EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Annual Report of the Interaction with Patients and Consumers

Management Board meeting, 4 October 2012

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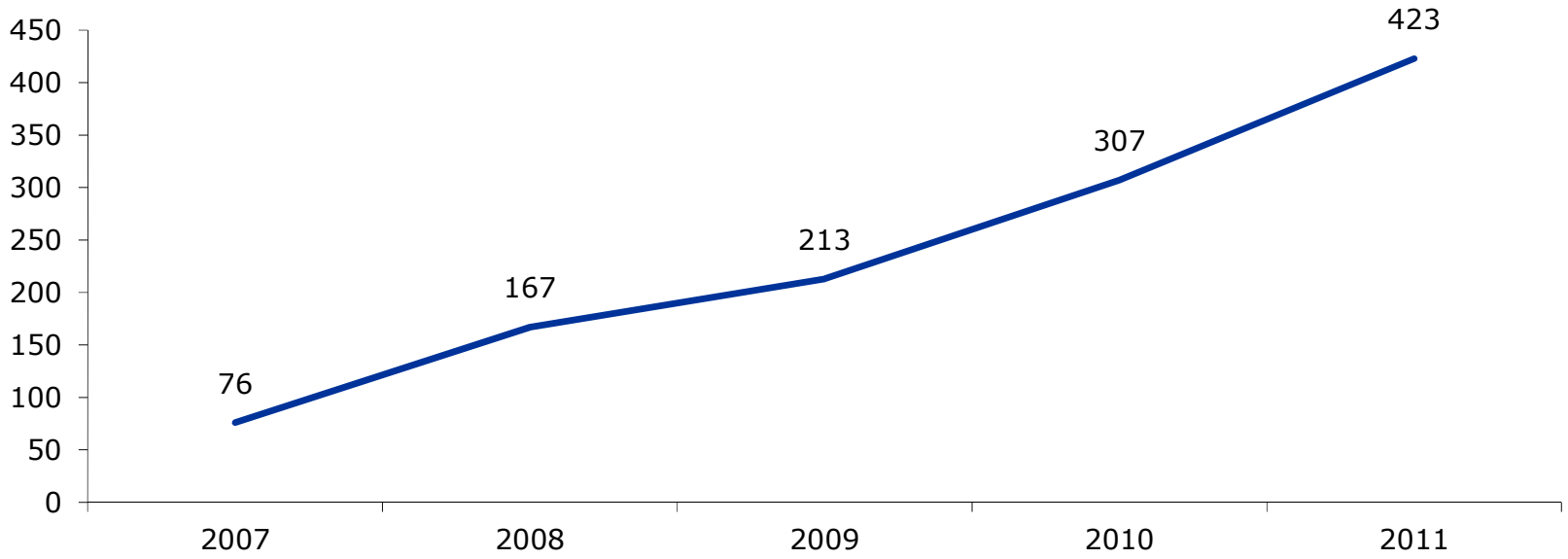
Introduction

- Detailed overview of all EMA activities where patients, consumers and their organisations (PCOs) have been involved during 2011
- Provides comparison to preceeding 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

