THE NEW EU INNOVATION NETWORK (EU-IN)

SME Info Day 17.11.2017

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Finnish Medicines Agency (Fimea)

Contents

WHY AN EU-INNOVATION NETWORK?

In 2015, EMA and EU national competent authorities strengthened their collaboration to support medicine innovation and early development of new medicines in the EU by establishing the EU innovation network.


HMA

30 September 2016

Mandate of the European Innovation Net
6 September 2016

1. Background

Innovative medicines development projects emerge throughout Europe,
Medium-Sized Enterprises (SMEs), hospitals and academia. The Innovat
opean Medicines Agency (EMA) and innovation offices of National Co-
important role in supporting innovation in an early phase of de
, dialogue and understanding of regulatory requirements.

EMA and the HMAs adopted the **mandate** of the EU Innovation Network in October 2016

Mission

- The objective of the EU Innovation Network is to facilitate the development of innovative medicines 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 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 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**.

KEY AIMS

Sharing experience and knowledge by discussing case-studies, with sponsor agreement, to identify challenges for emerging innovation and leading experts in innovative fields, where appropriate

Utilising the contacts of the NCAs with local academic groups and other innovators including SMEs, consortia etc.

Supporting the EU network training centre (EU-NTC) by identifying training needs in the regulatory network

Facilitating the establishment of innovation offices in other regulatory agencies through sharing best practices

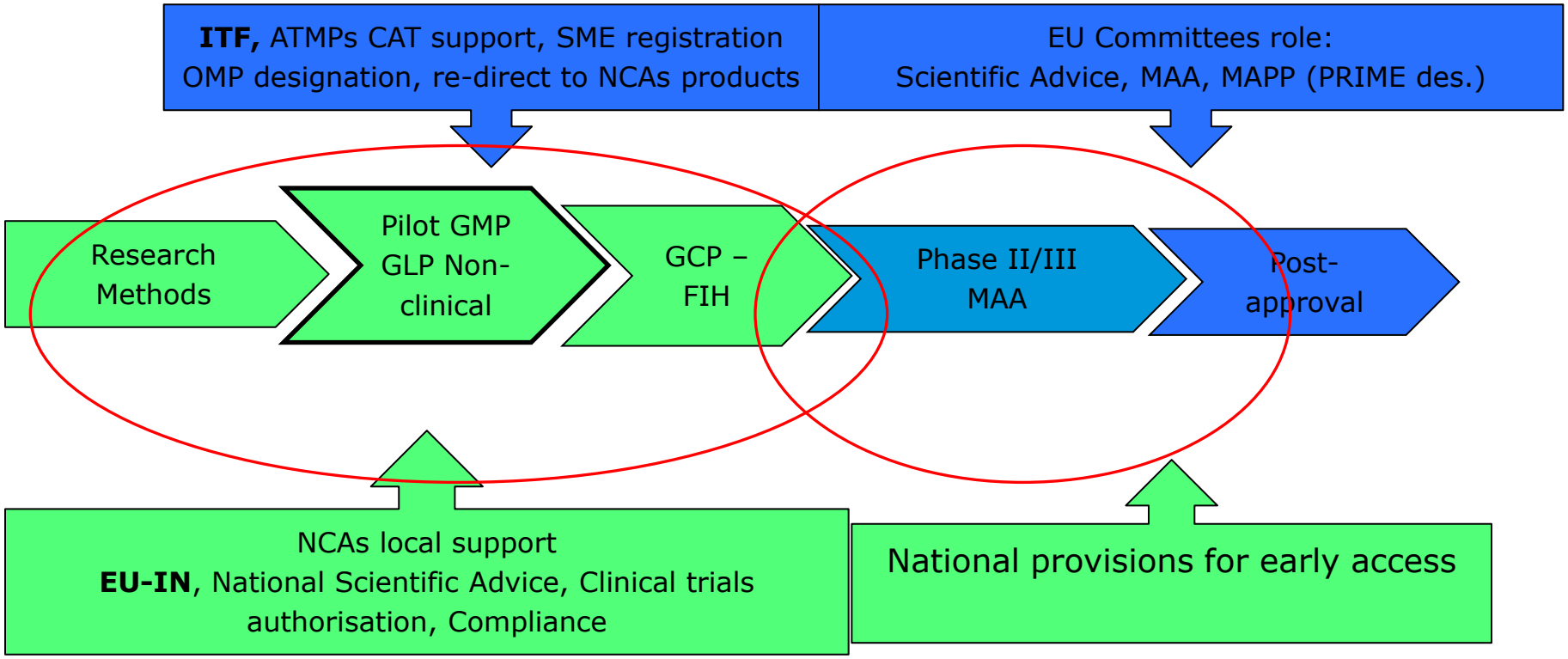
Identifying emerging trends that may require regulatory guidance and support by the European medicines regulatory network

