EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication

Revised framework for interaction between the European Medicines Agency and healthcare professionals and their organisations

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Table of contents

1. Executive Summary

The revised framework describes the objectives and consolidates the methodology of the Agency's interaction with healthcare professionals in relation to medicines for human use. Its ultimate goal is to promote participatory design in EMA's work and ensure a sustainable model of interaction with healthcare professionals.

The Agency has interacted with healthcare professionals since its inception. Following the implementation of relevant legislative provisions, the EMA Management Board and certain scientific committees include healthcare professionals' representatives as members.

In 2011, a first formal framework of interaction with healthcare professionals was adopted by the EMA Management Board. The present document incorporates experience gained since then and aligns the interaction objectives with those of the EU Network strategy to 2020 as well as complements the objectives set in each EMA dedicated framework of collaboration with academia[1], patients and consumers[2], and industry[3] stakeholders.

Both principles and methods used are aligned with the EMA stakeholder relations management framework[4].

The framework is based on the established regular interaction with a network of European healthcare professionals' organisations, aiming to:

- Support the Agency in order to access the best possible **independent expertise** in **clinical practice**, to incorporate the real-world experience into drug development, benefit/risk evaluation and monitoring;
- Contribute to a more efficient and targeted **communication** to healthcare professionals, which can facilitate the transfer of information along the patient journey as a mean to promote patient safety and optimal use of medicines;
- Enhance healthcare professionals' organisations' **understanding** of the role and activities of the EU medicines Regulatory Network.

The framework defines healthcare professionals' organisations as non-profit organisations that have an interest in patient care, and where healthcare professionals represent a majority of members in governing bodies.

The framework recognises the importance of interacting with the representative healthcare professional organisations via a network of eligible organisations and through the EMA working party of healthcare professionals (HCPWP). The framework also recognises the importance of the involvement of healthcare professionals as experts in the field of clinical practice (e.g. in general practice/family medicine) and foresees the establishment of pools of experts to facilitate the process of involvement, particularly in product-related activities. It also recognises the need to stimulate areas of shared interest with academia and to further strengthen the established collaboration with patient and consumer organisations.

[1] Framework of collaboration between the European Medicines Agency and academia - link to framework document to be added
[2] Revised framework for interaction between the European Medicines Agency and patients and consumers and their organisations
[3] Framework for interaction between the European Medicines Agency and industry stakeholders
[4] EMA stakeholder relations management framework

A report on the progress of the interaction with healthcare professionals and their organisations will be presented annually to the EMA Management Board.

2. Introduction

The European Medicines Agency's mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public health in the European Union.

To achieve its mission, the European Medicines Agency (the Agency or EMA hereafter) works with thousands of experts who serve the Agency's scientific committees, working parties and scientific assessment teams. The great majority of these experts are healthcare professionals who are made available to the Agency, among others, by the national competent authorities of the EU and EEA.

In addition, the Agency closely cooperates with its various stakeholders including healthcare professionals' organisations, patients and consumers' organisations, scientific and academic societies, and the pharmaceutical industry. Stakeholder relations and their management have evolved over time since the Agency's creation and are guided by fundamental principles of transparency, independence and integrity, accountability, appropriate interaction, broad representation, effective communication, and continuous improvement.

Regulation (EC) No 726/2004 gives responsibilities to the EMA, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, including healthcare professionals. The Pharmaceutical legislation not only defines the framework for providing clear and useful information to healthcare professionals but also calls for the Agency to implement specific forms of interaction with healthcare professional organisations and their representatives. For example, healthcare professionals are represented in the EMA Management Board, the Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT), and the Pharmacovigilance and Risk Assessment Committee (PRAC). Furthermore, the Agency has put in place methods to collect healthcare professionals' input through direct consultation and by their involvement as accredited experts in accordance with Article 62 (2) of Regulation (EC) No 726/2004.

