EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sixth report on EMA's interaction with patients and consumers organisations (2012)

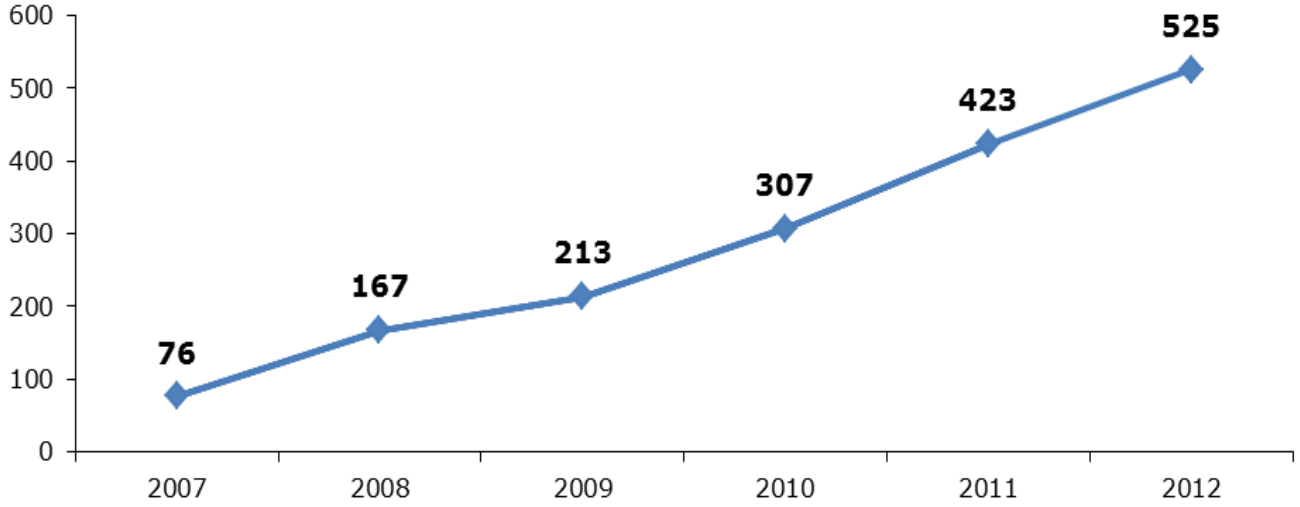
Presented by: Nathalie Bere
Public Information and Stakeholder Networking

Introduction

- Detailed overview of all EMA activities where patients, consumers and their organisations have been involved throughout 2012
- Provides comparison to preceding years
- Will be presented to the EMA Management Board and published on EMA website
- Demonstrates an extensive collaboration between EMA and PCOs was again achieved during 2012

