EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fifth report on the interaction with patients' and consumers' organisations (2011)

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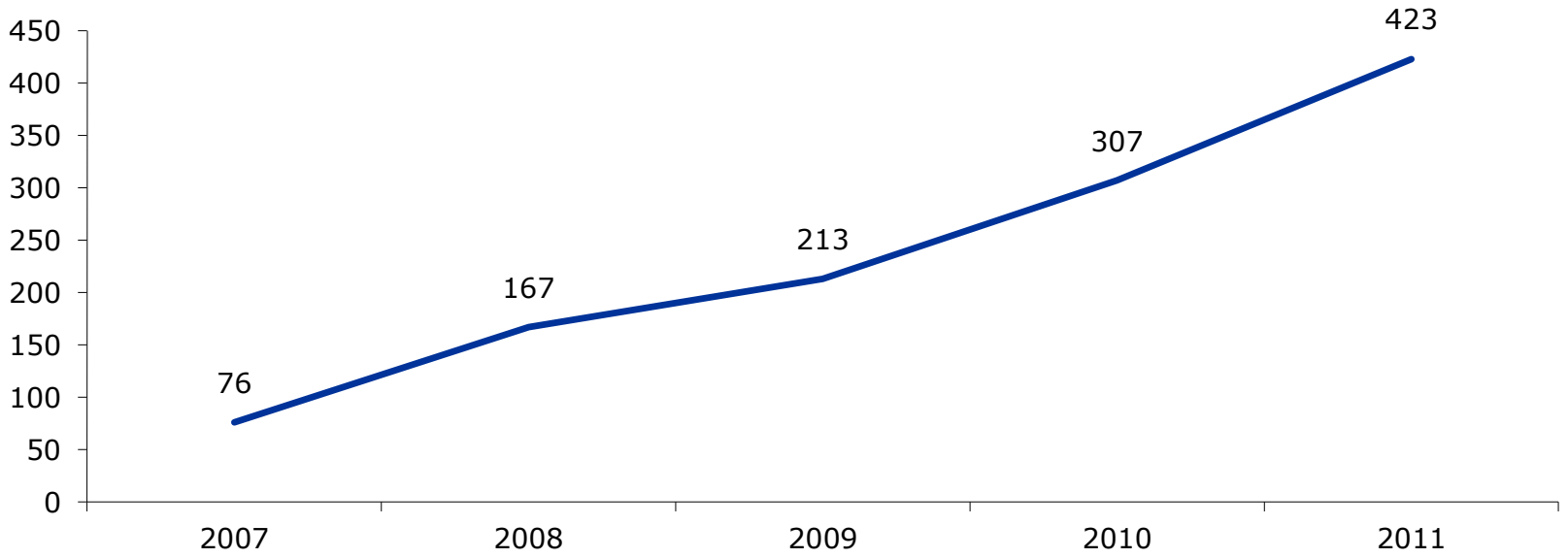
Public Information and Stakeholder Networking

Introduction

- Detailed overview of all EMA activities where patients, consumers and their organisations (PCOs) have been involved during 2011
- Provides comparison to preceding years
- Highlights future steps for interaction
- Presented to the EMA Management Board and published on EMA website
- During 2011 an extensive collaboration between EMA and PCOs was again achieved

