treatment and good health outcomes, not on selling or prescribing more antibiotics than necessary (also see Responsible Business Practices on p.59).

2026 AMR BENCHMARK

EXTENDED FINDINGS

THEMATIC ANALYSIS | RESEARCH & DEVELOPMENT

Some of the deadliest threats get attention, but many critical pathogens slip through the cracks

RESEARCH & DEVELOPMENT

In analysing the antimicrobial research and development (R&D) pipeline, the Benchmark focuses on infections caused by priority pathogens listed on the World Health Organization (WHO)'s second iteration of the bacterial Priority Pathogen List (2024)[1] and first iteration of the fungal Priority Pathogen List (2022).[2] These lists identify the pathogens that represent the most urgent threats to global health due to rising antimicrobial resistance (AMR), by grouping them into 'critical', high' and 'medium' to help focus R&D efforts where they are most needed.

This iteration of the Benchmark identifies a continued contraction of the pipelines among the seven large research-based (LRB) companies assessed, with a 35% decline in the number of projects in development since the last Benchmark. Furthermore, only three LRBs (GSK, Otsuka and Shionogi) continue to develop antimicrobials with innovative characteristics that have the potential to overcome resistance where older drugs fail. The dwindling pipelines of the other four LRBs – Johnson & Johnson, MSD, Pfizer and Sanofi – focus on either vaccines and/ or adaptive R&D which offer primarily expanded indications or incremental improvements, but no new preventive or therapeutic options.

Projects in development across all phases of 15 company pipelines

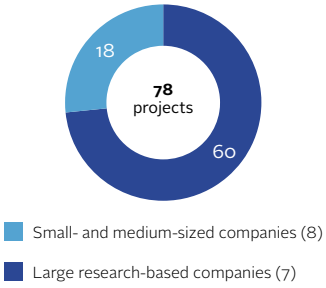


FIGURE 1 **Overview of antimicrobial pipeline projects across large research-based companies**

Of the seven large research-based companies analysed in the 2026 AMR Benchmark, GSK has by far the antimicrobial pipeline, with 30 projects in development. Shionogi and Pfizer follow, with eight projects each.

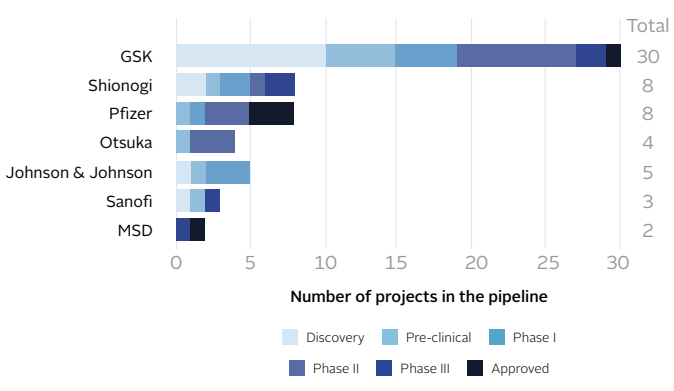
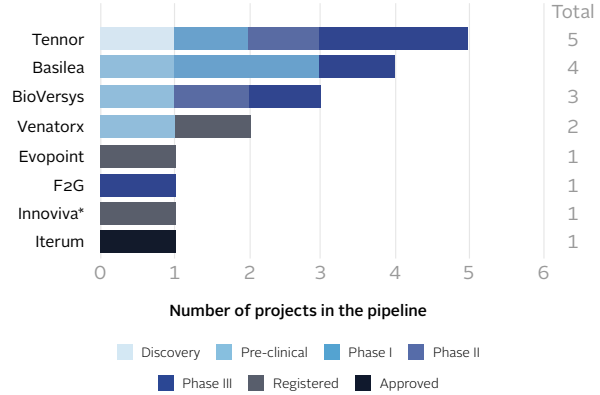


FIGURE 2 **Overview of antimicrobial pipeline projects across small- and medium-sized enterprises (SMEs)**

The 2026 AMR Benchmark also analysed the antimicrobial pipelines of eight SMEs, with these companies plugging critical gaps and driving innovation in antimicrobial R&D.



* Innoviva's pipeline project was approved after the period of analysis for the 2026 AMR Benchmark concluded.

Although the gradual departure of big pharma from antimicrobial R&D has been extensively documented, the continued downward trajectory in both the quantity and quality of pipeline candidates means that options to treat life-threatening resistant infections are running out. By contrast, small- and medium-sized enterprises (SMEs), which are newly assessed in the 2026 Benchmark, are plugging critical gaps and driving innovation – despite having miniscule resources in comparison. Collectively, the eight SMEs assessed account for almost a quarter of all projects in development. (Also see Industry Trends on p.20).

Despite focus on select threats, pipeline gaps persist

As indicated in Figure 3 on the next page, a closer look at the pipeline shows that overall pipeline activity for antifungal and antibacterial medicines is thin and unlikely to deliver enough new treatments to address future resistance trends. R&D activity is somewhat proportional to the pathogen's priority level, with those classified as critical or urgent receiving the highest emphasis. There is a strong focus on Enterobacterales (resistant to carbapenems and cephalosporins), both critical pathogens responsible for a wide range of infections, including community acquired urinary tract infections (UTIs) and hospital acquired infections, which are among the leading causes of deaths related to drug resistance in low- and middle-income countries (LMICs).[3]

For example, Venatorx's cefepime–taniborbactam demonstrates potent activity against resistant strains of Enterobacterales and is currently undergoing regulatory review for complicated UTIs. There is also moderate focus on resistant *Mycobacterium tuberculosis*, although most ongoing trials concentrate on adaptive R&D rather than truly novel agents, with only three innovative candidates having reached late-stage development (also see Key Finding on p.26). This limited pipeline raises concerns about the long-term availability of effective options for drug-resistant tuberculosis, particularly in LMICs which bear over 95%[4] of the burden and where substantial treatment gaps persist.

Some bacterial pathogens have no coverage

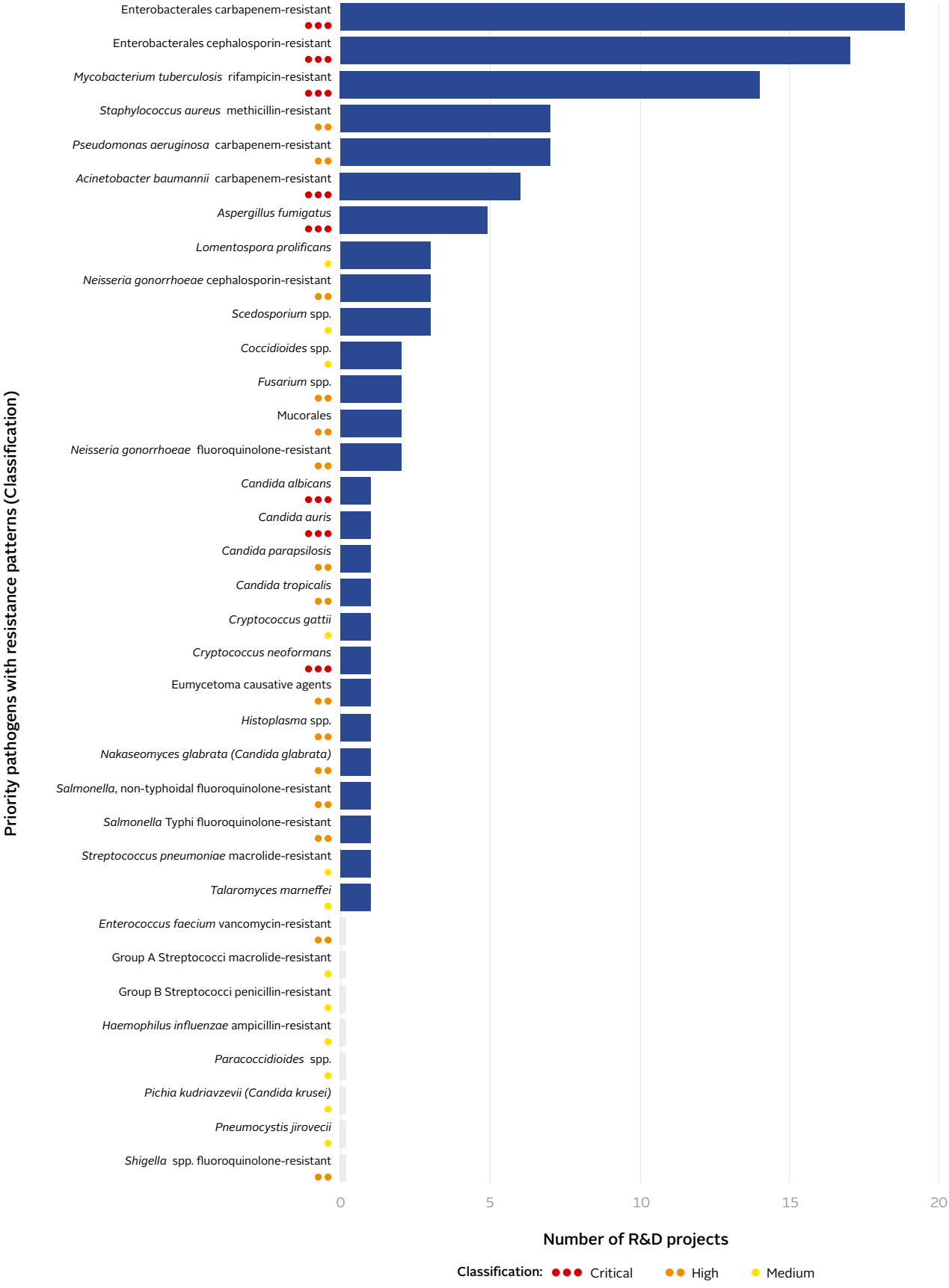
On the other end of the spectrum, pipeline activity is limited or absent for resistant strains of *Salmonella* Typhi and *Shigella* spp (both high-priority pathogens). These bacteria cause diarrhoeal disease, which is the third leading cause of infectious disease mortality in children under five in LMICs.[5] Additionally, the antibacterial pipeline for *Streptococcus pneumoniae* – a leading bacterial cause of childhood pneumonia[5] – is almost empty. Although the introduction of pneumococcal conjugate vaccines (PCVs) has dramatically reduced childhood pneumonia in many countries, vaccine coverage in LMICs is often incomplete or delayed. More than 99% of 176,000 children under five who succumb to drug-resistant pneumonia annually live in LMICs,[5] highlighting the stark inequity that still persists. Overall, paediatric development for resistant pathogens is especially sparse,with only 13% of antimicrobial medicine candidates in clinical development specifically developed for children under five (also see Key Finding on p.30).

Fungal pathogen coverage is extremely thin

While most antifungal pathogens are represented in the pipeline, coverage is still thin with just a handful of candidates covering each pathogen. For example, there is some coverage for *Cryptococcus neoformans*, a critical priority and leading cause of HIV-related deaths, with the vast majority of the 120,000 per year occurring in sub-Saharan Africa.[6] There are no candidates in the pipeline for *Pneumocystis jirovecii* (medium priority), an opportunistic fungal pneumonia with a mortality rate of up to 50%.[7] Current standard treatments are not well tolerated, indicating an R&D gap, especially for vulnerable patients who are not on antiretroviral treatments. With antifungal resistance on the rise, and access to current treatment limited in low-resource settings, there is a major R&D gap for oral formulations that are accessible in LMICs. For detailed analysis, see the Antifungals Spotlight on p.43.

FIGURE 3 **R&D efforts for new antimicrobials cluster on select threats, creating blind spots for other critical pathogens**

Several medicines across the pipelines of the 15 companies assessed address multiple WHO priority pathogens, but distribution across pathogens is heavily skewed. While some high-priority gram-negative bacteria – which are among the most drug-resistant pathogens – are being prioritised, major gaps remain for other critical pathogens, highlighting an urgent need for new treatments.



>> R&D continues after the Antifungals Spotlight

THEMATIC ANALYSIS | SPOTLIGHT ON ANTIFUNGALS

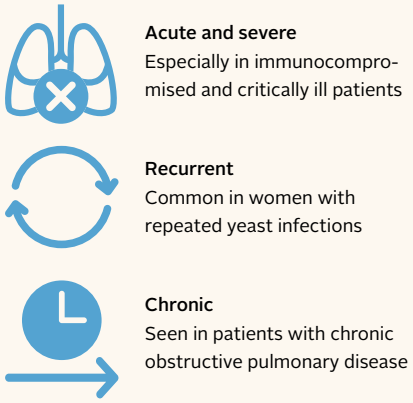
As we battle bacterial superbugs, antifungal resistance is taking root

While awareness of resistance against bacteria has been significantly increasing in past decades, fungal resistance has been historically overlooked in AMR policy, funding and pharmaceutical innovation. Globally, fungal infections are already responsible for 3.8 million deaths a year,[1] but even these numbers are likely underestimated.[2] Accurate diagnosis of fungal infections is still a major challenge, as many laboratories worldwide lack this capability;[3] insights on the prevalence and effects of antifungal resistance are also limited by the fact that antifungal medicines and fungal pathogens are less likely to be included in surveillance programmes (also see AMR Surveillance on p.64).

The rise in antifungal resistance is leading to more frequent, difficult-to-treat fungal infections that are causing an increased number of deaths and putting millions at risk. The emergence of lethal multidrug-resistant strains, like *Aspergillus fumigatus*, is especially concerning. This common mould exists everywhere around us – in soil, air and other organic matter – and can cause serious infections (invasive aspergillosis) in people with weakened immune systems such as those living with HIV, cancer patients, those with lung disease or who have received an organ transplant.[4] Over 2 million people around the world develop invasive aspergillosis infections every year,[1] and around 30 million people are at risk of infection.[5] Even when optimal treatment is provided, 30-60% of those who contract invasive aspergillosis die from the infection.[5]

The world has learned hard lessons from the rise of bacterial superbugs. Antifungal resistance is sending the same warning - failure to act swiftly, risks confronting another global resistance crisis.

Why are fungal infections so dangerous?



SOURCE: Gaffi - Fungal Disease Frequency (n.d.)

In an already sparse anti-infective pipeline, new antifungal treatments are even more limited

Developing new antifungal agents is complex. The strong similarities between fungal and human cells makes it difficult to design selective antifungal agents that harm fungi without harming the people being treated.[6] For example, many current standard antifungal treatments have strong side effects, especially in immunocompromised patients who often need prolonged treatment at higher doses. Similarly, people who are enrolled for clinical trials often have underlying conditions, or are already on other treatments, which can lead to drug-drug interactions and adverse outcomes.

However, in the face of rising antifungal resistance, relying on the four antifungal classes (azoles, allylamines, echinocandins, polyenes) that have been around for decades will leave us with limited treatment options – putting people across the globe at risk. The recent surge in drug-resistant *Candida auris* infections across hospitals in Europe has shown just how rapidly fungal infections can spread.[7] For people living in low- and middle-income countries (LMICs) – where access to diagnostics and second-line treatments are limited – resistant fungal infections are more likely to be deadly.

Despite this growing global threat, of the 56 antimicrobial medicines across the research and development (R&D) pipelines of companies assessed in the Benchmark, only 5 projects targeting fungal pathogens are in clinical development. Of these, 3 are being developed by SMEs (also see Industry Trends on p.20 and Best Practice on p.69). Of note is F2G's olorofim, which shows potent activity against difficult-to-treat, azole-resistant mould infections and a favourable safety profile.

▶ F2G's promising antifungal agent

F2G's olorofim, the first member of the orotimide class shows encouraging activity against azole-resistant *Aspergillus fumigatus*, which causes invasive aspergillosis and is deemed 'critical' on the World Health Organization (WHO) Fungal Priority Pathogen list.[8] This makes olorofim one of the few new antifungal drugs in late-stage clinical development that targets a critical pathogen, offering a potential treatment option for patients when current options are not suitable. Moreover, olorofim's side effects are not as severe as is typically the case with antifungal agents.[9] Its oral formulation also makes treatment easier and more accessible for patients – especially those requiring long-term treatment for chronic or allergic fungal diseases.

Registration and supply of existing antifungal medicines are skewed towards fluconazole

With limited innovation, we depend on the few products that are on the market. However, companies' antifungal medicines are even less widely registered in LMICs than antibiotics - registrations for antifungals are 40% less. Moreover, antifungals are also supplied in even fewer LMICs and are less likely to be supported by an access strategy. (For more on access strategies, see p.49.)

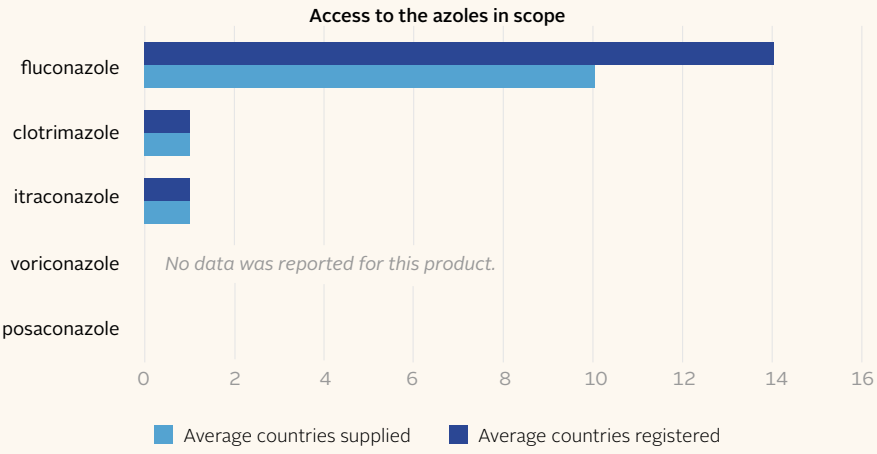
Among the antifungal products selected for analysis in the Benchmark, which were chosen based on global sales, azoles remain the most important class for companies. However, resistance to the azole class is increasing, especially due to its dual use in agriculture and human health (see sidebar).

Of the 24 off-patent products analysed, 16 belong to this class, with fluconazole included in over half of companies' portfolios – making it the most marketed antifungal drug. It is also the most widely registered and supplied azole in companies' portfolios (see Figure 4 below). The risk here is that if resistance to azoles becomes more widespread, over-reliance on a few products in this class can amplify resistance and lead to these products becoming less effective.

> **"In an already sparse anti-infective pipeline, new antifungal treatments are even more limited."**

FIGURE 4 **In the 113 low- and middle-income countries covered by the Benchmark, the antifungal fluconazole is most widely registered and supplied by companies**

Among the five types of azoles in companies' portfolios, fluconazole is the most widely registered. Over-reliance on a few products in this class can amplify resistance and lead to these products becoming less effective.



Dual use of antifungals is fuelling resistance

The risks of no new drug classes and a thin development pipeline are exacerbated by the dual use of antifungal products in agriculture and human health.[10] Antifungal agents used in agriculture for controlling plant disease and increasing crop yields have similar ingredients and modes of action to those used in human medicines, giving fungi more chances to adapt and fight back.[2] This makes it harder to treat infections when people get sick.

The use of triazoles especially has been found to be a major driver of azole-resistant infections in humans.[11] Considering the heavy reliance on azoles in human medicines, as well as limited progress in innovation, it is essential to get ahead of antifungal resistance with new treatments.

▶ Pfizer stands out for making its antifungal products accessible, including a treatment for patients with invasive aspergillosis

Of the 17 companies assessed, Pfizer registers its off-patent antifungal medicines most widely. It also shows clear access strategies for these medicines. Furthermore, Pfizer is one of the two companies with an on-patent antifungal product in its portfolio. For its in-licensed on-patent product (Cresemba®), which is indicated, among others, for patients with invasive aspergillosis, Pfizer also shows clear strategies to improve access in a country in scope of the Benchmark. The company has launched patient support programmes in both the public and private sectors to help make this innovative treatment accessible to patients in the country. At the same time, paediatric trials for this drug are ongoing (also see Key Finding on p.30).

> "Antifungal medicines with better safety profiles and effectiveness are urgently needed."

WHAT NEXT?

Many of the challenges we see in the antibiotic market are more pronounced with antifungals, making timely action against the rising burden of antifungal resistance critical.

- It is crucial that large research-based companies still active in antimicrobial R&D step up their efforts to develop antifungal products with better safety profiles and effectiveness against a wide range of infections caused by fungal pathogens. In parallel, corresponding access and stewardship plans can ensure these products reach the patients who need them.
- Funders can increase the inclusion of antifungal pathogens, guided by WHO's Fungal Priority Pathogen list,[8] and products in tailored incentives to stimulate innovation and ensure a sustainable market.
- Companies can strengthen access to existing antifungals by ensuring registration and reliable supply of both generic and novel antifungals in LMICs. This includes adopting equitable pricing and access models based on public health needs to reach populations most in need.
- To ensure early detection and rapid infection control, diagnostic companies can play a role in developing diagnostics that can be used at point-of-care and have a broad range of detecting fungal pathogens.

For more on how industry and global health stakeholders can help address the overall dearth in antimicrobial R&D, see p.48.

>> R&D continues on next page.

Nine companies have innovative antimicrobials in the pipeline that can deliver genuine therapeutic or public-health impact

Since most antimicrobials on the market have been around for decades and come from a limited number of chemical classes, new pipeline candidates that are similar in nature are more likely to face the same resistance patterns sooner. Therefore, the uniqueness of new pipeline candidates is indicative of the ability to combat resistance and remain effective for longer. As outlined in the infographic below, WHO sets out four innovation criteria used to judge whether a new antimicrobial candidate represents a meaningful therapeutic advance.[8] Three of these criteria focus on molecular novelty (new class, new target, new mode of action), while the fourth (no cross resistance) evaluates activity against organisms resistant to current drugs. In addition, the Benchmark's 'other' criterion considers additional characteristics that provide greater practical advantages for patient care in LMICs, for example, new oral formulations that facilitate outpatient treatment, where the current standard of care requires injections.

What makes an antibiotic innovative?

The Benchmark applied the World Health Organization's innovation criteria[8] to assess pipeline candidates, and also accounted for 'other' innovative features that may strengthen real-world utility in low- and middle-income countries

- Using new chemical compounds than those currently available to develop the drug (New class)
- Targeting new processes that are essential for the survival of bacteria (New targets)
- Developing new ways of how the drug work (New mode of action)
- The effectiveness of the new drug is not affected by existing resistance mechanisms (No cross-resistance)
- Other criteria that provide meaningful clinical utility through forms of innovation that fall outside the scope of WHO's criteria ('Other' innovativeness criteria)

Across the seven LRBs and eight SMEs assessed, only 15 unique antimicrobial candidates (co-) developed by nine companies qualify as innovative. Of these, 13 fulfil at least one of WHO's four innovation criteria, and an additional two projects are classified by the Benchmark as having 'other' innovative characteristics not captured by WHO's criteria. This includes Iterum's ORLYNVAH™, which does not meet WHO's innovation criteria, but is notable as the first oral penem-class antibiotic, previously available only as injectables.

Of the nine companies with innovative pipeline candidates, Shionogi leads efforts with four, followed closely by GSK with three. Aside from these two LRBs, it is SMEs that are collectively plugging gaps for innovation, with six of the eight assessed having innovative candidates in development targeting critical or high priority pathogens (also see Best Practice on p.69). However, the number off innovative candidates is low overall, signalling that not only is overall breadth of the pipeline limited, but the quality is also lacking.

Ultimately, the low number of innovative candidates in development (15 in total) means that the industry is not developing novel candidates at a rate to outpace the development of resistance. This underscores the urgency for increased and renewed investment in innovative R&D from both companies and public funders alike to accelerate development and curb AMR.

It's not only a resistance problem – it's an access issue

While the dearth in new drugs is alarming, lack of access appropriate access to treatment remains a critical issue – especially in LMICs. When patients cannot access the right treatment, infections become harder to control and further perpetuate resistance. Therefore, it is crucial that companies begin access and stewardship planning during product development – beginning in Phase II at the latest – to ensure appropriate access to those who need it, and that medicines remain effective for as long as possible. Access plans should encompass a range of different elements to overcome barriers to availability, affordability and continuous supply, whereas stewardship plans should include approaches to safeguard effectiveness such as surveillance or guidance to prevent overuse (see Figure 5).

FIGURE 5 **What should companies focus on when developing access and stewardship plans for their lifesaving drugs?** While access plans are crucial for the availability, affordability and continuous supply of medicines and vaccines, stewardship plans can prevent overuse and help ensure that medicines stay effective as long as possible. Access and stewardship plans should be project-specific and account for all barriers to access during product development.

Examples of how companies address different elements in access planning:

- **Availability**: Venatorx has a licensing agreement with the Global Antibiotic Research and Development Partnership (GARDP) for cefepime–taniborbactam, covering countries within the Benchmark's scope. Access is enabled through partnerships with Everest Medicines for 11 Asian countries, GARDP for 64 LMICs, and Menarini for 96 countries across Latin America and the Middle East. Through GARDP, countries with the highest burdens of carbapenem-resistant pathogens are prioritised.
- **Affordability**: Innoviva's licence with GARDP for zoliflodacin – whose December 2025 approval marked the first oral therapy for gonorrhoea in decades. Innoviva's licence with GARDP extends registration and commercialisation rights to all LMICs assessed by the Benchmark, with GARDP partnering with a generic manufacturer to register and market the drug in South Africa and Thailand, with a transparent pricing structure that puts a ceiling on the distributor's retail price.
- **Sustainable supply**: GSK plans for continuous supply of its medicines. Examples include market research in LMICs to understand unmet need and the use of demand-forecasting tools, consideration of relevant pooled procurement mechanisms and partnering to manufacture and supply products to countries with a high burden of disease.

Approximately one quarter of projects assessed (26%) have no access or stewardship plan in place, which indicates that patients in LMICs face serious delays in accessing treatments for resistant infections or may not have access at all. The consequence of this is twofold: it denies patients appropriate care and insufficient access to effective medicines is a major contributor to the spread of AMR.

In general, company reporting on access and stewardship plans is poor, with a focus on overarching policies and approaches, rather than taking concrete project-level characteristics into account. This, in turn, reduces the extent to which the potential implementation and impact of these plans can be assessed. In some instances, companies have implemented concrete plans and take project-specific characteristics into account, but these plans vary in scope and depth (see plans profiled in the Key Finding on p.26). For 25% of projects, companies have developed either an access plan or a stewardship plan, but not both. Failure to integrate access and stewardship planning undermines the potential public health impact addressing only one dimension means companies' efforts may not fully support appropriate access while also balancing appropriate use.

WHAT NEXT?

Combatting AMR requires collaboration across the public and private sectors, combining resources, and industry know-how to drive innovation. Despite a number of collaborators providing funding to incentivise AMR R&D, the continued exodus of big pharma players from AMR R&D and dwindling pipelines indicates that partnerships in R&D are not enough to sustain innovation at the rate that's needed. Addressing this suggests a more holistic approach is needed, including additional market incentives post-approval, supportive regulatory and policy reforms and a stronger focus on prioritising access in countries with high unmet need.

Governments and policy makers play a crucial role in shaping sustainable markets; without continued industry innovation and investment, global efforts to curb resistance cannot succeed.

Companies can act by:

- Partnering with trusted funders and access-oriented organisations, such as CARB-X and BARDA to de-risk investment, and GARDP to support registration, scale access and stewardship in LMICs to maximise the public health impact of new developments.
- Developing project-specific access and stewardship plans for their pipeline candidates to ensure new products reach the patients who need them without delay. These plans should prioritise countries with high disease burdens and that have national AMR action plans in place.
- Utilise tools to implement access and stewardship plans. This includes the Stewardship & Access Plan (SAP) Development Guide,[9] which was developed by a working group of experts, including the Access to Medicine Foundation, and led by the Wellcome Trust, which offers practical guidance on how to accelerate access to new antibacterial products while ensuring responsible use.

THEMATIC ANALYSIS | ACCESS STRATEGIES

Navigating between access and excess: If the right drugs aren't available, infections cannot be treated

APPROPRIATE ACCESS & STEWARDSHIP

Tackling the rise in resistance to antibiotics and antifungals requires striking a fine balance between curbing overuse and ensuring timely access to everyone who needs them. When appropriate first-line treatments are not locally available, doctors may be forced to prescribe suboptimal alternatives. Without the right medicines, even common infections – such as pneumonia or urinary tract infections – can become untreatable. And when the wrong medicines are used, pathogens have the opportunity to develop resistance, potentially leading to serious or even life-threatening infections.

Yet large segments of the global population, particularly those living in low- and middle-income countries (LMICs), still face limited access to appropriate treatments. For example, in 2019, across eight* countries in scope of the Benchmark, the available supply of antibiotics was sufficient to treat only about 6.9% of the estimated 1.4 million people with carbapenem-resistant gram-negative infections[1]. With this type of infection, an individual is at risk of developing bloodstream infections or pneumonia if left untreated. The 93% access gap reflects a best-case scenario for these countries, as some antibiotics may have been prescribed inappropriately.

By implementing access and stewardship strategies, companies can make their lifesaving antimicrobials available and affordable to people living in LMICs, while also guaranteeing their responsible use. Ensuring such access protects not only individual patients but also global public health.

Appropriate access hinges on stewardship
To help ensure appropriate access, companies can implement a variety of access strategies, which are explored in this section of the Benchmark. However, appropriate access also depends on effective stewardship strategies, as making antimicrobials widely available must go hand in hand with ensuring they are used responsibly to preserve their effectiveness.

Read more about stewardship in the section on Responsible Business Practices on p. 59.

Just over half of assessed products accompanied by access strategies

Across the portfolios of the 17 large research-based companies and generic medicine manufacturers analysed by the Benchmark, 146 products were assessed. These include both on-patent and off-patent/generic antibacterials, antifungals and vaccines. Among them, just 44% are covered by tailored access strategies, signaling considerable room for improvement (for more on this topic, see the Industry Trends section on p. 20). A range of access strategies are associated with these products, with national tenders emerging as the most common approach for supplying them in LMICs.

Leveraging tenders and beyond to expand access in LMICs

National tenders are government-run purchasing processes that invite suppliers to compete to provide medicines, with contracts typically awarded to the company meeting quality requirements at the lowest price. Their predominance as an access strategy is unsurprising, as most antibiotics and antifungals are off-patent and produced by multiple generic manufacturers, creating highly competitive markets where tender-based procurement enables governments to secure affordable supply.

Participating in tenders – particularly national tenders – remains one of the most reliable ways to ensure lifesaving antibiotics and antifungals reach populations at scale. For example, by securing the national tender for amoxicillin/clavulanic acid (see box-out alongside) in Jordan, Hikma is responsible for supplying the antibiotic

Why is amoxicillin/clavulanic acid so critical?

Amoxicillin/clavulanic acid is a widely used antibiotic that most people tolerate well and can effectively treat many common infections.

WHO recommends amoxicillin/clavulanic acid as the first choice, preferred first line treatment for several types of infections, including:

- Abdominal infections
- Lower respiratory tract infections
- Urinary tract infections
- Sinus infections

** Includes Bangladesh, Brazil, Egypt, India, Kenya, Mexico, Pakistan and South Africa.*

to all patients covered by the country's national insurance schemes. As a result, the antibiotic – classified by the World Health Organization (WHO) under its Access group (see box-out) – can now reach approximately 65% of the country's population. This demonstrates the tangible impact that national tenders can have, and highlights a pathway other companies can take to help bridge gaps in access.

Still, the reality can look very different from one country to another. The structure of a country's healthcare system, especially the degree of insurance coverage, how medicines are paid for and how much patients pay out of pocket, can limit the extent to which national tenders end up improving access. This helps explain why, even with a competitive generic market for off-patent antimicrobials, many LMICs continue to face limited access. Access barriers are shaped by local contexts and take many forms, but all ultimately hinder the affordability and availability of medicines.

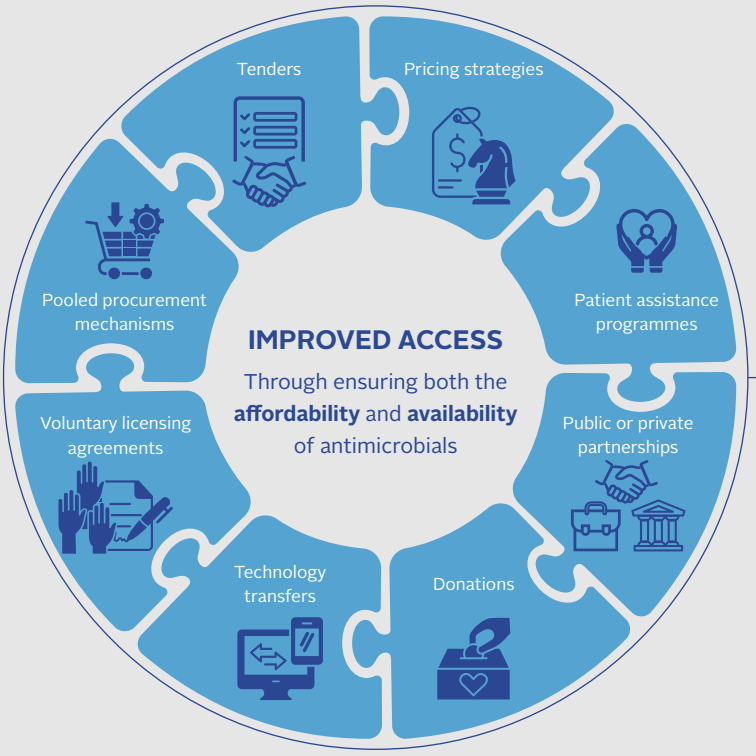
Therefore, to improve access in these diverse settings, companies can develop tailored access strategies – beyond traditional tendering models – that take into consideration the realities of each country's patient population (see infographic below). This need is particularly relevant for innovative, on-patent antibacterial and antifungal medicines, which come with higher price tags. As set out in the next pages of this section, the Benchmark identified examples of how companies are employing tailored strategies to address the affordability and availability of these lifesaving products they produce.

What is AWaRE?

AWaRe antibiotics is a classification system created by the World Health Organization (WHO) to guide the responsible use of antibiotics and combat antimicrobial resistance (AMR).

- **Access:** First-choice antibiotics for common infections – effective, safe, and have a lower risk of resistance.
- **Watch:** Higher risk of resistance – should be used only for specific infections.
- **Reserve:** Last-resort antibiotics – used only when other options fail.

TACKLING ACCESS BARRIERS: HOW COMPANIES CAN ADVANCE AFFORDABILITY AND AVAILABILITY WITH TAILORED STRATEGIES



Enables the right patient to access the right antimicrobial at the right time - regardless of where they live or their financial circumstances.

WHAT ARE COMPANIES DOING TO EXPAND PRODUCT AVAILABILITY?

▶ Voluntary licensing agreements

Access to innovative antibiotics and antifungals in LMICs is often significantly delayed after these medicines are already approved for use because these markets are not prioritised. Voluntary licensing agreements can help address this gap by expanding access in countries where a company has no presence or chooses not to enter the market. Historically, such agreements have not been applied to antibiotics outside of those used to treat tuberculosis, but some companies are now exploring this strategy to improve access in LMICs.

In June 2022, **Shionogi** and GARDP entered a first-of-its kind agreement for the Reserve antibiotic cefiderocol, used to treat gram-negative bacterial infections. This marked the first voluntary licensing agreement for an antibiotic targeting serious bacterial infections between a pharmaceutical company and an access-orientated international organisation.

MSD and **Sun Pharma** also entered into a voluntary licensing agreement for Reserve antibiotic tedizolid in May of 2024, allowing Sun Pharma to develop, manufacture and commercialise tedizolid in India – the company's home market. This innovative antibiotic is used to treat ABSSSIs, which is one of the most common infections in India, accounting for 29-32% of all infections[2] and 50,000 deaths annually in the country[4]. According to Sun Pharma, approximately 300 million patients in India were expected to gain access to tedizolid between May 2024 (when the agreement was established) and September 2025. This voluntary licensing agreement therefore represents a major step toward addressing India's high burden of ABSSSIs, significantly expanding the availability of this critical antibiotic where it is most needed.

▶ Pricing strategies

Limited availability of medicines in public hospitals and clinics in some LMICs may mean doctors are forced to prescribe sub-optimal treatments. Tailored pricing strategies are one approach being used to address this gap.

Doxycycline is a broad-spectrum Access antibiotic and can be used to treat a range of bacterial infections, including urinary tract infections, which affect 50–60% of women at least once during their adult lives[3]. To increase availability of doxycycline in Brazil, **Pfizer** offers discounts to pharmacies. Ensuring that pharmacies and public hospitals can afford stocking a broad range of antibiotics and antifungals is vital to enable doctors to prescribe appropriate treatments, effectively cure infections and curb rising resistance levels.

▶ Technology transfers

High reliance on imported medicines can make LMICs vulnerable to stockouts and shortages. Facilitating technology transfers to local manufacturers is an efficient strategy to enhance self-sufficiency in LMICs, limit dependency on imported medicines and improve health system resilience.

In Brazil, **GSK** has entered into an agreement with two public health institutions, Fiocruz and Funed, to transfer the complete manufacturing process for its meningococcal vaccine Menveo®. Local production is expected to boost self-reliance while maintaining a sustainable supply, which is particularly relevant given the vaccine's inclusion in the national immunisation programme for adolescents. This agreement builds on a long-standing partnership between GSK and Fiocruz, which have been working together since 1985 to provide the Brazilian population with access to much-needed vaccines.

WHAT ACTIONS ARE COMPANIES TAKING TO MAKE PRODUCTS MORE AFFORDABLE?

▶ Pricing strategies

In many LMICs, high out-of-pocket costs put lifesaving medicines out of reach. To help address this, two companies are implementing tailored pricing strategies.

In Jordan, oritavancin – an on-patent Reserve antibiotic indicated for treating acute bacterial skin and skin structure infections (ABSSSI) – is only available through the private sector via **Hikma**, making the company's access strategy decisions, and their impact on affordability, particularly critical for Jordanian patients. To improve affordability, Hikma is offering patients a direct discount of 35% off the list price. Discounts are one pricing strategy pharmaceutical companies can use to make medicines more affordable, particularly for on-patent products in markets with low consumer purchasing power.

Meropenem is a broad-spectrum Watch antibiotic used to treat serious bacterial infections, particularly when resistance to first-line antibiotics is suspected, making it increasingly important in the face of rising resistance (see 'AWaRE' box-out on previous page). To address affordability barriers in the public sector in Nigeria, Pfizer has implemented an innovative payment strategy for this product. First, the co-payment is shared between **Pfizer**, the National Health Insurance and the patient. In addition, the payment structure offers flexibility: patients can receive meropenem immediately and are only required to make an initial payment within 30 days. This approach helps ensure that financial constraints do not delay access to essential treatment and reflects Pfizer's active consideration of patients' ability to pay when designing its access strategies.

>> Examples continue on next page.

▶ Pooled procurement mechanisms

Fragmented demand and limited purchasing power in some LMICs make independent vaccine procurement both costly and less attractive to manufacturers, resulting in access strategies that differ substantially from those used for medicines. Participation in pooled procurement mechanisms is the main approach used for vaccines and can be an effective way to broaden access to these essential products. Instead of each country negotiating separately with pharmaceutical companies, a supranational entity aggregates demand and pools resources, enabling more affordable prices and efficient supply logistics.

Sanofi is supplying its Hexaxim® vaccine (a fully liquid hexavalent vaccine protecting against diphtheria, acellular pertussis, tetanus, inactivated poliomyelitis, hepatitis b and Haemophilus influenzae type b) through the PAHO Revolving Fund in Latin America. This mechanism, which is a regional pooled procurement mechanism, has enabled participating countries – including Brazil, Colombia, Paraguary and Peru – to secure access to Hexaxim® at Sanofi's lowest price.

Company efforts demonstrate potential to overcome barriers

While the gap in appropriate access in LMICs is still a life-threatening reality, these efforts from companies showcase the ability they have to help tackle some of the access barriers faced by people in these settings. Given that only 44% of assessed products are covered by a tailored access strategy, applying such approaches more broadly, could enhance the accessibility of antibacterials, antifungals and vaccines in LMICs.

Of course, this is not without its challenges; while antibiotics have traditionally had a low-price tag, new Reserve antibiotics are often highly priced, and smaller associated order quantities make it difficult to scale access effectively.

WHAT NEXT?

Pharmaceutical companies play a central role in ensuring that lifesaving antimicrobials reach the right people at the right time. However, meaningful and sustainable progress requires action from a wider set of stakeholders – including governments, NGOs and funders – to address access barriers holistically and ensure sustainable access.

Each stakeholder has a distinct but complementary role to play. Working in tandem, they can tackle persistent barriers by drawing on the strategies highlighted throughout this chapter. While some of these approaches are already in use, they could be applied far more broadly to strengthen access.

Through effective partnerships, companies can address multiple access challenges and improve the reliability of supply. These partnerships may take many forms: technology transfer to expand local manufacturing capacity, collaborations with insurers to share patient co-payments or cooperation with NGOs that already have strong distribution networks. Governments can further reinforce these efforts by offering incentives that encourage such agreements.

Companies can also leverage public procurement systems – and where available, pooled procurement mechanisms – to secure a stable supply of antimicrobials and reach more people at scale. Governments are essential in coordinating these mechanisms and ensuring the consistent availability of first-line antibiotics, supported by universal healthcare systems that facilitate equitable provision. For medicines that fall outside these channels and remain out of reach, companies can implement tailored pricing models, such as tiered pricing, to make essential treatments more affordable for underserved populations.

THEMATIC ANALYSIS | SUPPLY

From source to patient: How are companies ensuring continuous supply of quality-assured antimicrobials?

APPROPRIATE ACCESS & STEWARDSHIP

People living in low-and middle-income countries (LMICs) are on the frontlines of antimicrobial resistance (AMR), yet they too often face major barriers to accessing lifesaving antibacterial and antifungal medicines and vaccines. When the right treatments are unavailable, patients may receive medicines that are ineffective or inappropriate for their infection, resulting in delayed recovery, worsened infections, higher risk of death – while also accelerating the development of AMR.

This vulnerability in the face of disruptions is heightened in LMICs, where availability challenges are especially complex (also see Access Strategies on p.49). Fragile infrastructure, affordability constraints and inconsistent procurement systems can all make timely access difficult and leave antimicrobials out of reach. Among these barriers, a fragmented global supply chain for antimicrobials remains a critical challenge.

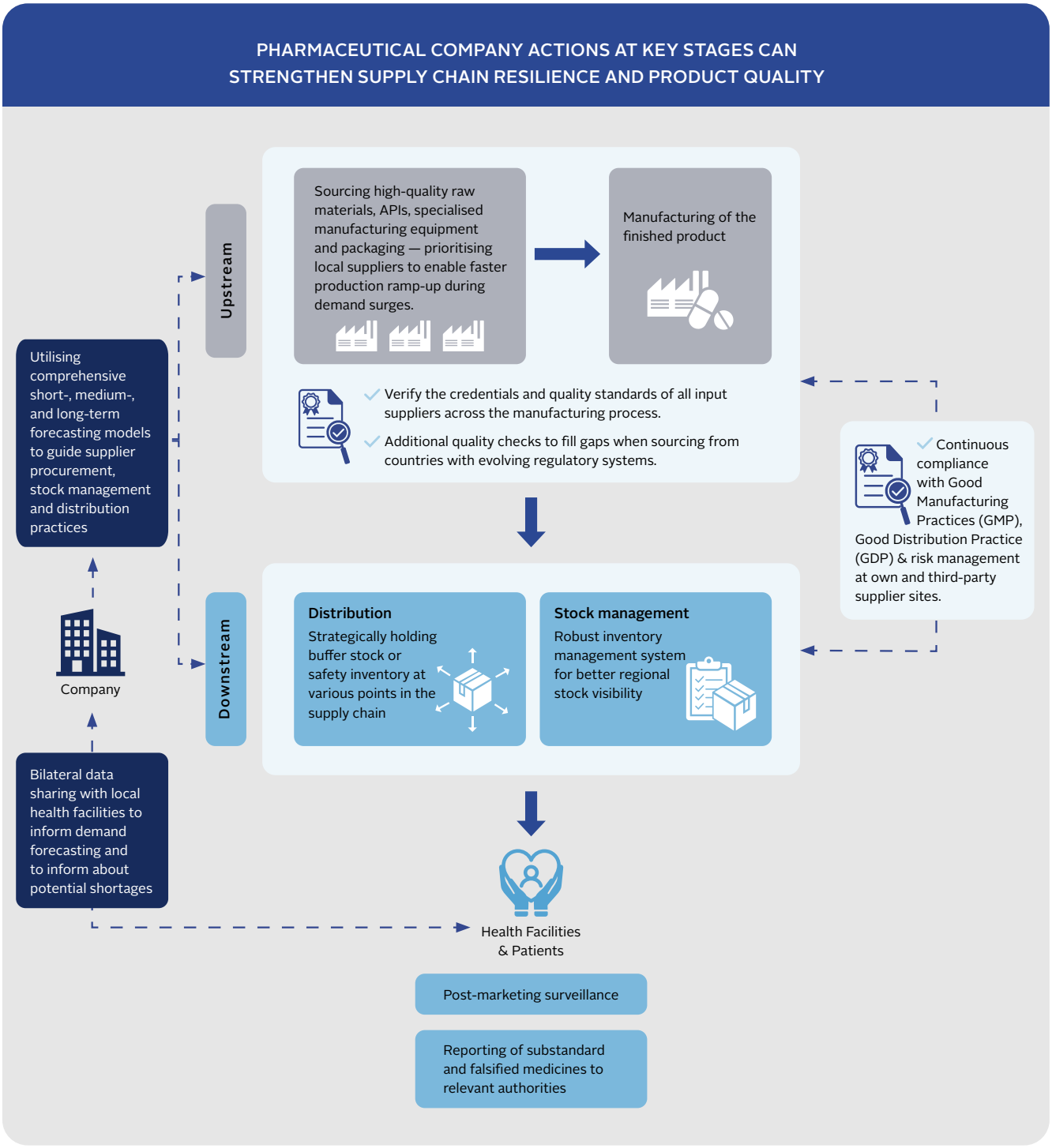
Producing a single antibiotic, for example, requires coordination among multiple players. Pharmaceutical companies must first secure quality-assured raw materials and specialised components, including active pharmaceutical ingredients (APIs) and reactionary intermediates, to produce these lifesaving drugs. Production also requires critical manufacturing equipment, such as freeze-dryers, which are often needed for antibiotics where sterility is essential.[1] Once produced, ensuring the right antibiotics reach the right people at the right time depends on effective demand forecasting, careful planning and efficient procurement and distribution. Yet disruptions can occur at any stage of the supply chain – from unexpected factory closure and dependence on a small number of suppliers to disruptions to the global distribution chain – all of which can compromise product quality or cause shortages and stockouts of critical antibiotics (see box-out).

As the producers of these lifesaving medicines, pharmaceutical companies play a key role in mitigating shortages and stockouts and ensuring a continuous supply – with several strategies they can adopt to do so (also see infographic on next page).

The 2026 AMR Benchmark assessed how seven large research-based companies and ten generic medicine manufacturers apply these strategies to maintain the supply of quality assured antimicrobials in LMICs.

When the chain breaks: Consequences of the amoxicillin supply shortages

In 2022-2023, there was a sudden global surge in respiratory infections that lead to increased demand for amoxicillin, including paediatric formulations. The shortages were attributed to manufacturing delays and production capacity issues, and heavy reliance on a handful of suppliers for sourcing ingredients[2]. Of the 17 sites producing the amoxicillin active pharmaceutical ingredient (API), eight are in China, six in Europe and three in India, highlighting the concentration and vulnerability of global production[3] Healthcare providers had to resort to prescribing broader-spectrum, less effective antibiotics, increasing the risk of AMR. Paediatric shortages also caused dangerous treatment delays; the case of a two-year-old dying in the UK from sepsis after being unable to receive amoxicillin brings the fatal consequences of lack of access into sharp relief. [4]



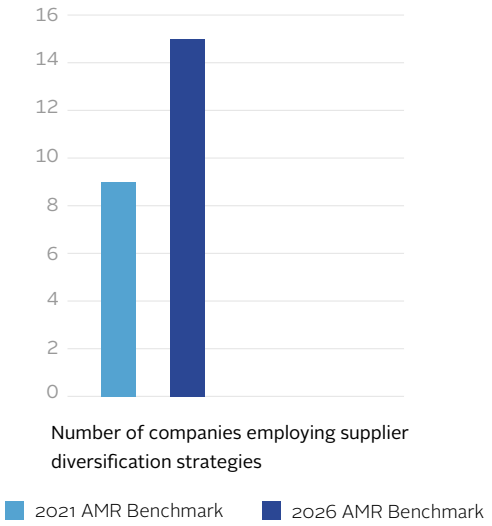
More companies are implementing supplier diversification as a strategy to mitigate risks in the antibiotic supply chain

In assessing the 17 companies' various strategies to strengthen supply chain resilience, the Benchmark finds that companies have made notable progress in implementing supplier diversification strategies. In fact, this has nearly doubled since the previous Benchmark (see Figure 6 on next page).

Upstream, companies are focusing on supplier diversification strategies aimed at sourcing from multiple qualified suppliers of APIs and raw materials. Viatris, for example, leverages its local, regional and global manufacturing sites, sourcing approximately 50% of its APIs from Europe, North America and emerging markets. Given the limited number of qualified suppliers for APIs and key intermediates, this is critical.

FIGURE 6 **Companies' supplier diversification strategies: 2021 vs 2026**

The number of companies implementing supplier diversification strategies to mitigate product stockouts has increased substantially – from 9 of 17 companies in the 2021 Benchmark* to 15 of 17 in the 2026 AMR Benchmark. Only two companies – Fresenius Kabi and Otsuka – do not report employing supplier diversification strategies.



**Two companies previously assessed in the 2021 AMR Benchmark (Novartis and Hainan Hailing) are no longer in scope for the 2026 AMR Benchmark and have been replaced with generic medicine manufacturers, Hikma and Sandoz. Even though 17 companies were in scope in 2021, Aurobindo was not assessed on supplier diversification because the company manufactured all its APIs in-house at the time.*

Currently, China and India are estimated to produce over 80% of the global API supply,[5] which represents a significant vulnerability for global supply chains. Moreover, APIs and other raw materials are typically in short supply, which compounds this fragility: not only are suppliers limited but supply itself is often not enough to cover existing needs. For instance, the global amoxicillin shortage in 2022–2023 was driven in part by constrained supply of amoxicillin API, as major API manufacturers in China reduced output due to rising production costs and COVID-19 pandemic-related disruptions – leaving finished-dose manufacturers unable to meet demand despite having production capacity.[6, 7]

Companies take early steps to source more locally to strengthen upstream supply

Among companies' efforts to diversify supply, the Benchmark finds that ten are more actively pursuing local sourcing of raw materials or finished products: Abbott, Alkem, Aurobindo, Cipla, Hikma, Pfizer, Sandoz, Sun Pharma, Teva, and Viatris. Where capacity for quality assured manufacturing exists, companies can procure from qualified local suppliers, as this can help shorten supply chains, reduce lead times and costs and strengthen resilience to global disruptions.

Currently, the companies taking this approach predominantly operate in countries that are antibiotic manufacturing hubs – such as India – or where local production capacity is already well established. Of the ten companies, six stand out for the ways they leverage local capacity in LMICs – whether by sourcing a large share of their products locally, or by reducing single-source dependency by ensuring that additional suppliers meet required quality standards.

▶ **Four companies with operations in India leverage existing local capacity**

Alkem, **Aurobindo** and **Sun Pharma** report strong engagement in local sourcing practices, with 90%, >70%, and 83% of their input materials or procurement, respectively, sourced from domestic suppliers in India. As Indian-based generic medicine manufacturers, they leverage the country's well-established pharmaceutical manufacturing

infrastructure to reduce dependence on overseas suppliers and mitigate associated supply chain risks. In Aurobindo's case, its substantial level of local sourcing also reflects the company's high degree of vertical integration, allowing key inputs to be produced in-house rather than procured from third-party domestic suppliers.

To reduce vulnerability to supply chain disruptions, **Abbott** – which operates pharmaceutical manufacturing plants in India – reports employing a local sourcing strategy for key products, including critical antibiotics and antifungals, which involves procuring of key materials from multiple supplier manufacturing sites in the country.

▶ Beyond India: Two companies have policies aimed at reducing single-source dependency in other LMICs

In the five LMICs where **Hikma** maintains manufacturing operations (Algeria, Egypt, Jordan, Morocco and Tunisia), the company works to strengthen supply continuity by diversifying its sources of APIs, raw materials and packaging within these countries. As part of its local sourcing efforts, Hikma ensures that alternative suppliers meet global standards by conducting quality and compliance assessments in line with Good Manufacturing Practice (GMP) standards, thereby reducing reliance on single-source suppliers and mitigating the risk of supply disruptions while ensuring quality is upheld (also see next section).

Pfizer adopts a global multi-sourced procurement strategy designed to mitigate single-source dependency, including in LMICs. The company engages a diverse portfolio of upstream suppliers, with a deliberate emphasis on integrating qualified local vendors into its sourcing networks – particularly for APIs. By decentralising procurement and fostering regional supply capabilities, Pfizer improves its capacity to respond swiftly to disruptions, maintain continuity of supply and build more sustainable, market-adapted operations.

Companies are responsible for safeguarding product quality, for both upstream inputs and in markets downstream

In addition to employing strategies, such as supplier diversification, to ensure timely and reliable supply, pharmaceutical companies play a critical role in ensuring quality assurance along the supply chain (see box-out)

This is especially vital when companies source locally in LMICs where regulatory oversight may be limited or less advanced. When procuring from suppliers from these countries, companies must also take additional steps to safeguard quality, for example by implementing more frequent audits, additional supplier verification steps, or transferring skills, technology and manufacturing methods to local suppliers to help them meet required standards. Based on companies' submissions to the Benchmark on their efforts to expand access in LMICs (see Access Strategies on p.49), examples from three companies were identified that also lend strength to local supply. GSK, Otsuka and Shionogi report actively engaging in technology transfers of their critical antimicrobials in LMICs to boost self-reliance while ensuring global quality standards.

In Brazil, GSK has entered into an agreement with two public health institutions, Fiocruz and Funed, to transfer the complete manufacturing process for its meningococcal vaccine Menveo® (also highlighted in Access Strategies on p.51). Otsuka has partnered with generic medicine manufacturer Viatris to complete a full technology transfer for adult and paediatric formulations of its antibiotic delamanid – which is used to treat tuberculosis (TB) – in India, where the burden of TB is extremely high. By partnering with the Global Antibiotic Research & Development Partnership (GARDP), Shionogi has engaged in a assisted development programme for its critical Reserve antibiotic, cefiderocol. As a result, Orchid Pharma is the production base for cefiderocol for the 135 countries covered by GARDP, including the entirety of sub-Saharan Africa.

