EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 June 2016
EMA/48651/2016

European Medicines Agency (EMA) stakeholder relations management framework

Executive summary

This document defines guiding principles for the European Medicines Agency's management of key stakeholder interactions. The Agency aims to structure stakeholder relations and better support its strategic priorities.

These general principles stem from the EMA's experience in interacting with stakeholder associations representing patients and consumers, healthcare professionals, the pharmaceutical industry and more recently academia.

Although the level of interaction may vary, the Agency's overall management of stakeholder interaction is based on the fundamental principles of:

- transparency,
- independence and integrity,
- accountability,
- appropriate interaction,
- broad representation,
- effective communication, and
- continuous improvement.

Commonalities in stakeholder relations management are captured with a view to streamlining the working methodology where possible. This includes development of a common approach to assessing the needs and expectations of stakeholder groups, monitoring the interaction through regular surveys, streamlining communication, meeting fora and reporting.

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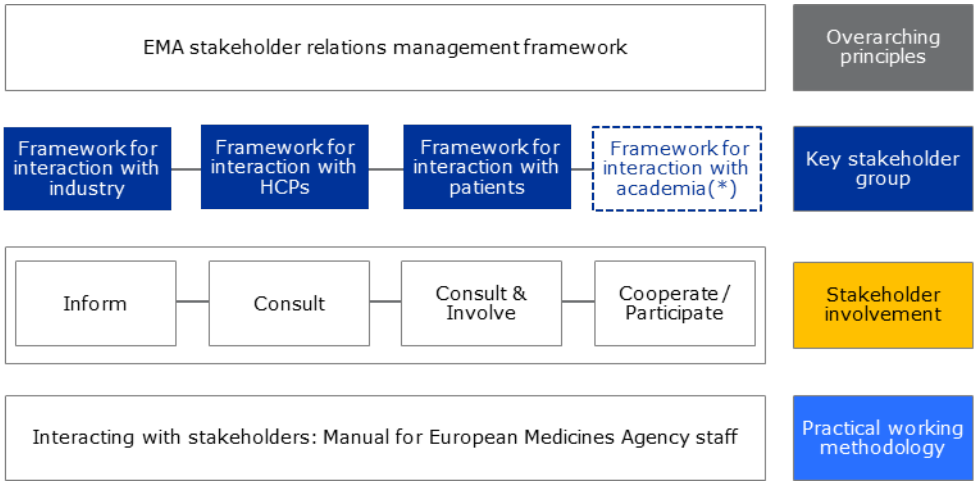
1. Background and context

The Agency has been interacting with its stakeholders since its inception. These stakeholder relations have evolved over time and the type and degree of interaction is varied depending on the stakeholder groups and fields of Agency activity.

Stakeholders are defined as organisations, associations and parties interacting with the European Medicines Agency (the Agency or EMA hereafter), which have an interest in or are influenced by the work of the EMA and its partners. The term 'partners' distinguishes the Agency's operational links within the European regulatory network and encompasses the national competent authorities, the European Commission, European Parliament and other European Institutions. They also include international (organisations) partners, such as, the World Health Organisation (WHO), US FDA, Health Canada, and Japanese regulatory authorities (MHLW and PMDA), etc.

Pursuant to Article 78 of Regulation (EC) No 726/2004, which calls for the Agency, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, the EMA has developed a series of framework documents to formalise its interaction with its main stakeholder groups (Patients and consumers, EMA/637573/2014; Healthcare Professionals, EMA/688885/2010; Industry stakeholders, EMA/591272/2014). While these frameworks are stakeholder specific, all interaction efforts should be consistent with the overarching stakeholder relation management principles, which are described in this document.



* planned for 2016/17

Additionally, EMA has put in place a new working methodology in terms of the level of stakeholder involvement (inform, consult, consult & involve, cooperate / participate).

Addressing the 'inform' aspect of the methodology, which is covered by the EMA's approach to transparency, is an important feature of the Agency's operations. The EMA publishes information on its scientific and non-scientific operations, explanation of its decisions and procedures, and organises stakeholder events. In addition, the public has the right to request information and documents from the Agency in accordance with its rules on access to documents and on access to information.