Overall number of patients and consumers involved in Agency activities

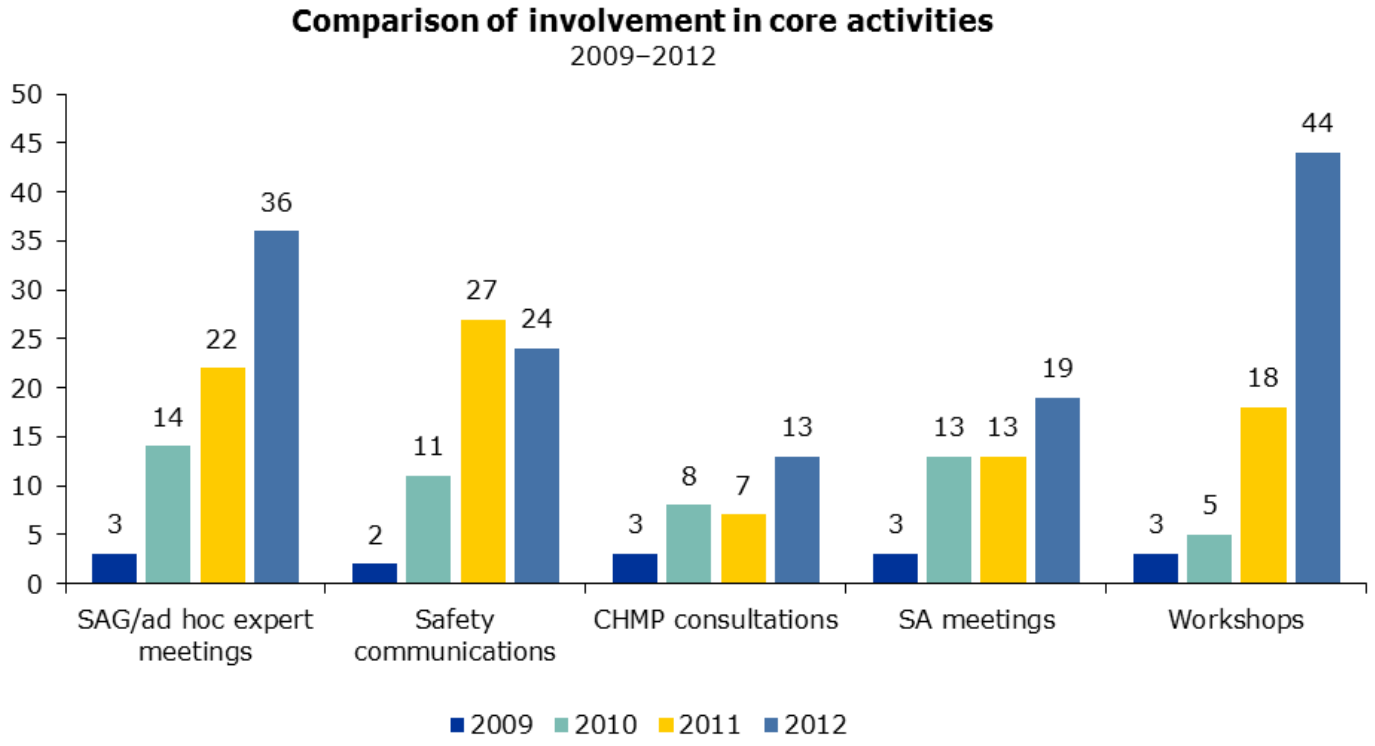
2007–2012



Number of patients/consumers involved

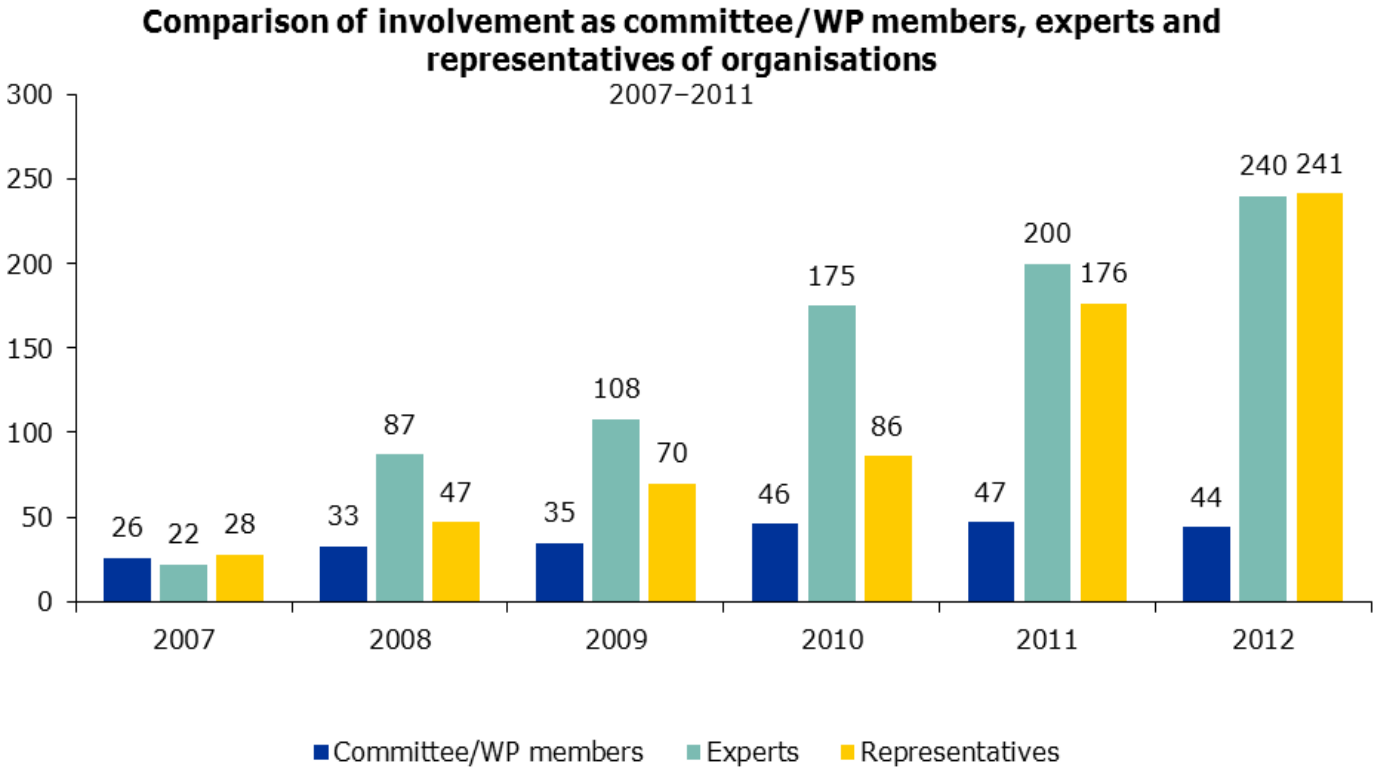
Increase relates mainly to:

- Increased participation in Scientific Advisory Group (SAG) and ad-hoc expert group meetings,
- Increased participation in scientific advice meetings,
- Increase in Committee consultations with PCOs
- Increase in number of package leaflets reviewed
- Increased participation in workshops
- Increased in overall involvement in established and ad-hoc activities


Comparison of involvement in core activities
2009–2012
50
45
40
35
30
25
20
15
10
5
0
3
14
22
36
2
11
27
24
3
8
7
13
3
13
13
19
3
5
18
44
SAG/ad hoc expert meetings
Safety communications
CHMP consultations
SA meetings
Workshops
2009
2010
2011
2012

Activities are split into three categories;

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


Comparison of involvement as committee/WP members, experts and representatives of organisations
2007–2011
300
250
200
150
100
50
0
26
22
28
33
87
47
35
108
70
46
175
86
47
200
176
44
240
241
2007
2008
2009
2010
2011
2012
Committee/WP members
Experts
Representatives

Members:

MB: 2 members, **COMP:** 3 members, **PDCO:** 3 members and 3 alternates.

CAT: No members during 2012. **PRAC** (patient members appointed in 2013).

PhVWP: 1 observer, 1 alternate, **HCPWG**: 2 observers.

Experts:

240 experts were involved in Agency activities during 2012:

- SAG/ad-hoc expert meetings; 36 representatives (22 in 2011);
- SA meetings; 19 representatives (13 in 2011);
- COMP consultations x 2
- Review of package leaflets; 102 reviewed (71 in 2011);
- Review of safety communications (24) and EPAR summaries (36).
- Participation in EMA annual training session (21)