Safeguarding quality across the supply chain

The World Health Organization (WHO) defines pharmaceutical quality assurance (QA) as the sum of all activities and responsibilities required to ensure that the medicine that reaches the patient is safe, effective and acceptable. As suppliers of essential health products, pharmaceutical companies hold responsibility for both the upstream and downstream aspects of QA. Upstream, this includes implementing robust oversight and quality standards of suppliers of raw materials and active ingredients. Without appropriate QA, companies risk sourcing substandard or contaminated products – for example, APIs that might contain impurities or harmful substances – which could further worsen AMR. Downstream, this includes ensuring internal and third-party manufacturing processes adhere to Good Manufacturing Practice standards, ensuring that distributors adhere to Good Storage and Distribution Practices, conducting post-marketing surveillance and taking corrective actions, if needed.

▶ Most companies meet quality compliance, but stricter measures lack in LMICs

The Benchmark finds that most companies are meeting baseline expectations for supplier compliance and quality across the board. Of the 17 companies, 15 report conducting routine GMP audits of all their potential suppliers (16 in 2021). Alkem and MSD did not submit this information to the Benchmark. Notably, and in line with the 2021 Benchmark, all companies confirmed GMP compliance across the sites they own and operate.

In certain LMICs where companies' suppliers operate, regulatory capacity can be more limited, requiring more stringent quality assurance measures from companies. Accordingly, the Benchmark also assessed whether companies are implementing additional safeguards for their suppliers in countries with evolving regulatory authorities and oversight – particularly those at Maturity Level 1 or 2, as defined by WHO's Global Benchmarking Tool. Only one company – GSK – reported evidence of such safeguards, underscoring the gap in proactive measures being taken by companies that go beyond baseline checks.

What steps are companies taking to secure supply downstream?

Once antimicrobials are manufactured, they still need to progress through the supply chain and reach patients. By employing downstream strategies to ensure continuous supply, companies can ensure their lifesaving medicines actually reach the people who need them safely, reliably and in the right quantities.

To this end, accurate demand forecasting is critical. Implementing both short-term (monthly) and long-term (at least 12 months horizon) forecasting helps companies anticipate needs, plan production and respond quickly to potential supply bottlenecks. Governments and procurers also have a critical role to play in providing companies with accurate and timely health data. By developing robust epidemiological frameworks that contain, for example, disease surveillance data, or trends in prevalence or incidence, and communicating demand information to companies, they can support more accurate demand planning.

▶ Ten companies use at least a 12-month demand forecasting outlook

The Benchmark finds that ten companies – Abbott, Aurobindo, Cipla, GSK, Hikma, Sandoz, Sanofi, Shionogi, Teva, and Viatris – all use forecasting with a horizon of at least 12 months, updated monthly (except Viatris, which updates daily).

These frequent updates support agile supply planning, which is particularly important for responding to sudden or localised increases in infections, and ensuring that hospitals and clinics do not run out of critical antimicrobials. However, multi-year, longer-term forecasting is also essential. Antimicrobials often have limited shelf lives, rely on APIs with long lead times and face complex manufacturing and quality-assurance requirements. Without longer-term forecasts, companies might not be able to secure APIs or may struggle to align their production capacity with demand. In the case of vaccines, which have complex and lengthy manufacturing processes with lead times of up to three years, long-term forecasts are critical.[8] Additionally, when informed by epidemiological data and resistance trends, such longer-term forecasting exercise can help companies anticipate changes in disease patterns and treatment needs, supporting more resilient supply. Sanofi, Shionogi and Teva specifically extend their horizons to at least three years. Notably, GSK and Sandoz engage in annual long-term demand forecasting of up to ten years.

▶ Eight companies regularly share demand forecasts with stakeholders

In many LMICs, national governments – often acting as the primary public procurers – carry out country-level demand and supply forecasting to ensure that national

"Most companies are meeting baseline expectations for supplier compliance and quality across the board. Of the 17 companies, 15 report conducting routine GMP audits of all their potential suppliers (16 in 2021)."

health plans are adequately supported. Pharmaceutical companies, by contrast, are responsible for planning their own manufacturing, inventory and distribution capacity to ensure they produce and deliver the appropriate quantities of antimicrobials. By proactively sharing demand forecast data with health ministries and public health organisations, companies can help better align supply and demand and ensure that the right quantities of antibiotics and antifungals are delivered.

Nine out of the 17 companies report regularly sharing demand forecasts with country-level stakeholders. Notably, GSK reports holding regular meetings with local health authorities in least developed and low-income countries to address in-country requirements and strengthen demand forecasting.

Sharing data

Large R&D based companies

Generic medicine manufacturers

Maintaining buffer stocks

Large R&D based companies

Generic medicine manufacturers

Robust inventory management systems

Large R&D based companies

Generic medicine manufacturers

▶ Most companies keep buffer stocks, but fewer have robust inventory systems

Combining buffer stocks with strong inventory systems ensures a reliable antimicrobial supply by providing a safety net while using resources efficiently – especially in times of crisis. While 16 companies report keeping buffer or safety stocks, only 12 implement automated inventory management systems that can provide real-time visibility to ensure the right levels of supply and prevent stockouts.

Abbott, for example, has introduced an automated tool that tracks potential shortages based on daily supply and demand data from all its markets. The tool predicts possible shortfalls and reallocates products as needed to minimise disruptions. Viatris also uses its Rapid Response Advanced Planning System that allows daily updates on demand, inventory and potential shortages to be shared across its global operations. It also maintains higher safety stocks for high-risk products based on demand patterns, supply stability and overall risk assessments. Cipla reports maintaining buffer stocks in 15 LMICs, taking a region-specific approach. In emerging markets and countries served by large institutional procurers, the company operates primarily on a make-to-order basis. By contrast, in other countries, it uses direct-to-distributor models. Supplying only against confirmed customer orders helps reduce the risk of product expiry and waste, while direct-to-distributor arrangements streamline logistics and shorten delivery times so that medicines reach patients more quickly.

These measures companies are taking are encouraging and can help ensuring that critical medicines remain available even when disruptions occur upstream, ultimately reducing the likelihood and duration of stockouts and shortages.

WHAT NEXT?

It is encouraging to see that pharmaceutical companies continue to take important steps to build resilient supply and safeguard the quality of their critical products in LMICs, with many newly addressing supply chain fragmentation through supplier diversification and local sourcing.

Continued efforts to reduce reliance on single-source or limited supply chains for both APIs and key starting materials are crucial. This can be achieved by expanding raw material supplier networks, forming partnerships to strengthen local production capacity and evaluating which suppliers to work with. At the same time, companies must maintain rigorous quality assurance and risk management across the entire chain, while reinforcing additional quality safeguards in LMICs markets with higher risks.

Companies can further improve their practices in stock management, by maintaining decentralised buffer stocks and adopting automated inventory management systems to strengthen visibility and responsiveness to local needs. Success will also depend on companies and LMIC partners collaborating more actively to share valuable data, which can support more accurate forecasting and earlier identification of supply risks. By strengthening their frameworks and systems to product timely, reliable and actionable health data, governments can further support accurate demand planning.

THEMATIC ANALYSIS | RESPONSIBLE BUSINESS PRACTICES

At the crossroads of stewardship and influence: How business practices can safeguard patients against AMR

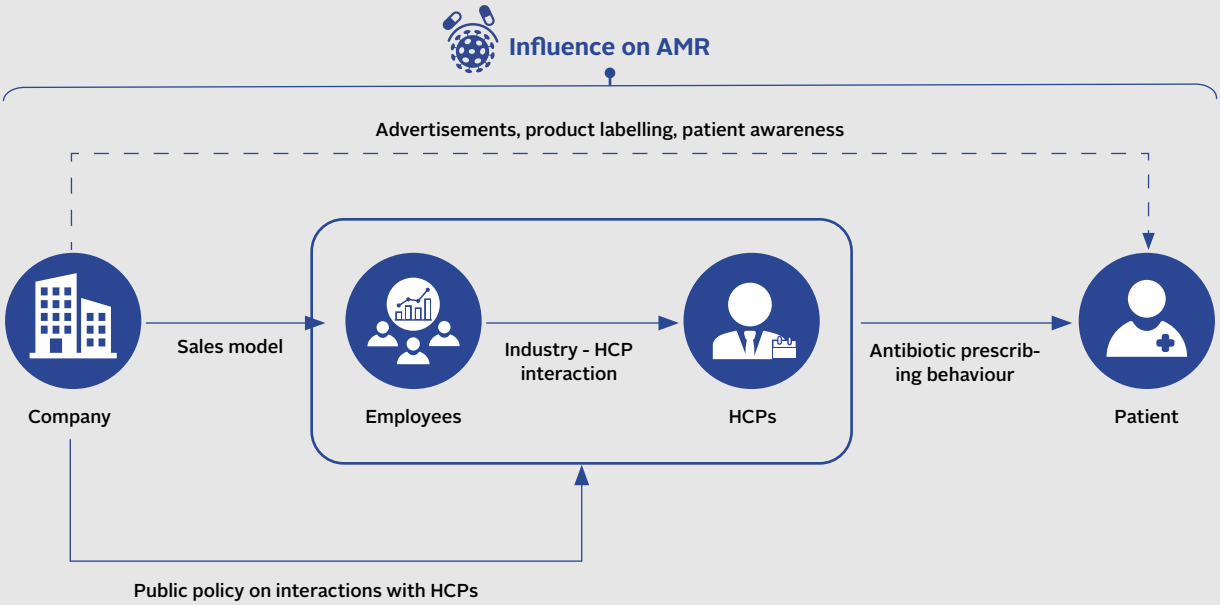
APPROPRIATE ACCESS & STEWARDSHIP

The way pharmaceutical companies conduct business can shape the health of patients who rely on their products. Marketing and sales practices, for example, can influence how healthcare professionals (HCPs) prescribe medicines, and whether patients receive treatment that truly meets their needs.[1] When these business practices are not managed responsibly, they can create commercial pressures that contribute to the misuse and overuse of antibiotics.[2] This, in turn, fuels antimicrobial resistance (AMR) and leaves patients vulnerable to infections that are increasingly harder, and sometimes impossible, to treat.

By implementing strong stewardship principles across their business operations (see infographic below), companies that produce and market lifesaving antimicrobials can reduce commercial pressures that potentially lead to the inappropriate prescribing of these products. The 2026 AMR Benchmark assessed the business practices of seven large research-based companies and ten medicine manufactures to determine whether these companies consider stewardship holistically across commercial operations – through both sales practices and implementing policies that govern ethical interactions with HCPs.

FROM COMPANY TO PATIENT: THE CHAIN OF INFLUENCE ON ANTIBIOTIC USE

Companies can ensure their sales models and public policies on interactions with health-care professionals (HCPs) are managed responsibly, so their business practices help ensure their medicines are prescribed appropriately.



Zeroing in on sales practices: Minimal movement since previously established progress

By removing links between bonuses and sales volume or refraining from promoting antibacterial and antifungal medicines through sales agents, companies can help ensure that prescribing decisions remain free from commercial influence

Since its first iteration in 2018, the AMR Benchmark has assessed these approaches to sales practices for antimicrobial products of both large research-based pharmaceutical companies and generic producers. Over time, there has been steady progress across the industry, with more companies either fully or partially decoupling sales incentives or removing the use of sales agents for antimicrobials. Encouragingly, the previous iteration of the Benchmark (2021) found notable progress, especially from generic producers. As set out in Figure 7, ten of the 17 companies assessed at the time implemented these responsible measures as their primary sales model. Four other companies signalled a positive direction of travel by adjusting the sales practices of specific products or piloting sales models that aimed to either remove the component of sales volumes entirely, or limit promotion in some countries or for certain products.

Now, in the 2026 Benchmark, 13 of the 17 companies assessed take measures to mitigate the risk of overselling antimicrobials, with seven – Aurobindo, Fresenius Kabi, Otsuka, Sanofi, Shionogi, Teva and Viatris – all showing clear evidence of implementing a responsible sales model as their primary approach in their sales practices. These seven companies either fully decouple sales bonuses from volume or do not use sales agents, which exemplifies the responsible approach needed in antimicrobial sales.

FIGURE 7 **13 companies now take measures to mitigate the risk of overselling antimicrobials**

**Two companies previously assessed in the 2021 AMR Benchmark (Novartis and Hainan Hailing) are no longer in scope of the 2026 AMR Benchmark and have been replaced with generic medicine manufacturers, Hikma and Sandoz.*

While companies have largely sustained their efforts since the previous Benchmark, some have slightly stalled. For instance, one company, operating under a non-disclosure agreement, newly reported linking an increased proportion of bonuses to sales volume targets. Additionally, no updates on whether the pilot schemes reported in the 2021 Benchmark (see 2021 AMR Benchmark, pp. 114–117 and 138–140) have been implemented or expanded were provided by companies to the 2026 Benchmark.* Viatris stands out as the only company to provide clear evidence of improvement: it now reports that it does not deploy sales agents for its entire generic portfolio, as well as for selected branded products. In 2021, Viatris only reported this for two of its products in scope at the time – its antifungal medicine flucytosine and its anti-tuberculosis medicine pretomanid.

**In 2021, Abbott and MSD reported running pilot projects where they fully decoupled incentives for sales agents from sales volume targets in some countries.*

The opportunities and challenges for change in a company's sales model differ between large research-based companies and generic medicine manufacturers due to their distinct business models. Large-research based companies may have stronger commercial interests tied to individual on-patent products, while generic medicine manufacturers often sell a broad range of off-patent antibacterial and antifungal medicines as part of larger product bundles, which can naturally reduce the incentive to oversell any single product type. Nevertheless, the fairly even spread between the seven large research-based companies (3) and generic producers (4) that implement strong responsible sales practices to mitigate the risks of overselling demonstrates that tailored approaches across company types are possible.

Companies' public policies ensure ethical interactions with HCPs to varying degrees

In addition to the longstanding assessment of sales practices, the 2026 Benchmark analysed how companies are governing interactions with HCPs for the first time. Interactions between HCPs and the industry can spark collaboration and offer important advantages[1] (see figure alongside). With their extensive knowledge and deep expertise on the antimicrobials they develop, manufacture and supply, companies are well positioned to provide valuable guidance and support to HCPs, including for appropriate prescribing and, in turn, strengthening stewardship.

However, due to different interests, interactions between HCPs and companies can also be affected by potential conflicts of interests (CoIs).[3] Companies should therefore make efforts to govern these interactions through their public policies, ensuring their benefits are realised responsibly. In addition to mitigating potential CoIs, companies can also ensure that interactions with HCPs are justified by a legitimate need. Where transfers of value (ToVs) are made to HCPs – for example, payments, gifts and sponsored travel for consulting, research or educational purposes – companies can ensure these are made at fair market value or governed by set limits. To determine how comprehensive companies' efforts are, the Benchmark assessed public policies that govern HCP interactions against these four criteria (see Table 1).

Potential benefits of industry-healthcare professional (HCP) collaboration

Combines industry resources with clinical expertise to develop, test and deliver life-saving drugs and medical devices

Knowledge and training for HCPs on new products

Improved patient care through safer, better-designed medical solutions

Access to new drugs in LMICs through improved HCP awareness

TABLE 1 **How comprehensive are company policies that govern HCP interactions?**

The 2026 AMR Benchmark assessed company policies governing healthcare professional (HCP) interactions against four criteria. Among the seven large research-based pharmaceutical companies, GSK and Pfizer meet all four. Across the ten generic medicine manufacturers, Abbott, Sandoz and Teva meet at least two.

Companies	Ensuring a legitimate need	Mitigating conflicts of interest	Payments at fair market value	Setting limits on ToVs
Abbott	○	○	●	●
Alkem	○	○	○	○
Aurobindo	○	○	○	○
Cipla	○	○	○	●
Fresenius Kabi	○	○	●	○
GSK	●	●	●	●
Hikma	○	○	○	○
Johnson & Johnson	●	●	●	○
MSD	○	○	○	○
Otsuka	●	○	●	○
Pfizer	●	●	●	●
Sandoz	●	○	●	○
Sanofi	●	●	●	○
Shiongi	●	○	○	●
Sun Pharma	●	○	○	○
Teva	●	○	●	○
Viatris	○	○	○	○

Alkem, Aurobindo, Hikma, MSD and Viatris have public policies on business ethics in place. However, they do not address any of the criteria assessed by the Benchmark.

▶ GSK and Pfizer stand out for most comprehensive policies

Of the 17 companies assessed, only GSK and Pfizer cover all of these aspects in their public policy – thereby limiting undue influence on prescribing and supporting ethical engagement between industry and HCPs. While large research-based companies generally perform better in regulating interactions with HCPs, with the exception of MSD, some generic medicine manufacturers, including Abbott, Sandoz and Teva also show good performance by addressing at least two out of the four criteria assessed.

Across all companies, the need for legitimate interactions is addressed the most, while only a few companies have clear rules on managing CoIs between employees and HCPs. Without such measures, CoIs can compromise the objectivity of clinical decisions and place commercial interests ahead of patient needs.

Only five companies address appropriate use across their business practices

As set out in the infographic earlier in this section, effectively safeguarding products – and the lives of patients – against AMR requires companies to address stewardship through responsible business practices across the healthcare continuum. For companies, this means taking a holistic approach that aims to mitigate AMR risks through both sales practices and HCP interactions. When considering this, only five of the 17 companies assessed – Otsuka, Pfizer, Sanofi, Shionogi and Teva – stand out for taking a holistic approach by embedding clear principles that foster stewardship across both their sales models and public policies.

While only a handful of companies adopt this holistic approach, the Benchmark also finds that some companies already take strong steps in at least parts of their business practices. For example, while GSK stands out in regulating its interactions with HCPs, it does not incorporate clear principles that foster stewardship in its sales model. On the other hand, while Aurobindo stands out in its sales model, it does not address stewardship in its interactions with HCPs. Building on these foundations, there remains an opportunity for these companies, and others, to integrate stewardship more broadly across their business practices, thereby advancing toward a comprehensive approach.

> “Otsuka, Pfizer, Sanofi, Shionogi and Teva stand out for taking a holistic approach by embedding clear principles that foster stewardship across both their sales models and public policies.”

Almost half of companies go beyond mandatory requirements in disclosing transfers of value to HCPs

While the implementation of responsible business practices relies heavily on self-regulation by companies, transparency around interactions with HCPs is key to enhancing company accountability. It also enables patients to make informed decisions, while providing governments with insights into how these interactions influence antibiotic prescriptions and use.[3] Companies can contribute to transparency around such interactions by, for instance, publicly disclosing financial and non-financial ToVs to HCPs.

In many countries, transparency around ToVs is mandated by national law or regulated by industry codes of practices, such as the International Federation of Pharmaceutical Manufacturers and Associations’ (IFPMA) code or the European Federation of Pharmaceutical Industries and Associations’ (EFPIA) code. Seven of the companies assessed also go beyond these mandatory requirements and voluntarily disclose this information in at least one country where they are not required by law to do so: GSK, MSD, Otsuka, Pfizer, Sandoz, Sun Pharma and Viatris.

GSK and Sandoz stand out among the seven companies for voluntarily disclosing information on ToVs in multiple countries, as well as clearly making this information on all countries publicly accessible on their websites (also see Best Practice on p.75). While Otsuka at least makes this information available for multiple countries where it publicly discloses its data, the accessibility of data from other companies remains a key issue. Some countries have stepped up and introduced public centralised data

platforms, where this data can be freely accessed, including the United States' Open Payments database[4] and the United Kingdom's Disclosure UK platform.[5] However, the level of data sharing among companies differs, and data remains fragmented across countries.

Beyond the disclosure of ToVs, approximately half of the companies add provisions on transparency in their public policies on interactions with HCPs. This clearly sets transparency out as an expectation for companies and formalises it as part of company practice.

WHAT NEXT?

- Companies can work towards fully decoupling incentives from sales volumes or refrain from including promotional activities for antibacterial and antifungal medicines in their sales strategies. Seven companies already show this commitment to stewardship – an approach that other companies can try and emulate to ensure the risk of overselling for financial gain is completely removed as practice.
- As self-regulation continues to serve as the foundation of many companies' business practices, it is essential that companies continue to strengthen these frameworks. This includes implementing comprehensive public policies to effectively govern ToVs and interactions with HCPs. Companies can also enhance transparency around ToVs and, where feasible, disclose data on interactions with indivdiual HCPs to promote greater accountability.
- Industry and the healthcare community can work together to support the harmonisation and accessibility of disclosed data. For instance, establishing a collaborative system for declaring payments would advance transparency and strengthen ethical collaboration, ultimately helping to ensure that interactions serve the best interests of patients.
- Governments also have a critical role to play in ensuring that patient needs and care remain at the centre of all engagements. By introducing legislation, such as the Sunshine Act (see sidebar), that requires public reporting from companies, governments can help foster transparency and accountability.

Shedding light: The Sunshine Act as a model for transparency

Enacted in 2010, the Physician Payments Sunshine Act requires pharmaceutical and medical device companies in the US to publicly report most payments and transfers of value (ToVs) made to healthcare professionals (HCPs).[6] The data is published in the Open Payments database, managed by the Centers for Medicare & Medicaid Services (CMS), allowing anyone – including patients – to see financial relationships between industry and HCPs. Other countries could consider introducing similar legislation to enhance transparency, accountability and trust in these relationships

THEMATIC ANALYSIS | AMR SURVEILLANCE

Understanding the spread of superbugs is critical to treating them

APPROPRIATE ACCESS & STEWARDSHIP

Protecting patients from drug-resistant infections requires knowing where antimicrobial resistance (AMR) is emerging, how widespread it is and how it is changing. Surveillance provides this information through the systematic collection and analysis of data, enabling healthcare professionals (HCPs) and policymakers to make informed decisions about treatment guidelines and strategies for controlling the spread of AMR[1]. For patients, this can help ensure they receive the right treatment, at the right time.

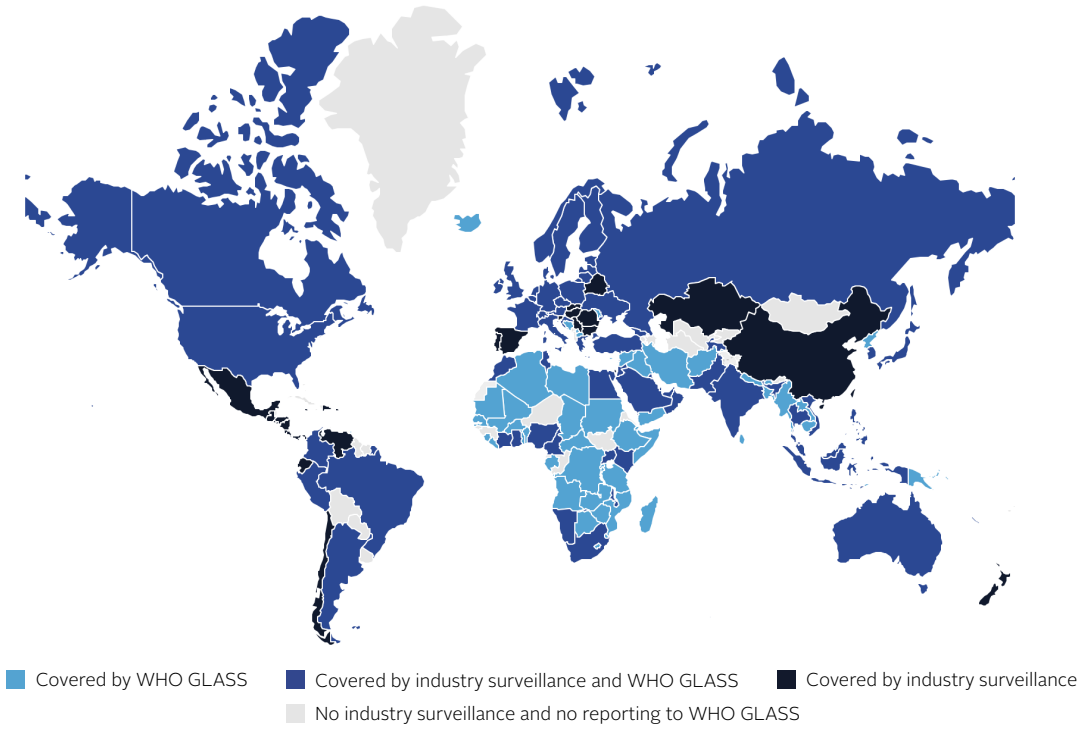
Companies can already help fill surveillance gaps in 15 LMICs

At present, many low- and middle-income countries (LMICs) lack reliable surveillance data on AMR[2], weakening their ability to respond effectively to this growing threat (see map). But in at least 15 of the 113 countries covered by the Benchmark, companies may be able to fill current blind spots in local data. Industry surveillance is already in place, yet no data from these countries is reported to the World Health Organization (WHO) Global Antimicrobial Resistance and Use Surveillance System (GLASS) system (see sidebar on next page).[3] This means that while data may exist for these settings, accessibility is limited and depends on companies voluntarily sharing it.

What is industry surveillance?

This refers to AMR monitoring programmes companies engage in to track trends of drug resistance, optimise product use, prolong product lifespan and develop new products. These programmes often arise from post-marketing requirements or mandated surveillance studies during clinical development. Ownership of resulting data varies depending on the type of surveillance programme.

FIGURE 8 **Global coverage of AMR surveillance systems**



More data means better tracking and smarter prescriptions

Rates of resistance are often higher in places with limited surveillance capacity[4]. But in countries covered by industry-run surveillance, pharmaceutical companies have a clear opportunity to share the data they already collect to help address this issue. While data ownership can vary depending on the programme, potentially limiting some companies' ability to share results, companies that have been involved in a programme for some time can advocate for data sharing with the organisation managing the data, such as IHMA or JMI Laboratories. When joining a new programme, companies can also prioritise those that already have clear data-sharing practices. Doing so could provide information on resistance patterns not currently reported to GLASS, helping to build a more comprehensive picture of AMR and, in turn, supporting HCPs in prescribing the most effective antibiotics for patients.

Even in countries with WHO GLASS coverage or where some local surveillance exists, such data could add value, as it is typically generated through standardised methods in accredited laboratories using samples from around the world, making it likely to be consistent, reliable and comparable across settings[2]. This is particularly relevant for medicines in development or those newly introduced to the market, which are often not yet captured within the GLASS surveillance system, as early resistance data can guide their appropriate use and oversight.

What is the World Health Organization (WHO) Global Antimicrobial Resistance and Use Surveillance System (GLASS)?
Launched in 2015, WHO GLASS supports countries in tracking AMR trends, comparing data across nations and monitoring antibiotic use and resistance. It provides guidelines, technical support and standardised methods for national surveillance and publishes the data that countries submit themselves. According to the 2025 WHO GLASS report, country participation in this surveillance system has increased four-fold since 2016, with 52% of countries reporting AMR data in 2023.[4] Nevertheless, regional gaps in surveillance data persist.

Companies demonstrate clear areas of strength in surveillance efforts, setting examples for others

Among the companies that were also assessed in the 2021 AMR Benchmark, three fewer are involved in surveillance, as their programmes or contractual agreements have ended. However, several of the programmes currently operating are robust and well-designed, demonstrating clear methodologies, strong data sharing and coordination efforts. Having high-quality programmes that incorporate these factors enhances surveillance and contributes to a stronger understanding of AMR, which is vital in strengthening responses to this threat.

▶ Over half of company surveillance programmes utilise clear methodologies

Central to achieving reliable data is having a clear methodology for programmes that monitor how bacteria respond to antibiotics. Encouragingly, 12 of the 21 assessed surveillance programmes have well-defined methodological approaches, while seven demonstrate partly clear methodologies. One programme reports a methodology that is unclear for assessment, and only one programme does not report a methodology at all.

Beyond following a clear methodology to collect data, companies can also strive to be transparent about these approaches. This ensures that the reliability of the data can be assessed, compared across systems and trusted for wider public health use. In this area, there is room for improvement among companies, as none share all key details about their methodologies publicly.

▶ Data sharing: Pfizer leads with regular updates and raw data publication

Consistent tracking and public reporting of AMR data makes it possible to respond to new resistance patterns and adapt treatment guidelines for improved patient outcomes.

Pfizer's Antimicrobial Testing Leadership and Surveillance program (ATLAS) tracks and and shares data online every six months[5], while MSD's Study for Monitoring Antimicrobial Resistance Trends (SMART) was also observed sharing data multiple times during the period of analysis. In contrast, most companies only share data once studies or programmes are completed, limiting the ability to monitor resistance in real time.

Although aggregated data remains the main format for data sharing, sharing

"Consistent tracking and public reporting of AMR data makes it possible to respond to new resistance patterns and adapt treatment guidelines for improved patient outcomes."

raw data is more useful for a broader range of public health purposes, as it allows for more detailed and flexible analyses. Pfizer consistently shares raw data from ATLAS via the AMR Register – a publicly accessible platform that compiles industry and academic AMR surveillance data. During the 2026 Benchmark's period of analysis, GSK, Pfizer and Venatorx reported doing the same, but not on a regular basis.

Besides sharing raw data publicly, companies also have a clear opportunity to directly share such data with Early Warning Systems, such as WHO GLASS EAR or EARS-Net, especially for new antibiotics. These systems are designed to monitor and analyse surveillance data in real or near real time, enabling timely responses to emerging resistance trends. They may operate at the national or regional level. By contributing data to these systems, companies can help healthcare authorities respond more quickly and effectively to resistant strains or outbreaks. No company currently shares data directly with Early Warning Systems.

Across the board, greater consistency in both the timing and format of data sharing would significantly enhance the value of industry surveillance for public health.

Companies coordinate surveillance efforts with SENTRY Antimicrobial Surveillance Program

Although a few companies that were included in the 2021 Benchmark are no longer involved in surveillance, ongoing programmes are becoming more interconnected overall. This harmonisation makes data collection easier, allows datasets to be combined and strengthens global AMR monitoring. For example, by participating in JMI Laboratories' SENTRY Antimicrobial Surveillance Program, Basilea, Iterum, Pfizer, Sandoz and Shionogi support coordination efforts.

Some examples of how companies are working with SENTRY

- Under the umbrella of SENTRY, **Basilea** has initiated global surveillance for its antibacterial and antifungal medicines, including its own products, fosmanogepix and cefepime-taniborbactam. BAL2062 is planned to be included in 2026.
- **Pfizer** provides financial support to SENTRY to test antifungal drugs, including its new innovative antifungal medicines. The data is subsequently loaded into the ATLAS website. New antibacterial compounds owned by Pfizer have also been integrated into the surveillance system.
- **Shionogi** provides financial support to SENTRY to conduct cefiderocol susceptibility testing.

Across all programmes, there are still opportunities to harmonise data collection and analysis. While most surveillance programmes follow CLSI breakpoints – standard thresholds used to determine whether infections are susceptible to antimicrobials – there is considerable variation in other aspects of methodology and surveillance objectives. For example, while ATLAS uses 97 unique labels for sample sources, WHO GLASS clearly categorises them into a handful of labels[6]. Although not all elements can be harmonised, especially during data collection, there is potential to develop shared guidance or frameworks to promote greater consistency in reporting and analysis.

WHAT NEXT?

While companies are not solely responsible for AMR surveillance, industry-led initiatives can help fill current data gaps by providing valuable insights into resistance trends in LMICs, where other data sources may be limited or absent.

In addition to current efforts, companies can further strengthen the surveillance ecosystem by sharing emerging resistance trends with Early Warning Systems. When resistance is detected, timely notification of public health authorities enables rapid action to prevent further spread. This is especially true for emerging resistance to newly marketed drugs or those still in development, which is more often detected by industry surveillance.

In the long term, however, governments must step up in building local infrastructure and systems for sustainable data collection and sharing.

Going forward, collaboration between pharmaceutical companies and public health bodies to combine and harmonise data collection will be critical for comprehensive AMR surveillance. At the very least, reporting and sharing practices should be better aligned to more effectively monitor and limit the spread of AMR. WHO GLASS provides a strong example of this, offering a standardised framework for collecting and reporting national AMR data that ensures reliability and comparability across countries. Establishing similar frameworks or guidance for integrating industry and national surveillance data would streamline collaboration and help close current gaps in AMR monitoring, particularly in LMICs.

2026 AMR BENCHMARK

BEST PRACTICES

RESEARCH & DEVELOPMENT

1 BEST PRACTICE

RESPONSIBLE MANUFACTURING

1 BEST PRACTICE

APPROPRIATE ACCESS & STEWARDSHIP

3 BEST PRACTICES

THEMATIC ANALYSIS | BEST PRACTICES

Best Practices in the 2026 AMR Benchmark

The 2026 AMR Benchmark has identified five 'Best Practices' across the three Research Areas. There is one in Research & Development, one in Responsible Manufacturing and three in Appropriate Access & Stewardship. Some of these focus on a single company, while others draw on examples from several companies.

The aim of a Best Practice

The diffusion of Best Practices is one of the Access to Medicine Foundation's mechanisms for supporting the pharmaceutical industry in achieving greater access to medicine. Best Practices are shared to accelerate adoption of similar practices by other companies, and to help raise the overall level of standard practice. Furthermore, recognising those companies trialling or scaling up innovative, unique policies or initiatives is an important way of acknowledging companies that stand out from peers and are willing to risk new approaches to advance efforts.

What defines a Best Practice in the Benchmark?

Best Practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best Practices are not new practices – they have already been conceived of, applied and proven to meet at least some of the following criteria:

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

In different Research Areas within the Benchmark (for example, in Research & Development vs. Appropriate Access & Stewardship), the way in which a Best Practice is identified may be different. Best Practice need not be unique among companies; it might be an example of a 'gold standard' of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations. Best Practices should be considered as an exemplar of positive practices in the corresponding Research Area in comparison to those of the other companies that submitted data within the current period of analysis. These Best Practices are identified based on evidence of progress submitted in the data collection period and verified with public information and through consultation with experts, where appropriate.

How Best Practices were selected for the 2026 AMR Benchmark

To determine which of the company's practices would be highlighted as Best Practice, the AMR Research Team evaluated all aspects of company practices, compiling those that met the criteria used for the purpose of scoring with additional standards for each Research Area, where necessary. Company practices that met these outlined criteria were reviewed and finalised by the Foundation's senior management with additional input from experts in the corresponding field, when required.

RESEARCH & DEVELOPMENT ▶ PIPELINES & INNOVATION

GSK sustains leadership in antimicrobial R&D, with SMEs driving innovation

WHICH COMPANIES DEMONSTRATE BEST PRACTICE?	
Large research-based companies	GSK
Small and medium-sized enterprises (SMEs)	Basilea, BioVersys, F2G, Innoviva, Iterum and Venatorx are also noted in this Best Practice for developing innovative antibacterial and antifungal candidates. Collectively, SMEs are developing 50% of all innovative projects in scope of the Benchmark.

HIGHLIGHTS OF THIS BEST PRACTICE	
Action	GSK maintains its leading position in antimicrobial research and development (R&D) with a broad and diverse pipeline, despite the scientific and commercial challenges in the field.
Aim	To address the significant unmet need for novel antibiotics as resistance rates continue to rise.
Location	Global

It is well established that antimicrobial resistance (AMR) continues to intensify, reducing the effectiveness of existing treatments and leaving limited options for patients with resistant infections. At the same time, developing new antimicrobials is complex, costly and commercially unviable for most companies, leading many to reduce or withdraw their investment and presence in the field.

Against this backdrop, GSK remains one of the few large research-based pharmaceutical companies to sustain active engagement in antimicrobial research and development (R&D), with the strongest and most diverse pipeline in the sector. Furthermore, all of GSK's late-stage pipeline projects are supported by access and stewardship plans, which can help ensure these products are available and used responsibly when they reach the market.

GSK has maintained its pipeline size over the past five years, with the number of projects reducing only slightly since the 2021 Benchmark (from 31 to 30). With 30 projects currently in scope, GSK's pipeline is more than three times the size of the next two largest pipelines – Pfizer and Shionogi – each with eight projects. This scale and breadth demonstrate GSK's leadership in antimicrobial R&D across every iteration of the Benchmark (2018, 2020 and 2021) and provide a strong example of best practice in the sector.

Focusing on critical pathogens amid limited approvals

GSK's antimicrobial portfolio includes both therapeutic candidates and preventive vaccines, addressing a wide range of 'high'- and 'critical'-priority pathogens as defined by the World Health Organization (WHO).

The company applies its long-running expertise in antimicrobial research across multiple disease areas, with a strong focus on gram-negative bacteria and high-priority pathogens, including *Mycobacterium tuberculosis*, which causes tuberculosis (TB). TB is a major public health threat in low- and middle-income countries, especially in sub-Saharan Africa.

GSK's vaccine pipeline comprises 13 projects targeting several pathogen groups, including Enterobacterales and *Streptococcus pneumoniae*, and is the only company in scope developing vaccines for *Salmonella* and *Shigella* spp. (See GSK's Report Card on p.89 for a full breakdown of its antimicrobial pipeline.)

While the company maintains its broad and diverse pipeline, new market approvals remain scarce across the sector. GSK is one of only two large research-based companies to bring an antibiotic medicine to patients during the period analysed, with gepotidacin – a first-in-class antibiotic featuring a novel mode of action – approved for uncomplicated urinary tract infections. Pfizer is the other, with aztreonam-avibactam and ceftazidime-avibactam for neonates and infants (also see Key Finding on p.26).

> "Alongside the sustained scale and diversity of GSK's pipeline, SMEs are helping to ensure that progress continues across both antibacterial and antifungal development in a challenging environment."

SMEs step up alongside GSK to address critical gaps

Small- and medium-sized enterprises (SMEs) play an important role in driving antimicrobial innovation, particularly in areas where larger companies have limited activity. Only three large research-based pharmaceutical companies currently have innovative antibacterial candidates in development – GSK (3), Shionogi (4) and Otsuka (1) – none of which have innovative antifungal candidates. Projects in the pipelines of Johnson & Johnson, MSD, Pfizer and Sanofi are either vaccines, which fall outside the scope, or adaptations of existing products that do not meet any of the five 'innovation criteria' in the Benchmark's framework for analysis (see box-out).

By contrast, six of the eight SMEs assessed in the Benchmark – Basilea, BioVersys, F2G, Innoviva, Iterum and Venatorx – are developing innovative antibacterial and antifungal candidates, collectively representing the half of all innovative projects in scope. When considering antifungal R&D specifically, SMEs are responsible for 60% (3 of 5) of projects in clinical development in scope of the Benchmark. This includes all antifungal projects, not only the innovative candidates, highlighting the significant role SMEs play in addressing a historically overlooked research area, especially given the growing global burden of invasive fungal infections (also see Antifungals Spotlight on p.43).

These contributions, alongside the sustained scale and diversity of GSK's pipeline, help ensure that progress continues across both antibacterial and antifungal development in a challenging environment.

WHAT IS AN 'INNOVATIVE' PROJECT?

The WHO defines four innovation criteria to assess whether new antibacterial and antifungal candidates are innovative. The Benchmark applies these criteria – and adds a fifth – to capture a broader range of clinical benefits:

1. New chemical class

2. New target

3. New mode of action

4. No known cross-resistance

5. 'Other' criteria that provide meaningful clinical utility beyond the four WHO criteria, as assessed by the Benchmark (e.g., an oral formulation that improves use in low- and middle-income countries).

Meeting one or more of these criteria indicates a medicine's potential to remain effective for longer. For example, drugs from entirely new chemical classes are less likely to encounter existing bacterial resistance.

Looking ahead: Lessons for the sector

As bacterial and fungal evolution inherently leads to the emergence of resistance, its rise over time is inevitable. Sustaining activity in the antimicrobial pipeline is therefore vital, as existing medicines will eventually lose effectiveness. GSK's long-term commitment, reflected in a broad and diverse portfolio of antibacterial and vaccine candidates, and the role of SMEs in driving continued innovation in the sector together represent a strong example of best practice.

Progress also depends on collaboration across public and private sectors. Partnerships with organisations such as the Global Antibiotic Research and Development Partnership (GARDP), Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), UNITE4TB and Wellcome Trust can help support antimicrobial R&D. Lasting advances will require stronger measures across access and stewardship planning, market incentives and policy reforms prioritising countries with the highest unmet need, ensuring that new treatments reach the patients who need them most.

RESPONSIBLE MANUFACTURING ▶ SUPPLIER COMPLIANCE

Companies take hands-on approach to suppliers' wastewater management practices

WHICH COMPANIES DEMONSTRATE BEST PRACTICE?	
Large research-based companies	GSK and Shionogi
Generic medicine manufacturers	Abbott, Aurobindo, Cipla and Sandoz
HIGHLIGHTS OF THIS BEST PRACTICE	
Action	Companies provide additional support to third-party suppliers and/or implement antimicrobial resistance (AMR)-related contractual provisions on waste management to ensure compliance with antibacterial discharge limits.
Aim	Antibacterial discharge limit compliance across antibacterial supply chains to prevent the development and spread of AMR.
Location	Global

A major yet often overlooked driver of antimicrobial resistance (AMR) is the release of active pharmaceutical ingredients (APIs) from antibiotic manufacturing into the environment. When wastewater containing this residue enters local ecosystems, it can create breeding grounds for bacteria that become resistant to antibiotics, putting people at risk and making vital medicines less effective.

Antibiotic manufacturing occurs within highly fragmented supply chains, with production sites located around the world. Without proper wastewater management, these facilities can become key points of antibiotic release into the environment. Pharmaceutical companies can reduce the risk of AMR by enforcing robust manufacturing standards not only at their own sites, but also at those of suppliers, who often produce APIs and drug products on their behalf.

As the main customers and coordinators in these supply chains, companies have the ability and responsibility to ensure supplier compliance with recommended discharge limits, helping to protect people in local communities and prevent the spread of AMR.

> "These companies are demonstrating a willingness to go the extra mile in preventing antibiotic pollution across supply chains."

Efforts aim to ensure discharge compliance across supply chains

Six companies – Abbott, Aurobindo, Cipla, GSK, Sandoz and Shionogi – are taking a more active role in engaging their suppliers to comply with discharge limits via different practices. Outlined by the AMR Industry Alliance (AMR IA) Antibiotic Manufacturing Standard and World Health Organization (WHO) guidance, these limits aim to minimise the risk of resistance and environmental harm.

Company efforts generally take two forms: offering additional support to suppliers to achieve compliance and including AMR-related waste provisions in supplier contracts. The six companies highlighted here were selected because they demonstrate strength in these areas – or have high levels of supplier site or product compliance. By extending oversight and deepening engagement beyond their own facilities, these companies are demonstrating a willingness to go the extra mile in preventing antibiotic pollution across supply chains

What types of additional support are companies offering suppliers?

All six companies take the standard approach of asking suppliers to implement corrective actions themselves when discharge limits are exceeded or require an audit every one to three years. However, five companies go further by helping suppliers measure and achieve compliance through additional practices.

- **Abbott** offers free wastewater analysis to all suppliers whose estimated antibiotic discharges are higher than the safe limit, based on mass balance calculations.
- **Cipla** conducts workshops with suppliers on how to quantify discharge levels with mass balance calculations, in line with the AMR IA Standard.
- **GSK** tailors engagement plans for each supplier and conducts desktop-based assessments to evaluate adherence to discharge limits. When non-compliance is identified, it provides one-on-one support with mass balance calculations and guidance on adjusting waste management processes to meet limits.
- **Sandoz** collaborates with suppliers through its audit and relationship management teams to create corrective and preventive action (CAPA) plans when antibiotic concentrations in wastewater go beyond safe levels.
- **Shionogi** helps each of its suppliers determine the most appropriate methods for quantifying antibacterial discharges, based on their specific facilities and equipment.

These more targeted, tailored practices demonstrate a proactive and collaborative approach to responsible manufacturing, with companies educating and supporting suppliers at different stages to improve discharge management.

Contract provisions can also bolster compliance

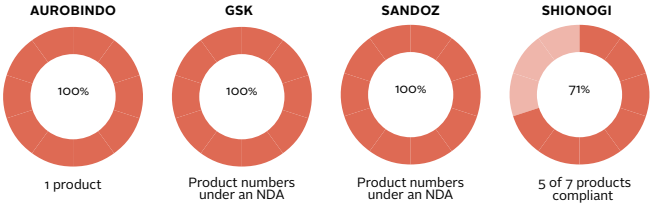
Apart from Cipla, all companies include discharge-level compliance expectations in supplier contracts. These provisions are guided by recognised industry initiatives, such as the Pharmaceutical Supply Chain Initiative (PSCI) framework* and the AMR IA Standard. They refer to the assessment and control of antibacterial discharges to ensure they remain below the predicted no-effect concentrations (PNECs) – the levels at which antibiotics are unlikely to cause environmental or resistance-related harm.

Including such provisions can help strengthen accountability across supply chains and ensure that manufacturing and environmental standards are enforceable rather than just voluntary.

Extra measures yield results, setting example for others to follow

Among the four companies that report supplier compliance, performance is consistently high – showing that the more active supplier engagement pays off. Specifically, Aurobindo, GSK and Sandoz report 100% compliance, and Shionogi reports compliance for five out of seven products made by its suppliers.

SUPPLIER SITE COMPLIANCE



Taking this progress forward

By proactively ensuring supplier compliance with discharge limits – through contractual provisions, additional support or, ideally, both – companies can more effectively strengthen responsible manufacturing across supply chains. Combining both approaches not only set clear expectations but also give suppliers the guidance and tools they need to actually deliver on them.

While most of the companies referenced in this Best Practice report being compliant with discharge limits in the receiving environment (i.e., rivers and waterways), ensuring compliance before the release of wastewaters into the environment would further help protect ecosystems and communities worldwide. This would be in line with measures recommended by WHO. Collectively, the industry should work towards this, as mitigating antibiotic discharges at the source can improve control of AMR and safeguard global health (also see Key Finding on p.33).

APPROPRIATE ACCESS & STEWARDSHIP ▶ REGISTRATION

Aurobindo leads with a portfolio-wide approach to registration in East Africa

WHICH COMPANIES DEMONSTRATE BEST PRACTICE?	
Generic medicine manufacturers	Aurobindo
HIGHLIGHTS OF THIS BEST PRACTICE	
Action	Registering off-patent antibacterial and antifungal medicines in East Africa via the East African Community's Medicine Regulatory Harmonisation (EAC-MRH).
Aim	Registration across its antimicrobial portfolio in the East African Community (EAC).
Location	EAC, including Burundi, The Democratic Republic of the Congo, Kenya, Rwanda, Somalia, South Sudan, Tanzania and Uganda.

Ensuring patients have timely access to the antibiotics they need is crucial to controlling the spread of antimicrobial resistance (AMR). But before a medicine can be made available to people in a country, it often must be registered there – meaning it has been reviewed and approved for commercialisation by the national regulatory authority (NRA). Pharmaceutical companies, as the producers of antibacterial and antifungal medicines, help determine where their products are accessible by choosing where to file for registration.

Despite facing a disproportionate burden of AMR, countries in sub-Saharan Africa have low registration rates for antibiotics. As a result, treatment options are often limited in these settings, putting people at risk of untreatable infections. Pharmaceutical companies cite factors such as lengthy approval processes and high costs as barriers to filing for registration in these markets. Furthermore, the relatively small market size in many of these countries limits their commercial attractiveness.

Aurobindo's approach to registration sets it apart in East Africa

Across all generic medicine manufacturers, Aurobindo performs best in widely registering off-patent (generic) antibacterial and antifungal medicines. The company's efforts to register these products – which typically have low profit margins due to competition but are essential for treating infections – help ensure patients can access effective treatments without delays or high costs.

One region where these efforts are particularly apparent is the East African Community (EAC), a regional bloc within sub-Saharan Africa consisting of Burundi, The Democratic Republic of the Congo, Kenya, Rwanda, Somalia, South Sudan, Tanzania and Uganda. Here, Aurobindo engages with the East African Community Medicines Regulatory Harmonization (EAC-MRH) programme to support product registration. This programme enables these countries to jointly evaluate the safety, quality and effectiveness of medical products, led by a lead and a co-lead NRA (see box-out).

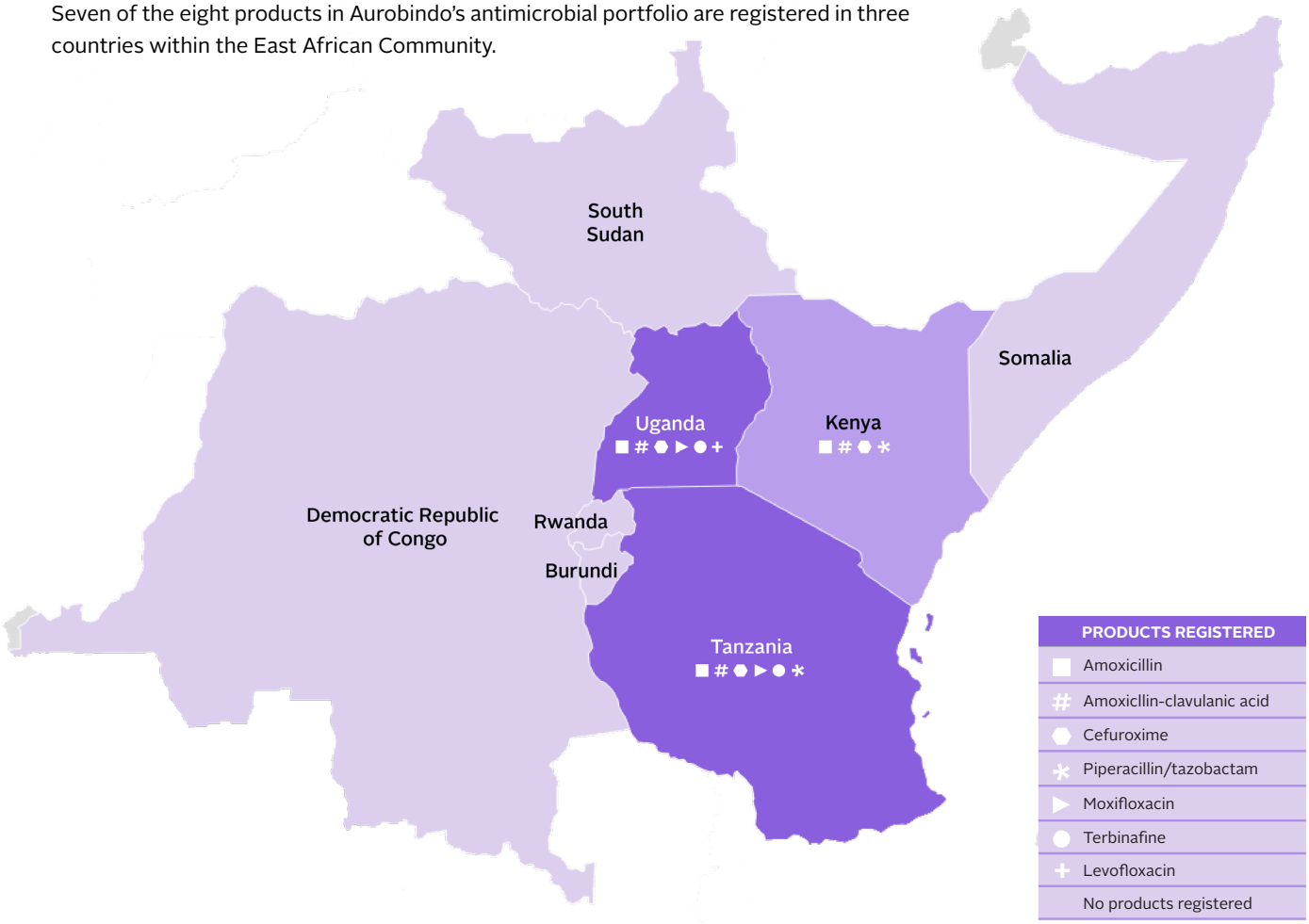
THE EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC-MRH) PROGRAMME

The EAC-MRH programme was established in 2012 to streamline the registration of medicines across the five founding East African Community (EAC) countries: Burundi, Kenya, Rwanda, Tanzania and Uganda. The initiative later expanded to include additional member states, with The Democratic Republic of the Congo joining most recently in 2022.

The programme enables joint assessments of product applications by the national regulatory authorities (NRAs) of participating countries. While evidence on the impact of these joint assessments is mixed, the programme has led to shorter approval timelines, improved information sharing among regulators and strengthened assessment capacity across the region. However, it is important to note that each NRA still makes its own final registration decision even after a joint assessment.

AUROBINDO'S REGISTRATIONS ACROSS EAST AFRICA

Seven of the eight products in Aurobindo's antimicrobial portfolio are registered in three countries within the East African Community.



Aurobindo is the only company in scope to report utilising the EAC-MRH, applying this registration pathway for all products assessed. Other companies register primarily through national registration pathways –where each country's NRA reviews applications on its own – or through World Health Organization (WHO) mechanisms such as the prequalification programme or the Collaborative Registration Procedure (CRP). Furthermore, these are typically used for just a single product.

This makes Aurobindo stand out, as it is taking a systematic, region-wide approach to ensuring its products are approved and accessible across East Africa – rather than a one-off effort. The impact of Aurobindo's efforts is evident in the number of registrations the company has achieved within the region (see above map). By registering its products widely through the EAC-MRH programme or directly with NRAs, Aurobindo is helping to improve medicine availability and strengthen the region's capacity to respond to resistant infections. Moreover, Aurobindo reports that use of the EAC-MRH has resulted in faster assessments and shorter national approval timelines.

Encouraging broader, region-wide registration across companies

Other companies can look to Aurobindo's example of pursuing registration across its antimicrobial portfolio in this region. Although registration can be challenging in low- and middle-income countries (LMICs), companies can engage early with regulators to clarify requirements and address potential obstacles in the registration process. They should identify the most effective strategy for bringing products to market – whether through national mechanisms, WHO prequalification or reliance on Stringent Regulatory Authorities (SRAs) – recognising that the best approach depends on the specific context and each country's needs. As demonstrated by Aurobindo, companies can also leverage regional regulatory harmonisation, which allows a single application to cover multiple countries. Taking a broad, regional approach like this can reduce registration timelines and costs while ensuring faster access for people who need these treatments most.

APPROPRIATE ACCESS & STEWARDSHIP ▶ TRANSPARENCY

GSK and Sandoz raise the standard for reporting transfers of value

WHICH COMPANIES DEMONSTRATE BEST PRACTICE?	
Large research-based companies	GSK
Generic medicine manufacturers	Sandoz
HIGHLIGHTS OF THIS BEST PRACTICE	
Action	Companies transparently publish transfers of value (ToVs) in multiple countries.
Aim	Provide clear and easily accessible information on ToVs in a single, central location for the public.
Location	Global

Collaboration between pharmaceutical companies and healthcare professionals (HCPs) is essential in driving medical innovation, improving healthcare delivery and ultimately benefitting patients. However, without transparency, these relationships risk creating conflicts of interest that could influence prescribing decisions and undermine public trust.

Transfers of value (ToVs) – payments or benefits provided by companies to HCPs or healthcare organisations (HCOs) – should therefore be disclosed publicly to ensure these interactions remain ethical and accountable. Transparency provides insights into the impact of these interactions and how they may contribute to anti-microbial resistance (AMR) when medicines are prescribed inappropriately, while also demonstrating that collaborations are conducted responsibly and in patients' best interests.