Principles on stakeholder consultation ('consult'/'consult & involve') are being developed to streamline the Agency's approach and to align it with EC Better Regulation Guidelines (SWD(2015) 111 final). In addition, new rules of procedure on the organisation and conduct of public hearings have been drawn up (EMA/624809/2013). Public hearings, held on a case-by-case basis, offer a channel to hear the public's views and concerns related to the safety, whilst also considering the therapeutic effects of a particular medicine.

In addition, the EMA has a policy which outlines its approach to engaging ('cooperate/participate') with stakeholders in external regulatory science projects (EMA/14946/2013).

Further details on the working methodologies specific to each stakeholder group are available in the relevant framework documents.

Finally, the Agency is developing a manual for interacting with stakeholders, which aims to support the systematic integration and translation of the overarching principles and relevant frameworks for interaction into the Agency's day-to-day operations. With a view to ensuring consistent stakeholder interactions across the Agency, the manual provides practical guidance, including a regular stakeholder mapping and prioritisation process.

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

All aforementioned documents are listed under the references section of this document and should be read in conjunction with these overarching principles.

2. Objectives and scope

The objective of this document is to describe core stakeholder relation management principles applicable to EMA's key stakeholder groups in order to:

- Promote appropriate engagement and dialogue on topics concerning medicines for human and veterinary use;
- Improve communication to manage expectations and provide efficient, targeted and timely information, in a proactive manner;
- Enhance stakeholders' understanding of the EU medicines Regulatory network and the role of regulators and enrich EMA's understanding of issues that are pertinent from the stakeholders' perspective throughout the lifecycle of a medicinal product;
- Increase transparency on how EMA engages with stakeholders.

By applying such principles, the Agency aims to structure stakeholder relations and better support its strategic priorities.

The stakeholder groups falling within the scope of this document are limited to patients and consumers' organisations, healthcare professionals' organisations, scientific and academic societies and representative associations of the pharmaceutical industry active in either the human or veterinary medicines fields. The purpose of this document is not to address the management of relations with the Media, the general public, individual pharmaceutical companies and service providers.

3. Stakeholder relation management principles

The Agency places a high priority on open, proactive and meaningful dialogue with all of its stakeholders, and is committed to providing information which is clear and transparent.

Although the level of interaction may vary, the Agency's overall management of stakeholder interaction is based on the fundamental principles of transparency, independence and integrity, accountability, appropriate interaction, broad representation, effective communication, and continuous improvement.

3.1. Transparency

Transparency is an important feature of the Agency's operations. As for any public authority, the Agency strives towards being as open as possible about how it works and how it reaches its opinions and decisions. This is fundamental and stands out as an essential principle in stakeholders' relation management, underpinning all of the other principles outlined below.

Indeed transparent relationships between the Agency and its stakeholders, be them with patient organisations, healthcare professionals, consumer organisations, academia or the pharmaceutical industry, support an open exchange of opinions, stimulate the generation and documentation of ideas and promote sound decision-making.

3.2. Independence and integrity

The Agency, its staff, members of the Management Board and Scientific Committees, rapporteurs and experts are working with relevant stakeholders for the protection of public and animal health.

Integrity and high standards of professional conduct in its relations with stakeholders are crucial for the independence of the EMA, and for its reputation vis-à-vis the public in its execution of European Union policy in the field of public and animal health. The EMA's Code of Conduct is actively applied to support the proper functioning of the Agency in accordance with its role and responsibilities.

3.3. Accountability

Accountability underpins the EMA's legitimacy and drives its effectiveness. The Agency is committed to being accountable for all it undertakes and the progress it achieves. This is essential for the quality of its work and to maintain public trust.

The Agency is, first and foremost, accountable to the public whose health it seeks to protect and promote. It is also accountable to its stakeholders, whose activities and policies are impacted by its actions and decisions.

3.4. Appropriate interaction

Establishing adequate and relevant reciprocal relations based on mutual trust and respect is paramount to relation management principles.

