EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Framework for interaction between the European Medicines Agency and healthcare professionals

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1. Executive Summary

This framework, as requested by the EMA Management Board, describes the objectives and the terms of reference for the Agency's interaction with healthcare professionals in relation to medicines for human use.

The Agency has interacted with healthcare professionals since it began operating. It has also implemented relevant legislative provisions, and the EMA Management Board and certain scientific committees include healthcare professionals as members. However, a recent analysis has concluded that although healthcare professionals are an integral part of the Agency's work, gaps still remain in terms of interaction with organisations representing healthcare professionals, and that a structured framework is called for. In addition, there is a need to implement a monitoring system to report regularly on the progress and achievements of this structured interaction.

The framework is based on the establishment of 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 any matter related to medicines. This will help, among others, to obtain information on the current use of medicines in real **clinical practice** and their therapeutic environment, for the purposes of benefit/risk decision-making;
- Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines;
- Enhance healthcare professionals' organisations' **understanding** of the role of the EU medicines Regulatory Network.

The framework defines healthcare professionals' organisations as not-for-profit organisations that have an interest in patient care, and where healthcare professionals represent a majority of members in governing bodies. The given definition ranges from those organisations mainly centred on patient care to other associations such as learned and academic societies, focused on research activities, but which may have an interest in medicines and in the Agency's work and which ultimately aim at a benefit for patients.

The framework foresees the formalisation of the current CHMP working group with healthcare professionals, which will become an EMA working party (HCP WP) with links to all human scientific committees. The group will be a platform for dialogue and exchange of information with healthcare professionals' organisations on relevant issues concerning medicines for human use. It will include 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). It will be mandated to monitor the progress of the interaction and will help to further identify gaps and priorities.

The framework is accompanied by criteria to be fulfilled by healthcare professionals' organisations in order to be involved in the work of the Agency. These criteria will ensure that the Agency establishes contact with the most suitable organisations representing European healthcare professionals in a transparent manner.

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

2. Introduction

In order to fulfil its tasks, the European Medicines Agency (the Agency or EMA hereafter) works with a network of over 5,000 European experts who serve the Agency's scientific committees, working parties and scientific assessment teams. The great majority of these experts are healthcare professionals and are made available to the Agency, among others, by the national competent authorities of the EU and EEA. In addition, the Agency requires close cooperation and partnership with its various stakeholders including healthcare professionals' organisations, patients and consumers' organisations, scientific and academic societies, and the pharmaceutical industry.

The Agency has interacted with its stakeholders since its creation in 1995. Although these stakeholder relations have evolved over time, the type and degree of interaction has been varied in terms of different stakeholder groups and different fields of Agency activity.

In 2004 the Agency proposed to its Management Board to develop specific frameworks for interaction with its various stakeholders. This proposal aimed to apply a more structured approach to stakeholder relations and to tackle new challenges, such as the implementation of Community legislation and the Agency's strategic priorities for that period. In December 2005, the Agency's Management Board took a first step in this process by endorsing a specific framework for interaction with patients and consumers' organisations.

The Agency has now developed a specific framework for interaction with healthcare professionals, which takes account of their needs and expectations as well as the Agency's interests and aims. These are to raise awareness about its activities, to strengthen itself as an authoritative source of information and to encourage and facilitate communication with healthcare professionals. This framework takes into account the new legislation on pharmacovigilance and is flexible enough to adapt to future legislative proposals such as the one on information to patients. It was endorsed by the Management Board during its meeting held on December 2011.

3. Rationale – why do we need a framework?

The Pharmaceutical legislation calls for the Agency to implement specific forms of interaction with healthcare professionals. For example, healthcare professionals are represented in the EMA Management Board, the Paediatric Committee and the Committee on Advanced Therapies. Furthermore, Regulation (EC) No 726/2004 gives additional responsibilities to the EMA, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, including healthcare professionals. In addition to direct interaction with healthcare professionals' organisations, the legislation also defines the framework for providing clear and useful information to them. Although many of these provisions have already been implemented, there is a need to have a system in place to monitor them and to report at regular intervals. As of 2011 the Agency will be faced with the implementation of new pieces of EU legislation, in particular the one in pharmacovigilance, which will further expand the areas in which healthcare professionals will be involved.

A review of current practices in the Agency concluded that although healthcare professionals are an integral part of the Agency's work (healthcare professionals are fundamental to the evaluation of medicines as members of Scientific Committees and as individual experts in the European regulatory network) there is a gap in relation to interactions with healthcare professionals' organisations that calls for a structured framework to ensure these interactions happen and are monitored.

The Agency's Road Map to 2015 identifies the growing importance of involving and facilitating participation of civil society (patients/users of medicines and healthcare professionals) in the Agency's

activities as a way to support the Road Map's strategic objectives, namely: 1) Addressing Public Health Needs; 2) Facilitating Access to Medicines; and 3) Optimising the Safe and Rational Use of Medicines.