GSK and Sandoz exemplify this approach by voluntarily making ToVs information clearly accessible across a wide range of countries, setting a best-practice example for transparency and accountability.

> "Both companies disclose transfers of value for all countries where they report such interactions, providing a single, clearly accessible source of information."

Voluntarily advancing transparency

Both companies disclose ToVs for all countries where they report such interactions, providing a single, clearly accessible source of information on their websites. For each country, the reports are organised by year and include direct links to the disclosure documents. GSK and Sandoz also go beyond mandatory obligations, making this information publicly available in multiple countries where no legal requirements or codes of practice apply. In addition, GSK shares data on interactions with individual HCPs where the law allows and otherwise provides aggregated information that combines data from multiple HCPs to protect individual privacy.

Beyond website publication, both companies also submit their ToVs data to other stakeholders where applicable, such as national platforms like the US CMS Open Payments website or the ABPI disclosure portal in the UK. While these publicly available platforms increase visibility, the primary responsibility for transparent reporting remains with the companies themselves.

In comparison, most other companies disclose ToVs only where legally mandated, under other codes of practice or in just one country beyond these requirements, often in fragmented formats that require external searches to locate.

Demonstrating long-term, accessible ToVs reporting

GSK has led voluntary disclosure efforts since 2017, initially reporting aggregate payments to HCPs and HCOs before expanding to include individual HCP data, where allowed by law. Its multi-year, country-level reporting demonstrates a sustainable approach that can be maintained and updated in future years. Sandoz has similarly committed to continuous, multi-year reporting, including in countries without mandatory disclosure requirements.

By centralising data, maintaining long-term reporting and disclosing across multiple countries, both companies demonstrate that ToVs information can be publicly accessible and comprehensible. Their approach provides a replicable model for other pharmaceutical companies while remaining compliant with local legislation.

Companies positioned to drive change, guided by government oversight

Continued progress in ToVs transparency relies on proactive company action supported by regulatory frameworks. Following GSK and Sandoz's practice, companies can improve self-regulation by sharing clear, easy-to-access data on interactions with individual HCPs where the law allows. Industry and HCPs can also collaborate to harmonise disclosure systems through publicly available centralised platforms, making data easier to compare internationally and supporting ethical collaboration and effective oversight.

Additionally, companies can further safeguard patient care by decoupling incentives from sales volumes and keeping them separate from the promotion of antibacterial and antifungal medicines. These measures help reduce the risk of inappropriate prescribing and preserve the effectiveness of essential medicines.

Besides company action, government oversight remains an important factor. Regulations such as the US Sunshine Act – a federal law requiring companies to disclose ToVs above a specified annual value (also see Responsible Business Practices on p.59) – complement voluntary initiatives, creating a consistent and reliable framework for disclosure. When combined with company-led efforts, strong policies and active oversight, these measures can drive lasting progress – ensuring that openness in collaborations between companies and HCPs continues to protect both patients and public health.

APPROPRIATE ACCESS & STEWARDSHIP ▶ SUPPORTIVE DIAGNOSTICS

Companies support diagnostic capacity to safeguard medicines against drug resistance

WHICH COMPANIES DEMONSTRATE BEST PRACTICE?	
Large research-based companies	Johnson & Johnson, Otsuka and Pfizer
Generic medicine manufacturers	Cipla
HIGHLIGHTS OF THIS BEST PRACTICE	
Action	Companies are supporting diagnostic capacity by either providing necessary tools to hospitals or helping to train healthcare professionals.
Aim	Ensure that medicines are appropriately prescribed/used to maintain their efficacy.
Location	Global

To treat an infection effectively, the cause must first be identified. Diagnostics are the tools, tests and technologies used for this purpose – to determine the type of infection, identify the pathogens responsible and assess whether antibiotics are needed and which ones are most likely to work.

Nearly half of the global population (47%) have little to no access to essential diagnostics, a challenge that is particularly acute in low- and middle-income countries (LMICs).* Without these tools, patients in these countries may never receive the right treatments and/or could end up using antibiotics inappropriately, driving the spread of antimicrobial resistance (AMR).

For powerful, last-resort antibiotics and newer, innovative treatments that are vital in the fight against AMR, proper diagnostic capacity is crucial. Access to these drugs can be lifesaving, yet they often come with strict usage guidelines and should not be prescribed without appropriate testing, as improper use risks diminishing their effectiveness.

Because some LMICs lack diagnostic capacity, pharmaceutical companies can be hesitant to supply certain antibiotics in these markets, knowing that the necessary diagnostic tests to guide proper use are unavailable. While this cautious approach is intended to preserve the effectiveness of medicines, it can inadvertently deny patients access to lifesaving treatments, putting vulnerable populations at risk.

> "By supporting diagnostic capacity in LMICs, Cipla, Johnson & Johnson, Otsuka and Pfizer aim to ensure patients are prescribed the right antibiotics in a timely manner, promoting the responsible use of these medicines."

* Fleming KA, Horton S, Wilson ML, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. *The Lancet.* 2021;398(10315):1997-2050.

From training to supplies: How companies are supporting better diagnostics

Four companies – Cipla, Johnson & Johnson, Otsuka and Pfizer – demonstrate Best Practice in supporting diagnostic capacity in LMICs. Their actions aim to ensure patients are prescribed the right antibiotics in a timely manner, promoting the responsible use of these medicines.

In India, **Cipla** provides sensitivity discs and E-strips directly to hospitals to help doctors appropriately prescribe and use ceftazidime-avibactam. This is a powerful, last-resort antibiotic recommended as first-line treatment for severe infections caused by multidrug-resistant (MDR) gram-negative bacteria. Having access to these susceptibility tests allows healthcare professionals (HCPs) to determine whether the bacteria is susceptible or resistant to the antibiotic. Cipla also extends this initiative to two on-patent antibacterial medicines in its portfolio – cefepime-enmetazobactam (Cipenmet®; Esblocip®) and plazomicin (Zemdri®) – by providing hospitals with the corresponding sensitivity discs and E-strips for these products as well.

Johnson & Johnson is working to train more than 100,000 community healthcare workers in underserved regions of India where there are high rates of underdiagnosed tuberculosis (TB) – including Delhi, Hyderabad and Pune – to accelerate early diagnosis and address the persistent underdiagnosis of TB in the country. This initiative builds on a pilot that took place in 2024 in partnership with the Johnson & Johnson Foundation, the National TB Elimination Programme, PATH, and TB Alert India.

In more than 50 countries, **Otsuka** gives laboratories the pure delamanid compound for free so they can test how *Mycobacterium tuberculosis* bacteria respond to it. Delamanid is the active ingredient used in medicines that treat MDR-TB. These tests help determine whether the bacteria are susceptible or resistant to delamanid and therefore whether the drug is likely to be effective for treatment. In addition, Otsuka is collaborating with diagnostic companies to accelerate the development of delamanid drug susceptibility testing kits, which have reached the late stages of development ahead of production.

Between 2022 and 2025, **Pfizer** worked with around 30 hospitals in Colombia through the "Genomic Programme" – an epidemiological monitoring initiative that supported the in vitro screening of ceftazidime-avibactam (Zavicefta®). The programme, which ended in March 2025, helped hospital laboratories test bacteria against ceftazidime-avibactam – an antibiotic used to treat serious gram-negative bacterial infections – to see whether the bacteria were susceptible or resistant. By improving the speed and accuracy of lab results, the programme enabled HCPs to diagnose serious gram-negative infections more quickly and ensure that patients received the most effective antibiotic as early as possible.

Examples highlight how companies can step up to protect antibiotic efficacy

These examples demonstrate how Cipla, Johnson & Johnson, Otsuka and Pfizer are engaging in efforts to ensure their products are being used responsibly. By equipping local hospitals and laboratories with diagnostic tools and supporting HCP training, these companies are helping support more timely and appropriate treatment decisions for patients. Such steps not only protect patient health but also help curb AMR by preserving the effectiveness of vital antibiotics.

Although building or strengthening diagnostic capacity is not a core responsibility of pharmaceutical companies – and health systems cannot rely on them to provide such support in the long term – initiatives like these could help countries with limited resources in the years following a product's approval, when diagnostic access is still limited. Companies with powerful, last-resort antibiotics and innovative treatments with stringent usage guidelines could adopt similar approaches when expanding access to their products in LMICs. Doing so would allow patients currently facing drug-resistant infections to benefit from these much-needed treatments, while promoting their responsible use, preserving their long-term effectiveness and contributing to broader stewardship efforts.

2026 AMR BENCHMARK

BRINGING IT ALL TOGETHER

Cross-cutting insights and the road ahead

Antimicrobial resistance (AMR) is a major global challenge that demands coordinated action across sectors; no single stakeholder, including pharmaceutical companies, can tackle it alone. Nevertheless, pharmaceutical companies have a responsibility to contribute to addressing AMR within their sphere of influence, with opportunities to act at various stages of the pharmaceutical value chain.

The Industry Trends, Key Findings, thematic analyses and Best Practices in the 2026 AMR Benchmark highlight numerous strong examples – spanning strategies, products, and geographies – of company actions that effectively address AMR at different stages of the value chain. While no single pharmaceutical company typically covers every stage of the value chain for each of its antimicrobial products in a fully comprehensive way, many do show examples of progress at different points along it. The challenge now is to develop and apply approaches across more products and across more countries to ensure efforts can be maximised to curb AMR and save lives.

Drawing on examples covered in previous sections of the Report, as well as additional noteworthy examples, this closing section of the Benchmark provides a holistic picture of how companies are already demonstrating what is possible for individual products across every stage of the pharmaceutical value chain. From research and development, through manufacturing, to access and stewardship and measuring real-world patient reach, these examples illustrate the potential for companies to develop more comprehensive approaches.

From pipeline to patient: Examining how pharmaceutical companies combat AMR at each stage of the value chain

Research & Development

BREAKTHROUGH TREATMENTS FOR WOMEN'S HEALTH

Investing in research and development (R&D) to produce innovative medicines is essential to counteract AMR, as current treatment options continue to lose effectiveness. However, scientific and commercial challenges have diminished private sector investment, leaving just 15 candidates with innovative characteristics in the pipelines of the companies assessed in the Benchmark (also see R&D analysis on p.40). But even with this challenging outlook, recent breakthroughs have delivered two newly approved oral antibiotics – GSK's Blujea™ (gepotidacin) and Iterum's (sulopenem etzadroxil) ORLYNVAH™ – to treat uncomplicated urinary tract infections (uUTIs) in women. This is significant because uUTIs are some of the most common community-acquired bacterial infections globally, particularly in women who account for up to 80% of cases.[1,2,3] Until recently, no oral innovative antibiotics had been approved for decades, leaving women with fewer effective options and higher risk of treatment failure.

- GSK's Blujea (gepotidacin) is a new class of drug with a novel mechanism of action, offering a novel approach compared to existing antibiotics – and increasing the likelihood it will remain effective against drug-resistant pathogens for longer. In December 2025, gepotidacin received regulatory approval for an additional indication – the treatment of uncomplicated gonorrhoea. Alongside the approval of Innoviva's Nuzolvence® (zoliflodacin) for the same indication, this significantly expands the limited oral treatment options beyond the injectable standard of care.
- Although derived from the existing penem class of antibiotics, the 2024 approval of Iterum's sulopenem etzadroxil (ORLYNVAH™) marked the first and only oral penem antibiotic. This fills an important gap by enabling outpatient treatment of uUTIs for women with few or no treatment options.

Access & Stewardship planning in late-stage development

ACCELERATING ACCESS: PLANNING FOR NEW PRODUCTS WITHOUT DELAY

Starting access and stewardship planning for pipeline projects from Phase II helps ensure that products can reach the patients who need them as quickly as possible. Pfizer provides a strong example with its antibiotic aztreonam-avibactam (Emblaveo®), which received market authorisation in April 2024.

- Developed in partnership with AbbVie, Pfizer is responsible for access in low- and middle-income countries (LMICs). Pfizer's access plan addresses availability, supply and affordability, including equitable pricing strategies and the incorporation of the medicine into Pfizer's 'Accord for a Healthier World' initiative, ensuring its provision on a not-for-profit basis. For more on companies' efforts on access and stewardship planning, see the Key Finding on p.26.

Research & Development image - DC Studio on Freepik
Access & Stewardship planning in late-stage development image - Adrian Sulyok on Unsplash

Responsible manufacturing

PRODUCING LIFESAVING ANTIBACTERIALS RESPONSIBLY

Without proper and safe management of antibiotic waste, manufacturing facilities can release high levels of active pharmaceutical ingredients (APIs) into the environment, creating conditions that expose bacteria to these residues, which can accelerate the development of AMR. Therefore, companies must ensure that wastewater is safely treated – especially when producing last-resort antibiotics like cefiderocol (Fetroja®; Fetcroja®). Shionogi does just that.

▶ Shionogi reports that wastewater from its Kanegasaki plant in Japan is chemically analysed – a more accurate method than mass balance estimation – to ensure that all levels remain within the discharge limits set by both the AMR Industry Alliance and World Health Organization guidelines. Shionogi's efforts have been recognised, having recently received BSI Kitemark certification for its Kanegasaki antibacterial manufacturing facility, covering both the API and finished formulation of cefiderocol. This represents the first-ever BSI Kitemark certification in Japan for an antibacterial manufacturing facility and only the second case globally in which both the API and finished formulation processes for a product have been certified at a single site. In this way, the entire end-to-end manufacturing process is independently certified and safeguarded.

Registration

PRIORITISING REGISTRATION IN LMICS

Registering their products – whether that be directly with a country's national regulatory authority (NRA), or through mechanisms such as WHO Prequalification – is an essential first step for companies to ensure access to safe, quality-assured medicines. Among generic medicine manufacturers, Aurobindo stands out for widely registering its off-patent/generic antimicrobials, averaging 19 registrations out of the 113 countries in the scope of the Benchmark.

▶ One way Aurobindo achieves this is by engaging with the East African Community Medicine Harmonization Programme (EAC-MRH) to support product registration for multiple of its products. The EAC-MRH enables joint assessments by the NRAs of participating countries. This approach sets Aurobindo apart, reflecting a systematic effort to ensure broad access to its antimicrobial medicines across East Africa. Read more about Aurobindo's Best Practice on p.73.

Supply

PREVENTING STOCKOUTS AND SHORTAGES

Ensuring a continuous supply of quality-assured medicines is essential to preventing AMR by reducing treatment gaps, inappropriate antibiotic use, and exposure to substandard products. Viatris' approach combines several strong practices, demonstrating a cohesive strategy for managing supply and preventing stockouts of antimicrobials across its supply chain.

▶ These measures include a 24-month forecasting horizon supported by its Rapid Response Advanced Planning system, which provides daily updates on demand, inventory and potential shortages; strategic buffer stocks and dual sourcing for antimicrobials across local and global sites; and rigorous quality-assurance processes. This integrated approach highlights how long-term forecasting together with real-time demand and inventory oversight can help companies anticipate supply risks and maintain uninterrupted availability of essential antimicrobials.

Responsible manufacturing image - TravelScape on Freepik
Registration image - jannoon028 on Freepik
Supply image - usertrmk on Freepik

Access & Stewardship strategies

Access strategies

TAILORING ACCESS STRATEGIES FOR LMICS

Many populations in LMICs still face limited access to appropriate antimicrobial treatments, often due to country-specific access barriers. Pharmaceutical companies have a responsibility to address these challenges by implementing targeted, context-specific access strategies.

- For meropenem, in Nigeria, Pfizer has implemented an innovative payment strategy to address affordability barriers. Firstly, the co-payment is shared between Pfizer, the National Health Insurance and the patient. In addition, the payment structure offers flexibility: patients can receive meropenem immediately and are only required to make an initial payment within 30 days. This approach helps ensure that financial constraints do not delay access to essential treatment. To read more about how pharmaceutical companies are implementing access strategies to tackle barriers in LMICs, see Access Strategies on p.49.

Stewardship strategies – responsible business practices

IMPLEMENTING CORPORATE POLICIES TO SAFEGUARD PATIENTS

Pharmaceutical companies' business practices can have direct effects on patient health by influencing whether medicines are prescribed appropriately.

- Otsuka does not deploy any sales agents to promote its antibacterial or antifungal medicines in its portfolio, including on-patent antituberculosis medicine delamanid (Deltyba®), safeguarding it against the potential risks of inappropriate prescribing due to irresponsibly influencing healthcare professionals (HCPs). In addition to not deploying sales agents, Otsuka's policy ensures that any payments (or benefits) to HCPs are necessary, fair, and publicly disclosed in multiple countries to support impartial decision-making in patients' best interests.

Stewardship strategies – surveillance

TRACKING AND SHARING DATA TO MONITOR AMR

Surveillance is critical for monitoring where and how AMR is emerging and spreading, enabling policymakers and HCPs to make informed decisions that protect patients. Since 2002, GSK has operated a multinational surveillance programme, the Survey of Antibiotic Resistance (SOAR), which focuses on community-acquired respiratory tract infections.

- In addition to running the surveillance programme, GSK goes a step further by directly sharing the collected data with HCPs in both Pakistan and India. To facilitate this, GSK has launched dedicated platforms — the Pakistan Infection Index and the India Infection Index — where HCPs can access local antibiotic susceptibility data from SOAR for amoxicillin, amoxicillin-clavulanic acid and cefuroxime, helping to guide informed prescribing decisions and curb the further spread of AMR.

Access & Stewardship strategies image - Spencer Davis on Unsplash

Patient reach

TRANSLATING STRATEGIES TO IMPACT

Expanding access to essential antimicrobials in LMICs is imperative to improving health equity, and the most effective way for pharmaceutical companies to measure and monitor their efforts in this space is through the systematic measurement of patient reach.

▶ Sandoz employs a strong patient reach methodology, going beyond simply tracking sales data by accounting for defined daily doses and treatment duration, to provide an accurate estimate of the number patients of patients reached by its antimicrobials across all products assessed in the Benchmark. Sandoz was able to share disaggregated, country-level patient reach estimates for all nine of its medicines assessed by the Benchmark. To read more about how generic medicine manufacturers are measuring patient reach, see the Key Finding on p.36.

WHAT NEXT?

Companies have already demonstrated success in addressing AMR across the pharmaceutical value chain, and these noteworthy examples provide a strong foundation to build on and drive further progress. By mapping their current efforts to tackle AMR, pharmaceutical companies can better understand their strengths across the value chain and pinpoint the stages where their focus can have the most impact. Given the scale and complexity of AMR, gaps in individual companies' efforts are likely to remain. However, companies can look to partners for support and collaborate strategically with suppliers, governments, and other relevant organisations to close these gaps effectively.

In doing so, companies can continue to improve access to lifesaving antimicrobials, strengthen stewardship, ensure a reliable supply, all while simultaneously addressing AMR along the way. Monitoring and reporting on these efforts not only helps to refine their own strategies but also provides valuable insights for other companies earlier in their AMR journey, fostering industry wide learning and progress.

OPPORTUNITIES FOR COMPANIES TO ADVANCE PROGRESS

Individual company Report Cards (next section) include tailored Opportunities for each of the 25 companies assessed in the 2026 AMR Benchmark.

7
LARGE RESEARCH-BASED COMPANIES

10
GENERIC MEDICINE MANUFACTURERS

8
SMALL- AND MEDIUM-SIZED ENTERPRISES

Patient reach image - Towfiqu Barbhuiya on Unsplash

2026 AMR BENCHMARK

REPORT CARDS

7 LARGE RESEARCH-BASED COMPANIES

10 GENERIC MEDICINE MANUFACTURERS

8 SMALL- AND MEDIUM-SIZED ENTERPRISES

Guide to reading Report Cards

The 2026 AMR Benchmark includes 25 company Report Cards that provide detailed overviews of each assessed company's performance. This includes seven large research-based companies, ten generic medicine manufacturers and eight small- and medium-sized enterprises (SMEs).* Each Report Card includes a summary of the company's strengths and weaknesses, drivers behind changes in its ranking, as well as tailored 'Opportunities' for the company.

The Report Cards are divided into six sections, as set out below. Abbreviations and terminology used within the Report Cards are also provided on p.88.

1. Performance

Company's performance in the 2026 AMR Benchmark. Not all types of companies were assessed across the three Research Areas and indicators. SMEs, for example, are only assessed in Research & Development (see 'Performance by Research Area' below). For a comprehensive list of the indicators and scoring eligibility by company, see Appendices II and III. All companies were assessed based on information that was valid in the period of analysis (1 October 2023 to 30 September 2025). This data was either submitted by companies or found in the public domain.

2. Opportunities

Based on the 2026 AMR Benchmark analysis, the Access to Medicine Foundation has set out tailored 'Opportunities' for each company to improve efforts to curb AMR, taking account of company-specific characteristics. This includes its antimicrobial research and development (R&D) pipeline, access and stewardship planning during drug development, responsible manufacturing practices, registration and appropriate access and stewardship strategies of marketed products, as well as responsible business practices and AMR surveillance.

By pinpointing specific actions companies can take to make a positive impact in curbing AMR, these opportunities offer clear, practical and feasible ways in which companies can each maximise their efforts successfully.

These opportunities signal significant change-making potential for the company and are also valuable for investors and global health stakeholders as they engage with companies to drive change. Between Benchmark iterations, the Foundation continuously engages with all companies on their respective Opportunities, working with them to help turn the identified potential into meaningful impact.

3. Changes since 2023

These updates reflect where the company's efforts to curb AMR have changed most notably since the release of AMR Benchmark Opportunities: Company progress since 2021, which was published in November 2023. To ensure a complete and accurate picture, these changes are taken into account from 1 October 2023 – which also marks the start of analysis for the 2026 AMR Benchmark – up until 31 December 2025. Changes include:

- new, or updated activities and programmes.
- interesting developments, initiatives or activities that can contribute to mitigating AMR.
- notable new developments that have influenced a company's performance in the Benchmark.

4. Sales and operations

General description of the company's operations globally, including changes in its business (such as acquisitions or divestments) over the period of analysis. This information has been sourced from companies' annual reports, financial statements, websites, press releases and/or other news sources.

FIGURE 1 **Companies in scope for the 2026 AMR Benchmark by Research Area***

	Large research-based companies	Generic medicine manufac-turers	Small- and medium-sized enterprises
Research & Development	✓		✓
Responsible Manufacturing	✓	✓	
Appropriate Access & Stewardship	✓	✓	

Large research-based companies
GSK, Johnson & Johnson, Merck & Co, Otsuka, Pfizer, Sanofi, Shionogi

Generic medicine manufacturers
Abbott, Alkem, Aurobindo, Cipla, Fresenius Kabi, Hikma, Sandoz, Sun Pharma, Teva, Viatris

Small- and medium-sized enterprises
Basilea, BioVersys, Evopoint, F2G, Innoviva, Iterum, TenNor, Venatorx

*The Benchmark no longer evaluates Hainan Hailing or Novartis, while Hikma and Sandoz are newly included. Pulmocide, initially included in the 2026 AMR Benchmark Methodology among SMEs, was excluded from the 2026 AMR Benchmark Report due to the termination of its Phase II trial for opelconazole in January 2026.

5. Pipeline and portfolio summary

Given the different types of companies assessed in the 2026 AMR Benchmark, these summaries differ by company type. The information in these summaries is based on verified pipelines and portfolios submitted by the companies, as well as public sources.

- Research & Development (R&D) pipelines: For large research-based pharmaceutical companies and SMEs, this section looks at the size of the company's anti-infectives pipeline, specifically antibacterial and antifungal medicines, as well as vaccines, in development. The Benchmark also investigates how innovative these R&D projects are, whether they effectively address the most pressing gaps in the global antimicrobial R&D pipeline, and if they have the potential to treat the most severe drug-resistant infections. It also examines whether companies have access and stewardship plans in place for their late-stage development projects.
- Product portfolio: For large research-based companies and generic medicine manufacturers, this section indicates the number of products in the company's product portfolio, and a breakdown of the products selected by the Benchmark for analysis. Alkem Laboratories, Merck & Co., Inc (MSD), Sanofi and Sun Pharma did not disclose the number of products in their anti-infectives portfolio, so the summary figures in their Report Cards only show the products selected for analysis.

6. Performance by Research Area

- Overview of the company's performance in each Research Area measured by the 2026 Benchmark: Research & Development (R&D), Responsible Manufacturing and Access & Stewardship. Each area includes a summary of the company's overall performance, followed by 'indicator performance statements' that summarise a company's performance in specific indicators in that Area.
- Benchmarking is only undertaken within company types (i.e., performance is not assessed comparatively across different company types). To this end, performance points measured by indicators have been structured to be comparable across the same company types, while still describing the company's individual programmes, initiatives and approaches. Since SMEs are only assessed in the R&D Research Area, their overall performance is included at the start of their Report Card, and not in the Research Area.
- Examples included in a company's Report Card are not exhaustive but seek to showcase the standout findings for each indicator used to measure company performance.
- The 'Indicators evaluated' band at the top of each Research Area clearly shows by which indicators specific companies were assessed. For the purposes of creating indicator performance statements, the Research Team merged statements to include indicators that are related (see below).
- For some indicators, company performance is described using specific qualifiers (e.g., below/above average, clear/unclear, in few countries/in most countries). These are specific to company performance for a specific indicator and are not comparable across Research Areas or other indicators. For example:
  - Qualifiers used for indicator A.2 are based on the average score for large research-based companies for this indicator.
  - Qualifiers used for C.1 indicators (C.1.1-C.1.3) are based on the average number of countries where a company registers its products and are separated by product type. Company performance for registrations of paediatric formulations is based on the proportion of countries where it registers these formulations relative to the total number of countries where it registers the respective product.
  - Qualifiers used across C.2 indicators (C.2.1-C.2.3) are based on the company performance per individual indicator and separated by company type.

- Qualifiers used across the C.3 indicator are based on company performance per branch of the indicator ('Strategies to prevent stockouts and shortages' and 'Strategies to ensure quality-assured APIs and drug products').
- Qualifiers used to describe the methodology of AMR surveillance programmes in indicator C.5 are assigned per programme and based on the number of assessed methodological elements the company reports on.

FIGURE 2 **How the indicator performance statements are formulated across Research Areas**

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Large research-based companies and SMEs

- A.1.1, A.1.2, A.1.3 and A.1.4 performance statements have been merged into one statement. As such, there are only two R&D indicator performance statements.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Large research-based companies and generic medicine manufacturers

- B.1 and B.2 indicator performance statements remain separate.

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Large research-based companies and generic medicine manufacturers

- C.1.1, C.1.2 and C.1.3 performance statements have been merged into one statement. As such, there are only seven Appropriate Access & Stewardship indicator performance statements. The performance by indicator is shown in the accompanying graph in this section of the Report Card, with one bar representing one indicator. As such, when companies are not assessed on all three indicators, the graph will have fewer than three bars.
- For indicators C.1.1, C.1.2 and C.1.3, product registrations are calculated as averages across the products selected for analysis in order to assess company efforts across their portfolios.
- For indicators C.1.1, C.1.2 and C.1.3, countries with a high burden of disease are defined based on disability-adjusted life years (DALYs) per 100,000 population, using the indication for the product as listed on the World Health Organization Essential Medicines List (WHO EML) 2023. Per product, countries in the top quartile of DALYs rates are classified as high-burden. This analysis is based on data from the Institute for Health Metrics and Evaluation (IHME) Antimicrobial Resistance (AMR) dataset.
- Generic medicine manufacturers and SMEs are not assessed in C.5 'AMR Surveillance', but their efforts in this area (where applicable) have still been noted in their Report Cards.
- For the set of indicators assessing company efforts to ensure access to their products ('access metrics'), the Benchmark applies a separate geographic scope encompassing 113 countries, with a primary focus on LMICs. Company efforts outside this geographic scope are not reported. The 'access metrics' includes indicators A.2, C.1.1-C.1.3, C.2.1-C.2.3 and C.3.

TABLE 1 **Abbreviations and terminology used in the Report Cards**

General – appear across Research Areas	
AWaRe	WHO classification system that categorises antibiotics into three groups – Access, Watch and Reserve
CHAI	Clinton Health Access Initiative
GARDP	Global Antibiotic Research & Development Partnership
Gavi	Gavi, the Vaccine Alliance
HCP	Healthcare professional
LMICs	The term LMICs is used to denote all low- and middle-income countries in scope of the Benchmark.
LDCs	Least Developed Countries
LICs	Low-income countries
PAHO	Pan American Health Organization
• TB • MDR-TB • DR-TB	Tuberculosis Multidrug-resistant tuberculosis Drug-resistant tuberculosis
WHO	World Health Organization
Research & Development indicators	
BARDA	Biomedical Advanced Research and Development Authority
GMP	Good Manufacturing Practices
NIAID	National Institute of Allergy and Infectious Diseases
Innovation criteria	A project is classified as innovative if it meets at least one of the World Health Organization's (WHO's) four innovation criteria (new class/new target/new mode of action/no cross resistance), or it meets the Benchmark's 'other' criterion for innovation, which assesses real-world utility in low- and middle-income countries (LMICs).
Responsible Manufacturing indicators	
API	Active Pharmaceutical Ingredient
BSI Kitemark™	Third-party certification mark used as an independent verification indicator of conformance to a particular standard
CAPA	Corrective and Preventive Action plan
Mass balance estimation	Approach used to calculate antibiotic concentrations. This method relies on theoretical calculations based on estimated losses during the manufacturing process, as opposed to assessing antibiotic concentrations directly in wastewater samples.
PNEC	Predicted No-Effect Concentration
PSCI	Pharmaceutical Supply Chain Initiative
ZLD	Zero Liquid Discharge
Appropriate Access & Stewardship indicators	
ATLAS	The Antimicrobial Testing Leadership and Surveillance
GMP	Good Manufacturing Practices
Sales volume targets	Sales incentives for sales agents are often tied to volume targets, which can lead to over- or misselling of antimicrobial products. While it is best practice to avoid tying variable pay to sales volumes altogether, this should at least only represent a minimal portion of variable pay and be set at an aggregated level, not an individual level (per sales agent).
SMART	Study for Monitoring Antimicrobial Resistance Trends
ToVs	Transfers of value

OVERALL PERFORMANCE

77%

GSK plc

Research-based pharmaceutical company

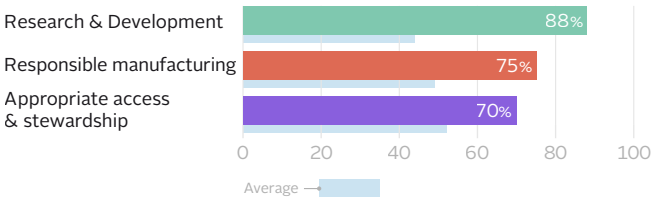
Stock exchange: LSE • Ticker: GSK • London, UK • Employees: 68,600

PERFORMANCE IN THE 2026 BENCHMARK

Leads among large research-based companies. GSK performs strongly across all Research Areas. It shows Best Practice by maintaining its pipeline size, ensuring ethical interactions with healthcare professionals through its public policy and engaging suppliers to support their wastewater management practices. Its leading position in R&D is evidenced by the largest pipeline of all companies, including the most pipeline projects targeting 'critical' and 'high' priority pathogens. In Appropriate Access & Stewardship, GSK also shows strong efforts to ensure access to its on- and off-patent products, surpassing its peers in implementing appropriate access and stewardship strategies.

How GSK was evaluated

How score was achieved



OPPORTUNITIES FOR GSK

Maintain R&D pipeline and focus on in-house R&D for high-burden resistant pathogens in LMICs. GSK maintains the largest and most diverse pipeline of therapeutics and preventive vaccines, addressing a broad range of priority pathogens and sustaining its lead despite industry-wide declines. GSK can further strengthen this position by continuing to invest in in-house discovery R&D targeting WHO-listed priority pathogens, particularly those driving high burdens of resistance in LMICs.

Ensure appropriate access to its innovative antibiotic gepotidacin (Blujepa™). In 2025 gepotidacin was approved for uncomplicated urinary tract infections (uUTIs) in female adults and paediatric patients over 12 years, marking the first new oral antibiotic class in almost 30 years for uUTIs. Subsequently, the product was approved for an additional indication – uncomplicated urogenital gonorrhoea. Although GSK has an access and stewardship plan in place, it can ensure appropriate access for women in LMICs by executing access strategies that prioritise countries with the highest unmet need.

Ensure reporting of compliance with discharge limits directly in wastewater. GSK reports 100% compliance with discharge limits set in the receiving environment for its own and its suppliers' products, based on mass balance estimations. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

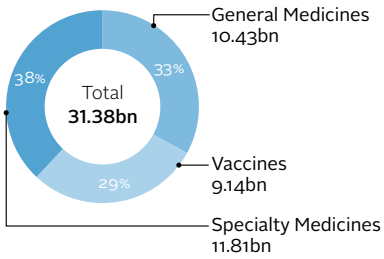
- In May 2024, GSK announced a £45 million pledge as a founding partner of the Fleming Initiative, an innovative and collaborative approach led by Imperial College Healthcare NHS Trust and Imperial College London, to tackle AMR around the world. In November 2025, the partnership launched six "Grand Challenges" research programmes aimed at harnessing some of the best scientific expertise and the latest technologies, including advanced AI, to find new ways to slow the progress of AMR.
- In September 2024, GSK's Worthing manufacturing site became the first in the UK to achieve the BSI Kitemark™ for Minimized Risk of AMR Certification. The site manufactures seven antibiotic products distributed to over 90 markets. GSK's Nashik facility in India subsequently achieved the same certification.
- In March 2025, the US Food and Drug Administration (FDA) approved GSK's innovative antibiotic gepotidacin (Bluejpa), which has a novel mechanism of action, for the treatment of uncomplicated urinary tract infections in women and girls under 12 years. In December 2025, the FDA expanded the approval to include the treatment of uncomplicated urogenital gonorrhoea.

GSK plc

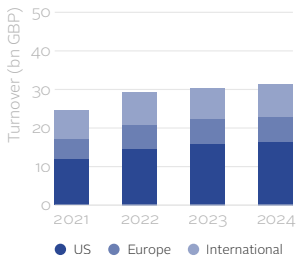
SALES AND OPERATIONS

Therapeutic areas: HIV, immunology, infectious diseases, inflammation, oncology, respiratory diseases
Product categories: Innovative medicines, vaccines
Investments in AMR: In 2024, GSK pledged GBP 45mn to support the Fleming Initiative. The same year, GSK also committed EUR 4.5mn to GARDP. GSK is a founding investor in the AMR Action Fund. It is unknown how much has been invested in the fund to date.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Turnover by business segment (2024) – GBP



Turnover by geographic region – GBP



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

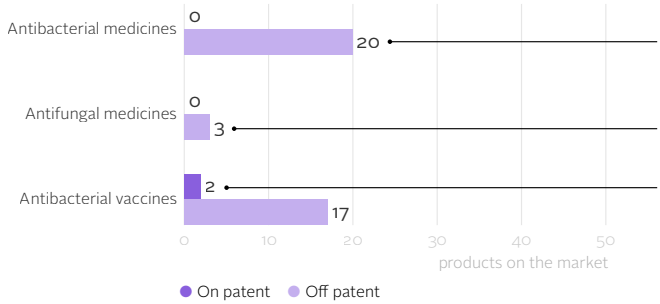
PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine			2	2	2	0	1	
Antifungal medicine			0	0	0	0	0	
Antibacterial vaccine			1	5	1	0	0	
Antifungal vaccine			0	0	0	0	0	
Total projects	10	6	3	7	3	0	1	30
Access plans				6**	3	0	1	10
Stewardship plans*				2	2	0	1	5

Specific product categories in discovery and pre-clinical phases cannot be disclosed.

PORTFOLIO *for diseases in scope*

42 products in GSK's anti-infective portfolio



9 products selected for analysis

amoxicillin (A), amoxicillin/clavulanic acid (A), ceftazidime (W), cefuroxime (W), colistin (R)

clotrimazole (F), terbinafine (F)

Menveo®, Synflorix®

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

*Stewardship plans are only assessed for medicines.

**Access plans were assessed for six Phase II projects; one additional project entered Phase II after data collection was completed and was therefore not assessed, as the company was not invited to submit information.

GSK plc

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Performs strongly. GSK has the largest pipeline of all companies, as well as the most pipeline projects addressing 'critical' and 'high' priority pathogens. It also leads in vaccine R&D, with its high number of vaccines in development. Among its pipeline candidates, GSK has three innovative medicines in development, the second highest of any company. It has access and stewardship plans in place for all late-stage projects that include a mix of overarching policies and some concrete project-specific approaches.

Largest pipeline targeting high and critical priority pathogens. GSK has by far the largest pipeline, with 30 projects targeting pathogens in scope. Among them, 1 antibacterial project – gepotidacin, indicated for uncomplicated urinary tract infections – received market approval within the period of analysis. (See figure on previous page for GSK's pipeline breakdown, including phases). Its vaccine pipeline (13) is larger and more diverse compared to other companies, targeting various pathogen groups, including Enterobacterales and *Streptococcus pneumoniae*. It is also the only company in scope developing vaccines for *Salmonella* and *Shigella* spp. GSK has the highest number of projects (23) addressing 'high' or 'critical' priority pathogens as defined by WHO. This includes projects targeting rifampicin-resistant *Mycobacterium TB* (critical), carbapenem-resistant Enterobacterales (critical), cephalosporin-resistant *Neisseria gonorrhoeae* (high) and vaccines to prevent Enterobacterales and Salmonella. GSK has 3 antibacterials in its pipeline classified as innovative, the second highest of any company: alpibectir, gepotidacin and ganfeborole, with each meeting at least 1 of WHO's defined innovation criteria. For example, ganfeborole (GSK3036656), for the treatment of TB, meets all 4 defined criteria: it has no known cross-resistance, belongs to a new chemical class, and has both a new target and a new mode of action. GSK reports having an in-house discovery programme related to several early-stage projects aiming to tackle both critical and high-priority pathogens.

Above-average performance, with systematic but sometimes general approach to access planning. GSK has access plans for all its 10 late-stage projects assessed, including elements for registration, equitable pricing and licensing agreements. In general, access planning combines project-specific and more general company-wide approaches. The company is conducting clinical trials across LMICs, including projects on urogenital infection, investigational oral TB medicines in South Africa and vaccine studies in African countries. The company indicates that trial site selection is based on unmet medical need and its intent to file for registration in that market. GSK has stewardship plans to ensure appropriate use and applies this to all its late-stage medicine projects (5). Actions include engaging in partnerships to build surveillance networks, supporting diagnosis.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Performs strongly. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports compliance with discharge limits for all antibacterial products manufactured at its own and its suppliers' sites. GSK's incorporation of AMR provisions in supplier contracts, and its hands-on approach to supporting suppliers' wastewater management practices, is highlighted as a Best Practice in the Benchmark. GSK publicly discloses quantification methods and aggregated level of compliance across its supply chain.

Mitigates AMR risk at both its own and suppliers' sites; reports 100% of antibacterials are compliant with discharge limits. GSK's comprehensive environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It estimates antibacterial discharges at its own sites annually using mass balance; if PNECs are exceeded, chemical analysis is performed for verification and CAPAs are implemented. The company reports that 100% of its antibacterial products are compliant with PNECs in the receiving environment, where wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured. 16 of its products have received a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification. GSK also requires its antibacterial suppliers to follow the Industry Standard, verifying estimations via chemical analysis. It conducts supplier audits every 3 years on average and has contractual provisions encompassing compliance with discharge limits. If PNECs are exceeded, GSK requests suppliers to implement CAPAs to ensure compliance. It reports that 100% of the antibacterial products manufactured by its suppliers are compliant with discharge limits in the receiving environment. GSK works with external waste treatment plants and reports requesting information from them (e.g. flow rates and operating parameters) for quantification of discharge levels. It also employs measures to treat wastewater prior to sending it to plants.

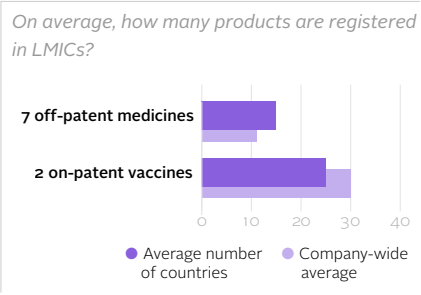
Publicly discloses comprehensive details on how it minimises the risk of AMR and ecological effects from antibacterial manufacturing; >99% of its antibacterials are compliant with limits. GSK publicly reports implementing the Industry Standard, quantifies discharge levels using mass balance, which it verifies by chemical analysis, as required, and achieves compliance with discharge limits at >99% of all its own sites and its key suppliers' sites. The company does not publicly disclose audit results with the actual discharge levels of its own sites or its suppliers' sites, nor the names and locations of its manufacturing sites for each manufactured antibacterial.

GSK plc

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Performs well. Registers its off-patent medicines in more countries on average than peers and effectively implements access and stewardship strategies for most assessed off-patent medicines, as well as comprehensive access strategies for the two on-patent vaccines evaluated. Its transparent reporting of transfers of value to ensure appropriate use is highlighted as a Best Practice in the Benchmark. GSK's approach to mitigate stockouts and shortages is comprehensive, and it engages in five multinational surveillance programmes, sharing aggregated data from three. However, GSK can increase its registrations for on-patent vaccines as it has fewer country registrations than peers.

GSK registers its off-patent medicines more widely than its peers, although its vaccines are registered less extensively.



GSK registers its off-patent medicines in 15 countries.* In many countries where it registers its off-patent medicines, it also registers paediatric formulations. For its off-patent Reserve antibiotic, colistin, there is no evidence of any registrations in countries in scope. The company's 2 on-patent vaccines are registered in 25 countries, including 3 countries where the corresponding disease burden is high. GSK received WHO Prequalification (WHO PQ) for both of its vaccines.

Above-average performance, with both access and stewardship strategies for 5 of 7 off-patent/generic products assessed. GSK's strategies are primarily implemented in the private sector, the prevailing market in the countries where strategies are reported. However, for 2 products, GSK has participated and been awarded public tenders. In addition, GSK partners with local manufacturers in 2 countries in scope of the Benchmark to produce 2 products. For all 5 products, GSK reports monitoring access strategies through country-level sales or prescription figures and also implements stewardship strategies to ensure responsible promotion. Strategies for 3 products are more comprehensive and include surveillance activities. For example, both amoxicillin and amoxicillin/clavulanic acid are included in the Survey of Antibiotic Resistance (SOAR) programme in Pakistan. GSK shares this surveillance data directly with HCPs through in-person meetings and a dedicated website, the Pakistan Infection Index.

Above-average performance, with comprehensive access strategies for the 2 on-patent vaccines assessed. For its ACWY meningococcal vaccine Menveo®, GSK has been awarded the contract to be the sole supplier for the immunisation of adolescents in Brazil, where the National Immunisation Programme includes 2 vaccines against meningococcal meningitis: 1 for infants and 1 for adolescents. A technology transfer for Menveo® manufacturing is currently underway with 2 Brazilian institutions, enhancing local production and capacity building. GSK's 10-valent pneumococcal conjugate vaccine, Synflorix®, is supplied through pooled procurement mechanisms via Gavi/UNICEF and PAHO. In 2024, GSK implemented a price reduction of Synflorix® for the Gavi tender until the end of the contract in 2028. GSK also participates in WHO's Humanitarian Mechanism, whereby Synflorix® is supplied at the reduced Gavi prices to countries facing humanitarian emergencies.

Strong efforts to mitigate stockouts/shortages. Strong reported evidence of systems to ensure product quality. GSK implements demand planning and data sharing through regular meetings with local health authorities in LDCs and LICs to address forecasting needs. It conducts 3-year forecasts with monthly market intelligence inputs, as well as annual long-term demand forecasting (up to 10 years), and shares plans with internal stakeholders in monthly sales and operations planning meetings. GSK maintains buffer stocks for both APIs and finished products for regional supply in at least 6 countries in scope of the Benchmark. Inventory levels are monitored with real-time data using just-in-time or hybrid inventory systems. It implements supplier diversification strategies for its critical antibacterial and antifungal medicines by establishing multiple manufacturing sites and sources critical raw materials from various suppliers. It mitigates substandard and falsified products by verifying suppliers through GMP audits and reporting cases to WHO and relevant authorities. It implements security features, such as serialised barcodes and tamper-evident packaging. In Pakistan, GSK works with governments and regulators to identify falsified medicine operations as an additional quality assurance step in a country with an evolving regulatory system.

Includes some elements to address appropriate use across its business practices. GSK does not decouple incentives for its sales agents from sales volume targets. Eligibility for participation in the sales incentive plan is contingent upon meeting criteria of ethical behaviour, compliance and product knowledge, as demonstrated by passing annual compliance and product knowledge assessments. Any additional details were disclosed under an NDA. Through its global public policy, GSK ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions and how to mitigate potential conflicts of interest. It also sets limits on transfers of value (ToVs) and ensures these are made at fair market value. GSK also voluntarily discloses information on ToVs on an individual level where this is permitted by law, and otherwise on an aggregated level. GSK transparently lists all countries where it discloses ToVs on its website. GSK applies its sales incentive plan and global policy to third parties working on its behalf.

GSK is active in 5 multinational surveillance programmes. GSK runs the multinational 'Survey of Antibiotic Resistance' (SOAR) programme. SOAR is conducted in study cycles of approximately 2-3 years, covering 2 genera of bacteria, 15 antibacterial medicines and 12 countries in its latest cycle. The company has already shared raw data from 2 study cycles via the AMR Register, making the data available upon request, and commits to continue to do this when the upcoming SOAR study is completed. Additionally, GSK is involved in 4 multinational surveillance programmes. Aggregated data from 3 of these programmes was shared via poster abstracts or peer-reviewed journals during the period of analysis. The methods GSK uses to collect surveillance data for all 5 programmes are largely clear, including: the type of surveillance; where the analysis is conducted and which breakpoints are used; how deduplication is considered; and how participating healthcare facilities are selected, although public disclosure is limited.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

41%

Johnson & Johnson

Research-based pharmaceutical company

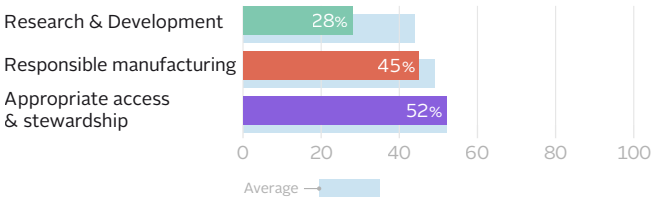
Stock exchange: NYSE • Ticker: JNJ • HQ: New Brunswick, New Jersey, USA • Employees: 138,100

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Johnson & Johnson's performance in R&D is low, with a significant decrease in projects, resulting in a small pipeline solely focused on *Mycobacterium tuberculosis*. Johnson & Johnson shows mixed performance across Responsible Manufacturing and Appropriate Access & Stewardship. Its environmental risk management strategy covers both its own and suppliers' sites, but the level of compliance is unclear for suppliers. It performs well in making bedaquiline, its sole product assessed, accessible through registrations and a comprehensive access strategy, and it shows Best Practice in supporting diagnostic capacity in India. However, it is no longer involved in AMR surveillance.

How Johnson & Johnson was evaluated

How score was achieved



OPPORTUNITIES FOR JOHNSON & JOHNSON

Advance bedaquiline (SIRTURO®) studies to address critical tuberculosis (TB) needs in LMICs. Johnson & Johnson's closure of its R&D infectious disease & vaccine unit signalled a shift away from developing medicines and vaccines for diseases that disproportionately affect people in LMICs, leaving its antituberculosis drug, bedaquiline (SIRTURO®) as the only medicine assessed in this year's Benchmark. Despite this shift, the company can continue to advance clinical trials for bedaquiline (SIRTURO®) that are still in the pipeline. This includes studies in children under five years and a novel long-acting injectable formulation, with potential for TB prevention in populations at high risk of developing the disease. As development of the long-acting formulation – which could offer advantages in adherence in the treatment of latent TB infection – progresses beyond Phase I, Johnson & Johnson can develop an access and stewardship plan to ensure access in countries with a high burden of multidrug-resistant TB.

Support AMR surveillance for bedaquiline (SIRTURO®). Johnson & Johnson does not report engaging in any AMR surveillance programmes, following the completion of its post-marketing surveillance programme on bedaquiline – the Bedaquiline Drug Resistance Emergence Assessment in MDR-TB (DREAM) programme – in 2019. To help ensure continued monitoring and appropriate use of bedaquiline, the company can collaborate with other organisations to integrate the product into existing surveillance programmes, such as SENTRY.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved. Johnson & Johnson publicly reports setting discharge limits in the receiving environment at its own and suppliers' sites, implementing mass balance estimations. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' sites – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

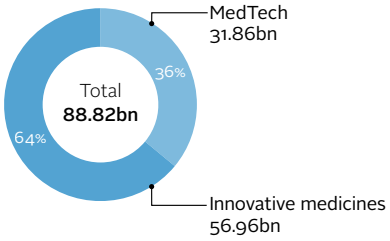
- In 2023, the company closed its research and development (R&D) unit for infectious diseases and vaccines. Consequently, Johnson & Johnson no longer has any vaccines in development, and only one discovery project.
- In 2024, Johnson & Johnson's manufacturing site in Geel, Belgium received the BSI Kitemark™ for Minimized Risk of AMR Certification for the manufacture of bedaquiline.
- In February 2025, Johnson & Johnson and partner Sanofi announced the termination of the Phase III E.mbrace trial evaluating an extraintestinal pathogenic *E. coli* (ExPEC) vaccine candidate. The vaccine was not sufficiently effective in preventing invasive *E. coli* disease (IED) compared to the placebo. No safety signals related to the vaccine were identified.
- In July 2024, the US Food and Drug Administration (FDA) granted traditional approval for bedaquiline (SIRTURO®) for use, in combination therapy, in adults and children (≥5 years, ≥15 kg) with pulmonary multidrug-resistant TB. The FDA converted the approval from accelerated to traditional approval following confirmation of clinical benefit in a confirmatory trial.

Johnson & Johnson

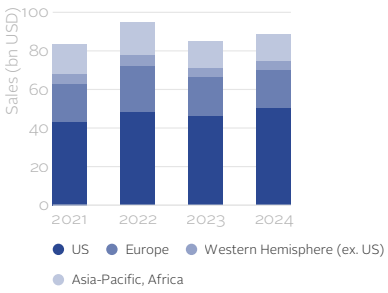
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, immunology, infectious diseases, metabolic disorders, neuroscience, oncology, pulmonary hypertension
Product categories: Innovative medicines and MedTech
Investments in AMR: In 2020, Johnson & Johnson was a founding partner and invested USD 100mn in the AMR Action Fund, with the goal of bringing 2 to 4 new antibiotics to patients by the end of 2030.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Sales by business segment (2024) – USD



Sales by geographic region – USD



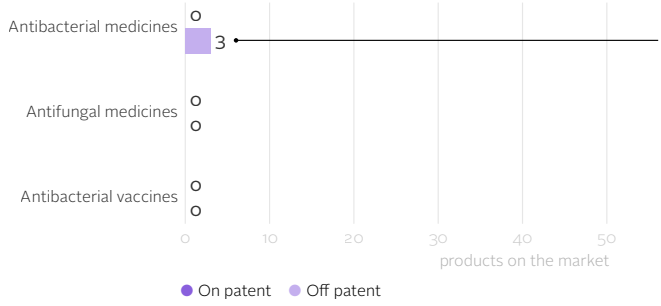
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	1	0	1	3	0	0	0	5
Antifungal medicine	0	0	0	0	0	0	0	0
Antibacterial vaccine	0	0	0	0	0	0	0	0
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	1	0	1	3	0	0	0	5
Access plans				1*	0	0	0	0
Stewardship plans				0	0	0	0	0

PORTFOLIO *for diseases in scope*

3 products in Johnson & Johnson's anti-infective portfolio



1 product selected for analysis

bedaquiline (T)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

*Access plans were assessed for only one project; consortium-led studies were not assessed.

Johnson & Johnson

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Low-performing. Johnson & Johnson has a small pipeline, which has decreased significantly in size since the last Benchmark. All its remaining pipeline projects target *Mycobacterium tuberculosis*, a 'critical' priority pathogen, but the company no longer has any vaccines or innovative antimicrobial medicines in development. It has an access plan in place for its sole late-stage candidate but did not report any stewardship measures.

Small pipeline focused on adaptations of existing medicines targeting rifampicin-resistant *Mycobacterium TB*. Johnson & Johnson's small pipeline includes 5 antibacterial projects targeting pathogens in scope. Most projects are adaptations of its approved drug SIRTURO® (bedaquiline); its 2 self-developed projects include a long-acting formulation (Phase I) and a paediatric version (Phase II). In addition to its own trials, the company takes part in 2 consortia (PAN-TB and UNITE4TB) where the adult formulation of SIRTURO® (bedaquiline) – which is already approved as part of combination therapy for pulmonary multidrug-resistant TB (MDR-TB) – is being evaluated for new combination therapies. In addition, there is also published information on JNJ-2901, a novel Q203 analogue that shows activity against multidrug-resistant *Mycobacterium TB* clinical strains. All projects (5) target rifampicin-resistant *Mycobacterium TB*, a 'critical' pathogen as defined by WHO. The company no longer has any vaccines in its pipeline targeting pathogens in scope, nor does it have any medicines in its pipeline meeting any WHO innovation criteria. The company reports having an active in-house discovery programme for TB.

Above-average performance with comprehensive access plan but limited stewardship efforts. Johnson & Johnson has an access plan for its late-stage project evaluating a dispersible formulation of bedaquiline for MDR-TB for children under 5, with the aim of expanding registration to age groups for which it is not yet approved. The paediatric clinical trial is ongoing in 3 countries in scope of the Benchmark. As SIRTURO® (bedaquiline) is already approved for MDR-TB and widely registered in countries in scope, the Benchmark did not evaluate access plans for consortium-led studies involving the product. Johnson & Johnson did not report a stewardship plan for its paediatric bedaquiline project.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Mid-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. It reports compliance levels achieved at its own sites (under an NDA) but not at its suppliers' sites, nor whether AMR provisions are included in supplier contracts. Johnson & Johnson publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own sites and suppliers' sites; reports antibacterial compliance with discharge limits for its own sites and tracks compliance for suppliers'. Johnson & Johnson's comprehensive environmental risk management strategy incorporates the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It quantifies antibacterial discharge levels at its own sites using mass balance estimation verified by chemical analysis, if applicable, with audits conducted every 3 years. Its underlying quantification details (i.e., dilution factors and timeframe) are unclear. The company reports the level of compliance achieved at its own sites under an NDA. However, it did receive a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification for bedaquiline at its manufacturing site in Geel, Belgium. The company requires antibacterial suppliers to follow the Industry Standard, including mass balance estimation, verified by chemical analysis. It conducts supplier audits at least once every 3 years using PSCI principles, including PNEC-based limits. It is unclear whether AMR provisions are in contracts or how many supplier products meet discharge limits. Information on its practices regarding external waste treatment plants is provided under an NDA.

