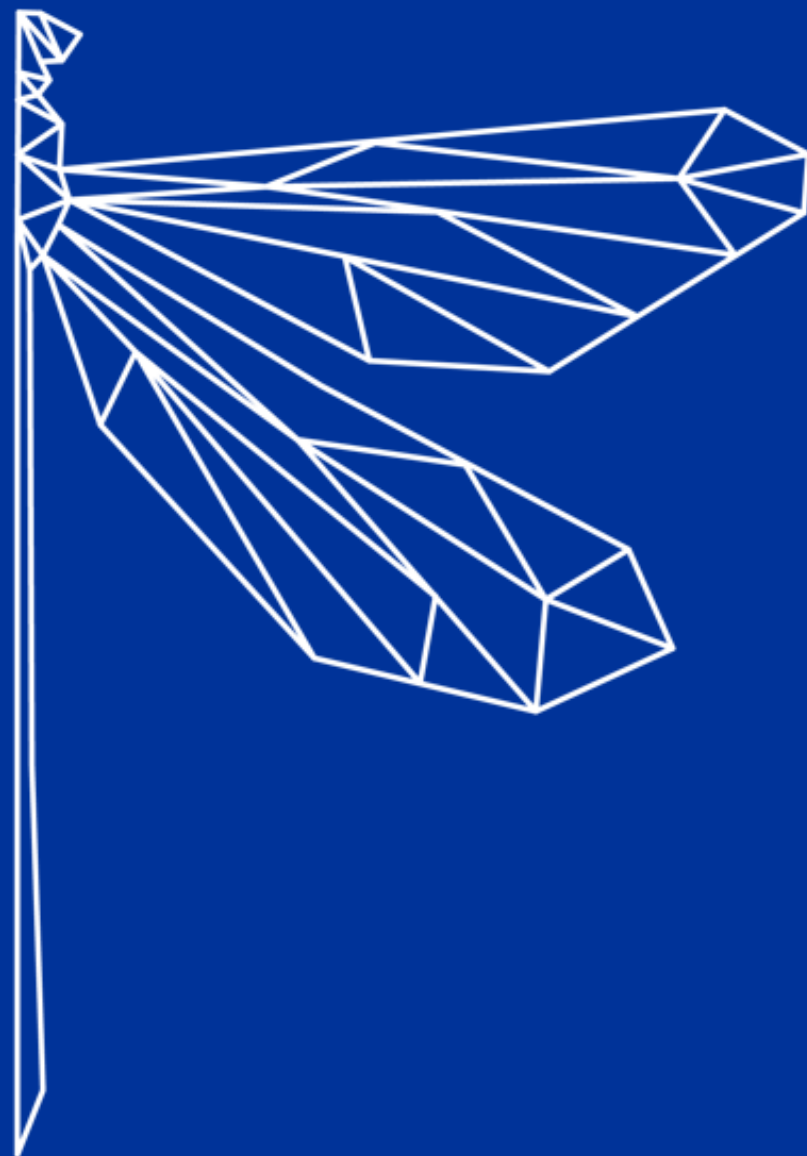


# New pharma legislation

Implementation & Stakeholder engagement

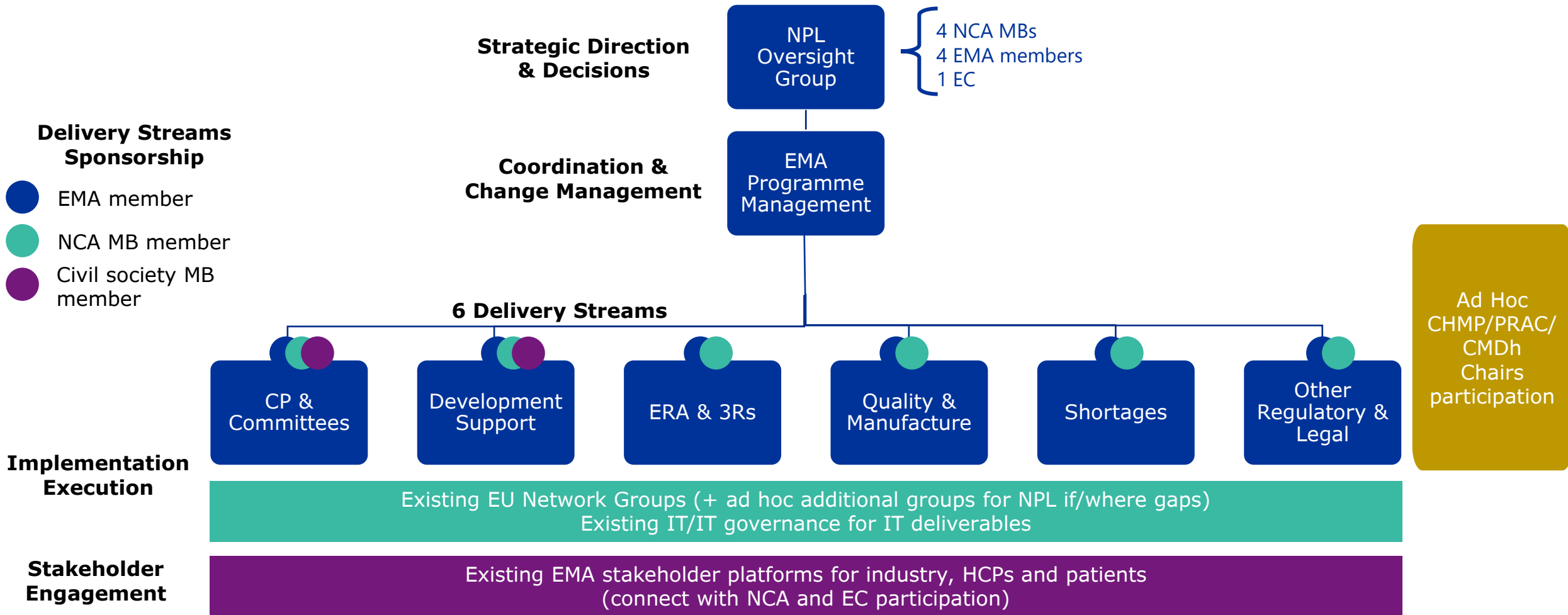
ISG meeting, 31.03.2026



# Key elements of the NPL



# NPL governance



# EMA, EC & MB members in the governance

## **NPL Oversight Group**

- Rui Santos Ivo (MB Chair, NCA)
- Maria Jesús Lamas Díaz (MB member, NCA and HMA MG Chair)
- Karl Broich (MB member, NCA)
- Nils Falk Bjerregaard (MB member, NCA)
- + with Helena Panayiotopoulou (MB member, NCA, EU Presidency), being involved in the initial phase
- Rainer Becker (EC); alternate: Olga Solomon (EC)
- Emer Cooke (EMA, ED)
- Alexis Nolte (EMA, H Div)
- Melanie Carr (EMA, S-Div)
- Peter Arlett (EMA, TDA TF)

# EMA, EC & MB members in the governance

## NPL Delivery Stream co-sponsors:

- 1. Centralised Procedure and Committees:** Francesca Day (EMA), Aimad Torqui (MB member, NCA), Denis Lacombe (MB member, HCPs); associate: John Borg (MB alternate, NCA)
- 2. Development Support:** Michael Berntgen (EMA), Catherine Paugam-Burtz (MB member, NCA), Virginie Hivert (MB member, Patients)
- 3. ERA/3R:** Jordi Torren Edo (EMA), Günter Waxenecker (MB member, NCA)
- 4. Quality and Manufacturing:** Evdokia Korakianiti (EMA), Gráinne Mary Power (MB member, NCA)
- 5. Shortages:** Emmanuel Cormier (EMA), Momir Radulovic (MB member, NCA); associate: Charles Denonne (MB alternate, NCA)
- 6. Other regulatory and legal:** Alberto Ganán (EMA), Ann Lindberg (MB member, NCA), Robert Nisticò (MB member, NCA); associate: Beatrix Horvath (MB alternate, NCA) [note: two MB co-sponsors because of diversity of topics]



# Pre-implementation phase: Roadmap development

*As implementation planning progresses, EMA is developing the roadmap and identifying when, where and how stakeholder engagement will be needed.*

Ongoing analysis of the legislative text

**What:** Analysis of the final legislative text and its implementation implications will help identify areas where consultation with industry may be needed.

**Why:** This will progressively clarify which topics would benefit most from industry input.

Progressive identification of priority topics

