Antimicrobial Resistance Benchmark 2026

METHODOLOGY

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The Access to Medicine Foundation is an independent nonprofit 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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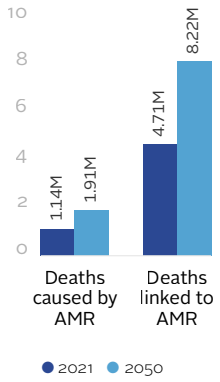
EXECUTIVE SUMMARY

Updated 2026 framework will track key pharma players' progress on curbing AMR

Ten years after the World Health Organization (WHO) declared antimicrobial resistance (AMR) a global health threat in 2014[1], 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 global health threat, with more people dying due to AMR than from HIV/AIDS and malaria and these numbers still expected to rise.[2] In 2021, it was estimated that AMR contributed to the deaths of 4.7 million people globally, with 1.14 million of these deaths occurring solely due to drug-resistant infections. By 2050, these deaths are projected to increase further, reaching 8.22 million and 1.91 million, respectively.[3]

To date, the 2022 report, *Global Burden of bacterial antimicrobial resistance in 2019: A systemic analysis*[2] has been the major reference point for impact and the burden of AMR globally. However, in 2024, new data revealed shifting trends in the global burden of AMR, providing insights on how drug resistance has developed since 2019 and how it is projected to evolve (see Figure 1 below).

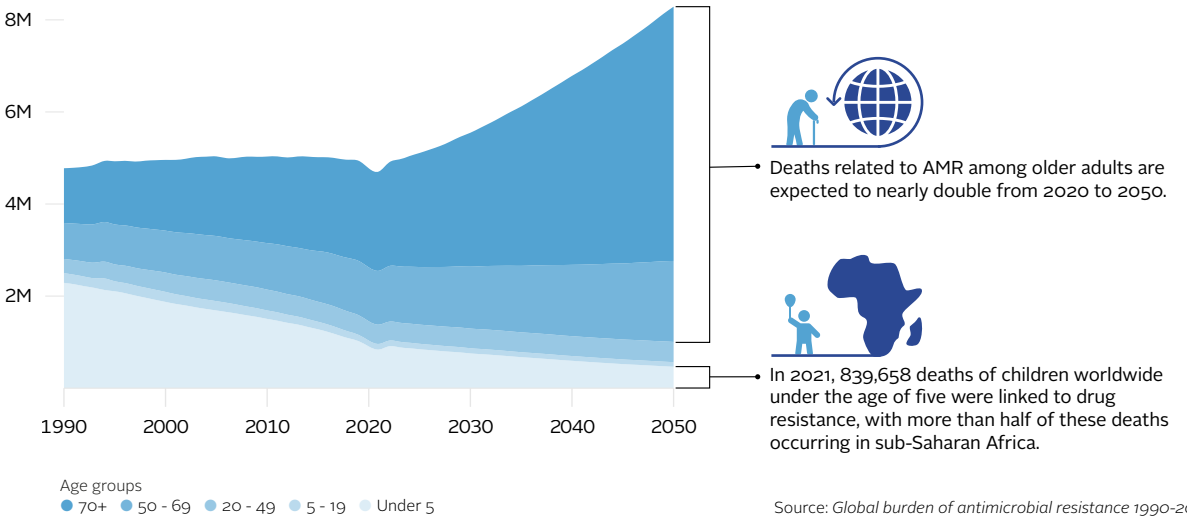
Deaths related to AMR are only expected to increase



Source: *Global burden of antimicrobial resistance 1990-2021: a systematic analysis with forecasts to 2050*, Naghavi et al., 2024

FIGURE 1 **The future of AMR: Global mortality projections towards 2050 and key age groups**

Estimates of the millions of deaths linked to AMR by age group, globally, between 1990 and 2050.



Source: *Global burden of antimicrobial resistance 1990-2021: a systematic analysis with forecasts to 2050*, Naghavi et al., 2024

Concerningly, these latest forecasts of AMR-associated deaths by age group show that deaths in older adults are expected to surge, nearly doubling by 2050. Encouragingly, AMR-associated deaths among young children under five are decreasing globally, illustrating the success of existing interventions, including vaccinations, in decreasing the global number of deaths in children. However, children under the age of five living in low-resource settings remain disproportionately affected, with over half of the 839,658 children who die living in sub-Saharan Africa.

The cost of inaction

Given these projections, the urgency in accelerating action against AMR is clear. While the sheer scale and pace of drug resistance requires collaborative action from global health stakeholders, pharmaceutical companies play a pivotal role in helping to curb AMR, especially in low- and middle-income countries (LMICs), where people face the greatest risk and over 80% of global deaths related to AMR occur.[3] Without decisive action from the companies that develop, manufacture and sell lifesaving antimicrobials, there will be no sustainable solution.

Current progress remains concentrated in wealthier countries, but if interventions revolving around the prevention and treatment of drug-resistant infections mirror those being undertaken in higher-income countries, and are employed more widely across LMICs, over 750,000 lives could already be saved each year.[4]

In addition to the devastating impact AMR will continue to have on the lives of people if efforts are not accelerated, it also poses a serious threat to the global economy. The burden of inaction is estimated to cause a USD 1.7 trillion annual reduction in global economic output by 2050.[5] However, investments in increased access to high-quality treatment, together with innovation in the development of new antimicrobials, can boost the global economy by an estimated USD 906 billion by 2050 and are predicted to cost USD 63 billion a year – only a fraction of the cost of inaction.[5]

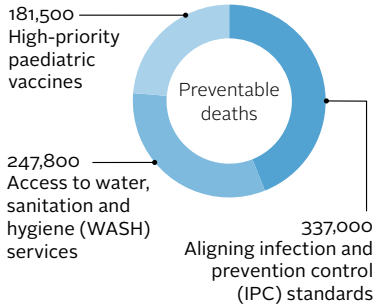
Investments in addressing AMR are not only vital for reaching underserved populations in LMICs but are also crucial for protecting the lives of those living in countries the world over. No community is immune to AMR and drug-resistant pathogens know no borders, making the emergence and spread of AMR anywhere a risk to the lives of everyone, everywhere.

How companies can make an impact as global priorities on AMR refocus

AMR is not an insurmountable challenge and now, more than ever before, it is being recognised as a top priority on the global political agenda, with 2024 signalling an inflection point in the collective and immediate response that is needed to save lives. The United Nations General Assembly (UNGA) high-level meeting in September 2024, for example, marked a significant step in long-needed collaborative action. There, UN members not only formally acknowledged the critical threat posed by AMR but also reached consensus on coordinated actions to address it,[6] and pledged to achieve a 10% reduction in AMR-associated global deaths by 2030.[7]

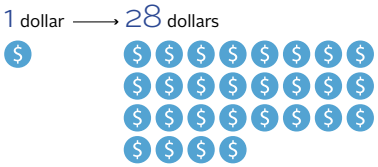
As part of the global consensus on what needs to be done to address AMR, there are clear areas where companies must play their part (see commitments in the table alongside).

Nearly 770,000 deaths can be prevented annually by employing existing AMR interventions more widely



Source: *Burden of bacterial antimicrobial resistance in low-income and middle-income countries avertible by existing interventions: an evidence review and modelling analysis*, Lewnard et al., 2024

Investments into AMR are estimated to yield positive investment returns



Source: *Forecasting the fallout from AMR: Economic impacts of antimicrobial resistance in food-producing animals*, McDonnell et al., 2024

Commitments from the political declaration on AMR include areas where pharma companies need to act:

- Improving access to antimicrobials
- Innovation in research and development
- Addressing environmental risks
- Surveillance and monitoring of resistance

Source: *Political declaration of the high-level meeting on antimicrobial resistance*, United Nations, 2024

Ahead of the high-level meeting, global stakeholders were already updating and developing new guidelines to outline priorities for action and had started to test new models for AMR governance. These guidelines have laid a foundation for further action on AMR and can support companies in taking concrete steps to advance their efforts. Examples include:

- New research and development (R&D) priorities defined by WHO, including the first ever fungal Priority Pathogen List in 2022 and an updated bacterial Priority Pathogen List in 2024.[8,9]
- The launch of a certification to demonstrate responsible manufacturing by the British Standards Institute (BSI) and AMR Industry Alliance in 2023,[10] followed by the publication of a new and independent guidance setting comprehensive standards for responsible manufacturing by WHO in 2024.[11]
- Countries, such as the UK, Sweden and Japan adopting new models to purchase antimicrobial products and incentivise R&D, including the now fully operational subscription-based model in the UK.[12]

While these developments are promising, leaders in the pharmaceutical industry must now urgently step up to help ensure the commitments of the political declaration come to fruition and culminate in real impact.

