ORDEM DOS FARMACÊUTICOS

Reunião Anual do Colégio de Especialidade ASSUNTOS REGULAMENTARES

26 DE MAIO
LISBOA

REGULAÇÃO EM TRANSFORMAÇÃO

INOVAÇÃO E ACESSO PARA OS DOENTES NA UE

Reunião Anual do Colégio de Especialidade de Assuntos Regulamentares

26 de maio de 2026

Ordem dos Farmacêuticos, Lisboa

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EMA
EUROPEAN MEDICINES AGENCY

New EU Pharmaceutical Legislation

Key areas affected by the reform and stakeholder involvement

Ivana Silva
Head of Stakeholder Engagement

Key elements of the NPL

A **simpler** regulatory environment

Stronger **safeguards** against **medicine shortages**

More **support** and **improved** conditions for **innovation**

Enhanced **environmental protection** and focus on **antimicrobial resistance**

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Key areas affected by the NPL

A simpler regulatory environment

Streamlined committee structure: from five to **two scientific committees (CHMP & PRAC)** for human medicines. Stronger expert, patient and healthcare professional involvement

Reduced assessment timelines

Marketing authorisation valid for an **unlimited period** by default, unless safety concerns arise

Digital submissions and electronic product information (ePI)

More support and improved conditions for innovation

Extended **scientific advice** with HTA bodies and expert panels & strengthened **PRIME support**

Regulatory sandbox for innovative medicines supervised by the competent authorities

Adapted frameworks for non-standard medicines (e.g. personalised therapies)

Improved **efficiency** of the process for **studying** of **medicines for children**

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Key areas affected by the NPL

Stronger safeguards against medicine shortages

Stronger **supply obligations** for companies

Notify shortages and withdrawals in **advance** and to have shortage **prevention plans**

Monitor of **expected** and **actual shortages** by both EMA and NCA

EU list of **critical medicines** and **supply-chain vulnerability** assessments

Enhanced environmental protection and focus on antimicrobial resistance

Enhanced **environmental risk assessment**

- ➢ including specific methodologies to assess antimicrobial resistance risks from antimicrobial manufacturing

Prudent use of antimicrobials

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NPL timeline

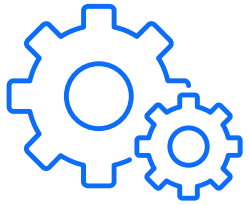
10 March

European Council published the full text of the NPL

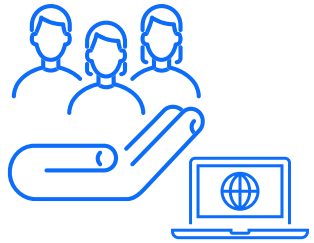
Q4 2026

Formal adoption by the European Parliament and the Council; publication in Official Journal

2026-2027



EMA, European Commission and EU Member States to **develop guidance** for applicants and marketing authorisation holders



Pro-active communication throughout implementation

A **dedicated EMA webpage** as a central repository for guidance and updates

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Keeping stakeholders informed and involved throughout implementation

Industry Standing Group

Rely on the ISG for regular updates on NPL implementation, including reporting from Platform Focus Groups.

PCWP/HCPWP

Rely on the PCWP/HCPWP for regular updates on NPL implementation, including feedback from representatives involved in topic-specific consultations.

TOPIC-SPECIFIC WEBINARS

Join targeted sessions on specific implementation topics when additional clarification or guidance is required.

PUBLIC CONSULTATION

Provide input on scientific guidelines as part of the standard EMA consultation process.

NPL webpage

Visit the new EMA NPL webpage to stay informed on updates, key activities and implementation progress.

NEWSLETTER

Receive updates on progress and activities through the Industry NPL section of the upcoming periodic Newsletter.

