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REVIEW ARTICLE

Transferable Exclusivity Extension Vouchers for Antimicrobials: Incentive Design, Implementation Challenges, and Policy Trade-Offs

Mario García-Díaz[1,2] · **Jorge Mestre-Ferrándiz**[3] · **Jaime Espín**[1,4,5]

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Abstract

Antimicrobial resistance (AMR) is one of the greatest threats to public health, and forecasts for 2050 are even worse. In response, the European Commission (EC) is proposing the Transferable Exclusivity Extension Voucher (TEEV), which aims to encourage the development of innovative antimicrobials. It consists of extending data exclusivity for a medicine selected by the beneficiary company or another company to which the voucher can be sold (i.e. not necessarily the antimicrobial). One requirement for obtaining it is to declare any public contributions received for the antimicrobial R&D. Based on a review of the literature and interviews with five AMR experts, a theoretical and real view of how the TEEV works and its estimated costs is presented, in addition to the impact that the requirement for transparency in R&D costs would have. On the one hand, the results show that a (well-designed) TEEV, coordinated by the EC, offers significant public health benefits compared with the cost of inaction and provides predictability for investors, although, by its nature, it delays the entry of generics/biosimilars and does not provide an access scheme to new antimicrobials. Recent assessments estimate the total healthcare cost at €162 million per voucher and the average cost for each Member State at €6 million. On the other hand, transparency of R&D costs could enable policymakers to design policies focused on public health needs and better design the optimal mix of (push and pull) incentives for new antimicrobials, but they run the risk of threatening trade secrets, discouraging private investment and promoting the application of cost-plus pricing regulations. In conclusion, the TEEV could be a great incentive to combat AMR inaction, but it has not yet been implemented and needs to be complemented by other push and pull incentives. Furthermore, more information is needed on the impact of R&D costs transparency in the context of antimicrobials.

Key Points for Decision Makers

A well-designed Transferable Exclusivity Extension Voucher (TEEV) offers a strong incentive to stimulate antimicrobial R&D in the face of inaction on antimicrobial resistance (AMR).

TEEV should be complemented by other push, and possibly pull, incentives which will also encourage Member States to implement national models for access to and funding of antimicrobial R&D.

There is a need to expand information on the impact of antimicrobial R&D cost transparency to address tensions surrounding this measure.

✉ Mario García-Díaz
mario.99.mgd@gmail.com

1 Andalusian School of Public Health, Granada, Spain

2 Faculty of Economics and Business, University of Granada, Granada, Spain

3 Department of Economics, University Carlos III, Madrid, Spain

4 Instituto de Investigación Biosanitaria ibs., Granada, Spain

5 CIBER of Epidemiology and Public Health (CIBERESP), Madrid, Spain

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1 Introduction

Antimicrobial resistance (AMR) has been identified as one of the greatest threats to global health [1–3]. In 2021, from an estimated 4.71 million deaths associated with AMR, 1.14 million were attributable to AMR [1]. Furthermore, between 2022 and 2050, AMR-attributable deaths have been projected to increase by nearly 70% and associated deaths by 67% [1]. In Europe, it is reported that AMR caused in the region of 35,000 deaths annually in 2023, generating a cost of approximately €1.5 billion to the healthcare systems of Member States (MS) [2–4]. Already in 2014, the review on AMR alarmingly projected that by 2050, up to 10 million deaths per year globally could occur due to this phenomenon, although there are other projections that go as high as 50 million deaths in the most extreme scenario if no effective measures are implemented, which would exceed cancer mortality [1, 2, 5]. While there are many factors underlying this trend, the overuse of antimicrobials is a key factor driving the rise of their resistance [1].

Taking into account the socioeconomic burden, AMR mortality varies by age and region, as illustrated by the work carried out by Global Burden of Disease (GBD) [1]. Between 1990 and 2021, mortality in children under 5 years of age decreased by 50%, while in adults over 50 years of age it increased, especially in the elderly aged 70 years and older, with an increase of > 80%. This trend is expected to continue until 2050, with an even greater increase in the elderly. Although infant mortality has declined, infections in children with sepsis are increasingly difficult to treat. Moreover, low- and middle-income countries are disproportionately impacted, with Sub-Saharan Africa remaining the region with the highest AMR-attributable mortality rate, despite the reduction in young children. Population ageing and increasing comorbidities, such as obesity and diabetes mellitus, will exacerbate the situation. By 2050, a global increase in AMR deaths is expected, with a higher contribution from people over 70 years of age and a lower contribution from children under 5 years of age. Without effective measures, the global economy could shrink by 3.8% by that date [6].

Despite the attention of the World Health Organization (WHO), the implementation of action plans against AMR has been insufficient in recent years [1]. Although the need for new antimicrobials (and diagnostics, but these are outside the scope of this paper) is evident, the development of these treatments remains limited, for multiple reasons discussed later, and few offer substantial improvements over existing ones [3, 7]. Indeed, and as the WHO annual reports on the state of development of antibacterials have been showing since 2017, with the latest edition published in 2024, currently there are 57 traditional antibacterial agents in the pipeline, with only 12 fulfilling at least one of the WHO innovation criteria; however, of these 12, only four are active against at least one WHO 'critical' pathogen, and six innovative agents are active against 'high and medium' priority pathogens [8, 9]. A key challenge is that the use of new antimicrobials must be reserved to avoid the emergence of resistance, which reduces their volume of sales and discourages investment in research and development (R&D) by the pharmaceutical industry [3]. A second key challenge is that the price, and indeed health technology assessment and reimbursement systems, do not reflect the wider societal value of these treatments [3]. Although public and philanthropic funding for AMR research has increased, the problem lies in the low profitability of the antimicrobials market [6]. Partly as a result, the abandonment of investment in this area by pharmaceutical companies (for example, the case of Achaogen) has been observed [10]. This is due not only to commercial reasons but also scientific complexity and long development times, limiting even more the return on investment [6]. As a consequence, access to new antimicrobials is put at risk [6].