Furthermore, the creation of a network of European healthcare professionals' organisations, as set out in this framework, not only prepares the ground for building confidence and trust in the regulatory system, but also gives the opportunity to strengthen the existing network of European experts. This will help the Agency to access the best possible **independent expertise** in any matter related to medicines, as healthcare professionals' organisations can provide a valuable source of expertise to the Agency in a wide range of relevant fields. Likewise, in the context of the EU regulatory network, the network of European healthcare professionals' organisations can help the EMA to gain a better understanding of how medicines are being used in **real clinical practice** (including their use out of the approved indication), how avoidable medication errors could be prevented, or on the effectiveness of risk minimisation measures and their impact on the work of healthcare professionals. This will also support a continuous assessment of benefits and risks throughout the product lifecycle of medicines marketed in Europe.

In addition, the network of European healthcare professionals' organisations can support and contribute to a more efficient and targeted **communication**, especially in relation to the benefits and risks of medicines and its rational use.

Finally, interaction with healthcare professionals is a necessary complement to interaction with patients and consumers, and allows the EMA to offer a platform of exchange and dialogue at European level where the views from all users of medicines can be considered. This should ultimately support the wider relationship between healthcare professionals and patients ('partnership in medicine taking').

4. Scope of interaction

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

It gives particular attention to healthcare professionals' organisations, as these are relevant intermediaries able to facilitate relations with the wider community of healthcare professionals.

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

The given definition ranges from those organisations mainly centred on patient care to other associations such as learned and academic societies, focused on research activities, but which may have an interest in medicines and in the Agency's work and which ultimately aim at a benefit for patients.

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 scope of interaction will also be extended to cover centres of academia. The existing initiatives in the area of paediatric medicinal products (EnprEMA – the Network of Paediatric Networks at the EMA) and in the area of pharmacoepidemiology and pharmacovigilance (ENCePP – the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) are taken as models which enable inter-network and stakeholder collaboration.

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 framework operates at a European level, which means the Agency will seek to establish contacts with European organisations rather than national ones. However, it is expected that the European organisations act as multipliers for information, dialogue and feedback, and that the effects of this interaction are disseminated within each organisation's structure (i.e. individual members and/or national level).

The interaction will cover areas of common interest for the Agency and healthcare professionals' organisations in relation to medicines for human use without going beyond the remit of the Agency's activities.

Experience has shown that healthcare professionals may have some unrealistic expectations about the Agency's activities, for instance in relation to guidelines or information on medicines. The Agency does not issue therapeutic guidelines, and it communicates on medicines but not on diseases as such. Achieving a better understanding of the EMA's role among the wider healthcare professional community is one aim of this reinforced framework for interaction.

5. Objectives

In order to contribute to the implementation of the Agency's Road Map to 2015, the framework aims at meeting the following specific objectives:

1. Enhance the participation of healthcare professionals' organisations in certain Agency activities, with the aim of obtaining information on the current use of medicines in clinical practice and their therapeutic environment, for the purposes of benefit/risk decision-making;
2. Provide clear and useful information on medicines to healthcare professionals' organisations, to support their role in the safe and rational use of medicines;
3. Optimise and further develop appropriate communication tools (content and delivery) that support the provision of information to and the collection of feedback from healthcare professionals;
4. Enhance healthcare professionals' organisations understanding of the mandate and work of the Agency and of the EU medicines Regulatory Network;
5. Facilitate and encourage the cascade of information to the constituencies of healthcare professionals' organisations (i.e. to reach out to healthcare professionals at national level).

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

6. Working methodology

Based on legal provisions and experience so far, healthcare professionals can participate in the Agency's activities as **members (and alternates)** of some of the Agency's scientific committees and of the Agency's Management Board. These members are appointed by the EU Institutions. Healthcare professionals can also contribute to the EMA's activities as individual **experts**. In addition, healthcare professionals may participate as **observers** in certain aspects of the Agency's work. Finally, healthcare professionals may, as **representatives of a specific organisation**, participate in Agency discussions

and attend part of a Committee, Working Party or Working Group meeting to express the views of the organisation on a specific issue.

Independently of the way healthcare professionals participate in the Agency's activities, they will all have to declare any interest and abide by the Agency's code of conduct. This will be reflected in the rules of involvement of members of healthcare professionals' organisations in EMA activities. In addition, the organisations involved should be fully transparent with regard to their activities and funding sources.

In order to achieve the objectives identified under section 5, the framework will rely on three critical elements:

- a network of European healthcare professionals' organisations;
- interaction with the EU Regulatory Network in the field of communication (with particular emphasis on safety communication); and
- a forum of exchange with healthcare professionals' organisations established within the Agency: the EMA Healthcare Professionals' Working Party (HCP WP).

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

The network's development will follow a stepwise approach as described below:

1. Evaluation by the Agency of European healthcare professional's organisations who fulfil specific eligibility criteria to be involved in its activities (primary level of interaction)

    1.1. Establishment of an evaluation process

    - Endorsement of eligibility criteria by the Management Board;
    - Launch of a call for expressions of interest via the EMA website. This call will remain constantly open to new applicants, who may apply at any time. The EMA will publish guidance on how eligibility is evaluated. An online form will be used to collect data from applicants;
    - Establishment of an evaluation committee within the Agency to assess whether applicants meet the eligibility criteria.