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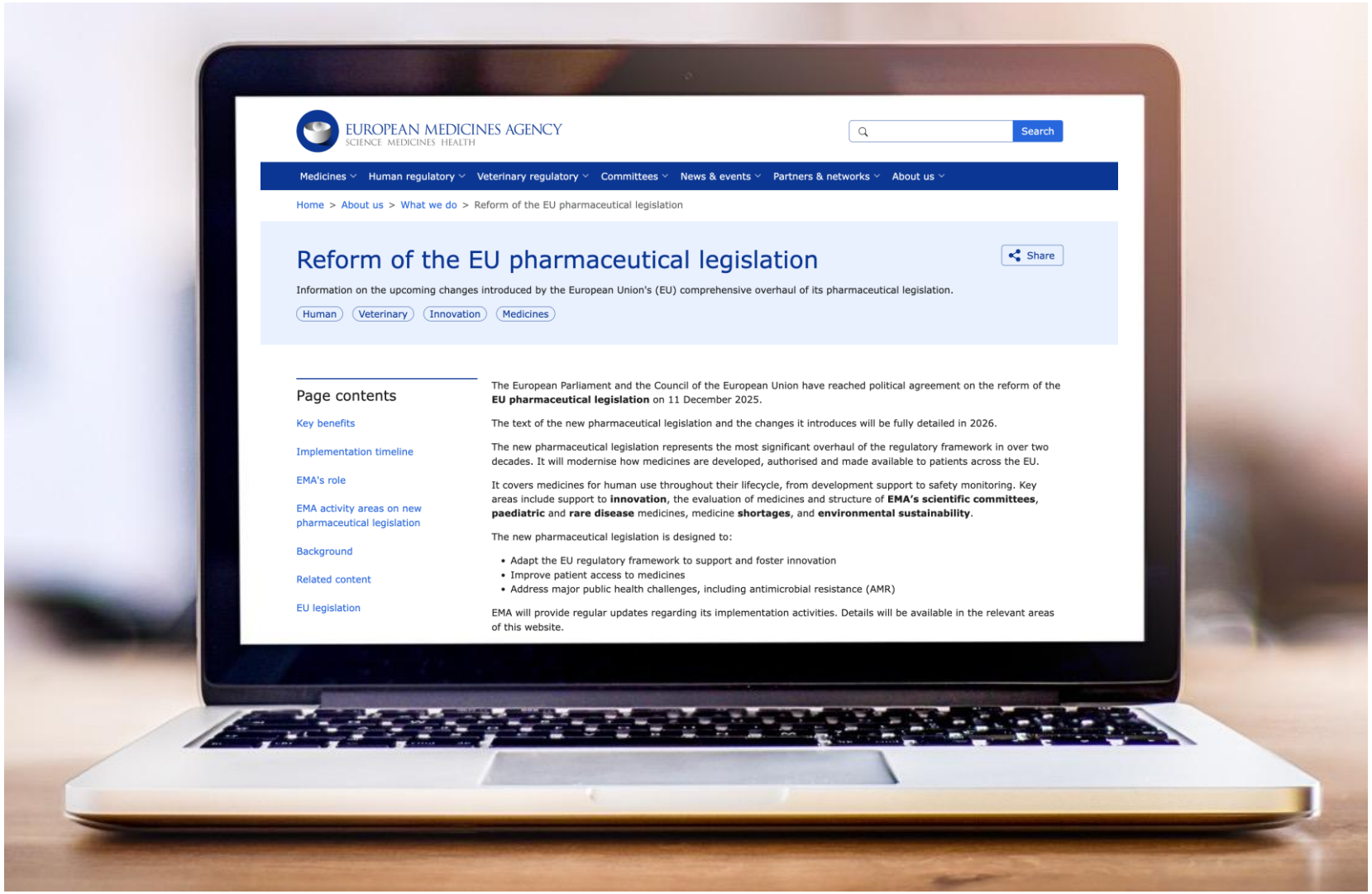
EMA NPL web page



[Reform of the EU pharmaceutical legislation | European Medicines Agency (EMA)](#) webpage

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Engaging patients and HCP representatives during NPL implementation

PCWP & HCPWP

What: Main reference forum for patients and healthcare professionals during NPL implementation.

When: In line with the regular PCWP/HCPWP meeting cycle (topics brought as needed).

