6th Meeting of the GLG on Antimicrobial Resistance

7-8 February

Adrian van den Hoven
Director General Medicines for Europe
**Introduction**

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
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)
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.

• 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!