How the new AMR Benchmark will set ambitious goals for companies to drive change

The Access to Medicine Foundation's AMR Benchmark 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 save patients from drug-resistant infections. The metrics for this assessment have evolved over the years and are grounded in multi-stakeholder consensus, including input from pharmaceutical companies, global health stakeholders and investors.

By evaluating company practices, the Benchmark serves as an accountability tool and incentivises the continuous improvement of companies, particularly by identifying best practices and linking them to tangible opportunities for companies. As such, the Benchmark also acts as a crucial resource for stakeholders, including

FIGURE 2 **From 2021 to 2026: Exploring key AMR Research Areas – A timeline of research reports and methodology refinement**

governments and investors, to inform policies and strategies to steer the industry's engagements in addressing AMR.

Following a five-year gap since the release of the 2021 AMR Benchmark, the Foundation will be publishing a new Benchmark in 2026, with this Methodology Report encompassing the analytical framework that will be used to assess companies on their efforts to curb AMR. Drawing on the findings from targeted research reports published by the AMR Programme over the past five years (see timeline on p.6), which focused on critical areas for companies in the field of AMR, this framework has been updated to reflect the priorities and developments against which companies can make progress.

What the Benchmark will measure

The 2026 Benchmark will evaluate the efforts of **26 companies** across three Research Areas (see Figure 3) within the period of analysis going from 1 October 2023 to 30 September 2025. This includes seven large research-based companies and ten generic medicine manufacturers, which together account for 30.7% of the global market share for antibiotics and antifungals by value.[13] To reflect the current R&D landscape, the Benchmark will also assess the efforts of nine SMEs that are leading in antibiotic and antifungal product development.

The companies in scope will be analysed according to their products and projects in development targeting all **bacterial and fungal infections**.

The **24 bacterial and 19 fungal pathogens** highlighted as R&D priorities by WHO are in scope for the Research & Development Research Area, and Centers for Disease Control and Prevention (CDC) priorities are no longer considered.

The Benchmark focuses on **medicines and vaccines** that target bacterial and fungal infections. This includes on-patent and off-patent products as well as those in clinical development.

The Benchmark tracks companies' progress in AMR **globally**. However, for the set of indicators measuring company efforts in ensuring access to their products ('access metrics'), the Benchmark adopts a separate geographic scope covering **113 countries** (see Figure 4), focusing mainly on LMICs.

FIGURE 3 **Companies in scope for each Research Area**

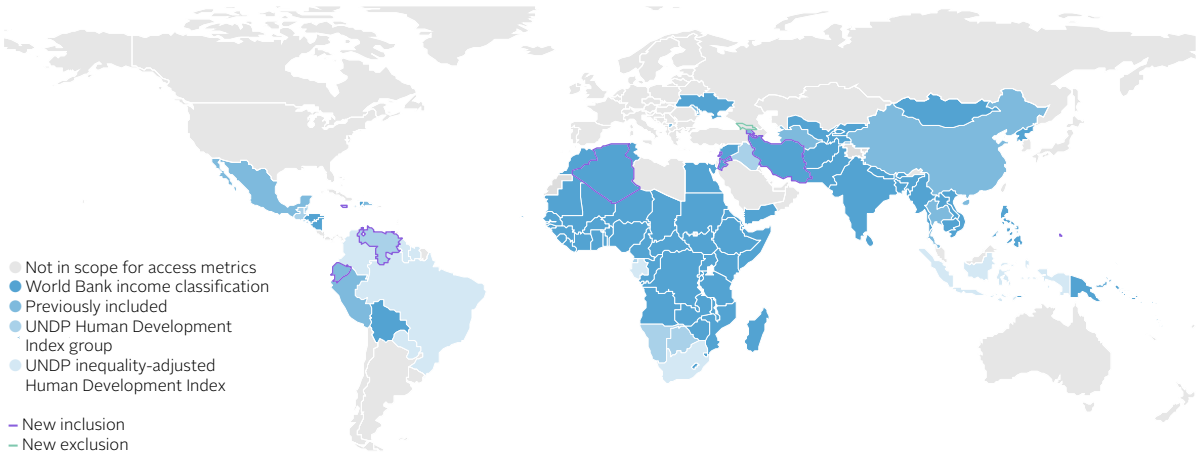
	Large research-based companies	Generic medicine manufacturers	Small- and medium-sized enterprises
Research & Development	✓		✓
Responsible Manufacturing	✓	✓	
Appropriate Access & Stewardship	✓	✓	

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, Pulmocide, TenNor, Venatorx

FIGURE 4 **Geographic scope for the access metrics of the 2026 Benchmark**



*The Benchmark no longer evaluates Hainan Hailing or Novartis, while Hikma and Sandoz are newly included.

How the Benchmark will measure

The methodology for the 2026 Benchmark is built on a robust analytical framework comprised of 16 equally weighted indicators. It aligns with the core role pharmaceutical companies can play in ensuring appropriate access to antimicrobial products while actively contributing to efforts to curb the rise of AMR.

16 INDICATORS ACROSS 3 RESEARCH AREAS

RESEARCH & DEVELOPMENT

5 INDICATORS: ●●●●●

R&D is critical in combatting AMR as it drives the innovation needed to stay ahead of rapidly evolving drug-resistant pathogens. However, despite this need, the development of new antimicrobial products has significantly diminished in recent decades. Large research-based companies have stepped back from research in this area in favour of more profitable products, leaving SMEs to drive innovation while navigating challenging market conditions with minimal support from larger pharmaceutical companies.

Through the R&D Research Area, the Benchmark aims to encourage companies to continue engaging – or re-engage – with this topic, highlight promising projects in the pipeline and ensure that companies are adequately planning for access and stewardship to deliver impact once these projects are approved.

SMEs' R&D ACTIVITIES TO BE ASSESSED

Key changes in the 2026 Benchmark: While this Research Area no longer includes an assessment of financial investments in R&D, it continues to evaluate pipeline health directly through other indicators. A few indicators have adopted an expanded scope, allowing for more R&D projects to be considered. A new 'innovativeness' parameter highlights projects with added clinical utility beyond the four WHO criteria, while the R&D gaps indicator now includes projects targeting high-priority pathogens and rifampicin-resistant *Mycobacterium tuberculosis*, alongside critical priority pathogens.

RESPONSIBLE MANUFACTURING

2 INDICATORS: ●●

Pharmaceutical companies must adopt responsible and transparent manufacturing practices to ensure that the production of their lifesaving medicines does not inadvertently accelerate the development of AMR. During the antibiotic manufacturing process, waste is often released into the environment, particularly into rivers, which are later used to source water for drinking and agriculture. If this waste contains high levels of active pharmaceutical ingredients (APIs), it poses a serious risk to the emergence and spread of AMR while also causing environmental damage.

This Research Area evaluates the breadth and depth of environmental risk-management strategies applied by companies at the company's own manufacturing sites, those of third-party suppliers and those of external waste treatment plants. This analysis offers valuable insights into the implementation of these strategies and whether the associated risk of AMR from manufacturing is successfully prevented.

ARE COMPANIES COMPLYING WITH DISCHARGE LIMITS?

Key changes in the 2026 Benchmark: The depth of this Research Area has evolved to reflect cross-industry progress. Rather than simply assessing whether companies set discharge limits, this iteration will examine whether companies are actively complying with these limits. Additionally, it will assess how various companies are quantifying their discharge levels. The emphasis will be less on public waste treatment plants, focusing predominantly on companies' own and suppliers' manufacturing sites, where they have greater control over waste management practices.