Purpose: Share overarching progress and upcoming milestones, clarify questions, gather high-level input, and keep alignment with patient/HCP representatives as implementation evolves.

Topic-specific consultations

What: Targeted consultations with patients and/or HCP representatives for specific implementation topics.

When: On a needed basis, triggered by concrete implementation questions and timelines.

Purpose: Work through practical implications, validate approaches, and collect operational input to inform implementation deliverables (e.g., guidance, communications, user needs, roll-out plans).

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EMA newsletter for industry stakeholders

[EMA Industry Highlights]

[Subscribe] to EMA Industry Highlights

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Involving stakeholders in EMA's work

Strategic, centralised and consistent engagement of stakeholders

- Aligned with frameworks of engagement
- Promoting multistakeholder engagement by design
- Ensuring engagement throughout the medicine development and evaluation lifecycle
- Providing advice on stakeholder involvement in workshops and consultations

Timely and targeted information

- Stakeholder database for organisations and individual patients, healthcare professionals and academia

Understanding stakeholders' needs and expectations

- Proactive collaboration through diverse network of eligible organisations
- Coordinated discussions through Working Parties (PCWP and HCPWP) and Industry Standing Group (ISG)

Capacity building for impactful involvement in EMA activities

Increase understanding and trust in science that underpins the EU network's output

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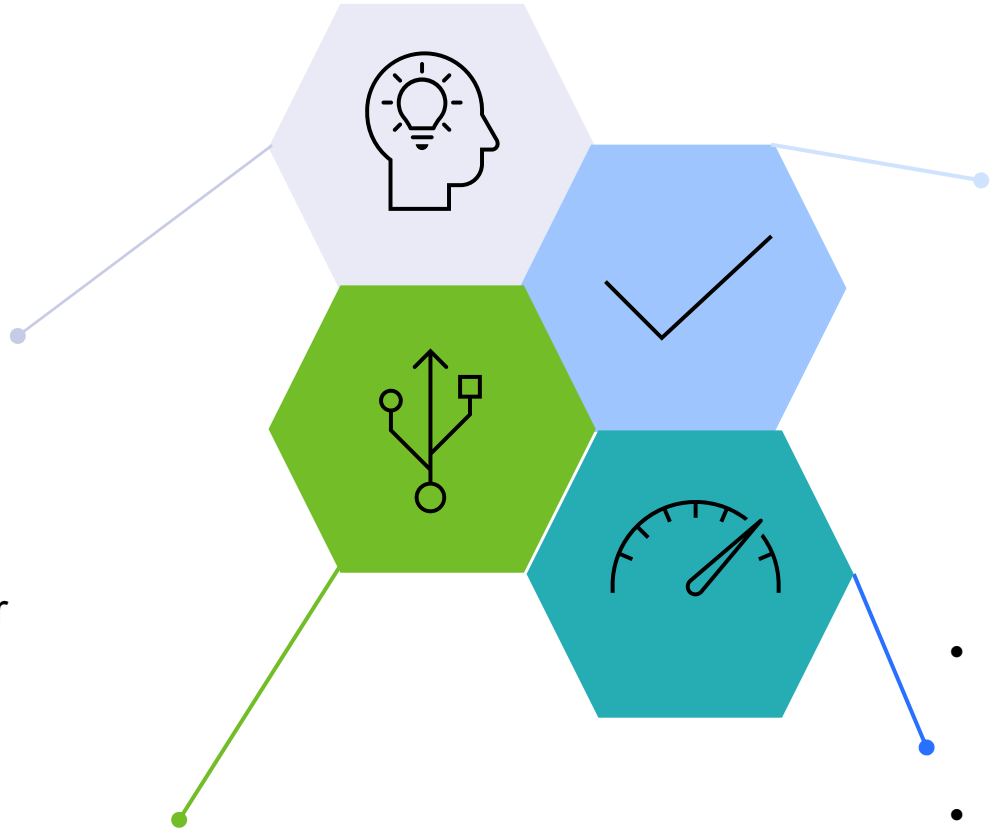
Regulatory excellence and simplification