Contributing to consolidating an EU expert view on topics relevant to innovative therapies and technologies

Promoting Heads of Medicines Agencies (HMAs) collaboration in the Innovative Medicines Initiative (IMI) projects

Addressing specific topics at the request of HMAs and EMA scientific committees

EU-IN for the EU seamless support to Innovation



Composition

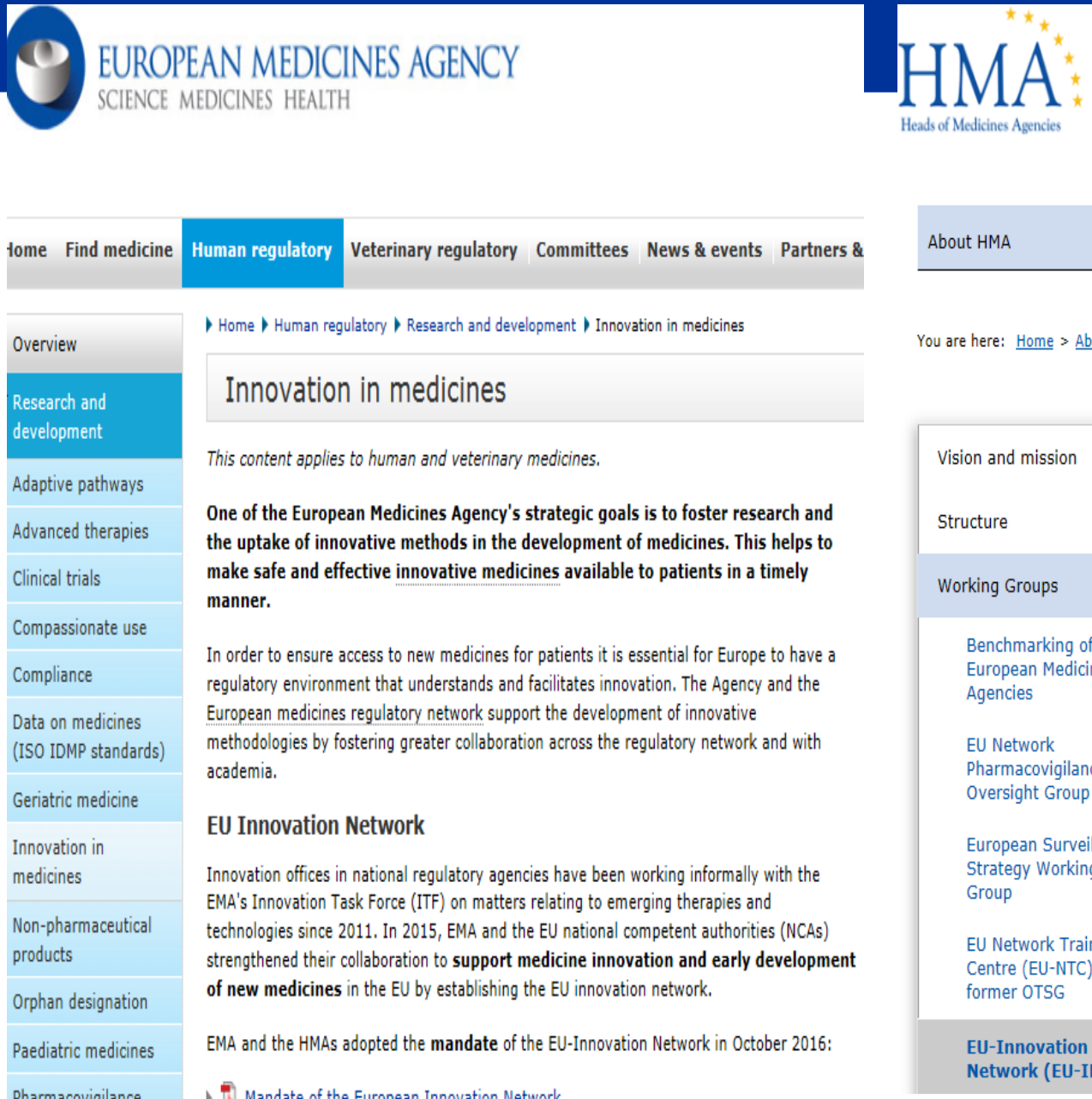
- The EU-IN is composed by representatives nominated by the interested NCAs as well as of the EMA ITF.
  - HMA and EMA have the oversight of the EU-IN. Members from participating NCAs will be joining on a voluntary basis.
  - The EU-IN is co-chaired for a term of three years by a NCA senior official nominated by the HMA (currently Esa Heinonen, Fimea) and an EMA's senior staff member (currently Marisa Papaluca).

