



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Engagement with stakeholders

2nd International Awareness Session - The EU medicines regulatory system
and the European Medicines Agency

Presented by Juan Garcia Burgos and Marie-Helene Pinheiro on 8 March 2018
Stakeholders and Communication Division

An agency of the European Union





EMA Stakeholder engagement principles

Context, background and objectives

Principles and Frameworks



An interaction foreseen by EU Legislation

Article 78

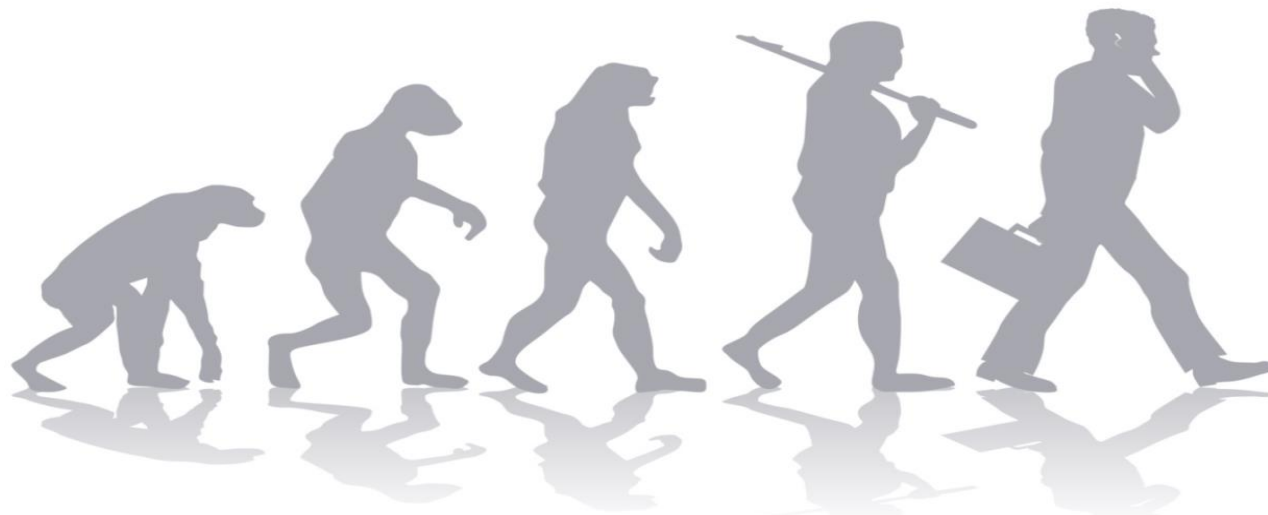
1. The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the health professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

2. The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees may, on an advisory basis,

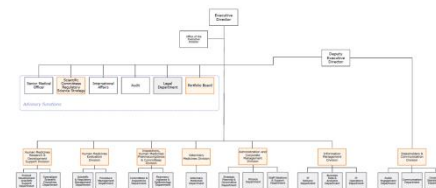


The EMA has been interacting with its stakeholders on various levels since its creation.

A natural evolution...



*Need for common principles, better coordination
and streamlining?*

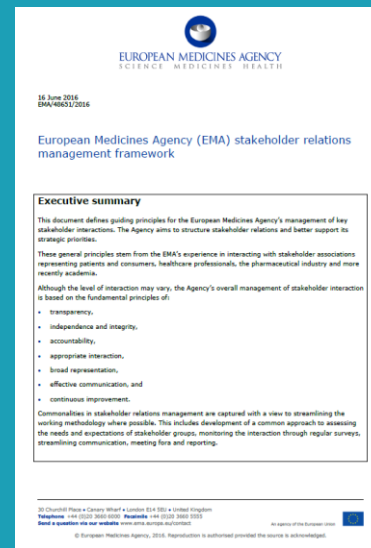


Stakeholder interaction must be based on the fundamental principles:

- *Transparency*
- *Independence and integrity*
- *Accountability*
- *Appropriate interaction*
- *Broad representation*
- *Effective communication*
- *Continuous improvement*