APPROPRIATE ACCESS & STEWARDSHIP

7 APPROPRIATE ACCESS INDICATORS: ●●●●●●●
2 STEWARDSHIP INDICATORS: ●●

To curb AMR, pharmaceutical companies must ensure patients have access to the right antibiotics at the right time, no matter where they live. The sheer lack of access to antibiotics and antifungals leads to more deaths from treatable infections than from drug-resistant ones.[14] At the same time, the overuse and misuse of antibiotics and antifungals remain the primary drivers of AMR. Therefore, striking a careful balance between access and stewardship is essential. This is not without its challenges; while antibiotics have traditionally had a low price tag, new Reserve antibiotics (also see definitions on p.33) are often highly priced, and smaller associated order quantities make it difficult to scale access effectively.

This Research Area focuses on understanding how pharmaceutical companies are expanding appropriate access to both on- and off-patent antibiotics and antifungals – examining everything from their approach to product registration to the access and stewardship strategies they employ. In doing so, the assessment identifies access gaps in which more can be done, as well as best practices that other companies can potentially adopt for different products to further enhance appropriate access.

INCREASED FOCUS ON PATIENT REACH

Key changes in the 2026 Benchmark: This Research Area now adopts 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. It also focuses on understanding the underlying methods behind companies' approaches to evaluating patient reach and monitoring resistance.

REVIEWING THE METHODOLOGY

Ensuring company actions focus on key areas that will drive progress in the fight to curb AMR

Since the release of the last Antimicrobial Resistance (AMR) Benchmark in 2021, the Access to Medicine Foundation has narrowed in on pharmaceutical companies' efforts to curb drug resistance through targeted research reports focusing on the key areas analysed in the 2021 Benchmark: access and stewardship (2022), responsible manufacturing (2023) and research and development (R&D) (2024). Additionally, in 2023, the AMR Programme published an update on companies' 'Opportunities' identified in the 2021 Benchmark to determine where progress has been made – and where they need to focus their actions in helping to address the rising threat of drug resistance.

Now, paving the way for the next iteration of the AMR Benchmark to be published in 2026, the AMR Research Team has drawn on findings across these reports, developments in the progression of the AMR landscape, as well as wide-ranging stakeholder consultations in preparing the new analytical framework that will form the bedrock of the 2026 AMR Benchmark assessment. The new collection of indicators forms a refreshed, comprehensive framework that will be used to chart companies' progress during the period of 1 October 2023 to 30 September 2025.

Accounting for change: Redesigning the Benchmark's metrics

To reflect the evolution of the AMR landscape since the last Benchmark, the Research Team extensively reviewed its framework of metrics, which are categorised into three areas: Research & Development, Responsible Manufacturing and Appropriate Access & Stewardship.

The review process eliminated the risk of redundant measures, highlighted opportunities for enhancing data and identified where scoring guidelines could be tightened. Specifically, the Research Team evaluated:

- Company and industry-level performance across indicators
- Distribution of scores per indicator
- Response rates and quality of the data submitted by companies

The refined metrics were designed to be tracked over time in longitudinal analyses and accommodate the diverse company types in scope of the methodology, including large research-based companies, generic medicine manufacturers and small- and medium-sized enterprises (SMEs).

With these priorities imbedded, the new framework will ensure that the upcoming analysis, to be published in the 2026 Benchmark, will be well supported, fair and meaningful, and define clear expectations for pharmaceutical companies' role in the fight against AMR.

In tandem with its internal review, the Research Team engaged with 38 external experts from the AMR sector between July and October of 2024. This group consisted of representatives from the private sector, non-profit organisations, research and academic institutions and other constituencies (see Figure 5) – including those working in low- and middle-income countries (LMICs). These engagements were based on targeted questions about the pharmaceutical industry's role in curbing AMR to ensure the proposed methodology aligns with the capabilities and responsibilities of the industry. The opportunity to provide feedback was provided to large research-based companies and generic medicine manufacturers in scope of the Benchmark, with ten of the 17 companies responding with inputs. Since the selection of the nine SMEs involved a rigorous process and occurred at a later stage, the SMEs did not have an opportunity to provide input. However, SMEs were represented by the Biotechnology Innovation Organization (BIO) as part of the Expert Review Committee (ERC).

FIGURE 5 **Stakeholder engagement for the 2026 Benchmark**

Expert Review Committee recommendations

Taking stakeholders' feedback into consideration, the Research Team drafted a proposal for the updated methodology, which was presented to an independent ERC on 17 October 2024 to gather further strategic inputs and guidance before endorsing it. The ERC is comprised of 13 independent experts in the field of AMR from global health organisations, top-level academic centres and public sector entities, as well as investors and pharmaceutical industry representatives. The members include:

- Chair of the Committee: Hans Hogerzeil, Professor in Global Health, University Medical Center Groningen (UMCG)
- Susana Almeida, Secretary General, International Generic and Biosimilar Medicines Association (IGBA)
- James Anderson, Executive Director of Global Health, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Jennifer Cohn, Director of Global Access, Global Antibiotic Research and Development Partnership (GARDP)
- Sabiha Essack, South African Research Chair in Antibiotic Resistance, University of KwaZulu-Natal
- Geentanjali Kapoor, Head, One Health Trust
- Amit Khurana, Programme Director Sustainable Food Systems, Centre for Science and Environment (CSE)
- Joakim Larsson, Professor of Environmental Pharmacology in the Department of Infectious Disease, University of Gothenburg
- Marc Mendelson, Division Head of Infectious Diseases and HIV Medicine at Grote Schuur Hospital, University of Cape Town
- Mirfin Mpundu, Executive Director, ReAct Africa
- Frank Wagemans, Senior Engagement Specialist, Achmea Investment Management
- Evelyn Wesangula, Senior Antimicrobial Resistance (AMR) Control Specialist, The East Central and Southern Africa Health Community
- Emily Wheeler, Director of Infectious Disease Policy, Biotechnology Innovation Organization (BIO)

In convening to review and ratify the methodology, the ERC considered the different drivers of drug resistance and responsibilities of companies raised during stakeholder consultations, revolving around companies' access and stewardship, manufacturing and R&D efforts.

The committee discussed the importance of stabilising access to antimicrobial products in LMICs, which will require companies to take more strategic action, such as aligning product registrations with the current product supplies in LMICs.

In tandem with this, companies also need to incorporate responsible business practices to prevent the misuse and overuse of their products after delivery, a major contributor to AMR.

Additionally, given the increasing focus on responsible manufacturing practices within the global AMR landscape, including the September 2024 release of the World Health Organization (WHO)'s guidance on responsible manufacturing,[11] the methodology will continue to encourage improvements by companies in this area.

The ERC also emphasised the importance of SMEs in developing innovative antimicrobials that target the most harmful pathogens. As leaders in the R&D of innovative products, these companies can help slow the progression of AMR, with more foresight and effort focused on access and stewardship planning.

Outcome: Refined scope and indicator set for the 2026 AMR Benchmark

With the ERC's recommendations and strategic guidance, wide consensus was reached on the necessary changes to previous indicators and scopes.

The new framework has been refined to include 16 indicators, four fewer than the previous iteration of the methodology. Two have been removed and two have been merged to reflect the evolution of AMR and the pharmaceutical landscape since 2021.

The updates have culminated in a more outcome-focused approach to analysing company activities. For example, when it comes to assessing companies' surveillance efforts, antibiotic discharge levels and patient reach strategies, the methodology will incite more concrete details on how surveillance datapoints are collected, how antibiotic discharge levels are quantified and how patient reach numbers are calculated.

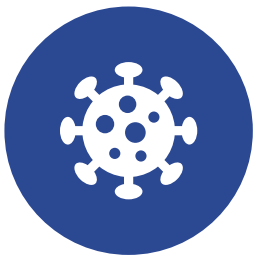
Additionally, to follow through on recommendations regarding the R&D of innovative antimicrobials, nine SMEs have been included in this research area, alongside large research-based companies, rather than in a separate report as in 2021. With the ratification of the methodology, the new approach for the upcoming iteration of the AMR Benchmark has been confirmed.

ANALYTICAL FRAMEWORK

WHAT THE BENCHMARK MEASURES

COMPANY SCOPE

DISEASE SCOPE



PRODUCT SCOPE

GEOGRAPHIC SCOPE

WHAT THE BENCHMARK MEASURES

Company scope

The AMR Benchmark assesses the activities of a cross-section of the pharmaceutical industry, including large research-based companies, generic medicine manufacturers and small- and medium-sized enterprises (SMEs), emphasising the most influential companies that play a key role in shaping the market. The 2026 Benchmark will assess seven large research-based companies and ten generic medicine manufacturers, which together account for nearly one-third (30.7%) of the global market share for antibiotics and antifungals by value.[13] In addition, the research and development (R&D) activities of nine SMEs are evaluated, five of which were assessed in standalone reports on R&D published in 2021 and 2024.

