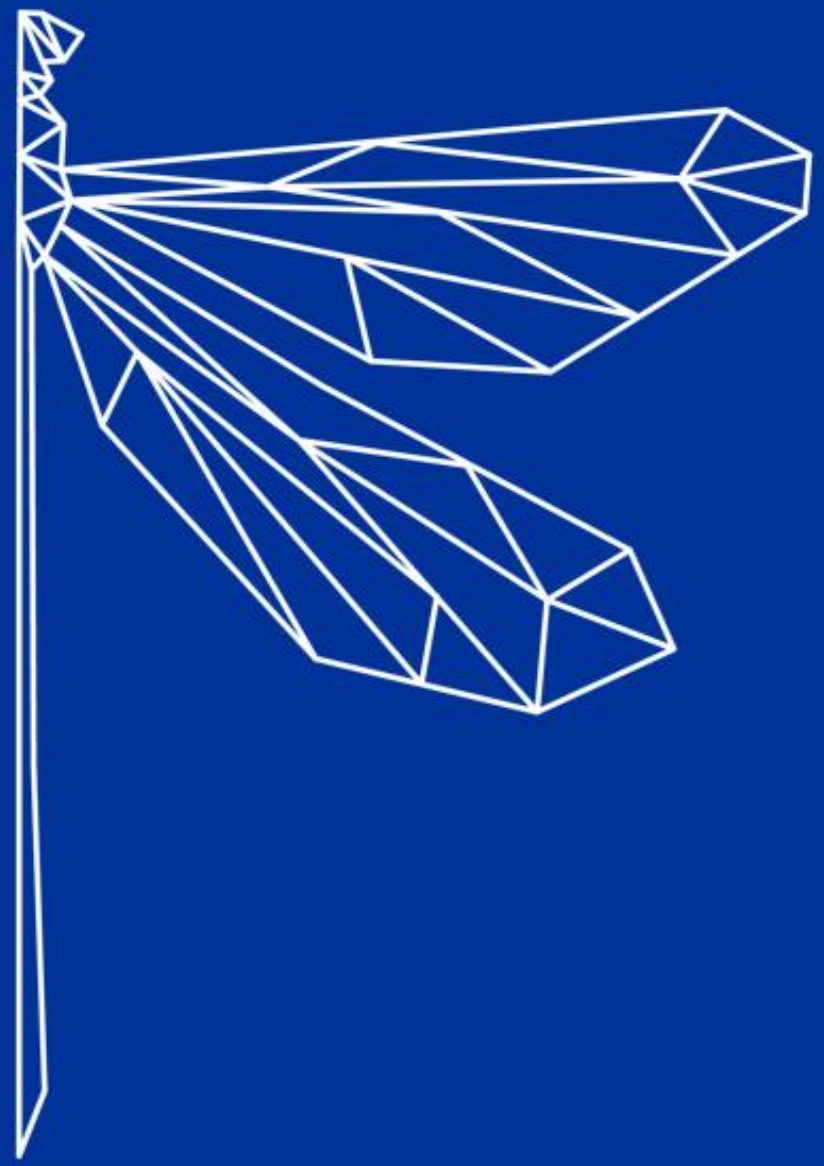
EMA
EUROPEAN MEDICINES AGENCY

New pharma legislation

Update on planning, priorities and engagement activities



ISG meeting, 29.06.2026

Industry priorities (ISG)