Given the challenge of AMR, the impact of antimicrobial overuse, and that the current business model for antimicrobials is based on revenues resulting from use, new incentives are being called for to encourage the commercialisation of innovative antimicrobials. Economic theory usually distinguishes between push and pull incentives, the former implying funding or rewarding R&D effort ex ante (sometimes tied to outcome via milestone payments) and prior to regulatory approval, and the latter rewarding R&D effort ex post if the outputs of R&D achieve health gains, and after regulatory approval. In particular, under pull incentives for new antimicrobials, one such mechanism being discussed—and in some cases implemented—is the 'delinkage model', which rewards investment in new antimicrobials independently of their direct volume of use [11]. In addition, several organisations and governments are discussing programmes to overcome barriers and encourage the development of new antimicrobials, mostly in terms of push [5].

One option to implement a delinkage model is the Transferable Exclusivity Extension Voucher (TEEV) [2–7, 12–15]. The basic idea is that if an antimicrobial meets predefined criteria, the company developing it will receive a voucher that confers an extra 12 months of regulatory data protection (to be used for the antimicrobial or for another of its own products), according to the European Commission's proposal [16]. However, the novelty of this system is that it is combined with the possibility of selling that extension to another company (to be used at its discretion—but with certain limitations). Previously, policy measures have included separately extended exclusivity and a voucher for a priority review by the US regulator, but not

combined and noting the voucher is to speed up the regulatory review process and not the extended exclusivity [17]. It is true, however, that around 20 years ago, TEEVs were discussed for treatments for neglected diseases but were never implemented [18].

The aims of this study are twofold. The first is to evaluate the TEEV as a (public) incentive to develop new antimicrobials—the incentive being in the form of allocating public money for the extension of the period of data exclusivity for the company using the voucher, whether on an antimicrobial or not, as included in the review of the EU Pharmaceutical Strategy. The second objective is to study the impact of the requirement for pharmaceutical companies to declare the R&D costs and sources of public funding used for the antimicrobial R&D process.

The discussion about incentives for new antimicrobials is not exclusive to the EU, as other countries are acting as well—albeit primarily from the push side [19]. The pull incentive programme, under the PASTEUR Act in the US, is still under discussion with some years' delay [3]. However, the focus of this article is the study of the TEEV and other mechanisms are outside its scope.

Importantly, the TEEV proposed by the EU contains, among other things, transparency conditions on any public contribution to R&D costs [4]. Nevertheless, the wording on the draft Directive is not identical to that on the proposal for Regulation; the former states "to ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding any direct financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products" [20] while the latter states that "a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial" [21].

This transparency requirement possibly follows the 72nd World Health Assembly (WHA) Resolution urging MS for improved transparency in the pharmaceutical market more generally [22]—reflected by the encouragement of greater transparency on sources of R&D funding and R&D costs. This issue is further explored in the paper.

This article is framed within a specific work package of the European project Health Innovation Next Generation Pricing & Payment Models (HI-PRIX), looking at the role of public contributions to the development of health innovations and its integration in value assessment and pricing/reimbursement decisions [23]. For this purpose, several case studies have been analysed, one of which being the TEEV.

2 Methodology

This article explores the European Commission's TEEV proposal for incentivising antimicrobial R&D in the face of the AMR problem. To this end, a narrative literature review was conducted to gather information on its main strengths and challenges, as well as the influence of the requirement for pharmaceutical companies to declare R&D costs and public funding sources during Pricing and Reimbursement (P&R) EU negotiations (at a national level). In addition, a series of interviews with different stakeholders familiar with the EC's proposal were conducted to obtain, in a qualitative way, further insights about this mechanism as an incentive. It is important to mention that a TEEV has never been implemented in practice for antimicrobials or other treatments, so these interviews were a critical part of our research.

2.1 Narrative Literature Review

This narrative literature review focused on identifying literature on the characteristics of the TEEV proposed by the EC, including the potential impact of the funding disclosure for the antimicrobial R&D process.

2.1.1 Inclusion and Exclusion Criteria

- Relevant articles containing the following information were included: (1) information on the characteristics of the TEEV for antimicrobials (either its proposal, operation, advantages, disadvantages or the social cost involved) or (2) information on the impact (positive or negative) of the transparency of R&D costs and sources of funding used. Thus, we excluded articles that only discussed the AMR problem but not the TEEV, articles that discussed other pull incentives, and articles that discussed transparency of R&D costs but not the impact of such a policy measure.

2.1.2 Search Strategy

The literature search was conducted between February and April 2025. The search strategy was carried out in two different blocks taking into account each of the inclusion criteria. For the first inclusion criterion, searches were carried out through PubMed, Google Scholar and Google, in addition to certain articles based on authors' knowledge of the issue. The keywords used were ('Transferable Exclusivity Extension Voucher' OR 'TEE' OR 'TEV' OR 'TEEV'). For the second inclusion criterion, bibliographic searches were carried out through PubMed, Google Scholar and Google, the keywords being 'impact', 'transparency' and 'R&D costs'.

