

# Protecting Access to essential antibiotics – Learnings from Sweden

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## The Threat of AMR

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.**<sup>1</sup>

It recognized around the world as a significant threat to global health and economic development. It is a major driver of death globally, potentially accounting for more deaths than HIV/AIDS and malaria worldwide.<sup>2</sup>



**1.2 million people**

Recent research shows that in 2019, more than 1.2 million people are estimated to have died *directly* from antibiotic-resistant bacterial infections.<sup>2</sup>



**4.95 million people**

It is estimated that 4.95 million people have died with *resistant infections playing a role*, though these infections may not have been the direct cause of death.<sup>2</sup>

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

By 2050, it is estimated that AMR will **be responsible for up to 10 million deaths annually**<sup>3</sup>, will cause more deaths than cancer unless concerted efforts are undertaken to counter its progression, **and result in \$1 trillion in additional healthcare costs.**<sup>3</sup>

As the progression of AMR can render antibiotics less effective, common infections, such as wound infections, urinary tract infections, c-sections and pneumonia will increasingly be associated with severe complications and increased risk of death.



## Antibiotic access challenges

Preserving the availability of a wide range of antibiotics is critical for ensuring doctors and patients have access to treatment and avoid the suboptimal use of antibiotics. However, healthcare systems across Europe are facing challenges in maintaining a consistent supply, a dilemma rooted in the market's distinctive dynamics for both high- and low-volume antibiotics.

Some high-volume antibiotics, crucial for various common infections and subject to years of price reductions, face discontinuation due to financial unviability. Low-volume antibiotics, vital for treating rare or severe conditions and essential in public health and AMR efforts, face production and viability challenges due to their limited use and unpredictable demand.

To ensure continued access to a wide range of antimicrobials, **we encourage policymakers and payers to foster a sustainable market for antibiotics, including older products.**



## Learnings from Sweden

**Sweden leads European countries in its proactive, evidence-based<sup>4</sup> response to the challenges that threaten the availability of antibiotics.**

On top, PLATINEA (PLATform for INnovation of Existing Antibiotics) collaboration platform in Sweden is a best practice and scalable model across Europe and globally for stakeholder collaboration to fight antimicrobial resistance. PLATINEA is working

to promote more effective antibiotic use in clinics, as well as to maintain supply security through helping health authorities build more sustainable market conditions for antibiotics.

As part of PLATINEA, Viatri's work is aligned with our global work to fight AMR, and underpins our deep commitment to advance access to medicines.

You can find out more about the work on PLATINEA by visiting [platinea.se](https://platinea.se) or [newsroom.viatri.com/stories-and-viewpoints](https://newsroom.viatri.com/stories-and-viewpoints).

The following measures have been proposed or enacted by health authorities in Sweden to preserve access to mature antibiotics; similar policies must be adopted across other European countries to protect access to antibiotics and combat AMR.

Measure (Proposed or Enacted)	Purpose	Application throughout Europe
The annual fee paid by manufacturers to keep their products registered with the Swedish authority should be waived.	The annual registration fee can make certain medicines with low prices economically unviable to continue producing. In these cases, manufacturers may pause or discontinue production.	Other EU countries should waive registration fees for critical antibiotics, particularly those at risk of shortage due to economic unviability.  For medicines in shortage, regulators should waive fees and fast-track the approval process to bring products back onto the market.
Common packaging should be allowed for all Nordic countries, rather than each country imposing their own distinct packaging requirements.	The existing requirement for different packages (different size, language, product information) adds to cost of goods without any benefit for patients. It also limits flexibility in distribution, as packaged medicines are locked into a single country.  Common packaging simplifies manufacturing and distribution, saving on costs and reducing viability challenges.	While common packaging requirements across Nordic countries is a step in the right direction, the EU should adopt 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.
In 2023, authorities raised the price ceiling for certain antibiotics.	Recent years have been marked by unprecedented increases in inflation and production costs. Price ceilings that do not account for this inflation can make it unviable for manufacturers to continue providing a product.	Member States should establish sustainable pricing policy. Antibiotic pricing must allow for continuous availability and for multiple suppliers to remain on the market, enabled by excluding critical off-patent antibiotics from price cuts and other price control regulation that fuel continued price erosion and shortage threats.
Rather than the traditional volume-based payment model, Sweden is piloting a model that pays manufacturers for maintaining a buffer stock of selected antibiotics.	The high volatility of antibiotic demand poses a dilemma for manufacturers who must prioritize investments in production capacity. Alternative payment models can help alleviate financial uncertainty and allow for more resilient supply.	Member States can explore alternative payment models that help align the interests of manufacturers with public health goals as well as create a more stable financial environment for manufacturers. More information on innovative payment models on Medicines for Europe website ( <a href="https://medicinesforeurope.com">medicinesforeurope.com</a> )



## Other policy solutions

In addition to measures being taken by Sweden, the following policy actions are needed to stabilize the market and safeguard access to mature antibiotics.

### Short term: immediate solutions to stabilize access

#### Stabilize pricing at sustainable levels.

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.
- 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 not accompanied 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.

1. United Nations Environment Program, *Bracing for Superbugs: Strengthening environmental action in the One Health response to antimicrobial resistance*, 2023
2. The Lancet, *Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis*
3. The World Health Organization *Antimicrobial Factsheet*, 2023
4. Sweden's approach to antibiotic sustainability is informed by PLATINEA, a multi-stakeholder collaborative forum that aims to optimize the use of antibiotics and combat antibiotic resistance.