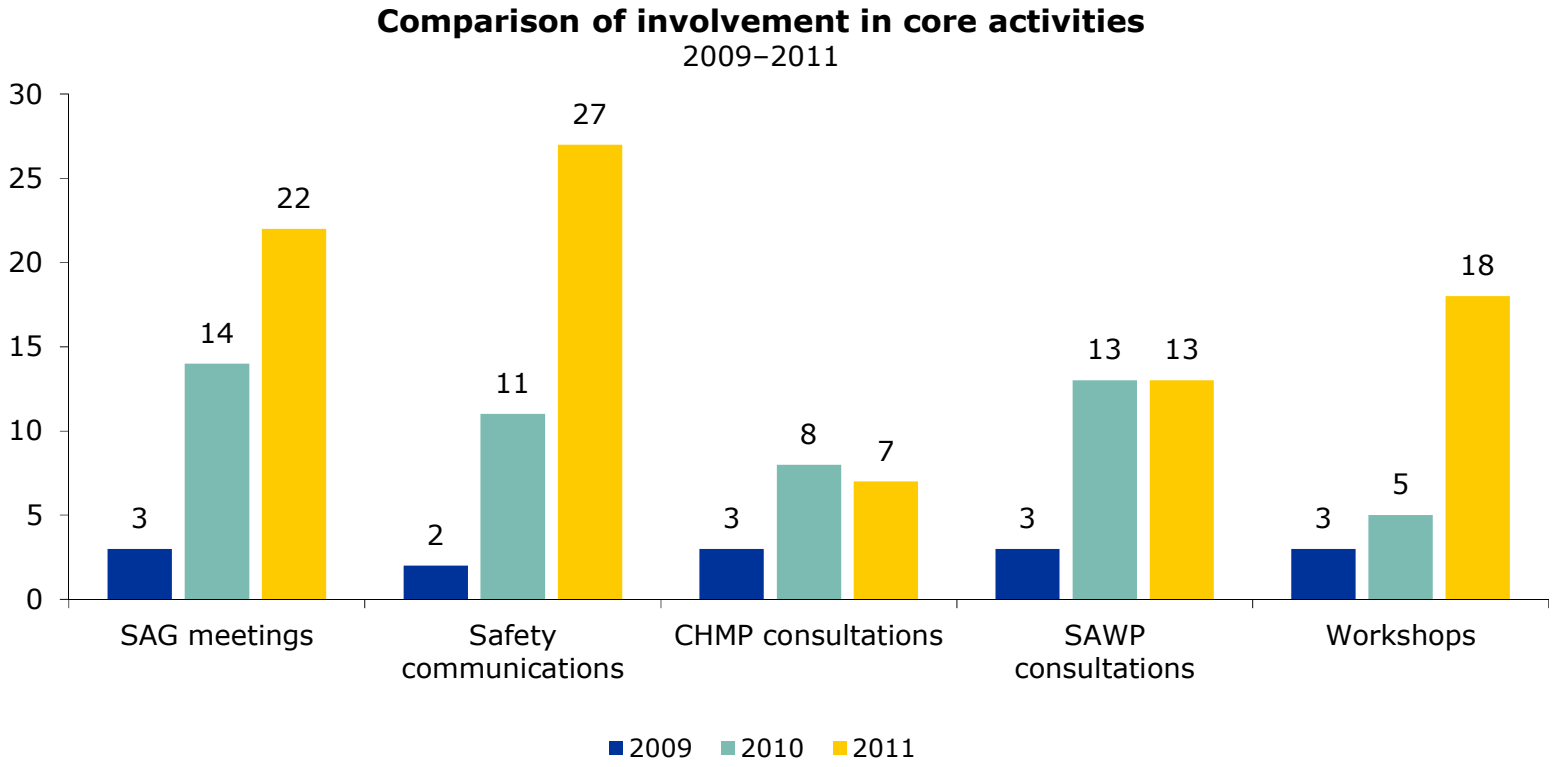
Overall number of patients and consumers involved in Agency activities
2007–2011



