



Folkhälsomyndigheten

Swedish experiences regarding access to antibiotics

1 March 2024



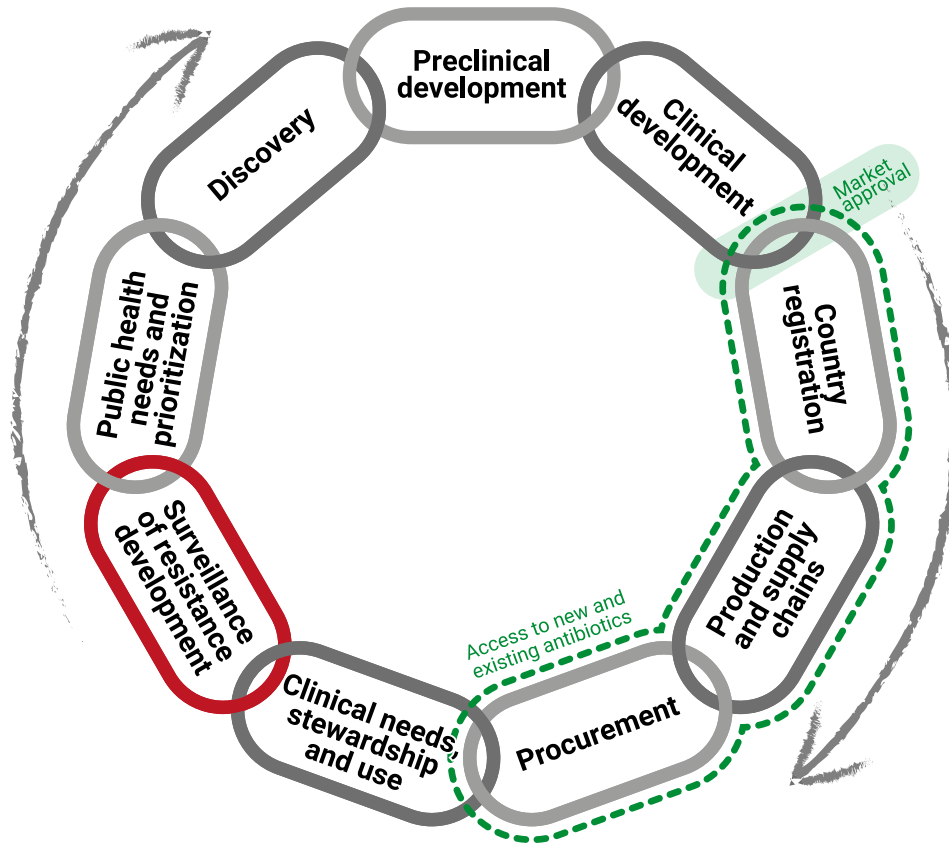
Access to antibiotics is needed to contain AMR

The right antibiotic at the right dose, for the right duration, and at the right time

➤ but problems with access can make this hard

In addition to preventing infections, minimizing the spread of resistant bacteria and using antibiotics responsibly
we need to ensure access to antibiotics to limit the development and spread of AMR

The antibiotic Research & Development and Access chain



As long as we use antibiotics, resistance will continue to emerge and we will need to develop new antibiotics and maintain sustainable and equitable access to existing antibiotics

High-Level Meeting on Antimicrobial Resistance,
Stockholm, 6–7 March 2023

Swedish governmental commissions

Two tracks:

Reimbursement model for new antibiotics

- To propose a model that ensures availability of certain new antibiotics in Sweden (2018-2023)
 - Builds on previous assignment 2016-2017 by Public Health Agency & Dental (TLV) and Pharmaceutical Benefits Agency
- New assignment for agreements to secure availability of antibiotics of particular medical value

Strengthen access to older off-patent antibiotics

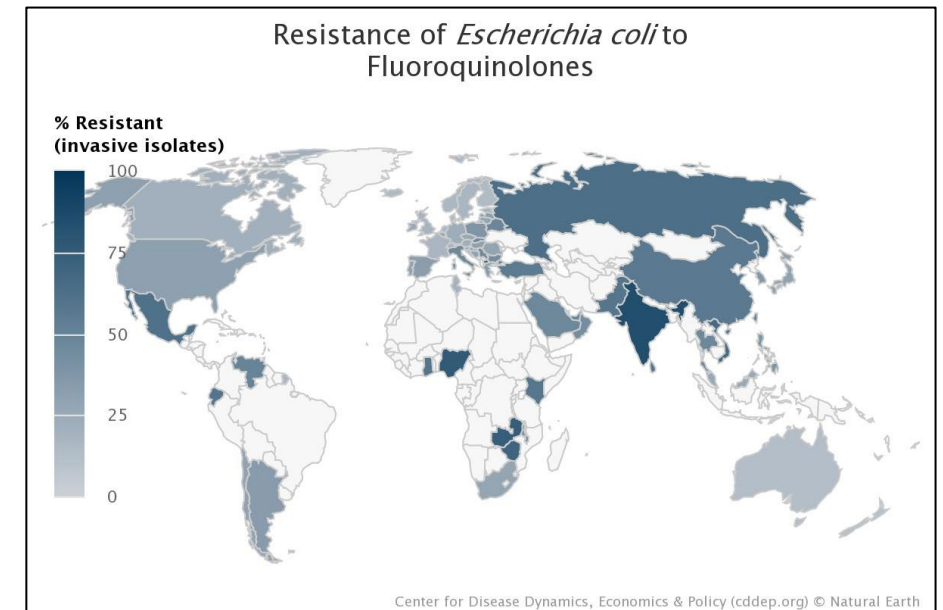
- to map the market and identify efforts to strengthen access to off-patent antibiotics (2021-2022)
 - Three Swedish agencies: Public Health Agency of Sweden, Dental and Pharmaceutical Benefits Agency (TLV), and Medical Products Agency
- Several follow-up assignments, concerning pricing, regulatory measures and buffer stocks

