

AMR Industry Alliance Policy Recommendations to Strengthen the Resilience of Antibiotic Supply

Antimicrobial Resistance (AMR) is a significant global health threat estimated to have directly contributed to 1.27 million deaths in 2019¹. To slow the spread of AMR, patients must have access to the right antimicrobial when needed. For this reason, antimicrobial supply chains must operate smoothly – but in many parts of the world, the supply chain is unstable, leading to limited antibiotic access for patients who need them.

To gain insight into the root causes of supply chain unsustainability among off-patent antimicrobials and identify potential policy solutions to address these issues, the AMR Industry Alliance commissioned a report from Charles River Associates (CRA) to analyze the factors that contribute to an unsustainable off-patent supply chain. [The report](#) generated conclusions based on a literature review, interviews with external experts, and case studies in five representative countries².

This report defines supply sustainability as a consistent and dependable supply of off-patent antibiotics. With sustainable supply chains (inclusive of raw material production through medicine distribution), the risk of shortages is reduced, and the impact of shortages is limited, with minimal disruptions or weaknesses.

Root Causes of Supply Chain Unsustainability

CRA identified five root causes behind supply chain unsustainability for off-patent antimicrobials:

- **Global antibiotic supply chains are vulnerable to supply problems because of their complexity and fragility.** Antimicrobial production is a lengthy and complex process that is difficult to monitor and predict due to the number of parties involved. In addition, antibiotics have specific manufacturing requirements and require specialized raw materials. Raw material or early-stage production problems can cause large delays down the line.
- **Antibiotics may experience unpredictable demand:** Infection and resistance trends can vary significantly over time. The lack of robust diagnostic testing and surveillance data slows the understanding of these trends. Demand for infectious disease treatments can sometimes change more rapidly than other therapeutic areas. It can take time for supply chains to respond to demand shifts.
- **Low commercial returns across the supply chain, coupled with the unsustainable pricing and procurement policies create an unsustainable market environment:** Low prices for older antimicrobials make it difficult for producers to recoup production costs or invest in supply chain risk mitigation and other improvements. This problem is exacerbated in the current economic environment of high inflation and increased production costs.

¹ Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet Accessed on January 23, 2023.

² This report was commissioned by the AMR Industry Alliance. The findings and conclusions contained within are those of the authors and do not necessarily reflect the views of the Alliance or those of the individual Alliance member organizations

- **Concentration into fewer API suppliers is both a symptom of the unsustainability of the market and a further driver of shortages:** According to a WHO report, only two API manufacturers produce 10 of the most commonly used antibiotics. This situation means there are few to no backup sources for some APIs, due to untenable commercial conditions.
- **Poor communication on demand undermines efficient supply chain management, and lack of collaboration among stakeholders contributes to unsustainability:** Countries have varying capabilities to monitor the distribution and storage of antimicrobials within their healthcare systems, and in some cases, hospitals and pharmacies have no way of monitoring supply chain issues upstream from distributors.

Policy Recommendations for Improved Resilience

The Alliance supports policies that improve supply chain sustainability and encourages its members and other stakeholders to consider the solutions listed below, which were identified as having high feasibility and potential impact:

- **Pricing approaches to recognize the value of off-patent drugs:** Many off-patent antimicrobials have been on the market for years and have seen significant reductions in price. Governments should consider reimbursement models that allow for increased prices when there is a risk of a shortage. In addition to other policies, this could help prevent manufacturers from leaving the market due to low commercial returns and free up funds for capital investments into supply chains.
- **Better use of diagnostic and surveillance data:** Increased use of diagnostic and surveillance data would allow for a better understanding of infectious disease epidemiology and AMR prevalence rates. It would enable data-backed demand forecasts, which would both increase predictability for manufacturers, as well as help to improve clinical care by enabling physicians to ensure patients receive the best treatment possible.
- **Sustainable tender policies requiring supply security and multiple winners:** Policies to ensure that tender contracts be awarded to multiple suppliers would encourage a higher number of suppliers to remain present in each market, strengthening supply chain sustainability. Procurement strategies should make use of most economically advantageous tender (MEAT) criteria, which allow contracting authorities to consider qualitative, technical, and sustainable aspects of tender submissions, as well as price, when making an award decision. Such policies would promote the development of healthy levels of supplier competition over the medium-term, strengthening supply chains.
- **Reducing financial disincentives to market entry:** Reductions in barriers to market entry could encourage more manufacturers to begin or re-start off-patent antimicrobial manufacturing. To that end, governments should consider revising or removing fees imposed during shortages and when re-filing for market authorization, increase regulatory flexibility to allow for faster movement of medicines between countries and for the approval of new manufacturers (particularly those who add to the diversity of the API supply), and adopt risk-sharing approaches that can help ensure supply chain sustainability over the long-term.

Collaboration between stakeholders

“Collaboration between stakeholders is required to tackle the complex issues related to off-patent antimicrobial availability and access.”

“The AMR Industry Alliance and its members are working to ensure that life-saving antimicrobials are available to patients worldwide. To support this work, the Alliance and its members are committed to partnering with other stakeholders – including multinational organizations, governments, healthcare providers, and NGOs – to increase the sustainability of off-patent antimicrobial supply chains and reduce access barriers.”

“The Alliance looks forward to further discussion on the barriers that prevent access to antimicrobials and the policy interventions to address them, and encourages working together with all stakeholders committed to fighting AMR.”

James Anderson, Chair of the AMR Industry Alliance Board