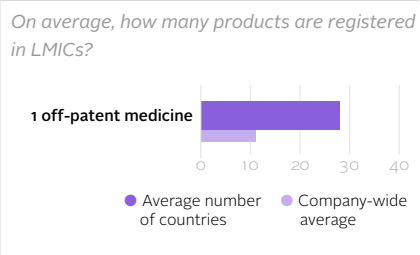
Publicly discloses basic details of its AMR mitigation strategy but is not transparent about compliance with discharge limits. Johnson & Johnson publicly reports implementing the Industry Standard, quantifying discharge levels using mass balance estimation and verifying levels by chemical analysis. For both its own sites and its suppliers' sites, the company publicly reports conducting onsite audits on PNEC compliance. However, audit results – including the actual discharge levels – are not publicly disclosed; nor are the number of products complying with PNECs, or the names and locations of manufacturing sites for each antibacterial product.

Johnson & Johnson

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Performs well by registering its sole in-scope medicine, bedaquiline (SIRTURO®), in more countries than peers and implementing access and stewardship strategies. Its support of improved diagnostics for bedaquiline in India is highlighted as a Best Practice in the Benchmark. The company takes steps to mitigate stockouts, maintaining buffer stocks of critical APIs and finished products. It addresses appropriate access through its business practices by not deploying sales agents for selected products, ensuring ethical interactions with healthcare professionals and fair market value transfers. However, it lacks efforts on surveillance, with no AMR programme participation.

Johnson & Johnson registers its sole product, bedaquiline, more widely than peers' off-patent medicines.



Johnson & Johnson registers its off-patent medicine targeting MDR-TB, bedaquiline (SIRTURO®), in 28 countries,* including 11 countries where the corresponding disease burden is high. It also registers a paediatric formulation of bedaquiline in 11 countries. The company engages in multiple procedures to facilitate registration, including WHO's Collaborative Registration Procedure for WHO-Listed Authorities.

Above-average performance, with comprehensive access strategy and some stewardship efforts for bedaquiline (SIRTURO®), the only off-patent/generic product assessed. Johnson & Johnson provides bedaquiline, a key component in the treatment regimen for MDR-TB, for supranational procurement across all countries served by the Stop TB Partnership's Global Drug Facility (GDF). Johnson & Johnson also granted GDF a licence to tender, procure and supply generic versions in the majority of LMICs. The company also does not enforce patents on bedaquiline in 134 LMICs; as such, bedaquiline was assessed as an off-patent product. The company reports the number of patients reached with bedaquiline. The company also ensures some level of responsible promotion and is working to address underdiagnosis of TB at a community level in India.

Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Johnson & Johnson implements demand planning and data sharing by forecasting demand of bedaquiline (SIRTURO®) based on local tender patterns and utilisation trends in countries with high burdens, and distributor demand forecasts. The company also maintains buffer stocks of critical APIs and finished products and implements an automated inventory management system to prevent stock disruptions. However, the forecasting horizon or any supplier diversification efforts are not disclosed. It mitigates substandard and falsified products by verifying suppliers through GMP audits, reporting incidents to relevant authorities and implementing security features. It reports that all its own and suppliers' sites are GMP compliant, however, it is unclear whether the company takes additional mitigation steps in countries with evolving regulatory systems.

Includes elements to address appropriate use across its business practices. Johnson & Johnson partly decouples incentives for its sales agents from sales volume targets, but these targets are set at the individual level. The ratio of quantitative and qualitative targets, the former including sales volume targets, was disclosed under an NDA. However, the sales incentive plan is not applicable for bedaquiline (SIRTURO®), as it does not deploy sales agents for the product. Through its global public positions/policy, Johnson & Johnson ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions and how to mitigate potential conflicts of interest. It also ensures that transfers of value (ToVs) are made at fair market value. While Johnson & Johnson abides by transparency requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Johnson & Johnson applies its public policy to third parties working on its behalf. For its sales incentive plan, this is handled on a case-by-case basis.

No activities in AMR surveillance. Johnson & Johnson was not involved in any AMR surveillance programmes during the period of analysis. Its previous surveillance programme 'Bedaquiline Drug Resistance Assessment in MDR-TB (DREAM)' ended in 2019.

*All registration numbers in this statement refer to the products selected for analysis and are based on the the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

19%

Merck & Co, Inc

Research-based pharmaceutical company

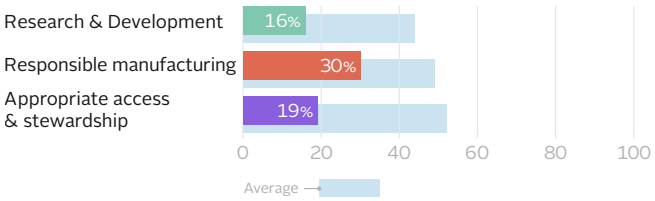
Stock exchange: NYSE • Ticker: MRK • HQ: Rahway, New Jersey, USA • Employees: 75,000

PERFORMANCE IN THE 2026 BENCHMARK*

Weak performance. MSD shows room for improvement in R&D and Appropriate Access & Stewardship. Clear evidence to ensure access to any of the products assessed is lacking, and its approach towards stewardship remains largely unclear. It has the smallest pipeline of all large research-based companies, focused on vaccines, with no projects targeting 'critical' or 'high' priority pathogens. Its performance in Responsible Manufacturing can also be strengthened. It reports an environmental risk management strategy, but details on quantification methods and compliance are limited, and transparency could be improved.

How MSD was evaluated

How score was achieved



OPPORTUNITIES FOR MSD

Expand breadth of R&D pipeline projects and depth of access and stewardship plans. MSD's pipeline size has declined by 85% compared to the previous Benchmark, which now has just two vaccine projects in clinical development. It can reinforce its commitment to AMR by diversifying its pipeline and focusing on vaccine development for resistant pathogens with high burdens in LMICs. In addition, it can expand the depth and breadth of access planning for its late-stage R&D projects, which is currently limited to registration in countries where clinical trials are conducted. These plans can be strengthened by incorporating equitable pricing, supply strategies and extending the scope to additional LMICs.

Expand appropriate access to its innovative medicines and vaccines. MSD has enabled generic supply for its Reserve antibiotic, tedizolid (Sivextro®), through a voluntary licensing agreement in India. However, it did not disclose appropriate access strategies for any of its other on-patent medicines or vaccines assessed. The company can expand access to its innovative products in LMICs through increased registrations, voluntary licensing, and/or appropriate access strategies, prioritising countries with the greatest unmet need.

Improve access to and transparency around its surveillance data. MSD already regularly shares aggregated data from its 'Study for Monitoring Antimicrobial Resistance' (SMART) surveillance programme publicly via its interactive data dashboard. While it also shared raw data from SMART with the AMR Register in the past, it has an opportunity to regularly update its dataset to enable access to up-to-date surveillance data. In addition, MSD can report more information on the methods used to collect and analyse its surveillance data and disclose this information publicly.

Ensure compliance with discharge limits directly in wastewater and improve transparency on antibacterial waste management practices. MSD publicly reports setting discharge limits in the receiving environment at its own and suppliers' sites. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' sites – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance. It can also publicly report the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

- In June 2024, MSD's newest pneumococcal conjugate vaccine, CAPVAXIVE™ (21-valent), received approval. The vaccine is indicated for adults and expands protection against additional *Streptococcus pneumoniae* serotypes, which can cause pneumococcal pneumonia and invasive infections, such as pneumococcal sepsis and pneumococcal meningitis.

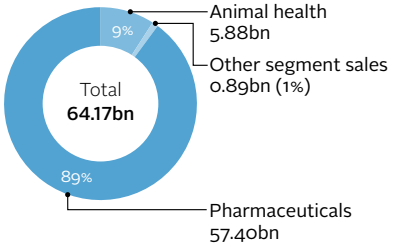
*For the 2026 AMR Benchmark, MSD declined to submit data meaning its evaluation is solely based on publicly available information.

Merck & Co, Inc

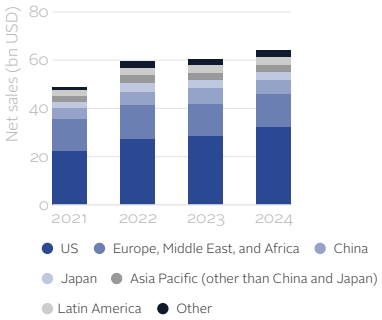
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, infectious diseases, metabolic diseases, neuroscience, oncology, vaccines
Product categories: Animal health, innovative medicines, vaccines
Investments in AMR: In 2020, MSD was a founding partner and invested USD 100mn over 10 years in the AMR Action Fund, with the goal of bringing 2 to 4 new antibiotics to patients by the end of 2030.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Net sales by business segment (2024) – USD



Net sales by geographic region – USD



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	0	0	0	0	0	0	0	0
Antifungal medicine	0	0	0	0	0	0	0	0
Antibacterial vaccine	0	0	0	0	1	0	1	2
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	0	0	0	0	1	0	1	2
Access plans				0	1	0	1	2

PORTFOLIO *for diseases in scope*
MSD has multiple products in its anti-infectives portfolio. However, it did not disclose the total number of products. The figure below shows a selection of products selected for analysis.

10 products selected for analysis

On Patent	Off Patent	Vaccines
• fidaxomicin (*Watch antibiotic*) • ceftolozane/tazobactam (*Reserve antibiotic*) • imipenem/cilastatin/relebactam (*Reserve antibiotic*) • tedizolid (*Reserve antibiotic*) • posaconazole (*Antifungal medicine*)	• imipenen/cilastatin sodium (*Watch antibiotic*) • caspofungin (*Antifungal medicine*)	• Liquid PedvaxHIB® • Vaxelis® • Vaxneuvance®

Merck & Co, Inc

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Weak performance. MSD has the smallest pipeline of all the large research-based pharmaceutical companies. It has no projects that address 'critical' or 'high' priority pathogens, nor does it have innovative antimicrobial medicines in clinical development. Its pipeline is focused on vaccine development. Although it has access plans in place for its late-stage candidates, they are limited to registration plans in countries where it conducts clinical research.

Small pipeline focused on sole pneumococcal vaccine. MSD's small pipeline includes 2 projects targeting a pathogen in scope. Both relate to CAPVAXIVE™ (V116), an antibacterial vaccine indicated for invasive pneumococcal disease and pneumonia, which received market approval for adults in 2024 (within the period of analysis). The second project, a Phase III trial of V116 in at-risk children aged 2-17 years, was recently completed. Neither project addresses 'high' or 'critical' priority pathogens as defined by WHO, nor does MSD have any innovative medicine in its pipeline; its only clinical projects are vaccines, which fall outside the scope of WHO's innovation assessment of medicines. MSD publicly reports in-house antibiotic discovery activities targeting pathogen(s) in scope, including research on darobactin and a narrow-spectrum Gram-negative asset.

Lagging performance with limited access planning. MSD has access plans for both its late-stage projects. Within its access plans, the company commits to securing registration in countries where it conducts clinical trials: South Africa, Colombia and Thailand. Beyond registration commitments, no additional plans for access were identified.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. It does not report the number of products manufactured at its own or supplier sites that meet discharge limits, or whether it incorporates AMR provisions into supplier contracts. MSD publicly discloses limited details of its AMR mitigation strategy.

Basic environmental risk management to mitigate AMR at both its own sites and suppliers'; tracks compliance of antibacterials with discharge limits. MSD's environmental risk-management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It quantifies antibacterial discharge levels at its own sites. However, the underlying quantification details are not disclosed, nor is the number of its antibacterial products that comply with PNECs. The company requires its antibacterial suppliers to follow the Industry Standard, as well, but it is unclear whether related contractual provisions have been implemented. It reviews supplier discharge levels through audits; however, it does not specify the quantification methods used, nor whether CAPAs are implemented if PNECs are exceeded. Additionally, MSD does not disclose how many antibacterial products meet discharge limits at its supplier sites. No information could be identified on whether MSD engages with external waste treatment plants to minimise AMR risk from manufacturing.

Publicly discloses limited details of its AMR mitigation strategy and is not transparent about compliance with discharge limits. MSD publicly reports implementing discharge limits across its supply chain, as outlined in the Industry Standard. However, for both its own sites and its suppliers' sites, it does not publicly disclose the quantification methods implemented, audit results, the number of products complying with PNECs or the names and locations of manufacturing sites for each of its antibacterial products.

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Weak performance. Takes some steps to ensure continuous supply through monthly demand planning, data sharing, and maintaining buffer stocks of 1-3 months' finished products. MSD also shows efforts in surveillance, running the multinational AMR surveillance programme 'Study for Monitoring Antimicrobial Resistance Trends' (SMART), and sharing aggregated data online. However, MSD did not report details on product registrations or access and stewardship strategies for any assessed products, leaving its efforts to expand access unclear. To what extent MSD addresses appropriate use across its business practices also remains unclear.

MSD's performance on product registrations is inconclusive. MSD does not disclose any registration data to the Benchmark. Based on public information, it is unclear if MSD engages in any mechanism to facilitate registrations for the products selected for analysis.

Below-average performance, with limited evidence of access and stewardship strategies for 5 on-patent products assessed. MSD has entered a licensing agreement with Sun Pharma to develop, manufacture and commercialise its Reserve antibiotic, tedizolid (SIVEXTRO®), in India. The second Reserve antibiotic assessed, ceftolozane/tazobactam (Zerbaxa®), is included in the 'Study for Monitoring Antimicrobial Resistance Trends (SMART)' surveillance programme, active in countries in scope; however, no evidence of access strategies has been found. MSD has not disclosed, either publicly or to the Benchmark, any specific access and stewardship strategies for the other 3 products assessed. However, the company reports a general approach for pricing and stewardship for its antibacterial and antifungal medicines in its 2024 Global AMR Action Plan. Only the total global number of patients reached across MSD's portfolio has been disclosed publicly.

Below-average performance, with no evidence of access and stewardship strategies for any of the 2 off-patent/generic products assessed. MSD has not disclosed, either publicly or to the Benchmark, any specific access and stewardship strategies for its antifungal, caspofungin, and its antibiotic, imipenem/cilastatin sodium. Nevertheless, the company's general approach for pricing and stewardship for its antibacterial and antifungal medicines, set out in its 2024 Global AMR Action Plan, includes a commitment to provide these products at their lowest price in lower-income countries. Only the total global number of patients reached across MSD's portfolio has been disclosed publicly.

Merck & Co, Inc

APPROPRIATE ACCESS & STEWARDSHIP *CONTINUED*

Below-average performance, with no evidence of access strategies for any of its 3 on-patent vaccines assessed. MSD has not disclosed, either publicly or to the Benchmark, any access strategies for the 3 products assessed: the pneumococcal 15-valent conjugate vaccine Vaxneuvance®, hexavalent combination vaccine (DTaP-IPV-Hib-HepB) Vaxelis® and haemophilus b conjugate vaccine Liquid PedvaxHIB®. Nevertheless, MSD publicly reports high-level commitments and policies to ensure access and affordability of its vaccines, including in LMICs. Only the total global number of patients reached across MSD's portfolio has been disclosed publicly.

Some efforts to mitigate stockouts/shortages. Limited reported evidence of systems to ensure product quality. MSD implements demand planning and data sharing through a monthly internal Integrated Business Planning process to review and communicate supply chain issues. It maintains direct communication with distributors and, in Brazil and China, also engages hospitals to monitor stock levels and projections. It communicates with customers about current or upcoming shortages, including their causes and expected duration, but does not specify a forecasting timeframe. MSD maintains the safety stock of 1-3 months' supply of finished goods at all its distribution centres to buffer against underestimated demand or supply delays. It also implements supplier diversification strategies through its global business development strategy, often involving sourcing from multiple global upstream suppliers, though local sourcing is not specified. It is also unclear whether MSD implements an automated inventory management system. It mitigates substandard and falsified products through its global product integrity strategy on tackling counterfeit products. However, MSD does not report verifying its suppliers' credentials, the number of sites that are GMP compliant or any additional quality measures implemented in countries with developing regulatory systems.

Does not address appropriate use across its business practices. It is unclear whether MSD at least partly decouples incentives for its sales agents from sales volume targets or whether incentives are also linked to other qualitative measures. However, targets are set at the individual level. MSD does not report whether it also applies its sales incentive plan to third parties working on its behalf. MSD's global public policy on business ethics does not explicitly specify measures to ensure ethical interactions with HCPs. MSD voluntarily discloses information on transfers of value publicly in New Zealand.

MSD is active in 1 multinational AMR surveillance programme. MSD runs the multinational 'Study for Monitoring Antimicrobial Resistance Trends' (SMART) programme, covering 44 genera of bacteria, 17 antibacterial medicines and 63 countries. Raw data from SMART has been shared with the AMR Register in the past and is still available upon request. No new raw data was shared during the period of analysis. However, updated aggregated data is available via the SMART website. The methods MSD uses to collect surveillance data for SMART are partially clear, including where the analysis is conducted and how deduplication is considered.

OVERALL PERFORMANCE

44%

Otsuka Pharmaceutical Co, Ltd

Research-based pharmaceutical company

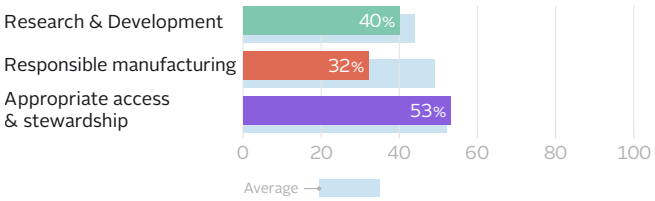
Stock exchange: TSE • Ticker: 4578 • HQ: Tokyo, Japan • Employees: 35,338

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Otsuka shows mixed performance across R&D and Appropriate Access & Stewardship. While it has a small pipeline, its innovative lead project, quabodepistat, targets a 'critical' priority pathogen and is accompanied by a comprehensive access plan. For delamanid, its sole product assessed, it exceeds peers in ensuring access through registrations and implementing a comprehensive access strategy, and it shows Best Practice by supporting diagnostic capacity in LMICs. It has potential to strengthen performance in Responsible Manufacturing, as it lacks public transparency on its strategy and only reports compliance at its own sites, but not at suppliers'.

How Otsuka was evaluated

How score was achieved



OPPORTUNITIES FOR OTSUKA

Expand access planning and paediatric development for projects targeting tuberculosis. Otsuka's pipeline solely focuses on projects that target *Mycobacterium tuberculosis* (RR-TB). The company has developed a comprehensive access and stewardship plan for its only late-stage R&D project, quabodepistat, an innovative tuberculosis treatment now in Phase III combination trials, which offers potential to shorten and simplify therapy compared to the standard of care. Once approved, Otsuka can ensure access to quabodepistat – which is identified as a priority for licensing by global health stakeholders – through multiple supply mechanisms, such as supranational supply, leveraging its already successful partnership with the Global Drug Facility (GDF) for delamanid, and/or through voluntary licensing to enable generic supply. In parallel, it can progress paediatric studies for quabodepistat – which is on WHO's paediatric TB (PADO-TB) watch list – to address critical treatment gaps and enable future use in children.

Expand appropriate access to delamanid for paediatric populations across LMICs. Otsuka provides access to both the adult and paediatric formulations of delamanid (Deltyba®), indicated for drug-resistant TB, through its collaboration with the GDF and via its technology transfer with a generic manufacturer. The adult formulation is registered in 14 LMICs. However, the paediatric formulation, indicated for children three years and older, is only registered in India. Otsuka can close the gap in registration and expand appropriate access in this age group by also registering delamanid's paediatric formulation in at least the same 14 LMICs, prioritising countries with a high unmet need.

Engage in AMR surveillance for delamanid. Otsuka does not report engaging in any AMR surveillance programmes and it did not report any progress on its plans to set up surveillance activities. Otsuka has an opportunity to start engaging in surveillance, particularly for its product delamanid, by either setting up its own surveillance programme or by collaborating with other organisations to integrate its product into existing surveillance programmes, such as SENTRY.

Formalise and publicly disclose comprehensive environmental risk management strategy to mitigate AMR. Otsuka does not report periodically quantifying antibacterial discharge from delamanid production at its own or its suppliers' sites. As a first step, it can begin periodic wastewater sampling to accurately quantify antibacterial discharge, in line with the 'stringent' WHO guidance, and ensure compliance with discharge limits directly in wastewater for both its own and its suppliers' sites. It can demonstrate progress by publicly reporting its antibacterial waste management practices, including compliance levels across its sites and suppliers', and the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

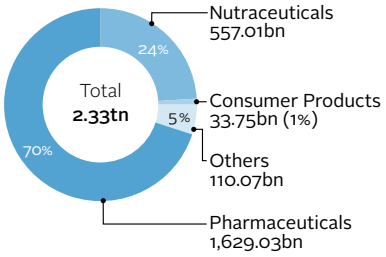
- In 2024, Otsuka agreed offering both its 50mg and 25mg delamanid (DELTYBA®) tablets to The Stop TB Partnership's Global Drug Facility's (GDF's) Strategic Rotating Stockpile (SRS) as consignment stock, enabling GDF to expand access to the drug in LMICs.
- In 2024, the World Health Organisation (WHO) recommended delamanid (DELTYBA®) as part of new oral, six- and nine-month regimens targeting multidrug-resistant or rifampicin-resistant tuberculosis (MDR/RR-TB). These regimens were also investigated in children, adolescents, pregnant and breastfeeding women – populations historically overlooked in TB clinical trials.
- PT Otsuka Indonesia and PT Amerta Indah Otsuka – subsidiaries of Otsuka Pharmaceutical Co., Ltd. (Japan) – received the Exemplar Award from Ending Workplace Tuberculosis (EWTB) for their efforts in curbing tuberculosis in the workplace through the FREE Tuberculosis at Workplaces programme. Since the launch of the programme in 2022, more than 70,000 employees have been screened for TB.

Otsuka Pharmaceutical Co, Ltd

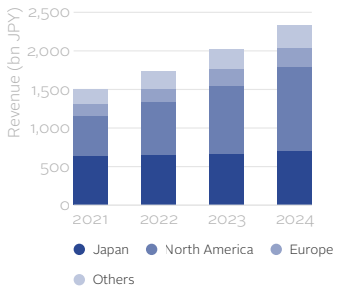
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, gastroenterology, oncology, ophthalmology, psychiatry & neurology, renal diseases, tuberculosis
Product categories: Diagnostics, innovative medicines, medical devices
Investments in AMR: In 2023, Otsuka increased its spending on TB research and invested a further USD 30 million. As such, it is one of the two largest private-sector spenders in TB research, accounting, together with one other company, for 53% of all private sector spending.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Revenue by business segment (2024) – JPY



Revenue by geographic region – JPY



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

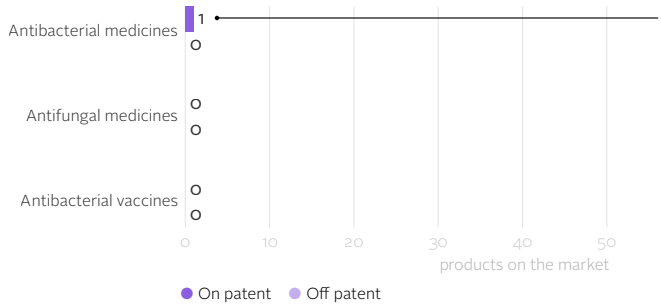
PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	0	1	0	2	1	0	0	4
Antifungal medicine	0	0	0	0	0	0	0	0
Antibacterial vaccine	0	0	0	0	0	0	0	0
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	0	1	0	2	1	0	0	4

Access plans			N/A*	1	0	0	1
Stewardship plans			N/A	1	0	0	1

PORTFOLIO *for diseases in scope*

1 product in Otsuka's anti-infective portfolio



1 product selected for analysis

delamanid (T)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

*Access plans were not assessed for consortium-led studies.

Otsuka Pharmaceutical Co, Ltd

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Mid-performing. Although it has a small pipeline, Otsuka's lead candidate, quabodepistat, is an innovative medicine and targets a 'critical' priority pathogen (*Mycobacterium tuberculosis*). In addition, it has a comprehensive access plan in place for quabodepistat that addresses barriers to availability, affordability and sustainable supply in LMICs.

Small pipeline focused on multidrug-resistant *Mycobacterium TB*, with 1 innovative candidate in clinical development. Otsuka's small pipeline of 4 projects, all targeting multidrug-resistant (including rifampicin-resistant) *Mycobacterium TB*, a 'critical' priority pathogen as defined by WHO. Its 2 self-developed projects include an adult (Phase III) and paediatric (pre-clinical) development of the antibacterial medicine quabodepistat (OPC-167832). In addition, Otsuka collaborates with 2 consortia (PAN-TB and UNITE4TB) where its antibacterial medicines, delamanid and quabodepistat (OPC-167832), are being evaluated in new TB combination regimens. Its clinical-stage antibacterial, quabodepistat, meets all 4 WHO-defined innovation criteria: it has no known cross-resistance (to date), belongs to a new chemical class, and has both a new target and a new mode of action. Otsuka is not active in vaccine development. The company reports having an active in-house discovery programme for TB.

Above-average performance with comprehensive access and stewardship plan. Otsuka has an access plan and stewardship plan in place for its late-stage project – antituberculosis drug, quabodepistat. The access plan outlines measures for availability, affordability and sustainable supply. Clinical trials are currently ongoing in 5 countries in scope: China, Moldova, Peru, Philippines and South Africa. In addition, Otsuka has a stewardship plan in place to ensure the responsible use of quabodepistat. Access plans for consortium-led studies were not assessed.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. At its own sites, it reports compliance with discharge limits for delamanid's API but not for the drug product. It does not report on the level of compliance achieved at its suppliers' sites or whether it incorporates AMR provisions into supplier contracts. Otsuka does not publicly disclose the quantification methods implemented, or the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own sites and suppliers' sites through general environmental risk management strategy; reports compliance of antibacterials with discharge limits for its own sites but not for suppliers'. Otsuka adopts management and treatment practices for wastewaters and solid wastes from antibiotic manufacturing to minimise the impact of antibacterial discharge to the environment, but does not follow the AMR Industry Alliance Antibiotic Manufacturing Standard or WHO guidelines. Otsuka manufactures both the API and finished product for its sole in-scope medicine, delamanid, at its own sites. While the company confirms it does not regularly measure its discharge levels, it performed quantification for the first time during the period of analysis, reporting that the API was not compliant, but the drug product was. One intermediate used in delamanid production is manufactured by a third-party supplier, which Otsuka requests to adopt waste treatment practices aligned with its own. However, it is unclear whether contractual provisions have been implemented. Furthermore, it does not report measuring or reviewing discharge levels of a delamanid intermediate manufactured at its supplier's sites, and therefore it does not disclose whether it meets these discharge limits. Regarding external wastewater treatment plants, the company states that wastewater from delamanid production is treated in-house, with no involvement of external treatment facilities.

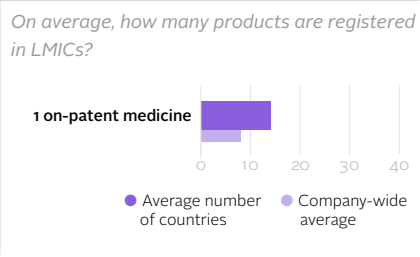
No publicly available information on environmental risk management to mitigate AMR. Otsuka does not publicly disclose practices to minimise the risk of AMR and ecological effects from antibacterial manufacturing at its own sites or its suppliers' sites. It therefore does not publicly disclose audit results, the number of products complying with PNECs, measured discharge levels or the names and locations of manufacturing sites per antibacterial product.

Otsuka Pharmaceutical Co, Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1 ●	C.1.2 ●	C.1.3 ●	C.2.1 ●	C.2.2 ●	C.2.3 ●	C.3 ●	C.4 ●	C.5 ●

Mid-performing. Performs well in registering its sole in-scope medicine, delamanid (Deltyba®), in more countries than peers. Implements comprehensive access and some stewardship strategies, with its support for improved diagnostics in LMICs highlighted as a Best Practice in the Benchmark. It mitigates stockouts through demand planning and bi-weekly data sharing. Otsuka addresses appropriate use across its business practices and does not deploy sales agents for delamanid. It ensures ethical interactions with healthcare professionals, fair market value transfers, and discloses transfers of value in some countries. However, Otsuka lacks efforts on surveillance, with no active participation in AMR programmes during the analysis period.

Otsuka registers its sole product, delamanid, more widely than peers' on-patent medicines.



Otsuka registers its on-patent medicine targeting MDR-TB, delamanid (Deltyba®), in 14 countries,* including 4 countries where the corresponding disease burden is high (India, Kyrgyzstan, South Africa and Ukraine). In addition, Otsuka registers a paediatric formulation of delamanid in India. Otsuka has not reported engaging in mechanisms to facilitate registrations for delamanid; however, the product obtained WHO Prequalification through Viatris, one of its access partners.

Above-average performance, with comprehensive access strategy and some stewardship efforts for the only on-patent product assessed, delamanid (Deltyba®). Otsuka provides access to delamanid, a key component of 1 of WHO's recommended DR-TB regimens, through supranational procurement via the Stop TB Partnership's Global Drug Facility in 136 eligible countries. The company also operates a compassionate use programme for patients in countries where the drug is not yet marketed. Since 2023, Otsuka has set the price at $1,190[1] per treatment course of delamanid, which remains the main cost driver of the DR-TB regimen.[2] Otsuka monitors both the number of treatment courses supplied, and the countries reached. During the analysis period, over 120,000 adult courses were delivered to more than 135 countries, along with 1,469 paediatric courses across all channels. Finally, the company implements stewardship strategies to ensure the responsible promotion of delamanid and provides it free of charge for susceptibility testing through a third party in more than 50 countries.

Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Otsuka implements demand planning and data sharing through biweekly sales and operations planning meetings and a 1-month forecast horizon. Forecasting is cross-referenced with WHO's MDR-TB reports to ensure sufficient stocks are maintained. It does not report sharing forecasts with external stakeholders. Otsuka maintains a 1.5-year average buffer stock for all countries where it has market authorisation and its finished delamanid product is available in consignment stock for other countries. Otsuka's inventory is managed through annual onsite checks, but it is unclear whether it implements an automated inventory management system or supplier diversification strategies. It mitigates substandard and falsified medicines by verifying suppliers through GMP audits and implementing security features, such as serialised barcodes and track-and-trace systems. However, it is unclear whether it reports cases to relevant stakeholders. It does report that 2/2 of its own sites and its sole of its supplier site are GMP compliant. Delamanid is only manufactured in countries with stringent regulatory authorities. Therefore, it is not applicable for Otsuka to take additional quality measures in countries with less mature regulatory systems.

Clearly addresses appropriate use across its business practices. Otsuka does not deploy sales agents to sell and/or promote its antibacterial medicine Deltyba® (delamanid) to HCPs. Through its national policies in Europe and the US, Otsuka ensures all interactions with HCPs are ethical by specifying the legitimate need of such interactions. It also ensures that transfers of value (ToVs) are made at fair market value. A list of some of the countries where Otsuka discloses ToVs can be easily accessed on its website, and Otsuka voluntarily discloses information on ToVs publicly in Russia. Otsuka also applies its public policy to third parties working on its behalf.

No activities in AMR surveillance. Otsuka was not involved in any AMR surveillance programmes during the period of analysis. However, in multiple countries it supported national surveillance efforts by providing pure substance for drug susceptibility testing beyond routine clinical practice.

*All registration numbers in this statement refer to the products selected for analysis and are based on the 113 countries in scope for 'access metrics'.

1. Results of the Global Drug Facility's 2024 Tender for Delamanid. (11 Nov 2024) https://www.stoptb.org/sites/default/files/documents/2024.11.11_DLM%20FAQ_FINAL_Posted%20with%20logo%20all%20pages.pdf

2. WHO Consolidated guidelines on tuberculosis. Module 3: Diagnosis. (April 2025) https://www.who.int/publications/i/item/9789240107984

OVERALL PERFORMANCE

53%

Pfizer Inc

Research-based pharmaceutical company

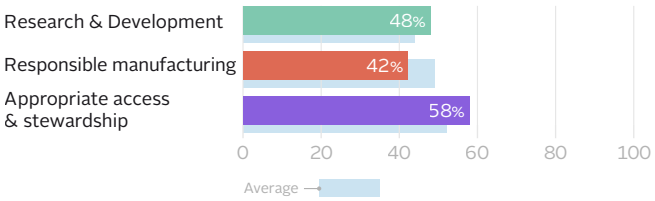
Stock exchange: NYSE • Ticker: PFE • HQ: New York, New York, USA • Employees: 81,000

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Pfizer shows mixed performance across all Research Areas. Its mid-sized pipeline includes projects targeting 'high' and 'critical pathogens' but does not include any medicines that meet WHO innovation criteria. Its environmental risk management strategy is comprehensive, but it lacks information on whether discharge targets are met across the supply chain as well as details on quantification methods. It demonstrates implementation of access and stewardship plans for select products and projects, with potential for wider adoption. This includes ceftazidime-avibactam (Zavicefta®), for which it demonstrates Best Practice in supporting diagnostic capacity in Colombia. Pfizer shows strong performance in registering its on- and off-patent medicines and adopting a robust approach to stewardship.

How Pfizer was evaluated

How score was achieved



OPPORTUNITIES FOR PFIZER

Expand breadth of R&D pipeline projects access and stewardship plans. Pfizer's AMR pipeline spans both medicines and vaccines. However, it has contracted by 38% since the last Benchmark, and none of the remaining antimicrobial projects meet WHO innovation criteria. This decline presents an opportunity for Pfizer to reinforce its commitment to AMR by diversifying its pipeline and increasing investment in vaccine development for resistant pathogens with high burdens in LMICs. In addition, it can expand access planning beyond the current 50% of late-stage candidates to cover the entire pipeline to ensure that products are supported by clear plans for affordability, registration and supply.

Expand appropriate access to on-patent medicines. Pfizer shows strong performance in its access strategies for its on-patent medicines, specifically its Reserve antibiotic ceftazidime-avibactam (Zavicefta®), which is registered and supplied widely across LMICs. While Pfizer has a strong access strategy for its on-patent antifungal medicine, isavuconazonium sulfate (Cresemba®), in a country in scope of the Benchmark, the product is only registered in nine countries in scope. Pfizer can expand access by registering the product in additional LMICs, and by implementing appropriate access strategies.

Strengthen stewardship through its sales practices. Pfizer already partly decouples incentives for its sales agents from sales volume targets. To ensure its sales practices in no way incentivise misuse or overuse of its antibacterial and antifungal medicines, Pfizer has an opportunity to either fully decouple incentives or stop deploying sales agents for these medicines altogether.

Ensure meeting discharge targets directly in wastewater and improve transparency on antibacterial waste management practices. Pfizer publicly reports setting discharge targets in the receiving environment at its own and suppliers' sites. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report meeting discharge targets directly in wastewater for all its own and suppliers' sites – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance. It can also publicly report the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

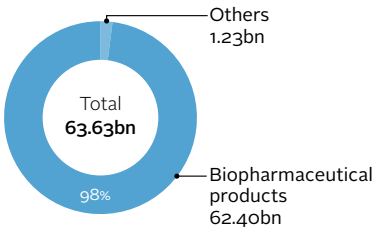
- In November 2023, Pfizer sold the rights to fosmanogepix, a first-in-class antifungal with a novel mechanism of action, to Basilea Pharmaceutica AG. Pfizer retains a right of first negotiation for commercialising fosmanogepix, once Phase III development is successfully completed.
- In May 2024, the National Health Service (NHS) of England published guidance on the Antimicrobial Products Subscription Model to set out commercial arrangements for selected antimicrobials. This permanent model builds on a pilot programme launched in July 2022, where a subscription-style contract was first awarded for Pfizer's ceftazidime-avibactam (Zavicefta®).
- In April 2024, EMBLAVEO (aztreonam-avibactam), a novel first-in-class ß-lactam/ß-lactamase inhibitor combination developed in partnership with AbbVie, received its first global marketing authorisation from the European Commission. The UK Medicines and Healthcare products Regulatory Agency (MHRA) and US Food and Drug Administration (FDA) subsequently approved the product as well.
- Pfizer participated in the pilot programme for the BSI certification in 2023. The company's manufacturing facility in Catania, Italy, has since earned the BSI Kitemark™ Certification under the AMR Industry Alliance Manufacturing Standard.

Pfizer Inc

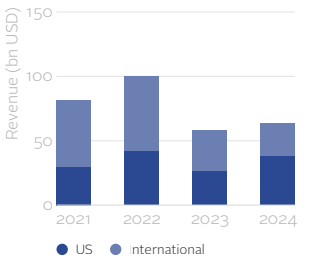
SALES AND OPERATIONS

Therapeutic areas: Anti-infectives, immunology, inflammation, internal medicine, oncology, rare diseases, vaccines
Product categories: Generic medicines & biosimilars, innovative medicines, vaccines
Investments in AMR: In 2020, Pfizer was a founding partner and invested USD 100mn in the AMR Action Fund, with the goal of bringing 2 to 4 new antibiotics to patients by the end of 2030.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Revenue by business segment (2024) – USD



Revenue by geographic region – USD



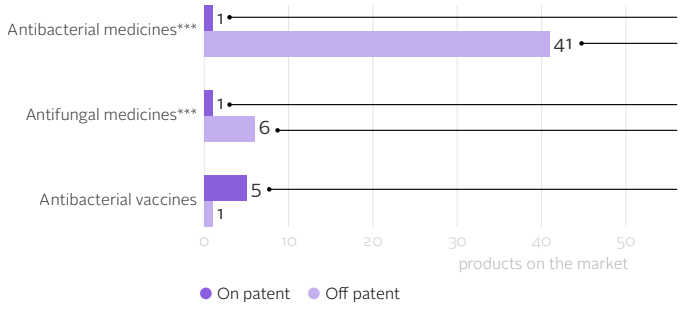
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	0	0	1	1	0	0	2	4
Antifungal medicine	0	0	0	0	0	0	1	1
Antibacterial vaccine	0	0	0	1	1	0	0	2
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	0	1*	1	2	1	0	3	8
Access plans				1	1	0	1	3
Stewardship plans**				1	0	0	3	4

PORTFOLIO *for diseases in scope*

55 products in Pfizer's anti-infective portfolio



17 products selected for analysis

ceftazidime/avibactam (R)
clindamycin (A), doxycycline (A), azithromycin (W), meropenem (W), linezolid (R), polymyxin b (R), ethambutol/isoniazid/pyrazinamide (T), rifabutin (T)
isavuconazole (F)
anidulafungin (F), fluconazole (F)
NeisVac-C®, Nimenrix®, Prevnar 13®,Prevenar 20™, Trumenba®

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

*The specific product type cannot be disclosed.
**Stewardship plans are only assessed for medicines.

***These numbers are estimates, as indicated by the company, and might be larger.

Pfizer Inc

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Mid-performing. Pfizer has a mid-sized pipeline, comprising both vaccines and antimicrobial medicines. Its pipeline candidates address both 'high' and 'critical' priority pathogens, but it has no medicine meeting WHO innovation criteria in development. Despite an above-average performance in access and stewardship planning, its approach remains inconsistent: some projects have comprehensive plans, while half of the candidates have none.

Second largest pipeline with a strong vaccine focus. Pfizer's medium-sized pipeline includes 8 projects targeting pathogens in scope. Of the 8 projects, 3 received marketing approval within the period of analysis. (See figure on previous page for Pfizer's pipeline breakdown, including phases). The company has the second-highest number of vaccines among companies, which address a range of pathogens including group B *Streptococcus* and *Streptococcus pneumoniae*. It has 6 projects addressing 'critical' or 'high' priority pathogens, as defined by WHO, including medicines targeting carbapenem-resistant, cephalosporin-resistant Enterobacterales (critical) and carbapenem-resistant *Pseudomonas aeruginosa* (high). Pfizer has no medicines in its pipeline that meet any of WHO's innovation criteria, nor does it have an active in-house discovery programme for antibacterial or antifungal medicines.

Above average performance, with comprehensive access plans, but only for some projects. Pfizer has access plans for 3 of its 6 late-stage projects: its antibiotic EMBLAVEO™ (aztreonam-avibactam) – for both paediatric and adult use – and for an investigational maternal vaccine to prevent Group B Streptococcus (GBS) transmission to infants. These plans focus on registration, equitable pricing and sustainable supply. For example, its GBS vaccine, developed in partnership with the Gates Foundation, includes equitable pricing mechanisms – a strategy for equitable deployment in LMICs. Clinical trials were conducted or are ongoing in countries in scope of the Benchmark for all 3 projects. Pfizer ran trials in 2 LMICs for the paediatric version of EMBLAVEO™ and in 6 LMICS for its adult version. It also ran trials for its vaccine in South Africa. Pfizer has a general portfolio-wide stewardship strategy applicable to all projects in the pipeline.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Mid-performing. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It incorporates AMR provisions into supplier contracts but does not report the number of products manufactured at its own or its suppliers' sites that meet discharge targets. Pfizer does not publicly disclose the quantification methods implemented, or the number of products that meet discharge targets across its supply chain.

Mitigates AMR risk at both its own sites and suppliers' sites; tracks whether discharge targets are met. Pfizer's comprehensive environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard) and WHO guidance. Pfizer estimates antibacterial discharges at its own sites using mass balance, verified by chemical analysis. If PNECs are exceeded, CAPAs are implemented (e.g., optimising waste collection and treatment strategies to reduce antibacterial discharge levels). Although Pfizer does not report the total number of antibacterial APIs and drug products manufactured at its own sites that meet discharge targets, it has received two BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certifications for products azithromycin and tigecycline. Pfizer requires its antibacterial suppliers to meet the Industry Standard. It audits suppliers based on the PSCI principles, which include discharge targets based on PNECs, and implements contractual provisions to support supplier expectations. If PNECs are exceeded, Pfizer helps suppliers develop CAPA plans. However, it does not report how many antibacterial products meet discharge targets at its supplier sites. The company also works with external wastewater treatment plants to dispose of waste and employs measures to treat wastewater prior to sending it, minimising AMR risk.

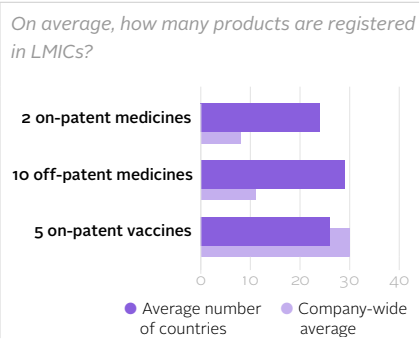
Publicly discloses limited details of its AMR mitigation strategy and is not publicly transparent about whether discharge targets are met. Pfizer publicly reports implementing the Industry Standard across its supply chain. However, it does not publicly disclose the specific quantification methods implemented; audit results; the number of products that meet PNECs; measured discharge levels; or the names and locations of manufacturing sites per antibacterial products for both its own sites and its suppliers' sites.

Pfizer Inc

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Performs well in registering its medicines more widely than peers, though its vaccines are registered less widely. Its approach to stewardship is strong, with involvement in six AMR surveillance programmes and the implementation of clear stewardship principles across its business practices. Pfizer demonstrates consistent efforts to expand access by reporting access strategies for 14 of the 17 products assessed, with its support of improved diagnostics for ceftazidime-avibactam (Zavicefta®) in Colombia highlighted as a Best Practice in the Benchmark. However, it does not disclose any monitoring of access strategies or related outcomes for the 12 medicines assessed.

Pfizer registers its on- and off-patent medicines more widely than its peers, although its vaccines are registered less extensively.



Pfizer registers its on-patent medicines in 24 countries* and its off-patent medicines in 29 countries. In a few countries where the company registers its off-patent medicines, it also registers paediatric formulations. Its on- and off-patent Reserve antibiotics and medicines targeting MDR-TB are registered in 26 countries, including 4 countries where the corresponding disease burden is high. Pfizer's on-patent vaccines are registered in 26 countries, including 1 country where the corresponding disease burden is high. For some of its vaccines, Pfizer engages in mechanisms to facilitate registrations in 7 countries in total, including WHO's Prequalification process and WHO's Collaborative Registration Procedure for WHO-listed Authorities.

Average performance, with access and stewardship strategies for 2 on-patent products assessed, but no outcomes data disclosed. Pfizer shows efforts in pursuing broader accessibility for both ceftazidime/avibactam (Zavicefta®) and isavuconazonium sulfate (Cresemba®). Zavicefta® is publicly reimbursed in Colombia, with no additional cost to patients. In a country in scope of the Benchmark, Pfizer provides financial support for Cresemba® through patient assistance programmes in both the public and private sectors. However, Pfizer did not disclose monitoring of its access strategies for either product or reporting any related outcomes. Pfizer implements stewardship activities for both products in the countries assessed. For example, the company reports a comprehensive strategy for Zavicefta®: it is included in the ATLAS surveillance programme, and Pfizer supports the Genomic Programme, a collaborative initiative focused on in vitro screening of Zavicefta® to facilitate diagnosis and inform appropriate treatment.

Average performance, with access and stewardship strategies across 9 of 10 off-patent/generic products assessed, but no outcomes data disclosed. For all 9 products, Pfizer discloses access strategies; 2 products are available in both the public and private sectors and 3 are distributed through national tenders. Additionally, Pfizer offers financial support for 4 products, either through pharmacy discounts or innovative payment models. For example, for anidulafungin – available only in the private sector – Pfizer partners with mPharma in Ghana to expand access to lower-income patients through flexible payment schemes. However, Pfizer did not disclose monitoring of its access strategies for any of the products or any related outcomes. Pfizer engages in stewardship for 8 of the 9 products, including surveillance and data sharing activities for 4 that are part of Pfizer's global surveillance programme, ATLAS. Country examples analysed included Namibia, Nigeria, the Philippines and South Africa.

Below-average performance, with access efforts for 3 of 5 on-patent vaccines assessed, but data on outcomes only provided for 1. Pfizer only discloses access strategies for pneumococcal vaccines Prevnar 13® and Prevnar 20®, and meningococcal vaccine Nimenrix®. The access strategies for Prevnar 13® and Prevnar 20® (the latest version, offering protection against 7 additional pneumococcal strains) differ in depth and quality. Pfizer reports that Prevnar 20® is available either in the private sector, via tenders or a combination. However, there is no information on the countries where each strategy applies or on their outcomes, such as doses supplied or patients reached. Prevnar 13® is distributed through several supranational mechanisms, including Gavi/UNICEF's Pneumococcal Advance Market Commitment (AMC), UNICEF's Humanitarian Mechanism and Pfizer has also worked with UNICEF to support access in middle-income countries.

Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Pfizer implements AI algorithms and historical data for demand planning and forecasting. This data is shared internally with manufacturing and commercial teams. However, the length of the forecasting horizon is not reported, and it does not report sharing forecasts with external stakeholders. Pfizer maintains buffer stocks across its network to mitigate supply and demand variability. Stock management is decentralised, residing within individual legal markets. Inventory is managed through automated systems with real-time alerts and predictive analytics, helping prevent shortages. It also implements a diversified sourcing strategy, utilising multiple upstream suppliers and engaging with local sourcing. Pfizer seeks to mitigate substandard and falsified products by monitoring GMP compliance at its own and suppliers' sites through GMP audits, reporting cases of falsified products to relevant authorities, and educating HCPs and patients globally. However, it does not disclose any additional quality measures implemented in countries with evolving regulatory systems.

Clearly addresses appropriate use across its business practices. Pfizer partly decouples incentives for its sales agents from sales volume targets, and targets are generally set at an aggregated level. A behavioural component is required as part of any sales incentive plan and has a focus on adherence to Pfizer's policies and standards. Pfizer does not disclose the proportion of variable pay it links to sales volume targets. In the UK, Pfizer fully decouples incentives from sales volumes targets. Through its global public policy, Pfizer ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions and how to mitigate potential conflicts of interest. It also sets limits on some transfers of value (ToVs) and ensures that all ToVs are made at fair market value. Pfizer voluntarily discloses information on ToVs publicly in Canada. Third parties acting on Pfizer's behalf are contractually required to abide by ethical standards laid out in Pfizer's public policy, though they are not covered by its sales incentive plan.

Active in 6 multi/national AMR surveillance programmes. Pfizer runs the multinational ATLAS programme, covering 59 genera of bacteria, 37 antibacterial medicines and 83 countries. Raw data from ATLAS is regularly shared and accessible upon request via the AMR Register. Aggregated data is publicly accessible via the updated ATLAS website, together with antifungal surveillance data from the multinational 'SENTRY Antimicrobial Surveillance Programme'. Beyond sharing its data, Pfizer funds the susceptibility testing of its own antifungal products for SENTRY and integrates its new compounds into the programme. SENTRY's antibacterial surveillance data can be accessed via SENTRY'S own website. Additionally, Pfizer funds 4 national surveillance programmes in China (2), Egypt (1) and Brazil (1). Aggregated data from 3 of these programmes is publicly accessible. The methods used to collect surveillance data for ATLAS, SENTRY and 3 national programmes are largely clear including: the type of surveillance; where the analysis is conducted and which breakpoints are used; how deduplication is considered; and how participating healthcare facilities are selected, although public disclosure is limited. The methods used for the third national programme are only partially clear.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

38%

Sanofi

Research-based pharmaceutical company

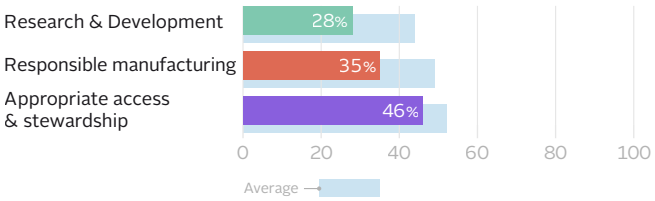
Stock exchange: EPA • Ticker: SAN • HQ: Paris, France • Employees: 82,878

PERFORMANCE IN THE 2026 BENCHMARK

Low-performing. Sanofi has opportunities to strengthen its efforts across R&D and Responsible Manufacturing, as it has a small pipeline focused on vaccines and a basic environmental risk management strategy, where underlying quantification and compliance levels remain unclear. Its performance in Appropriate Access & Stewardship is uneven. It provides no evidence of ensuring access to any of the assessed off-patent medicines, either through registrations or access strategies, but it is ahead of its peers in ensuring access for its on-patent vaccines. Sanofi does not demonstrate involvement in AMR surveillance.

How Sanofi was evaluated

How score was achieved



OPPORTUNITIES FOR SANOFI

Expand breadth of R&D pipeline and access plans. Sanofi's AMR pipeline size has reduced by 50% since the last Benchmark. It can diversify its pipeline investing in vaccine development to address resistant pathogens with high burdens in LMICs. In addition, it can enhance access planning for its late-stage pipeline candidate, SP0202 (21-valent pneumococcal vaccine conjugate), which is currently in Phase III, outlining concrete measures for access and clarifying in which LMICs its access plan applies.

Expand access to its newest on-patent vaccine, MenQuadfi®. Sanofi already registers its on-patent vaccines in an average of 38 LMICs, more than any of its peers. However, its newer vaccine MenQuadfi® – indicated for the prevention of invasive meningococcal disease from six weeks of age – is currently only registered in 14 countries. Sanofi can expand access to MenQuadfi® using strategies utilised for its other vaccines, such as expanding registration, implementing appropriate access strategies and supranational supply, prioritising countries with highest unmet need.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved. Sanofi publicly reports setting discharge limits in the receiving environment at its own and suppliers' sites, implementing mass balance estimations. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products and require supplier compliance through contractual provisions – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

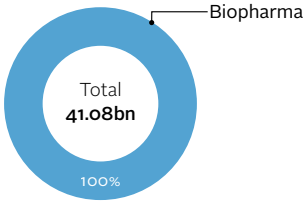
- In December 2024, Sanofi expanded its collaboration with SK Bioscience to work on developing, licensing and commercialising next-generation pneumococcal conjugate vaccines (PCVs) for both paediatric and adult populations.
- In June 2025, Sanofi received a US Food and Drug Administration (FDA) indication extension approval for its Meningococcal (Groups A, C, Y, W) Conjugate Vaccine (MenQuadfi®) to include children aged 6 weeks to 23 months.
- During the 2026 AMR Benchmark period of analysis, Sanofi engaged in technology transfer initiatives. In March 2025, Sanofi signed a collaboration agreement with Vietnam Vaccine Joint Stock Company (VNVC) to transfer vaccine manufacturing technology and expertise. In June 2025, Sanofi entered a strategic alliance with the Institute Pasteur and Brazil's Fiocruz.

Sanofi

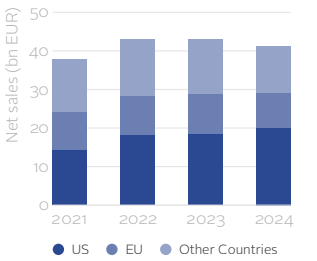
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, diabetes, immunology & inflammation, neurology, oncology, rare diseases
Product categories: Innovative medicines and vaccines
Investments in AMR: No notable investments identified.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Net sales by business segment (2024) – EUR



Net sales by geographic region – EUR



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine			o	o	o	o	o	
Antifungal medicine			o	o	o	o	o	
Antibacterial vaccine			o	o	1	o	o	
Antifungal vaccine			o	o	o	o	o	
Total projects	1	1	o	o	1	o	o	3
Access plans			o	1	o	o		1

Specific product categories in discovery and pre-clinical phases cannot be disclosed.

PORTFOLIO *for diseases in scope*
Sanofi has multiple products in its anti-infectives portfolio. However, it did not disclose the total number of products. The figure below shows a selection of products selected for analysis.

9 products selected for analysis

On Patent	Off Patent	Vaccines
None	• amoxicillin (*Access antibiotic*) • amoxicillin/clavulanic acid (*Access antibiotic*) • azithromycin (*Watch antibiotic*) • levofloxacin (*Antituberculosis medicine*) • rifampicin (*Antituberculosis medicine*) • clotrimazole (*Antifungal medicine*)	• Hexaxim® • Menactra® • MenQuadfi®

Sanofi

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Low-performing. Sanofi has a small pipeline, with one vaccine in clinical development, and no projects addressing 'critical' or 'high' priority pathogens. It does not engage in R&D for innovative antimicrobial medicines. Although it has an access plan in place for its sole late-stage candidate, the plan lacks concrete details, and the intended geographic reach is unclear.

Small pipeline focused on pneumococcal vaccine development. Sanofi's small pipeline includes 3 projects targeting pathogens in scope; one of these is a vaccine targeting *Streptococcus pneumoniae* which is currently in Phase III of clinical development. The company does not have any candidate in the pipeline that addresses 'critical' or 'high' priority pathogens as defined by WHO, neither does it have any innovative medicine in its pipeline; its sole clinical project (a vaccine) fell outside the scope of WHO's innovation assessment of medicines. Sanofi reports having an in-house discovery programme for pathogen(s) in scope.