FIGURE 6 **Companies in scope for the 2026 AMR Benchmark by Research Area**

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

Large research-based companies are selected for inclusion based on global market shares, as defined by largest volume or value of global sales of antibacterials and antifungals, using 2024 IQVIA sales data;* and/or if they have an anti-infective product portfolio and a pipeline during the period of analysis with at least one antibacterial or antifungal drug or vaccine that targets a priority pathogen in late-stage clinical development (Phase II or above), as identified by the World Health Organization (WHO).[8,9] The majority of selected companies rank in the top five of largest volume and/or value of global sales of antibacterials and antifungals. In addition, market leaders in antituberculosis medicines are prioritised for selection. When multiple companies fit the criteria, an element of continuity is considered to ensure longitudinal tracking of companies.

Generic medicine manufacturers are selected for inclusion based on global market shares, as defined by largest volume or value of global sales of antibacterials and antifungals, using 2024 IQVIA sales data.* All selected companies rank in the top ten of largest volume and/or value of global sales of antibacterials and antifungals. When multiple companies fit the criteria, an element of continuity is considered to ensure longitudinal tracking of companies.

Small- and medium-sized enterprises are selected for inclusion based on two criteria. First, at least one pipeline project of the SME targets WHO priority pathogens[8,9] and is in late-stage clinical development (Phase II or above) during the period of analysis. In case multiple SMEs fulfil these criteria, a selection is made to maintain a balance across antibacterial (including antituberculosis projects) and antifungal projects. Second, for a SME to be selected, the number of employees must be below 250.

Key changes for the 2026 AMR Benchmark

The 2026 Benchmark will assess all three groups of pharmaceutical companies in one report. Unlike the 2021 Benchmark, SMEs will not be assessed in a standalone report; instead, they will be assessed under the R&D Research Area to reflect the significant changes in the antimicrobial R&D landscape since the Benchmark's past iteration.

The selection of large research-based companies remains the same with the exception of Novartis, which has been removed from the scope of the 2026 Benchmark and substituted by Sandoz as a generic medicine manufacturer, due

*IQVIA Midas intelligence data on sales of antibacterials and antifungals globally from 2024. Data is limited to the private healthcare sector and refers to aggregate sales in 75 countries, the majority of which are low- and middle-income countries from Latin America & Caribbean, Middle East & North Africa, sub-Saharan Africa, East Asia & Pacific and South Asia.[13]

to Sandoz's spin-off from Novartis in 2023.[15] Additionally, Hainan Hailing will be removed as generic medicine manufacturer and Hikma will be added. This change is based on 2024 IQVIA sales data. Across all groups of companies, 11 have been continuously evaluated since 2018.**

TABLE 1 **Companies in scope for the 2026 AMR Benchmark**

Large research-based companies

		Country HQ	Ticker	Stock Exchange	Revenue (bn USD)***
1	GSK plc	GBR	GSK	LSE	38.6
2	Johnson & Johnson	USA	JNJ	NYSE	85.2
3	Merck & Co, Inc	USA	MRK	NYSE	60.1
4	Otsuka Pharmaceutical Co, Ltd	JPN	4578†	TSE	9.7
5	Pfizer Inc.	USA	PFE	NYSE	58.5
6	Sanofi	FRA	SAN	EPA	47.5
7	Shionogi & Co, Ltd	JPN	4507	TSE	3.1

Generic medicine manufacturers

		Country HQ	Ticker	Stock Exchange	Revenue (bn USD)***
1	Abbott Laboratories	USA	ABT	NYSE	40.1
2	Alkem Laboratories Ltd	IND	ALKEM	NSE	1.4
3	Aurobindo Pharma Ltd	IND	AUROPHARMA	NSE	3.0
4	Cipla Ltd	IND	CIPLA	NSE	2.7
5	Fresenius Kabi AG	DEU	FRE‡	XFRA	24.6
6	Hikma Pharmaceuticals plc	GBR	HIK	LSE	2.9
7	Sandoz	CHE	SDZNY	OTCQX	9.3
8	Sun Pharmaceutical Industries Ltd	IND	SUNPHARMA	NSE	5.3
9	Teva Pharmaceutical Industries Ltd	ISR	TEVA	NYSE	15.8
10	Viatris Inc	USA	VTRS	NASDAQ	15.4

Small- and medium-sized enterprises

		Country HQ	Ticker	Stock Exchange	Estimated number of employees	Pipeline candidates targeting priority pathogens in Phase II or III by December 2024 based on publicly available information
1	Basilea Pharmaceutica AG	CHE	BSLN.SW	SIX	51-200	III: Fosmanogepix
2	BioVersys	CHE	-	-	11-50	II: Alpibectir (BVL-GSK098) + ethionamide II: BV100
3	Evopoint Biosciences Co, Ltd	CHN	-	-	51-200	III: Funobactam (XNW4107) + imipenem + cilastatin
4	F2G	GBR	N/A	N/A	11-50	III: Olorofim
5	Innoviva, Inc	USA	INVA	NASDAQ		III: Zoliflodacin
6	Iterum Therapeutics plc	IRL	ITRM	NASDAQ	11-50	Approved: Sulopenem; sulopenem etzadroxil/probenecid§
7	Pulmocide	GBR	-	-	11-50	III: Opelconazole
8	TenNor Therapeutics	CHN	-	-	51-200	II: TNP-2092
9	Venatorx	USA	-	-	2-10	NDA: Cefepime + taniborbactam (VNRX-5133)

**This includes Viatris, which has been assessed as Mylan NV before its merger with Upjohn in 2020.[16]
***Revenue data from fiscal year 2023 (exchange rates of the last day of fiscal year were used from www.x-rates.com).

†Financial information (Ticker, Stock exchange, Revenue) is for Otsuka Holdings, the parent company of Otsuka Pharmaceutical Co, Ltd.

‡Ticker and Stock exchange information is for Fresenius SE & Co. KGaA, the parent company of Fresenius Kabi AG.

§ORLYNVAHTM (sulopenem; sulopenem etzadroxil/probenecid) was approved within the period of analysis, specifically on 25 October 2024.[17]

WHAT THE BENCHMARK MEASURES

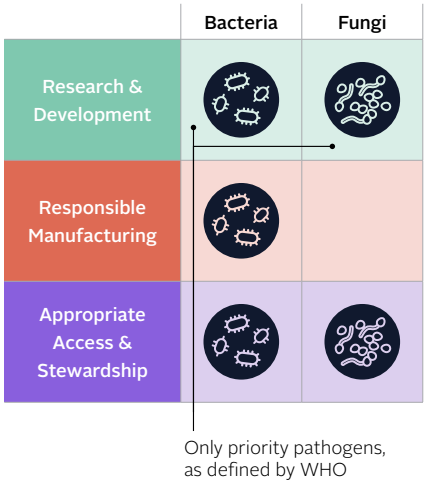
Disease scope

The AMR Benchmark evaluates pharmaceutical companies' actions in addressing the impact of drug resistance in infections caused by bacterial and fungal pathogens. Infections caused by viral pathogens or protozoa, such as HIV/AIDS and malaria respectively, are not in scope of the AMR Benchmark. Though they are also contributing to the rising threat of AMR, the research and development requirements and market structures for these diseases differ significantly from those for diseases caused by bacterial and fungal pathogens.

For each Research Area, the 2026 Benchmark adopts a slightly different disease scope:

- **Research & Development:** In this Research Area, the focus is on infections caused by priority pathogens listed on the World Health Organization (WHO)'s second iteration of the bacterial Priority Pathogen List (2024) and first iteration of the fungal Priority Pathogen List (2022), see Appendix I.[8,9] These lists identify the pathogens that represent the most urgent R&D priorities on a global level.
- **Responsible Manufacturing:** In this Research Area, the focus remains on bacterial pathogens. As with previous iterations of the Benchmark, fungal pathogens are excluded, as the capacity of fungi to transfer resistance in the natural environment to harmful fungi is unclear. This is in line with WHO's *Guidance on wastewater and solid waste management for manufacturing of antibiotics* (2024).[11]
- **Appropriate Access & Stewardship:** This Research Area considers all bacterial and fungal pathogens. Ensuring that patients can access the appropriate medicines if they contract any bacterial or fungal infection is crucial, as well as monitoring the resistance across all bacterial and fungal pathogens.

