

NPL Update

Engagement with industry during implementation

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Industry Standing Group, 11 December 2025



How we plan to engage Industry during NPL implementation



1

Multi-stakeholder workshop

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

When: Organised 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.



2

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.



3

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.

Operational engagement through the Industry Platforms



The Platforms provide the operational space to work through implementation topics with full stakeholder representation.

- The existing platforms (**Centralised Procedure, R&D, Pharmacovigilance**) remain the **primary channels** for topic-specific discussions.
- **Focus Groups (as needed):**
 - Established *within the relevant platform* for specific implementation questions.
 - Include **Industry representatives + EC + NCAs** to ensure full stakeholder representation.
 - Discussions are **operational**, focused on practical interpretation and implementation needs.
- **Feedback loop:**

Outcomes from Platform discussions will be reported back to the **Industry Standing Group** to ensure transparency and alignment.

Keeping stakeholders informed and involved throughout implementation



ISG

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



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.



TOPIC-SPECIFIC WEBINARS

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



NEWSLETTER

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



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