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

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M.GARCIA-DIAZ[1,2], J MESTRE-FERRANDIZ[3], J.ESPIN[1,4,5]

1. Andalusian School of Public Health, Granada, Spain; 2.Doctoral Program in 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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INTRODUCTION

- Antimicrobial resistance (AMR) is one of the greatest threats to public health, and forecasts for 2050 are even worse if we do not act.
- Given the challenge of AMR, the impact of antimicrobial overuse, and the current business model for antimicrobials, new incentives are being called for to encourage their innovation.
- European Commission (EC) is proposing the Transferable Exclusivity Extension Voucher (TEEV).
- One requirement for obtaining the TEEV is to declare any public contributions received for the antimicrobial R&D.

OBJECTIVE

- First, to evaluate the TEEV (advantages, disadvantages, cost, implementation) as a (public) incentive to develop new antimicrobials.
- Second, 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.

METHODS

This research contains a theoretical (literature review) and a practical perspective (interview with experts on AMR):

- **Narrative literature review**: 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.
- **Experts on AMR interviews:** practical information on the characteristics of the TEEV, how it could work in the real world after implementation, role as an element of public funding and the impact of having an R&D cost breakdown clause and sources of public funding.

TABLE 1. List of experts interviewed

Christine Årdal (Norwegian Institute)
Kevin Outterson (CARB-X/Boston)
Kristine Peers Giacomo Borgo (EFPIA)
Deepali Patel (AMR Action Fund)
Pierre Dubois (Toulouse School of Economics)

RESULTS

BENEFITS TEEV

- incentive for antimicrobials that achieves public health benefits against the cost of inaction
- Part of the TEEV cost is a transfer from generic companies to the TEEV user (non-immediate drop in price to production cost).
- Encourages Member States (MS) to implement their own financing and access mechanisms (UK and Sweden).

VS

BARRIERS TEEV

- Delays the entry of generics/biosimilars (an extra year of high prices).
- It does not contain an access scheme (nor delinkage models) for new antimicrobials, nor are there any specific supply agreements.
- Lack of predictability for payers regarding the cost of the voucher (variability).

ENABLERS TEEV → EASY TO IMPLEMENT (PHARMACEUTICAL LEGISLATION) | INDIRECT FUNDING (GENERICS DELAY) | CLEAR MECHANISM | GOOD ANTIMICROBIAL = ATTRACTS COUNTRIES

POSITIVE IMPACT OF R&D COSTS TRANSPARENCY

- Could help affordability in pricing with a focus on public health needs.
- Enables policymakers to design more tailored incentive policies (to complement push incentives).
- More accurate information for investors to take decisions.

VS

NEGATIVE IMPACT OF R&D COSTS TRANSPARENCY

- The administrative cost of declaring disaggregated costs is high.
- Difficult to allocate some (mostly preclinical) R&D costs to the specific product.
- It could lead to cost-plus pricing being used and not paying for the actual value.

TABLE 2. Social cost estimations and methodologies for the TEEV

Source	Methodology & Key Assumptions	Estimated Costs / Revenues
EC Impact Assessment (1)	- Based on historical sales of highest-selling medicines - 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**
OHE (2019) (2)	- Simulation incorporating resale value of vouchers, R&D costs of 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)**
EFPIA (2022) (3)	- Estimate based on lost savings from delayed genericisation plus administrative costs of implementing TEEV.	- **Societal cost: €426m per voucher**
CRA (2025) (4)	- 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

CONCLUSIONS

Given that AMR is becoming one of the greatest global public threats, the EC has launched the Transferable Exclusivity Voucher to combat it, but there are still various challenges ahead

- New mechanism not yet implemented
- Needs to be complemented with push and pull incentives
- Encouraging new national models
- Need for more information on the impact of transparency on antimicrobial R&D
- Assessing TEEV considering the problem of inaction

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CONTACT INFORMATION

jaime.espin.easp@juntadeandalucia.es