FIGURE 7 **Diseases in scope for the 2026 AMR Benchmark by Research Area**



Key changes for the 2026 AMR Benchmark

The 2026 Benchmark will no longer focus on priority pathogens identified by the Centers for Disease Control and Prevention (CDC), since these are limited to the most important R&D priorities for the US. Instead, the 2026 Benchmark will only consider WHO's Priority Pathogen Lists for R&D. This includes the pathogens within WHO's bacterial Priority Pathogen List (2024)[8] and WHO's fungal Priority Pathogen List (2022).[9]

WHAT THE BENCHMARK MEASURES

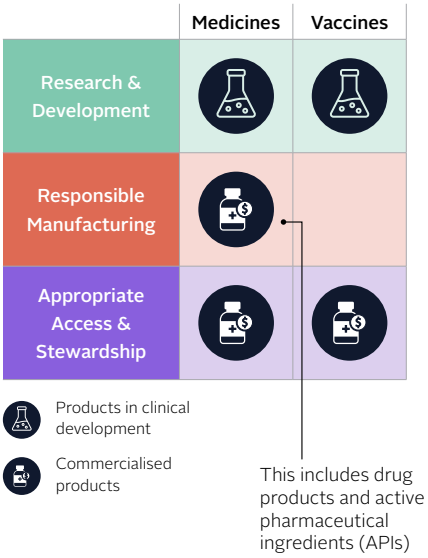
Product scope

The AMR Benchmark focuses on medicines and vaccines that target bacterial and fungal infections in humans. For medicines, this includes all innovative and adaptive medicines, branded generics and generic medicines (regardless of formulation) for direct treatment of bacterial and fungal pathogens or disease processes; medicines intended exclusively for symptomatic relief are not assessed. For vaccines, this includes preventive and therapeutic vaccines that target bacterial or fungal pathogens.

For each Research Area, the product scope is adapted to its particular focus:

- **Research & Development:** In this Research Area, the Benchmark zooms in on antibacterial and antifungal medicines and vaccines that target priority pathogens,[8,9] as listed under *disease scope* (see p.16). Projects in discovery, pre-clinical and clinical Phases I-III or those that are approved during the period of analysis are included.
- **Responsible Manufacturing:** In this Research Area, the Benchmark focuses on manufactured and/or marketed antibacterial medicines and active pharmaceutical ingredients (APIs). Antifungal APIs or drug products are excluded for this Research Area, as also discussed under *disease scope* (see p.16).
- **Appropriate Access & Stewardship:** In appropriate access, products are separated into on-patent medicines and vaccines and off-patent/generic medicines to capture the different strategies and practices that companies use to improve access to these products. For on-patent products, all patented antibacterial and antifungal medicines and vaccines are in scope. For off-patent/generic products, the focus is on each company's top off-patent medicines by sales volume using company's verification. This includes two antibiotics per group of the World Health Organization (WHO)'s 'AWaRe' categorisation (Access, Watch and Reserve),[18] two antifungal medicines and two antituberculosis medicines. As such, a maximum of ten off-patent products are included for analysis. Each of the selected off-patent/generic medicines must be listed on WHO's 2023 Essential Medicine List (EML).[19] In Stewardship, all marketed antibacterial and antifungal medicines are in scope.

FIGURE 8 **Products in scope for the 2026 AMR Benchmark by Research Area**



Key changes for the 2026 AMR Benchmark

The process of determining the product scope for the 2026 Benchmark remains the same as in the 2021 Benchmark. In line with WHO's *Guidance on wastewater and solid waste management for manufacturing of antibiotics* (2024), antifungal products remain out of scope for the Responsible Manufacturing Research Area.[11] However, changes in the final selection of products are possible due to new iterations of priority pathogen list(s), discussed further in *disease scope* (see p.16).

WHAT THE BENCHMARK MEASURES

Geographic scope

The emergence of antibacterial and antifungal resistance is a global health threat that transcends borders and impacts people across regions. Greater efforts to develop new antimicrobial products and safeguard the effectiveness of existing antibiotics are therefore urgently needed worldwide. To track companies' progress in these areas, the 2026 AMR Benchmark will continue to focus on all 218 countries and/or territories listed in the World Bank Country and Lending Group (2024*).[20]

However, since people living in low- and middle-income countries (LMICs) are disproportionately affected by AMR and appropriate access to antibacterial and antifungal medicines and vaccines remains unstable, the indicators that measure how companies ensure access in these countries (referred to as 'access metrics'**) are defined by a separate geographic scope.

Every two years, the Access to Medicine Foundation establishes this geographic scope during the methodology review for the Access to Medicine Index, which is applied to all the Foundation's research programmes to ensure consistency across initiatives. Following the review for the 2024 Access to Medicine Index, the geographic scope for the 'access metrics' of the 2026 Benchmark includes 113 countries (see Table 2). This scope is set using the criteria listed below.

Defining the geographic scope for 'access metrics' for the 2026 Benchmark

Step 1 Include all countries that were included in the last iteration of the Access to Medicine Index.[21]

Step 2 Include all countries classified as low-income or lower-middle-income countries, according to the most recent World Bank income group classification.[22]

Step 3 Include all countries defined as having low or medium human development, according to the United Nations Development Programme (UNDP)'s most recent Human Development Report (2021).[23]

Step 4 Include all high-development countries with a low inequality-adjusted human development index, according to the most recent UNDP Human Development Report (2021).[23] This enables the Benchmark to track higher-income countries with significant levels of inequality.

Step 5 Include all least developed countries (LDCs) as defined by the most recent United Nations Economic and Social Council (ECOSOC) list (2021).[24]

Key changes for the 2026 AMR Benchmark

Compared to the 2021 Benchmark, the next iteration of the Benchmark will follow the Foundation-wide geographic scope. Twelve new countries are in scope: Algeria, Armenia, Ecuador, Iran, Jamaica, Jordan, Lebanon, Marshall Islands, Saint Lucia, Samoa, Tonga and Venezuela. Furthermore, Georgia has been removed from the geographic scope for 'access metrics'.

*The Benchmark will consider all countries or territories listed in the World Bank Country and Lending Groups (June 2024). The World Bank warns that the term 'country' (used interchangeably with 'economy'), does not imply political independence but refers to any territory for which authorities report separate social or economic statistics.

** 'Access metrics' include indicators A.2, C.1.1-1.3, C.2.1-C.2.3 and C.3.

FIGURE 4 **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.

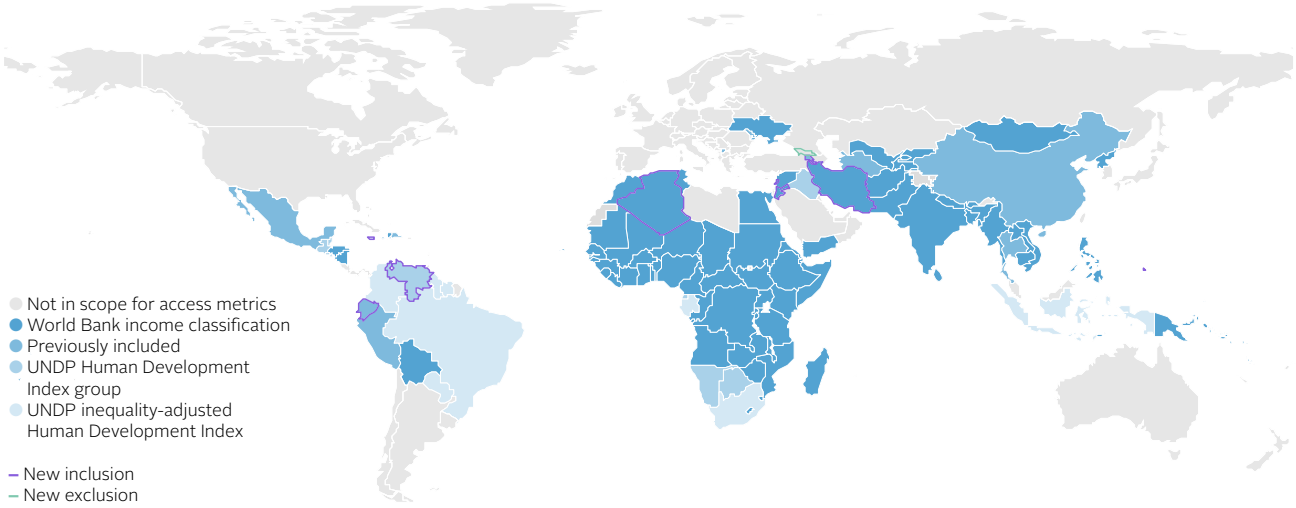


TABLE 2 **List of countries included in the geographic scope for 'access metrics'**

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
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
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
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.

