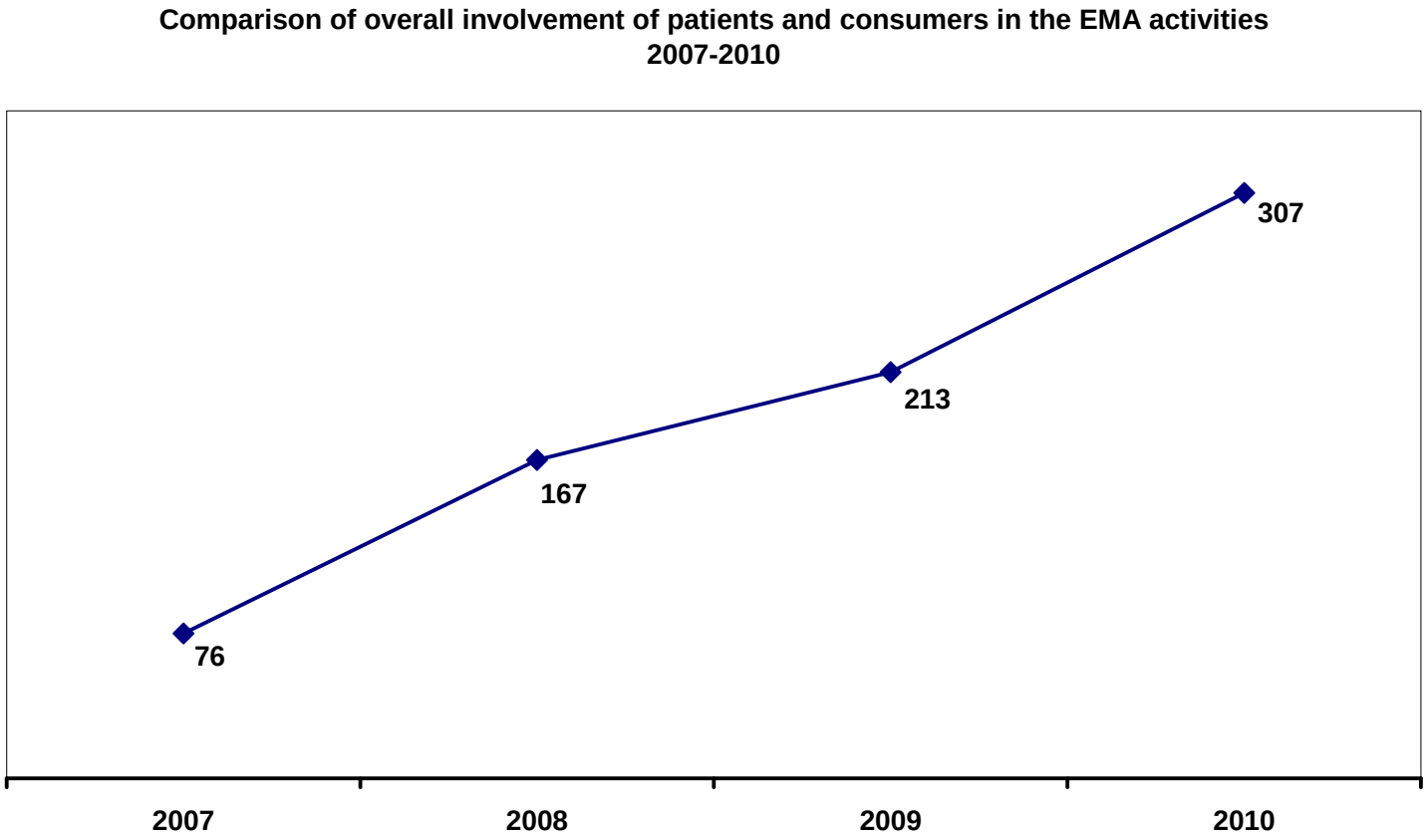
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Annual report on the interaction with patients' and consumers' organisations 2010