- 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**

Source: EC presentation to PCWP/HCPWP on 3 February 2026

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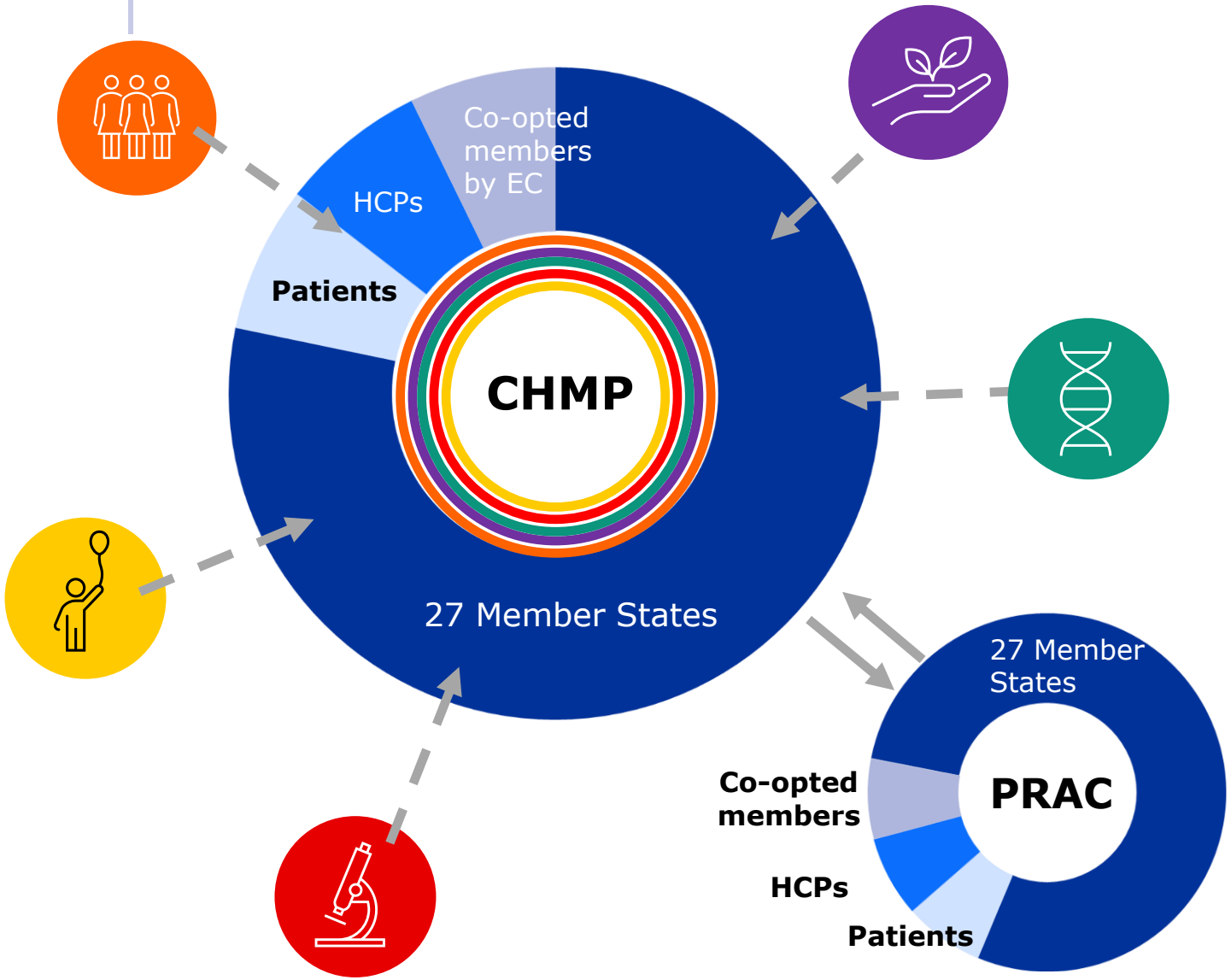
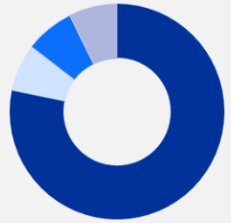
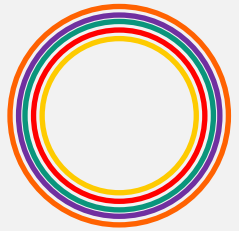
New EMA committee structure

