

A Revenue Guarantee Scheme as a tool to support Access to new antibiotic treatments

Summary

To combat the crisis of antibiotic resistance, solutions must incentivise innovation and ensure access to such treatments. An **annual revenue guarantee scheme** appears as an effective tool that can encourage antibiotic developers to invest in research and development by providing guaranteed revenue. The Swedish and UK models show that the deployment of revenue guarantees is a practical and viable solution that has been tested and shown positive results. The calculation shows that, for the public cost of bringing one new antibiotic to the market through a transferable exclusivity voucher, the proposed revenue guarantee scheme could ensure the availability of and access to **4 new antibiotics as well as support access to existing antibiotics**.

Antimicrobial resistance

Antimicrobial resistance is a global health crisis contributing to over 1.2 million deaths yearly.¹ According to the WHO, AMR remains one of the top 10 global public health threats facing humanity accounting for 1 in 5 deaths occurring in children under the age of five² and about half a million lives could have been saved in 2019 across the G7 states if all drug-resistant infections had been prevented³. The evolutionary process of bacteria's ability to become resistant to antibiotics will always exist.⁴ As antibiotic resistance emerges; new and effective treatments are needed and access to essential antibiotics must be ensured.

To address this antibiotic resistance crisis, there is a pressing need to incentivise the development and availability of new antibiotics. However, the current landscape for antibiotic research and development presents significant challenges, including high research and development costs, complex and expensive regulatory, price and reimbursement procedures, scientific hurdles, and a lack of profitability due to controlled usage and stewardship measures. Many of these products treat rare infections. While the value to public health, infection control, and combatting AMR is immense, low demand means that relying on volume sales to recoup innovation costs may

¹ Antimicrobial Resistance Collaborators, *Global burden of bacterial antimicrobial resistance in 2019: a systemic analysis* (2022) 399(10325) *The Lancet* 629-655.

² [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext)

³ https://www.rki.de/EN/Content/infections/antibiotic/brochure_IHME_RKI.pdf?__blob=publicationFile

⁴ Holmes, A.H.; Moore, L.S.P.; Sundsfjord, A.; Steinbakk, M.; Regmi, S.; Karkey, A.; Guerin, P.J.; Piddock, L.J.V. Understanding the mechanisms and drivers of antimicrobial resistance. *Lancet* 2016, 387, 176–187. [CrossRef]

not be viable, which is why there is a need for so-called pull incentives by offering financial return to reward innovation.

In the context of the revision of the pharmaceutical legislation, the European Commission recently proposed the introduction of Transferable Exclusivity Vouchers for antimicrobials. [Medicines for Europe's note on Transferable Vouchers](#) highlights our concerns linked to the introduction of TEVs, including the extension of monopolies on more profitable products, and the undue delay in access to generic and biosimilar medicines for patients.⁵

As an alternative, an Annual Revenue Guarantee Scheme was recommended by an EU-Joint Action study on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI).⁶

The Annual Revenue Guarantee Scheme would have the benefit of securing access to antibiotics, with the yearly payments being conditional on a MAH maintaining access to the antibiotics, and also supporting existing antibiotics, of which the availability is necessary to ensure that the new antibiotics are not overused, which can lead to faster resistance development.

Annual Revenue Guarantee Scheme

An annual revenue guarantee is a pull mechanism which can be implemented for innovative antibiotics (through a high yearly guarantee) but also for existing antibiotics (through lower guarantees).⁷

Under this scheme, manufacturers receive a set payment for a specified minimum volume of antibiotics produced (over a certain period), ensuring they have predictable revenue regardless of sales.⁸ The public funding payment is variable, covering the gap between the agreed value and actual yearly market sales.

This is important as the limited link between the revenue and the sales units incentivises access over consumption, thus reinforcing stewardship efforts.

Beyond the guaranteed volume, manufacturers are further incentivised by an additional payment per unit sold, encouraging sustained production and supply. This model ensures a consistent supply of antibiotics while making their development economically viable. It represents a mutually advantageous solution, benefiting both public health and the industry, by harmonising efforts against antibiotic resistance with sustainable market principles.