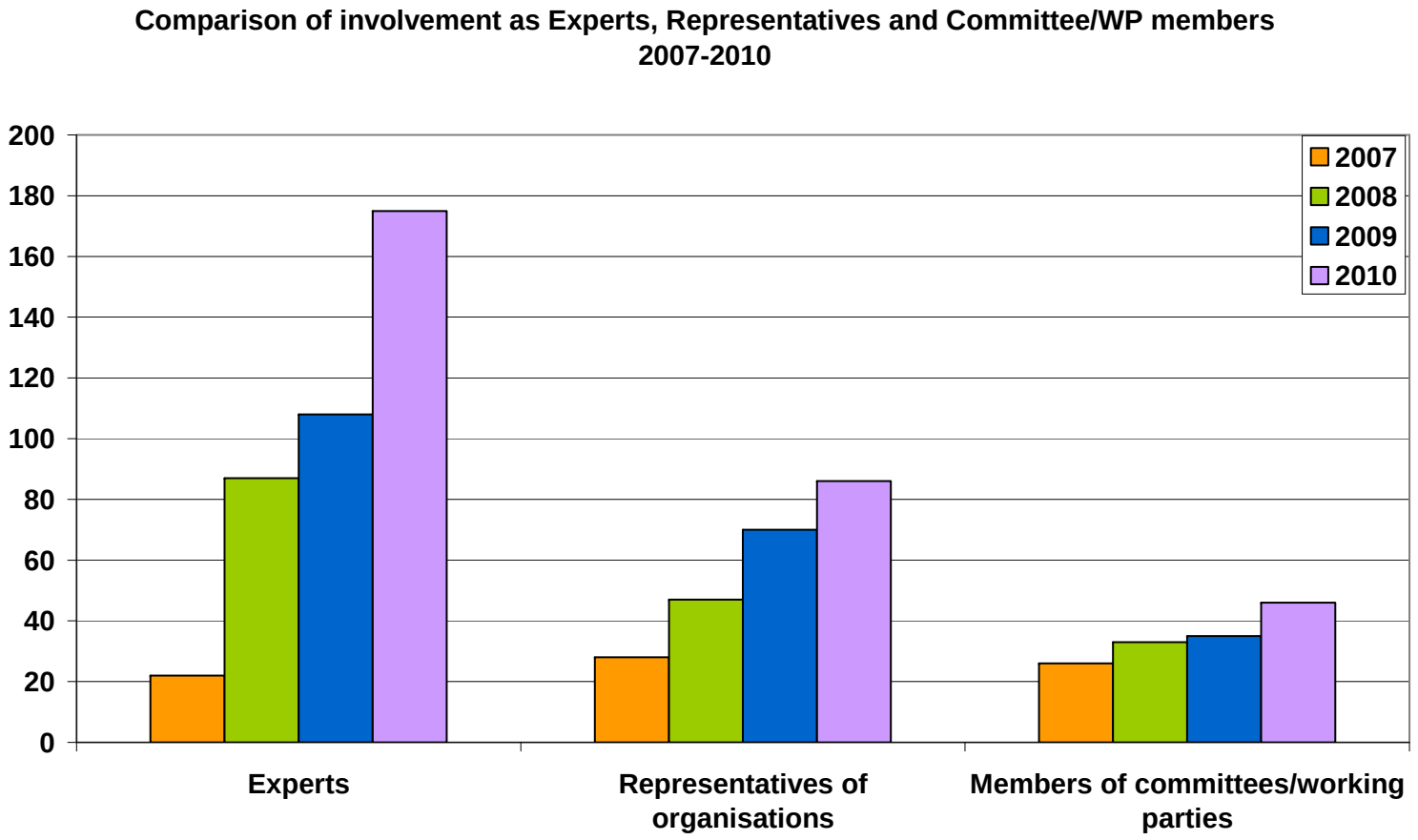
An agency of the European Union

- Requested by the EMA Management Board at the time of endorsement of the framework of interaction between the Agency and patients' /consumers' organisations (2005) to monitor progress.
- Includes information on the numbers of PCOs who have interacted with the EMA during 2010 with a detailed summary of the activities, with comparison to preceding years. Also highlights future steps.
- Includes results/analysis from the questionnaire on the level of satisfaction of patients and consumers involved in EMA during 2010.
- Will be presented to the MB on 6 October and then published on EMA website.

