EMA
EUROPEAN MEDICINES AGENCY

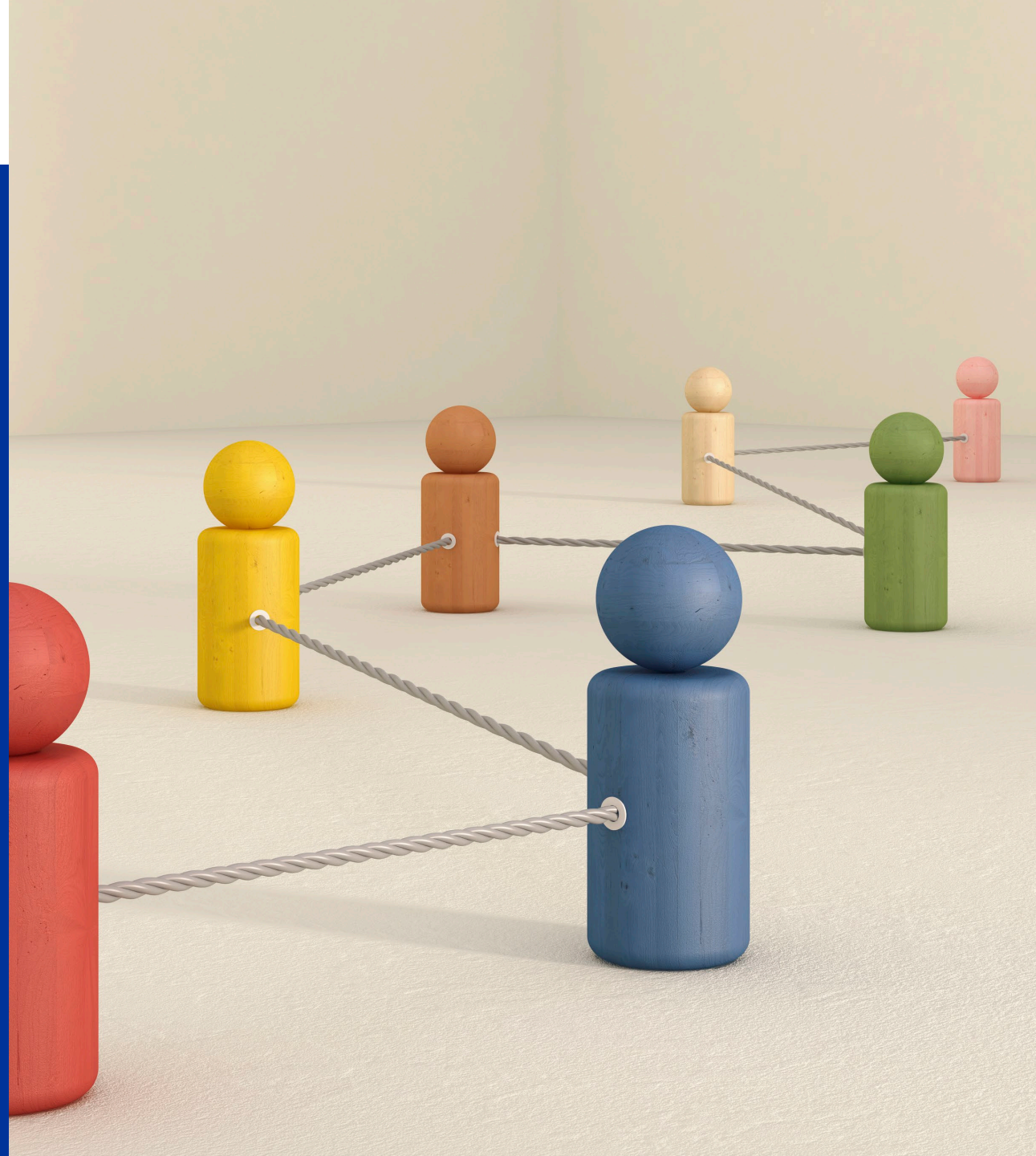
HMA
Heads of Medicines Agencies

EU-Innovation Network

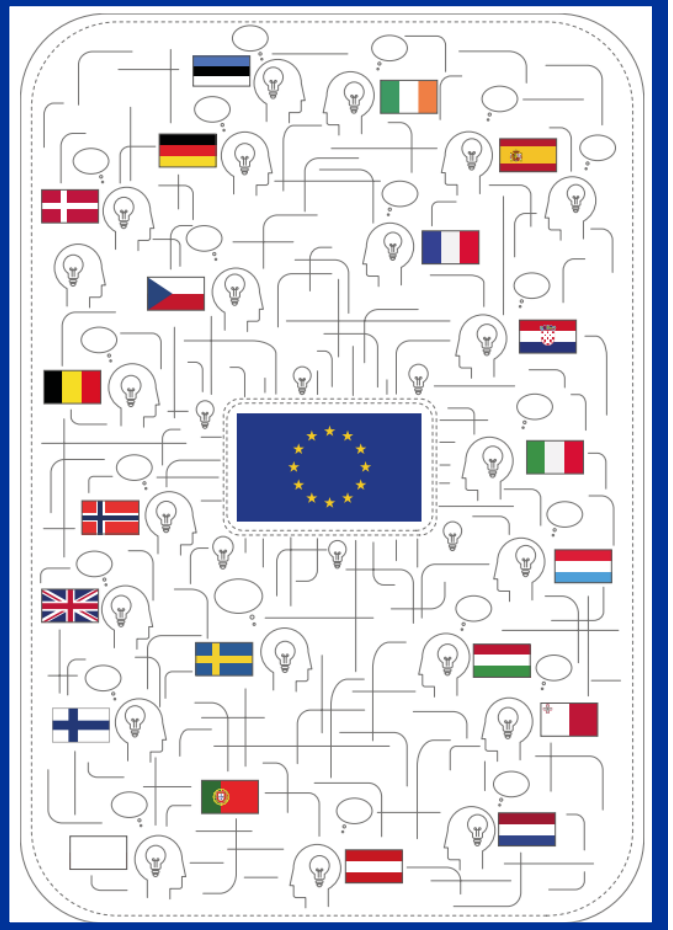
EMA Veterinary Innovation Day

13 March 2025

Valentina Cordò, PhD
Scientific specialist
Regulatory Science and Innovation Task Force



EU-IN: European Innovation Network



The Heads of Medicines Agencies (HMA) and EMA set up the EU-IN in 2015

AIM: strengthen collaboration between national competent authorities (NCAs) and EMA on regulatory matters relating to emerging therapies and associated technologies

- Co-chairs: Laurence O'Dwyer (HPRA-IE) & Falk Ehmann (EMA)
- Members: 23 representatives of NCAs (22 member states)
- Secretariat: EMA

Mission

Facilitate the development of innovative medicines and technologies for drug development by **addressing gaps in early regulatory support to innovation**

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COMMENT | 11 March 2024

The European Innovation Network as a hub for medicines innovation in Europe

The European Innovation Network is working to support the European medical innovation ecosystem by facilitating early dialogue between developers of medicines and regulators, as well as providing a platform for regulators to share information, good practices and expertise.

By Eleonora Agricola, Caroline Auriche-Benichou, Helena Baiao, Oriane Blanquie, Teodora Bodea, Tomáš Boráň, John-Joseph Borg, Valentina Cordo', Maria Di Marzo, Lars Dmowski Rugholm, Falk Ehmann, Rúna Hauksdóttir Hvannberg, Ralf Herold, Alar Irs, Simona Jurkovič Mlakar, Robert Klaus, Juha Kolehmainen, Christophe Lahorte, Wiebke Löbker, Anna Mäkinen Salmi, Yoana Nuevo Ordoñez, Laurence O'Dwyer, Anna Maria Gerdina Pasmooij, Ingvil Saeterdal, ... Katarzyna Zywiec + Show authors