EMA Stakeholder Relation Management Framework

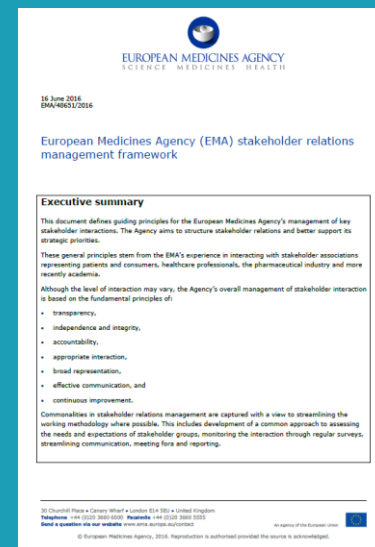
June 2016

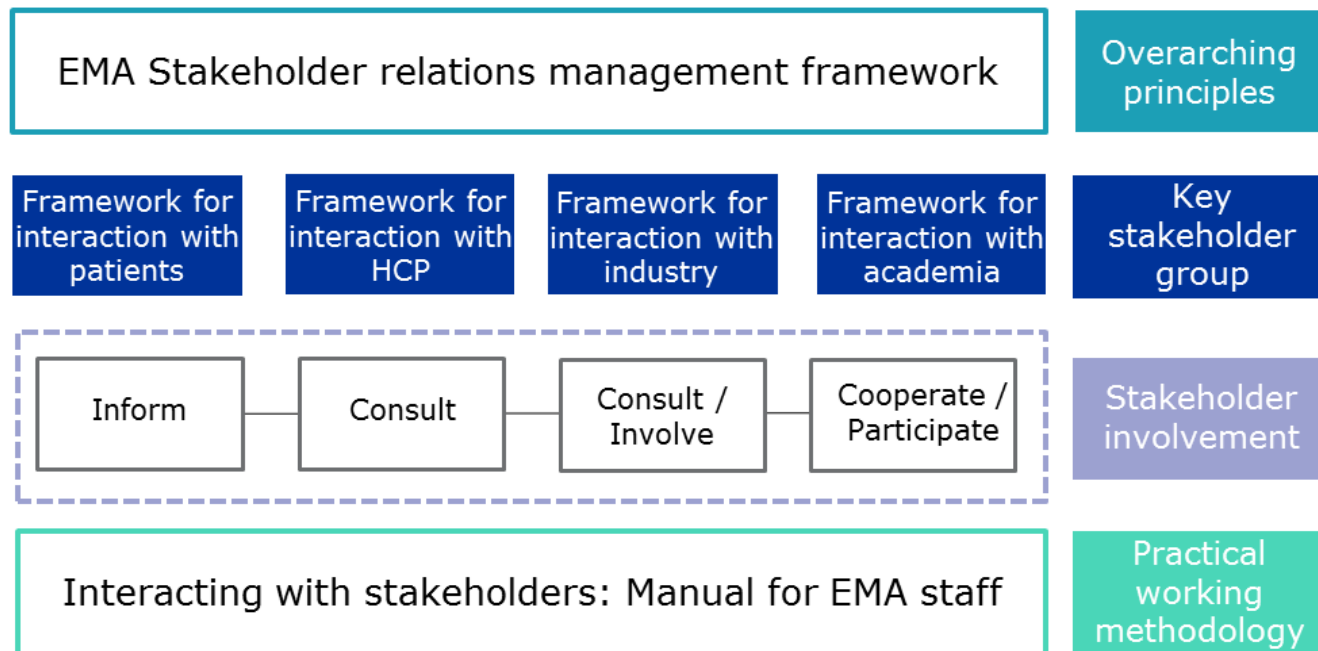


Agency aims to:

- Promote appropriate *engagement and dialogue*;
- Provide *efficient, targeted and timely information*, in a *proactive manner*;
- Enhance stakeholders' understanding of the *EU medicines Regulatory network* and enrich EMA's understanding of issues that are pertinent from the stakeholders' perspective;
- Increase *transparency* on how EMA engages with stakeholders;
- Structure stakeholder relations and *better support EMA's strategic priorities*.

EMA Stakeholder Relation Management Framework June 2016





Together, these building blocks ensure a **consistent approach to stakeholder relations management** across a variety of stakeholder groups and interaction types.