**What:** Topics will be identified based on implementation needs, stakeholder impact, topic maturity, and the need for technical or operational input.

**Why:** This will help ensure that engagement is targeted, timely and focused on priority areas.

Initial visibility on engagement areas

**What:** EMA aims to provide early visibility on topics where further industry engagement may be needed, starting at the June/July platform meetings.

**Why:** This will help provide an initial indication of possible consultation areas while allowing further detail on topics and timing to emerge progressively.

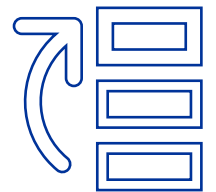
# Your input on implementation priorities

## Objective

To support roadmap development, EMA invites industry associations to jointly identify their priority topics for NPL implementation

## Our request

- Industry associations are invited to coordinate with their members and provide:
- up to 10 priority topics of common interest across industry;
- plus up to 3 additional topics specific to their sector, if needed;



## Timing

- Proposed deadline for written input: **mid-May 2026**
- Follow-up **exchange meeting** with associations to discuss the proposals and clarify priorities

# How we plan to engage Industry during NPL implementation



## Multi-stakeholder workshop

**What:** High-level workshop organised by EC with all stakeholder groups (EMA, NCAs, industry, patients, HCPs).

**When:** As soon as practicable after the publication of the final legislative text in the Official Journal.

**Purpose:** Provide an overview of the foreseen changes and gather early reflections to guide implementation planning.



## Industry Standing Group

**What:** Main reference forum for Industry during NPL implementation.

**When:** Quarterly, according to the current planning.

**Purpose:** Share overarching progress, clarify questions, gather high-level input, and ensure alignment across stakeholders.