Table 1 List of experts interviewed

Christine Årdal	Senior Scientist, Norwegian Institute of Public Health, Norway
Kevin Outterson	Professor, Boston University, United States
Kristine Peers	General Counsel, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Giacomo Borgo	Associate Director Public Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Deepali Patel	Director, International policy, AMR Action Fund, Switzerland
Pierre Dubois	Professor of Economics, Toulouse School of Economics, France

Through this bibliographic search strategy, 24 relevant articles for our research were finally selected, and 16 of them were identified via the 'grey literature'.

2.2 Interviews

Following the narrative literature review, expert interviews were carried out during the first quarter of 2025 to obtain practical information on the characteristics of the TEEV, how it could work in the real world after implementation, its role as an element of public funding and the impact of having an R&D cost breakdown clause and disclosure of sources of public funding.

2.2.1 Selection of Experts

The experts were chosen on the basis of the papers identified in the literature and authors' previous knowledge. We wanted a broad representation of views, given the different opinions expressed to date about the TEEV.

Broadly speaking, we identified the following profiles: (1) academic researchers, (2) representatives of the pharmaceutical industry, and (3) representatives of different R&D consortia to support preclinical research and clinical trials by small and medium-sized enterprises (SMEs) in the AMR field. The EC (proponents of the TEEV in Europe) was contacted, but no expert was proposed for the interview. Finally, 10 experts were contacted, and five of them were willing and able to undertake an interview.

2.2.2 Questionnaire

We prepared a semi-structured questionnaire (Supplementary Information 1, see electronic supplementary material [ESM]), which was shared in advance of the interviews. It had two sections given the objectives of the research, and in line with the literature review. The first set of questions focused on the role of the TEEV as a public financing incentive, what it facilitates, the barriers and enablers after its implementation, the evaluation of its impact, and the relation with other types of (push and pull) incentives. The second block of questions focused on the implications of requiring companies to disclose information on the breakdown of costs and sources of public R&D funding for the antimicrobial.

2.2.3 Interviews Undertaken

Five interviews were conducted with reputed experts who have previously worked on the problem of AMR—see Table 1.

These experts were sent the interview outline in advance. The interviews were conducted on the Google Meet® videoconferencing platform where they were recorded with the consent of each of the participants.

2.2.4 Collection and Analysis of Results

The interview recording was used to carry out an audio-to-text transcription using Word Online®. Through this same programme, the most important statements of each of the experts interviewed were analysed. Finally, the most relevant answers for this research were selected based on its objectives.

3 Results

3.1 Narrative Literature Review

3.1.1 European Commission's TEEV Proposal

In April 2023, the EC proposed a reform of EU pharmaceutical regulation, including the introduction of a TEEV as an incentive to address the antimicrobial innovation crisis [2, 4, 7, 13–15]. In this proposal, TEEVs would be subject to strict restrictions, such as:

1. a limit of 10 vouchers issued in a 15-year period[1],
2. stringent criteria for defining eligible priority antimicrobials, where at least one of the following criteria has

[1] Note that some of our interviewees mentioned that we will not be able to reach 10 new antimicrobials that meet the eligibility criteria defined for obtaining the TEEV anyway.

to be met: belonging to a new class of antimicrobials, having a different mechanism of action to those already authorised in the EU and/or including a previously unauthorised active substance that treats serious infections by multidrug-resistant organisms,
3. transparency conditions on any public contribution to R&D costs,
4. regulations on its use and transfer, including its application only during the first 4 years of data protection of a single centrally authorised product, and
5. eligibility criteria linked to the supply obligations of the priority antimicrobial in the EU [4, 15].

It is important to highlight that the EC proposal describes the TEEV as a centralised, temporary mechanism—while in parallel individual countries implement their national reimbursement reforms for access to new and existing antimicrobials that would guarantee revenue for the market authorisation holder (MAH) regardless of sales volumes [24].

In June 2025, however, the Council introduced new changes, probably the most significant one being a new clause stipulating that a transferred voucher (i.e. when used by a company not developing the antimicrobial) can only be used in the fifth year of the regulatory data protection period, and only if the MAH demonstrates (with an independent external auditor) that the annual gross EU sales of the product have not exceeded €490 million in any of the preceding four years (article 41) [25]. Two other changes worth highlighting are (i) to be eligible, a 'priority antimicrobial' now needs to "address multi-drug resistant organisms causing a severe or a life-threatening infection" and (ii) to prioritise an early launch in the EU, as the applicant will "need to demonstrate that the application for granting a marketing authorisation of the priority antimicrobial has been first submitted to the EMA or has been submitted no later than 90 days after the submission of the application for the first marketing authorisation outside the EU" (article 40) [25].

3.1.2 TEEV Advantages

Pharmaceutical companies support the TEEV because it (i) can provide an incentive of meaningful size to stimulate antimicrobial R&D; (ii) can benefit companies of all sizes without requiring upfront public funding; (iii) can provide developers with predictability, and (iv) delinks financial rewards from volume of prescriptions [7, 14, 26]. One of its main attractions is that it can be implemented, operated and coordinated at the EU level, without the need for individual action by MS, in a way that complements national initiatives, hence minimising the incentives for individual MS to freeride [15, 26]. In particular, the voucher would be geared to support and encourage the development of new antimicrobials targeting WHO priority pathogens which will generate a high return in terms of public health [15, 27] and could avoid any gaming around which drugs qualify for being awarded a TEEV.[2] The eligibility criteria linked to the supply obligations of the priority antimicrobial in the EU could provide security of supply, and its delinked nature is well aligned with stewardship efforts [15].[3]

In Europe, prices of generic/biosimilar manufacturers do not immediately fall to levels that reflect the true cost of production, generating a transfer of profits to generic companies; hence, the lost benefits forgone for society from delayed generic/biosimilar entry because of the TEEV would be more limited, improving the efficiency of the TEEV itself [12, 15]. While more efficient policy alternatives may exist in theory, their implementation in the short term is unlikely and they are not necessarily the correct comparator, so the TEEV remains a pragmatic and superior alternative to the status quo [15, 27], especially given the societal and economic benefits of developing new antimicrobials. Also, and importantly, the TEEV provides an opportunity for the EU to lead globally in incentivising innovation against AMR [26].