EMA Stakeholder engagement

Interactions with stakeholder groups

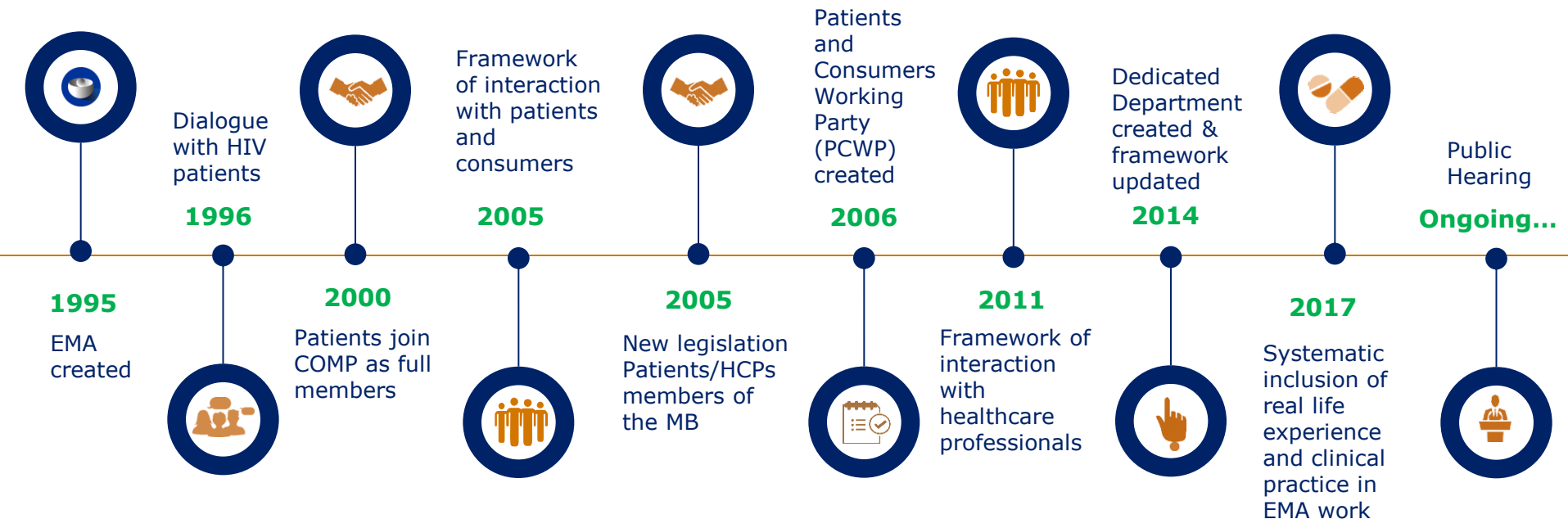


EMA Stakeholder engagement

*EMA and **patients, consumers and healthcare professionals***



A long journey...



Patients' and consumers' organisations



Learned societies/ healthcare professional organisations





Framework and working party

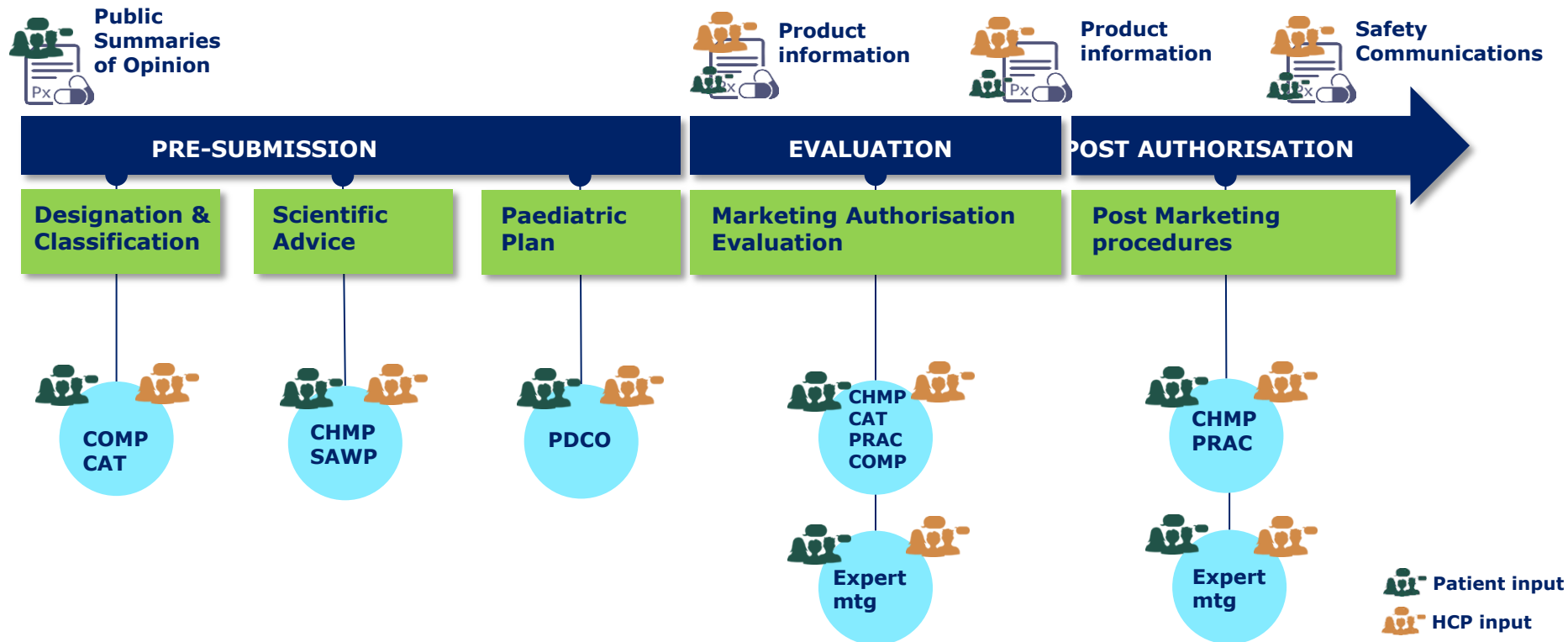


Healthcare Professionals' Working Party (HCPWP)



Patients' and Consumers' Working Party (PCWP)

Involvement along the medicine lifecycle at EMA



How does EMA engage?