## Industry platforms

**What:** Operational channels for topic-specific discussions within their respective domains.

**When:** According to regular schedule, topics activated as needed

**Purpose:** Work through practical and technical implementation topics with full stakeholder representation.

# Keeping stakeholders informed and involved throughout implementation



## ISG

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



## TOPIC-SPECIFIC WEBINARS

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



## NPL webpage

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



## PUBLIC CONSULTATION

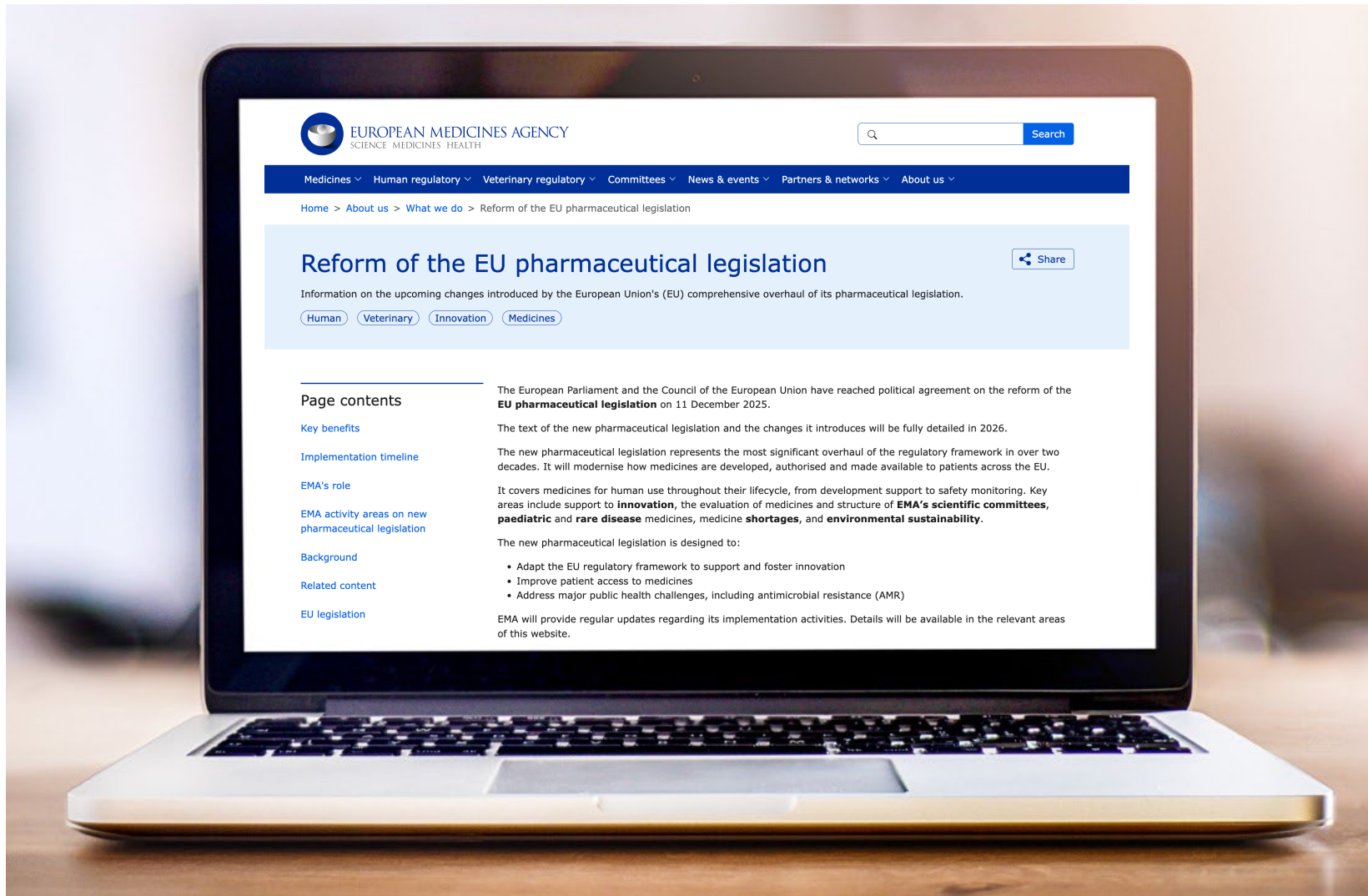
**Provide input** on scientific guidelines as part of the standard EMA consultation process.



## NEWSLETTER

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

# EMA NPL web page



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

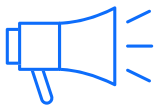
# EMA Industry Highlights



New quarterly newsletter providing regular updates on the Agency's regulatory and policy developments that may require action.



Helping industry stay informed and navigate the regulatory process more effectively.



31<sup>st</sup> March first issue will include:

- Welcome message from Melanie Carr (Head of Stakeholders and Communication)
- Steffen Thirstrup (Chief Medical Officer) vision on biosimilars
- Update on implementation plans for the Reform of EU pharmaceutical legislation

EMA Industry  
Highlights Newsletter



[Subscribe now](#)



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Thank you

Follow us

