EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Looking towards 2020 – Our Strategy for Public Engagement

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An agency of the European Union

EMA Stakeholder engagement – the journey thus far

Context, background and objectives
Principles and Frameworks

EMA Stakeholder engagement principles

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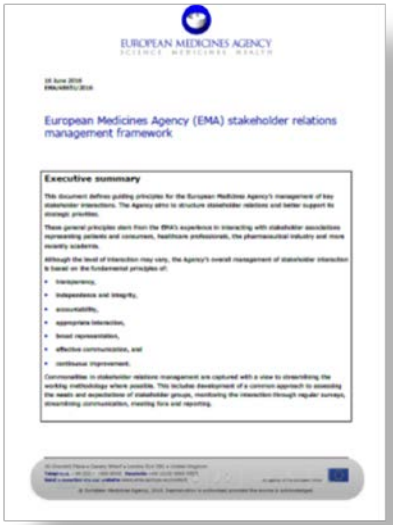
EMA Stakeholder Relation Management Framework – June 2016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European Medicines Agency (EMA) stakeholder relations management framework

Executive summary

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

Sets out fundamental principles that all our stakeholder interaction should be based on

EMA Stakeholder engagement principles

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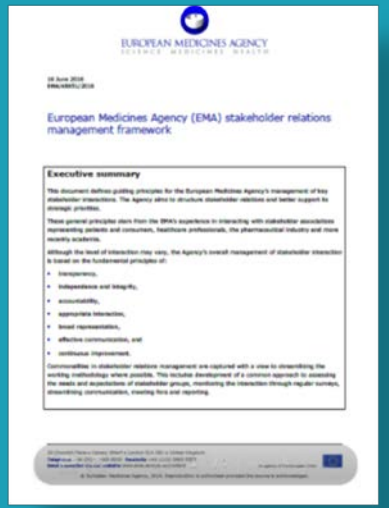
Agency's aim to:

- *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



EMA Stakeholder engagement principles

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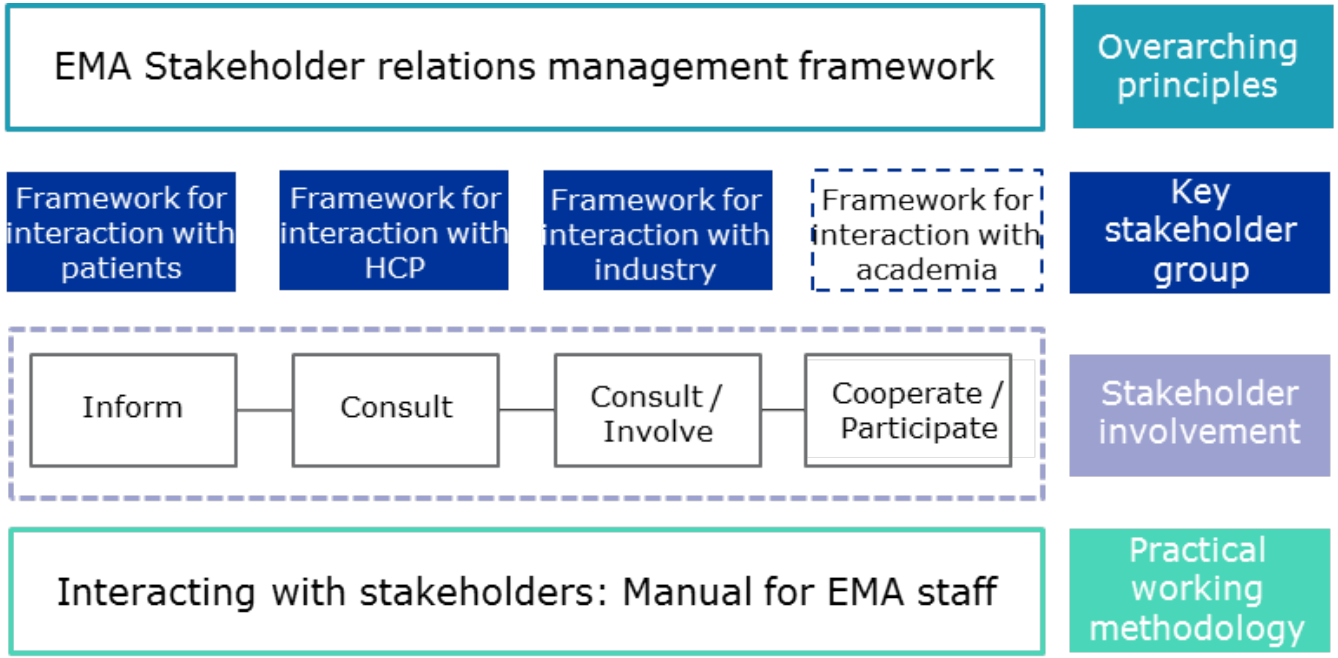
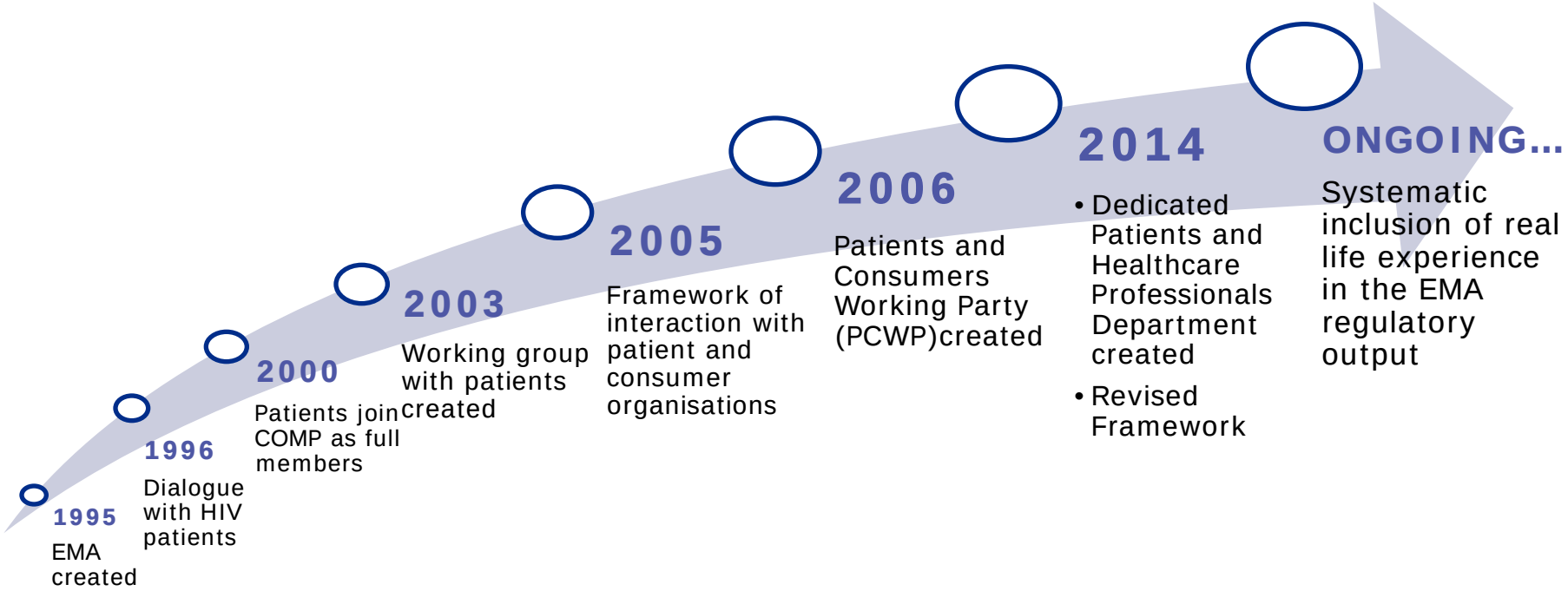