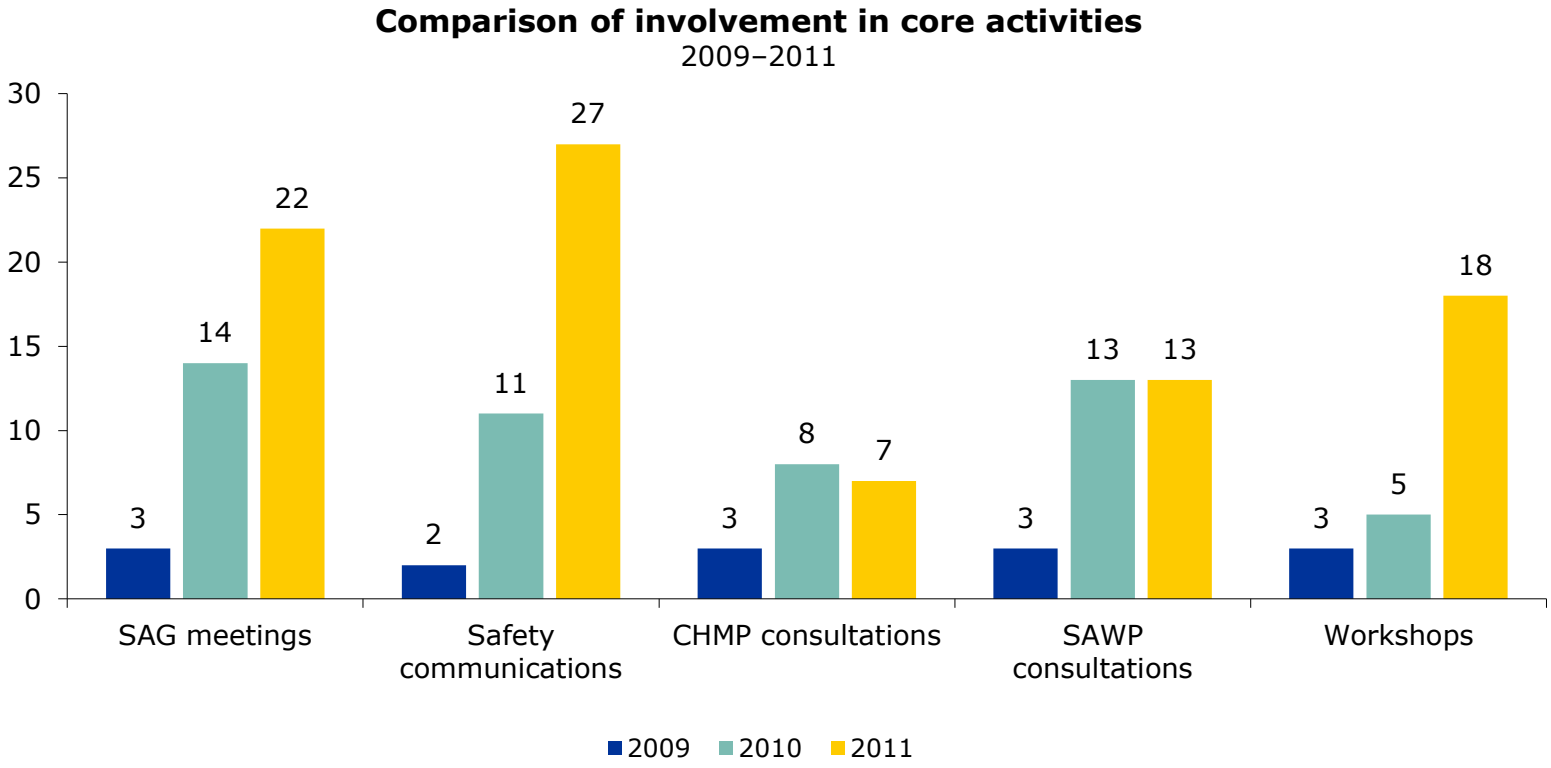
Overall number of patients and consumers involved in Agency activities
2007–2011



Number of patients/consumers involved

Growth relates mainly to:

- Increased participation in SAG and ad-hoc expert group meetings
- Increased review of safety communications (Q&As) and package leaflets
- Increase in activities related to the implementation of new pharmacovigilance legislation
- In addition to established on-going activities

