The Pharmaceutical Strategy's role in strengthening the 3Rs principle

Conference 'Advancing the 3Rs for Regulatory Testing of Medicines'

Antwerp Meeting and Convention Center, 31 January 2024

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A 4-part package – 26 April 2023

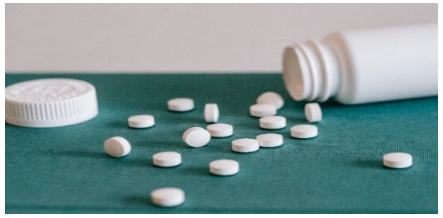
Chapeau communication

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

6 Key political objectives

No Single Market **ACCESS**	Shortages and Security of supply **AVAILABILTY**	Budgets **AFFORDABILITY**
Competitive regulatory framework	**Checking** Environmental Sustainability	**Combatting** AMR

Single market of medicines in the EU

Proposal for a revised pharmaceutical legislation

1) **Strengthen the 3Rs principle**
   - using the minimum number of animals
   - avoid causing pain, suffering, distress or lasting harm to animals
   - follow the available EMA and ICH guidelines
   - use new approach methodologies in place of animal testing, where possible

2) **Obligations for marketing authorisation applicants/holders**
   - demonstrate compliance w/ 3Rs principle
   - abridged applications – refer to studies conducted for reference medicinal product
   - carry out product-specific validation studies to replace animal-based control methods, where possible
   - reuse animal study results, where possible
   - use alternative testing approaches, where possible

Art 6 (5) Reg. and Art 6 (7) Dir.
Art 12 (4) (m) Reg. and Art 44 (1) (j) Dir.

Proposal for a revised pharmaceutical legislation

3) More cooperation between EU agencies and national competent authorities:

- scientific assessment of substances
- facilitating data sharing
- carrying out joint non-clinical studies

Reg. Art 138 (1) (ze), (zi), (zj), (zk)
Dir. Art 23 (4)

Thank you.

European Commission