EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How to involve patients in EMA activities and training tools available

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Interaction with patients and consumers Background

- Since the beginning the EMA has been **engaging** with patients & consumers
- Based on a "**Framework of interaction**", adopted in 2005
- Any organisation representing EU patients or consumers may express an interest to work with the Agency, however they must meet the defined **eligibility criteria** (application form on EMA website)

Criteria for involvement of organisations

- **Legitimacy**, with statutes registered in the European Union (EU)
- Clear **mission** and **objectives** with an interest in medicines
- European patient or consumer **representation**
- Adequate **structure** and consultation modalities
- **Accountability** and **transparency**

List of eligible patients'/consumers' organisations published on the EMA website

Eligible organisations

Patient/consumer involvement in EMA activities

- EMA **Working Party** with Patients' and Consumers' Organisations (**PCWP**)
  - 18 eligible organisations + representatives from Agency's committees
  - To provide recommendations to the Agency and its Committees on all matters related to medicines; a platform/forum for exchange between patients and regulators
- **Members of:**
  - Management Board (**MB**)
  - Committee for Orphan Medicinal Products (**COMP**)
  - Paediatric Committee (**PDCO**)
  - Committee for Advance Therapies (**CAT**)
  - Pharmacovigilance Risk Assessment Committee (**PRAC**)

Patient/consumer involvement in EMA activities

- Respond to ad-hoc requests on **assessment of products** from scientific committees and working parties
- Participation in **scientific advisory groups** (SAGs)
- Participation in **scientific advice/protocol assistance**
- **Review information on medicines**: Package leaflets, EPAR summaries, safety communications (Q&As) and other Agency documents for the public

Patient/consumer involvement in EMA activities

- Input in the preparation of **guidelines**
- 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**

Added value of involving patients in EMA

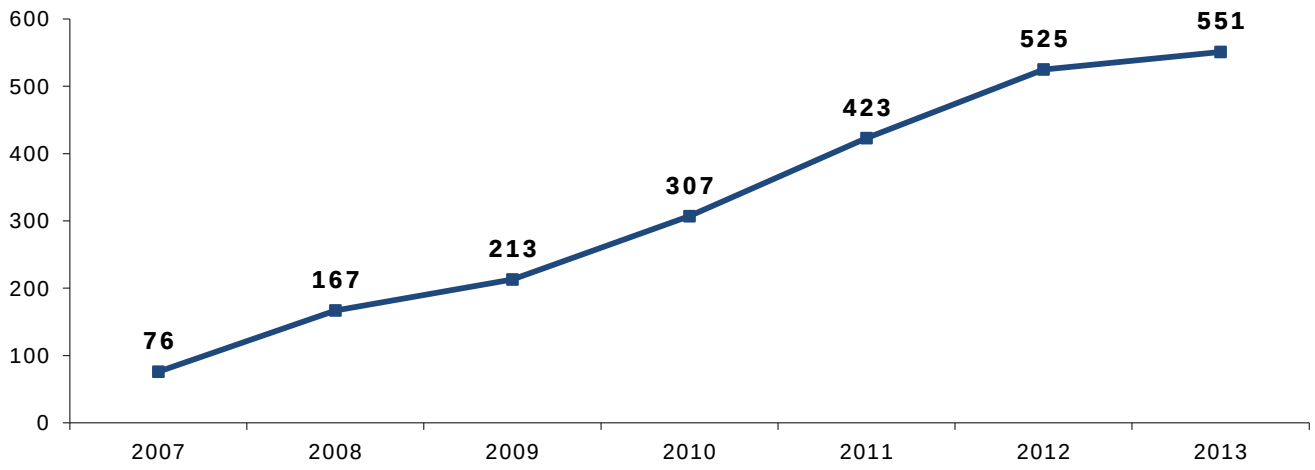
- They represent **patients interests** and bring a **unique real-life** experiences of the disease on behalf of those directly affected by regulatory decisions
- The **added value** that ‘lay experts’ bring to the activities of the Agency has been **well acknowledged** on many occasions