Suggestions to manage the financial uncertainty for payers have also been put forward in the form of safeguards or alternative models—some of which have been introduced, as mentioned before, including (i) adjusting the value of the TEEV and financial rewards according to the clinical benefit of the antibiotic, (ii) implementing an auction system in which a fixed reward is set and potential buyers bid for the minimum duration of regulatory exclusivity for which they are willing to receive the incentive, thus ensuring an efficient allocation of resources and obtaining a known certain reward for the developer [12], (iii) limiting the maximum net revenue that can be obtained with a TEEV, and allowing a variable duration or payment over time depending on expected revenues, or (iv) adjusting the period of data protection in which the voucher can be used, (v) using an intermediary to manage the allocation of TEEVs and avoid market distortions, and (vi) imposing additional requirements on innovators to ensure availability of the antimicrobial as a condition for receiving the TEEV [7, 14, 15, 28–30]. It should be noted that while the additional restrictions may result in lower costs to MS, they will also weaken the value of the incentive and have a negative impact on stimulating antimicrobial R&D.

Overall, according to the European Federation of Pharmaceutical Industries and Association (EFPIA), which has been very concerned about AMR and has commissioned substantial research on TEEV, the TEEV benefits to society

[2] We want to thank a reviewer for pointing this out.

[3] One reviewer suggested as another benefit that the 'public sector' only pays for success.

Table 2 Social costs estimations and methodologies for the TEEV

Source	Methodology and key assumptions	Estimated costs/revenues
European Commission (EC) Impact Assessment [7, 32, 33]	Based on historical sales of highest-selling medicines Simulated scenarios with 1 vs 3 vouchers per year Allocation of costs by MS pharmaceutical expenditure	Revenues: €500m per voucher (3/year) or €413m (1/year) Cost to payers: €561m/year (3 vouchers), €294m/year (1 voucher) Average cost per MS: < €10m
Office of Health Economics (OHE) (2019) [28]	Simulation incorporating resale value of vouchers, R&D costs of antibiotics Distinction between new vs existing class antibiotics Value sensitive to number of vouchers issued	Revenues: €350m (3 vouchers), €500m (2 vouchers) Incentives needed: €280m (existing class), €442m (new class) Duration: 7–10 months (existing), 9–12 months (new) Net cost: €350–840m/year (2 vouchers), €460–990m/year (3 vouchers)
European Federation of Pharmaceutical Industries and Association (EFPIA) (2022) [15, 26]	Estimate based on lost savings from delayed genericisation plus administrative costs of implementing TEEV	Societal cost: €426m per voucher
Charles River Associates (CRA) (2025) [34]	Forward-looking analysis of eligible medicines (2027–2029) New Council restrictions: voucher usable only in 5th year of data protection Cap at €490m annual revenue	Total cost: €162m (≈45% lower than EC's €294m) Average MS cost: €6m; outside EU4 < €7.2m

EU4 Germany, France, Italy and Spain, *MS* Member States, *TEEV* Transferable Exclusivity Extension Voucher

are likely to far exceed the costs, and the costs are lower than previously predicted [26]—see Table 2 for a summary.

3.1.3 TEEV Disadvantages

The biggest disadvantage highlighted by the literature is the delay in the entry of the generic/biosimilar alternative of the treatment subject to the TEEV (not the antimicrobial), implying that MS would be reimbursing the treatment for longer at a price without off-patent competition [2]. Second, but similarly to other delinkage type models, it has limitations in ensuring access to new antimicrobials, as granting them at the time of marketing authorisation does not ensure their availability on the market [4, 13, 14, 31]—albeit as mentioned later the TEEV could be supported by complementary access models. Their access will depend on local pricing and reimbursement arrangements, so developers may prioritise more profitable markets, limiting equitable access, even if these countries do have to pay indirectly for the new antibiotic, although the TEEV system could also be reinforced through contractual access provisions that oblige companies to ensure the supply of antimicrobials [13, 14, 31]. It could also have negative effects on the development of biosimilars and on the difficulty of access for patients [13, 31]. The possibility of these antimicrobials obtaining the TEEV failing to significantly combat resistant microbial infections, to be removed from the market for safety reasons, or not to be reimbursed by public healthcare systems due to a lack of cost effectiveness, have also been raised as potential disadvantages of the TEEV [4, 7, 14]—although it will depend, at least partly, on the eligibility criteria. Although not specific to TEEV, it does not differentiate by antibiotic quality either [31], which has also been a deemed as a disadvantage.

Reflecting on the need for a holistic approach when thinking about and designing incentives for new antimicrobials, it is not surprising that the EC recognises that this tool must necessarily be complemented by other measures for the development of antimicrobials in the EU [31].