Governance

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

Deliverables 2017

- Enhance visibility of the EU-IN e.g. via appropriate updates in EMA/HMAs web
- Draft format and pilot process for planning and reporting on activities to HMAs and EMA


EUROPEAN MEDICINES AGENCY
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Innovation in medicines
This content applies to human and veterinary medicines.
One of the European Medicines Agency's strategic goals is to foster research and the uptake of innovative methods in the development of medicines. This helps to make safe and effective innovative medicines available to patients in a timely manner.
In order to ensure access to new medicines for patients it is essential for Europe to have a regulatory environment that understands and facilitates innovation. The Agency and the European medicines regulatory network support the development of innovative methodologies by fostering greater collaboration across the regulatory network and with academia.
EU Innovation Network
Innovation offices in national regulatory agencies have been working informally with the EMA's Innovation Task Force (ITF) on matters relating to emerging therapies and technologies since 2011. In 2015, EMA and the EU national competent authorities (NCAs) strengthened their collaboration to support medicine innovation and early development of new medicines in the EU by establishing the EU innovation network.
EMA and the HMAs adopted the mandate of the EU-Innovation Network in October 2016:
Mandate of the European Innovation Network
About HMA
Human Medicines
Veteri
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Vision and mission
Structure
Working Groups
Benchmarking of European Medicines Agencies
EU Network Pharmacovigilance Oversight Group
European Surveillance Strategy Working Group
EU Network Training Centre (EU-NTC) - former OTSG
EU-Innovation Network (EU-IN)
EU-INNOVATION NETWORK (EU-IN)
EU-IN Introduction and Overview
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Key documents list

