National Competent Authorities support to innovation

Translating innovation into access for ATMPs

3° EU-IN multistakeholder meeting

Eleonora Agricola

Innovation and Scientific Advice EMA Office – AIFA

15/11/2024

Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA or EMA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	X	☐	☐	☐ optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	X	☐	☐	☐ optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

*Eleonora Agricola, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (Resolution n. 37 dated 13/10/2020).

N.B. I am not receiving any compensation


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Ionian Sea
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European Medicines Regulatory Network

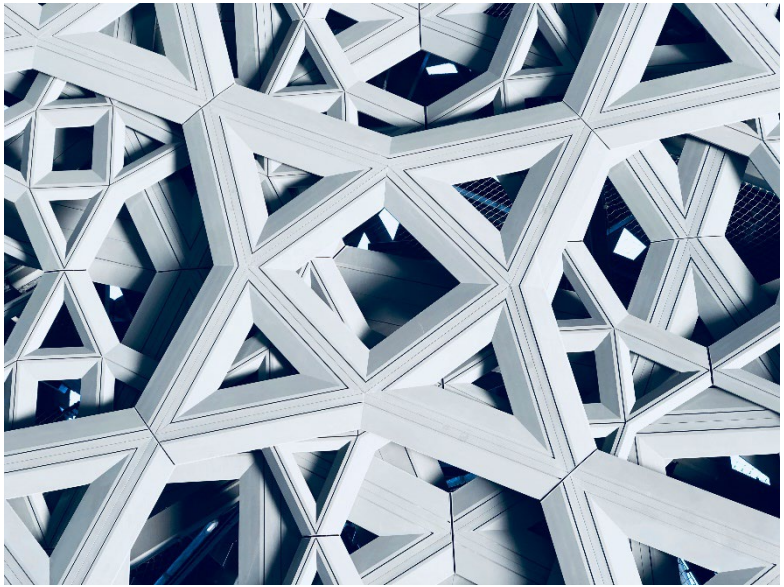
(EMRN)

EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

National Competent Authorities
(NCA)

National Competent Authorities (NCA)



Promote collaboration and integration across EMRN

Cross-contamination

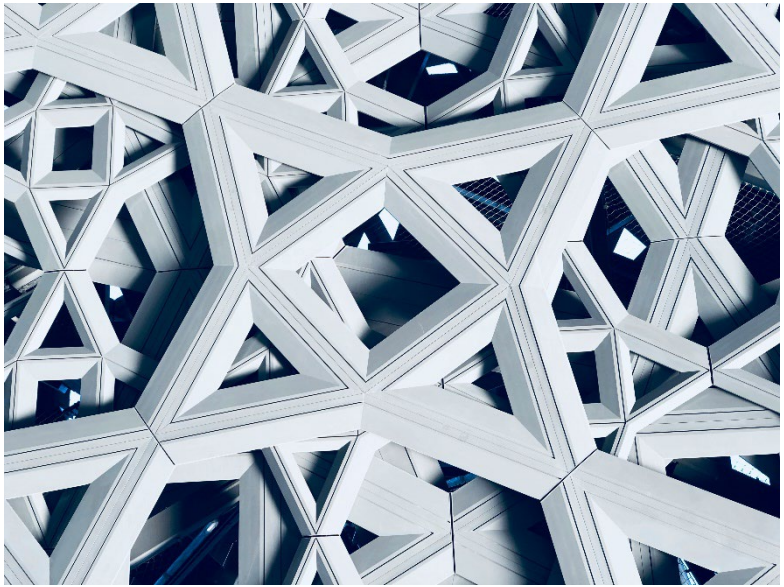
Sharing knowledge

Joint activities

Transverse topics

Ensure alignment

Avoid duplication



What the European Medicines Regulatory Network IS NOT for Innovation

The European Medicine Regulatory Network

IS NOT

- an obstacole
- a brake

Guarantee **timely access** to innovation for patients.

Provide developers with **regulatory and scientific tools** from the early stages of development.

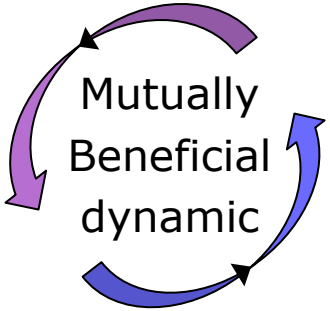
Facilitate innovation while ensuring **compliance with regulatory requirements**.

Keep up with the pace of innovation by **evolving the regulatory framework and network**.

Promote **Regulatory Science** to drive regulatory evolution.

Enhance the regulatory network by expanding **knowledge, skills, and expertise**.