3.1.4 Social Cost Estimations of the TEEV

Different studies have quantified the (social) cost of the TEEV, and the variability of estimates is due to the fact that the value of the voucher will depend on the demand of firms and the impact of the exclusivity extension, the difference between the monopoly price and the price of generics, and the different assumptions and methodologies [15]. Two important elements have to be considered to contextualise the cost of the voucher. First, the comparator used to assess its cost—in particular, relative to the cost of inaction, given the annual cost of AMR to healthcare systems in Europe is around €1.5 billion [2]. Second, we need to differentiate between the value of the TEEV to the company using it (for a non-antimicrobial most probably) and the cost to the MS. The former is equal to sales loss avoided through using the TEEV; the latter (i.e. the lost cost savings from delayed entry) will be equal to the difference between the sales of the

originator during the extended exclusivity in the year it is lost (i.e. with the voucher), and the combined originator and generic sales in the year immediately after loss of exclusivity (i.e. without the voucher) [3, 12]. Hence, countries with limited generic entry will have no forgone cost savings and the cost of the TEEV will be minimal [3, 12].

Table 2 summarises the key assumptions and results for four key articles assessing these costs.

The analysis by Charles River Associates (CRA) (2025) is probably the most realistic in our view, as it uses a forward-looking assessment (rather than historic, like most analyses) to identify eligible medicines that a TEEV could be applied to, as well as incorporating the further restrictions introduced by the Council mentioned in Sect. 3.1.1 (when it could be used during data protection and revenue caps for eligible products). This analysis estimates total cost to payers in the EU would be €162m—which is 45% lower than the original estimate of €294m from the Commission's impact assessment. This analysis, and following [32], estimates the average cost to an individual MS to be €6m; outside of the EU4 (Germany, France, Italy and Spain), every country will pay <€7.2m per TEEV.

Finally, and regarding the value of the incentive, it should be borne in mind that the company holding the voucher does not fully appropriate all the value of the extra revenues, because sales do not fall to zero immediately after patent expiry and part of the benefit is distributed in the supply chain [3, 12].

3.1.5 Positive Impact of R&D Cost Transparency

We did not identify any literature specifically assessing the impact of the requirement of developers of antimicrobials to report public investment received by them, but rather, about the effects of broader transparency around the pharmaceutical market in general and about R&D cost transparency more specifically. Greater transparency overall on the functioning of the medicines' market can play a role in an efficient biomedical innovation system, as it accelerates competition, optimises R&D by focusing it on priority public health needs and improving clinical care, and reduces unnecessary costs for medicines without great therapeutic value [35, 36]. This could allow for better negotiation of prices and access to essential treatments [35–37], and encourage good governance by governments which act in the public interest [38].

Regarding greater transparency in R&D costs specifically, its proponents—mainly coming from academia and non-governmental organisations (NGOs)—highlight several interrelated benefits. First, that it would help correct the lack of access to medicines by providing real information on development costs [35], allowing policymakers to design fairer and more necessary medical policies. Second, it would allow the regulation of prices in relation to underlying costs, aligned with R&D costs [35–37]; however, it is also true that cost-plus price regulation moves away from using health technology assessments to help determine prices.

Third, policymakers could assess which items could be calculated in the final total cost calculation and what weighting each item would get, which could help them assess the pharmaceutical industry's demands for the need to recover high R&D costs; avoiding 'paying twice' in the event that a substantial push funding has been made previously so that the pull funding could be reduced [35, 36]. Fourth, policymakers could assess the reliability of the data to check whether these disaggregated data are consistent with the limited periodic lump sum estimates, which vary between clinical trial phases, therapeutic areas, the number of patients required for the trial, or whether it has obtained any grants (i.e. push funding) [35]. Fifth, there may also be situations, such as COVID-19, where it would be useful for policymakers to have immediate access in the case of vaccine development [35].

Sixth, cost transparency could facilitate efficiency gains for the pharmaceutical industry, with a more efficient allocation of resources by medicine developers, by reducing duplicative research and fostering greater collaboration due to publicly available records and more open-access publications [39]. Seventh, at the financial level, transparency could benefit investors by providing reliable information for decision making, reducing biases in pricing, and lowering the cost of capital for pharmaceutical companies [39]. Eighth, cost information is important not only for estimating a company's future performance in order to prioritise its spending plans, but also for positive liquidity and valuation, lower external costs, and free competition financing [39]. Finally, tax authorities and financial regulators could benefit from the reduction of problems related to information frictions [39].

3.1.6 Negative Impact of R&D Cost Transparency

A number of disadvantages have been proposed in the literature—including from academia and industry. First, the administrative burden of reporting disaggregated costs is high, as it requires significant time and financial resources [35, 39]. Second, it is very difficult to assign some R&D costs (particularly for early discovery and preclinical before the molecule is selected) to specific products, including antimicrobials [35, 39]. Third, disclosure of these data could threaten trade secrets and affect the competitive business dynamics of medicine developers, thereby reducing access to new medicines [35, 39]. Fourth, the pharmaceutical industry warns that transparency of R&D costs can lead to wider use of cost-plus pricing and possibly not just for antimicrobials [37]. This could lead to lower prices and discourage investment in innovation [37]. Fifth, pharmaceutical companies

may stop offering tiered pricing to low- and middle-income countries if transparency facilitates downward negotiations in high-income countries, especially in systems with international reference pricing [39].

3.2 Interviews

Many of the issues identified from the literature review were discussed during the interviews, which provided additional useful insights on the topic.

3.2.1 Benefits of the TEEV

In all interviews, a key aspect discussed was whether the TEEV could be a better, or worse, incentive than other push or pull mechanisms being discussed for antimicrobials. Although there was no unanimous view on this, there was consensus that inaction should not be an option, and thus the discussion around pull incentives for new antimicrobials is necessary.

