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EU-Innovation Network Workplan 2024

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1. Introduction

This 2024 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 2025 and EMA's Regulatory Science Strategy to 2025. 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), Big Data Steering Group (BDSG) and the joint action on capacity building within the EU medicines regulatory network (IncreaseNET) are also taken into account with a view to supporting these initiatives and avoiding duplication.

Overarching EU-IN priorities and objectives:

- Enable early-stage research and investment in medicines and MedTech development in Europe.
- Operate a regulatory intelligence function to capture emerging science and technology trends.
- Build capability and support capacity of expertise within the network to address and engage with emerging innovation.

2. Promote involvement of Competent Authorities (CAs) in science and regulatory projects

- **Objectives:**
  - Optimise the outcome and impact of European regulatory science projects by harmonising efforts, enabling collaboration and avoiding duplication within the European Union.
- **Deliverables/actions:**
  - Raise awareness of future opportunities by facilitating discussions in relation to work programmes / funding calls (national and international (EU)).
  - Connect related projects harmonising efforts, enabling collaboration, and avoiding duplication.
  - Promote inclusion of project deliverables to address Regulatory Science Research Needs (RSRN).

3. 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 monthly discussion platform for competent authorities in relation to the classification of innovative borderline products.
    - Provide inputs on classification-related provisions as part of the revision of the EU pharmaceutical legislation.
    - Continue to monitor and discuss actual legal cases on product classification.
  - Organise a meeting on the classification of Faecal Microbiota Transplantation (FMT)-based products and agree on recommendations as applicable.

4. Simultaneous National Scientific Advice (SNSA)

- **Objectives:**
  - Provide multi-national Scientific and Regulatory Advice, enriching regulator's offerings to support developers of innovative medicinal products and related technologies.
  - Increase the consistency and efficiency of national SA provided by the different NCAs to bring the SNSA pilot concept to its maximum potential.
- **Deliverables/actions:**
  - Complete SNSA Phase 2 interim evaluation & report to HMA.
  - Continue with optimisation of the SNSA procedure: publish the SNSA optimized Flow Chart and an updated guidance for applicants as well as develop an internal guidance for NCAs, develop an optimised central coordination and data management approach.
  - Communication: hold training webinars for NCAs and applicants to increase uptake of the SNSA concept across the regulatory network and the life science sector in Europe.
  - Explore further development of the SNSA concept in close interaction with other working groups/project initiatives, e.g. ACT-EU, CTCG and other EU-IN groups.

5. Training, Education, Communication

- **Objectives:**
  - Promote regulatory awareness and knowledge amongst researchers and medicines developers with focus on SMEs, academia and patient groups and healthcare professionals.
  - Encourage early engagement of researchers, medicine developers and competent authorities promoting the use of available regulatory support mechanisms.
- **Deliverables/actions:**
  - Review and update available training materials with focus on previous STARS pilot and disseminate updated materials via a webinar.
  - Develop and make available guidance highlighting available regulatory tools and support for researchers and developers.

6. Promote the translation of innovation from bench to bedside

- **Objectives:**
  - Enable and promote the development, evaluation and access of innovative medicines within the European Union.
  - Support developers and academics with the implementation of Innovation aspects of the new Pharma legislative proposal.
- **Deliverables/actions:**
  - Organise a conference exploring key considerations relating to access to innovative products in the EU in collaboration with other relevant stakeholders (2H 2024).
  - Share experience and best practices in relation to innovation and support to innovators amongst Member States (linked to IncreaseNet).
  - Provide comments to HMA on specific proposals related to supports for innovation in the pharma legislative proposals.
  - Seeking input from the PCWP/HCPWP on the development and access to innovative medicines into consideration.

7. Horizon Scanning

- **Objectives:**
  - Early detection and sharing of trends of upcoming medicine technologies, intervention modalities, methodologies and methods.
  - Contribute to the implementation of recommendations to prepare the network for opportunities and challenges identified.
- **Deliverables/actions:**
  - Exchange best practices of Horizon Scanning with EU-IN members and apply it to new topics.
  - Finalise and publish horizon scanning reports on previously selected topics and progress recommendations from previous reports.
  - Facilitate and support the use of the new Topics, Relationships, Information assessment, Proposal generation (TRIP) tool developed by EMA for collaborative horizon scanning and working on regulatory science throughout the EMRN.
  - Increase engagement with external stakeholders and ensure coherence with other horizon scanning initiatives.

8. Fostering collaboration with Academia and non-for-profit organisations

- **Objectives:**
  - Enhance engagement between academia and regulatory authorities on topics of common interest.
  - Promote multinational academic and non-for-profit research and development in Europe.
- **Deliverables/actions:**
  - Deliver on selected Regulatory Science Research Needs (RSRN) with academic researchers.
  - Contribute to discussions on setting up a European Platform for Regulatory Science.
  - Share best practices and coordinate/streamline non-for-profit R&D within the EU medicines regulatory network.

9. Promote Collaboration and Integration across the Network

- **Objectives:**
  - Ensure collaboration and cooperation within the European Regulatory Network enabling best use of resources and avoiding duplication.
  - Enhance exchange and engagement with patients and healthcare professionals on innovation.
- **Deliverables/actions:**
  - Contribute to the work package on innovation (WP8) within the joint action on capacity building (IncreaseNet).
  - Continue supporting and contributing to relevant ACT EU priority actions including PA2 (with focus on support for academic sponsors), PA7 (scientific advice including SNSA) and PA10 (training curriculum).
  - Continue supporting and contributing to the Big Data Steering Group and share information in relation to significant updates and developments e.g. in relation to DARWIN or training initiatives.
  - Map existing innovation-related collaboration with patients and healthcare professionals across the EMRN.

10. Repurposing

- **Objectives:**
  - Support not-for-profit organisations including academia to gather and/or generate sufficient evidence on the use of established medicines in new indications, with the aim to bring new uses onto the label.
  - Support repurposing activities among the CAs.

- **Deliverables/actions:**
  - Finalisation and publication of the report on EU Repurposing Project Pilot including:
    - Monitoring the progress of the repurposing programs beyond scientific advice towards submitting new indications.
    - Identifying gaps in the existing guidance applicable to repurposing and evaluate the potential need for adaptations.
    - Conducting a survey to collect feedback from champions.
  - Prepare an overview of repurposed products.