Below-average performance, with access plan in place but unclear geographic reach. Sanofi has an access plan for its late-stage candidate, PCV21, a Pneumo Conjugate Vaccine for paediatric populations, developed in partnership with SK bioscience. Clinical trials have taken place, or are still underway, in 4 countries in scope of the Benchmark. The access plan features a registration strategy for some countries in scope (although exact countries are not specified) and an equitable pricing approach.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. It does not report the number of products manufactured at its own or suppliers' sites that meet discharge limits, or whether it incorporates AMR provisions into supplier contracts. Sanofi publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Basic environmental risk management to mitigate AMR at both its own sites and suppliers'; tracks compliance of antibacterials with discharge limits at its own sites. Sanofi's environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It estimates antibacterial discharges at its own sites using mass balance, but underlying quantification details (e.g., dilution factors and quantification timeframe) are unclear. It is also unclear whether Sanofi implements CAPAs when PNECs are exceeded. Additionally, Sanofi does not report the number of its antibacterial products that comply with PNECs. The company requires antibacterial suppliers to follow the Industry Standard, including mass balance estimation, which is verified by chemical analysis when applicable. Audits are conducted at a risk-based frequency using PSCI principles, including PNEC-based limits. It's unclear whether AMR provisions are in contracts or how many supplier products meet discharge limits. No information could be identified on whether Sanofi works with external waste treatment plants to minimise AMR risk from manufacturing.

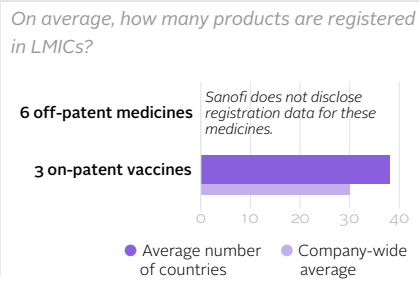
Publicly discloses basic details of its AMR mitigation strategy but is not publicly transparent about compliance with discharge limits. Sanofi publicly reports implementing the Industry Standard across its supply chain. For its own sites, it publicly reports quantifying discharge levels using mass balance estimation. However, it does not publicly disclose the audit results with measured discharge levels, the number of products complying with PNECs or the names and locations of manufacturing sites per antibacterial products for either its own sites or its suppliers' sites.

Sanofi

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Performs well in registering its 3 on-patent vaccines in more countries than peers, implementing comprehensive access strategies and supplying them through multiple channels. Sanofi addresses appropriate use by not deploying sales agents for any antibacterial or antifungal medicines within its portfolio. However, the company did not disclose registration data or access strategies for the off-patent medicines assessed; as such, its efforts to expand access to these products remain unclear. Sanofi lacks efforts on surveillance, with no involvement in AMR surveillance during the period of analysis.

Sanofi registers its on-patent vaccines more widely than its peers, though its performance for off-patent medicines is inconclusive.



Sanofi does not disclose any registration data for its off-patent antibacterial and antifungal medicines to the Benchmark. Its on-patent vaccines are registered in 38 countries,* including 3 countries where the corresponding disease burden is high. For some of its vaccines, Sanofi engages in WHO's Prequalification process to facilitate registrations.

Below-average performance, with no evidence of access and stewardship strategies for any of the 6 off-patent/generic products assessed. While Sanofi does not disclose any access or stewardship strategies for the 6 products analysed, the company does apply a general access-to-medicine strategy across its entire portfolio. In addition, 2 of the 6 products – levofloxacin and rifampicin – are part of Sanofi's Global Health Unit (GHU), through which the company offers its medicines at affordable prices across 40 LMICs. While the company tracks and reports quarterly on the number of patients receiving medicines through its GHU, it has not provided evidence of how many patients have specifically been reached with levofloxacin and rifampicin. For the other 4 assessed products, Sanofi does not provide any evidence of monitoring its access strategies, nor does it report the number of patients reached.

Above-average performance, providing access to all 3 on-patent vaccines assessed through multiple channels, including supranational procurement mechanisms. Sanofi discloses access strategies for its hexavalent vaccine Hexaxim® and both its meningococcal vaccines, Menactra® and MenQuadif®. Sanofi supplies Hexaxim® through the PAHO Revolving Fund at the lowest available price for all participating countries. In addition, Sanofi also provides Hexaxim® directly to self-procuring countries, such as Mexico and South Africa, where the company is working on a technology transfer to its local partner BIOVAC. Menactra® has been supplied through UNICEF, with Sanofi committing to a rapid response in case of confirmed outbreaks. As part of this, in 2024 Sanofi supplied 227,000 doses to Cameroon. The company plans to continue participating in the UNICEF tenders, while replacing the vaccine with the newer MenQuadfi®. During the period of analysis, MenQuadfi® was launched in Egypt and 192,000 doses were supplied in 2025.

Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Sanofi implements demand planning and data sharing through its internal Integrated Business Planning process, which involves collaboration across key departments (marketing, sales, supply chain, finance), and uses sales forecasts (up to 36 months) to inform planning. However, it does not report sharing forecasts with external stakeholders. Sanofi maintains buffer stocks and follows an inventory policy to set target levels for APIs and products, which is reviewed biennially to manage long-term risks and maintain optimal stock. It also implements dual sourcing for antibacterial and antifungal medicines. However, it is unclear whether it uses automated inventory systems. It mitigates substandard and falsified products by verifying suppliers through GMP audits and reports cases to relevant stakeholders. It also implements security measures, such as serialisation and AI-driven threat detection. However, it does not disclose the total number of sites that are GMP compliant or implement any additional quality measures implemented in countries with evolving regulatory systems.

Clearly addresses appropriate use across its business practices. Sanofi does not deploy sales agents to sell and/or promote its antibacterial and antifungal medicines to HCPs. Through its global public policy, Sanofi ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions and how to mitigate potential conflicts of interest. It also ensures that transfers of value (ToVs) are made at fair market value. While Sanofi abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated by law or other codes of practice. Sanofi's public policy also applies to third parties working on its behalf.

No involvement in AMR surveillance. Sanofi was not involved in any AMR surveillance programmes during the period of analysis.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

66%

Shionogi & Co, Ltd

Research-based pharmaceutical company

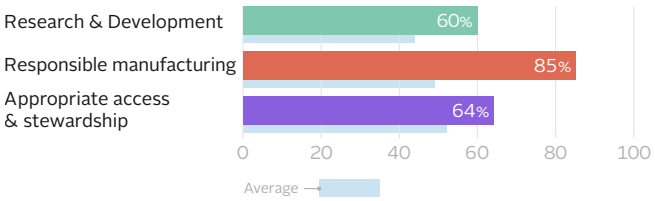
Stock exchange: TSE • Ticker: 4507 • HQ: Osaka, Japan • Employees: 4,959

PERFORMANCE IN THE 2026 BENCHMARK

Performs well. Shionogi performs well across all Research Areas, with specifically strong performance in Responsible Manufacturing. Here, Shionogi shows Best Practice in supporting supplier's wastewater management practices and demonstrates a comprehensive environmental risk management strategy at both its own and suppliers' sites. Across R&D and Appropriate Access & Stewardship, Shionogi is ahead of its peers in implementing access and stewardship plans and strategies; though performance is inconsistent across its pipeline projects. Its approach to stewardship is strong, including product-specific measures for its on-patent cefiderocol, though registrations for the product are limited.

How Shionogi was evaluated

How score was achieved



OPPORTUNITIES FOR SHIONOGI

Expand the depth of R&D access and stewardship plans for all late-stage projects. Shionogi has the most innovative pipeline across all large research-based companies in the AMR Benchmark, with access plans in place for two of its three late-stage candidates. It can strengthen its approach by ensuring that all late-stage projects are backed by comprehensive access and stewardship plans. For example, for its antifungal candidate, olorofim, developed in partnership with F2G, it can strengthen its plan by providing concrete details of access planning in countries with high burdens countries and demonstrate how affordability and supply are being addressed across the 20 LMICs where it holds commercialisation rights.

Improve access to and transparency around its surveillance data. Shionogi is active in three surveillance programmes, including its own 'Shionogi Cefiderocol Post-Marketing Japanese Surveillance Studies Programme'. While it publicly shares aggregated data from this programme, Shionogi has an opportunity to also provide public access to raw data, for example, through the AMR Register. In addition, Shionogi can report more information on the methods used to collect and analyse its surveillance data and disclose this information publicly.

Ensure compliance with discharge limits directly in wastewater. Shionogi publicly reports 100% compliance with discharge limits set in the receiving environment for its own products and 71% compliance for its suppliers' products, based on periodic sampling. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' sites – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

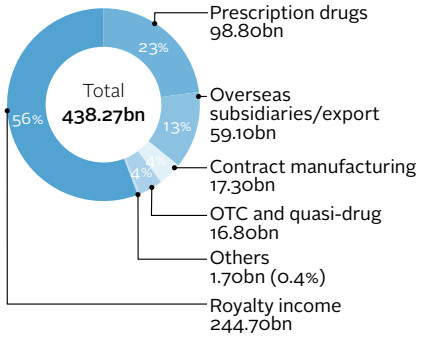
- In May 2024, the National Health Service (NHS) of England published guidance on the Antimicrobial Products Subscription Model to set out commercial arrangements for selected antimicrobials. This permanent model builds on a pilot programme launched in July 2022, where a subscription-style model was first awarded for Shionogi's cefiderocol (Fetroja®).
- In April 2025, Shionogi opened a US-based drug discovery laboratory to support antimicrobial research and development.
- In May 2025, Shionogi, Nagasaki University, Saraya, and Connect Afya signed a comprehensive partnership agreement aimed at supporting antimicrobial stewardship in Kenya.
- In July 2025, Shionogi and the Global Antibiotic Research and Development Partnership (GARDP) agreed to collaborate with Kenya's ministry of health to expand access to its antibiotic cefiderocol in the country. The initiative aims to support appropriate use of the drug in selected tertiary hospitals.
- In October 2025, Shionogi's Kanegasaki Plant received the BSI Kitemark™ for Minimized Risk of AMR Certification.

Shionogi & Co, Ltd

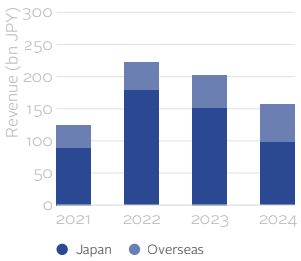
SALES AND OPERATIONS

Therapeutic areas: Analgesics, antibiotics, HIV, infectious diseases, rare diseases, women's health
Product categories: Diagnostics, innovative medicines, vaccines
Investments in AMR: In 2020, Shionogi was a founding partner and invested USD 20mn in the AMR Action Fund, with the goal of bringing 2 to 4 new antibiotics to patients by the end of 2030. It is unknown how much has been invested in the fund to date. In November 2024, it renewed its partnership with INCATE to support early-stage AMR innovators.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Revenue by business segment (2024) – JPY



Revenue by geographic region – JPY



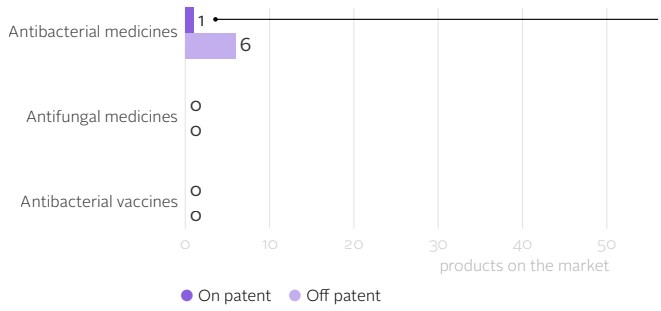
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	2	0	2	1	1	0	0	6
Antifungal medicine	0	0	0	0	1	0	0	1
Antibacterial vaccine	0	1	0	0	0	0	0	1
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	2	1	2	1	2	0	0	8
Access plans				0	2	0	0	2
Stewardship plans				0	2	0	0	2

PORTFOLIO *for diseases in scope*

7 products in Shionogi's anti-infective portfolio



1 product selected for analysis

cefiderocol (R)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

Shionogi & Co, Ltd

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Performs well. Shionogi has a mid-sized pipeline and stands out for having the most innovative projects targeting both 'high' and 'critical' pathogens. It performs above average in access and stewardship planning, however, its approach remains uneven across its three late-stage candidates.

Second largest and most innovative pipeline with diverse projects targeting high and critical priority pathogens. Shionogi's pipeline is the second largest among companies, with 8 projects targeting pathogens in scope: 6 antibacterial medicines, 1 antifungal medicine and 1 antibacterial vaccine. (See figure on previous page for Shionogi's pipeline breakdown, including phases). All 7 medicines in development target 'critical' or 'high' priority pathogens, as defined by WHO. This includes carbapenem-resistant *Acinetobacter baumannii* (critical) and carbapenem-resistant Enterobacterales (critical). Shionogi has the most innovative pipeline of all companies; with 4 medicines (3 antibacterial agents and 1 antifungal medicine) meeting at least 1 of WHO's 4 innovation criteria. For example, its project ORAvance, for complicated urinary tract infections, fulfils the criterion of no cross resistance, and its oral formulation offers a practical advantage for administration in LMICs. The company reports having an in-house discovery programme, focusing on the discovery of new beta-lactamase inhibitors.

Above average performance with some comprehensive access and stewardship plans, although not for all projects. Shionogi has access and stewardship plans for 2 of its 3 late-stage projects. Access plans include licensing agreements and technology transfers. For cefiderocol (Fetcroja®), an antibiotic for resistant gram-negative infections – currently under evaluation in paediatric populations – it has an early access programme and a licensing agreement with GARDP to provide the medicine in 135 countries, including LMICs. Stewardship planning for cefiderocol, is also integral to its GARDP partnership. In addition, it partners with F2G to develop the antifungal olorofim, where it is responsible for overseeing clinical trials, registration, supply and commercialisation in 79 countries, including 20 LMICs. Both companies have contractually committed to developing a joint access and stewardship plan within 60 days of the first global sale. However, specific details regarding access and affordability measures in LMICs remain unclear.

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Performs strongly. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It publicly reports product-specific levels of compliance achieved at its own and suppliers' sites, the quantification methods implemented, and the country-level locations of its antibacterial manufacturing sites. It incorporates AMR provisions into contracts with suppliers. Shionogi's hands-on approach to supporting suppliers' wastewater management practices is highlighted as a Best Practice in the Benchmark.

Mitigates AMR risk at both its own sites and suppliers' sites; reports 100% of antibacterials compliant with discharge limits for own sites and 71% for its suppliers' sites. Shionogi's comprehensive environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). Shionogi quantifies antibacterial discharges annually at its own sites using mass balance and chemical analysis. If PNECs are exceeded, CAPAs are implemented (e.g., diverting wastewater to holding tanks to prevent river discharge). It reports all 5 antibacterial products produced at its own sites are compliant with PNECs in the receiving environment, where wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured. It has received a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification for cefiderocol at its Kanegasaki Plant in Japan. Shionogi also requires antibacterial suppliers to follow the Industry Standard, including discharge quantification via mass balance estimation. It conducts annual supplier audits and enforces contractual provisions on discharge limit compliance. If PNECs are exceeded, it supports suppliers in developing CAPAs. It reports 5 of 7 supplier products are compliant in the receiving environment. Shionogi works with external waste treatment plants and ensures all solid waste and wastewater that it sends to plants is incinerated to mitigate AMR risk. It also audits these plants annually for technology suitability and contamination prevention protocols.

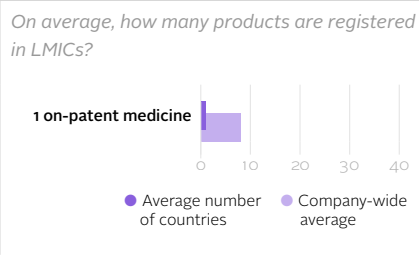
Publicly discloses comprehensive details of its AMR mitigation strategy, product-specific compliance information and country-level locations of all its manufacturing sites. Shionogi publicly reports implementing the Industry Standard, quantification through chemical analysis and achieving compliance with discharge limits for all 5 of its own products and 5 of its suppliers' 7 products. For both its own sites and its suppliers' sites, it publicly discloses aggregated product-specific audit results, including country-level locations of its manufacturing sites for each manufactured antibacterial, but the exact site names of its supplier sites are omitted. It also does not disclose the actual discharge levels measured.

Shionogi & Co, Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1 ●	C.1.2 ●	C.1.3 ●	C.2.1 ●	C.2.2 ●	C.2.3 ●	C.3 ●	C.4 ●	C.5 ●

Performs well. Demonstrates strong performance in ensuring continuous supply, with a comprehensive approach to mitigating stockouts and shortages and ensuring GMP compliance at its own and suppliers' sites. Shionogi clearly addresses appropriate use across its business practices by fully decoupling sales incentives from volume targets, ensuring ethical interactions with healthcare professionals, and setting limits on some transfers of value. It participates in three AMR surveillance programmes, sharing aggregated data. However, compared to peers, its sole product assessed, cefiderocol (Fetroja®), is registered in fewer countries on average.

Shionogi registers its sole product, cefiderocol, in fewer countries than peers' on-patent medicines.



Shionogi registers its on-patent Reserve antibiotic, cefiderocol (Fetroja®), in China,* which is not a country where the corresponding disease burden is high. However, it granted a voluntary licence to GARDP to supply the product in 135 countries, including LMICs in scope of the Benchmark. A specific paediatric formulation of cefiderocol is not approved yet, but currently in development. In addition, Shionogi engages in WHO's Prequalification process to facilitate registrations for cefiderocol.

Above-average performance, working towards broad access through a comprehensive access and stewardship strategy for the only on-patent product assessed, cefiderocol (Fetroja®). In 2022, Shionogi and GARDP signed a non-exclusive voluntary licensing agreement and, with CHAI, a collaboration agreement, to ensure broad access to the product. The licence covers 135 countries (106 in scope of the Benchmark). GARDP has entered a sublicensing agreement with Orchid Pharma, an India-based generic manufacturer, and Shionogi is currently conducting a technology transfer to Orchid Pharma to produce cefiderocol. As cefiderocol has not yet been launched in any GARDP territories, Shionogi is operating an early access programme in 3 countries in scope (Colombia, Guatemala and Mexico). The company does not report a methodology to monitor its access strategies, nor are any outcome metrics available at this stage. Shionogi implements a comprehensive stewardship strategy for the product, including responsible promotion activities and the SENTRY surveillance programme.

Strong efforts to mitigate stockouts/shortages. Strong reported evidence of systems to ensure product quality. Shionogi implements demand planning and data sharing by analysing historical market trends and monitoring public health and potential outbreaks. It provides monthly demand forecasts and uses sales and operations planning processes to communicate supply risks to internal and external stakeholders. Long-term forecasts are implemented for drugs with long lead times (i.e. cefiderocol >1.5 years), ranging from a 3- to 5-year forecasting horizon. It maintains 6-month buffer stocks of APIs and drug products and implements an automated inventory management system that updates inventory levels daily, providing regional supply chain teams with daily alerts on potential shortages. It also implements supplier diversification strategies through its Business Continuity Plans for each of its products, often involving sourcing from multiple upstream suppliers, though local sourcing is not specified. It mitigates substandard and falsified medicines by verifying suppliers through GMP audits and reports cases to relevant authorities. It reports that 2/2 of its own sites and 4/4 of its supplier sites are GMP compliant. Shionogi does not implement additional quality measures, as it does not manufacture in countries with less mature regulatory systems than stringent regulatory authorities.

Clearly addresses appropriate use across its business practices. Shionogi fully decouples incentives for its sales agents from sales volume targets. It does not specify any other qualitative targets that it links to its incentives. Through its global public policy, Shionogi ensures ethical interactions with HCPs, and for certain interactions it requires a defined legitimate need. It also sets limits on some transfers of value (ToVs). While Shionogi abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Shionogi applies its sales incentive plan and its global policy to third parties working on its behalf.

Active in 3 multi/national AMR surveillance programmes. Shionogi runs the national 'Shionogi Cefiderocol Post-Marketing Japanese Surveillance Studies Programme', which is conducted by a third party on Shionogi's behalf, covering 11 genera of bacteria and 13 antibacterial medicines. Aggregated results from the post-marketing surveillance are shared on Shionogi's website and are accessible for HCPs. Shionogi reports submitting surveillance data from this programme to the Japanese Ministry of Health, Labour and Welfare. Additionally, Shionogi funds the national 'Four Academic Societies Joint Antimicrobial Susceptibility Surveillance Programme' and the multinational 'SENTRY Antimicrobial Surveillance Programme'. Aggregated data for both programmes is publicly available via their respective websites. For SENTRY, Shionogi specifically funds the testing of its own antibacterial medicine (cefiderocol). The methods used to collect surveillance data for SENTRY are largely clear, including: the type of surveillance; where the analysis is conducted and which breakpoints are used; and how deduplication is considered. The methods used for both other programmes are only partially clear.

*All registration numbers in this statement refer to the products selected for analysis and are based on the the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

52%

Abbott Laboratories Ltd

Generic medicine manufacturer

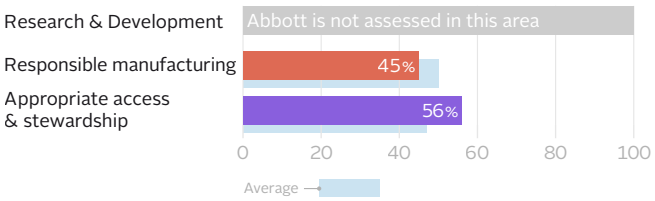
Stock exchange: NYSE • Ticker: ABT • HQ: Chicago, Illinois, USA • Employees: 114,000

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Although Abbott has room for improvement in Responsible Manufacturing due to a lack of information on compliance with discharge limits, it shows Best Practice by providing hands-on support to its suppliers for managing antibiotic waste from manufacturing. It is mid-performing in Appropriate Access & Stewardship, where it implements appropriate access and stewardship strategies for all nine products assessed but registers its products in fewer countries than other assessed generic medicine manufacturers.

How Abbott was evaluated

How score was achieved



OPPORTUNITIES FOR ABBOTT

Expand appropriate access to its Watch antibiotics in LMICs. Abbott has appropriate access strategies in place for all nine of its off-patent products assessed in India. However, registration of its Watch antibiotics, ceftriaxone and ciprofloxacin – the only products assessed for which it holds marketing authorisation – is limited to only two LMICs, on average. Abbott can further expand access to these much-needed antibiotics by registering them in additional LMICs and subsequently implementing appropriate access strategies in those markets, leveraging the approach used in India.

Scale up its responsible sales practices and strengthen its governance of interactions with healthcare professionals (HCPs). Abbott reports responsible sales practices in one country, as it does not promote a number of its off-patent antibacterial and antifungal products. To ensure company-wide responsible sales practices, the company has an opportunity to scale up this practice – either across medicines or across countries – or to fully decouple incentives from sales volume targets where it deploys sales agents. Moreover, Abbott can strengthen its public policy governing interactions with HCPs – and thereby address appropriate use of its antimicrobials – by including provisions on the legitimate need for these interactions and mitigating potential conflicts of interest, specifically between employees and HCPs.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved. Abbott publicly reports setting discharge limits in the receiving environment at its own and suppliers' sites, implementing mass balance estimations. To further safeguard AMR risk from antimicrobial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' sites – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

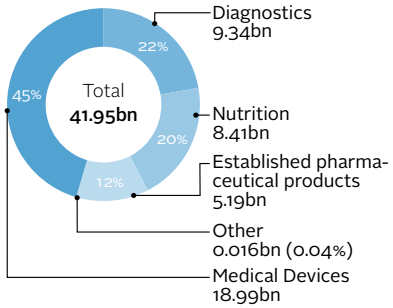
Aside from examples covered within the 2026 AMR Benchmark report analysis, no notable updates can be reported for Abbott since the *AMR Benchmark Opportunities: Company progress since 2021*, which was published in 2023.

Abbott Laboratories Ltd

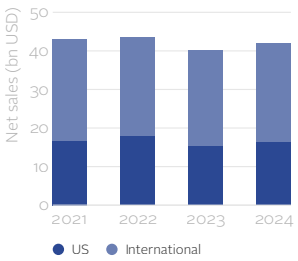
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, diabetes, gastroenterology, influenza, oncology, pain & central neuroscience, respiratory diseases, women's health
Product categories: Diagnostics, generic medicines & biosimilars, medical devices, vaccines
Investments in AMR: No notable investments identified.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Net sales by business segment (2024) – USD



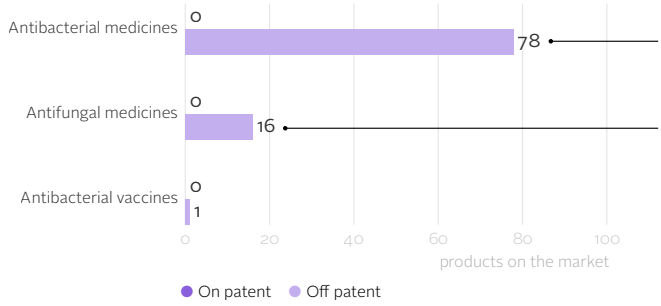
Net sales by geographic region – USD



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

95 products in Abbott's anti-infective portfolio



9 products selected for analysis

amoxicillin/clavulanic acid (A), gentamicin (A), ciprofloxacin (W), ceftriaxone (W), colistin (R), polymyxin b (R), clofazimine (T), streptomycin (T)

itraconazole (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic,
F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. It does not report whether its own and suppliers' sites meet discharge limits. However, Abbott's incorporation of AMR provisions into supplier contracts, and its hands-on approach to supporting suppliers' wastewater management practices, are highlighted as Best Practice in the Benchmark. It publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own sites and its suppliers' sites; tracks compliance of antibacterials with discharge limits. Abbott's environmental risk management strategy is based on an internal standard. It estimates antibacterial discharges at its own sites using mass balance; if PNECs are exceeded, chemical analysis is performed for verification and CAPAs are implemented. Abbott does not report the total number of antibacterial APIs and drug products manufactured at its own sites that comply with discharge limits. It reports requiring its suppliers to use estimation methods recommended by the PSCI, including mass balance estimations and discharge limits based on PNECs. It has contractual provisions requiring suppliers to comply with these limits and conducts supplier audits. However, Abbott does not report on the number of antibacterials manufactured by its suppliers that comply with discharge limits. Although Abbott reports primarily operating its own internal wastewater treatment plants, in the limited cases where it works with external wastewater treatment plants it employs measures to treat the antibacterial wastewater it sends to minimise AMR risk.

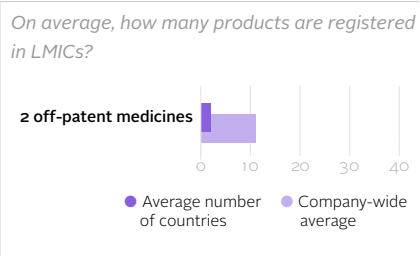
Publicly discloses basic details of its AMR mitigation strategy but is not transparent about compliance with discharge limits. Abbott publicly reports implementing an internal standard to quantify discharge levels including mass balance estimation, which is verified through chemical analysis if PNECs are exceeded. However, it does not publicly disclose audit results with the actual discharge levels, or the names and locations of its manufacturing sites for each manufactured antibacterial.

Abbott Laboratories Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Performs well in implementing appropriate access and stewardship strategies for all nine products assessed and using a standardised methodology for calculating patient reach across its portfolio. It also does well in stewardship, as it considers appropriate use across its business practices. Abbott has a comprehensive approach to mitigate stockouts and shortages and ensures GMP compliance at own and suppliers' sites. However, it can increase its registrations as it registers its products in fewer countries on average compared to peers.

Abbott registers its off-patent medicines in fewer countries than its peers.



Abbott registers its off-patent medicines in 2 countries.* No paediatric-specific products from the company were assessed. As Abbott's off-patent Reserve antibiotics are licensed, the company cannot register these products and only commercialises them. Abbott does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Above-average performance, with both access and stewardship strategies for all 9 off-patent/generic products assessed, and outcomes reported for 6. Abbott reports implementing access strategies for all 9 products assessed in India. The company demonstrates efforts in expanding access in the public sector by participating in annual public tenders – which are usually awarded based on the lowest price – for 6 products. For 4 of these, Abbott reports being awarded the tender as the sole supplier. The company has a standardised methodology to monitor its access strategies across its portfolio. For 6 of the 9 products, outcomes of the strategies are reported as doses supplied during the period of analysis; no data is shared for the other 3 products. For all 9 products, stewardship strategies only focus on responsible promotion and sales strategies, lacking engagement in surveillance or diagnostic activities.

Strong efforts to mitigate stockouts systems. Strong reported evidence of systems to ensure product quality. Abbott reports the details of its demand planning and forecasting efforts under an NDA. It mitigates shortage risks by keeping a buffer stock for critical APIs and finished products. Inventory levels are monitored daily using an automated planning system and demand tool that calculates how long stocks will last. Based on shortage risks, it reallocates products by adjusting safety stock levels. It implements a diversified sourcing strategy for its critical antibacterial and antifungal medicines to ensure alternative suppliers are available. In India, products are sourced from multiple upstream sites to reduce disruption risks. It mitigates substandard and falsified products by verifying suppliers through GMP audits, reporting all its own and suppliers' sites are GMP compliant, reporting cases to relevant stakeholders, and conducting monthly quality reviews and awareness campaigns. It is unclear whether the company takes additional mitigation steps in countries with evolving regulatory systems.

Includes elements to address appropriate use across its business practices. Abbott partly decouples incentives for its sales agents from sales volume targets. However, it does not report the proportion of variable pay it links to sales volume targets, the level at which sales targets are set, nor does it specify any other measures that are linked to incentives. Abbott's sales agents promote a broad portfolio of products to HCPs, which includes antibacterial and antifungal medicines. In one country in scope of the Benchmark, Abbott does not actively promote certain antibacterial and antifungal medicines. Through its global public policy, Abbott ensures ethical interactions with HCPs, and for certain interactions it sets limits and ensures transfers of value (ToVs) are made at fair market value. While Abbott abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated by law, or by other codes of practice. Abbott's global policy defines equal requirements for third parties working on its behalf. However, it is unclear if this is also the case for its sales incentive plan.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

14%

Alkem Laboratories Ltd

Generic medicine manufacturer

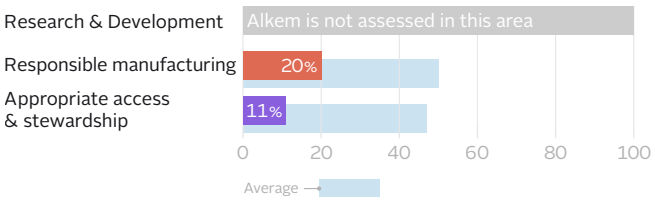
Stock exchange: NSE • Ticker: ALKEM • HQ: Mumbai, India • Employees: 21,000

PERFORMANCE IN THE 2026 BENCHMARK*

Weak performance. Alkem's performance in Responsible Manufacturing is limited due to the absence of an AMR-specific environmental risk management strategy to ensure responsible manufacturing practices. It also has potential to strengthen performance in Appropriate Access & Stewardship as it publicly reports limited measures to ensure continuous supply of its products in LMICs and does not disclose any access or stewardship strategies across the products selected for analysis.

How Alkem was evaluated

How score was achieved



OPPORTUNITIES FOR ALKEM

Expand appropriate access to its antibacterial and antifungal medicines. Alkem does not disclose any access strategies or provide evidence of registering any of its medicines in LMICs. The company can expand appropriate access to its products – for example, its Reserve antibiotic, colistin, indicated as a last-resort treatment for multidrug-resistant gram-negative infections – by expanding registrations and/or implementing appropriate access strategies in LMICs, prioritising countries with high unmet need.

Track product-level patient reach for off-patent antibacterial and antifungal drugs. Alkem does not disclose patient reach data for any of its assessed products. The company can improve in tracking patient reach – which is essential to enable measurement of appropriate access and support the responsible use of its medicines – by implementing a patient reach methodology and applying it across its entire portfolio, at both the product- and country-level.

Strengthen its governance of interactions with healthcare professionals. Alkem's public policy governing interactions with healthcare professionals (HCPs) does not include specific provisions to ensure they remain ethical. Alkem can strengthen its governance, and thereby address appropriate use of its antimicrobials, by including specific provisions to ensure a legitimate need for such interactions; mitigate potential conflicts of interest – specifically between employees and HCPs; limit transfers of value and ensure these are paid at fair market value.

Formalise and publicly disclose comprehensive environmental risk management strategy to mitigate AMR. Alkem publicly reports implementing general controls to minimise waste discharges, but not antibacterial-specific measures. As a first step, it can begin periodic wastewater sampling to accurately quantify antibacterial discharge, in line with the 'stringent' WHO guidance, and ensure compliance with discharge limits directly in wastewater for all its own and its suppliers' sites. It can demonstrate progress by publicly reporting its antibacterial waste management practices, including compliance levels across its sites and suppliers', and the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

Aside from examples covered within the 2026 AMR Benchmark report analysis, no notable updates can be reported for Alkem since the *AMR Benchmark Opportunities: Company progress since 2021*, which was published in 2023.

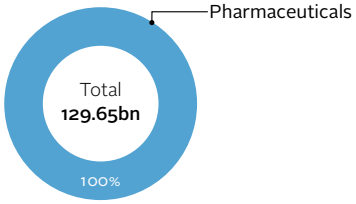
*For the 2026 AMR Benchmark, Alkem did not submit data.

Alkem Laboratories Ltd

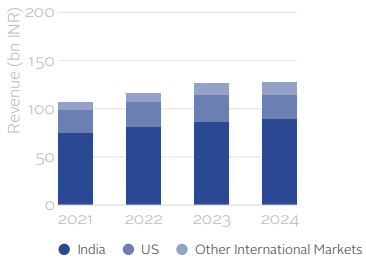
SALES AND OPERATIONS

Therapeutic areas: Anti-Infectives, cardiovascular, dermatology, diabetes, gastroenterology, gynecology, neurology, pain and analgesics, respiratory diseases
Product categories: Consumer health products, generic medicines & biosimilars
Investments in AMR: No notable investments identified.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Revenue by business segment (2025*) – INR



Revenue by geographic region – INR*



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*
Alkem has multiple products in its anti-infectives portfolio. However, it did not disclose the total number of products. The figure below shows a selection of products selected for analysis.

10 products selected for analysis

On Patent	Off Patent	Vaccines
None	• amoxicillin (*Access antibiotic*) • amoxicillin/clavulanic acid (*Access antibiotic*) • cefixime (*Watch antibiotic*) • cefotaxime (*Watch antibiotic*) • colistin (*Reserve antibiotic*) • fosfomycin (*Reserve antibiotic*) • isoniazid (*Antituberculosis medicine*) • linezolid (*Antituberculosis medicine*) • caspofungin (*Antifungal medicine*) • itraconazole (*Antifungal medicine*)	None

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1 ●	B.2 ●

Weak performance. Does not report an AMR-specific environmental risk management strategy at its own or suppliers' sites. It publicly reports initiating antibacterial discharge quantification at one site, although periodic quantification is lacking. As such, Alkem does not report the level of compliance achieved across its supply chain.

Mitigates AMR risk through general environmental risk management practices; does not track antibacterials' compliance with discharge limits. Alkem does not report, either publicly or to the Benchmark, an AMR-specific environmental risk management strategy, however, it publicly reports implementing ZLD technologies at 42% of its own sites. While no comprehensive strategy is in place, Alkem implements controls to minimise waste discharges and initiating a gap assessment with BSI Kitemark™ to assess antibacterial waste practices at 1 of its sites, including a CAPA plan. However, the company does not report periodically estimating antibacterial discharge at its own sites or at suppliers' sites. Therefore, it is unclear how many antibacterial products meet discharge limits at its own, or its suppliers' sites. No information could be identified on whether Alkem engages with external waste treatment plants to minimise AMR risk from manufacturing.

Publicly discloses limited details of its AMR mitigation strategy and is not transparent about compliance with discharge limits. Alkem publicly reports having made initial steps towards AMR mitigation (quantification at 1 manufacturing site, CAPAs), but any concrete periodic quantification of discharge levels or compliance with PNECs at its own sites or its suppliers' sites could not be identified. It therefore does not publicly disclose audit results with measured discharge levels. It does publicly disclose the city-level locations of its manufacturing sites (with 18 located in India and 2 in the US) and that 42% of its manufacturing sites have implemented ZLD, but it is unclear whether antibacterials are manufactured at these sites.

*In India, companies follow a financial year from April 1 to March 31, so their annual turnover and revenue figures (shown for 2025) may not align with other companies in the AMR Benchmark that report on a calendar-year basis (January–December) for which 2024 figures are shown.

Alkem Laboratories Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Weak performance. Performs poorly across the Appropriate Access and Stewardship Research Area, publicly reporting limited measures to mitigate stockouts and shortages and reporting GMP compliance only at its own sites. Its performance in stewardship can be improved, as it does not consider appropriate use across its business practices. Additionally, Alkem does not disclose, publicly or to the Benchmark, where it registers its products, nor does it report any access or stewardship strategies for the products assessed.

Alkem's performance on product registrations remains inconclusive. Alkem does not disclose any registration data to the Benchmark. Based on public information, it is unclear if Alkem engages in any mechanism to facilitate registrations for the products selected for analysis.

Below-average performance, with no evidence of access and stewardship strategies for its off-patent/generic antibacterial and antifungal medicines. Alkem has not disclosed, either publicly or to the Benchmark, access and stewardship strategies for any of the 10 products assessed in this category.

Limited action to mitigate stockouts/shortages. Limited reported evidence of systems to ensure product quality. Alkem publicly reports implementing strategies to promote supplier diversity by sourcing from local suppliers and working with multiple upstream suppliers. It reports that 90% of its input materials for Indian sites are sourced locally. However, there is no disclosure on demand planning or forecasting models implemented, buffer stock strategies, or the inventory management system used. It mitigates substandard and falsified products by implementing security features, such as holograms and security strips, and reports that all its sites are GMP compliant. However, it is unclear how many of its suppliers' sites are GMP compliant, or whether additional quality measures are implemented in countries with evolving regulatory systems.

Does not address appropriate use across its business practices. Alkem does not report, either publicly or to the Benchmark, whether it deploys sales agents and, if applicable, whether it decouples its incentives from sales volume targets or whether incentives are also linked to other qualitative measures. Through its global public policy Alkem ensures that interactions with HCPs are ethical. However, it does not include specific provisions supporting the appropriate use of antibacterial and antifungal medicines. Alkem does not voluntarily disclose transfers of value publicly in countries where it is not mandated by law, or by other codes of practice. Alkem applies its public policy to third parties working on its behalf. However, it is unclear if this is also the case for its sales incentive plan.

OVERALL PERFORMANCE

62%

Aurobindo Pharma Ltd

Generic medicine manufacturer

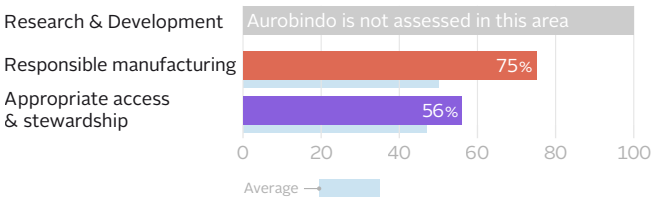
Stock exchange: NSE • Ticker: AUROPHARMA • HQ: Hyderabad, India • Employees: 40,000

PERFORMANCE IN THE 2026 BENCHMARK

Leads among generic medicine manufacturers. Aurobindo performs well across its evaluated Research Areas. It leads in Responsible Manufacturing among generic medicine manufacturers, reporting that all antibacterial products manufactured at its own and suppliers' sites are compliant with discharge limits, and demonstrating Best Practice for taking a hands-on approach to its suppliers' wastewater practices. Aurobindo performs at a mid-level in Appropriate Access & Stewardship. It registers its products in more countries than other assessed generic medicine manufacturers and demonstrates Best Practice through its portfolio-wide registration approach in East Africa and monitoring patient reach. However, there is room to strengthen its stewardship approach, as appropriate use is not consistently integrated across business practices.

How Aurobindo was evaluated

How score was achieved



OPPORTUNITIES FOR AUROBINDO

Expand appropriate access to paediatric formulations of antibacterial and antifungal medicines. Aurobindo registers its off-patent medicines in the highest number of countries among generic medicine manufacturers (19 LMICs on average), yet the company does not always register its child-friendly formulations in all of these countries. It can bridge this gap and expand access to paediatric formulations of its medicines through registration and implementing appropriate access strategies in at least the same countries it already registers the corresponding adult formulations.

Strengthen its governance of interactions with healthcare professionals. Aurobindo only includes clear principles governing interactions with healthcare professionals (HCPs) in its national public policy in the US. Aurobindo can strengthen its governance, and thereby address appropriate use of its antimicrobials, by clearly addressing interactions with HCPs globally and including specific provisions to ensure a legitimate need for such interactions; mitigate potential conflicts of interest – specifically between employees and HCPs; limit transfers of value and ensure these are paid at fair market value.

Ensure compliance with discharge limits directly in wastewater at all sites and improve transparency on levels of compliance achieved by its suppliers. Aurobindo reports 100% compliance with discharge limits set in the receiving environment for its own and its supplier's products based on mass balance estimations or directly in the wastewater under Zero Liquid Discharge conditions, but discloses this publicly only for its own products. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for both its own and suppliers' products – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

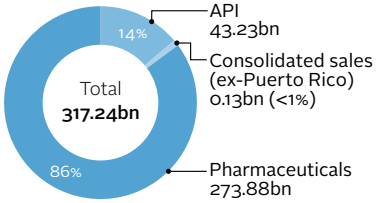
- In 2024, Aurobindo reported achieving Zero Liquid Discharge status at five of its manufacturing sites.

Aurobindo Pharma Ltd

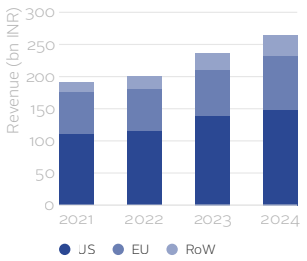
SALES AND OPERATIONS

Therapeutic areas: Anti-infectives, cardiovascular, central nervous system, dermatology, diabetes, gastroenterology, oncology, respiratory
Product categories: Generic medicines & biosimilars
Investments in AMR: No notable investments identified.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Turnover by business segment (2025*) – INR



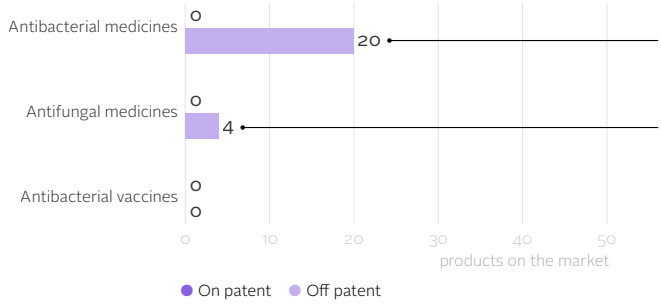
Revenue by geographic region – INR*



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

24 products in Aurobindo's anti-infective portfolio



8 products selected for analysis

amoxicillin (A), amoxicillin/clavulanic acid (A), cefuroxime (W), piperacillin/tazobactam (W), levofloxacin (T), moxifloxacin (T)

fluconazole (F), terbinafine (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Performs strongly. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at its own and suppliers' sites. It reports compliance of all antibacterial products manufactured at its own sites and its suppliers' sites. Aurobindo's incorporation of AMR provisions into supplier contracts, and its reporting on supplier compliance with discharge limits, is highlighted as a Best Practice in the Benchmark. Aurobindo publicly discloses the level of compliance achieved at its own sites, but not at its suppliers' sites, nor does it publicly share the quantification methods implemented.

Mitigates AMR risk at both its own sites and suppliers' sites; reports 100% of antibacterials are compliant with discharge limits. Aurobindo's environmental risk management strategy is based on the AMR Industry Alliance Standard (Industry Standard) and WHO guidance.
It has implemented ZLD systems at some antibiotic-producing sites, covering 7 of its 23 antibacterial products. Aurobindo estimates antibacterial discharges at its own sites using mass balance estimation; if PNECs are exceeded, chemical analysis is conducted and CAPA plans implemented. It reports that 100% of antibacterial products made at its own sites comply with discharge limits; 16 of 23 are compliant with PNECs in the receiving environment, where wastewater is already diluted. It reports wastewater is pretreated and sent to Common Effluent Treatment Plants (CETP) for further treatment prior to disposal. Contractual provisions require its sole antibacterial supplier to follow the Industry Standard and use PSCI-recommended quantification methods. Aurobindo also conducts supplier audits and reports that the supplier's product is compliant directly in the wastewater under ZLD conditions. Aurbobindo works with external wastewater treatment plants and reports employing measures to treat wastewater it sends to minimise AMR risk.

Publicly discloses basic details of its AMR mitigation strategy and 100% of its antibacterials are compliant with limits. Aurobindo publicly reports implementing the Industry Standard, quantifying discharge levels and achieving compliance with discharge limits in the receiving environment at 100% of its own sites. However, it does not disclose the audit results or actual discharge levels for its own operations or those of its suppliers. It does, however, publicly disclose the exact names and locations of its own sites by antibacterial product category, but not for its suppliers'.

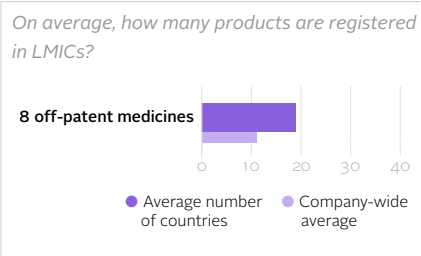
*In India, companies follow a financial year from April 1 to March 31, so their annual turnover and revenue figures (shown for 2025) may not align with other companies in the AMR Benchmark that report on a calendar-year basis (January–December) for which 2024 figures are shown.

Aurobindo Pharma Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Shows strong performance in registering its products in more countries on average compared to peers, as highlighted in a Best Practice in the Benchmark. Aurobindo also performs well in implementing general appropriate access and stewardship strategies and demonstrating efforts to monitor patient reach by tracking units sold at the country level for all eight products assessed. Its performance regarding stewardship is inconsistent, as appropriate use is considered in its sales practices, but not across its business practices.

Aurobindo registers its off-patent medicines more widely than its peers.



Aurobindo registers its off-patent medicines in 19 countries.* In many countries where the company registers its off-patent medicines, it also registers paediatric formulations. Its off-patent medicines targeting MDR-TB are registered in 9 countries, including 3 where the corresponding disease burden is high. For all products selected for analysis, Aurobindo engages in the East African Community Medicine Harmonization Programme to facilitate registrations in the region.

Average performance, with a general strategy to provide access to off-patent/generic products and high-level stewardship activities. Aurobindo implements the same access strategy across all 8 products assessed, participating in tenders in the public sector to promote competitiveness and more affordable prices, while also making the products available in the private sectors of the countries supplied. No further details on product- and country-specific strategies have been disclosed. The company demonstrates consistent efforts to monitor its access strategies by tracking units sold at the country level for all 8 products assessed. The company engages in some general stewardship activities for all products, such as responsible promotion and antimicrobial stewardship meetings with clinicians.

Strong efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Aurobindo implements demand planning and data sharing using a monthly rolling forecast with a long- to medium-range horizon. The plan is shared monthly with key internal stakeholders, including Customer Relations and Order Management teams. It also shares demand forecasts with external stakeholders. It maintains 5-6 month buffer stock for critical APIs and finished products. It implements an automated inventory management system with a demand-driven, buffer-based inventory approach, maintaining buffer above expected demand. It implements a diversified sourcing strategy for its critical antibacterial and antifungal medicines by prioritising local sourcing for key raw materials. For the products in scope, Aurobindo manufactures more than 96% of its APIs and 100% of finished products in-house. It mitigates substandard and falsified products by verifying suppliers through GMP audits. It also implements security features, such as serialised bar codes. However, it is unclear whether it takes additional mitigation steps in countries with evolving regulatory systems or informs relevant stakeholders when falsified medicine cases are identified.

Clearly addresses appropriate use in its sales practices, but not in its public policy. Aurobindo does not deploy sales agents to sell and/or promote its antibacterial and antifungal medicines to HCPs in most countries. In a few countries, a minor share of sales is made through sales agents, who promote a broad portfolio of products to HCPs, which includes antibacterial and antifungal medicines. For these agents, Aurobindo does not decouple incentives from sales volume targets. While Aurobindo does not apply its sales practices to third parties working on its behalf, it reports not paying incentives to third parties. Aurobindo's public policy on business ethics does not explicitly specify measures to ensure ethical interactions with HCPs. While Aurobindo abides by disclosure requirements, it does not voluntarily disclose transfers of value publicly in countries where it is not mandated to by law, or by other codes of practice.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

53%

Cipla Ltd

Generic medicine manufacturer

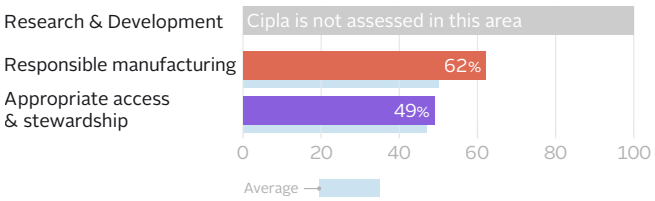
Stock exchange: NSE • Ticker: CIPLA • HQ: Mumbai, India • Employees: 45,189

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Cipla performs well in Responsible Manufacturing by publicly reporting all antibacterial products manufactured at its own sites comply with discharge limits, and demonstrating a Best Practice for taking a hands-on approach to its suppliers' wastewater practices. It has potential to strengthen performance in Appropriate Access & Stewardship, where its efforts are mixed. It performs strongly in ensuring continuous supply of its products in LMICs and demonstrates Best Practice for supporting diagnostic capacity to safeguard medicines against drug resistance. However, it registers its products in fewer countries than other assessed generic medicine manufacturers and can strengthen its access strategies for its on-patent medicines.

How Cipla was evaluated

How score was achieved



OPPORTUNITIES FOR CIPLA

Expand appropriate access to paediatric formulations of its off-patent antibacterial and antifungal medicines. Cipla registers its off-patent antibacterial and antifungal medicines in an average of six LMICs, yet the company does not always register child-friendly formulations in all of these countries. It can bridge this gap and expand access to paediatric formulations of its medicines through registration and implementing appropriate access strategies in at least the same countries it already registers the corresponding adult formulations.

Improve access to on-patent Reserve antibiotic plazomicin (Zemdri®) in LMICs, beyond India. Cipla only registers its on-patent Reserve antibiotic, plazomicin (Zemdri®), in India and its access strategy for the product remains unclear. Cipla can improve access to its product, indicated for complicated urinary tract infections in adults, by registering it in additional LMICs and implementing appropriate access and stewardship strategies – particularly for countries with a high unmet need.

Ensure compliance with discharge limits directly in wastewater at all sites and improve transparency on levels of compliance achieved by its suppliers. Cipla publicly reports 100% compliance with discharge limits set in the receiving environment for its own products based on mass balance estimations, or directly in the wastewater under Zero Liquid Discharge conditions. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for both its own and suppliers' products and require supplier compliance through contractual provisions – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

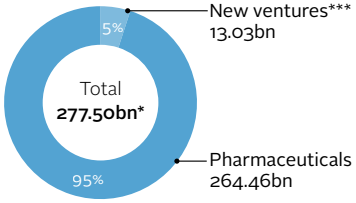
- In 2024, Cipla reported that 54% of its manufacturing sites had achieved Zero Liquid Discharge status.
- In June 2024, Cipla partnered with Orchid Pharma to launch antibiotic cefepime-enmetazobactam in India for the treatment of complicated urinary tract infections (cUTIs), hospital-acquired pneumonia and ventilator-associated pneumonia indications.
- In 2024, Cipla partnered with CSIR-CDRI to advance Ophthalmic Antifungal Treatment Development.
- In May 2025, Cipla launched ZEMDRI® (Plazomicin) in India, a novel treatment for cUTIs, including pyelonephritis, a severe kidney infection.

Cipla Ltd

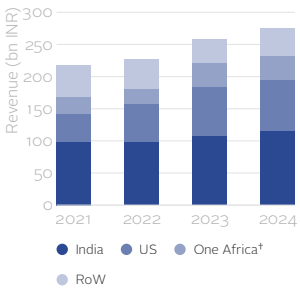
SALES AND OPERATIONS

Therapeutic areas: Anti-infectives, cardiovascular, central nervous system, dermatology, gastrointestinal, metabolic disorders, oncology, ophthalmology, orthopaedics, respiratory diseases, women's health, urology
Product categories: Consumer health products, diagnostics, generic medicines & biosimilars, innovative medicines, respiratory devices
Investments in AMR: No notable investments identified.
M&A news: In May 2024, Cipla acquired an additional stake in Achira Labs, increasing its holding to 27% (from 21% in June 2022). Achira develops point-of-care diagnostics for infectious diseases and AMR, enabling rapid pathogen identification to support timely, appropriate antibiotic use.

Revenue by business segment (2025) – INR**



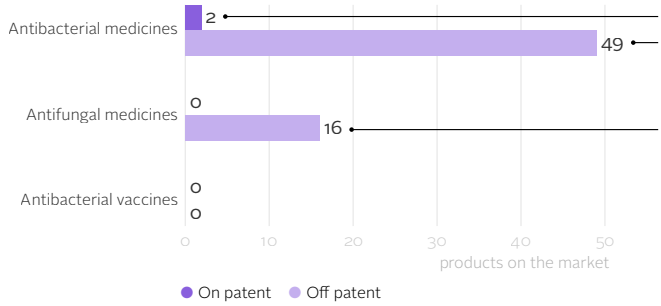
Revenue by geographic region – INR**



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

67 products in Cipla's anti-infective portfolio



12 products selected for analysis

cefepime/enmetazobactam (non-classified), plazomicin (R)
amoxicillin (A), amoxicillin/clavulanic acid (A), azithromycin (W), cefixime (W), ceftazidime/avibactam (R), colistin (R), amikacin (T), levofloxacin (T)

itraconazole (F), fluconazole (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic,
F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Performs well. Reports an environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports compliance with discharge limits at its own sites and its hands-on approach to supporting suppliers' wastewater management practices is highlighted as a Best Practice in the Benchmark. However, it does not report on supplier compliance and does not incorporate AMR provisions into supplier contracts. Cipla publicly discloses its quantification methods and the level of compliance achieved at its own sites, but not at its suppliers' sites.

