Global Policy Issue Brief –

Antimicrobial Resistance: Protecting Access to Antibiotics

At Viatris, we see healthcare not as it is, but as it should be. This future-focused outlook drives our commitment to policy solutions that help increase access to a broad range of trusted, quality medications for patients worldwide, regardless of geography or circumstance. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, supplying high-quality medicines to approximately 1 billion patients around the world annually.[1] Underscoring our commitment to addressing AMR through access, stewardship, and responsible manufacturing, we have approximately 90 antimicrobials in our global portfolio, are a founding member of the AMR Industry Alliance (AMRIA), and an adopter of the AMRIA Common Antibiotic Manufacturing Standard.

Public Policy Statement

Antimicrobial resistance (AMR) is a growing public health concern. Access to the right antibiotic at the right time is crucial in the fight against AMR, yet supply is threatened by the unsustainable market dynamics of off-patent antibiotics. Short- and long-term policy action is needed to safeguard access.

Issue Background

Antimicrobial resistance (AMR) is the result of microorganisms such as bacteria, viruses, parasites, and fungi becoming resistant to antimicrobials (e.g., antibiotics, fungicides, antivirals, and parasiticides) designed to kill or inhibit their growth.[2] It is a major driver of death globally, potentially accounting for more deaths than HIV/AIDS and malaria worldwide.[3] In 2019, more than 1.2 million people are estimated to have died directly from antibiotic-resistant bacterial infections, and the estimate grows to 4.95 million people when considering cases where resistant infections played a role but may not have been the direct cause of death.[3]

Unless concerted efforts are undertaken to counter its progression, AMR is projected to remain a significant threat to global health and economic development.

- By 2030, AMR is forecasted to push 24 million people into extreme poverty and cause global GDP to drop by $3.4 trillion annually.[2]
- Between 2025 and 2050, inaction on AMR is expected to directly cause 39 million deaths and be associated with 169 million.[4]

[1] Viatris, 2023 Sustainability Report
[2] UNEP, Bracing for Superbugs: Strengthening environmental action in the One Health response to antimicrobial resistance, 2023
[3] The Lancet, Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis
[4] The Lancet, Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050

Published January 2025 | Approved for External Use

- By 2050, it is estimated that AMR will be responsible for up to 10 million deaths annually[2] and result in $1 trillion in additional healthcare costs.[5]

As the progression of AMR can render antibiotics less effective, common infections, such as wound infections, urinary tract infections, and pneumonia will increasingly be associated with severe complications and increased risk of death. Progress on reducing the fatality of childhood and maternal infections such as pneumonia and childbed fever could be reversed. Common surgeries like c-sections and hip replacements could become much riskier. Non-vital surgeries could become difficult to justify due to the risk of resistant infection. As chemotherapy causes immune suppression, cancer treatment could become substantially riskier. With few options to treat potential infections, therapies that require immune suppression, such as organ transplants, could be untenable.[5,6]5 above

Importance for Access

In addition to antibiotic stewardship and proactive infection prevention, timely access to the optimal antibiotic is critical in the fight against AMR. However, the unsustainable market of off-patent antibiotics puts access to these medicines at risk.

The Unsustainable Market for Off-Patent Antibiotics

Healthcare systems around the world face the common challenge of maintaining a reliable supply of essential off-patent antibiotics. This challenge stems from the unique market dynamics associated with both high- and low-volume antibiotics:

- **High-volume antibiotics.** These are generally first-line antibiotics essential for treating a variety of common infections around the world, and most have a long history of use. Decades of market competition and price reductions have caused some products to face discontinuation due to the lack of financial viability of continued production.
- **Low-volume antibiotics.** These specialized antibiotics, including some pediatric formulations, are kept in reserve for the treatment of rare or severe infections. Their use may be limited to a small patient population, but their availability is important to public health, infection control, and combating AMR. With low volume, suppliers may struggle to cover the fixed costs of maintaining production capacity. Moreover, the unpredictability of demand, driven in part by infection outbreaks and shifting resistance patterns, creates manufacturing and viability challenges.

