



Pharmaceutical package Transferable Data Exclusivity Vouchers for priority antimicrobials

AMR One Health network meeting
1 March 2024

European Commission - DG SANTE

Combatting AMR

Current challenge:

AMR causes **35000 deaths per year** in the EU.
It amounts to +/-1.5 bn EUR per year in healthcare costs

By 2050, **10 million deaths globally each year**

Current market failure/ Lack of effective antimicrobials

Lack of market incentives
0,5 bln EUR cost of a new antibiotic

AMR toolbox

Measures on prudent use of antimicrobials – prescription, restricted quantities, education etc.

Regulatory incentives with transferable exclusivity vouchers under strict conditions

Financial incentives with **procurement mechanisms** (HERA)

5 Targets, incl on the total **EU consumption of antibiotics for humans** (ECDC) → reduction by 20% by 2030

(Council Recommendation)

AMR voucher

- Additional year of data protection
- Strict conditions (only novel antimicrobials, full transparency of all funding, obligation of supply, max 10 vouchers in 15 years, review after 15 years, etc.)

Regulatory incentives with transferable exclusivity vouchers under strict conditions



Transferable data protection voucher: allow the developer of a novel antimicrobial to benefit from **additional year of data protection** on a product in their portfolio, or sell the voucher to another company to use

Strict conditions e.g. only novel antimicrobials that address AMR, full transparency of all funding, obligation of supply, 1 time transfer etc.

Max 10 vouchers in 15 years, review after 15 years.

Economic considerations and conclusions (1 voucher/year scenario)

- Estimated* value/cost of each voucher: between €280 m and €440 m per product
- Likely share of value* - if there is one voucher/year: the buyer is likely to capture 43% of the value/cost *based on historic sales data
- Conclusions
 - Reward goes to antimicrobials that have proven to be a 'game changer' against AMR
 - Addresses market failure and helps increase reward of investment – attract venture capital
 - Can be implemented immediately: No ex ante budgetary appropriations required, no regulatory burden
 - Part of a broader toolkit against AMR
 - Measure is able finance the EU fair share of novel antimicrobial development
 - **Expected costs to health systems (€441m. which includes unserved patients in 1 voucher/y scenario)**
 - High cost for health systems should be weighed against cost of AMR/year (est.) €1,5bil. – 35.000 deaths/year.

Thank you



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