What support and resources are available?



Annual training day



Videos; EMA basics



Info-sheets



Webpages



One-to-one personalised support



EMA Stakeholder engagement

*EMA and **academia***



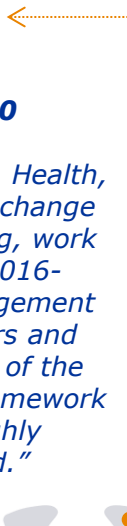
Closing the gap between academia and regulators: *a reality*



European Council conclusions on innovation for the benefit of patients (1-12-2014): "...in order to stimulate development, there is a need to facilitate the translation of scientific advance into innovative medicinal products that meet regulatory standards".



Horizon 2020 framework programme: Health, demographic change and well-being, work programme 2016-2017 "...Engagement with regulators and consideration of the regulatory framework issues are highly recommended."

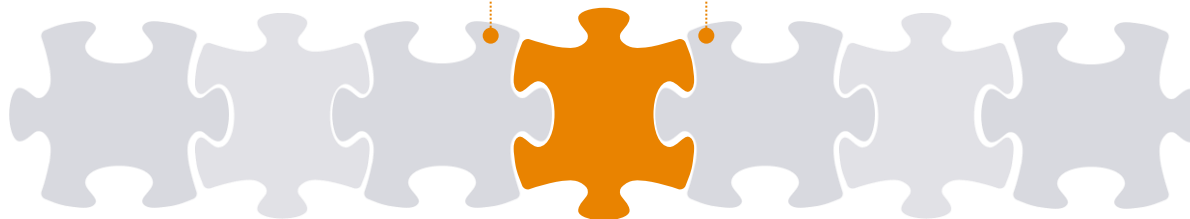


EU Medicines Agencies Network strategy to 2020 "...support for patient focused innovation and contribute to a vibrant life science sector in Europe."



EUROPEAN MEDICINES AGENCY
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European Medicine Agency work plan 2016-2017 "...the Agency will support a strengthening of the collaboration and integration across the network and with academia..."