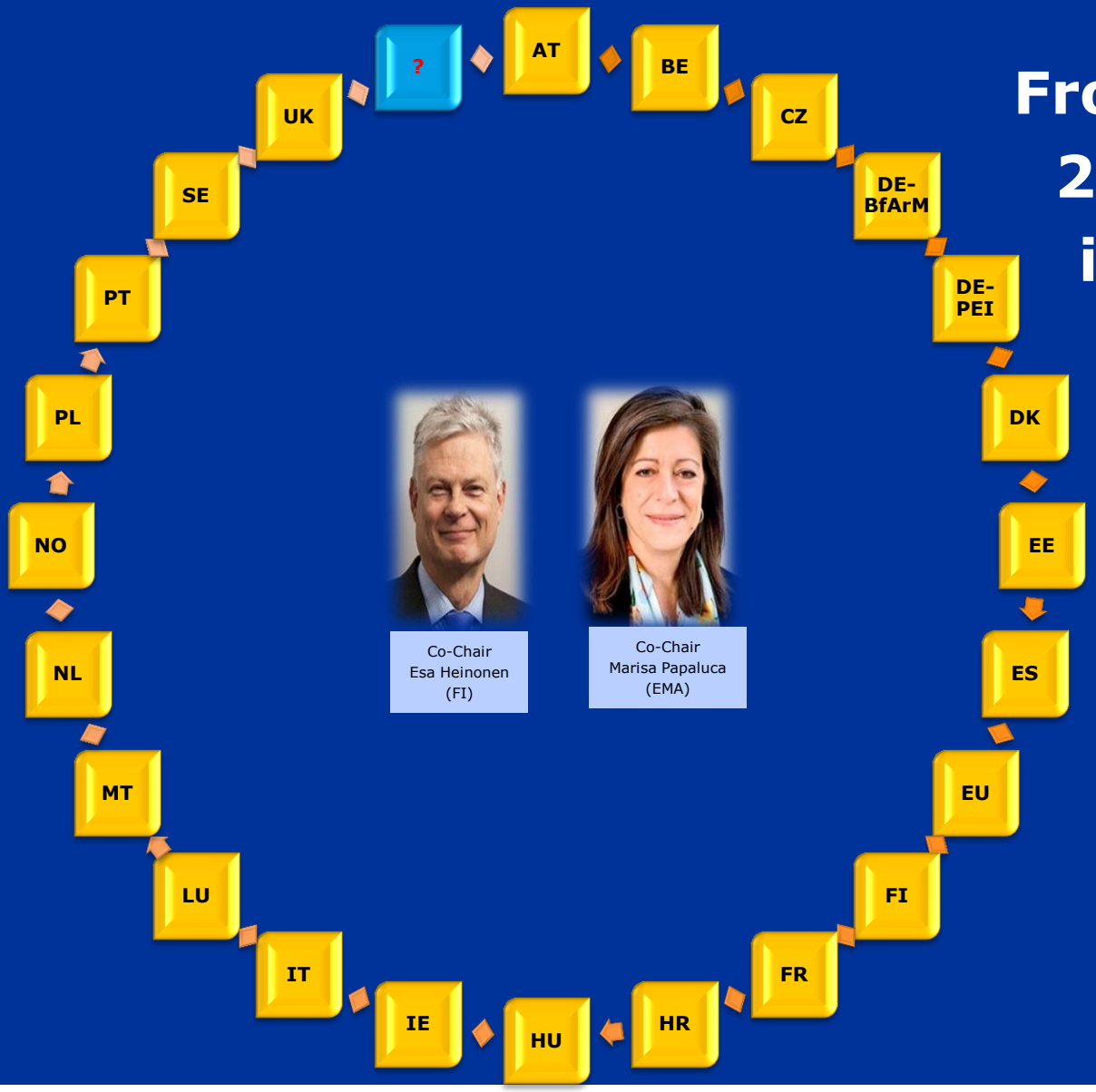
Deliverables 2017

- Reinforced EU-IN with extended membership of NCAs innovation offices

CURRENT COMPOSITION

EUROPEAN MEDICINES AGENCY

From 15 to 23 NCAs in 2017



Deliverables 2017

- Overview of the initiatives undertaken and stakeholders involved by Agencies to support promising innovative products in EU early in development

- Impact of measures taken – A drafting group has developed a questionnaire for regular feedback after each stakeholder interaction. (NL, PT and EMA)

Profile of the EU-IN core business

EUROPEAN MEDICINES AGENCY

The services of the Innovation Support Offices are directed to hospitals, academic groups and SMEs, research foundations, consortia.

Some have also expressed their willingness to hear from patient interest groups and or funding/networking organisations.

The scope is wide and includes along the lifecycle of products manufacturing processes, redaction of documents, facilities, GMP, import/export issues, antimicrobials, biostatistics, preparations for scientific advice meetings, pharmacovigilance, and HTA/Payers interactions

Deliverables 2017

- List of emerging challenges from innovative products discussed
- Identified regulatory science topics which require NTC training coordination

  - A preliminary list of emerging challenges and interesting cases has been already identified
  - Further case studies to be done (when more detailed data are provided by customers)
  - Nanomedicines and novel manufacturing strategies (e.g. 3D printing) have been flagged