The current framework describes the objectives and methods used by the Agency in its interaction with healthcare professionals with the aim to raise awareness about the Agency's activities, enhance targeted communication, and encourage and facilitate their participation in the Agency's work in relation to medicines for human use.

3. Rationale for revising the framework

In December 2011 the EMA Management Board adopted the first formal framework of interaction with healthcare professionals. Emphasis was given to the representative organisations as key intermediators with the broader communities of healthcare professionals and first port of call to identify individual experts and representatives to sustain the involvement of healthcare professionals in the EMA work. The overall aims were to enhance participation of healthcare professionals in EMA work and increase their understanding of the rationale behind regulatory actions.

The framework was progressively implemented and the very first steps were taken in 2012 with a number of European organisations covering different areas of practice and expertise joining the so called network of eligible healthcare professional organisations. The year of 2013 saw further progress with milestones such as the establishment of the Agency Human Scientific Committees' Working Party with Healthcare Professionals Organisations (HCPWP) and the further expansion and operation of the

network of eligible organisations. The publication of the first annual report on the progress of the interaction with healthcare professionals' organisations in 2014 constituted the final building block for the full implementation of the framework.

In 2015, focus was directed towards sustainability of healthcare professionals' involvement in the Agency's core activities. Improving both input from general practitioners/family doctors as a first step to increasing outreach to the broader primary care community and the intersection with clinical academics were identified as challenging areas for the interaction with healthcare professionals.

In December 2015, the EU Network strategy was also published setting up guiding objectives to 2020, in particular:

- Theme 1: Contributing to human health – focusing on a life-span approach with clinical drug development, licensing, use in clinical practice and monitoring viewed as a continuum.
- Theme 3: Optimising the operation of the network – seeking for active involvement of the stakeholders (in particular patients, healthcare professionals, and the scientific community) in the work of the regulatory authorities.

In June 2016, the Agency published an overarching stakeholder relations management framework[4] to structure stakeholder relations and better support strategic priorities, taking into account the general principles for stakeholder consultation outlined in the European Commission's Staff Working Document on Better Regulation Guidelines[5].

A HCPWP topic group was therefore asked to reflect on whether there was a need to review the framework for interaction between the Agency and healthcare professionals and in June 2016 the HCPWP agreed that the framework document should be updated to reflect the more proactive role of healthcare professionals in drug development, evaluation and monitoring, as well as the principles for stakeholder consultation set out by the Better Regulation Guidelines.

It is recognised that advances in adaptive design for clinical trials, personalised medicine, more extended use of real world evidence, and the public availability of clinical data will provide additional opportunities for engaging with healthcare professionals in the interface of clinical research and clinical practice. Taking into account the concomitant development of an EMA framework of collaboration with academia, and although it may be difficult to separate clinical practice from research and education, the healthcare professionals' framework will mainly focus on clinical practice whilst the academia's framework will put its emphasis on research and education, without pre-empting obvious areas of inter-relation.

Finally, and very importantly, the framework should continue to further strengthen the established collaboration with patient and consumer organisations.

4. Scope of interaction

The framework covers the interaction between the Agency and healthcare professionals in relation to medicines for human use.

The framework recognises the different roles of healthcare professionals as clinical investigators, prescribers, handlers, safety-guardians and communicators with an active role in different stages of a medicine's life-cycle and who contribute in various ways to the patient's journey within the health-care system.

[5] EC Better Regulation Guidelines, adopted in May 2015

The primary intention is to engage with healthcare professionals' organisations, operating at European level. The Agency considers these as relevant intermediaries able to facilitate relations with the wider community of healthcare professionals across the EU (i.e. individual members and/or national associations).

Healthcare professionals' organisations (HCPOs) are defined as not-for-profit[6] organisations that have an interest in patient care, and where healthcare professionals represent a majority of members in governing bodies.

Relevant organisations include: European organisations representing national organisations or individual healthcare professionals (e.g. generalists or specialists in a specific disease area); European organisations that exist to promote a scientific discipline/profession, and general umbrella organisations (e.g. representing either European specific disease organisations and/or national umbrella organisations).