ANALYTICAL FRAMEWORK

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2 INDICATORS

APPROPRIATE ACCESS & STEWARDSHIP

9 INDICATORS

HOW THE BENCHMARK MEASURES

Research & Development

Despite the urgent need for innovative antimicrobial products to combat the growing threat of antimicrobial resistance (AMR) and spread of superbugs, development of new antimicrobial products has diminished significantly in the last decades. This is predominantly due to large research-based pharmaceutical companies scaling back investments in this area in favour of more profitable projects. As a result, small- and medium-sized enterprises (SMEs) have become the driving force for innovation in antibacterials and antifungals, now accounting for 93% of clinical stage developments and 86.7% of preclinical stage developments.[25] However, further progress requires renewed commitment from large research-based pharmaceutical companies and continued dedication of SMEs in developing new medicines and vaccines, as the current pipeline remains woefully unequipped to address the threat posed by AMR.

This Research Area examines the Research & Development (R&D) pipelines of both large research-based pharmaceutical companies and SMEs and evaluates antibacterial and antifungal medicines, as well as vaccines, in development. Specifically, it 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. Such planning is an essential step to ensure that once drugs receive market approval, they are made accessible to all patients in need as soon as possible. Equally important, it ensures that drugs are used responsibly to safeguard their effectiveness for as long as possible.

Changes to the methodology for the 2026 Benchmark

- In the 2026 Benchmark methodology there are five indicators in the R&D Research Area, compared to the six in the 2021 Benchmark. Three out of the remaining five indicators in this Research Area have materially changed.
- In the 2026 Benchmark methodology, a group of nine SMEs will be evaluated based on their R&D activities, recognising their vital contributions in advancing new antibacterial and antifungal agents and ensuring that their efforts are represented in the 2026 Benchmark.
- In previous iterations of the Benchmark, the value of a company's financial investments in R&D was used as a proxy for pipeline health. The 2026 Benchmark will no longer use this metric (formerly indicator A.1 'R&D Investments') due to limitations in the ability to accurately measure R&D investments resulting from a lack of data transparency from companies. Moreover, pipeline health is also evaluated through other, more direct indicators within the R&D Research Area.
- With the removal of the indicator A.1, all subsequent indicator codes have been renumbered (A.2.1 became A.1.1, A.2.2 became A.1.2, and so on).
- Indicator A.1.2 'Innovativeness of pipeline' has been updated to explicitly outline the World Health Organization (WHO)'s Innovation Criteria, which provides a four-point framework to assess whether projects are considered innovative.[26] An additional assessment parameter, titled 'Other,' has been introduced to credit R&D projects that provided added clinical utility through innovations not covered by WHO's Innovation Criteria (e.g. oral formulations). To reflect these changes, the title of the indicator has been updated to 'Innovativeness of pipeline' (formerly 'Novelty of pipeline').
- The R&D Research Area no longer assesses R&D projects targeting pathogens classified as urgent threats by the Centers for Disease Control and Prevention (CDC). Instead, it solely references WHO's Priority Pathogen Lists, which provide a more globally comprehensive overview of the most pressing global R&D needs.[8,9] Indicator A.1.4 'Projects targeting R&D gaps' has also been expanded to include projects targeting rifampicin-resistant *Mycobacterium tuberculosis* and other high-priority pathogens, in addition to those targeting critical-priority pathogens. To reflect these changes, the title of the indicator has been updated to 'Projects targeting R&D gaps' (formerly 'Projects targeting critical priorities').

RESEARCH & DEVELOPMENT

	2026 Indicator	Indicator rationale	Change since 2021
Formerly A.1	**R&D Investments**		
	N/A	N/A	**Removed** as this indicator is a surrogate of healthy pipelines and failed to accurately measure R&D investments.
A.1.1	**Pipeline size**		
	The size of a company's R&D pipeline targeting priority pathogens, including antibacterial and antifungal medicines and vaccines (new chemical/biological entities and adaptations) developed either in-house or through collaborations.	To characterise the degree to which a company focuses on antibacterial and antifungal R&D.	**Retained** with no changes to indicator text.
A.1.2	**Innovativeness of pipeline**		
	The number of innovative, investigational clinical antibacterial and antifungal medicines targeting priority pathogens that the company is developing (either in-house or through collaborations). Projects in development are assessed against WHO's 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 adaptations that offer added clinical utility beyond the four WHO innovation criteria (e.g. oral formulations).	To encourage companies to invest in innovative antibacterial and antifungal medicines needed to combat resistance (and cross-resistance), thereby extending the effectiveness of these medicines, and to recognise companies that are actively developing innovative candidates.	**Modified** with material changes to indicator text.
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).	Vaccination against priority pathogens can help to minimise AMR by reducing transmission of infection and use of antimicrobials. This, in turn, helps to lower the risk of new resistance genes developing or selection of resistant strains.	**Retained** with no changes to indicator text.
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 and fungal priority pathogen lists. 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	To measure a company's commitment to addressing global R&D gaps by evaluating the number of antibacterial and antifungal medicines and vaccines targeting pathogens identified as high or critical priorities on WHO's priority pathogen lists.	**Modified** with material changes to indicator text.
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. *All R&D projects in the pipeline from Phase II onwards as well as recently approved products, developed either in-house or through collaborations.	To outline a company's efforts to ensure that, after market authorisation, successful antibacterial and antifungal medicine and vaccine candidates targeting priority pathogens are made available broadly, quickly and affordably, and are used appropriately.	**Modified** with material changes to indicator text.

HOW THE BENCHMARK MEASURES

Responsible Manufacturing

When pharmaceutical companies manufacture antibacterials, waste containing active pharmaceutical ingredients (APIs) is often released into the environment, triggering the emergence of resistance and environmental damage. To minimise these risks, companies can responsibly manage and dispose of their antibacterial manufacturing waste.

The Foundation has observed progress by companies in managing antibiotic waste since 2017, with the majority implementing environmental risk strategies. Now, it is key to understand if these changes are yielding results and to what degree. Therefore, the 2026 Benchmark takes a more outcome-based approach in assessing companies' efforts to manufacture responsibly and minimise the risk of AMR. This Research Area evaluates how their environmental risk-management strategies are implemented at the company's own manufacturing sites, those of third-party suppliers and those of external waste treatment plants. More specifically, it assesses whether companies set discharge limits for antibiotics in their wastewaters and comply with them, and the underlying methods companies employ to quantify the levels of antibacterials that are released into the environment. In addition, the level of transparency of companies regarding their waste practices is assessed.

WHO guidance and industry-driven certification stimulate responsible manufacturing

With the 2024 release of the World Health Organization (WHO)'s *Guidance on wastewater and solid waste management for manufacturing of antibiotics*, now an independent guidance is available to companies that supports the implementation of appropriate practices.[11] Prior to this independent guidance, the AMR Industry Alliance, in collaboration with the British Standards Institute (BSI), released its global Minimised Risk of Antimicrobial Resistance (AMR) Certification Programme in 2023. This certification programme evaluates conformance against the industry-developed Antibiotic Manufacturing Standard.[27] These developments not only show that there is increasing public awareness of the importance of antibiotic waste as a driver of AMR but also set a growing expectation to adopt more responsible manufacturing practices, especially since policy-makers and investors may adopt waste criteria in regulations and decisions regarding procurement and investments.