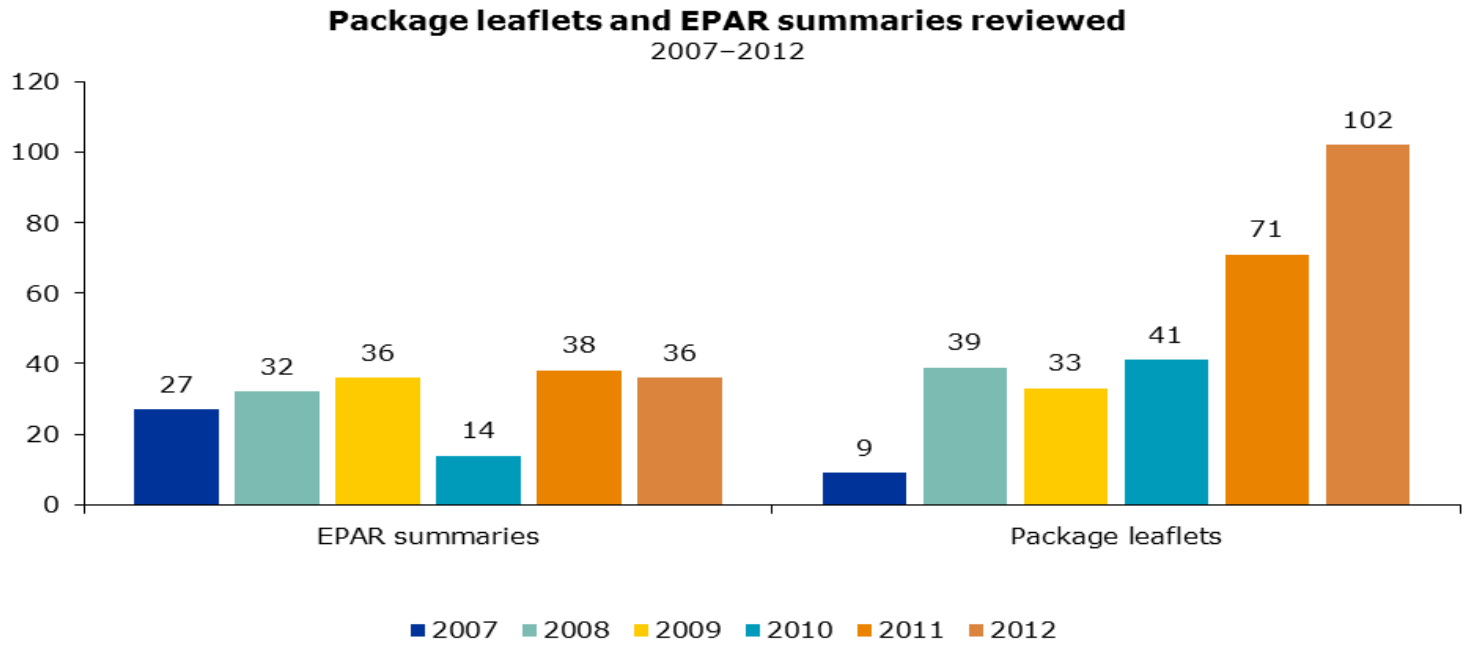
Representatives:

241 representatives of organisations were involved during 2012 (176 in 2011):

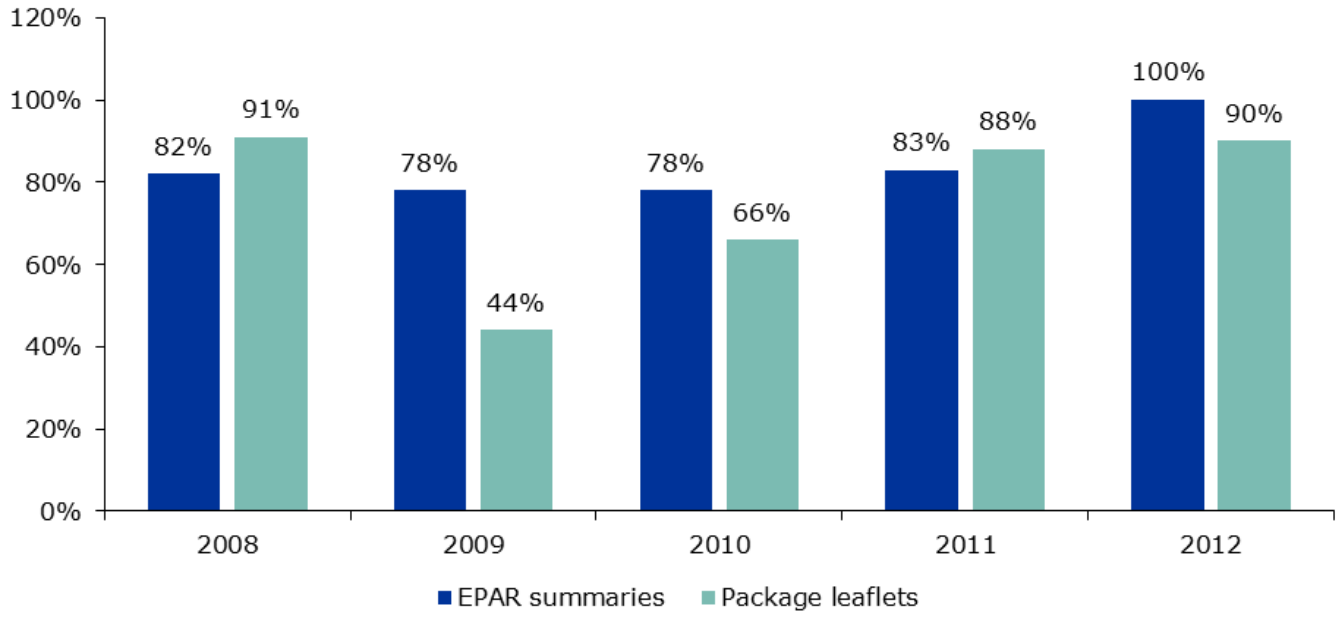
- Committee consultations (CHMP, COMP, PDCO, HMPC)
- EMA surveys (e.g. communication documents)
- Pharmcovigilance legislation forums
- Working groups (e.g. funding of organisations, EudraCT)
- Ad-hoc observers attending PCWP meetings
- Workshops