Deliverables 2017

- Pilot the tracking of the companies' journey in the national and EU regulatory pathway after the initial contact and discussion in the EU- IN
  - To be done when concrete cases moving to PRIME or other EMA platforms are identified

Deliverable: DRAFT Map MS involvement in 19 IMI projects

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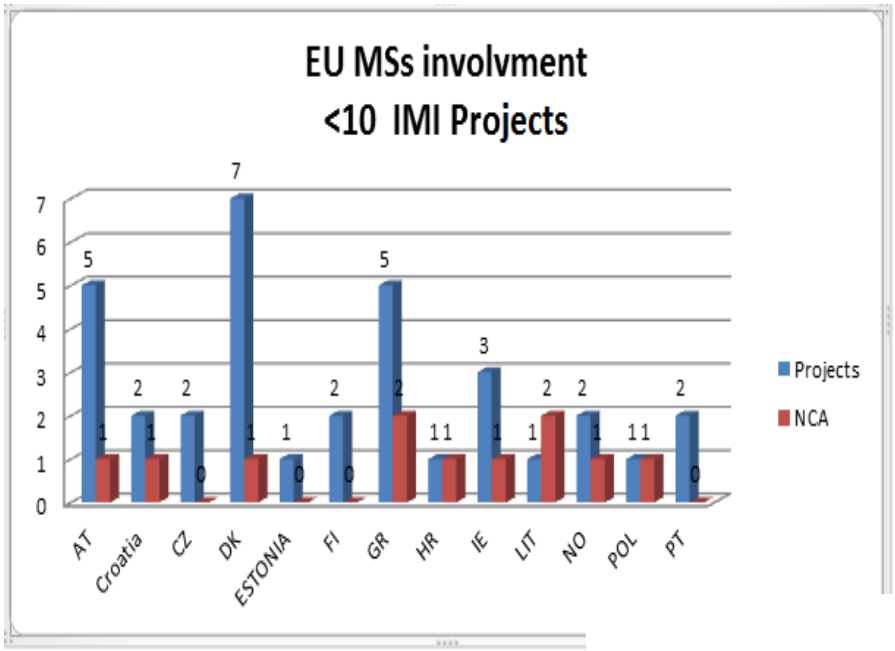
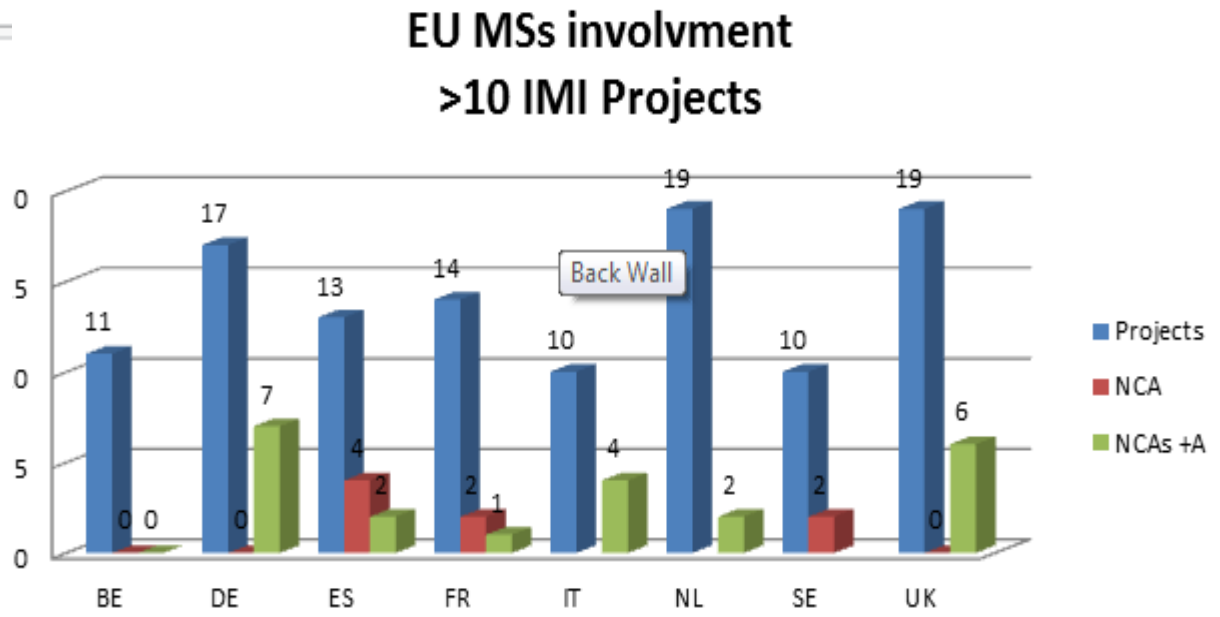


