EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of EMA's interaction with patients and consumers organisations (2013)

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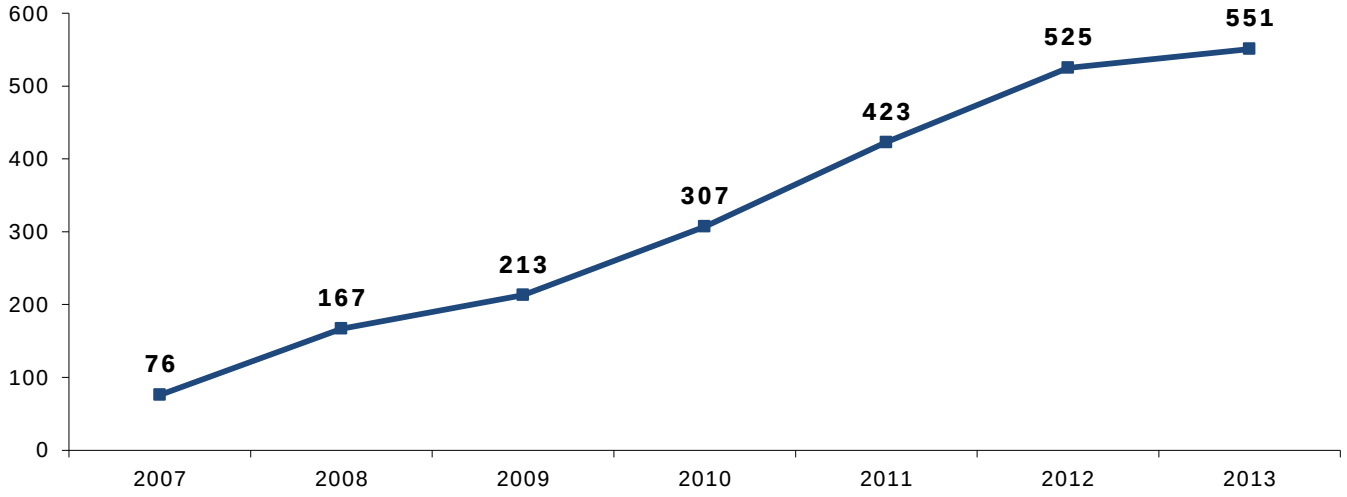
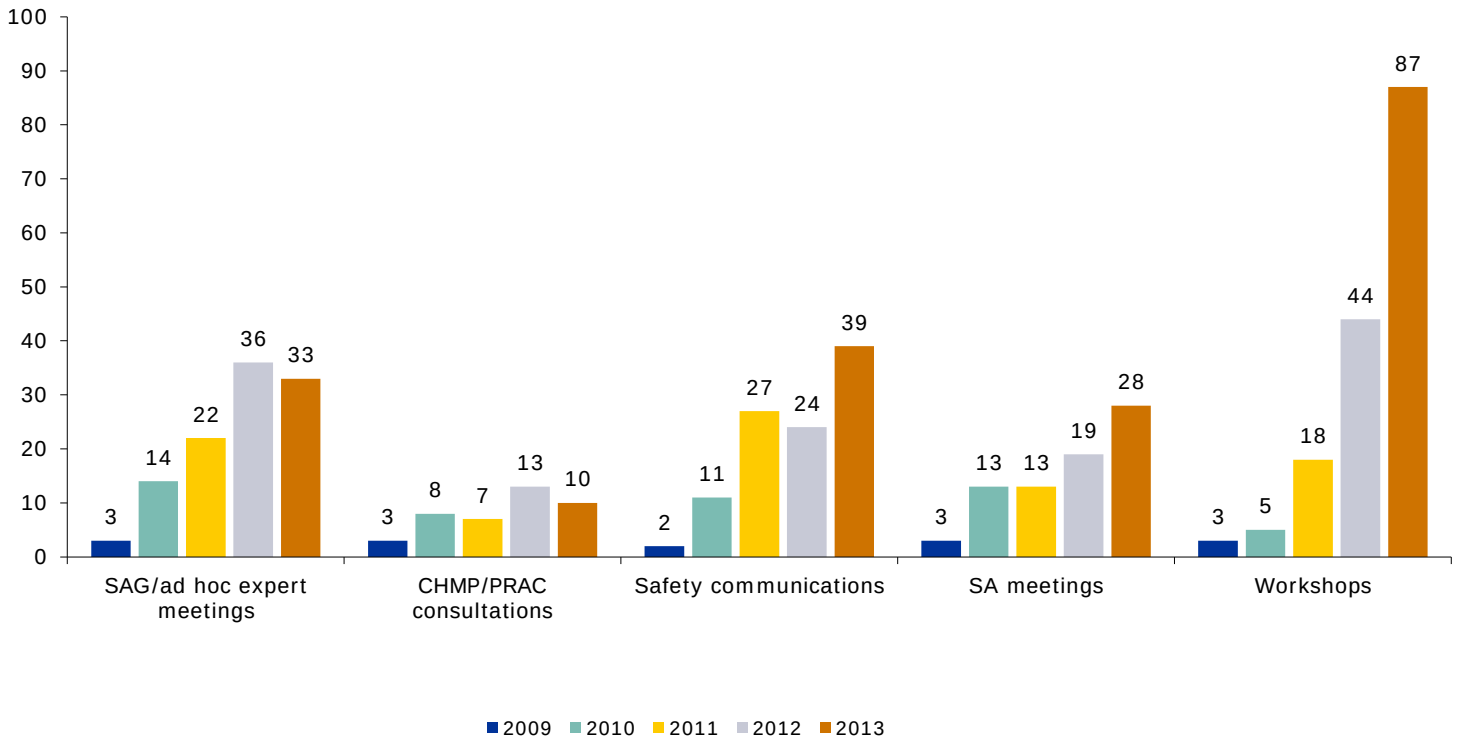
Introduction

