Novel EU incentives for antimicrobials: Time for ambitious action



The EU has identified AMR as one of the top three priority health threats





annual deaths in Europe, comparable to flu, tuberculosis and HIV/AIDS



€1.5 billion annually in healthcare costs

and productivity losses

combined



569 million extra hospital days by 2050

Antimicrobials are the cornerstone of modern medicine...



Antimicrobials have extended the average lifespan by

23 years



cancer patients need effective antimicrobials during their treatment



Without effective antimicrobials, medical procedures, such as surgery and organ transplantation, may become

too risky

...but no new classes of antibiotics have been discovered since the 1980s. The current pipeline is insufficient to tackle the rise in drug resistance



Low volume and low price To help stave off resistance, new antimicrobials are often held in reserve and used sparingly. Moreover, the value antimicrobials bring to patients and health systems is not adequately recognised. This contributes to making antimicrobial R&D a very risky process, with unsustainably low predicted returns.



Complex and risky science

Clinical development of antimicrobials has multifaceted challenges including recruiting sufficient patients, addressing stringent regulatory requirements, navigating the intricacies of infection settings and managing the emergence of resistance.



Inadequate financial incentives

The lack of sufficient financial incentives for antimicrobial R&D and commercialisation has become a critical barrier, hindering the development of new much-needed medicines.

New pull incentives are needed to revive the antimicrobial pipeline

Support R&D of new antimicrobials from the early stages of basic science to clinical trials Reward new antimicrobials that have successfully proven scientific viability and relevancy to the market

Create a sustainable marketplace that supports patient access

Push incentives

Basic science Preclinical

Clinical



Marketing

authorisation

Pull incentives

National access measures



Patient

access

Tax credits

• Grants

- Transferable exclusivity vouchers (TEV)
- Market entry rewards (MER)
- Revenue guarantee models (e.g. Sweden)
- National subscription models (e.g. UK)
- HTA and reimbursement reforms

To be effective, pull incentives should meet a set of key criteria



Size



Timeliness



Feasibility



Value for money



Predictability

Transferable exclusivity vouchers (TEV), if adequately designed, are a promising pull incentive option for the EU



Implementable via EU-level legislation



Pro-stewardship and prudent use



Supports companies of all sizes, including SMEs



F

TEV offers companies an opportunity to extend the market exclusivity of another product

of another product as reward for delivering an antimicrobial





Adresses the failure of the current incentive framework



Complementary to EU and national initiatives





Developer applies TEV to one of its



products



Antimicrobial product in development, targeting a priority pathogen



Developer applies for marketing authorisation



Antimicrobial receives
EU marketing
authorisation
and TEV



Developer sells TEV to another company



Company applies TEV to one of its products