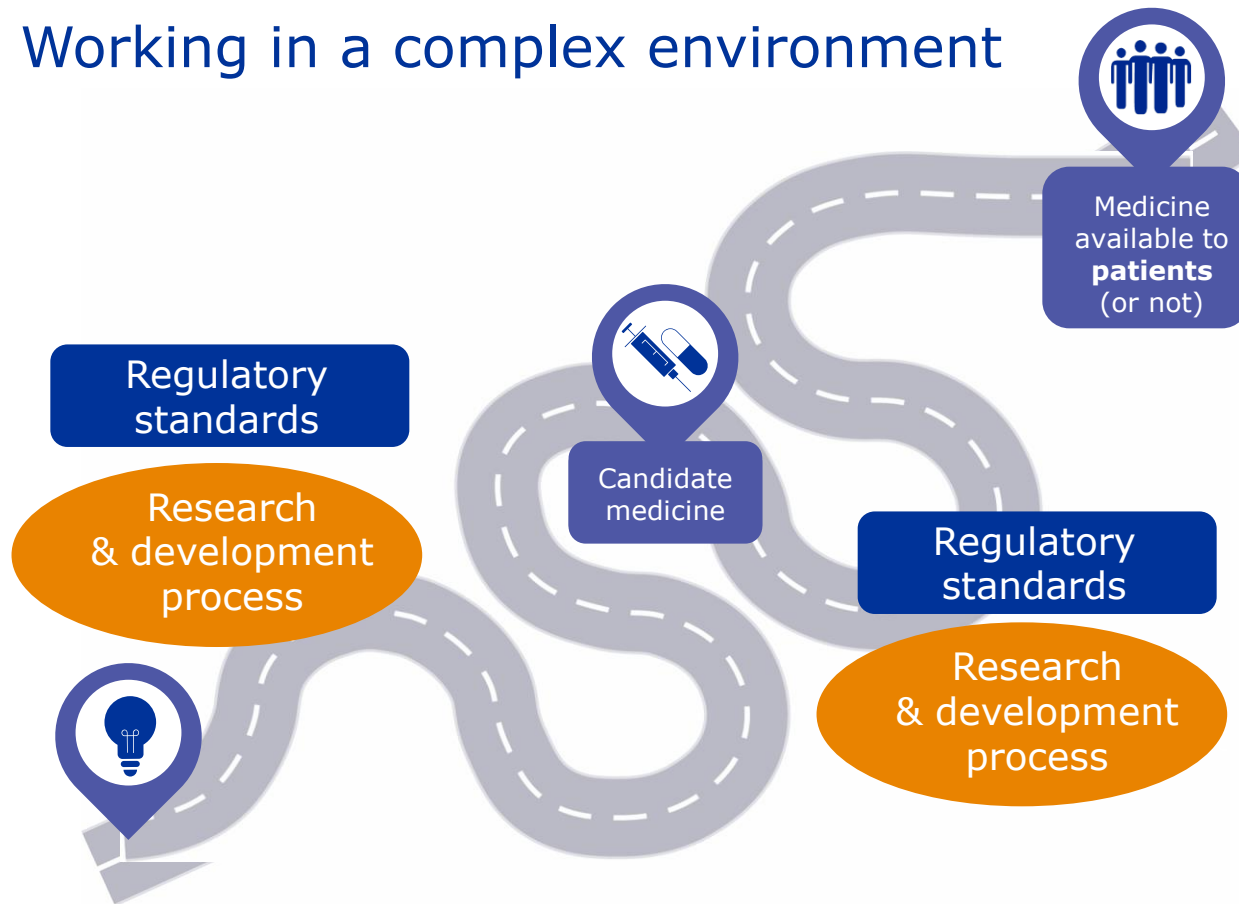


EMA and academia

- *There has always been an interaction between academia and regulators*
- *No direct mention of academia in regulations - many references to regulatory decisions based on **scientific evidence***
- *Framework created supporting **interaction and dialogue** between EMA, academia and broader EU scientific communities*
- *Revised healthcare professionals framework focused primarily on clinical practice*
- *Academia framework focuses on **research and education***
- *Common objectives shared in both frameworks*



Working in a complex environment





Framework of collaboration
with academia



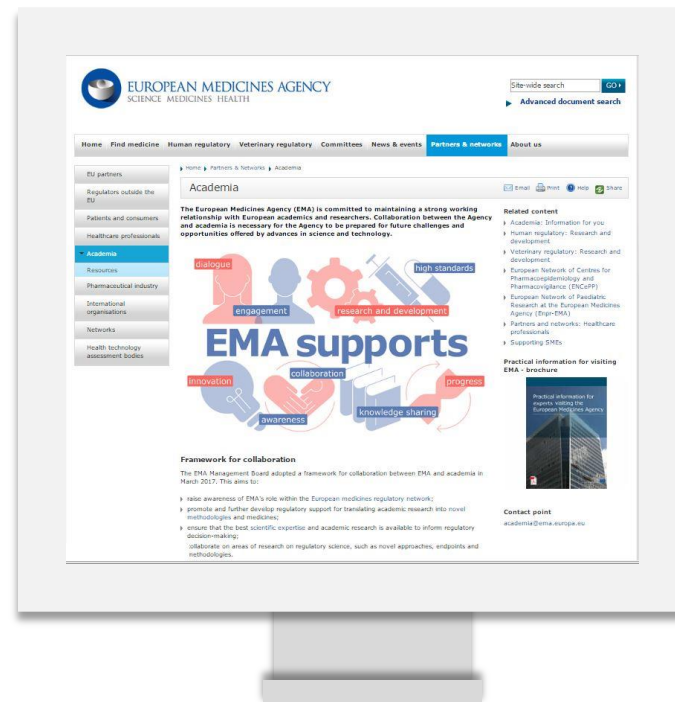
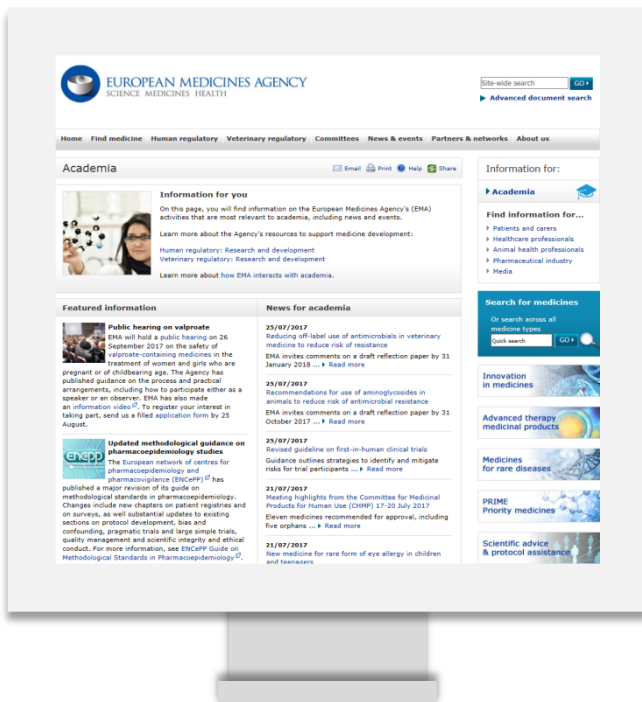
Academics and researchers and the EMA

The framework objectives are:

- Raise **awareness** of the work of the European medicines regulatory network
- Promote and further develop the **regulatory support** to academic research
- Support timely and effective evidence generation, regulatory **advice and guidance**
- Work in **collaboration** with the regulatory network in developing regulatory science



