



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Framework for interaction between the European Medicines Agency and industry stakeholders



1. Executive Summary

This framework describes the objectives and the terms of reference for the Agency's interaction with industry stakeholder groups active in the human and veterinary medicines fields. It aims to formalise and structure the interactions to facilitate and streamline communications between the Agency and pharmaceutical industry associations in line with principles of accountability, transparency and broad representation.

The EMA has been interacting with industry stakeholders on various levels since its creation. Industry is one of the Agency's key customers and communicating with pharmaceutical companies forms a major part of the day-to-day business. Although industry applicants are intrinsic to the Agency's functioning, gaps remain in terms of interaction with this stakeholder group and a structured framework is therefore called for. Encouraging effective stakeholder engagement is key to promoting good organisational governance and accountability.

The framework is based on the establishment of regular interactions with EU industry associations, aiming to:

- Provide a platform to **exchange views** and promote dialogue with stakeholders on topics concerning medicines for human and veterinary use;
- Improve communication and provide **efficient, targeted and timely information**, in a proactive manner;
- Enhance stakeholders' **understanding** of the EU medicines Regulatory framework and the role of the regulators and enrich the EMA's understanding of issues that are pertinent from the industry perspective for product development and licensing;
- Build on existing interactions between industry (including SMEs), academia and other stakeholders in the overall science, medicines, and healthcare arenas by **co-operating with established networks** and alliances;
- Increase **transparency** of stakeholders engaging with the EMA and report on the interaction.

The framework defines industry stakeholders as organisations representing the pharmaceutical industry, including EU umbrella organisations of national pharmaceutical industry associations, which are affected or impacted by or have an interest in the actions and aims of the Agency, its projects or policies.

The Agency will develop and publish the criteria to be fulfilled by industry associations to be eligible for involvement in the Agency's activities. These criteria will ensure that the Agency establishes contact with the most suitable organisations representing European industry stakeholders in a transparent manner.

The framework will be implemented taking into account the general principles for stakeholder consultation outlined in the European Commission's Staff Working Document on 'Better Regulation Guidelines', adopted in May 2015, and with reference to the European Commission's REFIT platform where relevant. Regular surveys will be undertaken to monitor the implementation of this framework and a report on the progress of the interaction with industry stakeholders will be published annually by the Agency.

2. Introduction

Stakeholders are defined as organisations, associations and parties interacting with EMA, which have an interest in or are influenced by the work of the EMA and its partners. The EMA's Stakeholders are identified in the Agency's Corporate Communications Strategy.

To fulfil its tasks, the European Medicines Agency (the Agency or EMA hereafter) requires cooperation with its various stakeholders, including the pharmaceutical industry, healthcare professionals' organisations, patients and consumers' organisations, scientific and academic societies.

The Agency has been interacting with its stakeholders since its creation. 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. Formal frameworks for cooperating with Patients and Healthcare Professionals were adopted by the EMA's Management Board in 2005 and 2011 respectively. A framework for interacting with industry associations has not previously been developed.

In 2012-2013, in the course of the EMA's reorganisation exercise, recommendations were made to consolidate and streamline the Agency's stakeholder relations and communication activities and to establish a centralised contact point to co-ordinate interaction with industry associations. In August 2014, a Corporate Stakeholders Department became operational within the Stakeholders and Communication Division of the EMA. The first task of this new department is to develop and implement a framework for interacting with industry stakeholders.

3. Rationale – why do we need a framework

The pharmaceutical industry is one of the Agency's key stakeholders and communicating with this group forms a major part of the day-to-day business. Points of interaction with the industry range from contacts with companies through early innovation task force or SME office briefings, business pipeline meetings, direct contacts during regulatory procedures, through to interaction with industry associations during workshops/events, and general correspondence. Industry stakeholders are consulted on general scientific and technical aspects of medicinal product development and authorisation, for example, pertaining to implementation of new legislation, guidelines and practical operation and performance of procedures.

Article 78 of [Regulation \(EC\) No 726/2004](#) calls for the Agency, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, including industry stakeholders.

“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.”

At a strategic level, the [Agency's Road Map to 2015](#) identified dialogue with the pharmaceutical industry as a key feature. The Road map further highlighted the growing diversification of this interaction and the increasing involvement of the generics and non-prescription medicines industries broadening from the initial focus on the innovative-medicines industry.

As the Agency has grown in size and the scope and complexity of its responsibilities under EU legislation have increased, its approach to stakeholder management has become fragmented. With the exception of SME and business pipeline related activities, contacts with industry organisations have in

the past been managed by the relevant operational units spread throughout the organisation which has made the co-ordination, consolidated overview, and allocation of resources sub-optimal. A more centralised interaction with industry associations as set out in this framework will provide the grounds for the Agency to build a consistent approach to this stakeholder group in a transparent manner.

4. Scope of interaction

This framework covers the interaction between the Agency and pharmaceutical industry associations, which have an interest in or are impacted by the work of EMA and its partners. This includes those organisations active in either the human or veterinary medicines fields.

The framework operates at a European level, which means the Agency will seek to establish contacts with European umbrella organisations where they exist. In their absence, national or regional associations, and exceptionally individual entities (e.g. not-for-profit entities representing multiple stakeholders), may also be considered. It should also be acknowledged that the environment for pharmaceuticals along the life cycle from development to market access is nowadays global and operating at multiple levels. Therefore, extending the interaction beyond EU Industry Organisations to international industry organisations may occur if and when applicable¹.