Pilot map of engagement being analysed.



Deliverables 2017

Develop Horizon scanning

- Drafting group establised to explore methodology and format for sharing and consolidating current approaches for horizon scanning (IE, ES, HU, UK, DE (PEI) and EMA)

Related HMA Working Group

- Borderline products – The HMA agreed to proceed with the establishment of an additional working group on MD-MP classification issues (UK, IE, BE and EMA).

EUROPEAN MEDICINES AGENCY

European Commission

Horizon 2020, DG Research and Innovation: Strengthen *Regulatory Sciences* and support for regulatory *Scientific Advice*

EU Innovation Network

Meeting 16.11.2017

HORIZON 2020

Conclusions

- We are strengthening the EU-IN in order to:
  - Share knowledge between the various Innovation Offices of NCAs and the EMA
  - Develop best practices for horizon scanning
  - Flag regulatory issues to be discussed at EMA level
  - Discuss about training needs of assessors with the EU Network Training Center
  - Improve our capabilities to help innovators – academic groups, SMEs, larger companies – to bring innovation forward from national level to EU level

Get in touch with us! > National innovation offices:

EU-IN	European Innovation Network / Secretariat@ema.europa.eu
EMA	European Medicines Agency (EMA) / itfsecretariat@ema.europa.eu
Belgium	Federal Agency for Medicines and Health Products (FAMHP) innovationoffice@fagg-afmps.be
Czech Republic	Státní ústav pro kontrolu léčiv (SUKL) innovation@sukl.cz
Denmark	Danish Medicines Agency (DKMA) innovation@dkma.dk
Germany	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) innovation@bfarm.de
Germany	Paul-Ehrlich-Institut (PEI) innovation@pei.de
Estonia	State Agency of Medicines innovatsioon@ravimiamet.ee
Ireland	An tÚdarás Rialála Táirgí Sláinte / Health Products Regulatory Authority (HPRA) innovationoffice@hpra.ie
Spain	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) innov_spain@aemps.es
France	Agence nationale de sécurité du médicament et des produits de santé (ANSM) innovation@ansm.sante.fr
Croatia	Agencija za Lijekove i Medicinske Proizvode (HALMED) innovation@halmed.hr
Italy	Agenzia Italiana del Farmaco (AIFA) innovation.office@aifa.gov.it
Luxemburg	Division de la Pharmacie et des Médicaments jacqueline.genoux-hames@ms.etat.lu
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYEI) innovation.office@ogyei.gov.hu
Malta	Awtorità dwar il-Mediċini (Medicines Authority) innovation.medicinesauthority@gov.mt
Netherland	College ter Beoordeling van Geneesmiddelen (MEB) _Dienstpostbus_Innovation@cbg-meb.nl
Austria	Bundesamt für Sicherheit im Gesundheitswesen (BASG-AGES) innovation@ages.at
Poland	Urząd Rejestracji Produktów Leczniczych, Wyrobow Medycznych i Produktów Biobójczych innowacjaPL@urpl.gov.pl
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED) garc@infarmed.pt
Finland	Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA) innovation.office@fimea.fi
Sweden	Läkemedelsverket (MPA) Registrator@mpa.se
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA) innovationoffice@mhra.gov.uk
Norway	Statens legemiddelverk (NOMA) Ask-us@legemiddelverket.no

Innovators meet regulators

EU-IN event at the EMA Annual SMEs Workshop 17 Nov 2017

> Welcome to the EU Innovation Network // EU-IN

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SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

Thank you for your attention !