Academia web pages



Promoting multi-stakeholder discussions



- **Advanced therapy medicines:** exploring solutions to foster development and expand patient access in Europe
- Identifying opportunities for '**big data**' in medicines development and regulatory science
- **E-Health** initiative
- **Shortages** and medicines **availability**



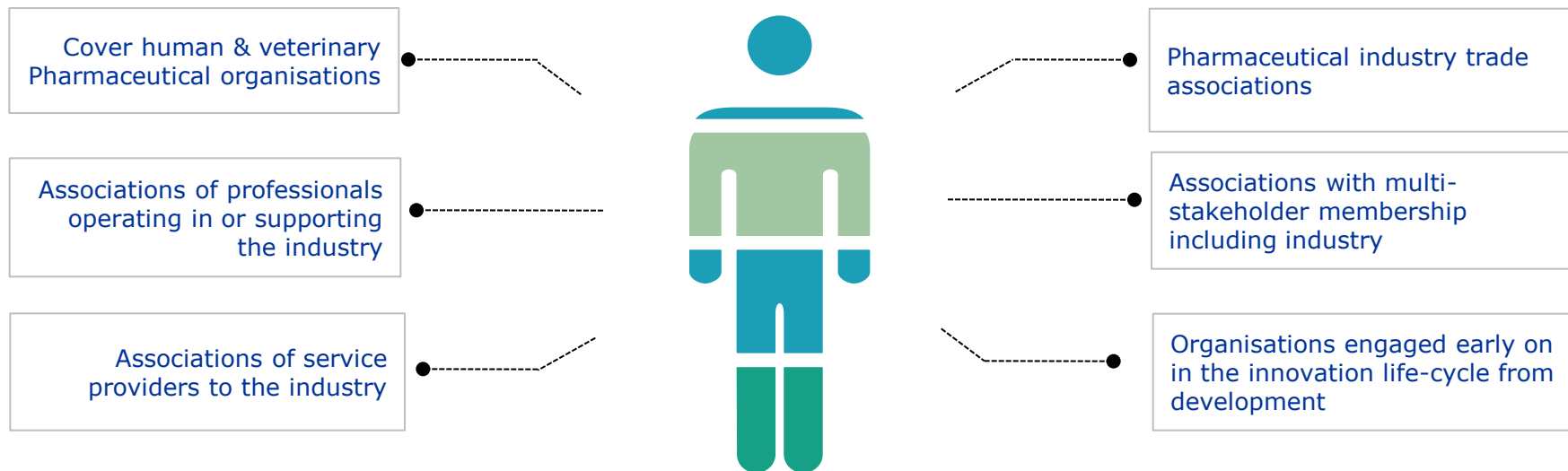
EMA Stakeholder engagement principles

*Interactions with **Industry Stakeholders***

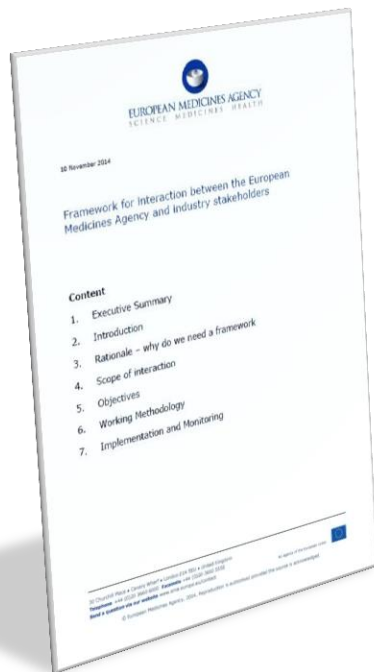
Scope of interaction – Who?

Industry stakeholders are organisations, associations and parties interacting with EMA which have interest in or are affected by the work of the Agency and its partners.

- *Interaction with industry "trade" associations*
- *NOT routine interaction with individual applicant companies*



Framework for interaction between EMA and industry associations



Purpose

Aims to **formalise** and **structure** our interaction with industry stakeholder groups.

Scope

Framework will **cover interaction** between Agency and industry associations.