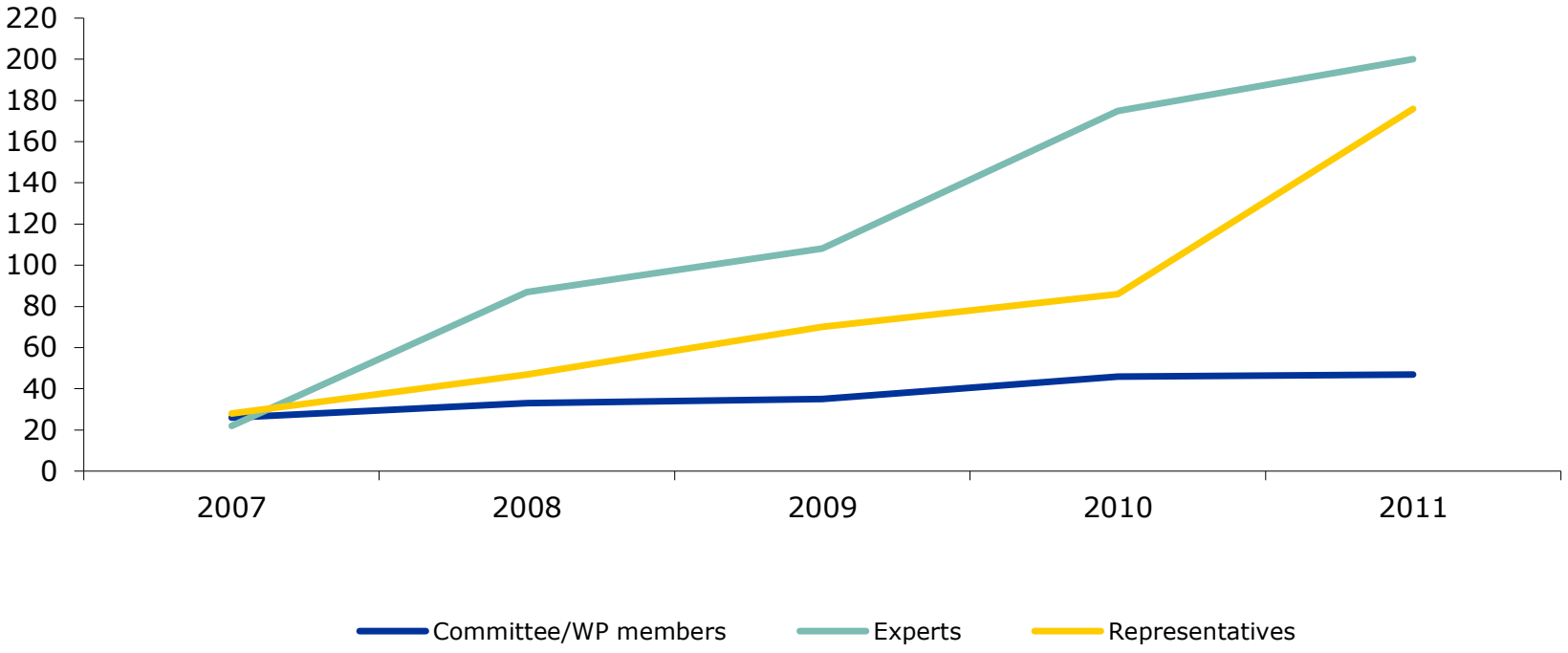

Comparison of involvement in core activities
2009–2011
30
25
20
15
10
5
0
3
14
22
2
11
27
3
8
7
3
13
13
3
5
18
SAG meetings
Safety communications
CHMP consultations
SAWP consultations
Workshops
2009
2010
2011

Activities are split into three categories;

1. activities in which patients/consumers are members, alternates or observers,
2. activities involving individual experts, and
3. activities requiring organisations' representatives.

Comparison of involvement as committee/WP members, experts and representatives of organisations

