EMA
EUROPEAN MEDICINES AGENCY

Implementation of the new pharmaceutical legislation (NPL)

16th Industry Stakeholder Platform on R&D

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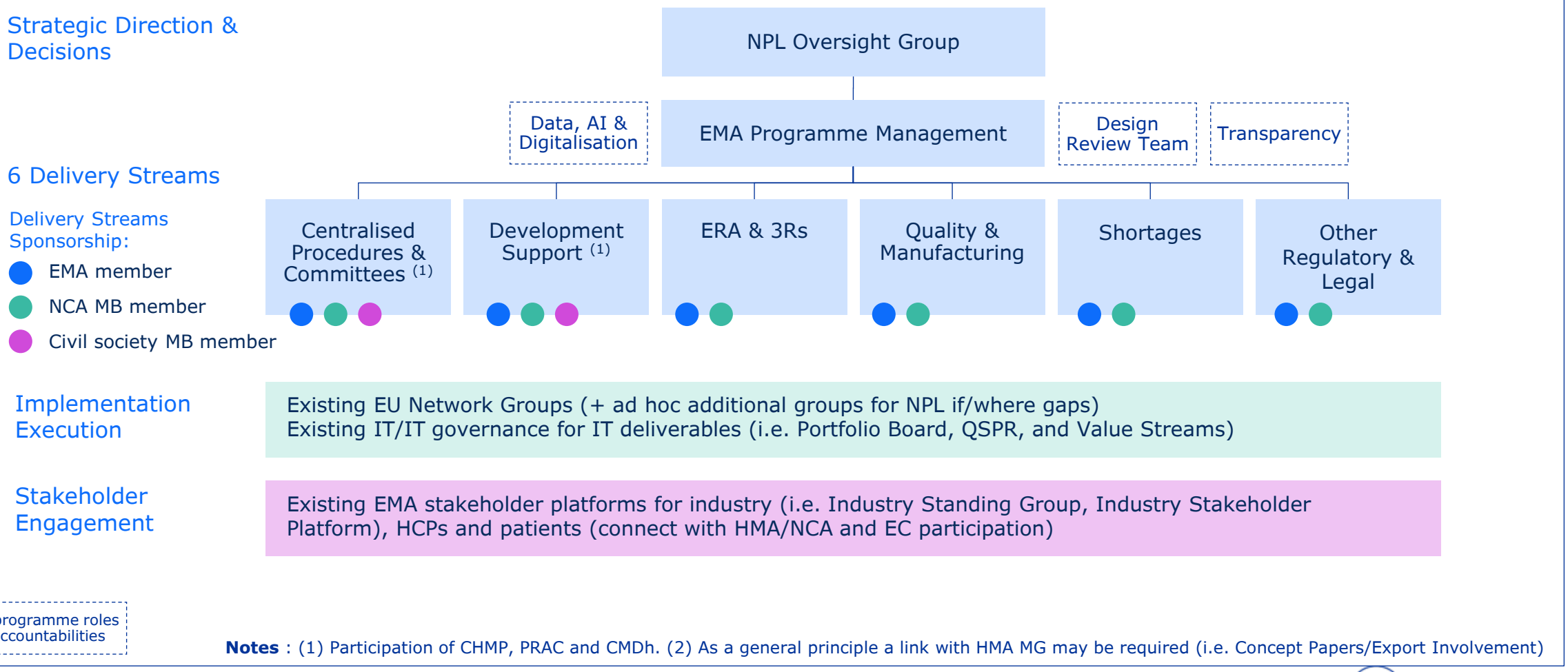
Programme governance structure



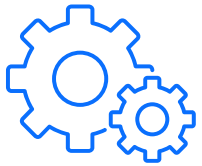
Notes : (1) Participation of CHMP, PRAC and CMDh. (2) As a general principle a link with HMA MG may be required (i.e. Concept Papers/Export Involvement)

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

NPL industry engagement model

INDUSTRY STANDING GROUP (ISG)
Main reference forum for industry

- Quarterly planning and updates
- Early visibility of cross-cutting topics
- Exchange on upcoming platform topics
- Overview of engagement activities (i.e., workshops, impact & readiness activities

INDUSTRY PLATFORMS / MEETINGS
Topic-specific engagement

- Focused discussion on specific delivery streams' topics (i.e., Annex II)
- Feedback on implementation approaches
- Discussion on practical challenges and solutions
- Alignment on cross-cutting topics

INDUSTRY PLATFORMS / MEETINGS

CENTRALISED PROCEDURE

Mostly topics under:

- Centralised Procedure & Committees, including procedural aspects of orphans & paediatric
- Other regulatory & Legal (i.e., Annex II, product information)

RESEARCH & DEVELOPMENT

Mostly topics under:

- Development Support (i.e., Scientific Advice, PRIME, Paediatric, Orphans)
- ERA & 3Rs

PHARMACOVIGILANCE

Mostly topics under:

- Pharmacovigilance

QUALITY & MANIFACTURING

Topics covered in *existing* Industry interactions with IWG / QWP *

- Quality : ASMFs, AQMFs, PTMFs
- Inspections : DCM, Inspectorate, GMP Surveillance System, JAP, EMA Inspectorate

(*) Inspection Working Groups / Quality Working Parties

Topics within DS2 – Development Support

Sandbox	Scientific advice	PRIME
Orphans	Paediatrics	Compassionate use
Classification of medicinal products	Not-for-profit repurposing	ATMPs and hospital exemptions

Topics/Projects within DS3 – Non-clinical, ERA & 3Rs

Non-clinical

(Reg. Art 6.1; Dir. Art 6.3; Reg. Art. 138zi, zj, zk, zl)

3Rs

Reg. Art 6.5, 12(m), 16.3, 138(ze, zi, zl) Dir. Art 6.7, 16.3

OSOA

Reg. Article 138(ze) & 139, Dir. Article 27

ERA-general & ERA-WP

(DIR Art. 22 & Reg. Art. 150*)*

ERA-registry

(Reg Art 104a)

ERA-monograph

(Dir Art 24)

ERA-catch up

(Dir Art 23)

ERA-GMO

(Reg Art. 7-9 & 177)

Non-clinical focused

ERA focused

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Thank you

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