

6th Meeting of the GLG on Antimicrobial Resistance

7-8 February

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AMR = top 10 global public health threat

**AMR = 1.27 million deaths
in 2019**

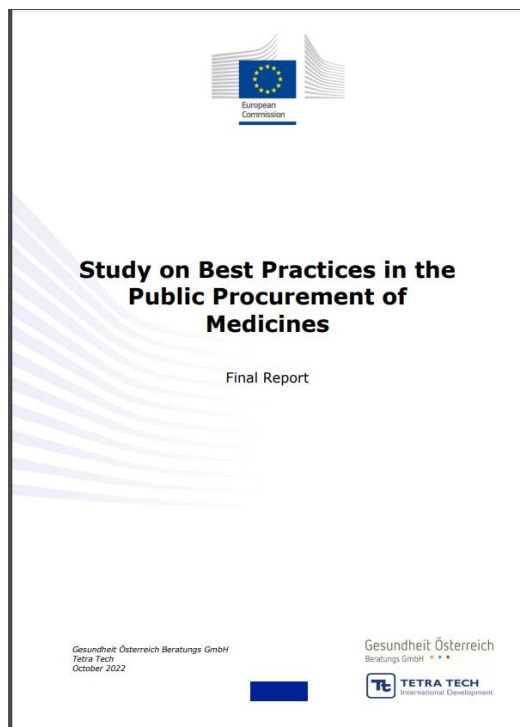
**Paediatric impact:
1/5 deaths >5 years old**

**If not addressed, AMR could lead to 10 million
deaths by 2050**

Key questions on: generic medicine availability and access

1. How do we **preserve a wide variety of antibiotics**? *Most EU countries do not have full WHO antibiotic lists (i.e., reserve list)*
2. How do we **reduce the risk of antibiotic shortages**? *Manufacturing is consolidated.*
3. How can the **medicines industry** contribute to the fight against AMR? *Let's reduce environmental risk.*

1. Optimising procurement policies for antibiotic medicine availability



OBJECTIVE

To strengthen and optimise public procurement of medicines (PPM) as a policy tool to enhance **accessibility, affordability** and **availability** of medicines, as well as to encourage **greener pharmaceutical design** and **manufacturing** and **support crisis preparedness**.

SCOPE

Public sector (incl. non-profit)
Outpatient & inpatient
Medicines (incl. vaccines)
32 countries (EU-27, EEA/EFTA, UK)

[Study one-pager](#)