2007–2011



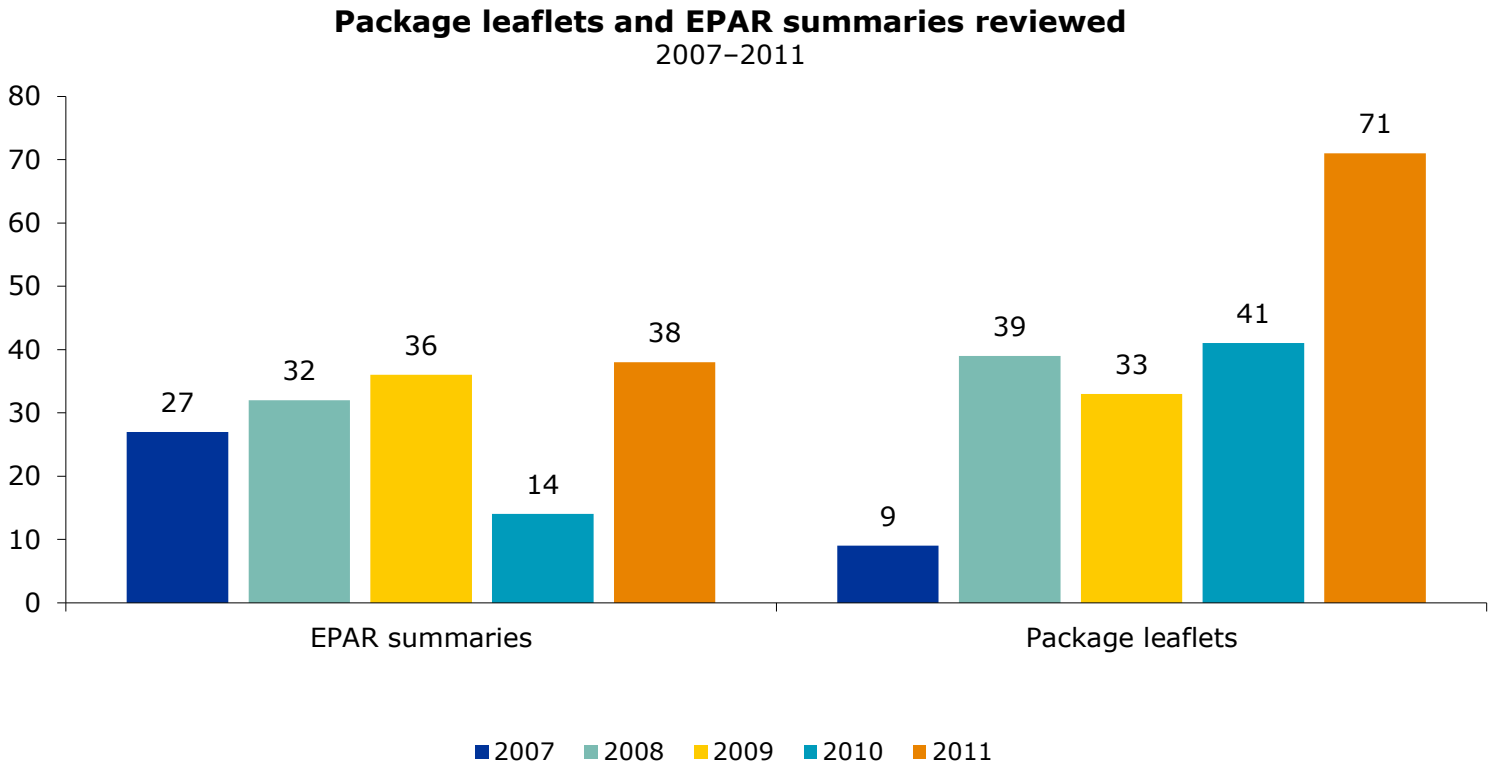
Members: The number of members/alternates/observers in EMA committees & working parties has remained predominately the same, as would be expected

Experts: 200 experts were involved in Agency activities during 2011 - increase relates mainly to involvement in:

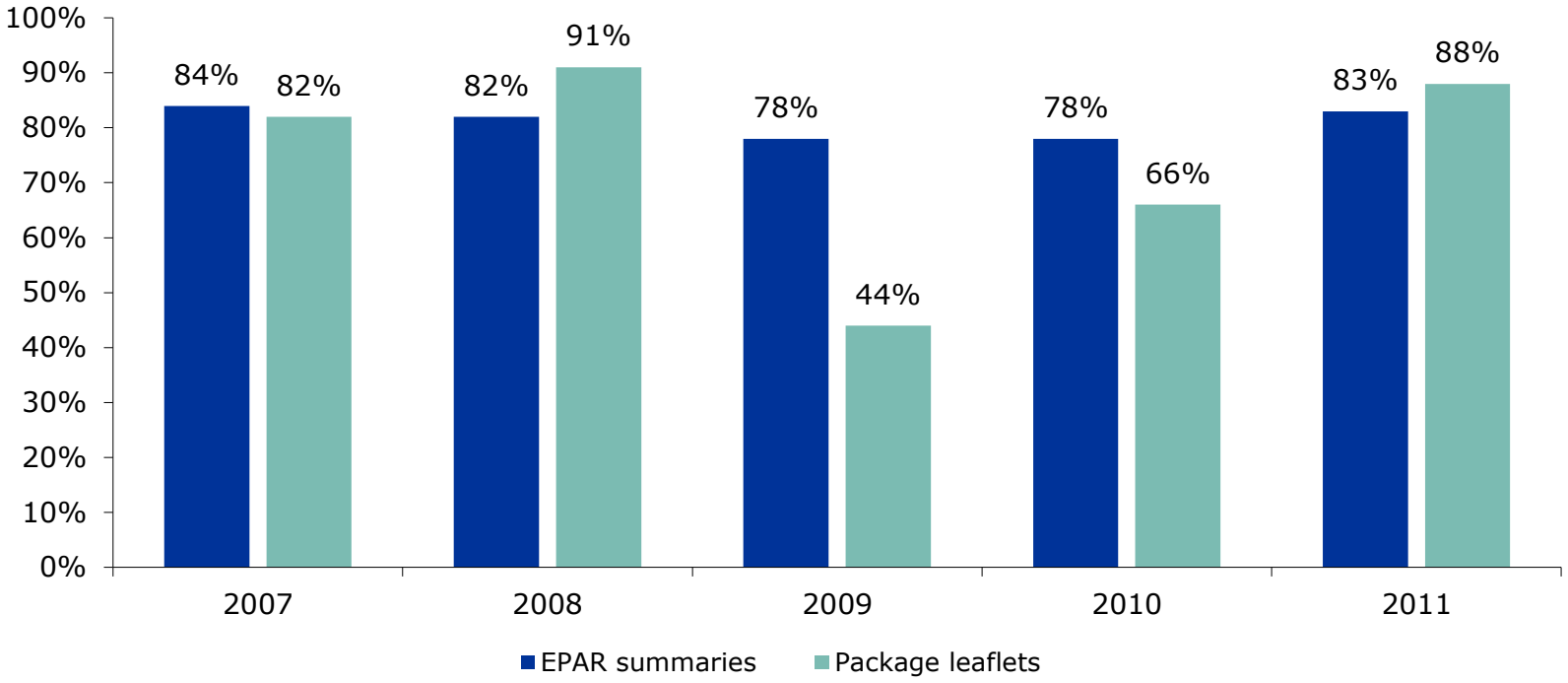
- SAG/ad-hoc expert meetings (3 participants in 2009, 14 in 2010 and 22 in 2011);
- Review of package leaflets (33 in 2009, 41 in 2010 and 71 in 2011);
- Review of EPAR Summaries (36 in 2009, 14 in 2010 and 38 in 2011)
- Review of safety communications (2 in 2009, 11 in 2010 and 27 in 2011).

