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EU-Innovation Network Workplan 2025

Contents

1. Introduction

This 2025 EU-Innovation Network Workplan lays out strategic goals and deliverables within the mandate of the EU-Innovation Network (EU-IN) that are intended to deliver on the European Medicines Agencies Network Strategy to 2028 (currently in draft) and EMA's Regulatory Science Strategy to 2026. The workplan also considers relevant actions described in the multi-annual work plans associated with these strategies.

The EU-IN has a joint mandate from EMA and HMA and is formed by members from both EMA and NCAs who are working together on the goals and deliverables outlined in this workplan.

Other relevant initiatives such as Accelerating Clinical Trials in the EU (ACT EU), the Network Data Steering Group (NDSG), the joint action on capacity building within the EU medicines regulatory network (IncreaseNET) and the ongoing review of the general EU pharmaceutical legislation are also considered with a view to supporting these initiatives and avoiding duplication.

EU-IN priorities and objectives:

- Enable early-stage research in medicines and MedTech development in Europe and promote its efficient translation into authorised medicines and ultimately into clinical practice.
- Operate a regulatory intelligence function to capture emerging science and technology trends and developments.
- Support the development of capability and expertise within the network to address and engage with emerging innovation.
- Facilitate the delivery of strategic priorities for the EMRN as outlined in the European Medicines Agencies Network Strategy (EMANS) and associated workplans.
- Contribute to the competitiveness of the European Innovation ecosystem by promoting mutual exchange and interactions between medicine regulators and stakeholders.

2. Promote the translation of Innovation from bench to bedside

Objectives:

- Enable and promote the development, evaluation and access of innovative medicines, and associated technologies and methodologies within the European Union.
- Optimise the outcome and impact of European regulatory science projects by promoting the involvement of Competent Authorities (CAs) in such projects.
- Promote multinational academic and non-for-profit research and development in Europe by collaboration with Academia and non-for-profit organisations.

Deliverables/Actions:

- Share experience and best practices in relation to innovation and support to innovators amongst Member States.

- Raise awareness of relevant national and EU projects, programmes and funding calls including Horizon Europe, Innovative Health Initiative (IHI) and EU4Health and share experiences between CAs in participating in regulatory science projects.

- Support the European Platform for Regulatory Science and delivery of selected Regulatory Science Research Needs (RSRN) with academic researchers.

- Contribute to activities related to the 20th year anniversary of the SME regulation.

3. Horizon Scanning

Objectives:

- Identify and share trends in medicine research and development and upcoming medicine technologies, intervention modalities, methodologies and methods.

- Contribute to the implementation of recommendations to prepare the EMRN for opportunities and challenges identified.

Deliverables/Actions:

- Finalise and publish horizon scanning reports and seek to progress implementation of recommendations from these and previous reports.

- Commence work on at least two new horizon scanning topics.

4. Optimisation of available regulatory support tools

Objectives:

- Promote and provide clear, lean and efficient regulatory support tools to stakeholders involved in the development of innovative medicines.

Deliverables/Actions:

- Develop and make available guidance highlighting available regulatory tools and support for researchers and developers.
- Implement next agreed steps for Simultaneous National Scientific Advice (SNSA).
- Engage with stakeholders to explore the suitability of available regulatory supports from their perspective and how these could be further optimised.

- Support the finalisation of the report on the repurposing pilot and contribute to the implementation of recommendations arising from the pilot.

5. Borderline Product Classification

Objectives:

- Provide clarity and consistency on the applicability of the legal basis, regulatory framework and evidence requirements for innovative products.

Deliverables/Actions:

- Provide a discussion platform for competent authorities in relation to the classification of innovative borderline products.
- Provide input on the classification related provisions of the draft new EU pharmaceutical legislation as requested.
- Continue to monitor and discuss actual legal cases on product classification.
- Strengthen collaboration with other European groups working on classification.

6. Promote Collaboration and Integration across the Network

Objectives:

- Enable best use of resources and efficiency of the EU Innovation Ecosystem by promoting collaboration and cooperation with other initiatives of the European Regulatory Network.
- Contribute to the competitiveness of the European Innovation ecosystem and support initiatives enabling and fostering the EU as an attractive region to do research, development and manufacturing of medicines.

Deliverables/Actions:

- Promote collaboration with other relevant European Regulatory Network initiatives e.g. IncreaseNET, ACT-EU, Network Data Steering Group (NDSG), ICMRA Innovation Network etc.
- Enhance exchange and engagement with all stakeholders including researchers, patients, industry and healthcare professionals working on the development of innovative medicinal products, technologies and methodologies on innovation.
- In conjunction with the Network Data Steering Group (NDSG), support the delivery of the artificial intelligence (AI) workplan for the European medicines regulatory network guiding the use of AI in medicines regulation in Europe to 2028.