Key highlights

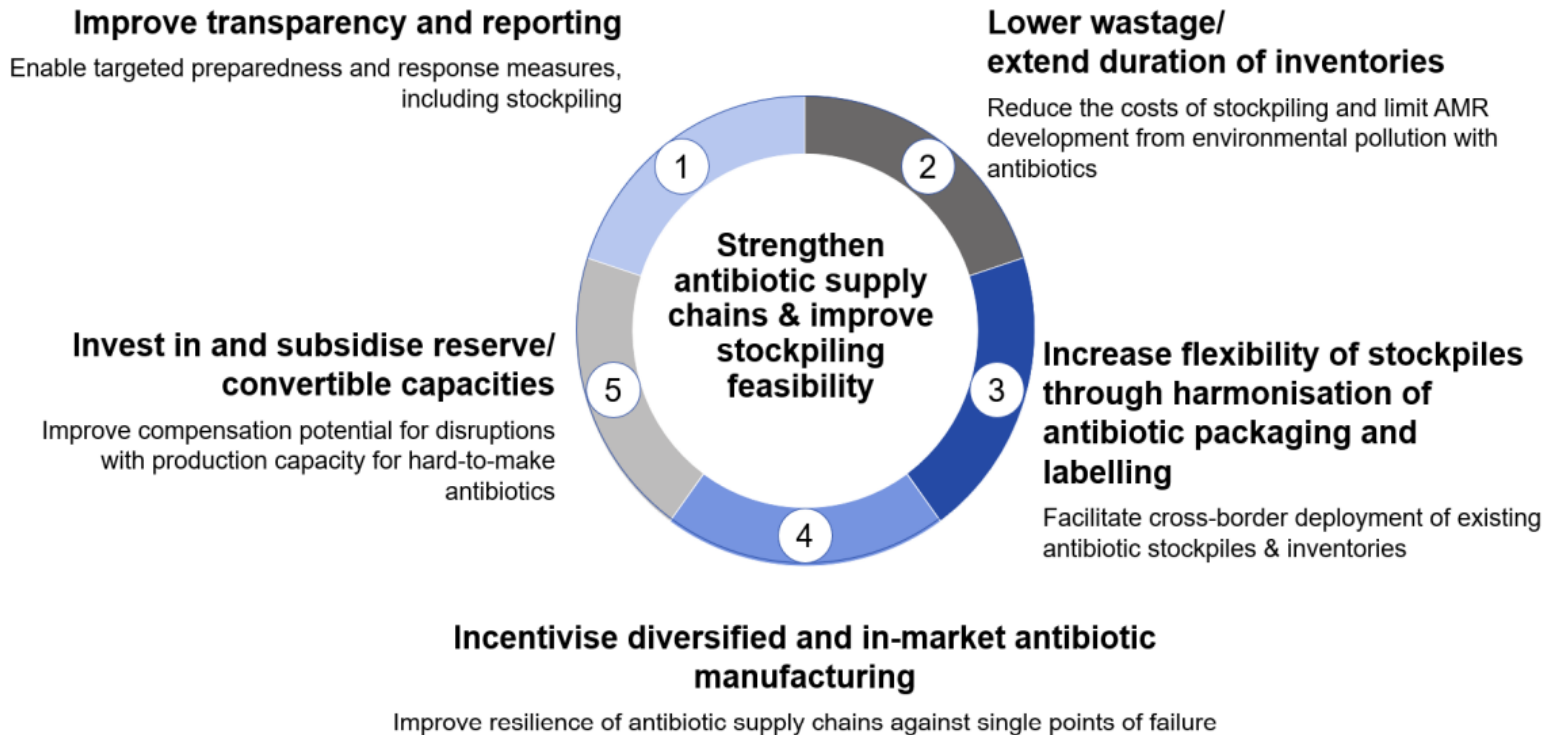
- Price only **award criterion** for procurement of medicines
 - Only 24% of procedures MEAT criteria (*predominantly in vaccines*)
 - MEAT criteria linked to **willingness to pay** for: **security of supply**, environmental criteria and added therapeutic value
- **Multiple winners** increase **availability of medicines** and **reduce the risk of medicine shortages**
- Policymakers encouraged to develop **PPM vision and strategy**
- **Intra-county and cross-country collaboration** encouraged (small volumes/small markets)



Lessons for LMICs:

- Clear **procurement strategy** needed for critical medicines
- **Security of supply**/environment cost = **insurance policy**
- Licensing/packaging issues – role for WHO

Crisis availability: HERA AMR Stockpiling Report



Lessons for LMICs:

- Assess availability of WHO antibiotic lists in your market
- Consider how to fund reserve antibiotics
- Collect (even imperfect) data on consumption/demand

2. Reducing shortage risks: Example Amoxicillin shortage

Demand driven shortage:

- 2020-21: amoxicillin/clav demand fell in EU --> **reduction of production capacity**
- 2022: amoxicillin/clav demand increased in EU (+35-50%; pediatric +300-500%) --> **increase of production capacity – too late for pediatric!**

How to improve demand prediction/supply chain planning?

- Centers for disease control dialogue w/ manufacturers --> 1 year planning required!
- Risk sharing on building up reserves: Who will pay for over-supply?
- How to avoid hoarding? Improve data on consumption --> serialisation data = consumption data

Supply chain consolidation

- Antibiotic production consolidated due to large volume/low price policies
- Consolidated supply chains = limited ability to react
- Adapt market policies to encourage investment in diversification

Lessons for LMICs:

- Consider demand planning with antibiotic manufacturers
- Markets: are antibiotics "*essential/critical*" or "*commodities*"?

Report on the **sustainability of the off-patent supply chain** to be published on 15 Feb also highlights the importance of **reimbursement models that allow for increased prices, increased use of diagnostic and surveillance data, tender contracts to multiple suppliers and reductions in barriers to market** as means to reduce shortage risks.

3. Reducing AMR risks: Antibiotic Environmental Manufacturing Standard

- AMRIA [Antibiotic Manufacturing Standard](#): critical step to define and drive implementation of responsible manufacturing to mitigate environmental risk.
- Applies to **manufacture of API and drug product (DP)**, such as a capsule or solution that contains the API, generally in association with other ingredients.
- Manufacturing emissions of APIs are typically not regulated --> AMRIA standard fills key gap as **all manufacturers can freely adopt the standard**.
- AMRIA Standard and forthcoming **Certification Scheme** --> critical step to drive responsible manufacturing practices
- Next Steps:
 - Can be recognised in **procurement criteria**
 - Can be used for **pricing and reimbursement** criteria
 - Education/**information for HCPs and patients**

Thank you for your attention!