Increasing involvement

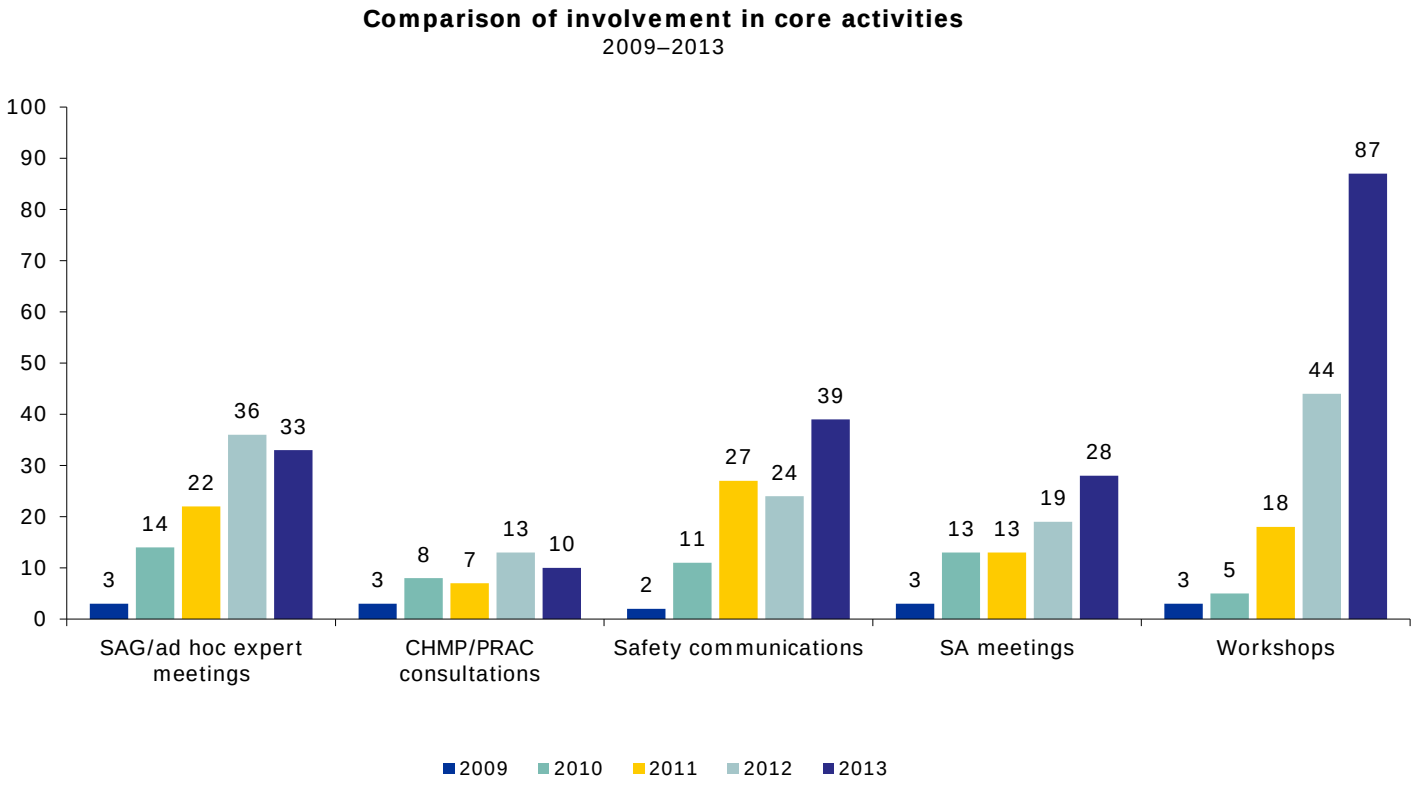
- The **interaction** between the Agency and patients/consumers has been increasing steadily since 2005; both in numbers and range of activities
- **Eligible** organisations increased from **19** in 2007 to **37** today
- **PCWP membership** was enlarged to 19 organisations in 2013
- Involvement is more **formal** and **systematic**

Increasing number of patients involved in EMA activities

Overall number of patient & consumer involvement in EMA activities
2007–2013



Increasing range of EMA activities



Challenges

- **Resources** within the organisations and the Agency
- Comprehensive, tailored **training** to facilitate participation
- Definition of **patient role** in the different activities / committees
- Finding **suitable experts** (e.g. language barrier, availability)

The impact of interaction

- **Improves the outcome** of regulatory decisions
- Increases **transparency** and builds **confidence** in the regulatory system
- Involvement at **operational level** leads to **tangible impact** on outcomes e.g.
  - Patients' views on benefit-risk deliberations contributes to **final recommendations** from the committees
  - Review of product information and safety communications - **50%** of comments are **taken into account**.

Training

- Adapted to the activity in which patients participate
- Catalogue of tools/material
  - EMA website
  - Written information
  - In-house training
  - Personalised assistance

www.ema.europa.eu