



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Cooperation between EMA and patients' and healthcare professionals' organisations

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An agency of the European Union





# EMA collaboration with patients and healthcare professionals

1996: . Building the foundation of the interaction between EMA and patients

→ Management Board warned of the danger of neglecting partnership with stakeholders, public, health professions and pharmaceutical industry.

“The Board will therefore keep a careful watch on these partnership and take them fully into account in shaping policies”.

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→ EMA started dialogue with HIV patients on the value of surrogate markers in the approval of anti HIV drugs leading to the early approval of protease inhibitors.

2014: . Real life experience of patients is now routinely embedded in regulatory output

. Clinical practice is becoming an important element of the regulatory process



# Interaction with patients/consumers' and healthcare professionals organisations

A unique model of interaction:

- Frameworks of interaction and
- Eligibility criteria





## The frameworks rely on three critical elements

- A network of patients' consumers' and healthcare professionals' organisations;
- Interaction with the EU Regulatory Network in the field of communication (with particular emphasis on safety communication);
- Fora of exchange with the organisations established within the Agency:  
The EMA Patients' and Consumers' organisations Working Party (PCWP).
- The EMA Healthcare professionals' organisations Working Party (HCPWP)



# Criteria to be fulfilled by organisations involved in EMA activities (eligibility criteria)

- **Legitimacy** (statutes registered in one of the Member States of the EU/EEA);
- **Mission/objectives** (clearly defined and should agree to have them published on the EMA website)
- **Activities** (specific interest in medicinal products, which should be documented, as part of its activities);
- **Representation** (representative throughout the EU/EEA);
- **Structure** (governing bodies which are elected by their members, who shall be patients or healthcare professionals respectively);
- **Accountability and Consultation Modalities** (statements and opinions of the organisation should reflect the views and opinions of its members and adequate consultation procedures with those members should be in place);
- **Transparency** (disclosure to EMA of all sources of funding; relationships with corporate sponsorship should be clear and transparent).



# Network of patients and consumers 37 eligible organisations

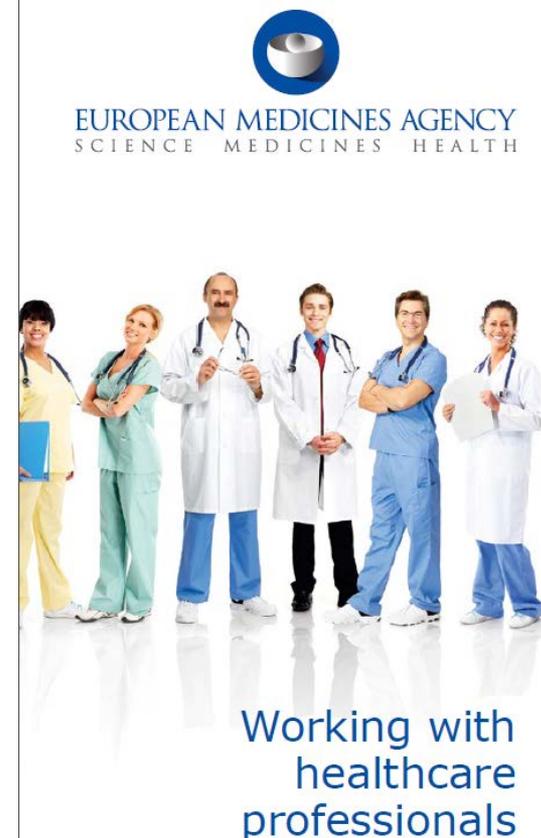


Fabry International



# Network of European healthcare professional organisations ('eligible HCPOs')

- 28 eligible organisations by end of April 2014





# Patients and healthcare professionals in EMA governance

Patients and healthcare professionals are members of the Management Board:

- 2 patients' representatives
- 2 healthcare professionals' representatives:
  - 1 for the human medicines
  - 1 for the veterinary medicines



# Involvement as Members of scientific committees <sup>1/2</sup>

Patients and healthcare professionals as Members of scientific committees:

- Committee for Orphan Medicinal Product (COMP) – (patients only)
- Paediatric Committee (PDCO)
- Committee for Advanced Therapies (CAT)
- Pharmacovigilance and Risk Assessment (PRAC)

The Committee for Medicinal Products for Human Use (CHMP) has no member representing patients.



# Involvement in other EMA activities

## Patients and healthcare professionals as representatives of their organisation

- Members of **PCWP and HCPWP**
- Consultation on **guidelines**
- Consultation on **policies**
- Involvement in several on-going **EU-wide initiatives**, *e.g.*:
  - **EudraCT** (EU clinical trials register), **Eudravigilance** (adverse reaction data), **ENCEPP** (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance), and **Enpr-EMA** (European Network of Paediatric Research)
- Participate in Agency **conferences** and **workshops**



## Involvement in product-related activities <sup>2/2</sup>

### Patients and healthcare professionals as experts:

- Participate in Scientific Advice/Protocol Assistance during product development
- Participate in Scientific Advisory Groups (SAG) meetings during the evaluation phase
- Review communication material and information on medicines, particularly safety communication and other agency documents intended to the public



# Pre-requisite to participation

- Process and structure in place
  - Declaration of interest – confidentiality undertaking
  - Personalised support
  - Role of patients' organisations
- Identify situations where they bring added value (e.g. benefit-risk evaluation)



# Challenges

- Identify when regulators should get views from individual versus patient community
- Develop means to identify and manage differences of view between patients and between patients and other stakeholders
- Ensure that patients' and healthcare professionals' views come from independent sources
- Look at training/support to maximise input
- Research how to collect and use the wealth of information available from patients and physicians in post-marketing phase
- Identify and address all legal, regulatory, financial issues that could give rise to procedural barriers to patients' and healthcare professionals' involvement



## Conclusion

European Medicines Agency engagement with patients/consumers and healthcare professionals is key in addressing public health challenges.