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Mandate of the EU Innovation Network (EU-IN)

1. Background

The EU Innovation Network (EU-IN) is a working group established to support the European Medicines Regulatory Network (EMRN) to facilitate the development of innovative medicines and associated technologies in the European Union (EU).

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) created the EU-IN in 2015 to strengthen the collaboration between national competent authorities (NCA) and EMA on regulatory matters relating to emerging therapies and associated technologies.

The EU-IN's aim is to improve regulatory support for medicine developers at national and European level from an early stage of development to facilitate the development of innovative medicines, make investment in such medicines and technologies more appealing and ultimately help to improve treatment options for healthcare professionals and patient outcomes.

2. Objectives

High level EU-IN priorities and objectives include:

- 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

Activities of the EU-IN to achieve its objectives include:

- Provide a platform for regulators to share knowledge, good practices and enable collaboration among the European Innovation Ecosystem focused on support for early-stage innovative developments.
- Identify emerging trends through horizon scanning.
- Propose, discuss and share opinions on borderline and classification issues to facilitate increased consistency and harmonization across the EU.
- Promote further harmonisation and increase efficiency of scientific-regulatory advice and innovation support offerings enabling innovative developments across the EU
- Promote the involvement and collaboration of the EMRN in EU level funding programs enabling relevant outcomes benefitting patients.
- Identify and help to progress regulatory science research needs in conjunction with relevant stakeholders

3. Governance

- The EU-IN and its activities are co-governed by HMA and EMA.
- The EU-IN is co-chaired by a NCA member nominated by HMA and an EMA staff member for a term of three years. The HMA co-chair is appointed by HMA following a call for expressions of interest for a term of three years, which may be renewed once.
- The annual EU-IN workplan shall be presented and adopted at the first HMA meeting of the year. The co-chairs report to HMA and EMA on the progress and performance of the network, and on specific topics upon request.
- EMA provides administrative and scientific secretariat to the EU-IN.
- The EU-IN is composed of representatives from national competent authorities' innovation offices (or other units as appropriate) and the EMA's Innovation Task Force. Participation is on a voluntary basis.

4. Meetings

- Ten virtual meetings and one face-to-face meeting are held per year.
- Stakeholder meetings (i.e. workshops, conferences, webinars) may be arranged on specific topics.
- EU-IN members are to be reimbursed in accordance with EMA reimbursement rules.