Changes to the methodology for the 2026 Benchmark

- In the 2026 Benchmark Methodology there are two indicators in the Responsible Manufacturing Research Area, compared to the three in the 2021 Benchmark Methodology. The two remaining indicators in this Research Area have materially changed.
- Indicator B.1 'Minimising AMR and environmental risk from manufacturing' is modified to put more emphasis on company performance in achieving compliance with discharge limits for APIs and drug products manufactured at its own and suppliers' manufacturing sites. There will be less focus on public wastewater treatment plants because companies have limited responsibility for and influence over waste management practices of such plants. In addition, compliance will be assessed on a product level instead of per manufacturing site, as this approach is more specific and in line with WHO's guidance and companies' data submissions for the AMR Industry Alliance – an industry association that self-reports on industry progress on AMR.[11]
- Indicator B.1 is modified to put more emphasis on 'how' a company quantifies discharge levels instead of 'whether' the company quantifies such levels. This will provide more insights into if the methods employed by companies are appropriate. WHO's guidance will serve as best practice.[11]
- Indicator B.2 'Disclosure on minimising AMR and environmental risk from manufacturing' is modified to reflect the modifications in B.1 and put more emphasis on disclosing antibacterial discharge levels, performance on compliance with discharge limits at own and suppliers' manufacturing sites and the methods used for quantifying discharge levels.
- The former B.3 indicator 'Manufacturing high-quality antibacterials' on quality-assured products is merged with C.3 'Ensuring continuous supply' and removed as a standalone indicator. The resulting merged C.3 indicator is now called 'Mitigating stockouts and shortages of quality-assured products'.

RESPONSIBLE MANUFACTURING

	2026 Indicator	Indicator rationale	Change since 2021
B.1	**Minimising AMR and environmental risk from manufacturing** The company 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 applies to: (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 (c) External waste treatment plants For (a) and (b) the following elements are included: 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	To assess how a company minimises the impact of antibacterial manufacturing on AMR and the environment for each phase of manufacturing.	**Modified** with material changes to indicator text.
B.2	**Disclosure on minimising AMR and environmental risk from manufacturing** The company publishes the following elements on how AMR and environmental risk from manufacturing antibacterials (APIs and drug products) is minimised, which should be 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 aggregate/anonymised ones.	To assess how much information a company makes available publicly to allow independent third parties to analyse and compare companies' performances in minimising AMR and environmental risk from manufacturing antibacterials.	**Modified** with material changes to indicator text.
Formerly B.3	**Manufacturing high-quality antibacterials** N/A	N/A	**Merged** with indicator C.3 and **removed** as standalone indicator.

HOW THE BENCHMARK MEASURES

Appropriate Access & Stewardship

To help slow the progression of drug resistance, pharmaceutical companies must strike a balance between access and stewardship efforts. This requires a balanced effort of ensuring that communities have access to the full spectrum of antimicrobial products, so that patients can be given the correct treatments when necessary, while also actively preventing these products from being overused or misused.

The 2026 Benchmark will take a more integrated approach in examining companies' access and stewardship efforts than previous iterations of the report, emphasising the strong link between the two issues. This Research Area focuses on metrics related to how companies improve access to their on- and off-patent products in low- and middle-income countries (LMICs) through strategies involving product registrations, equitable pricing models and voluntary licensing agreements. It also examines how companies measure the outcomes of these access strategies, including tracking the number of patients reached. To incorporate the importance of stewardship, the Research Area also captures companies' efforts to monitor resistance against their medicines and uphold responsible business practices.

Changes to the methodology for the 2026 Benchmark

- Nine out of 11 indicators are retained in the Appropriate Access & Stewardship Research Area, all of which have materially changed. Of the two indicators that were removed, one was merged with a retained indicator, while the other was removed entirely.
- Under indicators C.1.1 'Registration of on-patent antibacterial and antifungal medicines', C.1.2 'Registration of off-patent/generic antibacterial and antifungal medicines' and C.1.3 'Registration of on-patent antibacterial and antifungal vaccines' companies' engagement in mechanisms to facilitate broad registrations, such as collaborative registration procedures or joint assessment procedures, are newly considered for analysis.
- Indicators C.2.1 'Expanding access to on-patent antibacterial and antifungal medicines', C.2.2 'Expanding access to off-patent/generic antibacterial and antifungal medicines' and C.2.3 'Expanding access to on-patent antibacterial and antifungal vaccines' have been updated to assess whether companies monitor the performance of access strategies and measure the number of patients reached. For the first time, the indicators will also adopt an integrated approach, assessing both access and stewardship at the product level. Following this, the indicator titles have been updated to 'Expanding appropriate access'.
- Indicator C.3 'Ensuring continuous supply' has been merged with the former indicator B.3 'Manufacturing high-quality antibacterials'. Therefore, C.3 now includes additional elements on the quality-assurance of manufactured and/or supplied active pharmaceutical ingredients (APIs) and drug products. Furthermore, the indicator has been updated to put more focus on the mitigation of stockouts and shortages. To reflect these changes, the indicator title has been modified to 'Mitigating stockouts and shortages of quality-assured products'.
- Former indicators C.4 'Educational stewardship activities' and C.5 'Responsible promotional practices' have been merged into indicator C.4, the title of which has been updated to 'Responsible business practices'. The indicator has been modified to refine expectations for sales practices, to exclude the assessment of marketing materials, and to include a new element on ethical interactions with healthcare professionals (HCPs). The latter entails the mitigation of conflicts of interest for transfers of values (e.g., continuous medical education (CME)).
- Former indicator C.6 'Stewardship-oriented adaptations for patients' has been removed due to a lack of universal standards and defined expectations for companies beyond existing regulatory requirements. Additionally, variations in regulatory frameworks hinder a consistent assessment across companies and countries in scope.
- Former indicator C.7 'AMR surveillance' has been updated to set new expectations for sharing raw data without undue delay and to put more emphasis on the methodological approach of the company's surveillance activities. Its new indicator code is C.5.

APPROPRIATE ACCESS & STEWARDSHIP

	2026 Indicator	Indicator rationale	Change since 2021
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).	Filing to register new antibacterial and antifungal medicines is a critical step to enable more widespread access and demonstrates a commitment to reach patient populations in need. The use of mechanisms designed to facilitate broad product registration can accelerate the timely availability of products while ensuring that they are safe and meet stringent quality standards for international procurement.	**Modified** with material changes to indicator text.
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).	Filing to register off-patent and generic antibacterial and antifungal medicines is a critical step to enable more widespread access and demonstrates a commitment to reach patient populations in need. The use of mechanisms designed to facilitate broad product registration can accelerate the timely availability of products while ensuring that they are safe and meet stringent quality standards for international procurement.	**Modified** with material changes to indicator text.
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).	Filing to register new antibacterial and antifungal vaccines is a critical step to enable more widespread access and demonstrates a commitment to reach patient populations in need. The use of mechanisms designed to facilitate broad product registration can accelerate the timely availability of products while ensuring that they are safe and meet stringent quality standards for international procurement.	**Modified** with material changes to indicator text.

	2026 Indicator	Indicator rationale	Change since 2021
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. *The characteristics of a population such as age, gender, income level, education level, employment and ethnicity.	By expanding access to its portfolio of on-patent antibiotic and antifungal medicines, a company can make a significant impact in combatting AMR. Ensuring HCPs have access to the right treatments enables them to prescribe the appropriate antibiotics or antifungals when needed, which can help curb the spread of AMR. Furthermore, improving accessibility to these essential medicines can prevent countless avoidable deaths from treatable infections. Moreover, to evaluate the effectiveness of their access strategies, it is important that companies measure key outcomes – such as the number of patients reached. Tracking these metrics enables companies and their partners to identify gaps in access and allocate resources appropriately in order to address disparities.	**Modified** with material changes to indicator text.
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. *The characteristics of a population such as age, gender, income level, education level, employment and ethnicity.	By expanding access to its portfolio of off-patent/generic antibiotic and antifungal medicines, a company can make a significant impact in combatting AMR. Ensuring HCPs have access to the right treatments enables them to prescribe the appropriate antibiotics or antifungals when needed can also help curb the spread of AMR. Furthermore, improving accessibility to these essential medicines can prevent countless avoidable deaths from treatable infections. Moreover, to evaluate the effectiveness of their access strategies, it is important that companies measure key outcomes – such as the number of patients reached. Tracking these metrics enables companies and their partners to identify gaps in access and allocate resources appropriately in order to address disparities.	**Modified** with material changes to indicator text.

