



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication

## Revised framework for interaction between the European Medicines Agency and patients and consumers and their organisations



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# 1. Executive Summary

The revised framework describes the objectives and consolidates the methodology of the Agency's interaction with patients and consumers in relation to medicines for human use.

The Agency has interacted with its stakeholders since it began operating. Following the implementation of relevant legislative provisions, the EMA Management Board and certain scientific committees include patients and consumers as members.

The framework is based on the establishment of regular interaction with a network of European patients' and consumers' organisations, aiming at:

- Supporting the Agency to access real-life experiences of diseases and their management and to obtain information on the current use of medicines. This will contribute to understanding the value, as perceived by patients, of the scientific evidence provided during the evaluation process for the purposes of benefit/risk decision-making;
- Contributing to more efficient and targeted communication to patients and consumers, to support their role in the safe and rational use of medicines;
- Enhancing patients and consumers' organisations' understanding of the role of the EU medicines Regulatory Network.

The framework defines patients and consumers' organisations as not-for-profit organisations that have an interest in patient care, and where patients and consumers represent a majority of members in governing bodies.

The framework recognises the importance of interacting with the patients' and consumers' organisations via a network of eligible organisations and through the EMA working party of patients and consumers' organisations. It foresees the creation of a pool of disease-specific patient experts to facilitate the process of involvement, particularly in product-related activities. It also recognises the necessity to develop capacities of patients to facilitate their integration in the Agency's work while raising awareness about EMA and the European regulatory network. A report on the progress of the interaction with patients and consumers and their organisations will be presented annually to the EMA Management Board.

## 2. Introduction

The Agency has interacted with its stakeholders since its creation in 1995. These stakeholder relations have evolved over time and the type and degree of interaction varies depending upon the stakeholder group concerned and the field of Agency activity.

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 patients and consumers. In addition to direct interaction with patients' and consumers' organisations, the legislation also defines the framework for providing clear and useful information to them. Furthermore, the Pharmaceutical legislation calls for the Agency to implement specific forms of interaction with patients' and consumers' organisations and their representatives. For example, patients are represented in the EMA Management Board, the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmacovigilance and Risk Assessment Committee (PRAC). In addition the Agency has put in place methods to collect patients' input through direct consultation.

The great majority of experts involved in the evaluation of medicines are scientists. They are made available to the Agency by the national competent authorities of the EU and EEA. However beyond the scientific assessment, there is an increasing need to understand the day-to-day use of the medicines and to better inform the users about the medicines in order to promote their safe and rational use. To achieve this ambitious objective, the Agency engages in 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 experience acquired to date demonstrates that the participation of patients in the Agency's activities has resulted in increased transparency and trust in regulatory processes and mutual respect between regulators and the community of patients and consumers. It is also acknowledged that their contribution to the evaluation of medicines enriches the quality of the opinion given by the scientific committees. This positive experience confirms the importance for the Agency to continue supporting and facilitating patient contribution to its work.

Finally, interaction with patients and consumers is a necessary complement to interaction with healthcare professionals, and allows the EMA to provide a platform of exchange and dialogue at European level where the views from all users of medicines (patients and healthcare professionals) can be considered.

### **3. Rationale for revising the framework?**

The framework of EMA interaction with patients' and consumers' organisations was adopted by the Management Board on 15 December 2005.

Its objective was to define the approach to patients' and consumers' relations and to tackle new challenges, such as the implementation of Community legislation and the Agency's strategic priorities at that time. These objectives have been fulfilled with the creation of the EMA Working Party with Patients' and Consumers' Organisations as well as the implementation of the recommendations on transparency, product information, pharmacovigilance and interaction with the scientific committees.

In December 2009, the Management Board reviewed the progress made and requested a revision of the initial framework to further integrate these interactions in a more structured way and build on the achievements of the working party. The Board sought clarification on the role of patients and consumers in scientific committees and proposed to strengthen the support provided to patients and consumers participating in EMA activities.

To respond to the Management Board request, the Agency took action by:

- Defining the role of patients in scientific committees
- Developing a proposal to involve patients in the benefit/risk evaluation at level of the Committee for Human Medicinal Products (CHMP)
- Developing a training programme
- Introducing the concept of double daily allowance for patients and healthcare professionals participating in EMA activities under certain conditions

The current revision of the framework relies on the existing robust and efficient model. Its aim is to strengthen this model and reach out to a wider audience while remaining flexible enough to accommodate for future legislative and strategic initiatives such as the EMA Road Map to 2020.

## 4. Scope of interaction

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

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

Patients' organisations are defined as not-for profit organisations that are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies.

Relevant organisations include: general umbrella organisations (*e.g.* representing either European disease-specific organisations and/or national umbrella organisations) and European disease specific organisations representing national organisations or individual patients on acute and/or chronic diseases.

Consumers' organisations are defined as not-for profit organisations that defend and promote the general interests of European consumers - citizens as purchasers or users of goods and services

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 patients' and consumers' organisations while respecting the remit of the Agency's activities.