57 different patient/consumer organisations (46 in 2011); increase in number of organisations mainly due to increase in involvement of patients for SAG and SA meetings.

Review of Package Leaflets & EPAR Summaries

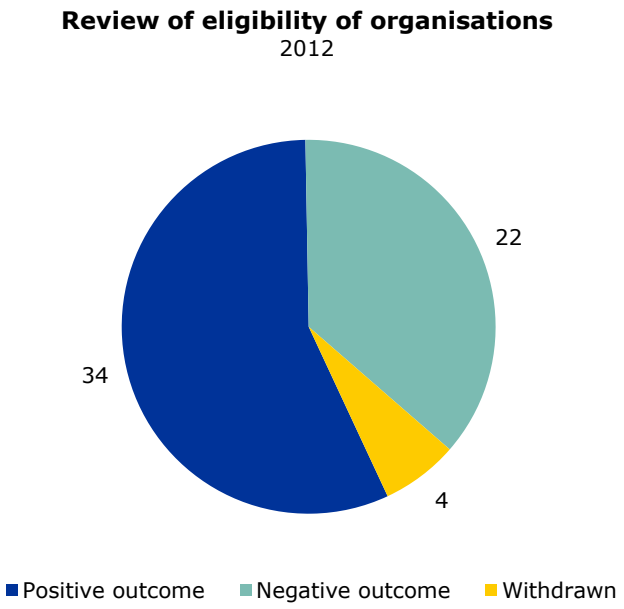


Percentage of package leaflets and EPAR summaries reviewed
2007–2012



Eligible Organisations

- There are 34 eligible patient/consumer organisations working with the Agency. During 2012 (1 new organisation became eligible, 2 merged into 1).



EMA Working Party with Patients & 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 (6 in 2013);
- 1 member from the EMA secretariat;
- Observers from the CMD-h, HCP WG, PhVWP and MB.

Four PCWP meetings held during 2012; one with all 'eligible' organisations, two joint with the Healthcare Professionals' Working Group (HCP WG) and one-day training session.

PCWP representatives involved in many EU-wide 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

Activities involving patients and consumers during 2012:

Increased involvement in **benefit / risk** evaluations

- **CHMP consultations:** 3 specific consultations with PCOs on medicines / issues under evaluation
- 2 patient representatives involved in COMP consultations, 2 in PDCO consultations, consultation with HMPC
- **SAG/expert meetings -** 36 patients participated as patient experts in 25 meetings - have provided unique information in terms of real life experiences and views.
- **Scientific Advice Working Party –** 19 patients' representatives participated as experts in specific scientific advice requests for protocol assistance (orphan drugs). From 2013 are also involved in SA for non-orphan medicines.

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)
- **Additional monitoring of medicines** & direct patient reporting - impact on the package leaflet; PCOs extensively consulted on the black symbol and related text

Involvement in EMA workshops/conferences/info sessions/expert meetings

- EMA meeting with Thalidomide Patients' and victims' organisations
- Workshop on preparation/publication of RMP summaries
- Workshop on Advanced Therapies
- Pharmacogenomics workshop
- Cycstic Fibrosis workshop
- Geriatric medicines workshop
- Anti-bacterial workshop
- Quality of Life oncology workshop
- Enpr-EMA workshop
- Workshop on paediatric gauchers
- Involvement in other external conferences/info sessions

Training

- **Annual training** session held in November on 'pharmacovigilance legislation, and also overview of the centralised procedure

Conclusion

- The involvement of PCOs continues to be extremely beneficial;
- They are a recognised and integral part of the Agency's work
- With the passing years, their involvement continues to increase and expand, but also evolves ensuring 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.