Several benefits of the TEEV raised during the interviews overlap with those identified by the literature review. Two benefits particularly highlighted were (i) having one incentive at the EU level is much more effective than individual Member State actions, as it would give, among other things, greater predictability for investors; (ii) it. will motivate other countries to act and pay their fair share of antimicrobial R&D, including the US to implement the Pasteur Act. In addition, it was suggested during an interview that the push for the voucher from the EC is precisely to put pressure on MS to come up with their own national market entry rewards. It is important to remember that the Commission deems the TEEV as a 'temporary mechanism', as MS implement other mechanisms. The cases of the UK and Sweden were raised during the interviews as good examples of these national 'delinkage' models—which at least partially de-risk the R&D, assuming the antimicrobial meets the eligibility requirements. It is true there are important differences between these two models; Sweden pays only for access to antibiotics already in the market, so it would be a 'delinked access pull incentive model'; while the UK reimburses for R&D for new antimicrobials, making it a 'delinked R&D pull incentive model'.

Another benefit raised during our interviews was that given the reward is granted at marketing authorisation, investors can see how they will recoup their investment earlier, relative to subscriptions models where they need to stay invested for a (possibly) long time to receive the full reward, reducing the expected returns due to discounting.

There was agreement that the impact of the voucher would ultimately depend on how it is implemented in practice, and that push and pull mechanisms would need to complement each other, rather than considering them as an 'either-or' option. In fact, the TEEV cannot be the incentive that covers the entire total incentive required. It is important to consider that ultimately, the objective is both to ensure access to effective antibiotics for Europe, and for Europe to cover its fair share of R&D—but the first aim is not sustainable without the second.

3.2.2 Barriers to the Implementation of the TEEV

A number of barriers to the implementation of the voucher were raised by our interviewees—noting that some of the barriers apply generally to any delinkage model. We have grouped them according to the following six themes—where elements of themes 1, 2, 3, and 5 are also reflected in the literature.

1. *Tensions between the EU and individual MS:* during the discussions prior to the publication of the relevant documents outlining the TEEV, several MS voiced their disagreement with it (for example, see the 'non paper' from a selection of MS) [40], primarily because the MS would bear the cost.
2. *Lack of predictability for payers and cost of the voucher:* in line with the first barrier, some interviewees raised the lack of predictability for payers in terms of the cost of the voucher, as it would, at least theoretically, depend on the success of the treatment with extended exclusivity, which most probably will not be the antimicrobial. But as mentioned by some of our interviewees, off-patent competition is far from perfect in Europe, sometimes because of regulation, and hence the cost of the voucher needs to factor in the rents that the generic/biosimilar companies would have otherwise enjoyed if they had entered. Also, the possibility of including 'guardrails' would be able to limit the impact to health care systems' finances—although during an interview it was questioned how these safeguards would work in practice. Another issue related to the cost of the voucher, and its one-off transaction nature, is what would happen if, for whatever reason, the antibiotic is removed from the market. As noted before, some of these uncertainties have been resolved with the recent changes suggested by the Council.
3. *Does not address 'access' issues:* there was general agreement amongst our interviewees that the TEEV does not address access issues (given the nature of the incentive being a one-off transaction)—but that this can apply to other delinkage-type models. However, it would be possible to sign supply agreements/contracts between countries and companies to ensure this—which could be part of the pricing and reimbursement negotiations and stewardship programmes that take place at the national level. Moreover, to be granted the voucher, the applicant

will nevertheless need to "demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market". In the market access sphere, companies are required to have stewardship and access plans for their antibiotic, and hence, MS and their health systems also need to be involved here—these interdependencies, and that no one single actor can solve the problem, were raised as something probably not well known. Another aspect discussed was the need to think about a global stewardship plan, beyond Europe, especially in those regions where the AMR burden is highest. Through this plan, the issue of global access could be discussed[4].

4. *Increased uncertainty for investors:* given the limited real-life experience with the voucher, and the timeframes involved, our interviewees suggested that it is simply not sufficient as an incentive if it is unfinished or uncertain. Two factors were mentioned related to this point: on the one hand, political uncertainty surrounding the debate causing delays in implementing the regulations; on the other, the need to provide as much certainty and detail as possible on its functioning, including the size of the reward and the eligibility criteria, to ensure investors are able to ascertain with clarity, early on, whether the product will be eligible for the voucher, and that the rules will not change over time.
5. *Degree of complexity and possibility of gaming the system:* there was a discussion about the trade-offs between simplicity and acceptability; a 'too-simple' mechanism will not be able to include safeguards, but if too complex, it will be more difficult to implement. Related to the operationalisation of the incentive, some interviewees also raised the possibility of companies deciding strategically when to use the voucher; for instance, a small company might hold a voucher while waiting for a higher bid, while a large company might hold a voucher while waiting for a commercial drug to complete testing. There is, nevertheless, a time value of money, meaning a company would generally rather make the returns today than in the future, so it is unlikely that it would hold the voucher for an extended period of time. Restrictions on the data exclusivity period remaining to be eligible for the voucher makes that gaming more difficult, however. The possibility of creating an auction was also discussed (in line with Dubois et al. [12]), but there were differing views about its usefulness—one interviewee argued it was complex while others argued it would be an efficient way to operationalise the voucher.
6. Finally, political inertia and a lack of public concern, coupled with the perception that this is a giveaway to 'big pharma', was also seen as a barrier despite the fact that there are many small innovative antibiotic companies. Related to this point, it was argued that the quality of the data on AMR and its impact and cost to the system and the economy more generally is far from perfect. For example, good empirical evidence of the cost of AMR in hospitals is limited, in part because it is not possible to clearly identify the causes of some antimicrobial failures in hospitals. This prevents raising awareness.