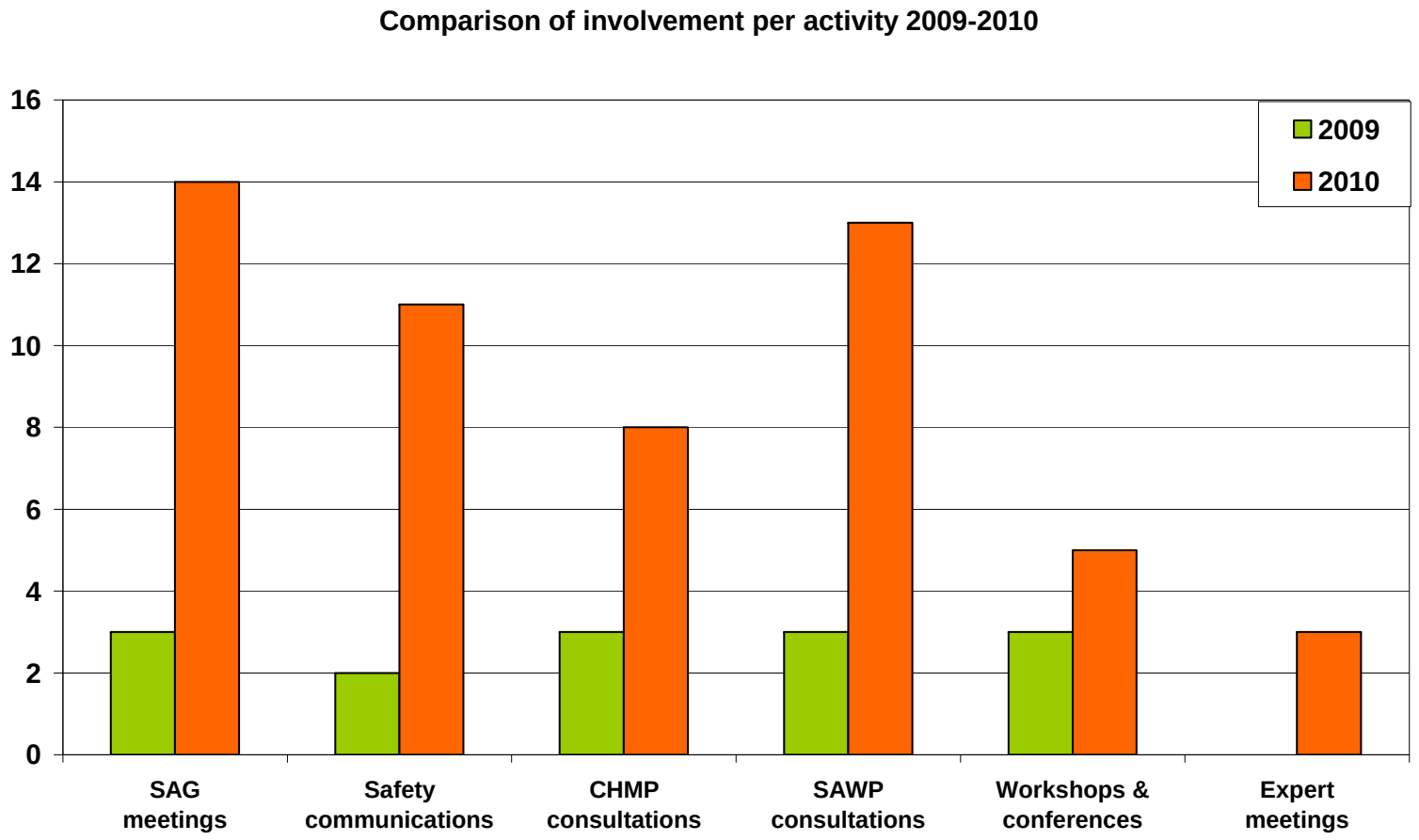
So far, every year the number of patients/consumers involved in EMA activities has increased, and 2010 is no exception.



This increase includes activities where patients /consumers are acting as members, individual experts, or representatives of their organisations'.



2010 has been a very busy year with an expanding range of Agency's activities.



Review of documents

- Increased participation in the review of EMA documents (EPAR summaries, Package Leaflets, safety 'Q&A' documents and press releases).

MB, Committees, Working parties

- Patients are members in the Agency's MB and its Scientific Committees; COMP, PDCO and CAT.
- Since April 2010 patients'/consumers' representatives are permanent representatives in the PhVWP.
- Patients' representatives also participated as experts in specific scientific advice requests, in the Scientific Advice Working Party.

Benefit / risk evaluations

There has been an increased involvement of PCOs in B/R evaluations carried out by the CHMP (CHMP consultations).

In addition patients have participated in several scientific advisory group (SAG) meetings convened at the request of the CHMP, to provide a patient perspective on the product-specific benefit-risk discussions.

Other activities

- Ongoing EU-wide initiatives, such as **EudraCT** (EU clinical trials register), **Eudravigilance** (publication of data), **ENCEPP** (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance), and more recently **Enp-EMA** (European Network of Paediatric Research).
- Working group on **clinical trials in 3rd countries** (reflection paper).
- Consultation on **policy issues** (e.g. transparency project, roadmap to 2015), and also on the formulation of the new EMA website.
- Participation in several **conferences**, **workshops** and **expert meetings** throughout the year, e.g. workshop on nanomedicines, Expert meeting on familial neurodegenerative diseases.

PCWP

- The PCWP has continued to play an essential role in the interaction between the EMA and patients'/consumers' organisations.
- One of the key features during 2010 was the enlargement of the PCWP membership by **5** additional PCOs; giving a total of **15** PCO members (13 alternates).
- In addition, the number of organisations applying and becoming eligible to work with the Agency has also increased, from **19** in 2007 to **29** by the end of 2010. (currently 32).

Conclusions and next steps

- 2010 = important increase in the number of patients and consumers who have been involved in EMA activities; from **77** in 2007, to **307** in **2010** = participation at many levels of the Agency's work.
- Previous reports have provided evidence that the actions identified in the 'Framework of interaction' have been implemented and that formal interaction has been established between patients'/consumers' organisations and the EMA.
- There remains scope to broaden the extent of involvement, as highlighted within the reflection paper adopted by the MB in 2009.

- The "**Framework of interaction**" between the EMA and PCOs will be revised during 2011/2012, including the following:
  - Explore how patients and consumers can be further involved in the benefit/risk assessment of medicinal products.
  - Define the specific role of patients and consumers within the different scientific committees.
  - Investigate further training in different areas and prepare a training strategy.
- Further increase the network of experts and eligible organisations in order to cover as many therapeutic areas as possible.
- Continue to be involved in the preparation of information oriented to patients and the general public, including EPARS, PLs, safety communications and press releases where appropriate.
- The adoption of the new pharmacovigilance legislation (effective July 2012), will lead to PCOs being further involved in regulatory activities.

- The next progress report will be presented to the Management Board in 2013 further to the revision of the framework of interaction

Any questions?