Mitigates AMR risk at both its own sites and suppliers' sites; reports 100% of antibacterials are compliant with limits for its own sites and sets expectations for suppliers. Cipla's environmental risk management is based on the AMR Industry Alliance Standard (Industry Standard) and WHO guidance. It implements ZLD systems at 70% of its antibiotic manufacturing sites, all based in India. Cipla estimates antibacterial discharges at its own sites using mass balance, which are verified by chemical analysis annually. Cipla reports that 100% of antibacterial products manufactured at its own sites are compliant with PNECs in the receiving environment. At sites where ZLD systems are not installed, the wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured despite compliance in the receiving environment. Two of its products received a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification, namely azithromycin and ciprofloxacin. Cipla asks its suppliers to follow the Industry Standard and conducts capability building workshops. It also reports having reviewed discharge levels of its suppliers once. However, it does not report the number of antibacterials manufactured by its suppliers that comply with discharge limits and does not include AMR provisions in its supplier contracts. Cipla works with external wastewater treatment plants and reports employing measures to treat wastewater it sends to minimise AMR risk.

Publicly discloses basic details of its AMR mitigation strategy and 100% of its antibacterials are compliant with limits. Cipla publicly reports implementing the Industry Standard and ZLD systems at 67% of its manufacturing sites, quantifying discharge levels through mass balance methods – which is verified through chemical analysis – and achieving compliance with discharge limits in the receiving environment at 100% of its own sites. However, it does not disclose audit results or actual discharge levels for its own operations, or those of its suppliers, nor does it disclose details of the quantification methods used to assess antibacterial discharge levels. Additionally, the company does not publicly disclose the names and locations of its manufacturing sites for each manufactured antibacterial.

*The total of business segments is not equal to the total revenue (INR 275.48bn), due to the substraction of the inter segment revenue.

**In India, companies follow a financial year from April 1 to March 31, so their annual turnover and revenue figures (shown for 2025) may not align with other companies in the AMR Benchmark that report on a calendar-year basis (January-December) for which 2024 figures are shown.

***Includes operations of the Company, consumer healthcare, biosimilars and specialty business.

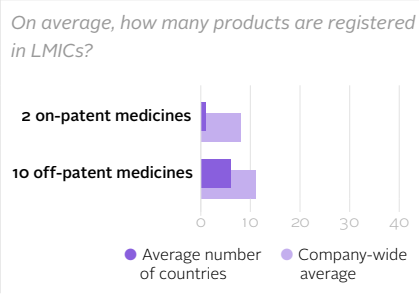
†South Africa reported separately until 2024–2025; One Africa (including South Africa, sub-Saharan Africa and Cipla Global Access) reported since.

Cipla Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1 ●	C.1.2 ●	C.1.3 ●	C.2.1 ●	C.2.2 ●	C.2.3 ●	C.3 ●	C.4 ●	C.5 ●

Low-performing. Shows strong performance in ensuring continuous supply, as it has a comprehensive approach to mitigate stockouts and shortages and ensures GMP compliance at its own and suppliers' sites. Its performance in implementing access and stewardship strategies is inconsistent, reporting limited access efforts for its on-patent medicines. However, Cipla's support of improved diagnostics for three assessed antibiotic medicines, two of which are classified as Reserve, in India is highlighted as a Best Practice in the Benchmark. Cipla can increase its registrations as it registers its products less widely compared to peers.

Cipla registers its on- and off-patent medicines in fewer countries than its peers.



Cipla registers its on-patent medicines in India and its off-patent medicines in 6 countries.* Of all the off-patent medicines assessed, a paediatric formulation of 1 medicine is registered in just 1 country in total. Its on- and off-patent Reserve antibiotics and medicines targeting MDR-TB are registered in 4 countries, including 2 countries where the corresponding disease burden is high. Specifically for its medicine targeting MDR-TB, levofloxacin, Cipla engages in WHO's Prequalification process to facilitate registrations.

Below-average performance, with stewardship strategies for 2 on-patent products assessed, but detailed access strategies are lacking. Cipla makes both products included in the analysis – plazomicin (Zemdri®) and cefepime-enmetazobactam (Cipenmet®; Esblocip®) – available in India; however, no data is reported on the access strategies applied to these products. Cipla demonstrates efforts to monitor its access strategies by reporting the number of units sold in India for both products during the period of analysis. For both products, the company implements stewardship strategies in India, focusing on responsible promotion and sales practices, as well as the availability of supportive diagnostic tools, such as sensitivity discs and E-strips.

Average performance, with access and stewardship strategies for 7 of 10 off-patent products assessed and outcomes reported for all 10. Cipla reports having access strategies for 7 of the 10 products assessed but shares limited information on these strategies. Most products are available in both the public and private sectors in India, while 2 – amikacin and colistin – are only supplied in the private sector. Cipla provides evidence of tracking its strategies by reporting units sold during the period of analysis for all 10 products. Cipla implements stewardship strategies for 7 products, most of which involve general activities targeting the responsible promotion of antibiotics. For the Reserve antibiotic, ceftazidime-avibactam, Cipla supported improved diagnostic capacity by providing hospitals with sensitivity discs and E-strips to facilitate the product's appropriate use.

Strong efforts to mitigate stockouts/shortages. Strong reported evidence of systems to ensure product quality. Cipla implements demand planning and data sharing through monthly demand forecasts, maintaining a 12-24 month rolling forecast for India and a 24-month forecast for Africa. These are shared with internal teams to inform procurement, capacity planning and manufacturing decisions. It maintains a buffer stock for critical APIs and finished products in India and South Africa. Its inventory management systems are tailored to market needs, with defined inventory norms and buffer stock strategies. In emerging markets, B2B production is based on confirmed orders to align supply with demand and prevent inventory build-up. For direct-to-market sales, inventory is managed using market-specific systems with predefined stock levels and buffer stock requirements aligned to local demand. It implements supplier diversification strategies in India by reducing dependency on Chinese suppliers, promoting domestic API manufacturing, identifying alternate sources for high-value and single-source APIs, and investing in in-house API production. It mitigates substandard and falsified products by verifying suppliers through GMP audits and reports cases to relevant stakeholders.

Includes elements to address appropriate use across its business practices. Cipla partly decouples incentives for its sales agents from sales volume targets. Less than 1% of variable pay is linked to sales volume targets. However, Cipla does not specify which other measures it links its incentives to. Through its global public policy, Cipla ensures ethical interactions with HCPs, and for certain interactions it sets limits for transfers of value (ToVs). While Cipla abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Cipla does not apply its public policy to third parties working on its behalf and it is unclear if this is the case for its sales incentive plan.

Active in 1 national AMR surveillance programme. *While Cipla is not assessed for its activities in AMR surveillance as a generic medicine manufacturer, its involvement in 1 AMR surveillance programme was identified during the period of analysis. Cipla collaborated with JMI Laboratories for the 'Plazomicin Surveillance Studies', which was part of its postmarketing surveillance requirements and ended in December 2023. The programme covered 8 genera of bacterial pathogens, 14 antibacterial medicines and 1 country. Aggregated data was shared through poster presentations at international conferences, funded by Cipla. The methods used to collect surveillance data are partially clear, including: which breakpoints are used and which healthcare facilities are selected.*

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

44%

Fresenius Kabi AG

Generic medicine manufacturer

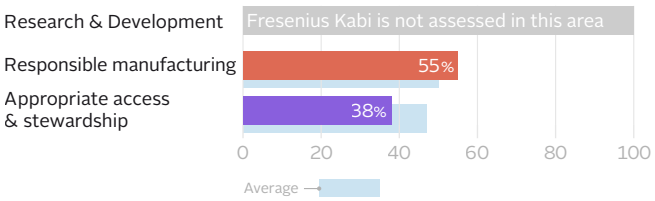
Stock exchange: XFRA • Ticker: FRE • HQ: Bad Homburg, Germany • Employees: 41,586

PERFORMANCE IN THE 2026 BENCHMARK

Low-performing. Fresenius Kabi is mid-performing in Responsible Manufacturing, where it reports partial compliance with discharge limits for the antibacterial products manufactured at its own and suppliers' sites. It has potential to strengthen performance in Appropriate Access & Stewardship, where its efforts are mixed. Although it registers its products in more countries than other assessed generic medicine manufacturers, it implements general but not product-specific stewardship strategies and reports limited measures to mitigate stockout and shortages of its products in LMICs.

How Fresenius Kabi was evaluated

How score was achieved



OPPORTUNITIES FOR FRESENIUS KABI

Expand registrations of its antibacterial and antifungal medicines. Fresenius Kabi registers its off-patent medicines in 12 LMICs, on average. It can expand appropriate access to its Reserve antibiotics, colistin and polymyxin b, which are registered in one country, by prioritising access in countries with high unmet need.

Track product-level patient reach for off-patent antibacterial and antifungal drugs. Fresenius Kabi has a general global strategy for expanding access to its medicines. However, it discloses an aggregate number of patients reached across its entire portfolio and does not disclose the methodology used to calculate it. Fresenius Kabi can improve this approach by reporting patient reach data at a more granular product- and country- level, which is essential for measuring both appropriate access and supporting responsible use of its medicines.

Implement wider strategies to mitigate stockouts and shortages. Fresenius Kabi reports implementing demand planning and maintaining buffer stocks of its products. To further mitigate shortage risks, the company can implement several strategies. These include establishing two-way data-sharing arrangements with local stakeholders – focusing specifically on regions with developing forecasting capabilities – to gather more accurate and reliable local demand indications. Furthermore, where feasible, it can strategically build supplier redundancies for critical antimicrobials and implement additional quality controls at manufacturing sites or supplier facilities when sourcing locally from LMICs with evolving regulatory systems.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved. Fresenius Kabi reports 49% compliance with discharge limits set in the receiving environment for its own products, based on mass balance estimations, and 86% compliance for its suppliers' products. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products and require supplier compliance through contractual provision – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

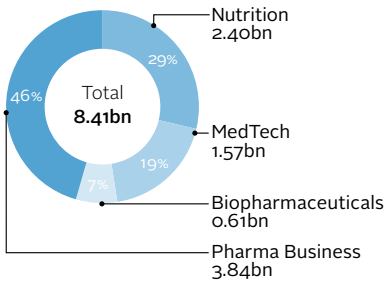
- As of 2025, Fresenius Kabi has earned four BSI Kitemark™ Certifications for Minimized Risk of AMR. These include certifications for ceftriaxone, manufactured at its site in Portugal; amikacin, manufactured at its site in Austria; and linezolid and amikacin, manufactured at its site in Poland.
- In November 2025, the US Food and Drug Administration (FDA) approved Dalbavancin for Injection (for single-dose regimen use only) – a generic formulation of the FDA reference-listed drug Dalvance® – for the treatment of acute bacterial skin and skin structure infections in adult and paediatric patients.

Fresenius Kabi AG

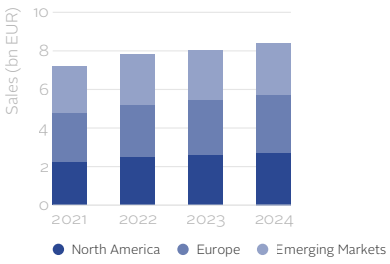
SALES AND OPERATIONS

Therapeutic areas: Anaesthetics & analgesics, anti-infectives, autoimmune diseases, critical care, cell therapies, diabetes, hematology, immunology, infusion therapies, oncology, osteoporosis
Product categories: Consumer health products, generic medicines & biosimilars, medical devices
Investments in AMR: No notable investments identified.
M&A news: In September 2024, Fresenius Kabi divested its subsidiary Laboratorio Sanderson in Chile, which manufactures and supplies hospital antimicrobial injectables across Chile and the wider Latin American region, to Medifarma.

Revenue by business segment (2024) – EUR



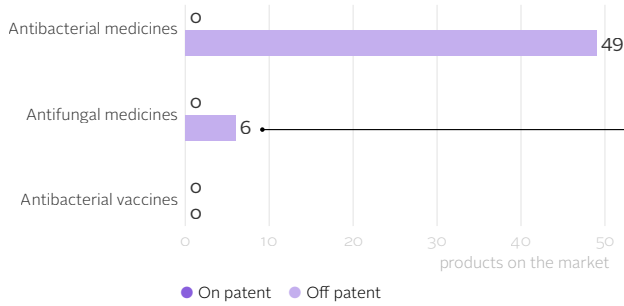
Sales by geographic region – EUR



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

55 products in Fresenius Kabi's anti-infective portfolio



10 products selected for analysis

- Antibacterial medicines: doxycycline (A), metronidazole (A), meropenem (W), piperacillin/tazobactam (W), colistin (R), polymyxin b (R), linezolid (T), moxifloxacin (T)
- Antifungal medicines: fluconazole (F), micafungin (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Mid-performing. Reports an environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports the level of compliance achieved at its own and suppliers' sites but does not incorporate AMR provisions into supplier contracts. Fresenius Kabi publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own its sites and suppliers' sites; tracks compliance of antibacterials with discharge limits. Fresenius Kabi's environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). To measure discharge levels at its sites, it uses mass balance estimation, chemical analysis, or both – initially over 1 year, then at a risk-based frequency. If PNECs are exceeded, CAPAs are implemented. Fresenius reports 49% of its antibacterial products are compliant in the receiving environment. It has received 4 BSI Kitemark™ Certifications for Minimized Risk of AMR. The company requires its antibacterial suppliers to follow the Industry Standard and to implement estimation methods recommended by the PSCI. It conducts supplier audits based on PSCI compliance but does not include AMR provisions in its supplier contracts. It reports 86% of its suppliers' antibacterial products are compliant in the receiving environment. The company works with external wastewater treatment plants and reports requesting information from them to inform quantification of discharge levels. It also employs measures to treat wastewater it sends to external plants.

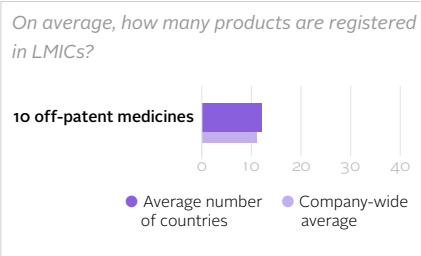
Publicly discloses basic details of its AMR mitigation strategy but is not transparent about compliance with discharge limits. Fresenius Kabi publicly reports implementing the Industry Standard and quantifying discharge levels using mass balance estimation. However, it does not disclose audit results, the number of products complying with PNECs, or the names and locations of manufacturing sites for each manufactured antibacterial.

Fresenius Kabi AG

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Low-performing. Performs well in registration by registering its products in more countries on average compared to peers. It also does well in stewardship, as it considers appropriate use across its business practices. However, Fresenius Kabi can improve in implementing product-specific access and stewardship strategies, as it only follows a general global strategy for expanding access, and provides a patient reach number at an aggregated level. Its measures to mitigate stockouts and shortages are limited.

Fresenius Kabi registers its off-patent medicines more widely than its peers.



Fresenius Kabi registers its off-patent medicines in 12 countries.* No paediatric-specific products from the company were assessed. Its Reserve antibiotics and medicines targeting MDR-TB are registered in 6 countries, including 2 countries where the corresponding disease burden is high. Fresenius Kabi does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Below-average performance, with a global access strategy but no reporting on any stewardship initiatives or outcomes data for off-patent/generic antibacterial and antifungal medicines. For all 10 products assessed Fresenius Kabi only discloses a general global strategy for expanding access, which includes participation in government tenders. The company does not report any country- or product-specific data for its access and stewardship strategies. Fresenius Kabi reports only an aggregated number of patients reached across its entire portfolio and provides no details on the methods or metrics used to monitor its strategies.

Limited action to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Fresenius Kabi implements demand planning and maintains buffer stocks of its products. However, it does not report on the inventory management system it uses, or any supplier diversification efforts to mitigate stockouts and shortages in the countries in scope. Fresenius Kabi reports conducting GMP audits to verify supplier credentials and reports cases of substandard incidents to relevant authorities. It also implements track-and-trace systems and smart labels, but this is mentioned in the context of streamlining the delivery process rather than mitigating instances of drug falsification.

Includes elements to address appropriate use across its business practices. Fresenius Kabi does not deploy sales agents to sell and/or promote the majority of its antibacterial and antifungal medicines in most countries. Where sales agents are deployed, Fresenius Kabi partly decouples incentives for its sales agents from sales volume targets and targets are set at the group or business segment level. 15% of variable pay is linked to achieving sustainability measures (ESG targets). Through its global policy, Fresenius Kabi ensures all interactions with HCPs are ethical by ensuring that transfers of value (ToVs) are made at fair market value. While Fresenius Kabi abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Fresenius Kabi does not apply its public policy to third parties working on its behalf and it is unclear if this is the case for its sales incentive plan.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

44%

Hikma Pharmaceuticals plc

Generic medicine manufacturer

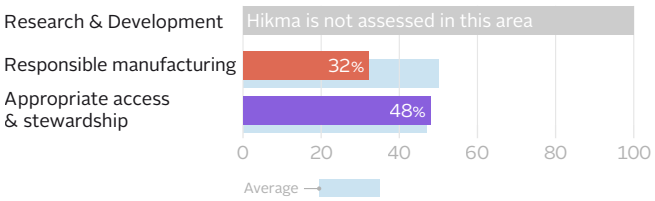
Stock exchange: LSE • Ticker: HIK • HQ: London, UK • Employees: 9,500

PERFORMANCE IN THE 2026 BENCHMARK

Low-performing. Hikma has opportunities to improve in Responsible Manufacturing as it does not report an AMR-specific environmental risk management strategy to ensure responsible manufacturing practices or the level of compliance with discharge limits achieved at its own sites. It also has potential to strengthen performance in Appropriate Access & Stewardship, where it shows mixed efforts. Although, it performs well in appropriate access strategies and monitoring patient reach for off-patent products, it could improve by making its stewardship approach more consistent and expanding registrations, as its products are registered in fewer countries than other assessed generic medicine manufacturers.

How Hikma was evaluated

How score was achieved



OPPORTUNITIES FOR HIKMA

Expand registrations to its off-patent antibacterial and antifungal medicines across the MENA region. Hikma has a strong presence in the Middle East and North Africa (MENA) region, which the company can utilise to further expand access to antimicrobial medicines across the region. Hikma performs well in its appropriate access strategies for off-patent antibacterial and antifungal medicines but only registers them in 4 LMICs on average. It can register its products more consistently across the MENA region and continue to also register child-friendly registrations in those same countries.

Strengthen stewardship strategies for on-patent antibiotics. Hikma has two on-patent Reserve antibiotics in its portfolio: meropenem-vaborbactam (Vabomere®) and oritavancin (Orbactiv®). Both are indicated for serious infections caused by resistant bacteria and are especially important given the high incidence of drug-resistance in the MENA region. However, currently, Hikma's stewardship strategies for the products lack depth and only report engaging in responsible business practice activities. Hikma can strengthen its stewardship strategies by engaging in surveillance and ensuring the availability of supportive diagnostics, to ensure these products stay effective for as long as possible.

Formalise comprehensive environmental risk management strategy to mitigate AMR and improve transparency on antibacterial waste management practices. Hikma reports implementing general controls to minimise waste discharges, but not antibacterial-specific measures. As a first step, it can begin periodic wastewater sampling to accurately quantify antibacterial discharge, in line with the 'stringent' WHO guidance, and ensure compliance with discharge limits directly in wastewater for all its own and its suppliers' sites. It can demonstrate progress by publicly reporting its antibacterial waste management practices, including compliance levels across its sites and suppliers', and the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

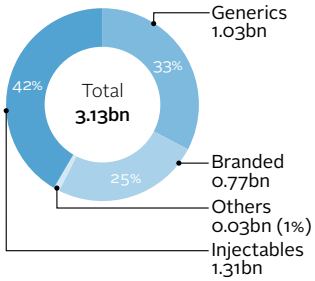
Hikma is newly assessed in the 2026 AMR Benchmark. The company was not evaluated in the 2021 AMR Benchmark or in *AMR Benchmark Opportunities: Company progress since 2021*, which was published in 2023. As such, there are no changes reported for Hikma as there are no comparative progress updates to be made.

Hikma Pharmaceuticals plc

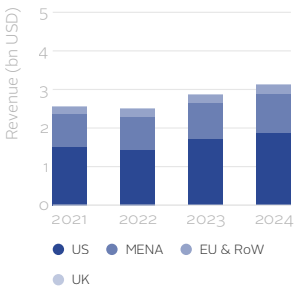
SALES AND OPERATIONS

Therapeutic areas: Anti-infectives, cardiovascular, central nervous system, diabetes, gastrointestinal, respiratory diseases, oncology, and others
Product categories: Generic medicines & biosimilars, innovative medicines (in-licensed)
Investments in AMR: No notable investments identified.
M&A news: In September 2024, Hikma acquired Xellia Pharmaceuticals' US finished dosage form business and related assets, including its anti-infective products, such as the ready-to-use formulation, Vanco Ready® (vancomycin), launched in 2019.

Revenue by business segment (2024) – USD



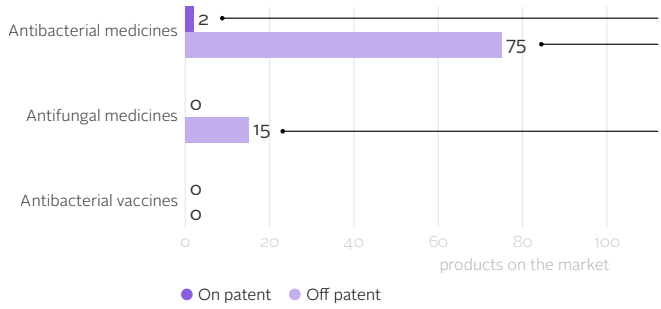
Revenue by geographic region – USD*



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

92 products in Hikma's anti-infective portfolio



11 products selected for analysis

meropenem/vaborbactam (R), oritavancin (R)
amoxicillin/clavulanic acid (A), metronidazole (A), azithromycin (W), cefixime (W), colistin (R), linezolid (T), meropenem (T)
fluconazole (F), micafungin (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Low-performing. Does not report an AMR-specific environmental risk management strategy at its own sites. For its own sites, it does not report periodically quantifying antibacterial discharge levels. For its suppliers, AMR-mitigation strategies and the level of compliance achieved are reported.

Reports a general environmental risk management strategy, without a specific aim to limit AMR. Hikma does not report implementing waste treatment practices specifically aimed at reducing AMR risk from antibacterial discharge at its own sites. It reports adopting wastewater quality limits in alignment with World Bank Group guidelines, but these practices do not explicitly address antibacterial discharge or AMR-specific risks. Equally, the company does not report estimating antibacterial discharge at its own sites or assessing levels against PNECs. Therefore, it is unclear how many antibacterial products comply with discharge limits at its own sites. While Hikma does not specifically require suppliers to implement antibacterial waste practices, it does report that some of its suppliers have practices in place. For example, its amoxicillin suppliers conduct monthly sampling at all sites and estimate discharge levels in line with the AMR Industry Alliance Antibiotic Manufacturing Standard and are compliant with PNECs. All its other antibacterial suppliers implement ZLD systems. However, the company does not include AMR provisions in its supplier contracts. No information could be identified on whether Hikma works with external waste treatment plants to minimise AMR risk from manufacturing.

No publicly available information on environmental risk management to mitigate AMR. Hikma does not publicly report quantification of antibacterial discharge levels at its own sites, or its suppliers' sites, and therefore does not publicly disclose audit results, measured discharge levels, or the names and locations of manufacturing sites for each antibacterial product.

*From 2023 onwards, Hikma started including Canada in North America's revenue (previously in Europe and RoW). Here the categories have been kept as they were previously, and continued to include Canada in RoW (Canada revenue – 2024: $24M; 2023: $23M; 2022: $18M).

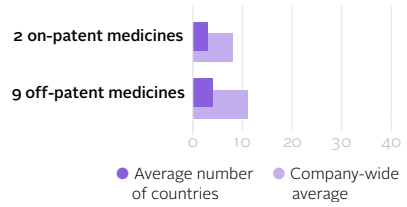
Hikma Pharmaceuticals plc

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Low-performing. Performs well in implementing appropriate access strategies for all products assessed and using a standardised methodology for calculating patient reach across its off-patent portfolio. However, its product-specific stewardship efforts are limited and only implemented for its on-patent medicines. Hikma's performance regarding stewardship is inconsistent, as appropriate use is considered in its sales practices, but not across its business practices. It has an opportunity to expand registrations, as it registers its products in less countries on average compared to peers.

Hikma registers its on- and off-patent medicines in fewer countries than its peers.

On average, how many products are registered in LMICs?



Hikma registers its on-patent medicines in 3 countries* and its off-patent medicines in 4 countries. In many countries where Hikma registers its off-patent medicines, it also registers paediatric formulations. Its on- and off-patent Reserve antibiotics and medicines targeting MDR-TB are registered in 3 countries, with 1 product (linezolid) being registered in a total of 1 country with a corresponding high disease burden (Iraq). Hikma does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Average performance, with access strategies reported and monitored for 2 on-patent products assessed, but limited stewardship activities. Both products assessed, 2 Reserve antibiotics, are available only in the private market in Jordan. For oritavancin (Orbactiv®), Hikma provides a 35% discount on the list price and is also working on its inclusion in army hospitals, which cover more than 25% of the population.

The company monitors the performance of its strategies by tracking the number of vials supplied to hospitals each month, and by monitoring pharmacies' stock availability and the number of patients actively receiving treatment. Hikma reports the number of vials supplied for both products during the period of analysis. However, considering that both products are Reserve antibiotics, the company shows limited stewardship efforts, only implementing responsible promotion strategies.

Above-average performance, implementing and monitoring access strategies for all 9 off-patent/generic products assessed, but no evidence of engaging in stewardship activities. Hikma has access strategies for all 9 products assessed, but 8 are only available in the private sectors of the country examples analysed, and limited details are provided. For one product, amoxicillin/clavulanic acid, Hikma is the sole supplier in Jordan's national tender, making the company responsible for providing the product to most of the population covered by public insurance. The company shows consistent efforts in monitoring its strategies by applying a standardised methodology to calculate patient reach, and reporting the units sold or patients reached during the period of analysis for all 9 products. However, Hikma does not demonstrate any evidence of implementing stewardship strategies for any of the 9 products.

Strong efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Hikma implements demand planning and data sharing through a monthly rolling forecast with a 24-month horizon and creates a 5-year business plan for each product. However, it is unclear whether the company shares this information with relevant internal or external stakeholders. Hikma reports implementing an automated inventory management system and implementing buffer stock strategies tailored to each product, based on its value and demand predictability. It also reports implementing strategies to promote supplier diversity by sourcing its APIs from multiple upstream suppliers, with 59-60% of spending going to local suppliers in the MENA region. It mitigates substandard and falsified products by verifying suppliers through GMP audits, reports incidents to relevant authorities and implements security features, such as serialised barcodes, track-and-trace systems and smart labels. However, it does not disclose any additional quality measures implemented in countries with evolving regulatory systems.

Includes elements to address appropriate use in its sales practices, but not in its public policy. Hikma partly decouples incentives for its sales agents from sales volume targets, and targets are set at the individual level. Hikma does not report the proportion of variable pay it links to sales volume targets, nor does it specify any other measures that it links to incentives. Through its global public policy, Hikma ensures that interactions with HCPs are ethical. However, it does not include specific provisions supporting the appropriate use of antibacterial and antifungal medicines. While Hikma abides by disclosure requirements, it does not voluntarily disclose transfers of value publicly in countries where it is not mandated to by law, or by other codes of practice. Hikma applies its public policy to third parties working on its behalf. However, it is unclear if this is also the case for its sales incentive plan.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'. Hikma has a sales presence in 18 of these countries although, globally, it sells its products in 56 countries.

OVERALL PERFORMANCE

60%

Sandoz

Generic medicine manufacturer

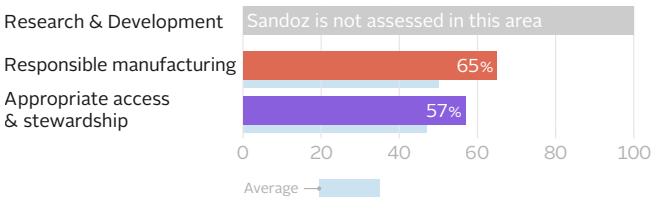
Stock exchange: SIX • Ticker: SDZ• Basel, Switzerland • Employees: 23,000

PERFORMANCE IN THE 2026 BENCHMARK

Performs well. Sandoz performs well in Responsible Manufacturing, reporting that all antibacterial products manufactured at its own and suppliers' sites are compliant with discharge limits, and demonstrating Best Practice for taking a hands-on approach to its suppliers' wastewater practices. It is mid-performing in Appropriate Access & Stewardship. Although it also demonstrates Best Practice for transparently publishing transfers of value in multiple countries, registers its products in more countries than other assessed generic medicine manufacturers and monitoring patient reach, it does not report product-specific access strategies.

How Sandoz was evaluated

How score was achieved



OPPORTUNITIES FOR SANDOZ

Ensure appropriate access to its antibacterial and antifungal medicines. Sandoz registers its off-patent medicines in 12 LMICs, on average, and stands out for consistently registering its child-friendly formulations across the same countries. However, for five products there is a gap between the countries where they are registered and supplied. It can bridge this gap by ensuring its medicines are consistently supplied in countries where it registers its products, for example, in sub-Saharan African countries where the burden of AMR is disproportionally high.

Strengthen its governance of interactions with healthcare professionals. Through its public policy governing interactions with healthcare professionals, Sandoz already ensures that such interactions are based on a legitimate need and that transfers of value (ToVs) are made at fair market value. Sandoz can strengthen its policy, and thereby address appropriate use of its antimicrobials, by including provisions to specifically mitigate potential conflicts of interests betweeen employees and healthcare professionals and by setting limits on ToVs.

Ensure compliance with discharge limits directly in wastewater and improve transparency on antibacterial waste management practices. Sandoz reports 100% compliance with discharge limits set in the receiving environment for its own and its suppliers' products. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

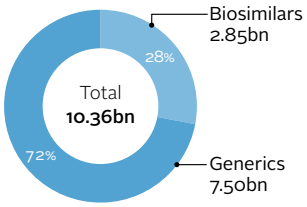
Sandoz is newly assessed in the 2026 AMR Benchmark. The company was not evaluated in the 2021 AMR Benchmark or in *AMR Benchmark Opportunities: Company progress since 2021*, which was published in 2023. As such, there are no changes reported for Sandoz as there are no comparative progress updates to be made.

Sandoz

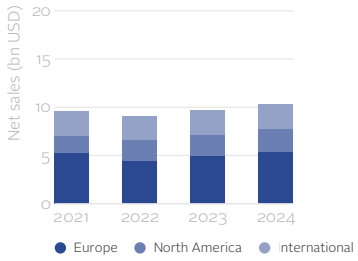
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, central nervous system, dermatology, endocrinology, gastroenterology, infectious diseases, oncology, ophthalmology, respiratory diseases, rheumatology, women's health
Product categories: Consumer health products, generic medicines & biosimilars, medical devices
Investments in AMR: In June 2024, Sandoz invested EUR 50mn to open a new facility for penicillins in Kundl, Austria. The new facility adds 20% to its current annual production capacity. The investment is the final part of a EUR 200mn total investment in its Kundl site to upgrade penicillin API manufacturing and increase the output of finished products.
M&A news: In April 2024, Sandoz's Chinese business, including its portfolio of established products such as the antifungal voriconazole and its product pipeline, was acquired by Aspen Pharmacare Holdings.

Net sales by business segment (2024) – USD



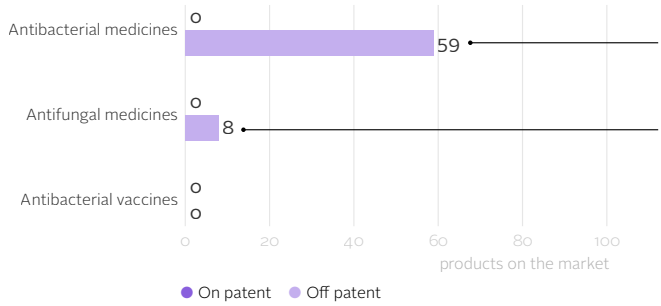
Net sales by geographic region – USD



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

67 products in Sandoz's anti-infective portfolio



9 products selected for analysis

amoxicillin (A), amoxicillin/clavulanic acid (A), azithromycin (W), ciprofloxacin (W), linezolid (R), ethambutol (T), rifampicin (T)

fluconazole (F), micafungin (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1 ●	B.2 ●

Performs well. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports compliance with discharge limits of all antibacterial products manufactured at both its own and suppliers' sites. In addition, Sandoz' incorporation of AMR provisions into supplier contracts, and its hands-on approach to supporting suppliers' wastewater management practices, is highlighted as a Best Practice in the Benchmark. It publicly discloses the quantification methods implemented and the level of compliance achieved across its own sites, but not across its supplier sites.

Mitigates AMR risk at both its own sites and suppliers' sites; reports 100% of antibacterials are compliant with discharge limits. Sandoz's comprehensive environmental risk management is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). The company estimates antibacterial discharge levels annually at its own sites using mass balance estimation; if PNECs are exceeded, chemical analysis is performed for verification and CAPAs are implemented (e.g., introduction of additional pretreatment and cleaning steps). Sandoz reports that all its products manufactured at its own sites are compliant with discharge limits in the receiving environment, where wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured. 9 products received a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification. Sandoz requires its antibacterial suppliers to follow the Industry Standard and introduced contractual provisions that encompass compliance with discharge limits. It reviews discharge levels through supplier audits and, if PNECs are exceeded, it requires suppliers to implement CAPAs (e.g., improving spill containment and cleaning practices). Sandoz reports that all its suppliers' products comply with discharge limits in the receiving environment. The company employs conservative measures

Sandoz

RESPONSIBLE MANUFACTURING *CONTINUED*

to ensure PNEC compliance of wastewater prior to sending it to plants and reports testing the wastewater of 1 plant biannually.

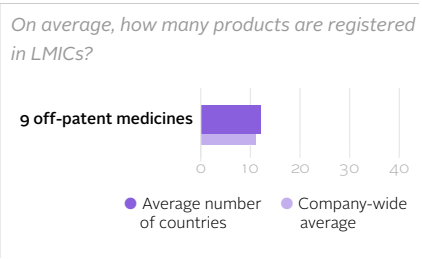
Publicly discloses basic details of its AMR mitigation strategy and is not publicly transparent about suppliers' compliance with discharge limits. Sandoz publicly reports implementing the Industry Standard and quantifying discharge levels using mass balance estimation, which is verified through chemical analysis. For both its own sites and its suppliers' sites, it publicly reports conducting onsite audits on PNEC compliance but only discloses the number of own sites that are compliant. The audit results with the actual discharge levels are not publicly disclosed, nor are the number of its products complying with PNECs or the names and locations of manufacturing sites for each antibacterial product.

APPROPRIATE ACCESS & STEWARDSHIP

Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
	●	●	●	●	●	●	●	●	●

Mid-performing. Shows strong performance in ensuring continuous supply, as it has a comprehensive approach to mitigate stockouts and shortages. It also performs well by registering its products more widely compared to peers and using a standardised methodology for calculating patient reach across its portfolio. Its transparency in reporting transfers of value to ensure appropriate use is highlighted as a Best Practice in the Benchmark. However, Sandoz does not disclose whether it tailors access strategies to specific products or countries, reporting only general access strategies.

Sandoz registers its off-patent medicines more widely than its peers.



Sandoz registers its off-patent medicines in 12 countries.* In most countries where Sandoz registers its off-patent medicines, it also registers paediatric formulations. Its sole Reserve antibiotic, linezolid, is registered in a total of 2 countries. Sandoz does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Average performance, with general strategies to ensure access and stewardship for 9 off-patent/generic products assessed. Sandoz did not disclose whether it tailors strategies to expand access for specific products or countries. It does cite strategic partnerships as one of the key ways to expand access to its 9 products, including partnerships with Americares and Direct Relief to donate medicines to patients affected by humanitarian crises. 2 products – amoxicillin and azithromycin – have been donated to 30 and 16 LMICs, respectively. Sandoz has a standardised methodology to measure patient reach and reports the corresponding numbers at the country level for all 9 products. For 1 product, micafungin, Sandoz reports product-specific responsible promotion activities during its launch in the Philippines. However, for the 8 remaining products, Sandoz only reports a general portfolio-wide approach focused on responsible promotion and sales.

Strong efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Sandoz implements demand planning and data sharing by conducting 3-year forecasts with monthly updates, as well as annual long-term demand forecasting of up to 10 years. It receives real country-level demand forecasts and utilises public/private databases to provide supply forecasts of several weeks to authorities. It maintains buffer stock for its key APIs and drug products, but it is unclear whether an automated inventory system is implemented. It implements supplier diversification strategies for its key APIs and drug product, including dual sourcing, manufacturing line redundancies within the same factory and prioritising local sourcing. Sandoz mitigates substandard and falsified products by verifying suppliers through GMP audits and reporting incidents to relevant authorities. It reports that all its own and its suppliers' sites are GMP compliant. However, it is unclear whether the company takes additional mitigation steps in countries with evolving regulatory systems.

Includes elements to address appropriate use across its business practices. While Sandoz's sales incentive plan differs by country and sales role, it at least partly decouples incentives for its sales agents from sales targets in some countries. Sandoz does not report the proportion of variable pay it links to sales targets, nor does it specify any other measures that it links to incentives for any country. Sales targets can be set at the individual or on an aggregated level, or a combination of both. Through its global public policy, Sandoz ensures ethical interactions with HCPs, and for certain interactions it requires a defined legitimate need. It also ensures that transfers of value (ToVs) are made at fair market value. The full list of countries where Sandoz is disclosing ToVs can be easily accessed on its website. In Canada, Japan, Iceland and Ukraine, Sandoz voluntarily discloses information on ToVs. Sandoz applies its public policy to third parties working on its behalf. However, it is unclear if this is also the case for its sales incentive plan.

Active in 2 multi/national AMR surveillance programmes. *While Sandoz is not assessed for its activities in AMR surveillance as a generic medicine manufacturer, its involvement in 2 AMR surveillance programmes was identified during the period of analysis. Since 2024, Sandoz has collaborated with JMI Laboratories for the 'International Surveillance Progamme for Micafungin', which runs under the umbrella of the 'SENTRY Antimicrobial Surveillance Programme', covering 1 genus of fungal pathogens, 1 antifungal medicine, and countries from North America, Europe, Latin America and Asia-Pacific regions. Aggregated data will be published as part of the ongoing data sharing via SENTRY's website. In addition, Sandoz funds the KOROUN study, which conducts national surveillance of bacterial infections in Poland. Aggregated data from this programme can be accessed via journal articles and on the programme's website. The methods used to collect surveillance data for the 'International Surveillance Programme for Micafungin' are in line with SENTRY methods and are therefore largely clear. The methods used for KOROUN are only partially clear.*

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

38%

Sun Pharmaceutical Industries Ltd

Generic medicine manufacturer

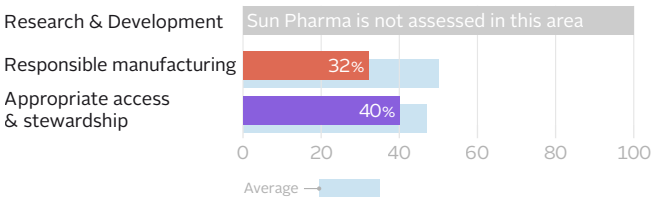
Stock exchange: NSE • Ticker: SUNPHARMA • HQ: Goregaon, India • Employees: 43,000

PERFORMANCE IN THE 2026 BENCHMARK

Low-performing. Sun Pharma has opportunities to improve in Responsible Manufacturing, reporting an environmental risk management strategy aimed at mitigating AMR at its own but not at its suppliers' sites. It also has potential to strengthen performance in Appropriate Access & Stewardship, where its efforts are mixed. Although it performs well in its efforts to mitigate stockouts and shortages of its products in LMICs, it registers its products in fewer countries than other assessed generic medicine manufacturers and implements access and stewardship strategies for less than half of the products assessed.

How Sun Pharma was evaluated

How score was achieved



OPPORTUNITIES FOR SUN PHARMA

Expand appropriate access to paediatric formulations of its antibacterial and antifungal medicines. Sun Pharma registers its off-patent medicines in an average of eight LMICs, yet it only registers child-friendly formulations of its Access antibiotics in India. It can bridge this gap and expand access to paediatric formulations by registering them more widely and implementing appropriate access strategies in at least the same countries where it already registers the corresponding adult formulations.

Expand patient reach monitoring to all off-patent antibacterial and antifungal medicines. Sun Pharma reports the number of patients reached for one on-patent and one off-patent medicine only but does not do so consistently across its off-patent portfolio. It can improve its approach to tracking patient reach – which is essential to enable measurement of appropriate access and support the responsible use of its medicines – by tracking patient reach consistently across its entire portfolio, at both the product- and country-level.

Strengthen its responsible business practices. Sun Pharma does not decouple incentives for its sales agents from sales volume targets. It can start ensuring its sales practices do not incentivise misuse or overuse of its antibacterial and antifungal medicines by at least beginning to decouple incentives from sales volume targets or stop deploying sales agents for these medicines altogether. Moreover, Sun Pharma can strengthen its public policy governing interactions with healthcare professionals (HCPs), and thereby address appropriate use of its antimicrobials, by including provisions to mitigate potential conflicts of interest – specifically between employees and HCPs; limit transfers of value and ensure these are made at fair market value.

Ensure compliance with discharge limits directly in wastewater at supplier sites and improve transparency on antibacterial waste management practices. Sun Pharma reports 100% compliance with discharge limits directly in the wastewater for its own sites under Zero Liquid Discharge conditions, but it does not report supplier site compliance. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for its suppliers' sites and require supplier compliance through contractual provisions – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance. It can also publicly report the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

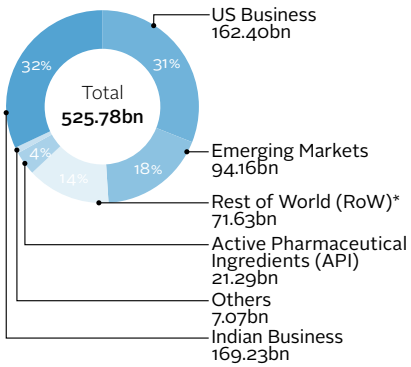
- In 2024 in India, Sun Pharma launched tedizolid phosphate (STARIZO®) – a new antibiotic targeting acute bacterial skin and skin structure infection – under a licensing agreement with MSD.

Sun Pharmaceutical Industries Ltd

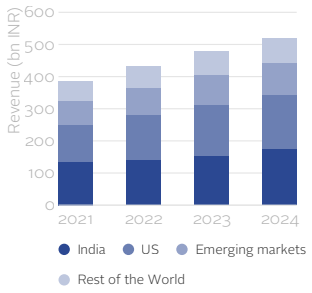
SALES AND OPERATIONS

Therapeutic areas: Anti-infectives, cardiology, dental, dermatology, diabetes, gastroenterology, gynaecology, nephrology, neurology, oncology, ophthalmology, psychiatry, respiratory diseases, urology
Product categories: Generic medicines & biosimilars
Investments in AMR: No notable investments identified.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Revenue by business segment (2025) – INR**



Revenue by geographic region – INR**



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*
Sun Pharma has multiple products in its anti-infectives portfolio. However, it did not disclose the total number of products. The figure below shows a selection of products selected for analysis.

8 products selected for analysis

On Patent	Off Patent	Vaccines
• tedizolid (Reserve antibiotic)***	• amoxicillin (*Access antibiotic*) • amoxicillin/clavulanic acid (*Access antibiotic*) • ciprofloxacin (*Watch antibiotic*) • clarithromycin (*Watch antibiotic*) • levofloxacin (*Antituberculosis medicine*) • itraconazole (*Antifungal medicine*) • voriconazole (*Antifungal medicine*)	None

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1 ●	B.2 ●

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR risk at its own sites, but not at its suppliers'. It reports compliance with discharge limits across all its own sites. For its suppliers, it does not report the level of compliance achieved and does not incorporate AMR provisions into contracts. It does not publicly disclose the quantification methods implemented, or the level of compliance achieved across its supply chain.

Basic environmental risk management to mitigate AMR at its own sites but not suppliers'; initial stages of discharge quantification, tracks compliance of antibacterials with discharge limits for its own sites. Sun Pharma reports adopting management and treatment practices for wastewaters and solid wastes from antibiotic manufacturing to minimise the impact of antibacterial discharge to the environment based on the PSCI principles. This includes mass balance estimation and complying with discharge limits based on PNECs. The company reports initiating the quantification of the concentration of antibiotics in wastewaters for its own sites, but no details on the quantification methods implemented are known. It reports implementing ZLD systems at all its antibacterial manufacturing sites, therefore complying with PNECs outlined in the PSCI guidance. The company does not report reviewing antibacterial discharge at its supplier sites. Therefore, it is unclear how many antibacterial products meet discharge limits at its supplier sites. Sun Pharma reports that its wastewater is treated in an internal wastewater treatment facility and its solid waste is sent to an incineration site for disposal.

No publicly available information on environmental risk management to mitigate AMR. Sun Pharma publicly reports implementing ZLD at 16 of its global manufacturing sites. However, it does not publicly report quantification of antibacterial discharge levels at its own sites, or its suppliers' sites, and therefore does not publicly disclose audit results, measured discharge levels, or the names and locations of manufacturing sites for each antibacterial product.

*RoW includes Western Europe, Canada, Israel, Japan, Australia, New Zealand and other markets.

**In India, companies follow a financial year from April 1 to March 31, so their annual turnover and revenue figures (shown for 2025) may not align with other companies in the AMR Benchmark that report on a calendar-year basis (January-December) for which 2024 figures are shown.

***Sun Pharma reports that other manufacturers are in the process of regulatory approval for tedizolid in India.

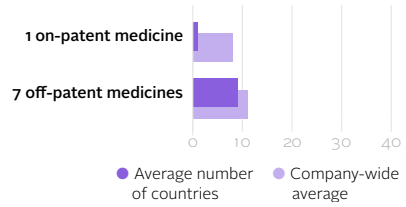
Sun Pharmaceutical Industries Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1 ●	C.1.2 ●	C.1.3 ●	C.2.1 ●	C.2.2 ●	C.2.3 ●	C.3 ●	C.4 ●	C.5 ●

Low-performing. Performs well in ensuring continuous supply by implementing strategies to mitigate stockouts and shortages. Its performance on stewardship is inconsistent, as appropriate use is considered in its governance of interactions with healthcare professionals, but not across its business practices. Sun Pharma can improve its registration coverage and implementation of access and stewardship strategies. It registers its products in less countries on average compared to peers and only implements specific strategies for four out of the nine products assessed.

Sun Pharma registers its on- and off-patent medicines in fewer countries than its peers.

On average, how many products are registered in LMICs?



Sun Pharma registers its on-patent medicine, tedizolid, in India and its off-patent medicines in 9 countries.* Of all the off-patent medicines assessed, 2 paediatric formulations (for 2 different medicines) are registered in just 1 country in total. Its on- and off-patent Reserve antibiotics and medicines targeting MDR-TB are registered in 2 countries, including 1 country where the corresponding disease burden is high. Sun Pharma does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Average performance, with limited access and stewardship strategy for the only on-patent product assessed, tedizolid (STARIZO®), but robust patient reach methodology. Sun Pharma supplies its antibiotic, tedizolid, in India, but the reported access strategy lacks detail and primarily relies on Sun Pharma's established distribution and supply networks in the country. The company calculates patient reach by considering the number of units sold and the units required to complete a treatment course and reports the number of patients reached in India during the period of analysis. As part of its stewardship strategy, Sun Pharma shows efforts to ensure the availability of susceptibility tests, enabling HCPs to make rapid diagnoses and ultimately safeguard against overuse or inappropriate use of the product.

Below-average performance, with limited evidence of implementing access and stewardship strategies for 3 of 7 off-patent/generic products assessed. Sun Pharma reports access strategies for 3 products assessed: levofloxacin, amoxicillin-clavulanic acid and clarithromycin. It reports that levofloxacin is available in the private sector in India via private clinics and pharmacies, but no details of the strategies for amoxicillin-clavulanic acid and clarithromycin are reported. It also reports using a methodology to measure patient reach and provides the number of patients reached with levofloxacin in India, but no patient reach data is reported for amoxicillin-clavulanic acid or clarithromycin. However, Sun Pharma shows efforts in implementing stewardship strategies for these 2 products, focusing on initiatives for their responsible promotion, including the development of formulations that match approved dosage amounts to encourage appropriate use.

Strong efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Sun Pharma implements demand planning and data sharing by analysing historical market trends and internal sales data. It implements a forecasting horizon of 3 months and shares demand forecasts with internal and external stakeholders. It maintains buffer stocks of its APIs and products based on internal norms and forecasts. It implements an automated inventory management system to identify and mitigate supply continuity risks. It also implements supplier diversification initiatives through engaging with multiple upstream suppliers and sourcing 83% of its procurement from local suppliers. Sun Pharma mitigates substandard and falsified medicines by verifying suppliers through GMP audits and reports cases to relevant stakeholders. However, it does not disclose any additional quality measures implemented in countries with evolving regulatory systems.

Includes elements to address appropriate use in its public policy, but not in its sales practices. Sun Pharma does not decouple incentives for its sales agents from sales volume targets and it does not report linking incentives to qualitative measures. Sales volume targets are set at the individual level. Through its global public policy, Sun Pharma ensures ethical interactions with HCPs, and for certain interactions it requires a defined legitimate need. This includes interactions where HCPs are hired to provide services for Sun Pharma. It voluntarily discloses information on transfers of value publicly in the UK. While Sun Pharma's sales practices do not apply to third parties working on its behalf, its public policy does.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

55%

Teva Pharmaceutical Industries Ltd

Generic medicine manufacturer

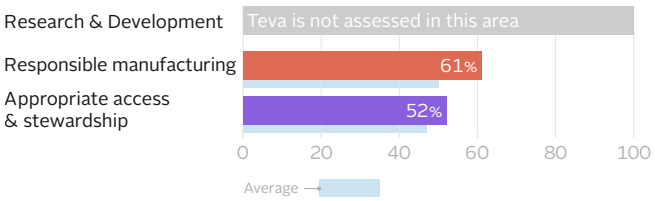
Stock exchange: NYSE • Ticker: TEVA • HQ: Tel Aviv, Israel • Employees: 37,000

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Teva performs well in Responsible Manufacturing, reporting partial compliance with discharge limits achieved at its own and suppliers' sites. It is mid-performing in Appropriate Access & Stewardship. It shows strong stewardship across its business practices and performs well in mitigating stockouts and shortages of its products in LMICs. However, it registers its products in fewer countries than other assessed generic medicine manufacturers and has product-specific access and stewardship strategies for just three of its 10 products assessed.

How Teva was evaluated

How score was achieved



OPPORTUNITIES FOR TEVA

Expand appropriate access to its antibacterial and antifungal medicines. Teva has access strategies for only three of its ten medicines assessed and registers them, on average, in only three LMICs. It can expand access to its medicines by registering them more widely and/or implementing appropriate access strategies in LMICs. For example, for its Reserve antibiotic, linezolid, it can expand access beyond the one country where it is currently registered, priortising countries with a high unmet need.

Strengthen its governance of interactions with healthcare professionals and improve transparency. Through its public policy governing interactions with healthcare professionals (HCPs), Teva already ensures that such interactions are based on a legitimate need and that transfers of value (ToVs) are made at fair market value. Teva can strengthen its policy, and thereby address appropriate use of its antimicrobials, by including provisions to mitigate potential conflicts of interest – specifically between employees and HCPs – and setting limits on ToVs. It can also publicly disclose ToV information in more countries, including in those where this is not mandated by law or, if applicable, other codes of practice.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved by its suppliers. Teva reports 73% compliance with discharge limits set in the receiving environment for its own sites, based on mass balance estimations and ~17% compliance for its suppliers' sites, but publicly discloses only its own site compliance. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' sites – a step beyond its current practice of setting discharge limits in receiving water – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

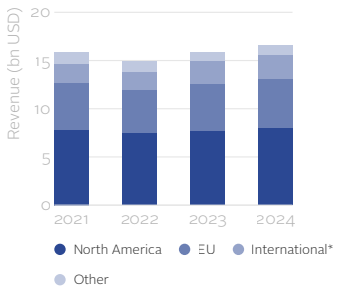
- In 2023, Teva was one of the first two companies to obtain the BSI Kitemark™ for Minimized Risk of AMR Certification. As of 2025, Teva has earned two Certifications.
- Since 2025, Teva has partnered with Clarivate to increase appropriate antimicrobial prescribing in Kenya through the launch of a digital stewardship programme targeted to physicians and patients.
- Responding to a 2021 AMR Benchmark opportunity, Teva showed progress in the number of sites with safe discharge levels of antibiotics, with 73% of sites meeting these standards in 2024 (up from 31% in 2021 and 64% in 2022).

Teva Pharmaceutical Industries Ltd

SALES AND OPERATIONS

Therapeutic areas: Analgesics, cardiovascular, gastroenterology, immunology, migraine, neurodegenerative, neuropsychiatry, oncology, respiratory diseases
Product categories: Consumer health products, generic medicines & biosimilars
Investments in AMR: In 2021, Teva committed to invest USD 8mn over 10 years in the AMR Action Fund and had contributed approximately USD 1.2mn as of 2024.
M&A news: None identified in the antibacterial and/or antifungal sectors.

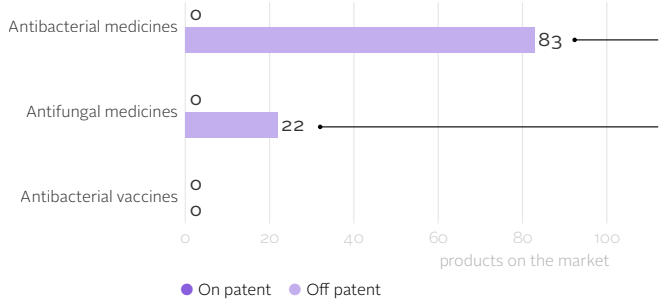
Revenue by geographic region – USD



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

105 products in Teva's anti-infective portfolio



10 products selected for analysis

amoxicillin (A), amoxicillin/clavulanic acid (A), azithromycin (W), ciprofloxacin (W), fosfomycin (R), linezolid (R), levofloxacin (T), moxifloxacin (T)

clotrimazole (F), fluconazole (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Performs well. Reports a comprehensive environmental risk-management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports on the level of compliance achieved at both its own and suppliers' sites. Teva also incorporates AMR provisions into supplier contracts. It publicly reports the quantification methods implemented and the level of compliance achieved at its own sites, but not at its suppliers'.

Mitigates AMR risk at both its own sites and suppliers' sites; tracks compliance of antibacterials with discharge limits. Teva's comprehensive environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). Teva estimates antibacterial discharges at its own sites using mass balance, verified by chemical analysis. However, the underlying details (e.g., dilution factors, timeframe) are not disclosed. Teva reviews the antimicrobial discharge level quantification programme implemented at its own sites every five years and implements CAPA plans if PNECs are exceeded (e.g., increased dry-cleaning and collection of rinse water for offsite incineration). While product-level compliance isn't reported, Teva states 19 of its 26 own manufacturing sites meet PNECs in the receiving environment, where wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured. It has also received five BSI Kitemark™ certifications for formulations of azithromycin and sulfamethoxazole-trimethoprim. Teva requires suppliers to follow the Industry Standard. It reviews supplier discharge levels via questionnaires and incorporates AMR provisions into contracts. It reports that 16 out of 97 supplier manufacturing sites comply with PNECs in the receiving environment. Each manufacturing site works with external waste treatment plants and employs measures to treat wastewater prior to sending it to plants.