Implementation

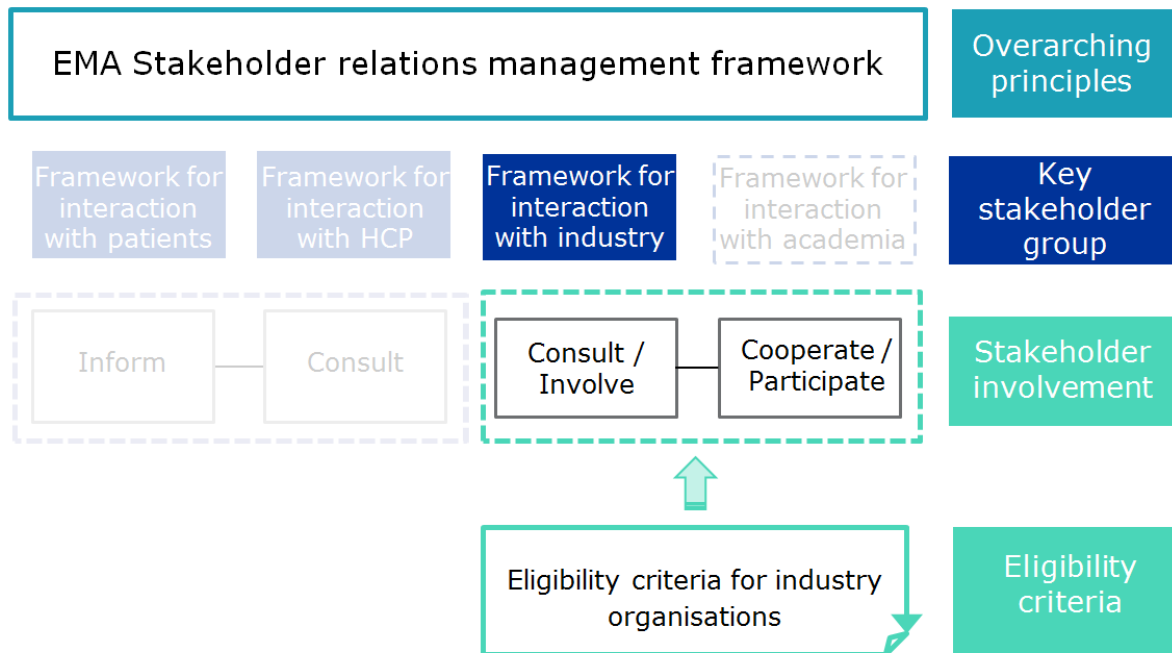
Monitoring and reporting on the interaction.

Key principles

- Facilitate & **streamline** communication
- **Structured** interaction
- **Accountability**
- **Transparency**
- **Broad representation** of the industry

Eligibility criteria for industry

These criteria do not apply to the Agency procedure for external consultation on documents, since such consultation is open to all external parties.



- Drawn up to ensure participating associations represent the broadest array of relevant pharmaceutical industry stakeholders.
- Designed taking into account the general principles for stakeholder consultation outlined in the European Commission's Better Regulation package.

Eligibility criteria for industry

- **Legitimacy:** EU wide representation with interests of a specific constituency; a legal entity registered in one of the Member States of the EU/EEA; non-for-profit.
- **Activities:** Clear defined mission/objectives and a legitimate interest in the areas of work of the EMA; a specific interest in medicinal products for human or veterinary use.
- **Entry in European Commission EU Transparency Register**
- **Representation:** Representative of all its members/affiliations throughout the EU/EEA with processes in place supporting information flow.
- **Structure:** Governing bodies, which are elected by their members, where applicable.

- The names of eligible industry stakeholder organisations will be published on the EMA website.
- The implementation of these eligibility criteria will be monitored and may be subject to review as experience is gained.





Important topic-driven meetings and targeted consultation

*Industry **consultation** on:*

- Operation of the **EU Medicines Regulatory Network** – EU Medicines Agencies Network strategy to 2020 – [April 2015](#);
- **EU Telematics implementation**: WS on Common submission portal – April 2015 and consultation on draft EU telematics strategy and road map [2015-2017](#);
- **New transparency measures** to implement EU Clinical Trial Regulation & Agency's **policy on publication of clinical data** (policy0070) [August 2015-December 2016](#);
- New scheme to reinforce support to human medicines for unmet medical needs (**PRIME**) [October 2015](#)

EU medicines Agencies Network Strategy to 2020



EU medicines Agencies Network Strategy to 2020

- 
HMA
Head of Medicines Agency
- 
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINE PEOPLE
- 17 December 2015
EMA/981314/14/2015
- EU Medicines Agencies Network Strategy to 2020**
Working together to improve health
- See website for contact details
- Head of Medicines Agency: Anne Zlotnik
European Medicines Agency, rue de la Woluwe 65
1200 Brussels, Belgium
- The European Union has the honour to sponsor this report of the Council of the EMA
- 



SME office: a single contact point to promote innovation and development of new medicines by Small and Medium Enterprises

- 1 Assignment of SME status
- 2 Regulatory Assistance
- 3 Fee Incentives
- 4 Translation Assistance
- 5 Training and Awareness
- 6 Partnering & Networking

sme@ema.europa.eu



Thank you for your attention

Acknowledgements

Ivana Silva
Nathalie Bere
Monica Ensini

Juan.Garcia@ema.europa.eu

Marie-Helene.Pinheiro@ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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Common challenges

- How to collect and use patient experience and clinical practice data: need for further research?
- Capacity-resources-funding
- Fair representation
- Outreach-engagement
- Managing potential conflicts of interest