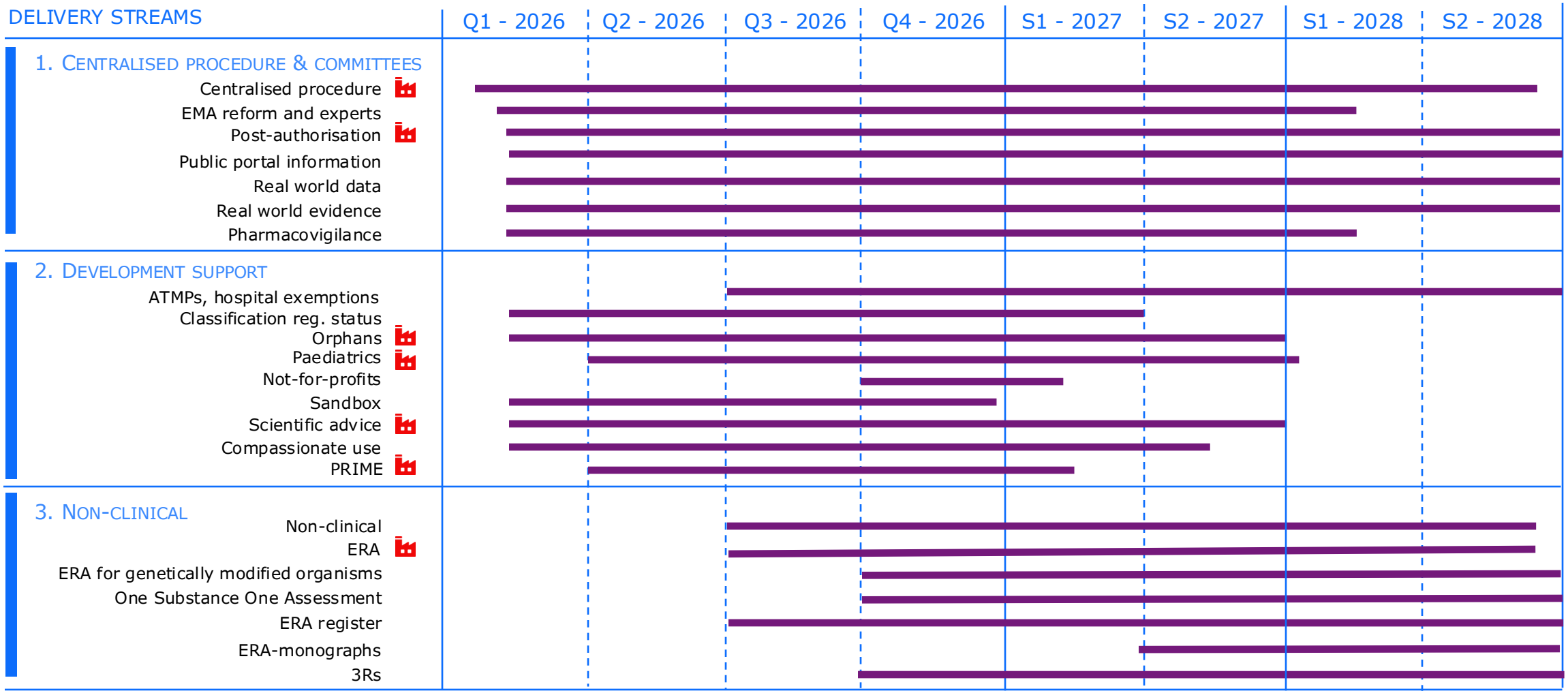
- Environmental Risk Assessment
- Centralised Procedure
- Annex II
- Definitions / Legal basis
- ePI, Labelling
- Scientific Advice, PRIME
- Paediatric
- Orphans
- Inspectorate
- Variations

Why have these topics emerged as priorities for industry stakeholders?

Trade association specific priorities (aside from the top 10)

- Access provisions under NPL
- Active Substance Master File (ASMF) / Active Quality Master File (AQMF) certification
- Decentralised manufacturing
- Duplicate marketing authorisations
- Electronic Product Information (ePI) and e-leaflets
- Export restriction notifications
- Generics, biosimilars and hybrid medicines
- Incentives
- Orphan medicines
- Paediatric clinical trial reporting timelines
- Platform Technology Master Files (PTMFs)
- Post-authorisation treatment optimisation studies
- Prescription criteria
- Pre-submission interactions
- Radiopharmaceuticals
- Regulatory Data Protection (RDP) and Marketing Exclusivity implementation
- Regulatory simplifications
- Treatment optimisation studies post-authorisation (Reg Art 20(d))
- Unmet Medical Need (UMN)

NPL 2026 – 2028 Roadmap (1/2)



NPL 2026 – 2028 Roadmap (2/2)

NPL industry engagement model

INDUSTRY STANDING GROUP (ISG)
Main reference forum for industry

- Quarterly planning, updates and escalation
- 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

Upcoming engagement activities

Research & Development Industry Platform

- 2 July 2026 (Initial discussion on R&D-related implementation topics)

Regulatory Sandbox Workshop

- 21 September 2026 (EU Regulatory Sandboxes – Accelerating Innovation with Confidence)

Biological Working Party and Quality Working Party Interested Parties meeting

- October 2026

SME Info-Day

- 6 November 2026 SME (Navigating EMA support: From development to market authorisation)

Multi-Stakeholder Workshop by European Commission

- Q4 2026 (Open to: EMA, NCAs, Industry, Patients, HCPs; Objective: Overview of foreseen changes and early reflections to support implementation planning)

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Thank you

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