3.2.3 Enablers of the TEEV

Eight enablers were raised by the interviewees. First, most of our interviewees highlighted that the implementation could be easier than for other incentives because it would be the responsibility of the EC and could be done via the pharmaceutical legislation package. Related to the nature of the incentive, a second enabler would be that funding is built indirectly through the system (via late entry of generics/biosimilars) and there is no need to draw a 'budget line'—which would be required for some other national-based pull mechanisms. Third, some of the estimates published of the cost of the voucher could be overestimated (especially given the point above about the lack of competition in the generics market in Europe, the level of sales of the non-antimicrobials that could potentially be subject to the voucher, and any additional restrictions imposed), plus the eligibility conditions give some predictability for generic/biosimilar manufacturers and payers. Fourth is the potential simplicity and clarity of the TEEV—but it will be critical to ensure there is clarity on how the model will work. Fifth, the voucher's financial magnitude or duration could depend on which stage the company is at when the policy is first implemented—those projects more advanced could potentially receive a lower reward relative to those which are in the early stages of development.

Sixth, having a really good antimicrobial against key resistant infections would also spur the interest of countries (including patients and health systems) who would be willing to 'sacrifice' the cost savings from the (handful of) non-antimicrobials which could see their exclusivity extended. Seventh, both the biotech companies and the bigger pharmaceutical companies are really advocating for it, as they can see this as something that could work, provided it is designed in the right way. Finally, policymakers who understand the mechanism and the economic concept behind the voucher are needed to be able to quantify the real social cost and consequences that the externalities of AMR between countries can bring—and especially relative to the cost of inaction.

[4] We thank a reviewer for making this point about global access, and while it comes at a cost, it is worth achieving.

3.2.4 Information on R&D Costs and Sources of Funding

A key aspect of the TEEV proposal in Europe is the requirement for applicants to provide information on all direct public financial support received for research related to the development of the priority antimicrobial, and that the information will be accessible to the public via a dedicated webpage. The details, as already mentioned, are still to be agreed, including whether the support comes from the EU or elsewhere, but could be a key element of the voucher, so the effects of such requirements were discussed during the interviews. We have grouped the interviewees' responses into three main themes: availability of data, value of the information, and use/impact on the price of the antibiotic.

In terms of availability of data, there was consensus that information on (direct) public support would already be available, from initiatives focused on combating AMR such as CARB-X (a global non-profit partnership focused on supporting the development of new antibacterial products), GARDP (a non-profit pharmaceutical research and development organisation that aims to assist antibiotic drug development to counter the threat of antibiotic resistance) or the European Commission's Health Emergency Preparedness and Response Authority (HERA). The first two now report to the AMR R&D Hub, where all public and charitable grants for R&D on antibiotics are collected and published. However, it was argued that it would be difficult to estimate the share of pre-clinical costs, especially if the company spun out of another company that acquired the asset from somebody else.

Hence, a critical aspect would be the point at which you start counting, and one option suggested was to focus on public investment after an Investigational New Drug (IND) application—which is when the regulatory agency authorises the company to administer an investigational medicine or biological product to humans for clinical trials. A source of such clinical data could be clinical trial registries (e.g. ClinicalTrials.gov). Other sources of the information could even be the recipients of the financial support (i.e. the private entities receiving the funding). The bigger pharmaceutical companies will probably report that information in their annual reports but that is less likely for SMEs. Still, some of the commercial deals between the different actors could contain some commercial in confidence material which would not be appropriate to make public.

Regarding the value of providing this evidence, there was generally scepticism about the usefulness and added value of asking companies to break down R&D costs, and could even be seen as a detractor for investors. Ultimately, the value of the information will depend on how it is used. Providing such information leads to increased transparency for payers, in terms of giving them some kind of reassurance about the magnitude if there has been public sector investment and could be helpful to ascertain how much additional push and pull funding is required, that is, companies who received no charitable or public funds should receive a larger reward than those who received substantial public funding.

However, while it has not been stated explicitly as an objective of this requirement, objections were raised by our interviewees to using this information to set prices, following cost-plus type regulations; cost-plus pricing with a focus on cost containment would not allow for payment according to value and would only be based on public costs rather than the full (i.e. public and private) costs, and it was argued that a risk-reward perspective should be used to ascertain optimal pricing levels. Moreover, it was argued that even though R&D of an antimicrobial could hypothetically be 100% publicly funded, prices would still need to reflect (the substantial) costs of manufacturing, pharmacovigilance, and so forth if a cost-plus mechanism is used to set the price. Finally, it is questionable whether any funding received by the company from outside the EU should be taken into account, given that the EU must stick to its fiscal accounts and not to whether some other country or charitable organisation has been more generous; that is, avoiding the 'double dipping' argument would not apply for funding coming from outside EU governments or charities.

4 Discussion

4.1 Summary of Key Findings

There is consensus that the TEEV, as a mechanism relative to the cost of inaction, could be an attractive proposition for developers, by allowing the extension of the regulatory data protection of any other medicine. If and when it is implemented in Europe, the key will be in the details, including the size of the reward and how the mechanism would work in practice, including eligibility criteria. Proponents of the voucher (which include industry but also academics) argue that sufficient guardrails or alternative implementation models via auctions, could be put in place to manage the financial uncertainties for payers, which is seen as one of its key barriers, and a recent estimate highlights that the additional restrictions being discussed at the time of writing this paper could lead to lower costs to MS due to a limited pool of potential candidates meeting the eligibility criteria. Also, being a European-wide mechanism implemented via pharmaceutical legislation, with no need for specific additional MS funding, and acting as a catalyst for other countries (including MS and the US) and regions to follow with delinkage-type models, have been highlighted.

