The EU Pharmaceutical Reform

Multi-stakeholder workshop on Real World Data (RWD) quality and experience in use of Real World Evidence (RWE) for regulatory decision-making

European Medicines Agency - 26 June 2023

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EU Pharmaceutical Reform

Builds on the **Pharmaceutical Strategy** for Europe (2020)

Supports EU citizens and industry

Addresses **long-standing challenges and public emergencies**

Marks a **European Health Union milestone**

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A 4-part package

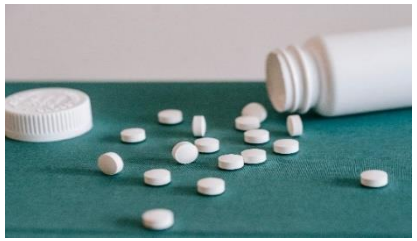
Chapeau communication

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

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6 key political objectives

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

Single market of medicines in the EU

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Streamlined and agile regulatory framework catering for innovation

Current challenge:

Longer approvals times than in other regions (US 244 days)

Administrative burden and compliance costs for the industry

The clock stop mechanism

Proposed solutions:

Faster autorisation:
a) 180 days standard procedure
b) 150 days accelerated procedure

Regulatory efficiency:
Improved EMA structure, simplified procedures, better use of data and digitisation, regulatory sandboxes

Pre-authorisation support to promising medicines to accelerate development and attract investments

Lower regulatory burden (especially important for SMEs and not-for-profits)

Regulatory simplification (1)

- Improved **clarity on the interplay** between EU legislative frameworks (e.g. medical devices, substances of human origin) (DIR Cpt I, REG Cpt V)
- Introduction of possibility for a scientific recommendation decision on **regulatory status** of a medicinal product under development (REG Art. 61 and 62)
- **Adapted frameworks** with specific regulatory requirements tailored to the characteristics of certain novel medicines (DIR Cpt II Sect 5)
- Reduction of assessment and **approval time** from 277 days to 226 days (DIR Art 30, REG Art 6,12,13)

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Regulatory simplification (2)

- Possibility for regulators to reject **immature applications** to limit clock stops that delay the decision (DIR Art 29(3), REG Art 10(2))
- **Electronic submission** of applications (DIR Art 6, REG Art 5(3),6(1))
- **Facilitate the use of electronic product information and multi-language packages**
- **Facilitation of repurposing** through a mandatory variation on the basis of data submitted from not-for-profit entities for repurposing of authorised medicinal products (REG Art 48) + Reg protection (4 years) for off-patent repurposed for which data has been generated (DIR art 84)

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Regulatory simplification (3)

- Strengthening the **early regulatory support** by EMA (for promising medicines under development for unmet medical needs (REG Cpt V), for SMEs)

- **Risk management plan** not required for off patent medicines (DIR Art 21)

- **Conditional marketing authorisation (**REG Art. 19)
  Marketing authorisation in **exceptional circumstances** (REG Art. 18/DIR Art. 45)

Optimisation of procedures

- Possibility for EMA to review **data in phases**, as they become available (rolling or phased review) (REG Art 6(2))

- **Active substance master file** to avoid duplication of assessment of chemical active substances (DIR Art 25)

- **No sunset clause**

- **No renewals**

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Thank you

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