Representatives: 46 different organisations interacted with the Agency during 2011, compared to 52 in 2010, 41 in 2009, 26 in 2008 and 24 in 2007. Slightly lower number of PCOs, but representatives involved increased significantly, from 86 in 2010 to 176 in 2011.

Review of Package Leaflets & EPAR Summaries

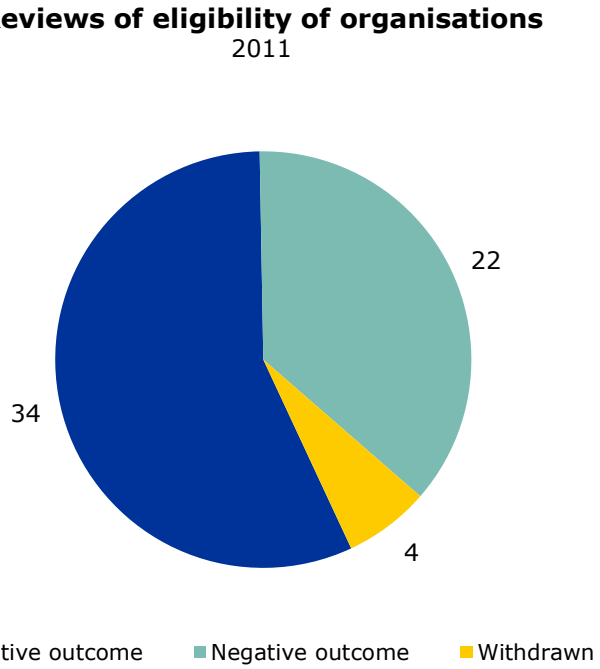


Percentage of package leaflets and EPAR summaries reviewed
2007–2011



Eligible Organisations

- There are now 34 different patient/consumer organisations working with the Agency across many different areas. During 2011, 5 organisations became eligible.



- During 2011, 46 patients'/consumers' organisations interacted with the EMA

EMA Working Party with Patients' and Consumers' Organisations (PCWP)

The PCWP continues to play a key role in the interaction between the EMA and PCOs.

- 15 members and 13 alternates representing PCOs;
- 5 members from the EMA Scientific Committees;
- 1 member from the EMA secretariat;
- Observers from the CMD-h, the HCP WG, the PhVWP and the MB.

Four PCWP meetings during 2011, including one with all 'eligible' organisations, and one joint with the Healthcare Professionals' Working Group (HCP WG) + one-day training session.