The European Innovation Network as a hub for medicines innovation in Europe

Goals of the EU-Innovation Network

- Promote the translation of innovative research into authorised medicines and ultimately into clinical practice
- Capture emerging science, technology trends and innovative developments
- Support the development of capability and expertise within the EU regulatory network
- Facilitate the delivery of the European Medicines Agencies Network Strategy (EMANS)
- Contribute to the competitiveness of the European Innovation ecosystem by promoting interactions between medicine regulators and stakeholders

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EU-IN workplan for 2025

Contents

EU-Innovation Network (EU-IN) - HMA

EU Innovation Network (EU-IN) - EMA

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Translating Innovation into access for ATMPs
3rd EU-Innovation Network multi-stakeholder meeting

Rome, 15 November 2024

Event webpage

Promote the translation of innovation from bench to bedside

Objectives:

- Enable and promote the development and evaluation of innovative medicines, and associated technologies within the EU
- Optimise the outcome and impact of European regulatory science projects by promoting the involvement of competent authorities in such projects
- Promote multinational academic and non-for-profit research and development in Europe by collaboration with academia and non-for-profit organisations

Activities:

- Share experience and best practices in relation to support to innovation
- Raise awareness of relevant national and EU projects, programmes and funding calls
- Support the European Platform for Regulatory Science Research and delivery of selected Regulatory Science Research Needs with academic researchers

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Published reports (EMA website):

- New Approach Methodologies
- Nanotechnology-based medicinal products
- Alzheimer's Disease
- Faecal Microbiota Transplantation
- Genome Editing

Horizon Scanning

Objectives:

- Identify and share trends in research and development, including innovative medicines, technologies, and methodologies
- Contribute to the implementation of recommendations to prepare the EU network for opportunities and challenges identified

Activities:

- 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

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Optimisation of available regulatory support tools

Objective:

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

Activities:

- 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

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Simultaneous National Scientific Advice (SNSA)

- Pilot between Feb 2020 and December 2024 to obtain national scientific advice from more than one national competent authority (NCA) *at the same time*
- Objectives:
  - More efficient and consistent advice
  - Share expertise within NCAs
- More than 100 applications
- SNSA covers the full product development cycle but many applications relate to clinical development phase *(e.g., planning a clinical trial running in multiple EU countries)*
- The procedure will be optimised in 2025

Guidance for applicants on SNSA

SNSA - continuation and further development during 2025

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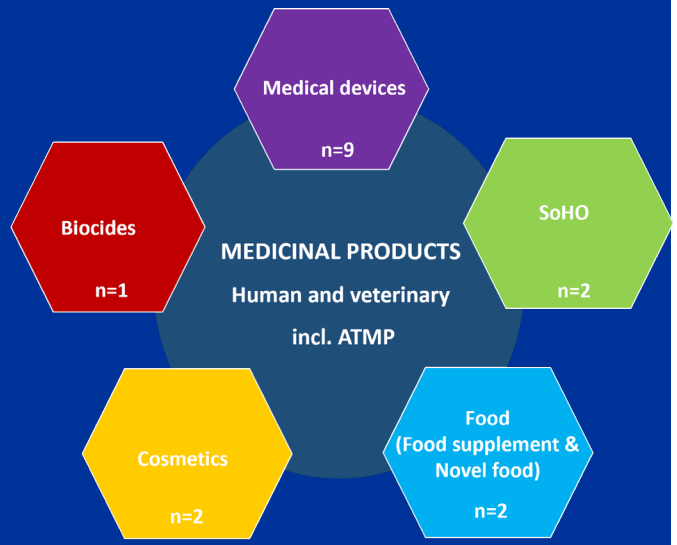
Borderline classification group (BLCG)

Borderline classification: product is not clearly covered by one legal framework/regulation due to the nature of the product.



SoHO: Substance of Human Origin

ATMP: Advanced Therapy Medicinal Product

Objective:

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

Activities:

- 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

Example *Medicinal product vs biocide for aquaculture*

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Thank you

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