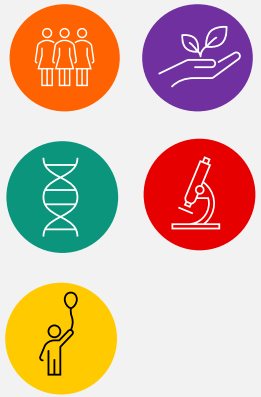




New Committee structure (CHMP/PRAC)



Experts from former committees



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

Input based on needs

Source: [EC presentation to PCWP/HCPWP on 3 February 2026]

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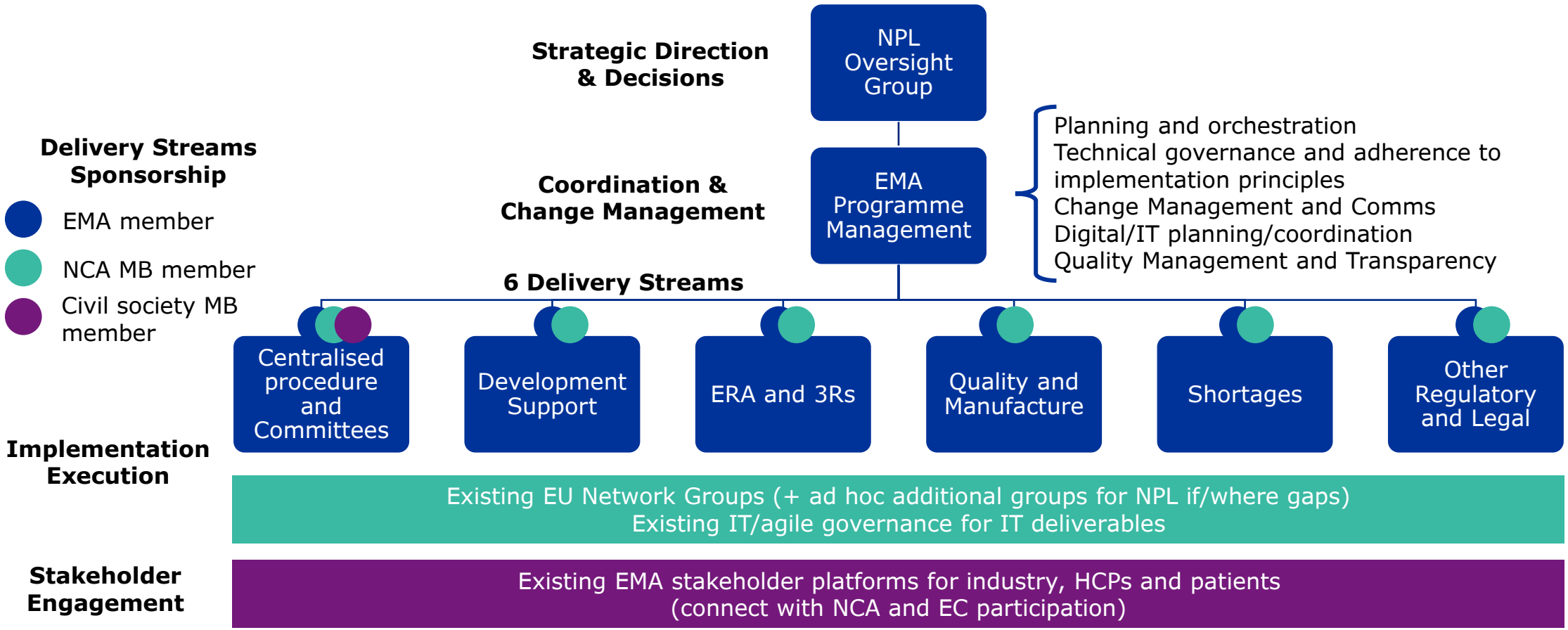
Proposed NPL governance structure



