



Pharmaceutical package TEV for priority antimicrobials

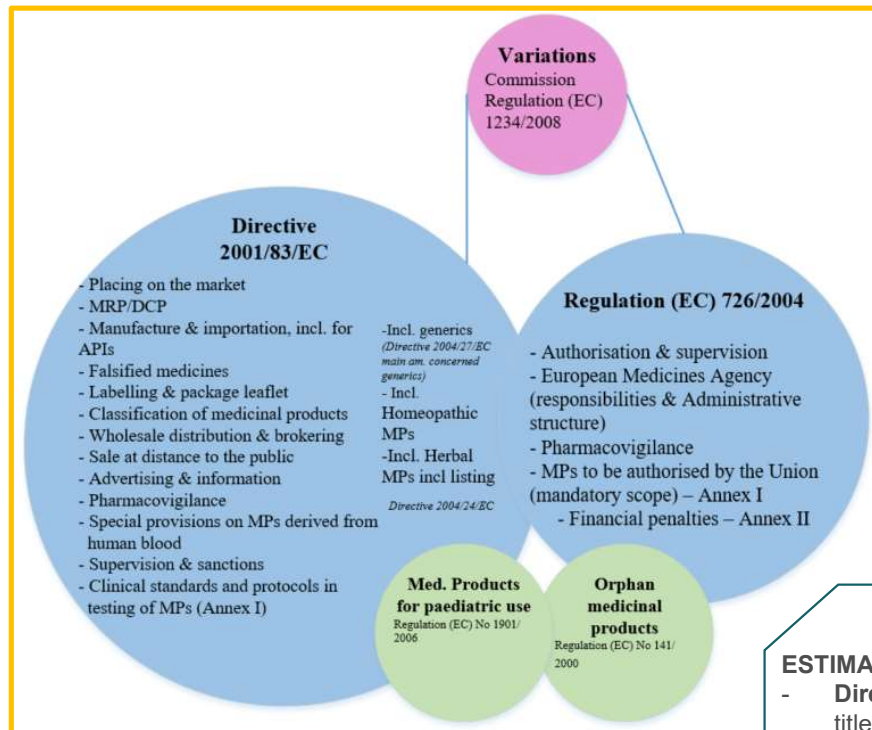
DNAMR

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European Commission – DG SANTE

Structure of the revision



Areas not changed in substance

- Homeopathic medicines
- Herbal medicines (exception: herbal committee)
- Falsified medicines
- Sale at distance to the public

Areas with minimum intervention

- Pharmacovigilance
- Wholesale distribution
- Advertising
- Clinical standards and protocols in testing

ESTIMATION

- **Directive 2001/83:** 13/14 titles revised – about 60-70% of 191 articles concerned.
- **Regulation 726/2004:** 4 titles revised – about 70% of the more than 65 articles concerned.

A 4-part package – April 2023

Chapeau communication

New Regulation

- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages and security of supply
- EMA governance

New Directive

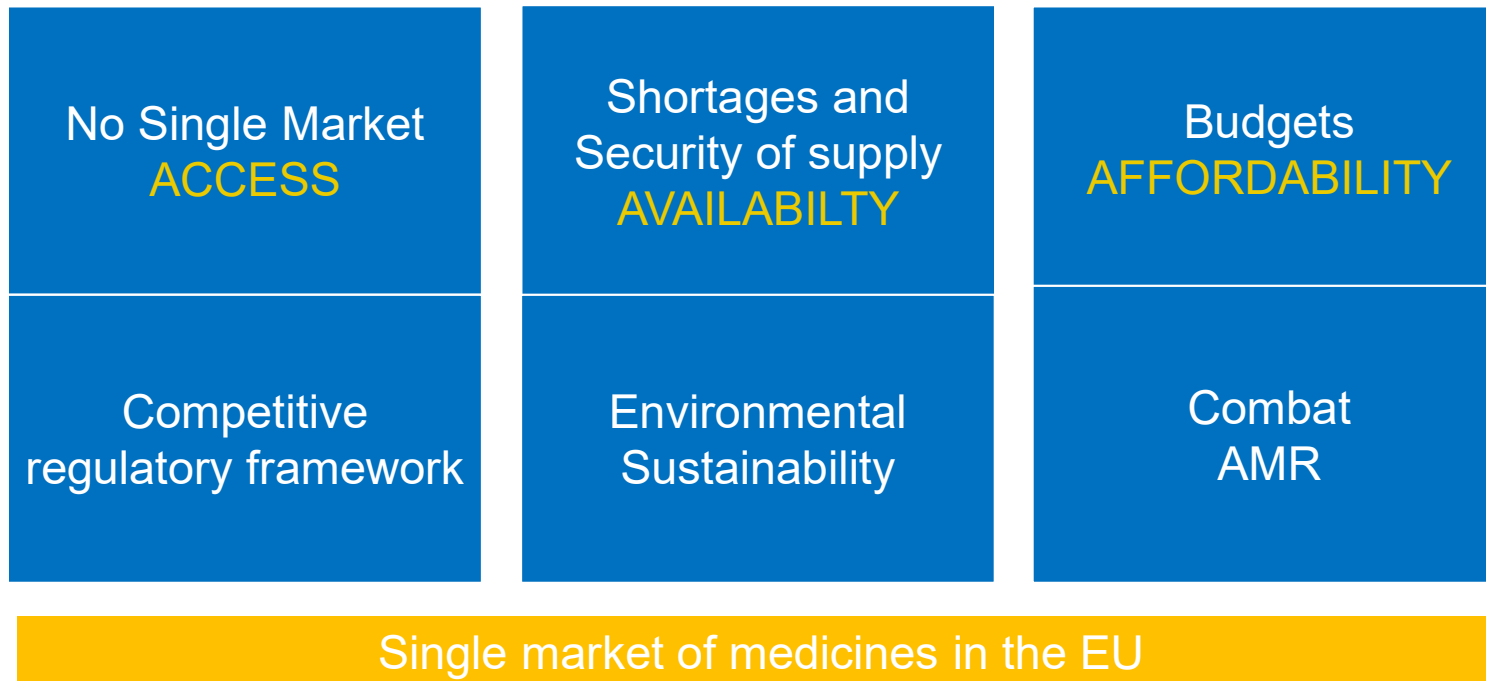
- Placing on the market of all medicines
- Authorisation and labelling requirements
- Strong incentives for access



Council Recommendation on AMR

3

6 Key political objectives



Combatting AMR

AMR toolbox:

- Proposal for a Council Recommendation on AMR
- Revision of the pharmaceutical legislation:
 - Measures on prudent use of antimicrobials
 - Regulatory incentives
- HERA work on AMR

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
 - Part of a broader toolkit against AMR
 - Addresses market failure and helps increase reward of investment – attract venture capital
 - Reward goes to antimicrobials that have proven to be a game changer 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.

Measures on prudent use of antimicrobials

Prescription
status

Environmental
measures

Educational
material

Stewardship plan for
antimicrobial
resistance

Package sizes

Other aspects

- Maintain production of existing antibiotics/avoid shortages
- Innovative revenue schemes
- International collaboration

Thank you



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