The scope of interaction will hence include those organisations operating in or supporting the pharmaceutical industry as applicable, such as:

- Industry trade associations representing pharmaceutical companies;
- Associations of professionals or service providers operating in or supporting the general interests of industry, i.e. not including those representing the interests of a particular company based on a fiduciary mandate;
- Organisations engaged early on in the innovation life-cycle from development;
- Associations with multiple stakeholders including industry members;
- Stakeholders operating in domains related to pharmaceuticals such as medical devices or HTA.

Interaction between the Agency and industry stakeholders is embedded in the context of the EU Regulatory Network (including the National Competent Authorities and the European Commission), and overall co-operation is necessary to achieve the objectives.

The interactions will cover areas of common interest for the Agency and industry stakeholders in relation to medicines for human and veterinary use. Queries relating to a specific product and/or regulatory procedure are handled by the relevant EMA operational departments and fall outside the scope of this framework document.

Compliance with the Agency's conflicts of interest policy will continue to be pivotal to the Agency's accountability and governance for engagement with all of its stakeholders.

5. Objectives

The framework aims to meet the following objectives:

- Provide a platform to **exchange views** and promote dialogue with stakeholders on issues concerning medicines for human and veterinary use;

¹ With reference to the Guidance Note for the international activities of the European Medicines Agency (Ref. Ares(2015)1744405 - 24/04/2015)

- Improve communication and provide **efficient, targeted and timely information** to stakeholders in a proactive manner;
- Enhance stakeholders' **understanding** of the EU medicines Regulatory framework and the role of the regulators and enrich the EMA's understanding of issues that are pertinent from the industry perspective for product development and licensing;
- Build on existing interactions between industry (including SMEs), academia and other stakeholders in the overall science, medicines, and healthcare arenas by **co-operating with established networks** and alliances (e.g. European Network of Centres for Pharmacoepidemiology and Pharmacovigilance - ENCePP) ;
- Increase **transparency** of stakeholders engaging with the EMA and report on the interaction.

6. Working Methodology

The new structure will operate within the Agency's management matrix to provide input on strategy and operations. Four levels of stakeholder involvement have been identified:

- Inform (to enable feedback e.g. news items, Q&As, information days);
- Consult (via written consultation e.g. guidelines development, public consultations on deliverables, focus groups);
- Consult & Involve (based on direct interactions e.g. focus groups) and,
- Co-operate (jointly engaging towards a common technical goal e.g. technical expert groups).

In order to achieve the objectives identified under section 5, the framework will focus on the following goals:

- Establish a public register of eligible organisations, setting out the criteria for stakeholders eligibility for participation in EMA activities;
- Set out the principles and levels of interaction;
- Align the approach with relevant EMA policies and principles for stakeholder engagement and consultation (under development);
- Establish fora for communicating and interacting with industry associations;
- Report on the interaction with this stakeholder group.

7. Implementation and Monitoring

Once this framework has been endorsed by the Management Board, the Agency will implement it based on a defined action plan outlined in Annex 1. The framework will be implemented taking into account the general principles for stakeholder consultation outlined in the European Commission's Staff Working Document on 'Better Regulation Guidelines', adopted in May 2015, and with reference to the European Commission's REFIT platform where applicable.

The specific activities of the corporate stakeholders' department will be incorporated in the annual EMA work programme. The EMA will implement the framework in cooperation with the EU Medicines Regulatory Network where relevant and in line with the EU Medicines Agencies Network Strategy to 2020.

A general survey of industry stakeholders on the human side was undertaken as part of the European Commission's Internal Audit Service audit carried out in May 2014 and follow-up surveys aimed at the

human medicines sector will be carried out regularly to obtain industry associations' views on the new approach. A survey of SMEs and their stakeholders was conducted in 2011, and a follow-up is also planned in 2015.

In implementing this framework, due care and attention will be placed on mitigating potential risks, which have been identified as follows:

- Conflicts of interests that could affect the independence and impartiality of the Agency and its experts;
- Participation of stakeholders not representing the broader industry stakeholder landscape;
- Contention between participating stakeholders.

The department will adhere to the Agency's conflicts of interest policy in determining the scope for participation. Transparency and accountability are essential to effective engagement since, explaining and reporting on stakeholder relations will reinforce management of risk and reputation.

Eligibility criteria will be drawn up to ensure participating associations represent the broadest array of relevant pharmaceutical industry stakeholders. Multi-stakeholder dialogue will be encouraged, with all eligible organisations meeting criteria for participation, to ensure representation of different views where they exist.

A report on the activities of the department will be published annually by the Agency.

Annex 1

Actions	Estimated timeframes for completion
• Identification of eligible organisations, setting out the criteria for stakeholders eligibility and inclusion in the Agency register for participation in EMA activities;	Q1 2016
• The development of an “Industry Stakeholder” information webpage and a dedicated contact point within the Agency to co-ordinate interaction;	Q1 2016
• Organisation of fora and meetings with selected or multi-stakeholder participation to discuss issues of common interest in co-operation with the European Commission, as well as the European Medicines Regulatory Network where relevant;	Ongoing
• Monitoring and reporting on the interaction with this stakeholder group;	Annually
• Share experience with NCAs and other EU Agencies.	Q4 2016