A new pharmaceutical framework for Europe

EAA Spring Convention

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The pharma reform – state of play

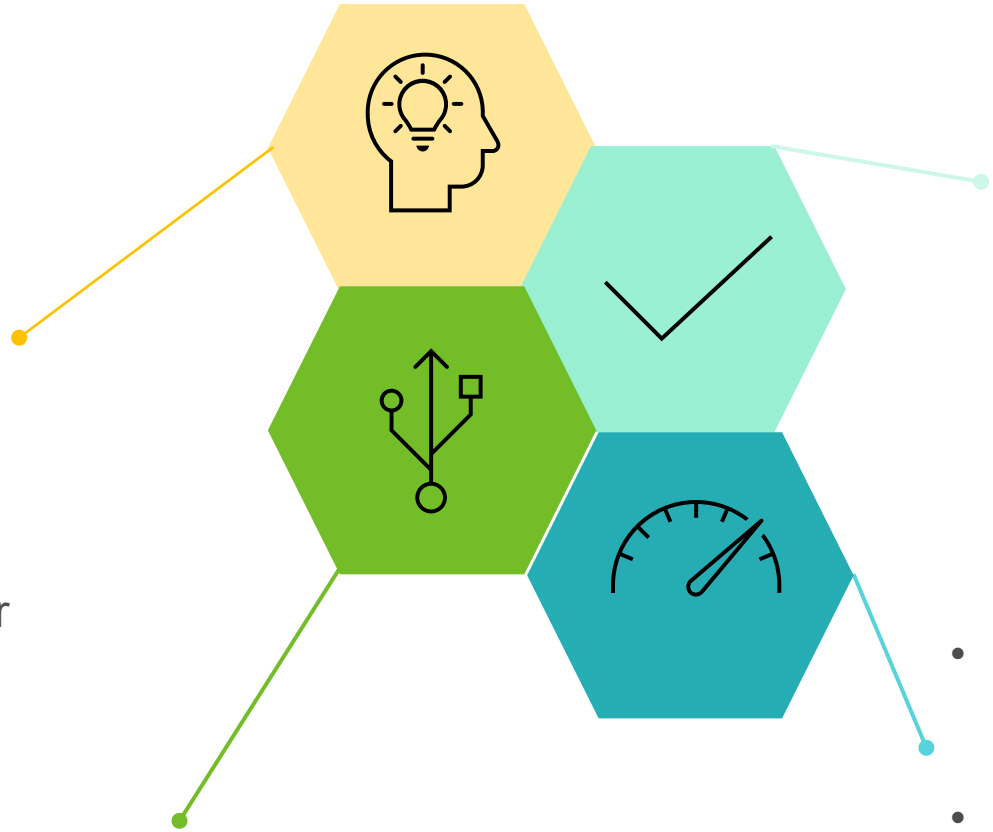
- Political agreement was reached in December
- Entry into force in late 2026
- General entry into application in 2028
- Some measures like regulatory sandboxes, vouchers for priority antimicrobials, applicable immediately
- Implementation: delegated and implementing acts is required

A new pharmaceutical framework that builds on the EU's strengths

- The reform package **revises the** 20 years old **EU rules for pharmaceuticals**
- A new Directive and Regulation update the current rules and absorb and adapt also the Orphan and Paediatric regulations, **simplifying and modernizing the framework**
- Objectives: guarantee the **safety, efficacy and quality** of medicines + **simplification and competitiveness** + improve **access, availability, affordability**
- The reform is complemented by the **Critical Medicines Act, the Biotech Act, the upcoming revision of the Medical Devices Regulation etc.**

Incentivising innovation by future proofing and simplification

- Regulatory **sandboxes** to pilot groundbreaking innovative therapies
- A voucher to develop innovative antimicrobials against **Anti Microbial Resistance (AMR)**
- **Adapted frameworks** with specific technical requirements tailored to the characteristics of certain novel medicines
- Strengthening **early regulatory support** by EMA, particularly for promising medicines under development for unmet medical needs



- **Simplification** of the **EMA structure** and function
- **Streamlining of regulatory procedures**
- Possibility for EMA to **review data in phases**, as they become available (phased review)
- **Better use of** expert **resources** for the authorisation/supervision of medicines

- **Reduction of EMA scientific assessment time** from 210 to 180 days (150 for accelerated)
- Limit **clock stops** during the screening of applications
- Early termination of **immature applications**

- Use of **real-world evidence**, and of health data for regulatory purposes
- **Electronic submission** of applications
- **Electronic Product Information**

Pharma legislation and HTA framework

- Parallel scientific advice with the joint scientific consultation carried out by the Member State Coordination Group on HTA
- Exchange of information and pooling of knowledge on general issues of scientific or technical nature EMA – HTA bodies
- Collaboration with EMA in preparing guidelines on UMN

Pharma legislation and HTA framework

- Bolar provision covering HTA assessments
- Joint meetings with regulatory bodies established under other Union legislation, to assess emerging trends and questions on the regulatory status of products
- CMA: collaborative procurement of medicines of common interest
- BTA: Coordination group on Health Technology Assessment part of the foresight panel for emerging health innovation

Thank you

European Commission