	2026 Indicator	Indicator rationale	Change since 2021
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. *The characteristics of a population such as age, gender, income level, education level, employment and ethnicity.	When a company addresses the accessibility and affordability of its innovative vaccines, this can help countries to reduce their burdens of infectious diseases, including resistant infections. This indicator evaluates whether companies engage with market-shaping or pooled procurement organisations – such as the United Nations International Children's Emergency Fund (UNICEF), Gavi, The Vaccine Alliance (Gavi) and The Global Fund to fight AIDS, Tuberculosis and Malaria – to enhance access. Importantly, it also assesses the extent to which companies implement access strategies for vaccines in countries which do not qualify for such support. Furthermore, to evaluate the success of their access strategies, companies should establish clear goals aimed at expanding access to patients. Effective strategies can be measured by an increase in the number of patients served, both in terms of current results and projected future outcomes.	**Modified** with material changes to indicator text.
C.3	**Mitigating stockouts and shortages of quality-assured products** The company employs a range of 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 components: 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 components: 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.	Accessibility of quality-assured on- and off-patent antibacterial and antifungal medicines and vaccines relies on companies having strategies to ensure their continuous supply. To safeguard uninterrupted supply, companies need to prepare for stockouts by ensuring the supply of APIs, maintaining a sufficient stock and aligning with external stakeholders on supply and demand. By upholding high standards for quality-assurance during manufacturing and ensuring quality further downstream, companies can minimise the likelihood that medicines with subtherapeutic dose levels and/or of suboptimal quality reach patients, which can contribute to the development and spread of AMR. When patients worldwide are guaranteed an uninterrupted supply of quality-assured products, this decreases the chance of obtaining substandard or falsified medicines which increase the risk of ineffective treatment and the spread of resistant infections.	**Modified** with material changes to indicator text, and merged with former indicator B.3.

	2026 Indicator	Indicator rationale	Change since 2021
Formerly C.4	**Educational stewardship activities**		
	N/A	N/A	**Merged** with former indicator C.5 and **removed** as standalone indicator.
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 HCPs which 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, where this is permitted by law. *Transfers of value could include payments for attending and/or speaking at events, provision of CME, funding of research studies or other non-monetary benefits directed at 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.	Decoupling sales agents' financial rewards from the volume of antibacterial and antifungal medicine they sell removes the incentive to engage in non-compliant behaviour (missell, oversell, or other undue influence) in order for the sales agents to obtain their compensation. This is not only important to curb AMR, but also to prevent diversion of scarce resources from health budgets. Pharmaceutical companies may sponsor CME programmes, research studies, or conferences. These activities could be biased in favour of the company's products and influence the decisions of HCPs leading to the inappropriate use or overuse of antibiotic and antifungal medicines. Creating transparency and accountability surrounding such 'transfers of values' is crucial in identifying drivers of antimicrobial misuse and promoting stewardship.	**Modified** with material changes to indicator text, and **merged** with former indicator C.4.
Formerly C.6	**Stewardship-oriented adaptations for patients**		
	N/A	N/A	**Removed**, there are no universal standards and defined expectations for companies beyond regulatory requirements.
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. *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.	By publicly sharing data on the surveillance of resistance, companies can assist in the effort to monitor the rise of resistance to antibacterial and antifungal medicines. Such data is an essential tool for governments and researchers to measure the current and future burden of resistant infections. If collected following a clear and standardised methodology, sharing surveillance data helps in forecasting and prioritising objectives for the design of stewardship policies. In the case of newly emerging resistance strains, collected data can also contribute to early warning systems, on the condition that it is shared without undue delay.	**Modified** with material changes to indicator text.

APPENDICES

Appendix I – Priority pathogens defined by the World Health Organization

	Pathogen	Resistance	Priority
Bacteria[8]	*Acinetobacter baumannii*	carbapenem-resistant	Critical
	Enterobacterales	third-generation cephalosporin-resistant	Critical
		carbapenem-resistant	Critical
	Salmonella Typhi	fluoroquinolone-resistant	High
	Shigella spp.	fluoroquinolone-resistant	High
	Enterococcus faecium	vancomycin-resistant	High
	Pseudomonas aeruginosa	carbapenem-resistant	High
	Non-typhoidal *Salmonella*	fluoroquinolone-resistant	High
	Neisseria gonorrhoeae	third-generation cephalosporin-resistant	High
		fluoroquinolone-resistant	High
	Staphylococcus aureus	methicillin-resistant	High
	Group A Streptococci	macrolide-resistant	Medium
	Streptococcus pneumoniae	macrolide-resistant	Medium
	Haemophilus influenzae	ampicillin-resistant	Medium
	Group B Streptococci	penicillin-resistant	Medium
	Mycobacterium tuberculosis	rifampicin-resistant	N/A
Fungi[9]	*Cryptococcus neoformans*	N/A	Critical
	Aspergillus fumigatus	N/A	Critical
	Candida auris	N/A	Critical
	Candida albicans	N/A	Critical
	Nakaseomyces glabrata (Candida glabrata)	N/A	High
	Eumycetoma causative agents	N/A	High
	Fusarium spp.	N/A	High
	Candida parapsilosis	N/A	High
	Histoplasma spp.	N/A	High
	Mucorales	N/A	High
	Candida tropicalis	N/A	High
	Scedosporium spp.	N/A	Medium
	Lomentospora prolificans	N/A	Medium
	Coccidioides spp.	N/A	Medium
	Pichia kudriavzevii (Candida krusei)	N/A	Medium
	Crptococcus gattii	N/A	Medium
	Talaromyces marneffei	N/A	Medium
	Pneumocystis jirovecii	N/A	Medium
	Paracoccidioides spp.	N/A	Medium

Appendix II – Strategies companies can consider when developing effective access and stewardship plans

Access strategies:	• Registration • Collaborative registration or availability mechanisms (e.g., EU-M4all, special importation waivers, WHO Collaborative Registration Procedure, WHO Prequalification) • Responsible intellectual property and licensing agreements • Early access programmes • Manufacturing and supply • Equitable pricing • Clinical trials in countries in scope and post-trial access commitments • Paediatric formulations • Product donation programmes
Stewardship strategies:	• Surveillance and data sharing • Responsible promotion and sales strategies • Availability of supportive diagnostics

Note: These lists are based on the Stewardship & Access Plan (SAP) Development Guide, which was developed by CARB-X in collaboration with the Access to Medicine Foundation and other partners. For more detailed guidance on developing a stewardship and access plan, it is advisable to refer directly to the guide.[28]

Appendix III – Definitions

Access plan
Plans to ensure that access needs in low- and middle-income countries (LMICs) 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 (WHO) 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 active pharmaceutical ingredient (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). 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.

Antimicrobial resistance (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)
Antimicrobial resistance 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 AMR.

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.[29]

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.[18]

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 LMICs.

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.[30]

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 API(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.

Environmental risk management (ERM)
In the context of antibacterial product manufacturing, environmental risk management (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 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)
Good manufacturing practice (GMP) is a system employed to ensure that products are consistently produced and controlled according to appropriate quality standards. 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 candidate meets at least one of the four criteria defined in WHO's report *2023 Antibacterial agents in clinical and preclinical development*: (1) new chemical class; (2) new target; (3) new mode of action (MoA); (4) absence of cross-resistance.[26]

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 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
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.[31]

Off-patent medicine
A medicine whose granted patent protection has expired and is no longer protected by exclusive marketing rights. Patent protection typically lasts for 20 years and is specific to each country.

On-patent/patented medicine
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.

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.

Period of analysis
The 2026 AMR Benchmark report will assess company activities taking place during a period of analysis going from 1 October 2023 to 30 September 2025. For the Research & Development 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.

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
Pathogens for which new medicines and vaccines are highly needed. Priority pathogens are informed by the bacterial and antifungal Priority Pathogen 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 (SME)
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).[32]

Stewardship plan
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.

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.[33]

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.

Voluntary licensing
An authorisation given by the patent holder to a generic company, allowing it to produce the patented medicine or vaccine, often at a lower cost. The licence usually sets quality requirements and defines the countries in which the licensee can sell the product.[34]

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 WHO that aims to expedite registration of prequalified finished pharmaceutical products. It accelerates registration through improved information sharing between WHO's 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.

World Health Organization Mode List of Essential Medicines (WHO EML)
A list published every two years by WHO, which lists all essential medicines recommended to be available in functioning health systems at all times.[19]

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