The **PCWP** was consulted by the pharmacovigilance working party (PhVWP) in relation to 5 procedures, and by the CMDh (mutual recognition & decentralised procedures – human) for 1 procedure.

PCWP representatives involved in other initiatives, e.g.

- The European Network of Paediatric Research (Enpr-EMA); patient representative member of the Enpr-EMA coordinating group
- The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP); PCO representative member of the steering group
- The Pharmacoepidemiological Research on Outcomes of Therapeutics (PROTECT); patient representatives are involved in the PROTECT consortium

EMA activities involving patients and consumers 2011

Members of:

- Agency's Management Board
- Scientific Committees (COMP, PDCO, CAT)
- PhVWP (from May 2010 – June 2012)
- Pharmacovigilance Risk Assessment Committee (PRAC) in the future.

CHMP consultations: Five specific with PCOs on products /issues under evaluation

Scientific Advice Working Party - 13 patients' representatives participated as experts in specific scientific advice requests for protocol assistance (orphan drugs).

- Increased involvement in **benefit / risk** evaluations through scientific advisory groups (SAGs);
- Patients with the specific condition under discussion have provided unique information in terms of real life experiences and views which have contributed to the product-specific benefit-risk deliberations and the overall assessment.
- During 2011, a total of 22 patients participated as patient experts in 18 different SAG/expert meetings

Activities related to the implementation of the new pharmacovigilance legislation

- 3 **stakeholder meetings** (including industry, patient/consumer and healthcare professional representatives, national medicines regulatory authorities and the European Commission) ; Several patient representatives gave presentations
- **Additional monitoring of medicines** & direct patient reporting - impact on the package leaflet; PCOs involved in written consultation on the design and selection of the symbol and proposed text – on-going
- **Direct patient reporting** form; PCOs reviewed initial draft form prepared by the EMA – on-going

Activities related to clinical trials

- **Reflection paper on third country clinical trials;** working group included 6 representatives from PCWP - final reflection paper published April 2012
- **EU clinical trials register;** 10 PCWP representatives part of EudraCT working group since 2010. Participated in development of the new public interface, including users guidance document and user-testing of the system. On-going work to improve functioning of the register

Access to Eudravigilance data

8 patient/consumer representatives part of **user-group**, in place since 2010 to assist in the implementation of the Eudravigilance access policy and the development of the public website giving access to Eudravigilance data.

Involved in preparation of guidance document and technicalities of public interface. The group will continue to be involved in future phases and modifications of the website.

Involvement in EMA workshops, conferences, info sessions and expert meetings

- Workshop on drug-related progressive multifocal leukoencephalopathy
- Ophthalmology Workshop
- HIV Prevention workshop
- Enpr-EMA Workshop
- EMA meeting with Thalidomide Patients' and victims' organisations
- Involvement in other external conferences/info sessions, e.g. EMA/DIA ENCePP infoday, Eudravigilance/DIA infoday, Joint TOPRA/EMA conference

Training

- **Annual training** session held in November on 'review of EMA documents addressed to the general public'; review of package leaflets, EPAR summaries and safety communications, and also overview of the centralised procedure
- **Training brainstorming** session held during February PCWP in order to gather information for development of a training strategy.

Framework of interaction

- Work has continued on the **revision of the framework** ;
- The revision will focus on:
  - Facilitating patient participation in benefit/risk deliberations
  - Defining the role of patients involved in the scientific committees
  - Delineating the training and support necessary to both facilitate and optimise patient involvement.
- Progress includes:
  - Adoption of document on the role of patients as members in scientific committees - published Dec 2011
  - 'Training brainstorming' session held February PCWP to gather information on the needs and expectations to develop a training strategy

Eligibility

The EMA and the PCWP will work on increasing transparency in its procedures for evaluation and re-evaluation of eligible organisations, and will explore how to develop the way potential conflicts of organisations are handled when working with the Agency.

Conclusion

The involvement of PCOs has proved to be extremely beneficial; they are now a recognised and integral part of the Agency's work and with the passing years, their involvement has not only increased and expanded, but has evolved and been refined to ensure it occurs in the most optimal manner possible.

This collaborative interaction allows patients to engage with the EMA to share their real-life experiences and in doing so, they provide valuable feedback which ultimately contributes to the quality of the decision-making process.

Conclusion

The next report on the interaction between the EMA and PCOs to be presented in 2013 will also include an analysis of the degree of satisfaction of patients and consumers involved in EMA activities during 2012.