A new pharmaceutical framework for Europe and its patients

PCWP – HCPWP joint meeting

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#HealthUnion

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

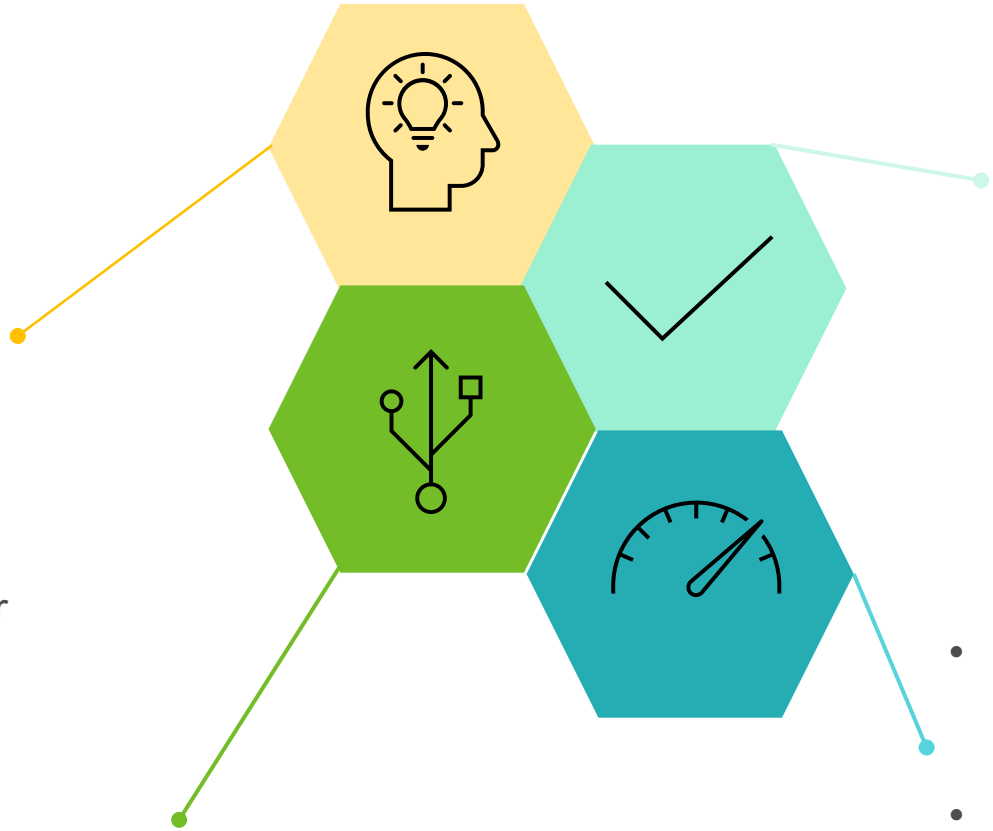
- The reform package **revises the** 20 years old **EU rules for pharmaceuticals**,
- A new Directive and Regulation update the current rules and merge the Orphan and Paediatric regulations, **simplifying the framework**
- **Patient-centric reform**
- Main objective: guarantee the **safety, efficacy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

Value delivered to patients

- Patients will benefit from **high-quality, innovative** medicines, including personalised treatments.
- New medicines will reach the market faster, improving **access to treatments**, especially for unmet medical needs.
- Novel **incentives** will help **overcome the current market failures** in the development **priority antimicrobials** against antimicrobial resistance. In addition, the EU will continue support the development of medicines for rare diseases and for children.
- Establish a comprehensive system to **address medicine shortages** across the Union.