Publicly discloses comprehensive AMR mitigation strategy, with 73% compliance for its own sites and tracks compliance at its suppliers' sites. Teva publicly reports implementing the Industry Standard and quantifying discharge levels using mass balance estimation. It reports achieving compliance with discharge limits at 73% of its own sites and tracking PNEC compliance for its suppliers' sites. For both its own sites and its suppliers' sites, it does not publicly disclose the number of products complying with PNECs, measured discharge levels, or the names and locations of manufacturing sites for each antibacterial product.

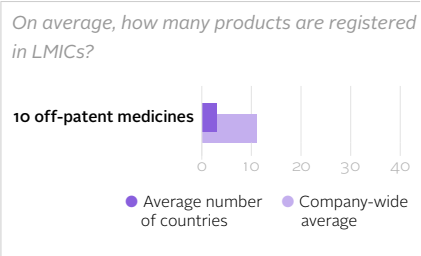
*Commencing January 1, 2024, Canada is reported under International Markets segment and is no longer included as part of United States segment (this is the case for both 2023/2024 figures). Could not obtain reclassified data from 2021-2022). Revenue by business segment is reported per region as depicted in Turnover by geographic region figure, above.

Teva Pharmaceutical Industries Ltd

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Shows strong performance in stewardship by clearly considering appropriate use across its business practices. It also performs well in ensuring continuous supply, as it has a comprehensive approach to mitigate stockouts and shortages and ensures GMP compliance at all its own and at several suppliers' sites. However, Teva can improve its registration coverage and implementation of access and stewardship strategies. While it has a portfolio-wide approach to expanding access and stewardship, it only reports product-specific strategies for three out of ten products assessed.

Teva registers its off-patent medicines in fewer countries than its peers.



Teva registers its off-patent medicines in 3 countries.* In many countries where Teva registers its off-patent medicines, it also registers paediatric formulations. Its Reserve antibiotics and medicines targeting MDR-TB are registered in 2 countries, including a total of 1 country where the corresponding disease burden is high. Teva does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Below-average performance, with limited evidence of implementing access and stewardship strategies for 3 of 10 off-patent/generic products assessed. Teva provides evidence of access strategies for only 3 products – amoxicillin, azithromycin and amoxicillin/clavulanic acid – and no stewardship strategies for any of them. However, Teva does have general access-to-medicine and stewardship policies in place that apply across its portfolio. Amoxicillin, azithromycin and amoxicillin/clavulanic acid are donated through different NGO partners, such as Direct Relief International, to a number of countries, including Haiti, Senegal and the Dominican Republic, respectively. The company reports the number of doses donated in these countries. While Teva does not report any stewardship strategies tailored to the products assessed, the company implements responsible promotion and sales practices for all its antibacterial and antifungal medicines.

Strong efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Teva implements demand planning and data sharing by using a monthly rolling forecast with a 36-month horizon. The plan is shared with key internal stakeholders annually. Teva does not report sharing forecasts with external stakeholders. It maintains buffer stocks of critical APIs and finished products and operates an automated inventory management system that provides real-time data and demand forecasts to trigger replenishment. Its supplier diversification strategies implement dual sourcing for certain products, as well as local sourcing. Teva mitigates substandard and falsified medicines by verifying suppliers through GMP audits, reporting cases to relevant authorities, assisting in the identification of counterfeit products and training local officials to recognise them. It reports that 48/48 of its own sites are GMP compliant, but it is unclear how many of its 41,000 suppliers are GMP compliant. It also does not implement additional quality measures in countries with evolving regulatory systems.

Clearly addresses appropriate use across its business practices. Teva does not deploy sales agents to sell and/or promote its antibacterial and antifungal medicines to HCPs. Through its global public policy, Teva ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions. It also ensures that transfers of value (ToVs) are made at fair market value. While Teva abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Teva's public policy also applies to third parties working on its behalf.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

57%

Viatris Inc

Generic medicine manufacturer

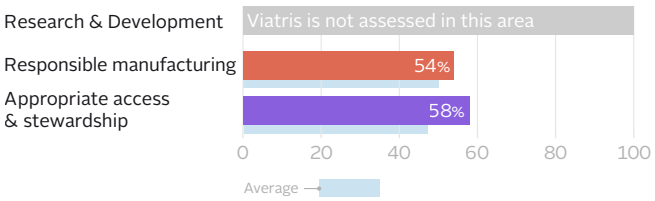
Stock exchange: NASDAQ • Ticker: VTRS • HQ: Canonsburg, Pennsylvania, USA • Employees: 32,000

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Viatris performs at a mid-level in Responsible Manufacturing as it reports the level of compliance with discharge limits achieved at its own and suppliers' sites but not publicly. It is also mid-performing in Appropriate Access & Stewardship, where its efforts are mixed. Viatris shows strong efforts in mitigating stockouts and shortages of its products in LMICs, monitoring patient reach and implementing access strategies for seven of its off-patent medicines. However, it does not implement product-specific stewardship strategies and registers its off-patent products in fewer countries than other assessed generic medicine manufacturers.

How Viatris was evaluated

How score was achieved



OPPORTUNITIES FOR VIATRIS

Expand appropriate access to paediatric formulations of its antibacterial and antifungal medicines. Viatris registers its off-patent antibacterial and antifungal medicines in an average of six LMICs, yet the company does not always register child-friendly formulations in all of these countries. It can bridge this gap and expand access to paediatric formulations of its medicines by registering them and implementing appropriate access strategies in at least the same countries where it already registers the corresponding adult formulations.

Scale up its responsible sales practices and strengthen its governance of interactions with healthcare professionals. Viatris already fully decouples incentives for its sales agents from sales volume targets for some branded medicines and does not deploy sales agents for its generic portfolio. To ensure responsible sales practices company-wide, it can extend this decoupling to all branded antibacterial and antifungal medicines or stop deploying sales agents for these medicines altogether. Moreover, Viatris can strengthen its public policy governing interactions with healthcare professionals (HCPs), and thereby address appropriate use of its antimicrobials, by including provisions to ensure a legitimate need for such interactions; mitigate potential conflicts of interest – specifically between employees and HCPs; limit transfers of value and ensure these are paid at fair market value.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved by its suppliers. Viatris reports 100% compliance with discharge limits set in the receiving environment for its own products, based on mass balance estimations, but only 77% compliance for its suppliers' high-volume products. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products and require supplier compliance through contractual provisions – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

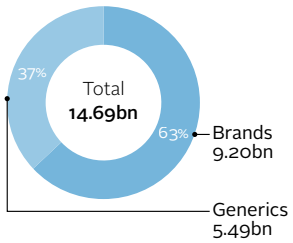
- Viatris has earned three BSI Kitemark™ Certifications under the AMR Industry Alliance (AMRIA) Manufacturing Standard. Two are for products manufactured at its site in Aurangabad, India, and the other is for a product manufactured at its site in Troisdorf, Germany.
- In 2024, Viatris contributed to the publication of the AMRIA Equitable and Responsible Access Roadmap as the co-chair of the AMRIA Access working group.
- In November 2025, Viatris announced a research collaboration agreement with Locus Biosciences to develop newly engineered bacteriophage products for ophthalmic bacterial infections – conditions associated with rising rates of AMR.

Viatris Inc

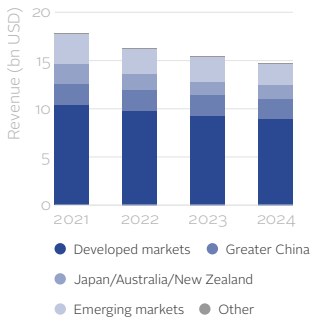
SALES AND OPERATIONS

Therapeutic areas: Anaesthetics, anti-infectives, cardiovascular, central nervous system, dermatology, diabetes, eyecare, gastroenterology, immunology, oncology, respiratory diseases & allergies, women's health
Product categories: Generic medicines
Investments in AMR: No notable investments identified.
M&A news: In June 2024, Viatris completed the divestment of its API Business in India to Matrix Pharma Private Limited.

Turnover by business segment (2024) – USD



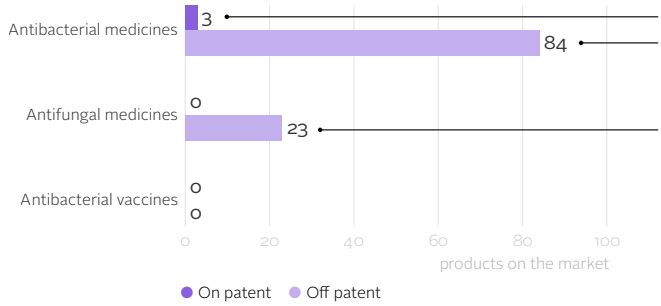
Revenue by geographic region – USD



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

110 products in Viatris' anti-infective portfolio



12 products selected for analysis

delamanid (T), pretomanid (T), tobramycin (inhaler) (W)

amoxicillin (A), amoxicillin/clavulanic acid (A), clarithromycin (W), vancomycin (W), linezolid (R), polymyxin b (R), levofloxacin (T)

fluconazole (F), itraconazole (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Mid-performing. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports on the level of compliance achieved across both its own and suppliers' sites. Viatris does not report incorporating AMR provisions into supplier contracts. It publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own sites and suppliers' sites; reports 100% of antibacterials compliant with discharge limits for own sites, tracks compliance of antibacterials for supplier sites. Viatris' comprehensive environmental risk management is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It reports implementing ZLD systems at some sites, with recycled water not being released into the environment, though the number of sites is not disclosed. It quantifies bacterial discharge annually at its own sites using mass balance estimation and chemical analysis. Quantification is based on 24-hour discharge levels and in cases where PNECs are exceeded, CAPAs are implemented. Viatris reports 100% of its antibacterial products comply with discharge limits in the receiving environment, where wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured. Three sites have received BSI Kitemark™ certifications for ciprofloxacin, pretomanid and clindamycin. The company requires suppliers to follow the Industry Standard, and it reviews discharge levels through audits. Viatris reports 77% of the antibacterial products manufactured by its suppliers comply with PNECs in the receiving environment, representing over 90% of its third-party produced antibacterial volume, but the exact number of products is provided under an NDA. No information is available on whether Viatris engages with external waste treatment plants to mitigate AMR risks from manufacturing.

Publicly discloses basic details of its AMR mitigation strategy but is not publicly transparent about compliance with discharge limits. Viatris publicly reports implementing the Industry Standard and quantifying discharge levels using mass balance estimation. For both its own sites and its suppliers' sites, it publicly reports conducting audits on PNEC compliance, but the audit results with the actual discharge levels are not publicly disclosed, nor is the number of products complying with PNECs or the names and locations of manufacturing sites for each antibacterial product.

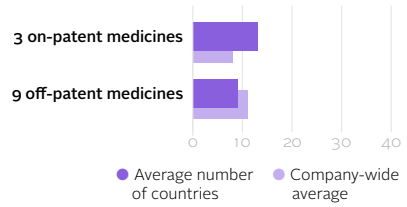
Viatris Inc

APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Mid-performing. Shows strong performance in ensuring continuous supply, as it has a comprehensive approach to mitigate stockouts and shortages and ensures GMP compliance at own and suppliers' sites. It also performs well in implementing appropriate access strategies, particularly for seven out of nine of its off-patent medicines, and using a standardised methodology for calculating patient reach. However, its stewardship strategies are limited to general policies across its portfolio. Viatris' performance on registration is inconsistent; on average, it registers on-patent medicines more widely and off-patent medicines less widely than peers.

Viatris registers its on-patent medicines more widely than its peers, although its off-patent medicines are registered less extensively.

On average, how many products are registered in LMICs?



Viatris registers its on-patent medicines in 13 countries* and its off-patent medicines in 6 countries. In a few countries where it registers its on- and off-patent medicines, it also registers paediatric formulations. Its on- and off-patent Reserve antibiotics and medicines targeting MDR-TB are registered in 12 countries, including 5 countries where the corresponding disease burden is high. For some of its medicines, Viatris engages in WHO's Prequalification process, facilitating registrations in a total of 4 countries.

Average performance, with access strategies for 2 of 3 on-patent products assessed, but limited stewardship efforts. Viatris provides access to 2 of the assessed products, delamanid (Deltyba®) and pretomanid (Dovprela®) – both key anti-TB drugs included in WHO-recommended regimens – through supranational procurement via the Stop TB Partnership's Global Drug Facility. The company also supplies delamanid, which has been licensed from originator company Otsuka, via a national tender in a country in scope of the Benchmark. Viatris reports using a methodology to measure patient reach for all 3 products, providing the number of patients reached through its access strategies in the country for delamanid and pretomanid. The company only reports a stewardship strategy for pretomanid, including the Pretomanid Resistance Surveillance Programme – which is a collaborative effort with the TB Alliance – as part of the post-marketing surveillance requirements. Viatris also funded a surveillance study in India, sharing the data available in an open-access journal article.

Above-average performance, implementing and monitoring access strategies for 7 of 9 off-patent/generic products assessed, but limited stewardship efforts. Viatris reports access strategies for 7 products assessed, all focused on the same country included in the Benchmark's scope. One product, linezolid, has a comprehensive access strategy, through which it is supplied via both national and supranational channels. The other 6 products are supplied exclusively in the private market. Viatris reports using a standardised methodology to measure patient reach and provides the number of patients reached for all 9 products. Viatris applies general stewardship policies across its portfolio, including responsible promotion.

Strong efforts to mitigate stockouts/shortages. Strong reported evidence of systems to ensure product quality. Viatris implements demand planning and data sharing through a 24-month forecast horizon. Its Rapid Response Advanced Planning system is updated daily and provides supply and demand information to key stakeholders, including commercial, warehousing and supply chain teams. It maintains buffer stocks of critical APIs and finished products, with higher safety stock levels for high-risk items based on demand volatility, supply instability and lead times. Inventory levels are monitored through its automated Rapid Response Advanced Planning system which alerts global operations on potential shortages. Its supplier diversification strategies implement dual sourcing for certain products and local sourcing. It mitigates substandard and falsified medicines by verifying suppliers through GMP audits, reporting incidents to relevant authorities and implementing security features, such as serialised barcodes and track-and-trace systems. It reports that 26/26 of its own sites and all its ~500 supplier sites are GMP compliant. However, it does not implement additional quality measures in countries with evolving regulatory systems.

Includes elements to address appropriate across its business practices. Viatris does not deploy sales agents to sell and/or promote its generic antibacterial and antifungal medicines to HCPs. For branded antibacterial and antifungal medicines, Viatris applies a different sales model, with information on this provided under an NDA. However, for some of these products, Viatris reports either full decoupling of incentives for its sales agents from sales volume targets or refraining from promoting them in the majority of countries. Through its global public policy, Viatris ensures that interactions with HCPs are ethical. However, it does not include specific provisions supporting the appropriate use of antibacterial and antifungal medicines. Viatris voluntarily discloses information on transfers of value publicly in Serbia. The company does apply its public policy to third parties working on its behalf, although it is unclear if it does so for its sales incentive plan.

Active in 1 multinational AMR surveillance programme and involvement in 1 study. *While Viatris is not assessed for its activities in AMR surveillance as a generic medicine manufacturer, its involvement in 1 AMR surveillance programme and 1 study was identified during the period of analysis. Viatris collaborates with the TB Alliance for the 'Pretomanid Resistance Surveillance Programme', which is part of its post-marketing surveillance requirements and ended in 2025. The programme covers 1 genus of bacterial pathogens, 1 antibacterial medicine and 8 countries. There is no evidence of data sharing during the period of analysis. In addition, Viatris funded a multicenter, retrospective, observational study in India. Aggregated data from this study has been shared in an open-access journal article. The methods used to collect surveillance data are unclear for the observational study and have not been reported for the surveillance programme.*

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.

OVERALL PERFORMANCE

70%

Basilea Pharmaceutica AG

SME

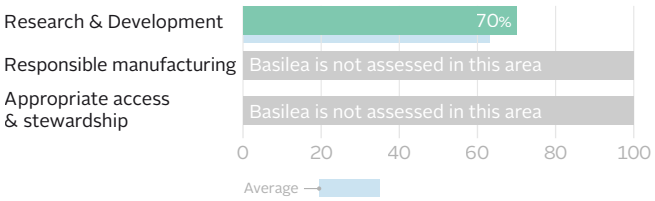
Stock exchange: SIX • Ticker: BSLN • HQ: Basel, Switzerland • Employees: 150

PERFORMANCE IN THE 2026 BENCHMARK

Performs well. With four antibacterial and antifungal candidates in development, Basilea has one of the most diverse pipelines among SMEs. All projects target 'critical' priority pathogens, and it demonstrates Best Practice for innovation, with all clinical-stage candidates classified as innovative, meeting at least one of WHO's innovation criteria. In addition, two candidates have oral formulations that meet the Benchmark's 'other' innovation criterion, which assesses real-world utility in LMICs. Both offer added clinical utility and can help overcome access barriers associated with intravenous-only options. It lacks efforts in access and stewardship planning because, as a development-only company, Basilea does not develop access plans for its projects, though it does participate in surveillance efforts.

How Basilea was evaluated

How score was achieved



OPPORTUNITIES FOR BASILEA

Diversify pipeline to address additional pathogens with high burdens in LMICs. Basilea's pipeline has a dual focus on antifungal and antibacterial medicines. The four projects in development cover a broad spectrum of WHO-listed critical-priority bacterial and fungal pathogens. As a development-only company, Basilea currently leads small- and medium-sized enterprises in the number of innovative medicines in its pipeline. The company has an opportunity to further expand and diversify its portfolio by addressing critical pathogens associated with high disease burdens in LMICs.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives
- **Financial stage:** Public (IPO completed in March 2004)
- **Products on the market:** Cresemba®, Zevtera®
- **Commercial partners:** As part of Basilea's business model, it does not directly market its developed products. To commercialise its products, Basilea collaborates with licensing partners Asahi Kasei, Astellas, CR Gosun, Innoviva Specialty Therapeutics and Pfizer, while it distributes its products through Advanz Pharma, AVIR Pharma, Hikma, Knight, Lancet and Unimedic Pharma. Basilea acquired the rights to fosmanogepix, a clinical-stage broad-spectrum antifungal candidate, from Pfizer in November 2023 and to ceftibuten-ledaborbactam etzadroxil, a clinical-stage oral antibiotic from Venatorx in August 2025.
- **Funding partners:** Fosmanogepix, BAL2062, and the Phase III programme for Zevtera® were funded in part by the US Department of Health and Human Services (HHS), through the Administration for Strategic Preparedness and Response (ASPR) and BARDA. BAL2420 received funding from CARB-X, with support also provided in part by HHS, ASPR, and BARDA. Furthermore, BARDA novated a contract from Venatorx to Basilea to support the development of ceftibuten-ledaborbactam etzadroxil in September 2025.

Basilea Pharmaceutica AG

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 4											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antifungal medicine(s)											
Fosmanogepix *Aspergillus* spp, including *Aspergillus fumigatus*, *Candida auris*, *Candida albicans*, *Nakaseomyces glabrata (Candida glabrata)*, *Fusarium* spp., Mucorales, *Candida parapsilosis*, *Candida tropicalis*, *Scedosporium* spp., *Lomentospora prolificans*	Critical, High, Medium								NCR, NC, NT, NMoA, O	No/Yes	BARDA
BAL2062 (formerly GR-2397, VL-2397 and ASP2397) *Aspergillus* spp, including *Aspergillus fumigatus*	Critical								NCR, NC	N/A	BARDA
Antibacterial medicine(s)											
Ceftibuten-ledaborbactam etzadroxil* Third-generation cephalosporin-resistant Enterobacterales, carbapenem-resistant Enterobacterales	Critical								NC, O	N/A	BARDA
BAL2420 (LptA inhibitor; antibiotics program) Carbapenem-resistant Enterobacterales	Critical								N/A	N/A	CARB-X

Abbreviations:
NC = New class, NCR = No cross-resistance, NMoA = New mode of action, NT = New target, O = Other innovation

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Pipeline of both antibacterial and antifungal medicines, with 3 innovative medicines. Basilea has 4 projects in its pipeline targeting pathogens in scope. Its 2 antifungal projects include BAL2062, which targets invasive mould infections, and fosmanogepix, which targets candidemia and invasive mould infections. Its antibacterial projects, BAL2420 and ceftibuten-ledaborbactam etzadroxil, both target Gram-negative Enterobacterales. Its 4 projects target pathogens that are classified as 'high' or 'critical' on either WHO's fungal or bacterial priority pathogen list. For example, *Aspergillosis fumigatus* (BAL2062) and *Candida* spp. (Fosmanogepix) and Enterobacterales. (See figure above for Basilea's full pipeline breakdown, including development phases and disease targets). Three projects – Fosmanogepix, BAL2062 and Ceftibuten-ledaborbactam – are classified as innovative, meeting at least 1 of WHO's 4 innovation criteria. Fosmanogepix meets all 4 criteria: it has no known cross-resistance, belongs to a new chemical class, and has both a new target and a new mode of action. BAL2062 meets 2 criteria (no cross resistance and new chemical class); ceftibuten-ledaborbactam meets one criterium (new chemical class). Ceftibuten-ledaborbactam and fosmanogepix also meet the Benchmark's 'other' criterion for innovativeness, as their oral formulations provide added clinical utility and address access barriers associated with intravenous-only options. The company's active in-house discovery programme focuses on novel antibiotic and antifungal compounds targeting WHO priority pathogens.

No access plan in place, but engaged in surveillance for its sole late-stage project. As a development-only company, Basilea focuses on bringing medicines through approval, leaving access programmes to commercial partners. As such, it did not report an access plan for its late-stage antifungal project, fosmanogepix. Clinical trials were conducted in Brazil, South Africa and Thailand. It does, however, have a stewardship plan for fosmanogepix. This involves global surveillance activities embedded in the SENTRY programme, an initiative that monitors AMR trends. Beyond surveillance, no further stewardship commitments were identified.

Active in 1 multinational AMR surveillance programme.
While Basilea is not assessed for its activities in AMR surveillance as an SME, its involvement in 1 AMR surveillance programme was identified during the period of analysis. Like 5 other companies in scope, Basilea is involved in the 'SENTRY Antimicrobial Surveillance Programme', which is run by JMI Laboratories, covering 88 and 43 genera of bacterial and fungal pathogens, 45 antibacterial and 8 antifungal medicines and 55 countries. Under the umbrella of SENTRY, Basilea has initiated global surveillance for its antibacterial and antifungal medicines, including its own products fosmanogepix and cefepime-taniborbactam; BAL2062 will be included starting 2026. SENTRY's antibacterial data can be accessed via its website; antifungal data is accessible via Pfizer's ATLAS website. The methods used to collect surveillance data for SENTRY are largely clear, including: the type of surveillance; where the analysis is conducted and which breakpoints are used; and how deduplication is considered.

*Basilea acquired the global rights to ceftibuten-ledaborbactam etzadroxil from Venatorx during the period of analysis.

OVERALL PERFORMANCE

60%

BioVersys AG

SME

Stock exchange: SIX • Ticker: BIOV • HQ: Basel, Switzerland • Employees: 32

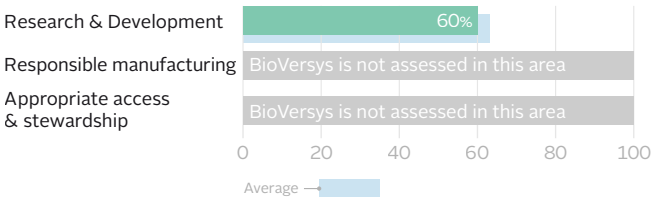
PERFORMANCE IN THE 2026 BENCHMARK

Performs well. All three of BioVersys' pipeline candidates target 'high' or 'critical' priority pathogens. It demonstrates Best Practice for innovation, with both clinical-stage candidates classified as innovative. One meets one of WHO's four innovation criteria; the other meets the Benchmark's 'other' innovation criterion, which assesses real-world utility in LMICs, due to its novel indication and formulation targeting a 'critical' priority pathogen. However, BioVersys can strengthen its access and stewardship planning, as it does not yet have plans in place for its late-stage projects, although clinical trials for one project are underway in LMICs, with plans to expand trials for another.

How BioVersys was evaluated

Research & Development	Responsible Manufacturing	Appropriate Access & Stewardship

How score was achieved



OPPORTUNITIES FOR BIOVERSYS

Work with partners and utilise existing guidance to develop access and stewardship plans. BioVersys' pipeline focuses on medicines targeting critical- and high-priority drug-resistant pathogens, specifically carbapenem-resistant *A. baumannii* (CRAB), *M. tuberculosis*, and *S. aureus* (including MRSA). BioVersys has not yet developed access and stewardship plans for either of its late-stage projects. When it develops access and stewardship plans, it can utilise the Stewardship & Access Plan (SAP) Development Guide and look for partners to strengthen its approach. For example, for its project BV100, targeting CRAB, currently in Phase III development, it can focus on regions with high *A. baumannii* resistance with limited alternative treatment options.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives
- **Financial stage:** Public (IPO completed in February 2025)
- **Products on the market:** None
- **Commercial partners:** BioVersys collaborates with Shionogi on the BV500 programme for non-tuberculous mycobacterial infections, aiming to develop novel ansamycin-based treatments. Additionally, the company has expanded its strategic partnership with GSK to advance the clinical development of alpibectir for tuberculosis, including both pulmonary and meningitis indications.
- **Funding partners:** BioVersys has received funding from the AMR Action Fund, CARB-X, CF AMR Syndicate, Cystic Fibrosis Trust, EDCTP, GIBF, GSK, the IMI2 Joint Undertaking, LifeArc and the Wellcome Trust to support the development of its antibacterial pipeline.

BioVersys AG

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 3											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antibacterial medicine(s)											
BV100 Carbapenem-resistant *Acinetobacter baumanii*	Critical								O	No/No	AMR Action Fund, Wellcome Trust
Alpibectir (BVL-GSK098) + ethionamide (Eto)/ prothionamide Rifampicin-resistant *Mycobacterium tuberculosis*	Critical								NC	No/No	EDCTP, GSK, IMI, Wellcome Trust
BV200 Methicillin-resistant *Staphylococcus aureus*	High								N/A	N/A	CARB-X, Swiss Innovation Agency (Swiss Accelerator innovation project)

Abbreviations:
NC = New class, O = Other innovation

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Pipeline of antibacterial medicines, including 2 innovative candidates in clinical development. BioVersys has 3 projects in its pipeline targeting pathogens in scope. All 3 are antibacterial medicines that target pathogens classified as 'high' or 'critical' on WHO's bacterial priority pathogen list: BV200 for methicillin-resistant *Staphylococcus aureus* (MRSA), alpibectir for multidrug-resistant *Mycobacterium TB* and BV100 for carbapenem-resistant *Acinetobacter baumannii* (CRAB). (See figure above for BioVersys' full pipeline breakdown including drug development phases). Two projects are considered innovative. Alpibectir meets 1 of WHO's 4 innovation criteria, as it belongs to a novel chemical class. In addition, BV-100 – although derived from an existing antibiotic – meets the Benchmark's 'other' innovative criterion due to its novel intravenous formulation and its development for a new indication targeting a critical-priority, resistant pathogen. BioVersys has an in-house discovery programme focused on highly resistant bacterial infections.

No evidence of access and stewardship planning. BioVersys has not yet developed access or stewardship plans for either of its late-stage projects (BV100 and alpibectir). Clinical trials for alpibectir – which is being developed in collaboration with GSK and the UNITE4TB consortium – are ongoing in South Africa. In addition, it plans to expand BV-100 trials to multiple countries in Southeast Asia through the ADVANCE-ID clinical trial network, targeting settings with very high levels of drug-resistant infections. However, beyond this no clear access plans were identified.

OVERALL PERFORMANCE

30%

Evopoint Biosciences Co, Ltd

SME

Stock exchange: N/A • Ticker: N/A • HQ: Suzhou, China • Employees: 210

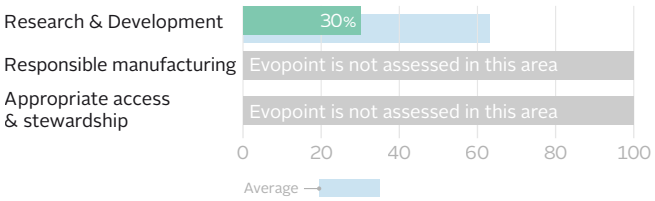
PERFORMANCE IN THE 2026 BENCHMARK*

Low-performing. Evopoint's sole pipeline project, funobactam, targets 'high' and 'critical' priority pathogens. However, it is not classified as innovative, as it does not meet any of WHO's innovation criteria – or the Benchmark's 'other' innovation criterion that assesses real-world utility in LMICs. In addition, it can strengthen its access and stewardship planning, with yet no plan in place for funobactam.

How Evopoint was evaluated

Research & Development	Responsible Manufacturing	Appropriate Access & Stewardship

How score was achieved



OPPORTUNITIES FOR EVOPOINT

Work with partners and utilise existing guidance to develop access and stewardship plans for funobactam. Evopoint's sole pipeline candidate, funobactum (XNW4107), targets several WHO-listed bacterial priority pathogens – namely Gram-negative carbapenem-resistant pathogens – and it is currently under regulatory review in China for hospital-acquired and ventilation-associated bacterial pneumonia. The company does not report an access or stewardship plan for funobactam. When it expands the access and stewardship plan it can utilise the Stewardship & Access Plan (SAP) Development Guide and work with partners to strengthen its approach, focusing on regions with high levels of resistance and significant clinical need, particularly in settings with limited or no treatment options.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives, oncology
- **Financial stage:** Private (Series E financing of RMB 700mn completed in February 2024; IPO filing submitted to China Securities Regulatory Commission in July 2025)
- **Products on the market:** None
- **Commercial partners:** Evopoint has an exclusive licensing agreement with Astellas for XNW27011, an antibody-drug conjugate in solid tumours, with Astellas holding worldwide rights except in select Asian markets. EVER001 (XNW1011/SN1011), a Bruton's tyrosine kinase inhibitor for renal diseases, has been licensed to Everest Medicines with global rights for development, manufacturing and commercialisation.
- **Funding partners:** Evopoint has received funding from Apricot Capital, CICC Capital, GIC, Guoxin Investment, Lepu Medical, Loyal Valley Capital, Oceanpine Capital and Tencent Investment, among other investors.

*For the 2026 AMR Benchmark, Evopoint declined to submit data.

Evopoint Biosciences Co, Ltd

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 1											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antibacterial medicine(s)											
Funobactam (XNW4107) + imipenem + cilastatin Carbapenem-resistant *Acinetobacter baumanii*, carbapenem-resistant Enterobacterales, carbapenem-resistant *Pseudomonas aeruginosa*	Critical, High								None	No/No	-

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

One antibacterial candidate targeting critical and high-priority pathogens undergoing regulatory review. Evopoint has 1 project in its pipeline targeting pathogens in scope. Its candidate, funobactam (XNW4107), an antibacterial medicine, is currently undergoing regulatory review in China for hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP). It targets 3 priority pathogens, including those defined as 'critical' and 'high' on WHO's bacterial priority pathogen list: carbapenem-resistant *Acinetobacter baumanii* (CRAB), carbapenem-resistant Enterobacterales and carbapenem-resistant *Pseudomonas aeruginosa*. Funobactam does not meet any of WHO's innovation criteria. The company did not report an active in-house discovery programme.

No access or stewardship plans in place for its sole late-stage project. Evopoint has not yet developed an access or stewardship plan for its sole late-stage project, Funobactam, nor are clinical trials ongoing in any countries in scope.

OVERALL PERFORMANCE

70%

F2G Ltd

SME

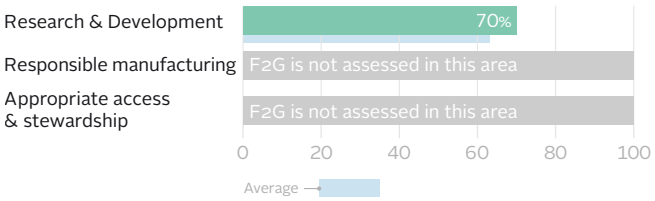
Stock exchange: N/A • Ticker: N/A • HQ: Cheshire, UK • Employees: 100

PERFORMANCE IN THE 2026 BENCHMARK

Performs well. F2G's sole pipeline candidate targets a 'critical' priority pathogen and is considered innovative, meeting all of WHO's innovation criteria, and F2G demonstrates Best Practice for innovation within the Benchmark. It performs well in access and stewardship planning, with a plan for olorofim that addresses availability and supply through a licensing agreement. However, concrete details, including affordability considerations, remain unclear.

How F2G was evaluated

How score was achieved



OPPORTUNITIES FOR F2G

Support partners with delivery of access and stewardship plans for olorofilm. F2G's pipeline candidate, olorofim, targets a range of fungal pathogens on WHO's fungal priority pathogen list. Through its partnership with Shionogi, the company plans to scale development and commercialisation, although specific measures to ensure access are yet to be confirmed. F2G could build on its collaboration by clarifying how the partnership may support global access and stewardship for olorofim, including how and where potential approaches to affordability and supply will be implemented in LMICs.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives
- **Financial stage:** Private (Series H1 financing of total USD 107.5mn committed by March 2025)
- **Products on the market:** None
- **Commercial partners:** F2G has partnered with Shionogi for the development and commercialisation of olorofim in Asia and Europe, with F2G retaining US rights.
- **Funding partners:** F2G has received funding from the AMR Action Fund, Advent Life Sciences, Blue Owl Healthcare Opportunities, Brace Pharmaceuticals, Forbion, ICG Life Sciences, Merifin Capital, Morningside Ventures, Novo Holdings, Sofinnova Partners and Symbiosis.

F2G Ltd

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 1											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antifungal medicine(s)											
Olorofim (formerly F901318) *Aspergillus fumigatus*, Eumycetoma causative agents, *Fusarium* spp., *Histoplasma* spp., *Scedosporium* spp., *Lomentora prolificans*, *Coccidioides* spp., *Talaromyces marneffei*	Critical, High, Medium								NCR, NC, NT, NMoA, O	Yes/Yes	Shionogi

Abbreviations:
NC = New class, NCR = No cross-resistance, NMoA = New mode of action, NT = New target, O = Other innovation

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1 ●	A.1.2 ●	A.1.3 ●	A.1.4 ●	A.2 ●

One innovative antifungal medicine in late-stage development targeting critical and high-priority pathogens. F2G, which focuses on rare fungal infections, has 1 project in its pipeline targeting pathogens in scope. Its candidate, olorofim (formerly F901318), is an antifungal currently in Phase III clinical development for invasive aspergillosis. It targets 8 priority pathogens, including *Aspergillosis fumigatus*, which is classified as 'critical' on WHO's fungal priority pathogen list. Olorofim is considered innovative, meeting all 4 of WHO's innovation criteria: it has no known cross-resistance, belongs to a new chemical class and has both a new target and a new mode of action. Additionally, the project demonstrates another innovative characteristic that enhances clinical utility, as its oral formulation may make it suitable for the long-term treatment of chronic and allergic fungal diseases. F2G has an active in-house discovery programme that led to the development of a new class of antifungal agents (orotomides).

Access and stewardship plan in place for 1 late-stage project. F2G has an access plan for its late-stage candidate, olorofim. This includes ongoing clinical trials in 4 countries in scope of the Benchmark (Brazil, China, Thailand and Vietnam) and an early access programme as a mechanism to make the antifungal available prior to market approval. F2G and its partner, Shionogi, have contractually committed to developing a joint access and stewardship plan within 60 days of the first global sale. The partnership model consists of a licensing agreement, where Shionogi oversees clinical trials, registration, supply and commercialisation in 79 countries, including 20 LMICs. In addition, Shionogi is considering collaborations, including sublicensing to generic manufacturers. F2G's stewardship plan for olorofim includes its introduction in specialised care settings under specific clinical conditions for patients with limited or no treatment options.

OVERALL PERFORMANCE

80%

Innoviva Specialty Therapeutics*

SME

Stock exchange: NASDAQ • Ticker: INVA • HQ: Burlingame, California, US • Employees: 147

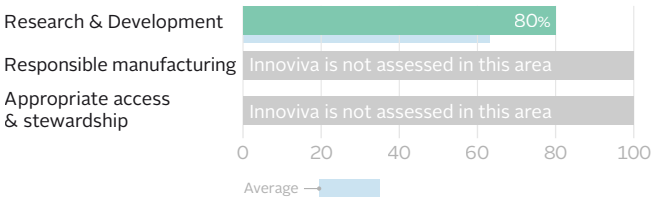
PERFORMANCE IN THE 2026 BENCHMARK

Strong performance. Innoviva's sole pipeline candidate, zoliflodacin (NUZOLVENCE®) – which was approved for the treatment of uncomplicated urogenital gonorrhoea after the analysis period concluded – has activity against a 'high' priority pathogen (cephalosporin-resistant *Neisseria gonorrhoeae*) and meets three of four of WHO's innovation criteria. It demonstrates a Best Practice for its innovative candidate and stands out for its robust access and stewardship plan for zoliflodacin, developed in partnership with GARDP. The plan addresses availability, affordability and supply barriers in LMICs, alongside stewardship plans to strengthen AMR surveillance.

How Innoviva was evaluated

Research & Development	Responsible Manufacturing	Appropriate Access & Stewardship

How score was achieved



OPPORTUNITIES FOR INNOVIVA

Support GARDP with delivery of access plans for zoliflodacin (NUZOLVENCE®). Recently approved for the treatment of uncomplicated urogenital gonorrhoea, zoliflodacin is an antibacterial medicine with activity against resistant strains of *N. gonorrhoeae*. Through its partnership with the Global Antibiotic Research and Development Partnership (GARDP), it has developed a comprehensive access and stewardship plan for zoliflodacin, under which GARDP holds manufacturing and supply rights for 168 LMICs, representing a comprehensive approach to ensuring global access and responsible use for this innovative antibiotic. After the recent US Food and Drug Administration approval of zoliflodacin, the company can support GARDP to ensure all elements of the access plan are fully realised.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives, critical care, respiratory diseases
- **Financial stage:** Public (IPO completed in October 2004)
- **Products on the market:** Giapreza®, NUZOLVENCE®, Xacduro®, Xerava®, Zevtera®
- **Commercial partners:** Innoviva commercialises the antibiotic Xacduro® in the US through its subsidiary Entasis Therapeutics, while Pfizer and Zai Lab hold rights in China. Its subsidiary La Jolla Pharmaceutical Company markets the vasoconstrictor Giapreza® and the antibitoic Xerava®. Innoviva also has exclusive US rights to Basilea's Zevtera®, retains commercial rights to zoliflodacin in major markets (with GARDP covering LMICs and some HICs) and maintains a legacy licensing and royalty partnership with GSK for respiratory drugs.
- **Funding partners:** Innoviva has partnered with GARDP to develop the antibiotic zoliflodacin, with GARDP funding its Phase III trial.

*a subsidiary of INNOVIVA, Inc.

Innoviva Specialty Therapeutics*

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 1											
Pipeline project Priority pathogens	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antibacterial medicine(s)											
Zoliflodacin* Third-generation cephalosporin-resistant *Neisseria gonorrhoeae*	High								NCR, NC, NMoA, O	Yes/Yes	GARDP, NIAID

Abbreviations:
NC = New class, NCR = No cross-resistance, NMoA = New mode of action, O = Other innovation

*Zoliflodacin was approved in December 2025 for uncomplicated urogenital gonorrhoea (after the period of analysis for the 2026 AMR Benchmark concluded).

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1 ●	A.1.2 ●	A.1.3 ●	A.1.4 ●	A.2 ●

One innovative antibacterial medicine targeting a high-priority pathogen. Innoviva has 1 project in its pipeline with activity against pathogens in scope, which was undergoing regulatory review during the period of analysis. Its antibacterial pipeline project, zoliflodacin, indicated for the treatment of uncomplicated urogenital gonorrhoea, has demonstrated activity against cephalosporin-resistant *Neisseria gonorrhoeae,* which is classified as 'high' priority on WHO's bacterial priority pathogen list. Zoliflodacin is considered innovative, meeting 3 of WHO's 4 innovation criteria: it has no known cross-resistance, belongs to a new chemical class and has a new mode of action. In addition, it is administered as a single-dose oral monotherapy, offering a simple alternative to the current injectable regimen for gonorrhoea. Innoviva did not report an active in-house discovery programme.

Comprehensive access and stewardship planning through GARDP partnership. Innoviva has an access plan for its late-stage candidate, zoliflodacin, developed by its partner GARDP. Through a licensing agreement, GARDP holds rights to register and commercialise in over 75% of countries worldwide, including all LICs. A WHO prequalification submission is planned, and a commercialisation agreement includes public-sector access obligations and equitable pricing. Early access is provided via a managed access programme for patients aged 12 years and older with uncomplicated gonorrhoea. GARDP also supports manufacturing scale-up and cost reduction, as well as Innoviva's stewardship plan for the project. Additionally, Innoviva completed trials in 2 LMICs in scope (South Africa and Thailand) for zoliflodacin. Stewardship is integral to the company's partnership with GARDP and includes ongoing collaborations with diagnostic companies to strengthen AMR surveillance by developing diagnostic tools and informing responsible clinical use of zoliflodacin.

*a subsidiary of INNOVIVA, Inc.

OVERALL PERFORMANCE

50%

Iterum Therapeutics plc

SME

Stock exchange: NASDAQ • Ticker: ITRM • HQ: Dublin, Ireland, USA • Employees: 9

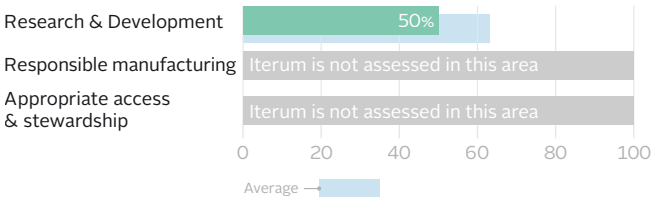
PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Iterum's sole pipeline candidate ORLYNVAH™ targets a 'critical' priority pathogen and was approved during the period of analysis. Although it doesn't meet WHO's innovation criteria, it demonstrates Best Practice by meeting the Benchmark's 'other' innovation criterion, which assesses real-world utility in LMICs; as the first approved oral penem, it enables outpatient treatment of resistant UTIs. It has a stewardship plan in place; however, access planning can be strengthened, as there are currently no defined plans to supply LMICs.

How Iterum was evaluated

Research & Development	Responsible Manufacturing	Appropriate Access & Stewardship

How score was achieved



OPPORTUNITIES FOR ITERUM

Work with partners to expand access and stewardship plans for ORLYNVAH™. Iterum's sulopenem/probenecid (ORYNVAH™) antibiotic was approved for uncomplicated urinary tract infections in 2024. In partnership with the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), the company published a stewardship and access plan outlining stewardship measures. While the plan has an initial focus on US and European markets, as Iterum's operational capacity expands, the company can collaborate with strategic partners to expand access in LMICs with high unmet medical need.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives
- **Financial stage:** Public (IPO completed in May 2018)
- **Products on the market:** ORLYNVAH™
- **Commercial partners:** Iterum has partnered with EVERSANA for the US commercialisation of ORLYNVAH™ and has a licensing agreement with Pfizer related to the product's development.
- **Funding partners:** Iterum has received funding from CARB-X for the development and commercialisation of the antibiotic sulopenem.

Iterum Therapeutics plc

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 1											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antibacterial medicine(s)											
ORLYNVAH™ (Oral sulopenem etzadroxil and probenecid) Third-generation cephalosporin-resistant Enterobacterales	Critical								O	No/Yes	-

Abbreviation:
O = Other innovation

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

One recently approved antibacterial medicine targeting a critical priority pathogen. Iterum Therapeutics has 1 project in its pipeline targeting pathogens in scope. Its antibacterial pipeline project, ORLYNVAH™ (Oral sulopenem etzadroxil and probenecid), received market approval for the treatment of uncomplicated urinary tract infections (UTIs) during the period analysis. ORLYNVAH™ targets 1 priority pathogen, cephalosporin-resistant Enterobacterales, classified as 'critical' in WHO's bacterial priority pathogen list. Although it does not meet WHO's innovation criteria, it meets the Benchmark's 'other' criterion for innovativeness as the first approved oral penem, enabling outpatient treatment of resistant UTIs. Iterum Therapeutics did not report an active in-house discovery programme.

No access plan for its sole late-stage project, but stewardship plan in place. Through its funder, CARB-X, Iterum published a stewardship and access plan for its antibiotic ORLYNVAH™, which received marketing approval during the period of analysis. The plan contains stewardship provisions, such as diagnostic support, appropriate use and surveillance, but it currently lacks concrete plans for access in LMICs. It did not conduct clinical trials for ORLYNVAH™ in any countries in scope.

Active in 1 multinational AMR surveillance programme.
While Iterum is not assessed for its activities in AMR surveillance as an SME, its involvement in 1 AMR surveillance programme was identified during the period of analysis. Like 5 other companies in scope, Iterum is involved in the 'SENTRY Antimicrobial Surveillance Programme', which is run by JMI Laboratories. While companies are involved with SENTRY in various ways, Iterum specifically sponsors the collection and analysis of surveillance data, including data for its project sulopenem etzadroxil/probenecid. In total, the SENTRY programme covers 88 and 43 genera of bacterial and fungal pathogens, 45 antibacterial and 8 antifungal medicines and 55 countries. SENTRY's antibacterial data can be accessed via its website; antifungal data is accessible via Pfizer's ATLAS website. The methods used to collect surveillance data for SENTRY are largely clear, including: the type of surveillance; where the analysis is conducted and which breakpoints are used; and how deduplication is considered. Further, Iterum plans to initiate a 5-year surveillance study as part of its post-marketing requirements and to take measures to make local susceptibility data available to prescribers.

OVERALL PERFORMANCE

60%

TenNor Therapeutics (Suzhou) Limited

SME

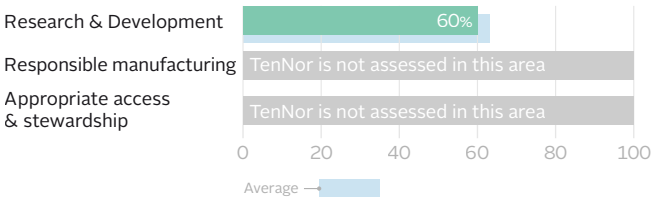
Stock exchange: N/A • Ticker: N/A • HQ: Suzhou, China • Employees: 52

PERFORMANCE IN THE 2026 BENCHMARK

Performs well. TenNor has the largest pipeline among its peers, with five projects in development. Although all projects target 'high' or 'critical' priority pathogens, none are categorised as innovative, according to WHO's criteria. It has a moderate performance in access and stewardship planning. Although plans are in place, there is room for improvement as they remain limited in depth and breadth.

How TenNor was evaluated

How score was achieved



OPPORTUNITIES FOR TENNOR

Expand access and stewardship plans for TNP-2092 beyond China. TenNor's pipeline, which focuses on bacterial biofilms, mostly targets methicillin-resistant *S. aureus* (MRSA), with one discovery-stage project focused on carbapenem-resistant *A. baumannii*. For TNP-2092, an antibacterial medicine targeting MRSA included in three late-stage projects, the company reports only limited access plans for China and provides no information on stewardship. TenNor can strengthen its China-focused plans by integrating stewardship provisions and, as operational capacity grows, expand its activities beyond China while broadening its access and stewardship planning. It can ultilise the Stewardship & Access Plan (SAP) Development Guide and work with partners to strengthen its approach, focusing on regions with high levels of resistance and significant clinical need, particularly in settings with limited or no treatment options.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives
- **Financial stage:** Private (Series E financing of over RMB 300mn achieved in October 2024, filed for Hong Kong Stock Exchange listing in July 2025)
- **Products on the market:** None
- **Commercial partners:** TenNor partners with Grand Life Sciences for rifasutenizol commercialisation in China.
- **Funding partners:** TenNor has secured funding from a diverse group of investors including the AMR Action Fund, Northern Light Venture Capital, WuXi AppTec, Zhongshan Venture Capital and other existing investors.

TenNor Therapeutics (Suzhou) Limited

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 5											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria	Access plan/ Stewardship plan	Key partners
Antibacterial medicine(s)											
TNP-2092 IV Methicillin-resistant *Staphylococcus aureus*	High	■	■	■	■	■			None	Yes/No	-
TNP-2092 IV Methicillin-resistant *Staphylococcus aureus*	High	■	■	■	■	■			None	Yes/No	-
TNP-2092 IA Methicillin-resistant *Staphylococcus aureus*	High	■	■	■	■				None	Yes/No	-
TNP-2092 TP Methicillin-resistant *Staphylococcus aureus*	High	■	■	■					None	N/A	-
MDR-GN Carbapenem-resistant *Acinetobacter baumanii*	Critical	■							N/A	N/A	-

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Pipeline of antibacterial medicines targeting critical and high-priority pathogens, but no innovative candidates. TenNor Therapeutics has 5 projects in its pipeline targeting pathogens in scope. These 5 projects are based on 2 distinct antibacterial medicines: the first, TNP-2092, is currently in clinical development for 3 different routes of administration (intravenous, intra-articular and topical) for 3 different indications focusing on bacterial biofilms. The other medicine (MDR-GN) is a bifunctional molecule indicated for carbapenem-resistant *Acinetobacter baumannii* (CRAB) infections. (See figure above for TenNor's full pipeline breakdown including drug development phases and disease targets). Each project targets 1 priority pathogen, including CRAB classified as 'critical', and methicillin-resistant *Staphylococcus aureus* (MRSA) classified as 'high' priority on WHO's bacterial priority pathogen list. TNP-2092 was assessed but did not meet any of WHO's 4 innovation criteria. The company has an active in-house discovery programme focused on CRAB.

Limited access and stewardship planning for 3 projects. TenNor has 3 projects in late-stage development and reports limited access planning for these projects. Although the company reports access planning related to registration, manufacturing and commercialisation in China, further access plans or stewardship plans for other countries in scope have not been disclosed.

OVERALL PERFORMANCE

80%

Venatorx Pharmaceuticals, Inc

SME

Stock exchange: N/A • Ticker: N/A • HQ: Malvern, Pennsylvania, USA • Employees: 79

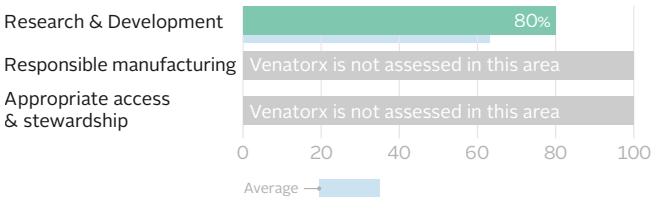
PERFORMANCE IN THE 2026 BENCHMARK*

Performs strongly. Both of Venatorx's pipeline candidates target 'critical' priority pathogens and the company demonstrates Best Practice by meeting at least one of WHO's four innovation criteria for both of them. It stands out for its robust access and stewardship plan for its sole late-stage candidate, cefepime-taniborbactam, developed in partnership with GARDP, which addresses availability and supply barriers in LMICs.

How Venatorx was evaluated

Research & Development	Responsible Manufacturing	Appropriate Access & Stewardship

How score was achieved



OPPORTUNITIES FOR VENATORX

Advance paediatric studies to strengthen access for future use in children. Venatorx's pipeline focuses mainly on multidrug-resistant Gram-negative pathogens and *S. aureus*, all classified as priority pathogens by WHO. It has a comprehensive access and stewardship plan in place for its late-stage candidate, Cefepime-taniborbactam (IV), through its partnership with the Global Antibiotic Research and Development Partnership (GARDP). It can build on this partnership to expand the development of cefepime-taniborbactam – which is on WHO's Paediatric Drug Optimisation watch list for antibiotics – to advance paediatric studies, which could help close critical treatment gaps for future use in children.

SALES AND OPERATIONS

- **Therapeutic areas:** Anti-infectives
- **Financial stage:** Private (Series C financing completed in April 2022)
- **Products on the market:** None
- **Commercial partners:** For the development and commercialisation of cefepime-taniborbactam, Venatorx has exclusive licensing agreements with Melinta Therapeutics for the US; Menarini Group for 96 countries across Europe, Latin America, Middle East, North Africa, Turkey and the Commonwealth of Independent States; Everest Medicines for 11 countries in Asia; and GARDP for 64 LMICs. Venatorx licensed the global rights of its clinical-stage oral antibiotic, ceftibuten-ledaborbactam, to Basilea in August 2025.
- **Funding partners:** Venatorx receives funding from Abingworth, the AMR Action Fund, CARB-X, BARDA, BioAdvance, DTRA, Foresite Capital, NIAID, Verstant Ventures and Wellcome Trust.

*For the 2026 AMR Benchmark, Venatorx declined to submit data. Regarding the partnership with GARDP on cefepime-taniborbactam, data was received from GARDP.

Venatorx Pharmaceuticals, Inc

SAMPLE OF PIPELINE ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

Total projects in scope: 2											
Pipeline project Priority or target pathogen(s)	Priority level	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Innovation criteria*	Access plan/ Stewardship plan**	Key partners
Antibacterial medicine(s)											
Cefepime-taniborbactam (IV) (VNRX-5133) Third-generation cephalosporin-resistant Enterobacterales, carbapenem-resistant Enterobacterales, carbapenem-resistant *Pseudomonas aeruginosa*, methicillin-resistant *Staphylococcus aureus*	Critical, High								NC	Yes/Yes	Everest Medicines, GARDP, Melinta Therapeutics, Menarini Group
Ceftibuten-ledaborbactam etzadroxil (VNRX-7145)* Third-generation cephalosporin-resistant Enterobacterales, carbapenem-resistant Enterobacterales	Critical								NC, O	N/A	BARDA, NIAID

Abbreviations:
NC = New class, O = Other innovation

PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Pipeline of antibacterial medicines targeting critical priority pathogens, with 2 innovative candidates. Venatorx has 2 pipeline projects targeting pathogens in scope, both of which are antibacterial medicines: ceftibuten-ledaborbactam Etzadroxil (VNRX-7145)*, currently in Phase I; and intravenous cefepime-taniborbactam (VNRX-5133), currently undergoing regulatory review for complicated urinary tract infections (cUTIs) and hospital-acquired/ventilator-associated bacterial pneumonia (HABP/VABP). (See figure above for Venatorx's full pipeline breakdown, including drug development phases and disease targets). Both projects target multiple priority pathogens, including carbapenem-resistant Enterobacterales and cephalosporin-resistant Enterobacterales, which are classified as 'critical' priority pathogens. Additionally, both projects are considered innovative and meet 1 of WHO's 4 innovation criteria (new chemical class). Ceftibuten-ledaborbactam etzadroxil (VNRX-7145) also meets the Benchmark's 'other' criterion, as the first oral treatment option with reliable activity against ESBL-producing Enterobacterales causing cUTIs. Venatorx did not report an active in-house discovery programme.

