EMA
EUROPEAN MEDICINES AGENCY

Engagement with Industry stakeholders

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Stakeholders' definition

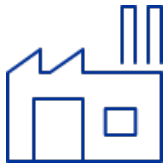
Stakeholders are defined: as organisations, associations and parties interacting with the European Medicines Agency, which have an interest in or are influenced by the work of the EMA and its partners.

EMA **key stakeholders' groups**:

Patients/Consumers organisations

Academia

Healthcare professional organisations



Industry organisations

Interactions are supported by an EMA stakeholders' database, which centralises stakeholders' contact details and areas of expressed interest in EMA activities and allows us to communicate with them in a targeted, effective and systematic manner.

Published frameworks

- EMA stakeholder relations management framework.
- Engagement framework: European Medicines Agency and patients, consumers and their organisations
- Revised framework for interaction between the European Medicines Agency and healthcare professionals and their organisations
- Framework for interaction between the European Medicines Agency and industry stakeholders
- Framework of collaboration with academia

Goals and objectives of stakeholder engagement

- facilitate implementation of EMA's priorities and new legislative proposals;
- Ensure informed EMA decisions that meet stakeholder's needs

- raising awareness and understanding of EMA's evolving role and its work

- reinforcing legitimacy of EMA actions and trust in the scientific and regulatory outcomes and in the EU system

Specific stakeholder's frameworks

EMA stakeholder's management framework

Overarching principles

Patients & consumers

Healthcare professionals

Industry EU trades

Academia

Key stakeholder's groups


INFORM


CONSULT


CONSULT & INVOLVE


COOPERATE & PARTICIPATE

Stakeholder's involvement

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

Industry stakeholders' framework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2 October 2015
EMA/591272/2014

Framework for interaction between the European Medicines Agency and industry stakeholders

- Pharmaceutical industry landing page
- Pharmaceutical industry webpage

PURPOSE

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

SCOPE

Framework covers 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

Industry EU trades involvement

INFORM

to enable feedback

- Announcement of review of policy or guidance
- Public events: info days, trainings, webinars

CONSULT

written consultation

- Public consultation on policies, guidance, strategies
- Surveys
- Q&As

CONSULT & INVOLVE

direct interaction

- Industry Standing Group
- EMA-Industry EU trade bilateral meetings
- R&D, CP, PhV platform meetings
- Targeted consultation meeting
- Interested Parties meetings (WP/Committees)
- Workshops, conferences

COOPERATE & PARTICIPATE

engaging towards a common technical goal

- Focus Groups
- Technical expert Group
- Implementation Working Group

CONSULT & INVOLVE
direct interaction

Industry Standing Group (ISG)

- Established in 2022, enables regular dialogue with industry stakeholders on strategic topics relating to human, veterinary medicines and medical devices (e.g. critical medicines act, REACH, EMANS, PED, PMS).
- This group also facilitates the implementation of new legislation in the European Union (EU) (e.g. HTAR, extended mandate, revised pharmaceutical legislation).
- Members: representatives of eligible industry stakeholders' organisations.
- Observers: EU network (EC, CHMP, CMDh, CVMP, CMDv), medical device, notified bodies.
- Quarterly meetings with publication of agendas, presentations and highlights.

Other Ad hoc observers may be invited to participate in ISG meetings and can include representatives of patients, consumers and healthcare professionals' organisations, other industry stakeholders' organisations, national competent authorities, European agencies and any other relevant EMA stakeholders.

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direct interaction

Industry annual bilateral meetings

- Annual bilateral meetings with pharmaceutical industry associations: the purpose is to exchange views and promote dialogue on high level and strategic topics of common interest.
  - Business priorities and pipelines forecast
  - Specific challenges/proposals organisation specific
- Attendance of EMA ED/DED and relevant management.
- Organised upon request from the Industry organisation.
- Publication of agendas and highlights.

CONSULT & INVOLVE
direct interaction

Industry stakeholders' platforms

- platform meetings with representatives of the pharmaceutical industry to address operational aspects linked to research and development for medicines, the centralised marketing authorisation procedure and pharmacovigilance.
- Publication of agendas, presentations and highlights.

R&D platform: address evidence generation during the life-cycle of medicines; focus on development support activities such as scientific advice and qualification, as well as on pediatric and orphan medicines.

2 meetings/year led by Evidence Generation Department

CP platform: discuss specific processes or issues to support continuous improvement and foster dialogue with pharmaceutical industry stakeholders. Provides updates on current operations, achievements and planned improvements.

2 meetings/year led by Committees and Quality Assurance Department

PhV platform: raise awareness of pharmacovigilance legislation requirements, promote dialogue and provide an opportunity for discussions on specific issues affecting the Agency's industry partners.

1 meeting/year led by Committees and Quality and Safety Department

R&D – Research and Development; CP – Centralised Procedure; PhV – pharmacovigilance

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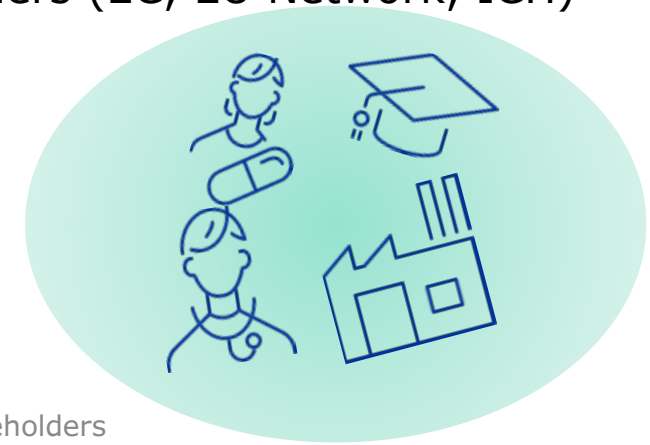
Multi-stakeholder approach

Main goal: ensure dialogue amongst stakeholders so that each specific perspective can be heard; work on a common final goal with patient at the center.

- Support impact assessment and implementation of new legislation.
- Support implementation of support cross-Agency implementation of strategies (such as EMANS, RSS, EMA's strategic focus areas and priorities.
- Support multi-stakeholder engagement in new areas (such as EMA's Extended Mandate; ACT EU, digitalisation).
- Support targeted or multi-stakeholders training and education on EMA activities in cooperation with EMA partners (EC, EU Network, ICH)



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Biennial overview of all engagement activities involving each stakeholders group as well as multi-stakeholders' initiatives

- EMA biennial report on EMA stakeholder engagement activities 2022-2023

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