EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revised framework of EMA interaction with patients, consumers and their organisations

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Introduction

- Interaction between EMA and patients/consumers and their representatives has a legal basis: Article 78 of Reg (EC) 726/2004
- EMA has put in place an effective and robust structure supporting development of trust and mutual respect between EMA and patients community
- The revised framework relies on this structure to reach out to a wider audience
- The framework is general/flexible enough to accommodate new legislative and strategic initiatives, *e.g.* EMA Road Map to 2020

Rationale

2006: Initial framework adopted by the Management Board

→ Its objectives have been fulfilled:

1. creation of PCWP
2. Implementation of PCWG recommendations

2009: The Management Board requested us to address two issues prior to the revision:

1. Role of patients in committees and particularly in benefit/risk evaluation
2. Training and financial support

→ Both have been addressed

2014: Revised framework to be adopted by the Management Board:

1. Clarify the objectives
2. Consolidate the methodology

Scope

- Patients, consumers and their organisations:
  - with clear definition of Patients/Consumers Organisations
  - at European level
- Interaction covers areas of common interest while remaining within the remit of the Agency

Objectives:

PARTICIPATION – CONSULTATION – INFORMATION

- Facilitate participation in benefit/risk evaluation and related activities throughout the life cycle of medicines to capture values and preferences and obtain information on the use of medicines from early development through evaluation and post-marketing surveillance.
- Ensure that patients, consumers and their organisations are listened to and consulted and where appropriate involved in development of plans and policies.
- Enhance organisation understanding of EMA role within the EU regulatory network regarding development, evaluation, monitoring and provision of information on medicines.
- Optimise communication tools (content and delivery) to support their role in the safe and rational use.

Working methodology

To achieve the objectives, the framework relies on 5 critical elements:

1. A network of European patients and consumers' organisations
2. A forum of exchange: EMA Working Party with Patients and Consumers' organisations
3. A pool of patients acting as experts in their disease and its management
4. Interaction with the EU Regulatory Network
5. Capacity-building focusing on training and raising awareness about EU regulatory system

Taking into account time, budget and availability constraints

Monitoring

- Yearly report on interaction to the Management Board:
  - Both quantitative and qualitative aspects
- Satisfaction survey every two years

The work and opportunities for improvement will be included in the Agency annual work programme and/or PCWP annual work plan, as appropriate.

Annex I - Action plan

- **Maintain the network of organisations**
- **Establish a pool of experts**:
  - Gap analysis
  - Call for expressions of interests
- **Promote participation**:
  - In early development/research: patients values and preferences
  - During evaluation: value of evidence
- **Develop capacity**:
  - Identify means to increase awareness on the Agency/Network role
  - Survey on current provision of training
  - Explore synergies between a range of training initiatives
- **Monitor and increase transparency on involvement**:
  - Cross-Agency collection of data both qualitative and quantitative
  - Identify methodologies to measure impact
  - Acknowledge patients' input and increase visibility