While this mechanism could generate public health benefits by encouraging the arrival of new antimicrobials that are effective against resistant pathogens, it also entails relevant

externalities. These include the possible delay in the entry of generics or biosimilars for a non-antimicrobial, either for another more lucrative treatment in the antimicrobial developer's pipeline, or for another more lucrative treatment from another company which has bought the voucher, which could entail high costs. As with other delinkage type mechanisms, the TEEV would need to be complemented with additional arrangements between countries and companies to ensure wide access to the antibiotic under the realms of stewardship programmes, especially when needed. Finally, it is an innovative instrument, which adds a significant degree of uncertainty.

One of the distinctive elements of the proposed EU TEEV is the requirement for transparency on any public contribution to R&D costs as an eligibility criterion. This is in line with the WHA Resolution, and supporters of this requirement—primarily academics and NGOs—claim it could have a significant positive impact by providing policymakers with tools to design fairer pharmaceutical policies and ensure greater affordability, avoiding taxpayers paying twice, and access to developed antimicrobials. However, and while there is no consensus on the impact of greater transparency on R&D costs and sources of funding, the implementation of this measure faces tensions with the protection of trade secrets, which may affect competitive business dynamics. It could encourage the use of cost-plus pricing regulation more widely if this requirement for antimicrobials specifically is extended to medicines more generally.

Broadly speaking, the interviews revealed three main results: (1) difficulties in estimating public costs at preclinical stages, although acknowledging the existence of different platforms that collect information on direct public funding at later (i.e. clinical) stages; (2) scepticism about the practical value of this information, arguing that it might even discourage private investment; (3) disagreement over the possible influence of other incentives (public or charitable) received by developers in certain countries on the size of the incentives granted by the EU; and (4) doubts about whether greater transparency would provide any usable information for policymakers. In addition, there is a debate about whether prices should be regulated based on R&D costs or through health technology assessment (HTA). A more plausible approach would be for transparency in the R&D costs of antimicrobials to help quantify the size of incentives, given that current HTA models fail to assess the benefits at earlier stages when incentives are granted, but are more effective in adjusting prices based on health benefits.

Finally, the TEEV in isolation would not be able to provide the full incentive, so it would need to be complemented with other pull incentives. For instance, HERA's 2023 report sets out four possible other pull incentives—one which has possibly received wider attention is the 'Revenue Guarantee' model, where payments operate as complements to ensure a yearly revenue value, and consists of 10 yearly payments starting from the year of market approval [41]. Moreover, this complement could only be paid if actual access was provided, and its size would be smaller if a TEEV was provided for that antimicrobial, but not zero. Related to the possibility of setting up an auction, another option would be using the funds generated during the auctions to pay for HERA revenue guarantees.[5,6]

4.2 Limitations

This research has several limitations that need to be taken into account when interpreting its results and implications. First, the research is based on a narrative literature review and semi-structured interviews with a limited number of experts, so although the approach allows for capturing a wide range of perspectives, it does not allow for establishing firm statistical evidence. Secondly, despite the attempt to include professionally and ideologically diverse expert profiles, the sample of interviewees may encounter selection biases, such as, for example, the lack of an interview with an EC representative. Thirdly, we found that, since the TEEV is an untested instrument in the EU, much of the analysis is based on theoretical models, expert opinions or indirect experiences. Fourth, although there is recent literature on the requirement for transparency of R&D costs, there are important contextual differences that may limit the transferability of these findings to practice.

5 Conclusions

AMR is a global public threat, which needs concerted global action. Unfortunately, while there are many initiatives in place to address AMR, these are still fragmented. However, Europe is leading the way in many spheres, and one of them is by advocating the use of TEEVs to incentivise the development of new antimicrobials. The purpose of this paper has been to explore the possibilities such incentive offer, by reviewing the evidence as well as by interviewing a selection of experts on the topic.

[5] We want to thank a reviewer for raising this poinnt.

[6] "On December 11, 2025, the European Council and Parliament reached a deal on the Pharma package – the TEEV has remained in place, albeit with the 'blockbuster clause', which limits the potential impact on national healthcare budgets by stipulating that the transferrable voucher cannot be used on products with annual gross sales of more than €490 million in the preceding four years (https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/)".

This particular type of incentive, combining extended exclusivity and a trading system, is a novel initiative globally, and it has yet to be implemented—indeed, the idea has been studied for two decades and we are now more clear about the contexts in which it should, or could, work. Given the need for a combination of push and pull incentives to incentivise new antimicrobials, a positive spillover of including this initiative in the draft European legislation has been encouraging European, and non-European, countries to test national-based delinkage pull models, or at least to start discussing these mechanisms. Indeed, it could be argued Europe is leading the way in combatting AMR.

At the time of writing this paper, it was unclear when the final decision will be made around the European pharmaceutical reform. It was also unclear (if and) how the voucher will be implemented in practice—but additional constraints on regulatory data protection and timing being discussed will narrow the selection of products to which the voucher could be applied to. There is a need to balance the additional costs to MS with the power of the incentive. Further assessment is also required to ascertain the impact of the condition requiring disclosure of public support for R&D of the antimicrobial, and what the intended (and unintended) consequences could be, now and in the future. In the meantime, it will be important to carefully assess the evidence available on the impact of TEEV, bearing in mind we simply cannot afford 'inaction' from policy makers, and the wider society.

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Declarations

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Ethical Approval Not applicable.

Consent to Participate Written informed consent was obtained from the individual(s) before taking part in the study. Participation was voluntary.

Consent for Publication Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Availability of Data and Material The statements from each interview have not been published in order to protect the confidentiality of the participants. However, the questionnaire used in the interview has been published in the electronic supplementary material.

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