European Medicines Regulatory Network



European Innovation Ecosystem

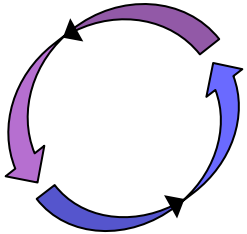
Towards the European medicines agencies network strategy 2028 (EMANS 2028)

Regulatory science, innovation and competitiveness

Open consultation: 30 November 2024

Smart regulation in a rapidly evolving world - EU-Innovation Network

European innovation ecosystem



EU-Innovation Network

22 **NCA-Innovation Offices** & **EMA Innovation Task Force**

Address, engage with and enable **early-stage research and innovation**

Prepare the EMAN to translate innovation into access

Promote **mutual exchange and interactions** between medicine regulators and stakeholders

EU-IN: collaboration and integration across the network

EU-Innovation Network

Big Data Steering Group

ACT EU

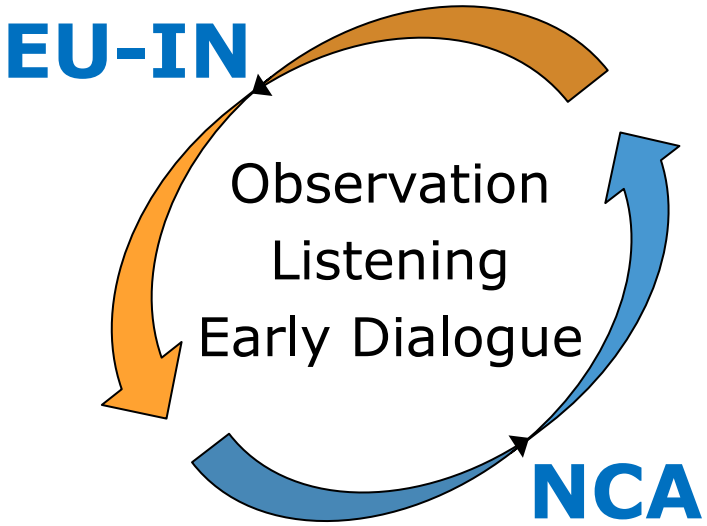
Quality Innovation Group

Scientific Advice Working Party

Innovation is one the domain in the working group/party's mandate

Innovation is a topic frequently crossed in working group/party's activities

Activities and tools



- Translation of EU Strategies into tangible outcomes for the EMRN and stakeholders
- Use of regulatory supports at national and EU level

Observation_EU-IN Horizon Scanning Reports

identifying **emerging trends** and topics in science and technology that have relevance to medical research and development.

reporting **challenges, opportunities** from a regulatory perspective.

including **recommendations** for action at ERMN and stakeholders.

1. **Faecal microbiota transplantation**
2. **Genome editing**
3. **Nanomedicine**
4. **Healthy ageing**
5. **Companion Diagnostics**

Listening & Early Dialogue_National Innovation Meeting

Initial and informal national entry point (in general, no fees)

Targeting **any Applicant**

Cover **regulatory, technical and scientific concerns** arising from innovative medicines, technologies and methodologies

Exchange of **information and early guidance** in the development process

Expression of the participating experts' opinions and **may not necessarily reflect the NCA's opinion**

Not constitute a **pre-assessment** of the documentation

NCA -> EU- IN (scale to the European network with the Applicant's agreement)

Early Dialogue_National Scientific Advice

National formal entry point (fees applied)

Targeting **any Applicant**

Cover **regulatory, technical and scientific concerns** on the different phases of the development of new and existing human medicinal products at any time before or after the authorisation

Guidance and direction on the best methods and study designs **to generate robust data**

Not legally binding on either NCA/EMA

Not constitute **a pre-assessment** of the documentation

NCA -> EU- IN; NCA -> SAWP

Early Dialogue_EU-IN Simultaneous National Scientific Advice

SNSA: Scientific Advice to **more than one NCA** at the same time

Pilot project: Phase 1 (Feb 2020-Dec 2021) + Phase 2 (Dec 2022-Dec 2024)

16 NCAs participating + 2 NCAs observer + CTCG if requested

Targeting **any Applicant**

Increase the **consistency and efficiency of national SA**

National formal entry point (fees applied)

Not legally binding on either Applicant or NCA/EMA

Not constitute **a pre-assessment** of the documentation

EU- IN -> NCA; EU-IN -> SAWP

Listening & Early Dialogue_Scientific Advice

EU-Innovation Network

Clinical Trial Coordination Group

Emergency Task Force

Scientific Advice Working Party

Accelerating Clinical Trials in the EU – ACT EU

Priority Action 7

Reinforce scientific advice coordination & clinical trial approval and design

SNSA: in earlier stages of development. Clinical trial-related advice from NCA where they intend to perform clinical trials.

EMA scientific advice: suitability of the proposed clinical development in multinational pivotal clinical trials to support a centralized marketing authorisation application.

Observation, Listening & Early Dialogue_

EU-IN Training, Education, Communication

Academia, researchers, SME, patients and healthcare professionals

Promote **regulatory awareness and knowledge**

Encourage **early engagement**

STARS
STRENGTHENING REGULATORY SCIENCE

IncreaseNET
Capacity.Competence.Confidence.

AIFA & Innovation

National Innovation Meetings

Fostering collaboration with academia

SNSA as observer

Other EU-IN activities (Horizon scanning, Borderline)

Big Data Steering Group (as EU-IN Representative)

ACT EU PA07 (as SAWP Representative) and PA10 (as EU-IN Representative)

EMA ITF meetings

STARS
STRENGTHENING REGULATORY SCIENCE

IncreaseNET
Capacity.Competence.Confidence.

ICMRA
International Coalition of Medicines Regulatory Authorities

The power to question is the basis of all human progress.

Indira Gandhi

It's better to know some of the questions than all of the answers.

James Thurber

MANY THANKS

Eleonora Agricola
Innovation and Scientific Advice EMA - Office
AIFA – Italian Medicines Agency

Email: e.agricola@aifa.gov.it
innovation.office@aifa.gov.it