    1.2. Publication of a list of eligible healthcare professionals' organisations on the Agency website

    Eligible organisations will be publicly listed on the EMA website. Eligibility will offer organisations a fast track for participation in Agency activities in their area of interest. It will also help the Agency make transparent decisions on the organisations selected for involvement.

    If an organisation is not found eligible, they will be informed of the reasons in writing. No information will be made public in case of a negative outcome. The organisation may re-apply at any time after reviewing the reasons for the negative outcome.

2. Set up of a public online registry (Stakeholder database)

    This will support a secondary level of interaction covering eligible and non-eligible healthcare professionals' organisations with whom the Agency may interact (e.g. disseminating information).

An online registry will bring more transparency, openness and equal opportunity for participation. For certain issues where no eligible organisations exist, the Agency may decide to consult or involve non-eligible organisations.

Inclusion of healthcare professionals' organisations in the public registry will be based on voluntary registration by the organisation, to be validated by the Agency.

It should be noted that this public online registry will also include other stakeholders, such as patients' and consumers' organisations and industry associations and is intended to increase transparency about the stakeholders with whom the Agency interacts.

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

Finally, the framework foresees the formalisation of the current CHMP working group with healthcare professionals, which will become the **EMA Healthcare Professionals Working Party (HCP WP)**, which will have links to all human scientific committees. The group will be a platform for dialogue and exchange with healthcare professionals' organisations on relevant issues concerning medicines for human use; through it the Agency will inform and will obtain feedback and contribution from healthcare professionals on various Agency's initiatives. It will include 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). It will be mandated to monitor the progress of the interaction and will help to further identify gaps and priorities in the overall interaction.

Members of the HCP WP are expected to be selected from the list of eligible healthcare professionals' organisations.

7. Implementation and monitoring

Once this framework has been endorsed by the Management Board, the Agency will implement it taking into account the action plan outlined in the table below.

Actions	Estimated timeframes for completion
• Establish a network of European healthcare professionals' organisations	
⇒ Establish an evaluation process for healthcare professionals' organisations who fulfil the eligibility criteria to be involved in the Agency's activities and keep it ongoing thereafter	1/2Q 2012
⇒ Set up a public online registry for the Agency's stakeholders, including eligible and non-eligible healthcare professionals' organisations, patients' and consumers' organisations and industry associations.	3/4Q 2013

Actions	Estimated timeframes for completion
• Establish the EMA Healthcare Professionals Working Party and ensure its full operation	
⇒ Launch a call for expression of interest to become member of the HCP WP among eligible healthcare professionals' organisations	3/4Q 2012
⇒ Agree on the mandate and rules of procedure of the HCP WP	3/4Q 2012
⇒ Develop appropriate links with the Agency's Management Board, human scientific committees and working parties	3/4Q 2012
• Enable the network of European healthcare professionals' organisations as a valuable source of independent expertise	
⇒ Develop specific procedures for identifying suitable independent experts who can timely contribute to EMA scientific committees, working parties, scientific advisory groups, etc	3/4Q 2012
⇒ Develop specific procedures for consultation of healthcare professionals' organisations by the EMA scientific committees, working parties, scientific advisory groups, rapporteur, etc, whenever it is needed.	1/2Q 2013
• Continue to develop specific dialogue and interaction with healthcare professionals' organisations on aspects related with quality, access and dissemination of information produced and managed by the Agency	1/2Q 2013
• Increase awareness and promote input on EMA guidelines under development among the scientific community at early stages	
⇒ Encourage working parties to establish dialogue with relevant healthcare professionals' organisations on the content of selected 'draft guidelines' and 'concept papers'	2012
⇒ Ensure dissemination of specific concept papers/draft guidelines to relevant healthcare professionals' organisations and encourage them to send comments.	Ongoing
• Facilitate healthcare professionals' organisations input and contribution to the implementation process of new legislation (e.g. pharmacovigilance)	Ongoing
• Monitor and increase transparency on the involvement of healthcare professionals' organisations in the Agency's activities	
⇒ Establish a system for regular cross-Agency collection of data for monitoring and reporting purposes	1Q 2012
⇒ Promote visibility of healthcare professionals' organisations input provided in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups (e.g. by reflecting their contribution in minutes, assessment reports, etc)	3/4Q 2012

Actions	Estimated timeframes for completion
⇒ Prepare an annual report on the progress of the interaction with healthcare professionals' organisations	3/4Q 2012

Since healthcare professionals are an integral part of the Agency's work and already take part in different activities, the implementation of the framework will mostly focus on establishing the network of European healthcare professionals' organisations, on putting in place systems to monitor the existing interaction and participation and on reporting on performance at regular intervals.

A report will be presented to the EMA Management Board and Human scientific committees in early 2013, and subsequently each year, on the progress made, including an analysis of performance indicators, feedback received from healthcare professionals' organisations and an overview of the work undertaken by the HCP WP.

The work to be undertaken in the context of the Agency's interaction with healthcare professionals' organisations will be incorporated in the Agency's annual Work Programme.