Reimbursement model for new antibiotics

Risk of insufficient availability in Sweden

- Low resistance rates
- Restrictive use
- Small market

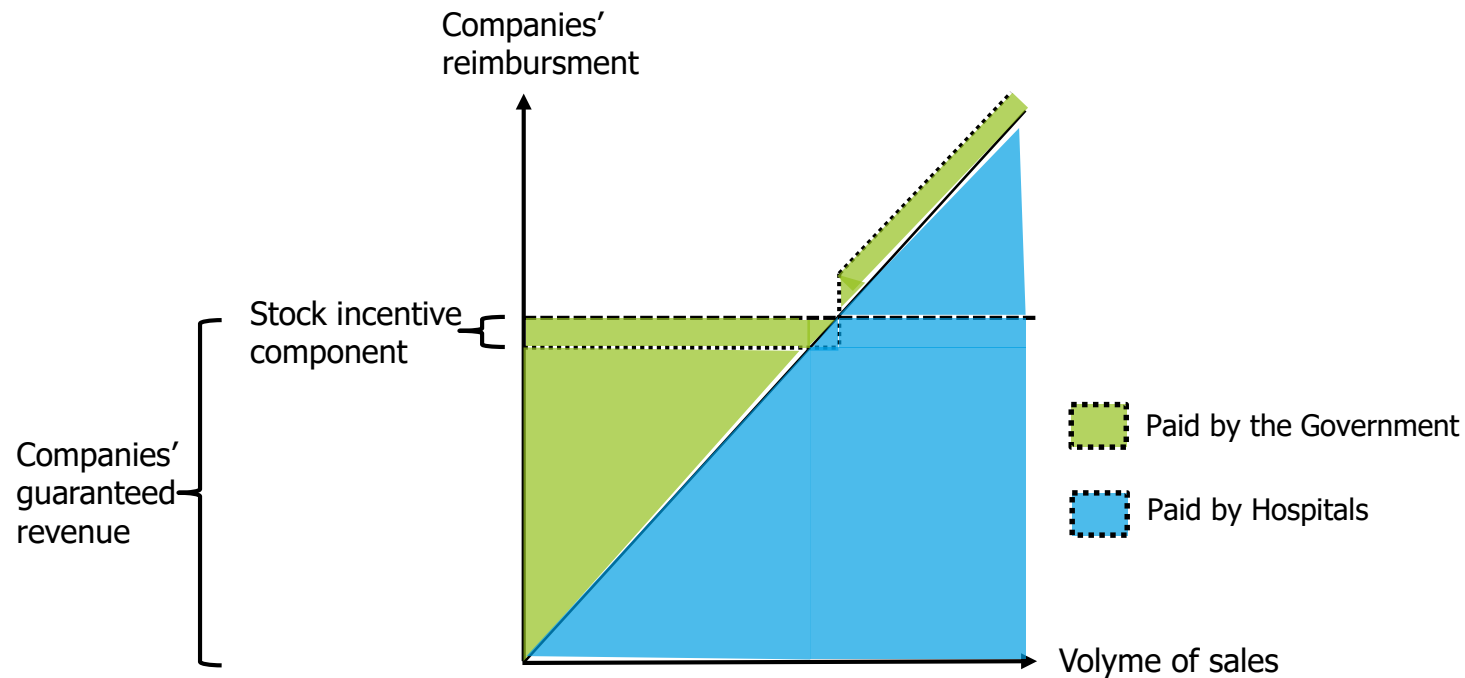
Some products face low demand
→ not available on the Swedish market.



Reimbursement model for new antibiotics

- The overall aim: to propose a model that ensures availability of certain antibiotics in Sweden
 - Intends to ensure access in Sweden to already marketed or newly approved products where we see a risk of lack of availability
 - Antibiotics with special medical value, with effect on carbapenem-resistant bacteria, WHO Priority Pathogens
 - The model refers to everyday supply (not for preparedness).
- Not a model for incentives for R&D, other parallel (push and pull) initiatives are needed

The reimbursement model



- Partially de-linked from the sales.
- The pharmaceutical companies are guaranteed a minimum payment in return for providing the product on the market.
- A stock incentive portion-regardless of sales.
- The hospitals continue to pay for their use.
- State and the government pays up to the guaranteed level.