The ultimate goal is to bring on board organisations that represent different fields of clinical expertise and practitioners in Europe (e.g. doctors, pharmacists, nurses; generalists or specialists), active within the broad spectrum of health care, including primary care.

Interaction between the Agency and healthcare professionals is embedded in the context of the EU Regulatory Network (including the National Competent Authorities and the European Commission), and overall cooperation is necessary to achieve the objectives set out in this framework.

The interaction will cover areas of common interest for the Agency and healthcare professionals' organisations in relation to medicines for human use within the remit of the Agency's mandate.

5. Objectives

In order to contribute to the implementation of the EU Network strategy and the Agency's multiannual work programme to 2020, the framework aims at meeting the following specific objectives:

1. Further develop healthcare professional organisations' awareness and understanding of the mandate and work of the Agency and of the EU medicines Regulatory Network as a means to increase their engagement and trust in the Agency's activities and promote a transparent regulatory system that reflects society's needs;
2. Enhance the participation of healthcare professionals in certain Agency activities – from early development to post-authorisation – with the aim of: a) obtaining information on standards of care, real use of medicines in clinical practice, use of biomarkers and new approaches for clinical trials, monitoring and treatment, b) identifying opportunities and challenges faced in healthcare provision, c) providing advice on study designs and methods and d) supporting benefit/risk decision-making;
3. Support the transfer of information on medicines to healthcare professionals, through targeted messages and appropriate use of cascading mechanisms with the ultimate goal of promoting patient safety and optimal use of medicines along the patient journey;

Achieving these objectives will necessitate close collaboration between the Agency, the National Competent Authorities and the European Commission in the context of the EU Regulatory Network, as

[6] A working definition of Non-profit organisation or non-profit legal entity is a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members

well as an active participation and good interaction with academia, as well as with healthcare professionals', patients' and consumers' organisations.

The commitment and volunteer nature of the work conducted by the representative members of healthcare professional organisations as well as that of individual experts involved in EMA activities, in addition to their clinical practice and/or clinical research work, also merits full recognition and appreciation.

6. Working methodology

Healthcare professionals can be involved in Agency activities either as representatives of healthcare professionals' organisations, representatives of their own organisations or as individual experts.

Figure 1 shows the different activities associated with these different types of representation.

Figure 1: Healthcare professionals in EMA activities and scope of representation

Organisations involved in EMA activities need to be fully transparent with regard to their activities and funding sources. When healthcare professionals participate in the Agency's activities as individual experts or as members/alternates of the EMA Management Board, scientific committees and working parties, they will all have to declare any interest and abide by the Agency's code of conduct. This is reflected in the rules of involvement of members of healthcare professionals' organisations in EMA activities.

In order to achieve the objectives identified under section 5, the framework will rely on the following critical elements, which embed the four levels of stakeholder involvement of the Agency's stakeholder relations management (see table 1):

1. Continuous mapping of international and European healthcare professionals' organisations with an interest in the Agency's activities;
2. A network of eligible healthcare professionals' organisations, compliant with the criteria for stakeholders eligibility for participation in EMA activities;
3. A forum of exchange with healthcare professionals' organisations established within the Agency: the EMA Healthcare Professionals' Working Party (HCPWP);

4. Pools of experts in particular fields of clinical practice (e.g. in general practice/family medicine) to facilitate healthcare professionals' involvement, particularly in product-related activities;

5. Interaction with the EU Regulatory Network particularly in the field of communication.

Table 1	
Inform – to enable feedback	e.g. dedicated web pages, relevant news items, Q&As, information days, information materials including videos and presentations for healthcare professionals interested in learning more about EMA activities
Consult – via written consultation	e.g. public consultation on policies or guidance, surveys
Consult and Involve – via direct interactions	e.g. multi-stakeholder meetings, workshops, conferences, public hearings, input into the development of regulatory guidelines and other regulatory procedures
Cooperate / participate – via direct interactions	e.g. HCPWP, scientific advisory groups and ad-hoc expert groups, focus groups, technical expert groups

The continuous **mapping of international and European healthcare professionals' organisations with an interest in Agency's activities** enables targeted communication with a broad group of organisations. Organisations can register with the EMA as an interested party to receive information and notice of written consultations in selective areas of interest (via stakeholdersDB@ema.europa.eu).