⁵ 'Note on Transferable Exclusivity Vouchers' (*Medicines for Europe*, March 2022)

<<https://www.medicinesforeurope.com/wp-content/uploads/2022/03/Medicines-for-Europe-Note-on-Transferable-Vouchers-March-2022.pdf>>

⁶ Ardal, C., Lacotte, Y., Edwards, S., Ploy, M.C. and European Union Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (EU-JAMRAI). *National facilitators and barriers to the implementation of incentives for antibiotic access and innovation* (2021) 10(6) *Antibiotics*, 10(6) 749.

⁷ European Commission, *Study on Bringing AMR medical countermeasures to the market – Final Report* (2023) Publications office of the European Union <https://op.europa.eu/en/publication-detail/-/publication/51b2c82c-c21b-11ed-8912-01aa75ed71a1/language-en/format-PDF/source-282347876>, p57.

⁸ *ibid.*

Examples of existing annual revenue guarantee schemes:

- Sweden⁹

In 2019, Sweden started a revenue guarantee pilot. Sweden's restrained use of antibiotics compared to other countries led to situations where certain products faced especially low demand, and maintaining a reliable supply was at risk. The pilot started in June 2020 and finished in December 2022 with five antibiotics selected based on criteria demonstrating an antibacterial spectrum with demonstrated good activity against multidrug-resistant *Enterobacterales*, having a bactericidal effect and approved for treatment on the WHO's critical priority pathogens list. The evaluation showed that the model was effective to ensure the availability of antibiotics earlier than other European countries.

- United Kingdom¹⁰

Another form of revenue guarantee is the subscription model of the United Kingdom, which is the first country in the world to have tested an innovative and fully delinked pull mechanism where the yearly payments are the only revenue allowed to suppliers, irrespective of the volume of units used in the UK market. This pilot pays companies a fixed annual fee for antimicrobials based on an HTA assessment that looks at non-traditional values, such as the insurance value of having the antibiotic available.

Estimating the cost of a comprehensive Revenue Guarantee Scheme

The HERA Study on Bringing Antimicrobial Resistance Medical Countermeasures to the Market¹¹ proposes "RG150" as an intermediate Annual Revenue Guarantee for new antibiotics. The expected global public cost for one RG150 pull intervention of 1 new antibiotic over 10 years, based on the average sales levels and market revenue in this period, is \$784 million (around €715 million), and this intervention makes 50% of projects profitable at the start of phase I, and about 75% at the start of phase II.¹¹

The cost of the current proposal of the transferable exclusivity vouchers is estimated at 2.9 billion EUR per new antibiotic.¹¹

⁹ The Public Health Agency of Sweden, 'Availability of antibiotics' (2023) <<https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/antibiotics-and-antimicrobial-resistance/availability-of-antibiotics/>>

¹⁰ NHS England, 'Antimicrobial products subscription model: guidance on commercial arrangements' (2023) <https://www.engage.england.nhs.uk/survey/the-antimicrobial-products-subscription-model/user_uploads/antimicrobial-products-subscription-model--guidance-on-commercial-arrangements--1.pdf>

¹¹ [Study on bringing AMR medical countermeasures to the market - Publications Office of the EU \(europa.eu\)](#)

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Funding of the scheme: Legal basis of payment

The funding necessary for an EU-wide revenue guarantee scheme might require co-funding by the EU and Member States.

EU funding for revenue guarantees can be provided through the EU4Health Programme, Horizon Europe, or a future HERA budget.

Revenue guarantees could be implemented through the use of Joint Procurement Agreements, and it could find its legal basis in Regulation (EU) 2022/2371 of 23 November 2022 on serious cross-border threats to health, which foresees a joint procurement procedure and agreement between the EU and the Member States to conclude “advance purchase” of medical countermeasures necessary for preparedness and response to serious cross-border threats to health.