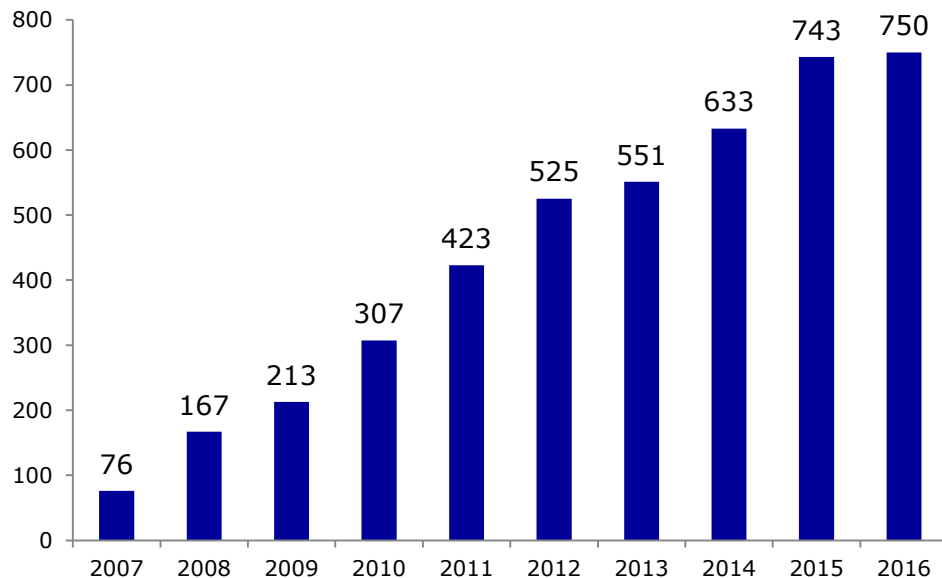
Healthcare professionals – who are they?

- *General practitioners and family physicians*
- *Hospital pharmacists*
- *Pharmaceutical group*
- *Nurses (specialised or general)*
- *Specialists (e.g. diabetes, oncology, epilepsy, geriatrics, paediatrics...)*

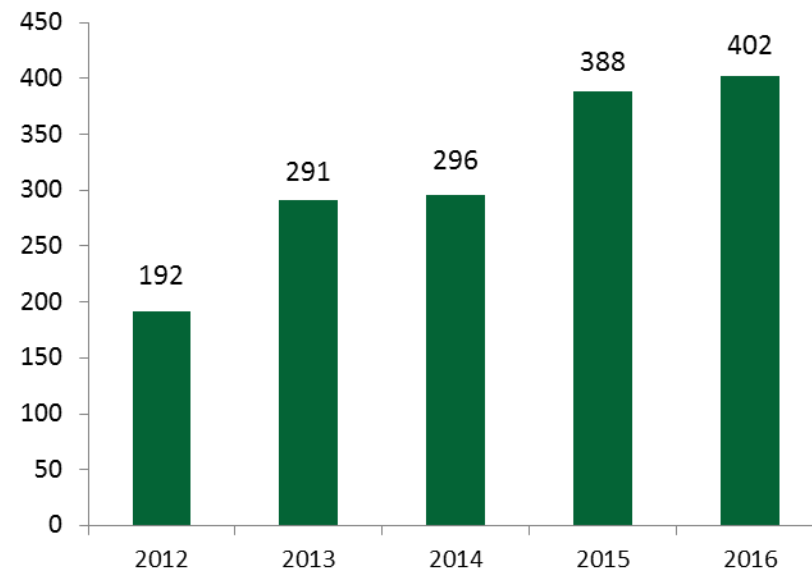


Increasing involvement in EMA activities

Patients and consumers (2007–2016)



Healthcare professionals (2012–2016)





Challenges for healthcare professionals

- *Maintaining **interest** and levels of **participation** in EMA activities*
- *Ensuring consistency in provision of **feedback***
- *Providing **contextualised information** of EMA activities*
- *Striking the **right balance** between clinical practice and academic/research interests*
- *Expanding **outreach***
- *Research how to **collect and use** the wealth of information available from healthcare professionals in post-marketing phase*



Challenges for academia

- Building of an effective **working model** for enhancing and fostering collaboration
- Creation of a **space of convergence** that would allow for changes in the modus operandi on both sides while balancing between the constraints of regulation and the free breathing space of research and innovation.
- Capacity and financial **resources** represent a major challenge for academics
- **Communication and engagement** are key areas



Individuals – database



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Involvement in EMA activities: registration for interested individuals

Personal Details

First Name	Last Name
Nationality	Country of Residence
Phone	Email Address
Education (Optional)	Languages Spoken

Representation

☐ Patient ☐ Consumer ☐ Carer ☐ Healthcare Professional ☐ Academic ☐ Other

Membership/Affiliation

Patient / Consumer Organisation

To select an "EMA eligible" organisation, click here ☐ [\[+\]](#)

EMA Committee

EMA Working Party

EMA is reaching out to individual patients interested in getting involved in Agency activities or receiving information.

Registration is available via the website along with Question and Answer document.

Registration form enables individuals to highlight areas of interest.