

Antimicrobial resistance (AMR)



Time for incentives: Transferable exclusivity extension (TEE)

WHY IS AMR A MAJOR PUBLIC HEALTH CRISIS?



Antimicrobial resistance (AMR) arises when bacteria, viruses, fungi, and parasites adapt over time and stop responding to medications, making illnesses harder to cure and raising the risk of disease transmission, life-threatening sickness, and death. As a result, **medications stop working**, and **diseases continue to progress**.

AMR has been declared by the World Health Organisation as one of the top ten global public health threats facing humanity¹ and has been listed as one of the top three health threats by the EU's Health Emergency Preparedness and Response Authority (HERA)

AS DRUG RESISTANCE RISES, SO DOES THE DEATH RATE²

OVER **400,000 DEATHS** WERE ASSOCIATED WITH ANTIMICROBIAL RESISTANCE IN EUROPE IN 2019³

BY 2050, THIS NUMBER MAY RISE TO **1.3 MILLION DEATHS PER YEAR**⁴

TO ADDRESS THE GROWING THREAT OF RESISTANCE, WE MUST ENSURE THE APPROPRIATE USE OF OUR EXISTING ANTIMICROBIALS AND ALSO ENSURE A ROBUST PIPELINE OF NEW ANTIMICROBIALS IS UNDER DEVELOPMENT TO KEEP PACE WITH RESISTANCE

While the need for new antimicrobials is pressing, the research pipeline has been drying up due to market failure⁵.

LOW VOLUME



Antimicrobials are used sparingly to preserve the effectiveness and slow the development of resistance. This, however, means that developers do not secure a sustainable return on their investment, and future investment is stifled. In recent years, a number of antibiotic-focused biotech companies have declared bankruptcy and pharmaceutical companies exited this space due to the lack of commercial sustainability.

LOW PRICE



HTA and reimbursement systems do not recognize the added value of new antimicrobials. Novel antibiotics are assessed similarly to other drugs with no specific HTA guidelines. Therefore, the societal value is not considered when making reimbursement decisions.

PENNY WISE, POUND FOOLISH



Reimbursement systems encourage the use of older, inexpensive treatments, even when a newer antibiotic may be more appropriate treatment for a patient.

LACK OF INCENTIVES



There are insufficient incentives to support companies in clinical development.



THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE CALLS FOR A NEW SOLUTION

HOW A TRANSFERABLE EXCLUSIVITY EXTENSION (TEE) CAN ADDRESS THE MARKET FAILURE FOR ANTIMICROBIALS?

The concept of transferable exclusivity extension (TEE) has been proposed as a potential solution to address the current economic challenges constraining R&D in the field of AMR. TEE would represent a **unique solution** addressing the challenge of antimicrobial R&D within a broader package of push and pull incentives.

BY INTRODUCING A TRANSFERABLE EXCLUSIVITY EXTENSION, THE EU WOULD REVIVE ANTIMICROBIAL R&D AT THE SCALE REQUIRED TO SUSTAIN OUR FIGHT AGAINST AMR

A research-based company successful in bringing an eligible priority antimicrobial to the market, would be entitled to receive a transferable right to extend the exclusivity period of another product. This TEE could be applied either by the same company that developed the new antimicrobial within its own portfolio or sold to another company.

Addresses the failure of the current incentive framework by offering a potential incentive at the scale required to **drive greater R&D** in new antimicrobials and that **recognises their broader societal value**

Supports all pharmaceutical companies of all sizes, including SMEs. It would also increase the attractiveness of the antimicrobial field

Provides **an opportunity for the EU to lead** in the development of a new form of incentive that could be replicated in other regions

TEE has the potential to deliver a **sustainable, robust pipeline** of new antimicrobials.

Pro-stewardship and respect to prudent use, leading to **improved medical outcomes for patients** by delinking financial reward from the volume of prescriptions, which underpins the standard R&D model

A recent study⁶ concludes that the **benefits of introducing TEE far exceed the costs for society**

Products "receiving" a TEE must have a reasonable remaining exclusivity period to provide **appropriate predictability to the generic industry**

1. WHO. Antimicrobial resistance (2019). <https://www.who.int/europe/news-room/fact-sheets/item/antimicrobial-resistance> there may be limited diagnostic tools and surveillance data to guide appropriate use. 2. Charles River Associates. A framework for assessing the potential net benefits realized through Transferable Exclusivity Extension (TEE) as an incentive for development of novel antimicrobials: FINAL REPORT (2022). <https://www.efpia.eu/media/676634/cra-efpia-a-framework-for-assessing-the-costs-and-benefits-of-tee-final-report.pdf> 3. Ibid. 4. Ibid. 5. WHO. Lack of new antibiotics threatens global efforts to contain drug-resistant infections (2020). <https://www.who.int/news/item/17-01-2020-lack-of-new-antibiotics-threatens-global-efforts-to-contain-drug-resistant-infections> 6. E.g., AMR could lead to an annual decrease in European Gross Domestic Product (GDP) of \$180bn-\$680bn by 2050. <https://www.efpia.eu/media/676634/cra-efpia-a-framework-for-assessing-the-costs-and-benefits-of-tee-final-report.pdf>