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## Mandate of the European Innovation Network

### 1. Background

Innovative medicines development projects emerge throughout Europe, especially from Small and Medium-Sized Enterprises (SMEs), hospitals and academia. The Innovation Task Force (ITF) of the European Medicines Agency (EMA) and innovation offices of National Competent Authorities (NCAs) play an important role in supporting innovation in an early phase of development by promoting awareness, dialogue and understanding of regulatory requirements.

NCA's innovation offices can identify local innovators, initiate early discussions with universities, consortia and local small enterprises, and prepare them so that they derive the maximum benefit from the EU supportive tools, especially scientific advice and PRIME schema.

The EU Medicines Agencies Network Strategy to 2020 recognises the important role of the EMA ITF and national innovation offices and urges to seek for greater collaboration and integration across the network. According to the HMA Multi-Annual Work Plan (MAWP), HMA should enable those national activities with high impact on drug development including clinical trials, scientific advice or the activity of the national innovation offices, to be aligned and designed to favour the development of new medicines with high value to society. More specifically, the MAWP (Action 11) states that HMA should support a coordinated and integrated view of NCAs' innovation offices and EMA's Innovation Task Force particularly in relation to the early identification of promising developments and its integration in the EU adaptive pathways, national designation of small and medium enterprises (SMEs) as well as investigate the possibility to establish harmonised criteria for borderline products.

As a response to the above-mentioned goals, it was proposed to establish an EU-wide network of "innovation offices" (EU-IN) as a working group reporting to both HMA and EMA. Its purpose is to support the European Medicines Regulatory Network (EMRN) strategy in facilitating innovation across EU by enhancing the access of SMEs and innovators to the available regulatory guidance and support. All interested NCAs may join on a voluntary basis to enrich the EU Innovation Network.

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See websites for contact details

Heads of Medicines Agencies [www.hma.eu](http://www.hma.eu)

European Medicines Agency [www.ema.europa.eu](http://www.ema.europa.eu)

## 2. Mission

The objective of the EU Innovation Network is to facilitate the development of innovative medicines and technologies for drug development by addressing gaps in early regulatory support to innovation by:

- Making the regulatory support available at national and EU level more visible and attractive to innovators since early stage;
- Reinforcing dialogue with innovators with a wider EU exposure of identified issues;
- Providing a platform for regulators to share good practices and multidisciplinary expertise and improve the flow of knowledge from early stage innovators (with their agreement) to NCAs and to EMA scientific committees;
- Identifying and encouraging sponsors of promising drug development projects, including combination products, digital devices and therapeutics and advanced therapy medicinal products, to move into the next appropriate regulatory level for national and EU advice and evaluation;
- Actively contributing to and integrating into relevant EU initiatives enabling innovative medicines development and access to patients.

## 3. Mandate

- The EU-IN develops an annual work plan to be agreed upon by the EMA and the HMAs.
- The EU-IN provides the EMA and the HMA with an annual update of the activities undertaken.
- Share experience and knowledge; discuss case-studies, with the agreement of the sponsors, to identify challenging issues for emerging innovation and, as appropriate, identify leading experts in innovative fields;
- Act as an integrative element helping to solve the challenges faced in national scientific or regulatory advice related to human and veterinary medicines and medical devices. Contact actively with various groups associated with scientific or regulatory advice; or giving recommendation on the interpretation of guidelines (e.g. CTFG, SAWP, HTA bodies, Big Data TF, medical device authorities) aiming to avoid overlapping work and enhance collaboration and convergence of opinions;
- Foster collaboration, leverage communication and openness regarding innovation initiatives at European and international level, bridging activities and sharing competencies, experience and knowledge;
- Support the EU-NTC in identifying areas where training may be required to ensure the appropriate capability in the network;
- Discuss best practices so that the EU network builds on success and encourages the establishment of innovation contacts points/offices in more regulatory agencies;
- Provide a common model for successful horizon scanning for HMA and EMA for the identification of emerging trends that may require actions by the European Medicines Regulatory Network in collaboration with other regulators at global level (e.g. through ICMRA);
- Contribute to the consolidation of EU expert views on emerging and challenging topics relevant to innovative therapies and technologies, flagging issues that need regulatory guidance and support;

- Discuss and share opinions on borderline and classification issues (in collaboration with other groups involved with borderline questions). Share selected national decisions on borderline questions and identify possible divergent decisions for discussion. Give recommendations on classification issues;
- Promote the involvement and collaboration of EMA/HMA on the Innovative Medicines Initiative (IMI) projects and other EU level funding programs (e.g. Horizon Europe);
- Address specific topics at request of HMAs and EMA Scientific Committees.

## 4. Composition and governance

The EU-IN is composed by representatives nominated by the interested NCAs as well as of the EMA ITF.

- HMA and EMA have the oversight of the EU-IN. Members from participating NCAs will be joining on a voluntary basis.
- Representatives from other groups involved with scientific and/or regulatory advice (CTFG, HTA, medical device authorities etc.) can be invited on ad hoc basis to the meetings.
- The EU-IN is co-chaired for a term of three years by a NCA senior official nominated by the HMA and an EMA's senior staff member.
- The EU-IN provides HMA and EMA with a report on the evolution and performance of the network, including benefits of the network to its members according to its annual work plan.
- The EMA staff, in close collaboration with participating officials and scientific committees, will provide administrative and scientific secretariat to the EU Innovation Network.
- The mandate of the group will be reviewed by the HMAs and the EMA after three years of operations.

## 5. Meeting frequency and organisation

EU-IN will have annually 7-8 teleconferences and two face to face meetings in the context of a meeting on innovation with relevant stakeholders like SMEs and academic groups.

### ***Meetings***

- The chairpersons will draft preliminary meeting agendas.
- Draft agenda and accompanying documents shall be circulated to members, at least one week before the meeting.
- Draft minutes of a meeting shall be made available to members no later than 1 month after the meeting.

### ***Working Methods***

- In aspiration, agreement is reached by consensus.
- The EU-IN may nominate one of its members to be a rapporteur for a topic, possibly supported by a drafting group.

- The members representing innovation offices will provide a summary of their annual activities according to a template that is used to derive data that are required to collate an annual report to HMA and EMA.

### ***Expenses and accommodation***

- In principle, employers of the attendees of face-to-face meetings will pay the costs of accommodation and travel unless the meeting is hosted by EMA.

## **6. Communication with the HMA and EMA**

- The role of the chairs includes acting as a liaison between EU-IN and both HMA and EMA.
- Documents of the EU-IN for publication and advice directed to external stakeholders should be referred to the HMA management group and EMA for approval.
- In addition, upon request from the HMA Management Group or the HMA Permanent Secretariat or the EMA, the EU-IN shall provide a report to the HMA on specific topics. Such reports may be in writing or orally depending on the request.

## **7. Revision of the mandate**

The mandate should be reviewed periodically (normally three years), but can be reviewed any time at the request of the EU-IN or the HMA.