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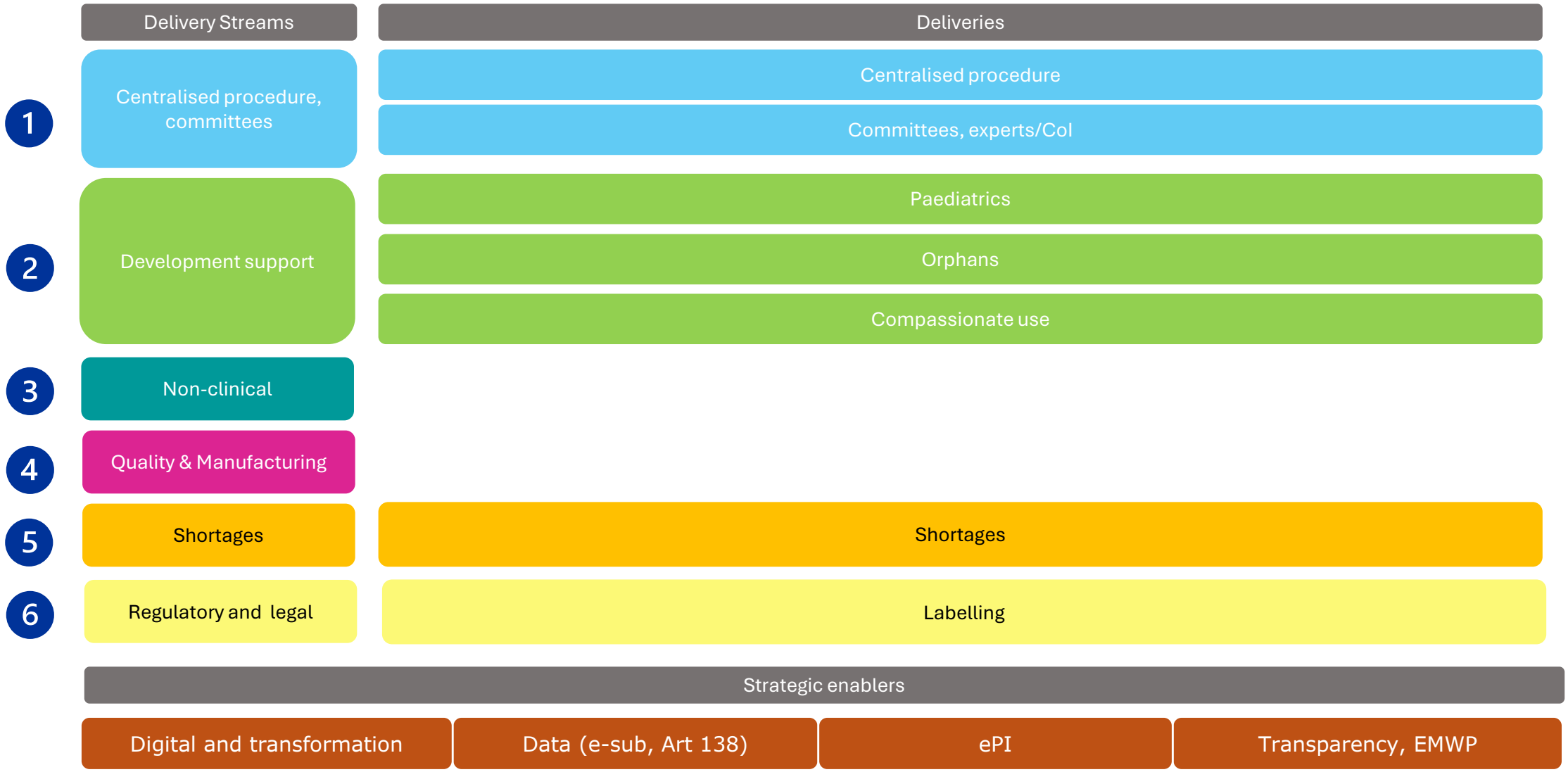
Delivery streams requiring patient and HCP input



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