Number of patients/consumers involved

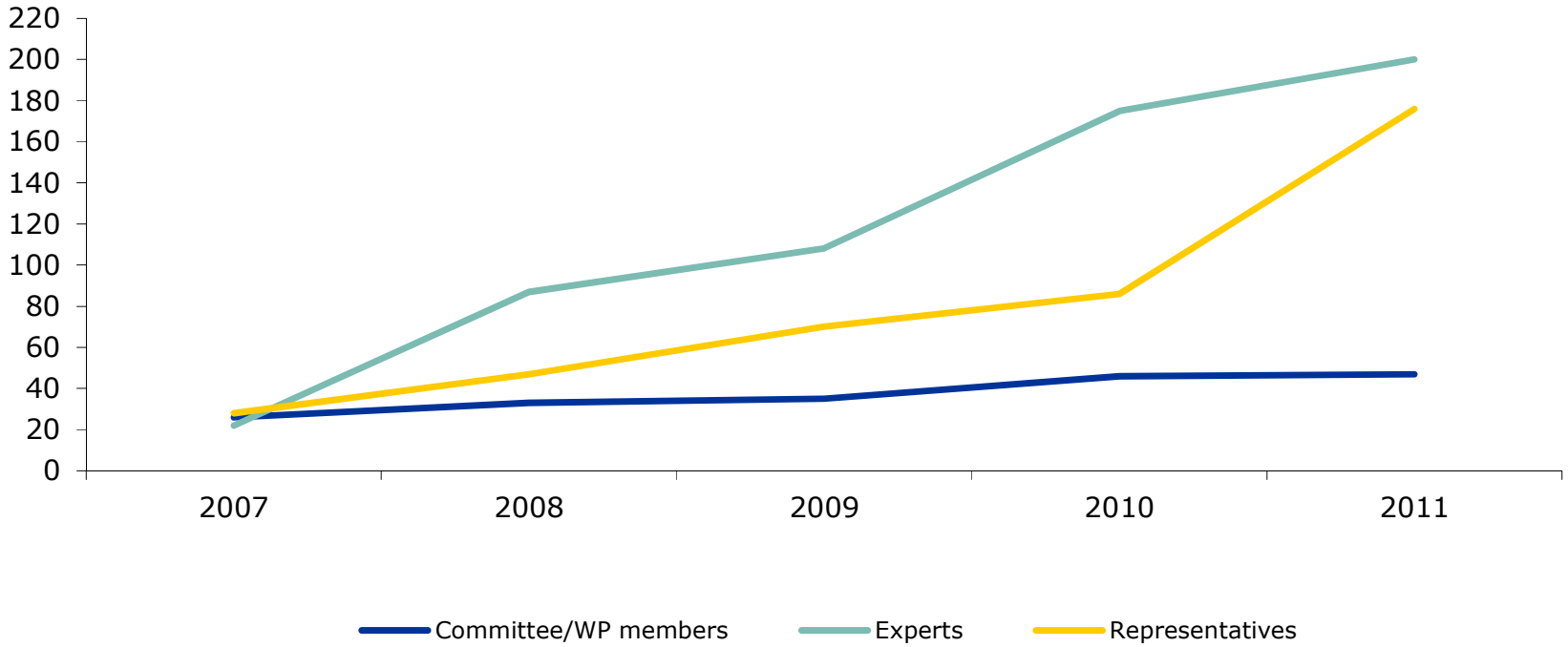
Growth relates mainly to:

- Increased participation in benefit-risk evaluation mainly in Scientific Advisory Groups and ad-hoc expert group meetings
- Increased number of safety communications (Q&As) and package leaflets reviewed
- Increase in activities related to the implementation of new pharmacovigilance legislation


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

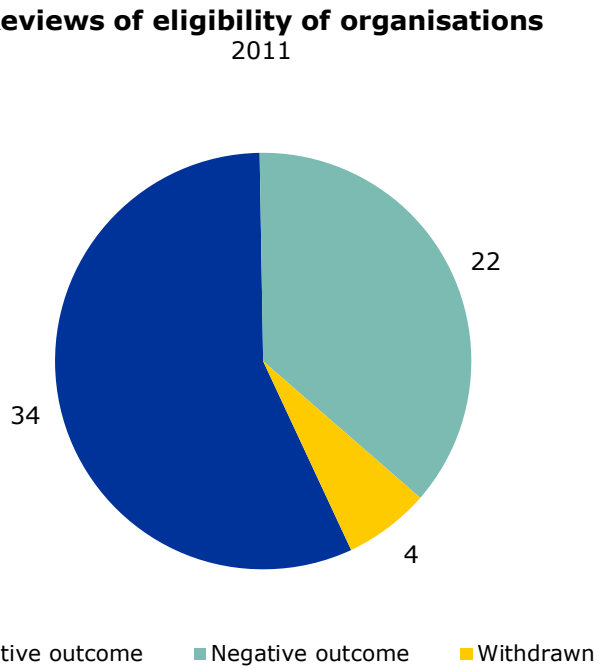
Comparison of involvement as committee/WP members, experts and representatives of organisations

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

Framework of interaction

The revision of the framework is ongoing

- The revision focuses 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:
  - Document "role of patients as members of scientific committees" published Dec 2011
  - Training programme to be finalised in 2012
  - Benefit-risk to be further discussed at PRAC

Eligibility

- Strengthening of the administrative process to evaluate and review eligibility.

  => More transparency in our process

  => More transparency in organisations' funding

- More transparency in funding allows the Agency to put in place mechanisms to address conflict of interest of the organisations involved in the Agency's activities.

Conclusion

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