Whether high-volume or low-volume, antibiotics are complex to produce relative to many other medicines, often requiring dedicated facilities or production lines to maintain sterile conditions and avoid cross-contamination. The challenging dynamics of sustaining a multisource competitive market for antibiotics are exacerbated by various regulatory

[5] The World Health Organization, Antimicrobial Resistance Factsheet, 2023
[6] ReACT, The Global Threat of Antibiotic Resistance

Published January 2025 | Approved for External Use

policies and procurement practices that introduce additional obstacles and costs, further hindering access. While there is often political attention to the discussion about incentivizing and stimulating development of new antibiotics, there is often little focus on ensuring a sustainable supply of off-patent antibiotics, which represent the vast majority of prescriptions. There is an urgent need to stabilize the market and safeguard access to a range of antibiotics, which can be achieved through immediate policy action as described below. In the long term, broader systemic changes are also needed.

Viewpoint

In light of the challenging market dynamics impacting antibiotics, policy action is needed to safeguard access and avoid accelerating AMR.

Short Term: Immediate Solutions to Stabilize Access

Establish Sustainable Pricing Policy. Antibiotic pricing must allow for continuous availability and for multiple suppliers to remain on the market.

- Maintaining prices at sustainable levels is enabled by excluding critical off-patent antibiotics from price cuts and other price control regulation that fuel continued price erosion and shortage threats.

Increase predictability of demand for suppliers. With accurate demand forecasts, suppliers can produce the optimal quantity of antibiotics, reducing the possibility of a shortfall or costly waste.

- Surveillance and forecasting systems should be improved, and existing AMR surveillance infrastructure and epidemiological data should be leveraged into accurate demand forecasts that are punctually communicated to suppliers.

Reduce financial barriers to market entry and reentry. The administrative burden associated with registering additional suppliers for existing antibiotics should be reduced.

- Registrations for off-patent antibiotics from new manufacturers could be fast-tracked to widen the pool of antibiotic suppliers as quickly as possible.
- Regulatory procedures and fees could be waived for manufacturers bringing a previously approved antibiotic back onto the market.

Adopt sustainable procurement practices. Procurement bodies should adopt best practices that foster a healthy market, encourage supply chain resilience, and reduce waste.

- Procurement contract awards should be based on criteria other than just price. Incorporating consideration for supply chain resilience, efforts to combat AMR, and environmental stewardship measures ensures these actions are valued and encouraged, whereas price-only procurement incentivizes further market and supply chain consolidation. For example, criteria could include compliance with the AMR Industry Alliance Antibiotic Manufacturing Standard.
- Procurement contracts should be awarded to multiple manufacturers to diversify supply, while avoiding over-fragmentation of the market.

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- Procurement practices should encourage participation from a broad set of suppliers by avoiding excessively stringent contract terms. This includes refraining from imposing penalties on suppliers for supply disruptions beyond their control and ensuring that penalties are proportionate to the contract's value.
- Lead times for supply after a procurement decision should be appropriate and based on product characteristics and manufacturing considerations.
- Procurement agreements should specify the volume to be supplied, fostering predictability and enabling production planning.

Introduce regulatory flexibility. Suppliers should not face unnecessary constraints on efficiently and cost-effectively moving antibiotics to where they are needed.

- Regulatory rules that prohibit products packaged for one country from being transferred to another where there is increased demand can cause an artificial shortage. This could be eliminated by introducing flexibility in packaging regulation that allows size-standardized, multilingual packs to be used across several countries, and by using electronic informational leaflets accessible through QR codes or online databases.
- Stockpiling adds to production costs, which further strains viability and can lead to a situation in which excess supply must sit unused in one country despite a demand spike in a neighboring country. Uncoordinated national or sub-national stockpiling requirements, particularly when unaccompanied by mechanisms to offset the associated costs, should be avoided.

Long term: Structural Fixes for Market Sustainability and Ongoing Access

While there are concrete measures that can foster short-term resilience in the supply of off-patent antibiotics, systemic changes to antibiotic payment models may be needed for both long-term sustained access to antibiotics and to address AMR. De-linking, or basing payment on the value of the continued availability of an existing antibiotic, rather than its sales volumes, would help align the interests of suppliers with public health goals as well as create a more stable financial environment for suppliers. Under this scheme, fewer suppliers would be incentivized to discontinue production, as they would instead be incentivized to achieve security of supply. There are several proposed alternative payment models being explored — it is important that policymakers take a consultative approach and for industry and governments to work collaboratively on potential solutions that address the market needs for both novel and off-patent antibiotics, and ultimately stabilize antibiotic access for people around the world.

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