Comprehensive access and stewardship plan for its sole late-stage project through partnerships. Venatorx has an access plan for its late-stage candidate, cefepime-taniborbactam, which is currently undergoing regulatory review. The project is currently on hold pending additional regulatory data. The company has established licensing agreements for cefepime-taniborbactam for countries in scope of the Benchmark via partnerships with Everest Medicines for 11 Asian countries; GARDP for 64 LMICs; and Menarini for 96 Latin American and Middle Eastern countries. Through GARDP, countries with the highest burdens of carbapenem-resistant pathogens are prioritised. Clinical trials have taken place in 5 countries in scope of the Benchmark (Brazil, China, Mexico, Peru and Ukraine). Venatorx has a stewardship plan in place for cefepime-taniborbactam. Through GARDP, which holds exclusive commercialisation rights in 64 LMICs, it prioritises countries with the highest burdens of carbapenem-resistant pathogens for access to adult and paediatric formulations. Stewardship is integral to the GARDP partnership and includes approaches to ensure appropriate use and preserve effectiveness of cefepime-taniborbactam.

Active in 1 multinational AMR surveillance programme.
While Venatorx is not assessed for its activities in AMR surveillance as an SME, new activities from its involvement with 1 AMR surveillance programme were identified during the period of analysis. The 'Global Evaluation of Antimicrobial Resistance via Surveillance' programme (GEARS), which was run by Venatorx until 2022, covered 9 genera of bacteria, 10 antibacterial medicines and 59 countries. Raw data from GEARS was shared via the AMR Register during the period of analysis, where it is now available upon request. The methods Venatorx used to collect surveillance data for GEARS are largely clear, including: the type of surveillance; where the analysis is conducted and which breakpoints are used; and how deduplication is considered.

*During the period of analysis for the 2026 AMR Benchmark, Venatorx granted Basilea the global rights to ceftibuten-ledaborbactam etzadroxil. However, it was still assessed within Venatorx's pipeline, as it was under Venatorx's development during the analysis period.

2026 AMR BENCHMARK

APPENDICES

APPENDIX I

References

KEY FINDINGS

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THEMATIC ANALYSIS

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APPENDIX II

Analysis, scoring and review process

Process for antimicrobial and antifungal portfolio analysis

The product selection process and analysis of a company's anti-infective portfolio size were conducted using information from various sources, including proprietary data from IQVIA and public disclosures from pharmaceutical companies, and were supplemented, where relevant, with data from company submissions. The Benchmark requested the companies in scope to review, verify and provide additional data on their antibacterial and antifungal products selected for analysis. Product data was aggregated at the INN level for each company (formulations, doses, routes of administration or brand names were not differentiated).

All patented antibacterial and antifungal medicines and vaccines in a company's portfolio are included for the analysis. For off-patent/generic products, the highest selling products from each company's off-patent anti-infective portfolio were selected based on 2024 IQVIA global sales data and corresponding verification by companies. This includes up to two antibiotics per group of the World Health Organization (WHO)'s 'AWaRe' categorisation (Access, Watch and Reserve), two antifungal medicines and two antituberculosis medicines. As such, a maximum of ten off-patent products were included for analysis. Each of the selected off-patent/generic medicines must be listed on WHO's 2023 Essential Medicine List (EML). The final number of products selected for analysis, across all companies, is 146 products.

Summary of the scoring process

Companies were assessed and scored by the Benchmark in three Research Areas: Research & Development, Responsible Manufacturing and Appropriate Access & Stewardship, with each area composed of several indicators. The assessment was based on the Methodology for the 2026 Antimicrobial Resistance Benchmark, published in January 2025, and available for download at accesstomedicinefoundation.org. Due to the variation between companies in scope, not all indicators were applicable to every company, as shown in the Indicators and Scoring Eligibility table in this Appendix.

Data review

The 2026 Benchmark evaluated the efforts of companies within the period of analysis going from 1 October 2023 to 30 September 2025. Companies were asked to verify the accuracy of publicly sourced data and to provide additional necessary information. Prior to analysis, the Benchmark team reviewed companies' submissions for each of the Research Areas.

- **Research & Development**: Antibacterial and antifungal medicines, as well as vaccines that target priority pathogens listed on World Health Organization (WHO)'s bacterial Priority Pathogen List (2024) and/or fungal Priority Pathogen List (2022) were included for the overall pipeline. Medicines in clinical development were classified as innovative if they fulfilled one or more of the following criteria: new chemical class; new target; new mode of action; no cross-resistance or the Benchmark's additional criterion of innovation. Access and stewardship planning data was assessed using company data submission and public sources (if available).

- **Responsible Manufacturing**: The Benchmark requested companies to share information on environmental risk management practices for antibacterial active pharmaceutical ingredients (APIs) and drug products at the company's own sites, suppliers' sites and external waste treatment plants. The Benchmark further requested whether any of the sites or plants set limits on antibacterial discharge, quantified the discharge levels, including the methods used, and achieved compliance with product-specific discharge limits. To assess public transparency on waste practices, the Research Team reviewed companies' public information on, e.g., corporate websites, annual reports and corporate social responsibility reports.

- **Appropriate Access & Stewardship**: The Benchmark requested companies to share data on their efforts to expand appropriate access to their antibacterial and antifungal medicines and vaccines and to share stewardship measures they implement to safeguard their medicines' effectiveness. For product registrations and appropriate access and stewardship strategies, these efforts were assessed on a product level, considering all products selected for analysis (as described above) and analysis was conducted in three groups: 1) on-patent antibacterial and antifungal medicines, 2) off-patent/generic antibacterial and antifungal medicines and 3) on-patent vaccines. A company's effort to ensure continuous supply of quality assured products and mitigate potential stockouts and shortages, as well as responsible business practices and AMR surveillance were assessed on the company level. Next to data directly shared by the company, information from the public domain was used across this Research Area.

Scoring

All indicators were scored on a zero- to five-point scale and weighted equally. When an indicator was not applicable to a company, the company's maximum attainable score was reduced by five points. The final performance percentage of a company was determined by dividing the total points scored by the total attainable points. Final scoring of the companies was the result of a multi-tiered analysis and quality assurance process (also see Appendix III).

Review process

Following clarification and cross-check of company scores, the Research Team wrote the various sections for the Benchmark report. Thematic analyses were reviewed by at least one external reviewer while Key Findings were reviewed by the Chair of the Expert Review Committee (ERC), Professor Hans Hogerzeil. The company Report Cards were fact checked by companies, and confidential information was requested to be lifted for publication

TABLE XX **Indicators and scoring eligibility**

IN SCOPE FOR	RESEARCH & DEVELOPMENT					RESPONSIBLE MANUFACURING		APPROPRIATE ACCESS & STEWARDSHIP								
	A.1.1	A.1.2	A.1.3	A.1.4	A.2	B.1	B.2	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
Large R&D-based pharmaceutical companies																
GSK	●	●	●	●	●	●	●		●	●		●	●	●	●	●
Johnson & Johnson	●	●	●	●	●	●	●		●			●		●	●	●
MSD	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Otsuka	●	●		●	●	●	●	●			●			●	●	●
Pfizer	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sanofi	●	●	●	●	●	●	●		●	●		●	●	●	●	●
Shionogi	●	●	●	●	●	●	●	●			●			●	●	●
Generic Medicine Manufacturers																
Abbott						●	●		●			●		●	●	
Alkem						●	●		●			●		●	●	
Aurobindo						●	●		●			●		●	●	
Cipla						●	●	●	●		●	●		●	●	
Fresenius Kabi						●	●		●			●		●	●	
Hikma						●	●	●	●		●	●		●	●	
Sandoz						●	●		●			●		●	●	
Sun Pharma						●	●	●	●		●	●		●	●	
Teva						●	●		●			●		●	●	
Viatris						●	●	●	●		●	●		●	●	
Small and medium-sized enterprises																
Basilea	●	●		●	●											
BioVersys	●	●		●	●											
Evopoint	●	●		●	●											
F2G	●	●		●	●											
Innoviva	●	●		●	●											
Iterum Therapeutics	●	●		●	●											
TenNor Therapeutics	●	●		●	●											
Venatorx	●	●		●	●											

APPENDIX III

Scoring guidelines

RESEARCH AREA: RESEARCH & DEVELOPMENT

A.1.1 PIPELINE SIZE

The size of a company's research & development (R&D) pipeline targeting priority pathogens, listed on the World Health Organization (WHO)'s bacterial Priority Pathogen List (2024) and fungal Priority Pathogen List (2022), including antibacterial and antifungal medicines and vaccines (new chemical/biological entities and adaptations) developed either in-house or through collaborations.

5-1 The aggregate number of R&D projects targeting pathogen(s) in scope that a company had in development, or received regulatory approval for, within the period of analysis.
This number is scaled across companies* and scored.

0 The company has no medicine or vaccine projects targeting pathogens in scope that were in development or received regulatory approval during the period of analysis.

N/A Generic medicine manufacturers are not assessed under this indicator.

*Separate scoring scales are applied to large research-based companies and small- and medium-sized enterprises.

A.1.2 INNOVATIVENESS OF PIPELINE

The number of innovative, investigational clinical antibacterial and antifungal medicines targeting priority pathogens, listed on WHO's bacterial Priority Pathogen List (2024) and fungal Priority Pathogen List (2022), that the company is developing (either in-house or through collaborations). Projects in development are assessed against WHO innovation criteria, namely: absence of known cross-resistance to existing antibiotics, new target (new molecular binding site), new mode of action and/or new class. In addition, the assessment will consider whether projects have any other innovative criteria that offer added clinical utility beyond the four WHO innovation criteria (e.g., oral formulations).

5-1 For large research-based companies: the sum of unique* antifungal and antibacterial medicines in the company's pipeline meeting at least one of WHO's four innovation criteria and/or the Benchmark's additional innovation criterion. This number is scaled across all large research-based companies and scored.
Or
For small- and medium-sized enterprises (SMEs): the proportion of unique* antifungal and antibacterial medicines within the company's pipeline meets at least one of WHO and/or Benchmark innovation criteria. This proportion is scaled across all SMEs and scored.

0 The company has no medicines in development that meet WHO or the Benchmark's 'other' innovation criteria.

N/A Generic medicine manufacturers are not assessed under this indicator.

*Counted once per molecule, regardless of the number of associated projects.

A.1.3 VACCINES IN THE PIPELINE

The number of vaccines that the company is developing for priority pathogens in scope of the methodology (either in-house or through collaborations).

5 Large research-based companies with a large vaccine pipeline (10 or more) targeting pathogen(s) in scope.

4 Large research-based companies with a moderate-sized vaccine pipeline (between 5 and 9 projects) targeting pathogen(s) in scope.

3 Large research-based companies with a relatively small vaccine pipeline (3 or 4 projects) targeting pathogens in scope.

2 Large research-based companies with small vaccine pipeline targeting pathogen(s) in scope (2 projects).

1 Large research-based companies with a very small vaccine pipeline (1 project) targeting pathogen(s) in scope.

0 Large research-based companies with no vaccines currently in their pipeline and prior R&D activity for vaccines targeting pathogen(s) in scope.

N/A Large research-based companies that have never engaged in vaccine development, generic medicine manufacturers and small- and medium-sized enterprises were not assessed under this indicator.

A.1.4 PROJECTS TARGETING R&D GAPS

The extent to which the company's R&D pipeline addresses global R&D needs, as defined by WHO's bacterial Priority Pathogen List (2024) and fungal Priority Pathogen List (2022).

i. The number of R&D projects in the company's pipeline targeting 'critical' priority pathogens and/or rifampicin-resistant *Mycobacterium tuberculosis*.
ii. The number of R&D projects in the company's pipeline targeting 'high'-priority pathogens.

5 Large research-based companies with 15 or more pipeline projects targeting pathogens classified as critical and/or high priority on WHO's bacterial and fungal priority pathogens list.
Or
Small- and medium-sized enterprises with 5 or more pipeline projects targeting pathogens classified as 'critical'- or 'high'-priority on WHO's bacterial and fungal priority pathogens list.

4 Large research-based companies with between 10 and 14 pipeline projects targeting pathogens classified as 'critical' and/or 'high' priority on WHO's bacterial and fungal priority pathogens list.
Or
Small- and medium-sized enterprises with 3 or 4 pipeline projects targeting pathogens classified as 'critical' or 'high' priority on WHO's bacterial and fungal priority pathogens list.

3 Large research-based companies with between 6 and 9 pipeline projects targeting pathogens classified as 'critical' and/or 'high' priority on WHO's bacterial and fungal priority pathogens list.
Or
Small- and medium-sized enterprises with 1 or 2 pipeline projects targeting pathogens classified as 'critical' and/or 'high' priority on WHO's bacterial and fungal priority pathogens list.

2 Large research-based companies with between 3 and 5 pipeline projects targeting pathogens classified as 'critical' and/or 'high' priority on WHO's bacterial and fungal priority pathogens list.

1 Large research-based companies with one or two projects pipeline project targeting pathogens classified as 'critical' and/or 'high' priority on WHO's bacterial and fungal priority pathogens list.

0 The company has no pipeline projects targeting pathogens classified as 'critical' or 'high' priority on WHO's bacterial and fungal priority pathogens list.

N/A Generic medicine manufacturers are not assessed under this indicator.

A.2 ACCESS AND STEWARDSHIP PLANNING

The extent to which the company has access and stewardship plans in place for late-stage* antibacterial and antifungal R&D projects targeting priority pathogens that consider:

i. Access in the 113 countries within the scope for access metrics and where the disease burden is the highest, and
ii. Stewardship globally. The specific strategies companies can use to address access and stewardship are detailed in Appendix II.

5-1 The extent to which the company has project-specific, integrated access and stewardship** plans in place for its late-stage antibacterial and antifungal R&D projects targeting WHO priority pathogens. Scoring is determined by:
- the proportion of late-stage candidates covered by access and stewardship plans;
- the quality and specificity of these plans, including whether they address availability, affordability and sustainable supply integrated with stewardship measures; and
- the breadth of geographic coverage

Scores for the three assessment criteria are first averaged across companies and then scaled to derive the final scores.

0 The company reports having neither access nor stewardship plans for any of its late-stage R&D projects.

N/A Generic medicine manufacturers are not assessed under this indicator.

*All R&D projects in the pipeline from Phase II onwards as well as recently approved products, developed either in-house or through collaborations.
**Stewardship plans are only assessed for late-stage antimicrobial candidates; vaccines are exempt.

RESEARCH AREA: RESPONSIBLE MANUFACTURING

B.1 MINIMISING AMR AND ENVIRONMENTAL RISK FROM MANUFACTURING

The company is assessed on whether it has an environmental risk-management strategy to minimise the risk of AMR and ecological effects caused by discharges of antibacterials from manufacturing into the environment. This includes the following assessment parameters:

i. Implementation of waste treatment/management practices for both liquid and solid antibacterial-containing wastes (including fermentation waste), taking AMR risk into account.
ii. Periodic quantification of the levels of antibacterials discharged in wastewaters during time of manufacturing.
iii. Achieving compliance with antibacterial discharge limits, based on predicted no-effect concentrations (PNECs) for resistance selection, set in wastewaters or the receiving environment.

These assessment parameters are considered for:

a. Antibacterial APIs and drug products manufactured at its owned and/or operated manufacturing sites.
b. Antibacterial APIs and drug products manufactured by its third-party suppliers.

There is a total of 7 elements to this indicator, corresponding to the 6 possible combinations of the three assessment parameters (i-iii), and the two site locations (a, b). The seventh element represents the assessment of a company's engagement with external wastewater treatment plants on mitigating AMR risk. There is a total of 22 points possible for companies to achieve. Element (iii) the level of compliance achieved is weighted more than elements (ii) quantification methods and (i) practices in that order. A company's score is then determined by the fraction of points it achieves out of the total, normalised to a continuous scale of 0-5. Some elements were not applicable to all companies (i.e. if they do not use external wastewater treatment plants) which were accounted for in the final scoring.

5-1 The extent to which the company reports having an environmental risk-management strategy, assessed on a continuous scale of 1 to 22 points to be achieved.

0 The company does not report having an environmental risk-management strategy that earns them any of the 22 points to be achieved.

B.2 DISCLOSURE ON MINIMISING AMR AND ENVIRONMENTAL RISK FROM MANUFACTURING

The company is assessed on its transparency on its environmental risk-management strategy to minimise the risk of AMR and ecological effects caused by discharges of antibacterials from manufacturing into the environment. This indicator assesses whether the company publishes the following five elements, easily accessible on the main company website and dated:

i. Evidence of implementing waste treatment/management practices for both liquid and solid antibacterial-containing wastes (including fermentation waste), taking AMR risk into account.
ii. Details and methods on periodic quantification of the levels of antibacterials discharged in wastewaters, including whether mass balance or chemical analysis is used during time of manufacturing to assess compliance with discharge limits, based on PNECs for resistance selection.
iii. Summary results of audits that includes the number/fraction products manufactured at own and supplier's sites that comply with discharge limits (set in wastewater effluent or receiving environment).
iv. Levels (concentrations) of antibacterial discharge from own and suppliers' manufacturing sites in wastewaters and/or receiving environments.
v. Per antibacterial API and/or drug product, the exact names and locations of own and supplier's manufacturing sites The Benchmark values detailed disclosures more highly than aggregated or anonymised ones.

5 The company publishes detailed information on all five elements.

3.0-4.5 The company publishes information on three to four elements with more detailed disclosures warranting a higher score.

1.0-2.5 The company publishes information on two to three elements with more detailed disclosures warranting a higher score.

0.5 The company publishes information on one element.

0 No information on the five elements could be identified in the public domain.

RESEARCH AREA: APPROPRIATE ACCESS & STEWARDSHIP

C.1.1 REGISTRATION OF ON-PATENT ANTIBACTERIAL AND ANTIFUNGAL MEDICINES

The company broadly files to register its on-patent antibacterial and antifungal medicines within the 113 countries in scope for access metrics, either by directly attaining approval from national regulatory authorities or engaging with mechanisms to facilitate broad product registrations (where applicable).

- 5 The company registers its on-patent medicines in the majority of the 113 countries in scope on average, including the majority of countries with a high burden of disease.* The company also systematically registers paediatric formulations in the same countries it already registers its on-patent medicines in.**
- 4-1 The average number of countries in which the company registers its on-patent medicines and how many of those have a high burden of disease*, scaled across companies. The extent to which the company systematically registers paediatric formulations in the same countries it already registers its on-patent medicines in.**
- 0 The company provides no evidence of registering any of its on-patent antibacterial and antifungal medicines in any of the 113 countries in scope.
- N/A All small- and medium-sized enterprises and companies without on-patent antibacterial or antifungal medicines in their portfolio are not assessed under this indicator.

*Countries with a high burden of disease are defined based on disability-adjusted life years (DALYs) per 100,000 population, using the indication for the product as listed on the World Health Organization Essential Medicines List (WHO EML) 2023 and the corresponding burden data from the IHME MICROBE dataset. Per product, countries in the top quartile of DALY rates are classified as high burden. Registrations in countries with a corresponding high burden of disease are assessed only for Reserve antibiotics and medicines targeting MDR-TB.
**Registrations of paediatric formulations are only assessed for companies which have such formulations in their portfolio.

C.1.2 REGISTRATION OF OFF-PATENT/GENERIC ANTIBACTERIAL AND ANTIFUNGAL MEDICINES

The company broadly files to register its off-patent and generic antibacterial and antifungal medicines within the 113 countries in scope for access metrics, either by directly attaining approval from national regulatory authorities or engaging with mechanisms to facilitate broad product registrations (where applicable).

- 5 The company registers its assessed off-patent medicines in the majority of the 113 countries in scope on average, including the majority of countries with a high corresponding burden of disease.* The company also systematically registers paediatric formulations in the same countries it already registers its off-patent medicines in.
- 4-1 The average number of countries in which the company registers the assessed off-patent medicines and how many of those have a high burden of disease*, scaled across companies. The extent to which the company systematically registers paediatric formulations in the same countries it already registers its off-patent medicines in.**
- 0 The company provides no evidence of registering any of its off-patent antibacterial and antifungal medicines assessed in any of the 113 countries in scope.
- N/A All small- and medium-sized enterprises and companies without off-patent antibacterial or antifungal medicines in their portfolio are not assessed under this indicator.

*Countries with a high burden of disease are defined based on disability-adjusted life years (DALYs) per 100,000 population, using the indication for the product as listed on the World Health Organization Essential Medicines List (WHO EML) 2023 and the corresponding burden data from the IHME MICROBE dataset. Per product, countries in the top quartile of DALY rates are classified as high burden. Registrations in countries with a corresponding high burden of disease are assessed only for Reserve antibiotics and medicines targeting MDR-TB.
**Registrations of paediatric formulations are only assessed for companies which have such formulations in their portfolio.

C.1.3 REGISTRATION OF ON-PATENT ANTIBACTERIAL AND ANTIFUNGAL VACCINES

The company broadly files to register its on-patent antibacterial and antifungal vaccines within the 113 countries in scope for access metrics, either by directly attaining approval from national regulatory authorities or engaging with mechanisms to facilitate broad product registrations (where applicable).

- 5 The company registers its on-patent vaccines in the majority of the 113 countries in scope on average, including the majority of countries with a high corresponding burden of disease.*
- 4-1 The average number of countries in which the company registers its on-patent vaccines and how many of those have a high burden of disease*, scaled across companies.
- 0 The company provides no evidence of registering any of its on-patent antibacterial vaccines assessed in any of the 113 countries in scope.
- N/A All small- and medium-sized enterprises and companies without on-patent antibacterial or antifungal vaccines in their portfolio are not assessed under this indicator.

*Countries with a high burden of disease are defined based on disability-adjusted life years (DALYs) per 100,000 population, using the indication for the product as listed on the World Health Organization Essential Medicines List (WHO EML) 2023 and the corresponding burden data from the IHME MICROBE dataset. Per product, countries in the top quartile of DALY rates are classified as high burden.

C.2.1 EXPANDING APPROPRIATE ACCESS TO ON-PATENT ANTIBACTERIAL AND ANTIFUNGAL MEDICINES

The company is actively working to expand appropriate access to on-patent antibacterial and antifungal medicines for people living within the 113 countries in scope for access metrics. The company has product-specific access and stewardship strategies in place for its products, along with clear processes to monitor the performance of these strategies and measure patient reach.

i. Access and stewardship strategies
The company's country- and product-specific access strategies aim to increase patient reach by enhancing both affordability and availability. These strategies consider the relevant payer's ability to pay, whether in the public sector (reimbursement authority) and/or the private sector (private insurance or self-pay), as well as the demographic characteristics* of each country. A variety of access strategies can be employed, including pricing strategies, voluntary licensing, patient assistance programmes, public or private partnerships, participation in pooled procurement mechanisms, technology transfers and donations.
In addition, the company implements product-specific stewardship strategies to ensure the appropriate use of its medicines and to safeguard their efficacy. These strategies may include surveillance and data sharing, responsible promotion and sales strategies, and ensuring the availability of supportive diagnostics.

ii. Monitoring the performance of access strategies and measuring patient reach
The company demonstrates a well-defined process for monitoring the performance of its product-specific access strategies, supported by a methodology to measure patient reach. The company can provide the number of patients reached during the period of analysis and can clearly explain how the number was calculated.

5 For all on-patent medicines selected for analysis, the company meets all following criteria:
(a) It applies a country- and product-specific access strategy(ies) that take(s) into account the relevant payer's ability to pay and the country's demographic characteristics*;
(b) it applies product-specific stewardship strategy(ies) to ensure appropriate use and to safeguard the efficacy of the medicine;
(c) it provides evidence of the methods used to monitor the strategy's performance, including how it calculates the number of patients reached and resulting number(s);
(d) it provides evidence of future plans to advance the access and stewardship strategy(ies).

4-1 For its on-patent medicines selected for analysis, the extent to which the company meets the following criteria:
(a) It applies a country- and product-specific access strategy(ies) that take(s) into account the relevant payer's ability to pay and the country's demographic characteristics*;
(b) it applies product-specific stewardship strategy(ies) to ensure appropriate use and to safeguard the efficacy of the medicine;
(c) it provides evidence of the methods used to monitor the strategy's performance, including how it calculates the number of patients reached and resulting number(s);
(d) it provides evidence of future plans to advance the access and stewardship strategy(ies).

0 For its on-patent medicines selected for analysis, the company meets none of the above listed criteria.

N/A All small- and medium-sized enterprises and companies without on-patent antibacterial or antifungal medicines in their portfolio are not assessed under this indicator.

*The characteristics of a population such as age, gender, income level, education level, employment and ethnicity.

C.2.2 EXPANDING APPROPRIATE ACCESS TO OFF-PATENT/GENERIC ANTIBACTERIAL AND ANTIFUNGAL MEDICINES

The company is actively working to expand appropriate access to off-patent and generic antibacterial and antifungal medicines for people living within the 113 countries in scope for access metrics. The company has product-specific access and stewardship strategies in place for its products, along with clear processes to monitor the performance of these strategies and measure patient reach.

i. Access and stewardship strategies
The company's country- and product-specific access strategies aim to increase patient reach by enhancing both affordability and availability. These strategies consider the relevant payer's ability to pay, whether in the public sector (reimbursement authority) and/or the private sector (private insurance or self-pay), as well as the demographic characteristics* of each country. A variety of access strategies can be employed, including pricing strategies, tenders, public or private partnerships, participation in pooled procurement mechanisms, technology transfers and donations.
In addition, the company implements product-specific stewardship strategies to ensure the appropriate use of its medicines and to safeguard their efficacy. These strategies may include surveillance and data sharing, responsible promotion and sales strategies, and ensuring the availability of supportive diagnostics.

ii. Monitoring the performance of access strategies and measuring patient reach
The company demonstrates a well-defined process for monitoring the performance of its product-specific access strategies, supported by a methodology to measure patient reach. The company can provide the number of patients reached during the period of analysis and can clearly explain how this number was calculated.

5 For all off-patent/generic medicines selected for analysis, the company meets all following criteria:
(a) It applies a country- and product-specific access strategy(ies) that take(s) into account the relevant payer's ability to pay and the country's demographic characteristics*;
(b) it applies product-specific stewardship strategy(ies) to ensure appropriate use and to safeguard the efficacy of the medicine;
(c) it provides evidence of the methods used to monitor the strategy's performance, including how it calculates the number of patients reached and resulting number(s);
(d) it provides evidence of future plans to advance the access and stewardship strategy(ies).

4-1 (a) For its off-patent/generic medicines selected for analysis, the extent to which the company meets the following criteria:
It applies a country- and product-specific access strategy(ies) that take(s) into account the relevant payer's ability to pay and the country's demographic characteristics*;
(b) it applies product-specific stewardship strategy(ies) to ensure appropriate use and to safeguard the efficacy of the medicine;
(c) it provides evidence of the methods used to monitor the strategy's performance, including how it calculates the number of patients reached and resulting number(s);
(d) it provides evidence of future plans to advance the access and stewardship strategy(ies).

o For its off-patent/generic medicines selected for analysis, the company meets none of the above listed criteria.

N/A All small- and medium-sized enterprises and companies without off-patent antibacterial or antifungal medicines in their portfolio are not assessed under this indicator.

*The characteristics of a population such as age, gender, income level, education level, employment and ethnicity.

C.2.3 EXPANDING APPROPRIATE ACCESS TO ON-PATENT ANTIBACTERIAL AND ANTIFUNGAL VACCINES

The company is actively working to expand appropriate access to on-patent antibacterial and antifungal vaccines for people living within the 113 countries in scope for access metrics. The company has product-specific access strategies in place for its products, along with clear processes to monitor the performance of these strategies and measure patient reach.

i. Access strategies
The company's country- and product-specific access strategies aim to increase patient reach by enhancing both affordability and availability. These strategies consider the relevant payer's ability to pay, whether in the public sector (reimbursement authority) and/or the private sector (private insurance or self-pay), as well as the demographic characteristics* of each country. A variety of access strategies can be employed, including participation in pooled procurement mechanisms, pricing strategies, tenders, public or private partnerships, technology transfers and/or donations.

ii. Monitoring the performance of access strategies and measuring patient reach
The company demonstrates a well-defined process for monitoring the performance of its access strategies, supported by a methodology to measure patient reach. The company can provide the number of patients reached during the period of analysis and can clearly explain how this number was calculated.

5 For all on-patent vaccines selected for analysis, the company meets all following criteria:
(a) It applies a country- and product-specific access strategy(ies) that take(s) into account the relevant payer's ability to pay and the country's demographic characteristics*;
(b) it provides evidence of the methods used to monitor the strategy's performance, including how it calculates the number of patients reached and resulting number(s);
(c) it provides evidence of future plans to advance the access strategy(ies).

4-1 For its on-patent medicines selected for analysis, the extent to which the company meets the following criteria:
(a) It applies a country- and product-specific access strategy(ies) that take(s) into account the relevant payer's ability to pay and the country's demographic characteristics*;
(b) it provides evidence of the methods used to monitor the strategy's performance, including how it calculates the number of patients reached and resulting number(s);
(c) it provides evidence of future plans to advance the access strategy(ies).

o For its on-patent vaccines selected for analysis, the company meets none of the above listed criteria.

N/A All small- and medium-sized enterprises and companies without on-patent antibacterial or antifungal vaccines in their portfolio are not assessed under this indicator.

*The characteristics of a population such as age, gender, income level, education level, employment and ethnicity.

C.3 MITIGATING STOCKOUTS AND SHORTAGES OF QUALITY-ASSURED PRODUCTS

Companies are assessed based on their strategies to prevent stockouts and shortages and to ensure the supply of quality-assured products for people living within the 113 countries in scope for access metrics.

Strategies to prevent stockouts and shortages include the following elements:

i. Bilateral data-sharing with countries or regions for demand planning.
ii. Maintaining a sufficient stock, including critical components at point of use and/or making efforts to decentralise stocks of finished products in regions/markets.
iii. Having a robust inventory management system in place, including conducting automated monitoring and planning of stock inventories (including duration and reporting of shortages).
iv. Implementing strategies to promote supplier diversity, e.g. by working with multiple upstream suppliers and/or sourcing from local suppliers.

Strategies to ensure quality-assured APIs and drug products include the following elements:

i. Mitigating the circulation of substandard and falsified medicines (including the verification of the credentials of suppliers and customers downstream and to which stakeholders the company reports encounters of falsified medicines).
ii. Complying with current Good Manufacturing Practice (GMP), as accepted by recognised national and international authorities, such as the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and the World Health Organization (WHO).
iii. Taking additional steps on quality assurance in countries with evolving regulatory systems.

Companies can achieve a total score of 15 points across this indicator, with nine available points in stockout mitigation strategies and six in quality assurance strategies. A company's score is then determined by the fraction of points it achieves out of the total, normalised to a continuous scale of 0-5. Some elements are not applicable to all companies which were accounted for in the final scoring.

5 The company demonstrates strategies for stockout mitigation and quality assurance that earns them all 15 points.

4-1 The company demonstrates strategies for stockout mitigation and quality assurance that earns them a total of 1-14 points.

o The company reports no evidence of strategies to mitigate stockouts and shortages of its products, or to ensure the quality of its products within the countries in scope.

C.4 RESPONSIBLE BUSINESS PRACTICES

The company implements responsible business practices that disincentivise overselling of antibacterial and antifungal medicines by either not using sales representatives for promotion or by fully decoupling bonuses for sales agents from sales volume targets. In case of only partial decoupling, the company demonstrates that, at a minimum, sales targets are not set at the individual level and that sales target bonuses represent a minimal portion of overall compensation.

The company has a clear public policy to ensure ethical interactions with healthcare professionals (HCPs). The policy has provisions specifying the legitimate need for the interaction, mitigating potential conflicts of interest and limiting transfers of value.* Additionally, the company voluntarily discloses information about such transfers of value (ToVs), where this is permitted by law.

This indicator consists of two elements: a company's 1) sales practices and 2) public policy. Both elements are scored independently on a scale of 0-5. The total score for this indicator is the average of both scores.

Sales practices

5 The company does not promote any of its antibacterial and/or antifungal medicines to HCPs or, in case of promotion, the company fully decouples incentives for sales agents from sales volume targets for all its antibacterial and/or antifungal medicines.

4 The company primarily does not promote its antibacterial and/or antifungal medicines to HCPs or in case of promotion, the company primarily does not couple incentives for sales agents with sales volume targets for its antibacterial and/or antifungal medicines. However, differences by country and/or product are considered.

3 The company at least partially decouples incentives for sales agents from sales volume targets. Additionally, targets are either set at the aggregated level, or the company implements other structural measures that reduce product-specific incentives to oversell.

2 The company at least partially decouples incentives for sales agents from sales volume targets, but targets are set at the individual level.

1 The company does not decouple incentives for sales agents from sales volume targets. However, incentives are also contingent on qualitative measures.

0 The company either does not decouple incentives for sales agents from sales volume targets, or it does not disclose information on engaging in responsible business practices.

Public policy

5 The company has a clear public policy that governs interactions with HCPs and meets all four criteria assessed. In addition, it also voluntarily discloses information on ToVs.

4 The company either has a clear public policy that governs interactions with HCPs meeting all four criteria assessed, or its policy meets three of the four criteria, and it also voluntarily discloses information on ToVs.

3 The company either has a clear public policy that governs interactions with HCPs meeting three of the four criteria assessed, or its policy meets one to two of the four criteria, and it also voluntarily discloses information on ToVs.

2 The company either has a clear public policy meeting that governs interactions with HCPs meeting one to two of the four criteria assessed, or its policy meets none of the four criteria, but it voluntarily discloses information on ToVs.

1 The company either has a clear public policy that governs interaction with HCPs meeting none of the four criteria assessed, or it voluntarily discloses information on ToVs.

0 The company does not have a clear global public policy that governs interactions with HCPs. The company does not voluntarily disclose information on ToVs.

Total

N/A Small- and medium-sized enterprises are not assessed under this indicator.

*Transfers of value could include payments for attending and/or speaking at events, provision of continuing medical education (CME), funding of research studies or other non-monetary benefits directed at healthcare professionals (HCPs). Companies should have a process in place to determine the legitimate need for interactions with HCPs and to ensure fair market value at both payment per interaction level and cumulative/overall payments per HCP.

C.5 AMR SURVEILLANCE

The company has, supports and/or contributes to antibacterial and/or antifungal surveillance programmes to track resistance of pathogens and shares the raw surveillance data publicly without undue delay. As part of its surveillance programme(s), the company follows a clear methodological approach* to identify trends of resistance.

If a company is involved in AMR surveillance, each programme is scored on a scale from 1-5. The final score is an average across all programmes (if applicable), whereby programmes managed directly by the company are weighed more than programmes supported by the company.

5 For the programme, raw data has been shared during the period of analysis, and a clear methodological approach has been reported.

4 For the programme, raw data has been shared during the period of analysis or a clear methodological approach has been reported. However, for the programme, at least aggregated data must have been shared, or at least a partly clear methodological approach must have been reported.

3 For the programme, aggregated data has been shared during the period analysis and a methodological approach has been reported. The methodological approach is at least partly clear.

2 For the programme, aggregated data has been shared during the period analysis or a methodological approach has been reported. The methodological approach is at least partly clear.

1 For the programme, no data has been shared during the period of analysis, and no methodological approach has been reported.

0 The company is not involved in any AMR surveillance programme during the period of analysis.

N/A Generic medicine manufacturers and small- and medium-sized enterprises are not assessed under this indicator.

*Determination of whether a company follows a clear methodological approach is made by identifying which data points are collected as part of the analysis and shared as part of the surveillance programme, and by how this data is collected. The latter can include (but is not limited to) sampling method, sample selection, sample size or site of analysis.

APPENDIX IV

Geographic scope

FIGURE XX **113 Countries in scope for access metrics in the 2026 AMR Benchmark**

While the primary scope of the Benchmark is global, the Benchmark specifically assesses companies' efforts in making their products accessible in 113 countries in its 'access metrics'. These include countries where access is most urgently needed, encompassing primarily low- and middle-income countries.

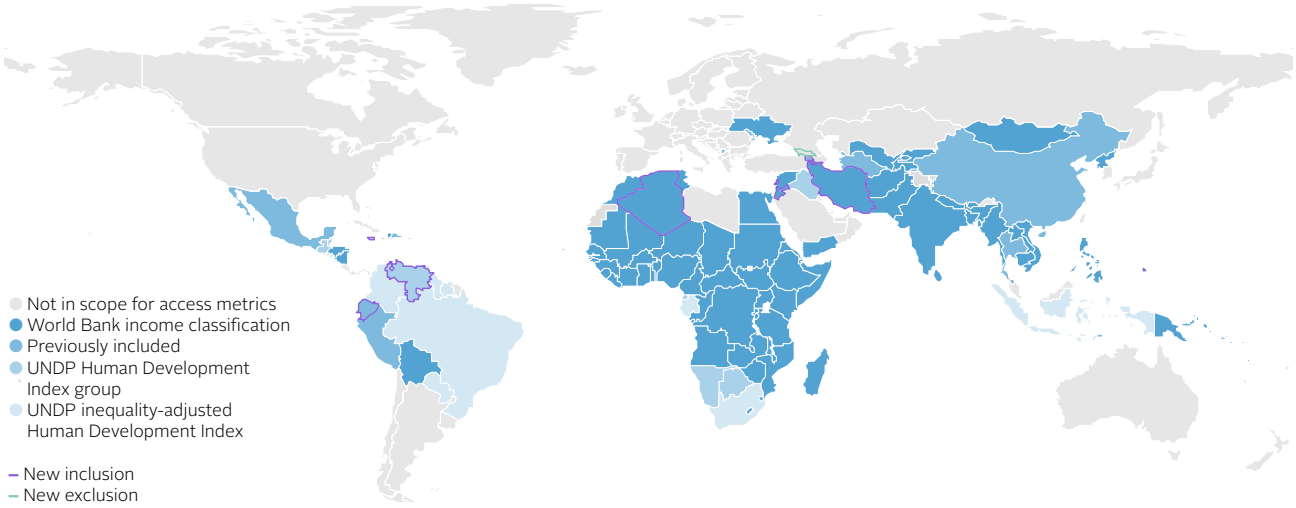

TABLE XX **List of countries included in the geographic scope for 'access metrics'**

Country	Country Classification
East Asia & Pacific	
Cambodia	LMIC
China	UMIC
Indonesia	UMIC
Kiribati	LMIC
Korea, Dem. People's Rep.	LIC
Lao PDR	LMIC
Marshall Islands	UMIC
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LMIC
Papua New Guinea	LMIC
Philippines	LMIC
Samoa	LMIC
Solomon Islands	LMIC
Thailand	UMIC
Timor-Leste	LMIC
Tonga	UMIC
Tuvalu	UMIC
Vanuatu	LMIC
Vietnam	LMIC
Europe & Central Asia	
Armenia	UMIC
Kosovo	UMIC
Kyrgyzstan	LMIC
Moldova	UMIC
Tajikistan	LMIC
Turkmenistan	UMIC
Ukraine	LMIC
Uzbekistan	LMIC

Country	Country Classification
Latin America & Caribbean	
Belize	UMIC
Bolivia, Plurinat. State	LMIC
Brazil	UMIC
Colombia	UMIC
Dominican Republic	UMIC
Ecuador	UMIC
El Salvador	UMIC
Guatemala	UMIC
Guyana*	HIC
Haiti	LMIC
Honduras	LMIC
Jamaica	UMIC
Mexico	UMIC
Nicaragua	LMIC
Paraguay	UMIC
Peru	UMIC
St. Lucia	UMIC
Suriname	UMIC
Venezuela	Unclassified
Middle East & North Africa	
Algeria	LMIC
Djibouti	LMIC
Egypt, Arab. Rep.	LMIC
Iran	LMIC
Iraq	UMIC
Jordan	LMIC
Lebanon	LMIC
Morocco	LMIC
Palestine, State of/ West Bank/Gaza	LMIC

Country	Country Classification
Syrian Arab Republic	LIC
Tunisia	LMIC
Yemen, Rep.	LIC
South Asia	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
India	LMIC
Maldives	UMIC
Nepal	LMIC
Pakistan	LMIC
Sri Lanka	LMIC
Sub-Saharan Africa	
Angola	LMIC
Benin	LMIC
Botswana	UMIC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cameroon	LMIC
Central African Republic	LIC
Chad	LIC
Comoros	LMIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	UMIC
Eritrea	LIC
Eswatini	LMIC
Ethiopia	LIC

Country	Country Classification
Gabon	UMIC
Gambia	LIC
Ghana	LMIC
Guinea	LMIC
Guinea-Bissau	LIC
Kenya	LMIC
Lesotho	LMIC
Liberia	LIC
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
Mozambique	LIC
Namibia	UMIC
Niger	LIC
Nigeria	LMIC
Rwanda	LIC
São Tomé and Príncipe	LMIC
Senegal	LMIC
Sierra Leone	LIC
Somalia	LIC
South Africa	UMIC
South Sudan	LIC
Sudan	LIC
Tanzania	LMIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LMIC

LIC Low-income country
LMIC Lower-middle-income country
UMIC Upper-middle-income country**
HIC High-income country**

*Guyana is included despite receiving a HIC classification in 2023.[22] Guyana will be kept in scope until 2028, after which it will be excluded if it does not meet other inclusion criteria.

**All UMICs and HICs in a low or medium UNDP Human Development Index group or with a low inequality-adjusted Human Development Index were included.

APPENDIX V

Definitions

Access plan
Plans to ensure that access needs in low- and middle-income countries are taken into consideration during the research & development (R&D) stage. Access plans can be developed in-house or in collaboration. They can include commitments and strategies, as well as more concrete access provisions, such as specific measures developed in partnership with other organisations that can enforce accountability. Potential components of an access plan include registration commitments, equitable pricing strategies, sufficient supply commitments, and applying for World Health Organization prequalification. Access plans facilitate availability, affordability and supply for patients in countries within the scope of the Benchmark.

Access strategy (product specific)
The range of mechanisms a company can implement to provide access to its product for a specific group of patients within a country. An access strategy can be composed of different elements, including pricing strategies and additional initiatives to improve the affordability and availability of the product. Access strategies with the biggest potential impact in terms of equitable access are those that aim to promote affordable access to medicine for all income groups of the population by considering the ability to pay of the payer, and by taking healthcare systems' needs and characteristics into account.

Active pharmaceutical ingredient (API)
The API is the active pharmaceutical component of a medicine that carries out its intended effects. Some medicines, such as combination therapies, have multiple active ingredients that target multiple disease pathways and/or symptoms. The inactive ingredients of a medicine are referred to as excipients.

Affordability
This refers to the payer's ability to pay for a product (whether or not they are the end user) – see 'payers' for definition. Affordability is one of the key dimensions for access to medicine. The Benchmark takes this into account when assessing pricing strategies for relevant products. A product's affordability depends on different factors, including socioeconomic, demographic and healthcare system characteristics, which should be considered by pharmaceutical companies when setting the price of the products.

AMR surveillance
The continuous and systematic collection, analysis and interpretation of antimicrobial infection and resistance-trend data needed for the planning, implementation, and evaluation of antimicrobial stewardship activities.

Antibacterial medicine
Antimicrobial medicine used to treat bacterial infections by directly targeting the bacteria that causes the infection or the disease process (as opposed to targeting the symptoms of the infection), typically referred to as antibiotics. Biocides are not considered antibacterial medicines.

Antifungal medicine
Antimicrobial medicine used to treat fungal infections by directly targeting the fungi that causes the infection (as opposed to targeting the symptoms of the infection or toxins produced by the pathogen).

Antimicrobial medicine
A medicine used to treat an infectious disease by directly targeting the bacteria, fungi, helminths, protozoa or viruses that cause the infection or the disease process (as opposed to targeting the symptoms of the infection).

Antimicrobial resistance (AMR)
AMR is the ability of microbes such as bacteria, viruses, fungi and parasites (protozoa or helminths) to grow in the presence of an antimicrobial substance (e.g., a medicine) that would normally kill them or limit their growth. Resistance is a consequence of evolution via natural or artificial selection.

Antimicrobial stewardship
A systematic and comprehensive process that aims to ensure that all aspects of prescribing, (e.g., drug, dose, duration), dispensing, and the use of antimicrobial medicines are consistent with the available evidence on how to minimise the emergence of antimicrobial resistance.

Appropriate access
Improving the availability, affordability and accessibility of antimicrobial medicines and vaccines while ensuring that these products are being used responsibly by limiting their overuse and misuse to ensure they stay effective for as long as possible.

Appropriate use of antimicrobials
The cost-effective use of antimicrobials, which maximises clinical therapeutic effect while minimising both drug-related toxicity and the development of antimicrobial resistance.[1]

AWaRe classification of antibiotics
Developed in 2017 by the WHO Expert Review Committee on Selection and Use of Essential Medicines as a tool to support antibiotic stewardship efforts at local, national and global levels. Antibiotics are classified into three groups: Access, Watch and Reserve, accounting for the impact of different antibiotics and antibiotic classes on AMR, to emphasise the importance of their appropriate use. It is updated every two years.[2]

Buffer stock
A reserve or surplus quantity of essential materials, components or finished products that a company maintains as a safeguard against potential disruptions in the supply chain.

Capacity building
The company forms partnerships with local stakeholders to increase capacity (e.g. by training of staff or obtaining equipment and other necessary resources) in order to strengthen the supply chain as well as skills, resources or processes in low-and middle-income countries

Conflict of interest (COI)
Within the context of pharmaceutical companies' engagement in public health-oriented initiatives, a conflict of interest potentially arises when the commercial interests of the company conflict with the primary interest of protecting and promoting public health.

Cross-resistance
Cross-resistance refers to the resistance developed to a usually effective antimicrobial medicine through exposure to a similarly acting substance. Cross-resistance can occur among human antimicrobials and is also observed between human antimicrobials and products used in animal health or agriculture (e.g., pesticides, herbicides or fungicides).

Diagnostics
Diagnostics or diagnostic tests are approaches used in clinical practice to identify with high accuracy the disease of a particular patient and thus to provide early and proper treatment.[3]

Drug product
The finished dosage form of a medicine obtained at the end of the manufacturing process, (e.g., the tablet, capsule, or solution containing the active pharmaceutical ingredient(s), generally, but not necessarily, in association with one or more other ingredients). Also referred to as a finished drug product, finished product or formulation.

Early access programmes
An Early Access Programme is a pathway allowing patients to access medicines that are yet unregistered in a country. These programmes typically include medicines for serious or life-threatening diseases when there are no other treatment options available, until marketing authorisation has been granted.

Environmental risk management (ERM)
In the context of antibacterial product manufacturing, ERM seeks to determine and manage environmental risks resulting from the production of antibacterials, such as the emergence of antibacterial resistance, to protect human health and the environment.

Equitable pricing strategy
A targeted pricing strategy which aims to improve access to medicine for those in need by considering the relevant payer's ability to pay, and by taking healthcare systems' needs and characteristics into account.

Fair market value assessment
Assessment that defines the appropriateness of payments made to healthcare professionals (HCPs). These provide structure to ensure ethical interactions between the pharmaceutical industry and HCPs with whom companies engage.

Falsified medicine
A medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Falsified medicines may contain no active ingredient, the wrong active ingredient or the wrong amount of the correct active ingredient.

Generic medicine
Pharmaceutical product developed and manufactured to be identical to the originator medicine already authorised. Generic medicines offer the same therapeutic and clinical benefits containing the same active pharmaceutical ingredient (API), dose, strength, and route of administration. Generic medicines are manufactured in compliance with the same stringent rules and regulations regarding quality, safety and efficacy as the originator medicine.

Good Manufacturing Practices (GMP)
To ensure that products are consistently produced and controlled according to appropriate quality standards, GMP systems are employed. Within pharmaceutical production this serves to minimise risks such as unexpected contamination, incorrect labelling or incorrect dose of the active ingredient. GMP covers all aspects of pharmaceutical production (e.g., starting materials, premises, equipment, training and personal hygiene of staff) and includes processes that provide documented proof that correct procedures are consistently followed at each step of the manufacturing process. GMP guidelines are established and overseen by regulatory agencies in individual countries or regions, as well as the WHO.

Healthcare Professional (HCP)
Any specialised worker in any branch of healthcare that provides preventive, curative or rehabilitative services to the community.

Innovative project
An innovative project is a pipeline candidate which meets at least one of the four criteria defined in WHO's report "2023 Antibacterial agents in clinical and preclinical development" (2024): (1) new chemical class; (2) new target; (3) new mode of action (MoA); (4) absence of cross-resistance[4] or the Benchmark's 'other' criterion for innovation which considers additional characteristics that provide greater practical advantages for patient care in LMICs beyond the criteria of WHO's assessment.

Late-stage drug development
In the context of the pharmaceutical R&D pipeline, medicine and vaccine candidates in Clinical phase II or Clinical phase III are considered to be in late-stage clinical development.

Mass Balance Approach
A method used to estimate the amount of antibacterial ingredients lost during the production process that subsequently could be present in waste. It consists of estimating the how much of the antibacterial ingredient is lost in the production process and will end up in waste, i.e., the mass balance, applying the removal efficiency of antibacterial residue through on-site treatment and other treatment plants and applying dilution factors resulting from water flows from treatment plants and rivers. This approach allows companies to estimate the final concentration of antibacterials in the receiving environment without directly measuring them in the wastewater samples.

National Regulatory Authority (NRA)
The national agencies responsible for ensuring that pharmaceutical products released for public distribution are evaluated properly and meet international standards of quality and safety and efficacy.[5]

Off-patent medicine
A medicine whose granted patent protection has expired and is no longer protected by or exclusive marketing rights. Patent protection typically lasts for 20 years and is specific to each country.

On-patent/patented medicine
A patented or on-patent medicine is a medicine that has received exclusivity rights, allowing the patent holder to prevent or stop others from making, using, selling or importing the medicine within the country that granted the patent.

Paediatric formulation
A paediatric formulation is a formulation adapted and approved for use in children up to 12 years of age. For the analysis in this report, paediatric formulations must be listed on the World Health Organization's Essential Medicines List for Children and must be distinct from the standard product. For example, an intravenous formulation where different doses can be administered to both adult and children does not qualify.

Patient assistance programmes
Programmes initiated by pharmaceutical companies which provide financial assistance or free-of-charge medicines for a defined patient population with limited ability to pay.

Patient reach
The number of people benefitting from access to a company's product(s), which can be demonstrated through, for example, annual sales volume divided by volume per patient or the estimated number of patients reached by a particular access strategy, initiative, or partnership.

Payers
Entities, including individuals, private health insurers, governments, and international organisations, which are responsible for funding and facilitating medical services. The entities vary based on the healthcare system's financial structure.

Period of analysis
The 2026 AMR Benchmark report will assess company activities taking place during a period of analysis going from 1st October 2023 to 30th September 2025. For the R&D research area, projects need to be ongoing, approved or awaiting approval by the end of the period of analysis.

Pooled procurement
A process through which a buyer pulls together demand to increase the total quantity of a specific product to include in a tender, in order to benefit from better procurement conditions and economies of scale.

Post-trial access
The continued provision of an investigational product or comparator to clinical trial participants following the end of the clinical trial in which they participated when continued treatment is beneficial.

Predicted No Effect Concentration (PNEC)
The highest estimated concentration at which no effects of concern are expected to occur in an ecosystem, such as the opportunity for resistance selection or harm to aquatic life. Typically referred to as discharge limits.

Priority pathogen
Priority pathogens are pathogens for which new medicines and vaccines are highly needed. Priority pathogens are informed by the bacterial and antifungal priority pathogens lists published by WHO and are based on unmet R&D needs and public health importance.

Public-private partnership (PPP)
A partnership between one or more public organisation(s) and a private sector company or companies for providing a public asset or service, in which the private party bears significant risk and management responsibility, and remuneration is linked to performance. The Programme also considers a partnership between a non-profit organisation and the private sector to be a PPP.

Responsible business practices
Promotional activities targeting the general public, patients, and healthcare professionals in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.

Small- and medium-sized enterprise (SMEs)
Enterprises can be classified in different categories according to their size; for this purpose, different criteria may be used, but the most common is number of people employed. SMEs employ fewer than 250 people and can be subdivided into micro enterprises (fewer than 10 employees), small enterprises (10 to 49 employees), medium-sized enterprises (50 to 249 employees).[6]

Stewardship plan
A stewardship plan is a plan set up to ensure that AMR-relevant public health needs are taken into consideration during R&D. These plans may be developed in-house or through collaborations and include commitments, strategies, concrete provisions, and other agreed-upon measures (typically developed in partnership) to enforce accountability. Stewardship plans facilitate the appropriate use of antimicrobial medicines and reduce the emergence of resistance. Examples include (but are not limited to) appropriate promotional practices and conducting surveillance studies.

Stringent Regulatory Authorities (SRAs)
A national drug regulation authority that is considered by the World Health Organization to implement stringent requirements in regard to quality, safety, and efficacy throughout the regulatory review of drugs and vaccines for marketing authorisation.

Substandard medicine
Also referred to as "out of specification", these are market-authorised medicines that fail to meet either quality standards or specifications, or both.[7]

Technology transfer
A pharmaceutical company transfers knowledge, tools and/or technology necessary for producing a specific product (e.g., medicine, vaccine) to a manufacturer. Technology transfer can improve the supply and availability of products, while also building manufacturing capacity that can be applied to other manufacturing processes.

Transfers of value (ToVs)
ToVs include all payments, benefits or other resources that are provided to healthcare professionals by pharmaceutical companies or their representatives. ToVs can be financial or non-financial, with non-financial examples including meals, gifts or other materials. They may be provided for a variety of purposes, such as consultation, education, research, travel or sponsorship.

Voluntary license
A voluntary license is an authorization given by the patent holder to a generic company, allowing it to produce the patented medicine or vaccine, often at a lower cost. The license usually sets quality requirements and defines the countries in which the licensee can sell the product.[8]

Wastewater
Wastewater or liquid waste that may contain antibiotic residues and is released from manufacturing facilities, hospitals, or other sources where antibiotics may be used or produced. Wastewater is often referred to as effluent and is considered safe when PNECs are met (see PNEC).

The World Health Organization (WHO) Collaborative Registration Procedure (CRP)
A procedure launched by the WHO that aims to expedite registration of prequalified finished pharmaceutical products. It accelerates registration through improved information sharing between the WHO prequalification system and national regulatory authorities. By leveraging assessment and inspection outputs already produced by WHO prequalification, and thereby eliminating duplicative regulatory work, it speeds up in-country registration of quality-assured products and contributes to their wider availability.

WHO Model List of Essential Medicines (WHO EML)
The WHO EML is a list published every two years by the WHO, which lists all essential medicines recommended to be available in functioning health systems at all times.[9]

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