Regulatory excellence 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

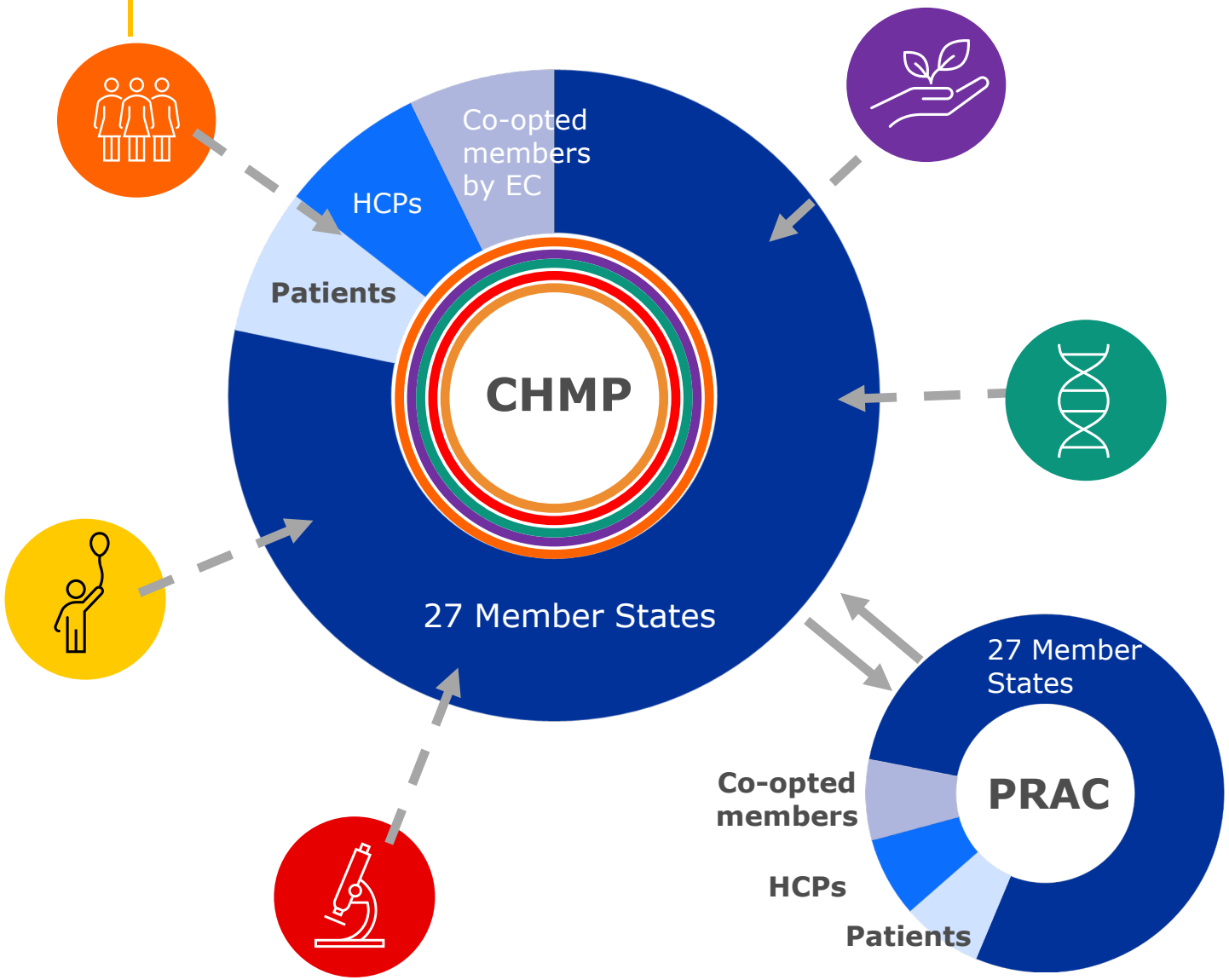


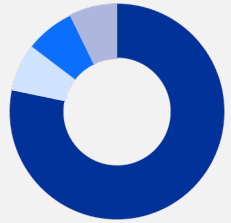
- **Simplification** of the **EMA structure** and function
- **Streamlining of regulatory procedures**
- Possibility for EMA to **review data in phases**, as they become available (phased review)
- **Better use of** expert **resources** for the authorisation/supervision of medicines

- **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**

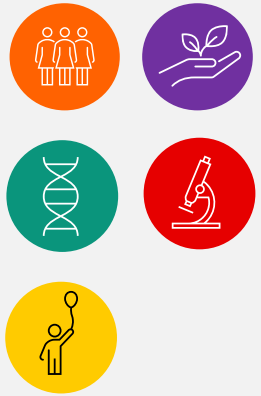
New EMA committee structure





New Committee structure (CHMP/PRAC)

Experts from former committees



Additional experts from pool of experts (incl. WPs/WGs/SAG/ES ECs)

Input based on needs

European Commission

Next steps

- Finalisation of technical aspects of text to be completed by end FEB 2026
- Formal approval by Council and European Parliament in the following weeks
- Entry into force in 2026 and entry into application in 2028 with some provisions, such as regulatory sandboxes and vouchers for priority antimicrobials, to be applicable earlier
- Implementation: the adoption of an important number of delegated and implementing acts is required - work to start in 2026

Thank you

European Commission