Conclusion

- The model was appropriate and effective to ensure the availability of certain antibiotics.
- The principles for selecting products and the tender specification for the procurement were appropriate
 - All products that meet the requirements in the procurement were included in the contract
 - Requirements for delivery time and warehouse location

New assignment for agreements to secure availability of certain antibiotics of particular medical value

- With adjustments regarding:
 - The compensation level
 - The calculation of the volume of the safety stock (to avoid large disposal)
 - Possibility to cancel or make new procurements depending on the medical need

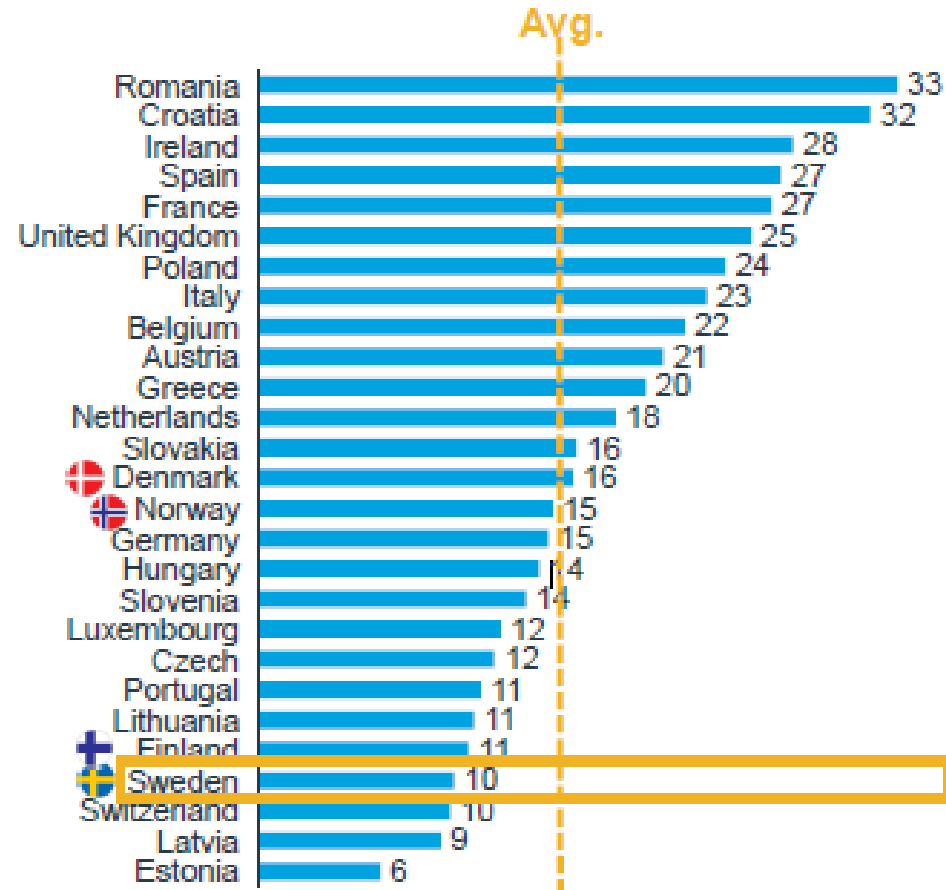
Strengthen access to older off-patent antibiotics

- To map the market and identify efforts to strengthen access to off-patent antibiotics.
 - Led to several follow-up assignments, concerning pricing, regulatory measures and stock-piling
- Work based on a list of antibiotic products of clinical value that were judged to be at risk for having a lack of availability in Sweden
 - Estimated size of consequences for healthcare if the product were not available
 - Currently marketed off-patent antibiotic products that in 2021 sold for less than SEK 3 million, or that have had repeated longer shortages.

The Goal:

The healthcare continues to have access to a wide range of effective off-patent antibiotics to treat infections and maintain a continued low level of resistance

Low use of antibiotic use in Sweden, similar to our Nordic neighbors



Antibiotic use in Sweden compared to other Nordic and European countries

More narrow-spectrum agents in Sweden

Sucre: IQVIA MIDAS och TLV

Suggested actions and measures



Ongoing assignment: feasibility to provide a buffer stock

Feasibility study on a reimbursement model to provide a buffer stock of certain antibiotic products

Preliminary suggestions for clinically prioritized off-patent antibiotics

- **Further prioritizing** from previous lists
 - Offer a **fixed annual reimbursement** from the state, for holding a defined buffer stock
 - Open procurement of specified substances, formulations and strengths
 - Consider **collaboration with the Nordic countries** to expand the market and to find coordination gains
 - Include and further elaborate with Platinea's ongoing work with mapping the Nordic antibiotic markets and needs (www.platinea.se). Currently very fragmented antibiotic markets.
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For sustainable access to antibiotics, measures along the entire chain are needed, from models to stimulate research and early development to models to launch and maintain products in markets.