Together, these building blocks ensure a consistent approach to stakeholder relation management across a variety of stakeholder and interaction types.

Interaction with patients – our journey



EMA and its stakeholders within medicines lifecycle

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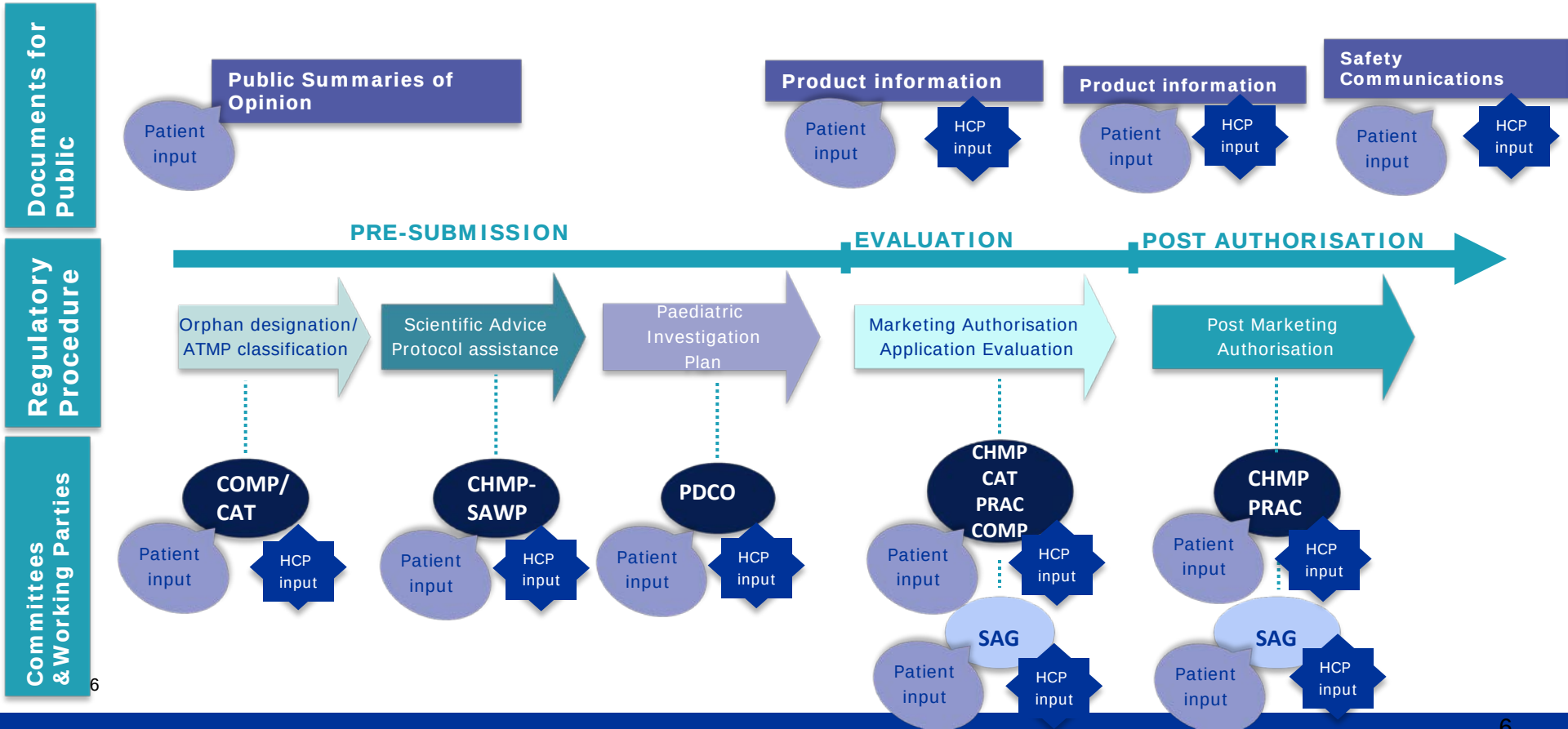
Patients / healthcare professionals involvement in EMA activities along medicines' lifecycle



EMA Stakeholder engagement – what next ?

Vision to 2020 & strategic objectives

EU Medicines Agencies Network Strategy to 2020

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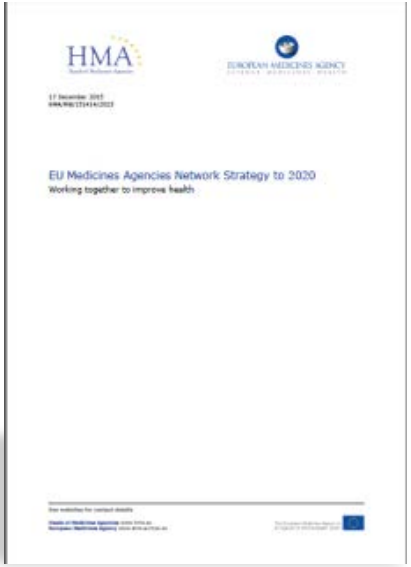
- Joint EMA and MS's high-level vision to 2020
- Lists joint key strategic priorities
- Complemented by MAWPs (multi-annual work plans) for EMA, HMA, CMDh and v

EU Medicines Agencies Network Strategy:

Strategy structured in 4 strategic themes

1. Contributing to human health
2. Contributing to animal and human health in relation to veterinary medicines
3. Optimising the operation of the Network
4. Contributing to the global regulatory environment



For each strategic theme, strategic objectives have been set

EMA Stakeholder engagement - strategic objectives

- Support achievement of Agency priorities
- Working closely with partners and stakeholders
- Provide high quality information on medicines

Theme 1: Contributing to Human Health

- Improve provision of information to patients and prescribers
- Discuss use of individual patient level data from clinical trials to help b/r decision making.

- Capture & incorporate patients' values and preferences into the scientific review process
- Explore how best to include patient & societal input into pharmaceutical innovation & regulation

Theme 3: Optimising the operation of the Network

- Working closely with “expert” patient community
- Involve patients, HCPs, academia to further integrate clinical practice & real life experience of disease and its management along a medicine’s lifecycle

- Capture communication needs and expectations of patients and stakeholders
- Share information on medicines within the network and with stakeholders

European Medicines Web Portal: Vision statement

- Make available free, reliable, unbiased online information on medicines for patients, consumers, carers, healthcare professionals and academia across the European Union
- Publish through a multilingual website interface key information on authorised medicines in Europe (irrespective of the licensing route) and provide clear signposting for audiences to information on national medicines agency web portals
- Provide a unique overview of the lifecycle of a single medicine (from clinical trial information until adverse drug reaction reports)
- Support high-level European initiatives on data availability (EU open-data agenda, Digital Agenda for Europe) by providing downloadable, consumable datasets
- Multi-annual project: building content and services over time and supported by implementation of SPOR and ISO-Standards on Identification of Medicinal Products (IDMP)

Thank you for your attention