Identifying the right level of interaction which is adapted to each of the Agency's stakeholder groups is essential to enable adequate, timely and pro-active communication with all relevant actors. Building on existing interactions between industry, SMEs, academia and other stakeholders in the overall science, medicines, and healthcare arena by co-operating with established networks and alliances is a key principle.

Interaction with stakeholders is also affected by time, budget and availability constraints on both sides: the organisations and the Agency. Streamlining these interactions and focussing on priorities where mutual benefit can be anticipated are two underlying conditions to achieve common objectives.

3.5. Broad representation

The Agency uses pre-defined and agreed eligibility criteria to ensure participating associations represent the broadest array of relevant EMA stakeholders. Multi-stakeholder dialogue is encouraged,

with all eligible organisations meeting criteria for participation, to ensure different viewpoints are captured.

Operating at European level, the Agency will seek to establish contacts with European umbrella organisations where they exist. In their absence, international, national or regional associations, and exceptionally individual stakeholders, may also be considered.

3.6. Effective communication

Communication with stakeholders should be open, transparent (when and as appropriate according to the topics being discussed), responsive, consistent and timely and allow for adequate feedback to be provided.

This entails listening to, understanding and evaluating stakeholders' expectations, incorporating their views into the Agency's strategy when appropriate, monitoring and analysing performance, reporting and implementation.

3.7. Continuous improvement

Interaction with key stakeholders should be continually monitored, through surveys and other means, to identify priority topics and areas for improvement.

This enables the Agency to address and respond to stakeholders' specific needs, adapt and focus the Agency's priorities where necessary. This is important for the Agency's resource planning and enables the Agency to keep abreast of developments and environmental changes, and to take early actions to prevent potential problems arising. This resource planning helps the Agency shape its annual priorities and contribute more effectively to make a positive impact on healthcare policy and practice, and ultimately on patient outcomes.

4. Working methodology

EMA has put in place a new structure responsible for coordinating and optimising its stakeholder relation management. This structure operates within the Agency's management matrix to provide input on strategy and operations.

Four levels of stakeholder involvement have been identified:

- **Inform** (e.g. announcement of review of policy or guidance; information days);
- **Consult** (written – e.g. public consultation on policies or guidance, surveys);
- **Consult and involve** (direct interactions – e.g. stakeholder meetings, workshops, stakeholder conferences, public hearings);
- **Cooperate / participate** (direct interactions - e.g. technical expert groups (Telematics, ENCePP, focus groups, technical expert groups, as appropriate).

In order to achieve its strategic objectives with regard to stakeholder relations management, the following principles of methodology have been identified and used by the Agency:

- Establish a public register of eligible organisations, setting out the criteria for stakeholders eligibility for participation in EMA activities;
- Establish fora for communicating and interacting with stakeholders associations;

- Monitor the interaction through regular surveys;
- Report to the Management Board on the interaction with each stakeholder group.

Further details on the working methodologies specific to each stakeholder group are available in the relevant framework documents.

5. Implementation

Once these principles for stakeholder relations management have been endorsed by the EMA Management Board, they will be applied across the Agency.

Any new specific frameworks developed and subsequent updates will adhere to these common principles. The principles will be subject to review based on experience.

References

Interaction with stakeholders:

- The framework of interaction with patients consumers and their relevant organisations: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500018013.pdf
- The eligibility criteria for patients and consumers organisations: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf
- The evaluation of the financial information from patients consumers and healthcare professionals organisations: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/06/WC500169003.pdf
- The framework of interaction with healthcare professional organisations: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/12/WC500119625.pdf
- The eligibility criteria for healthcare professional organisations: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/12/WC500119624.pdf
- The framework for interaction between the EMA and industry stakeholders http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195081.pdf
- The 2014 annual report on EMA interaction with patients, consumers and healthcare professionals: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/10/WC500195083.pdf
- Rules of procedures on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/04/WC500204895.pdf
- European Medicines Agency process for engaging in external regulatory sciences and process improvement research activities for public and animal health: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/03/WC500139888.pdf

EMA code of conduct:

- http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf