# Transferable data exclusivity voucher for priority antimicrobials in the new pharmaceutical legislation

12 November 2026

## Session 1: Introducing the concept

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# Combating AMR: challenges

- AMR causes over **35000 deaths per year** in the EU.
- It amounts to 11.7 bn EUR per year in healthcare costs for the EU/EEA
- By 2050, **10 million deaths globally each year**
- Market failure & need for innovation

# Combating AMR: New Pharmaceutical Legislation

- Prudent use
- Adaptative framework for bacteriophages
- EMA support
- Incentives

# Guidelines for voluntary subscription model for the joint procurement of antimicrobials



## Scope

- Any antimicrobial
- The contract to be awarded shall take the form of a multi-year subscription and include at least the following conditions:
  - De-linkage or partial de-linkage of funding from the volume of sales of the antimicrobial;
  - continuous and sufficient supply in pre-agreed quantities;
  - including, length of the subscription contract and the possibility of parallel procurement
- Guidelines, including the methodology for valuing and remunerating products to ensure economic viability of their supply



## State-of-play

- Consultation activities with Member States
- Consultation of industry through study with external contractor
- Consultation of further key stakeholders
- Next steps: finalisation of draft guidelines and start of consultation procedure



## Goal

guidelines available after the entry into force of the Regulation

# Transferable data exclusivity voucher

Transferable **regulatory data protection** voucher allows the developer of a novel antimicrobial product that fights AMR to benefit from additional **data protection (+12 months)** on that product, on another product in their portfolio or sell the voucher to another company to use

Commission may grant a transferable data exclusivity voucher to a '**priority antimicrobial**'

# Dimensions secured by the TEVs

## INNOVATION

- Reward goes to antimicrobials that have proven to be a ‘game changer’ against AMR

## AFFORDABILITY

- No ‘ex ante’ budgetary appropriation of public funds, blockbuster clause
- No regulatory burden
- Addresses market failure and helps increase reward of investment

## TRANSPARENCY

- Information on all direct financial received for R&D is a condition
- Any transfer and its value from applicant to any new holder shall be notified

## ACCESS - AVAILABILITY

- The applicant should demonstrate capacity of supply to the EU market (condition sine qua non)
- Voucher can be revoked if a request of supply, procurement or purchase is not fulfilled
- If a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection, it opens up to generic competition

# Priority antimicrobials

- Addition to the list of antimicrobials reserved for treatment for certain infections in humans
- Reserve the priority antimicrobial for human exclusive use for 10 years

# AMR TEV guidelines



## Scope

- Priority antimicrobials
- Scientific guidance to govern the scientific criteria set in the legislation
- Guidance for conditions (demonstrate capacity to supply and transparency on all direct financial support received for the development of the priority antimicrobial)



## State-of-play

- consultation process



## Goal

Guidelines available for the application of the Regulation

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