EMA
EUROPEAN MEDICINES AGENCY

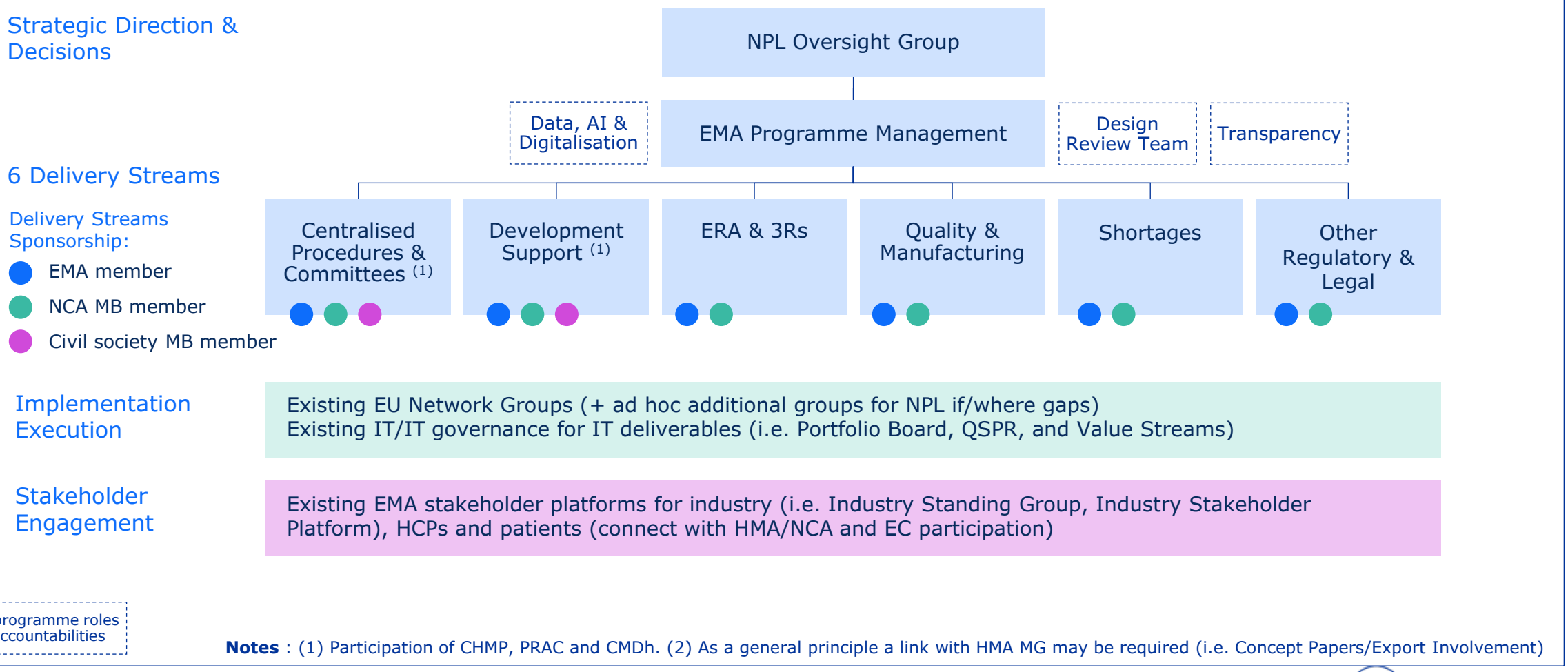
Implementation of the new pharmaceutical legislation (NPL)

16th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

15 June 2026

M. Fanari; M. Vogl; F. Day; Z. Hanaizi; A. Spinei (EMA)

Programme governance structure



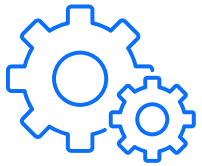
Notes : (1) Participation of CHMP, PRAC and CMDh. (2) As a general principle a link with HMA MG may be required (i.e. Concept Papers/Export Involvement)

Our goal for the past and coming months

Review of legislative texts and analyse their impact

Identify foreseeable actions and deliverables

Identify resources needed within EMA and network



Project planning based on prioritisation

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.

Topics/projects within DS 1 – Centralised Procedure and Committees

- Centralised Procedure – initial marketing authorisation
- Post-Authorisation procedures
- EMA reform and experts
- Pharmacovigilance
- Raw Data
- Real World Evidence
- Public Product Portal

DS1 currently has a priority on the iMAA and the EMA reform/experts.

Topics/Projects within DS4 - Quality and Manufacturing

Active Substance Master Files

(DIR Art. 25)

Additional Quality Master Files

(DIR Art. 26)

Platform technologies master files

(DIR Art. 26a)

Decentralised manufacturing

(DIR Art. 26b)

Surveillance and risk-based GMP inspections

(reliance, distant assessment, risk based inspection for API, joint inspections)

(DIR Art. 188, 189, 190, REG Art 53)

Joint Audit Programme

(mandate and expansion to GDP)

(REG Art. 54)

Inspectors Working Group

(establishment as EMA WG)

(REG Art. 142)

Agency Inspectorate

(REG Art. 52 & Annex III)

Quality focused

Inspections focused

Topics/projects within DS6 – Other regulatory & legal

- Annex II
- Transferable exclusivity voucher (TEV) for priority antimicrobials
- Conditional MA
- MA under exceptional circumstances
- Regulatory data protection, including scientific guidelines on unmet medical need and on criteria for proposing a comparator for a clinical trial
- Product information (ePI and PI-related guidances and template)
- Temporary emergency marketing authorisation
- Referrals
- EMA governance matters (e.g. international cooperation, security, protection against cyber attacks, budget)

DS6 has a strong focus on regulatory aspects – any process-related changes will be led by DS1

Other regulatory matters (eg definitions, legal basis, radiopharmaceuticals) will be incorporated within topics or other general guidance updates

Current priorities in DS6

Transferable exclusivity voucher for priority antimicrobials (TEV)

Implementation plan includes the development of relevant guidances in particular with respect to:

- Scientific considerations to support the justification that a product meets the criteria for 'priority antimicrobial' as defined in Article 40(3)
- Procedural guidance for the submission of requests for TEV in initial MA, transfer and use of voucher

Annex II

EMA and network to provide input on the content of Annex II for the drafting of the delegated act.

Main goals:

- Future-proofing while ensuring legal certainty
- Updating outdated content and integrating new concepts

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

Follow us