## 5. Objectives

This framework allows the Agency to further build transparency and trust with patients' and consumers' communities through their active engagement (**participation-consultation-information**). In order to achieve this goal the framework aims at meeting the following specific objectives:

1. Facilitate participation of patients and consumers in benefit/risk evaluation and related activities, to capture patients values and preferences and obtain information on the current use of medicines and their therapeutic environment, all along the lifecycle of the medicines, from early development throughout evaluation and post-marketing surveillance;
2. Ensure that patients, consumers and their representative organisations are listened to and consulted and where appropriate involved in the development of EMA policies and plans;
3. Enhance patients and consumers' organisations understanding of the mandate and role of the Agency and the EU Regulatory Network within the context of the development, evaluation monitoring and provision of information on medicines;
4. Optimise communication tools (content and delivery) to facilitate and encourage the cascade of information to the constituencies of patients and consumers' organisations (*i.e.* to reach out to individual patients and consumers) with the aim of supporting their role in the safe and rational use of medicines;

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 and their representative organisations.

## 6. Working methodology

Based on legal provisions and experience so far, patients and consumers 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. Patients and consumers can also contribute to the EMA's activities as individual **experts**. In addition, patients and consumers may, as **representatives of a specific organisation**, be consulted and participate in Agency discussions to express the views of the organisation on a specific issue. Occasionally, patients and consumers may participate as **observers** in certain aspects of the Agency's work.

When patients and consumers participate in the Agency's activities as individuals and not as representatives of their organisation, 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 patients and consumers' organisations in EMA activities. In addition, the organisations involved should be fully transparent with regard to their activities and funding sources.

The interaction with patients, consumers and their representatives are also affected by time, budget and availability constraints on both sides: organisations and Agency. Streamlining the interactions and focusing on areas where mutual benefit can be anticipated are two underlining principles to consider when implementing the framework.

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

1. A network of European patients' and consumers' organisations;
  2. A forum of exchange with patients' and consumers' organisations established within the Agency: the EMA Patients' and Consumers' Working Party (PCWP);
  3. A pool of individual patients acting as experts in their disease and its treatment to facilitate patients' involvement in medicines evaluation and information;
  4. Interaction with the EU Regulatory Network particularly in the field of communication;
  5. A programme of actions for capacity-building, focusing on training and raising awareness about the European regulatory system.
1. The **network of European patients' and consumers' organisations** allows 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 apply ('Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency (EMA) activities'). These criteria ensure that the Agency establishes contact with the most suitable organisations representing European patients and consumers in a transparent manner.

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

1.1. Evaluation by the Agency of European patients' and consumers' organisations that fulfil specific eligibility criteria to be involved in its activities (primary level of interaction).

⇒ 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 will be 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 patients' and consumers' organisations on the Agency website

Eligible organisations are 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.

2. The **EMA Patients' and Consumers' Working Party (PCWP)**, is a platform for dialogue and exchange with patients' and consumers' organisations on relevant issues concerning medicines for human use; through it the Agency will inform and will obtain feedback and contribution from patients and consumers on various Agency's initiatives. It includes a balanced representation of the different types of patients and consumers (such as general organisations representing patients, consumers or civil society, and organisations representing diseases within the mandatory scope of the centralised procedure for marketing authorisation, as well as organisations representing special populations not well represented in medicines development such as older people and women, 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 patients and consumers and their representative organisations. It also provides a forum to further identify gaps and priorities in the overall interaction.

Members of the PCWP are selected from the list of eligible patients and consumers' organisations.

3. **A pool of patients acting as experts in their disease and its treatment** will be created from two different sources:

- Through direct requests to the eligible organisations;
- 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 creation of the pool of experts will enable the Agency to quickly and efficiently identify patients that can be involved in product-related activities, review of product information and communication material.

Further guidance on the creation of this pool of experts will be published on the website. The names of the identified experts will be included in the European Expert Database. All personal information on applicant experts and experts included into the database is processed by EMA pursuant to Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000, on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

4. **Interaction between the network of European patients' and consumers' 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 validated and up-to-date information to patients and consumers 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.
5. **Capacity-building:** For their contribution to be meaningful, patients must have an understanding of the Agency's mandate as well as their expected role in the evaluation process. An EMA training programme is available. It is based on a tailored approach depending on the type of participation expected from the individuals. It is complemented by personalised and one-to-one support to patients involved in specific activities. Some patients' organisations or other collaborative projects have also developed trainings in order to empower patients to play a recognised advocacy role at European level. A reflection involving the different actors including the EU network Training Centre could further define a core curriculum and look for synergies of action in order to use training resources (both human and financial) in a more efficient way.

## 7. Implementation and monitoring

The Agency has developed a robust system for involving patients, consumers 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 the 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 the Annex I. An annual report on interactions will be presented to the EMA Management Board and Human scientific, including an analysis of performance indicators, feedback received from patients and consumers and their representative organisations through targeted surveys, an overview of the work undertaken by the PCWP as well as an overview of the activities common to patients, consumers and healthcare professionals.

Every two years an overall satisfaction survey will be distributed to patients and consumers who contributed to the Agency activities.

The work to be undertaken in the context of the Agency's interaction with patients' and consumers' organisations will be incorporated in the PCWP annual work programme and/or in the Agency's annual work programme, when appropriate.