The **network of European healthcare professionals' organisations** allows the Agency to build up consistent and targeted interactions with a core group of organisations across Europe with a diverse range of expertise and interests. Criteria for selection of organisations apply ('Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities'). These criteria ensure that the Agency establishes contact with the most suitable organisations representing European healthcare professionals in a transparent manner.

The network's development is based on a stepwise approach as described below:

- Evaluation by the Agency of European healthcare professional's organisations that fulfil specific eligibility criteria to be involved in its activities

  The evaluation process relies on:

  - The assessment of eligibility criteria endorsed by the Management Board;
  - An open call for expressions of interest via the EMA website. This call remains constantly open to new applicants, who may apply at any time. Guidance on how eligibility is evaluated is published on the EMA website and addresses particularly the transparency of funding sources and the relationship between the organisations and the pharmaceutical industry. An online form is used to collect data from applicants;
  - Assessment by an evaluation committee within the Agency to determine whether applicants meet the eligibility criteria.

- Publication of a list of eligible healthcare professionals' organisations on the Agency's website

  Eligible organisations will be publicly listed on the EMA website. Eligibility offers organisations a fast track for participation in Agency activities in their area of interest. The decision to include an organisation in EMA activities is based on a published list of criteria.

  The eligibility of the organisations is regularly reviewed by the Agency.

The **EMA Healthcare Professionals' Working Party (HCPWP)** is a platform for dialogue and exchange with healthcare professionals' organisations on relevant issues concerning medicines for human use; through it the Agency informs and obtains input and feedback from healthcare professionals on various Agency's initiatives. It includes balanced representation of different types of healthcare professionals (such as general practitioners, nurses, hospital and community pharmacists, specialist doctors, representatives of learned societies within the mandatory scope, etc.). Representatives of EMA human scientific committees are also members of the working party. Management Board observers and the European Commission are also invited to participate. The working party is mandated to monitor the progress of the interaction between the Agency and healthcare professionals and their representative organisations. It also provides a forum to further identify gaps and priorities in the overall interaction.

Members of the HCPWP are selected from the list of eligible healthcare professionals' organisations.

The establishment of **dedicated pools of experts in particular fields of clinical practice** (e.g. in general practice/family medicine) where a more targeted approach is considered necessary can facilitate healthcare professionals' involvement, particularly in product-related activities. These will be created through direct requests to the eligible organisations.

Interaction between the network of European healthcare professionals' organisations and the EU Regulatory Network in the field of communication provides a valuable contribution to support the existing structures for information dissemination in the Member States. Furthermore, collaboration between these networks promotes the provision of adequate information to healthcare professionals on the benefits and risks of medicines and contributes to the preparation and dissemination of clear messages on the safe and rational use of medicines intended to reach the public across the EU.

7. Implementation and monitoring

The Agency has developed a robust system for involving healthcare professionals and their representative organisations in its activities including the development of policies, regulatory guidance, and product related evaluation. The current activities as well as the modalities of interaction are described in Annex II.

Once this revised framework has been endorsed by the Management Board, it will be implemented by the Agency taking into account the action plan outlined in Annex I. The action plan may be updated separately, as needed.

An annual report will be presented to the EMA Management Board and Human scientific committees, including an analysis of performance indicators, feedback received from healthcare professionals and their representative organisations through targeted surveys, an overview of the work undertaken by the HCPWP as well as an overview of the activities common to patients, consumers and healthcare professionals.

The work to be undertaken in the context of the Agency's interaction with healthcare professionals' organisations will be incorporated in the HCPWP annual work programme and in the Agency's annual work programme, as appropriate.