- Quantitative overview of EMA activities where patients, consumers and their organisations have been involved throughout 2013
- Provides comparison to preceding years
- Has been included within the annual report for 2013, presented to the EMA Management Board and published on EMA website in 2014
- High level of interaction between EMA and PCOs achieved during 2013

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



Comparison of involvement in core activities
2009–2013



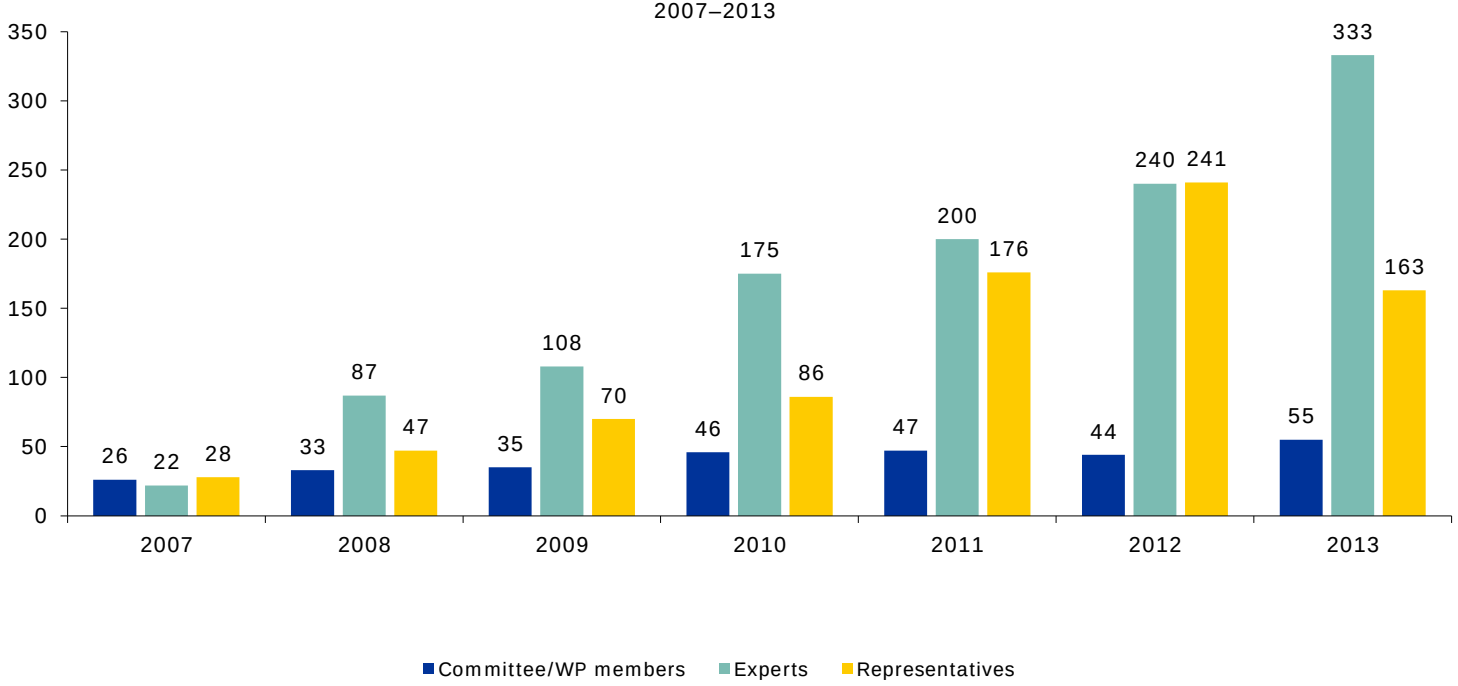
Activities are split into three categories;

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
2007–2013



Members of committees / working parties:

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

CAT: 2 members and 2 alternates. **PRAC** 1 member, 1 alternate.

HCPWP: 2 observers.

Experts:

333 experts were involved in Agency activities during 2013:

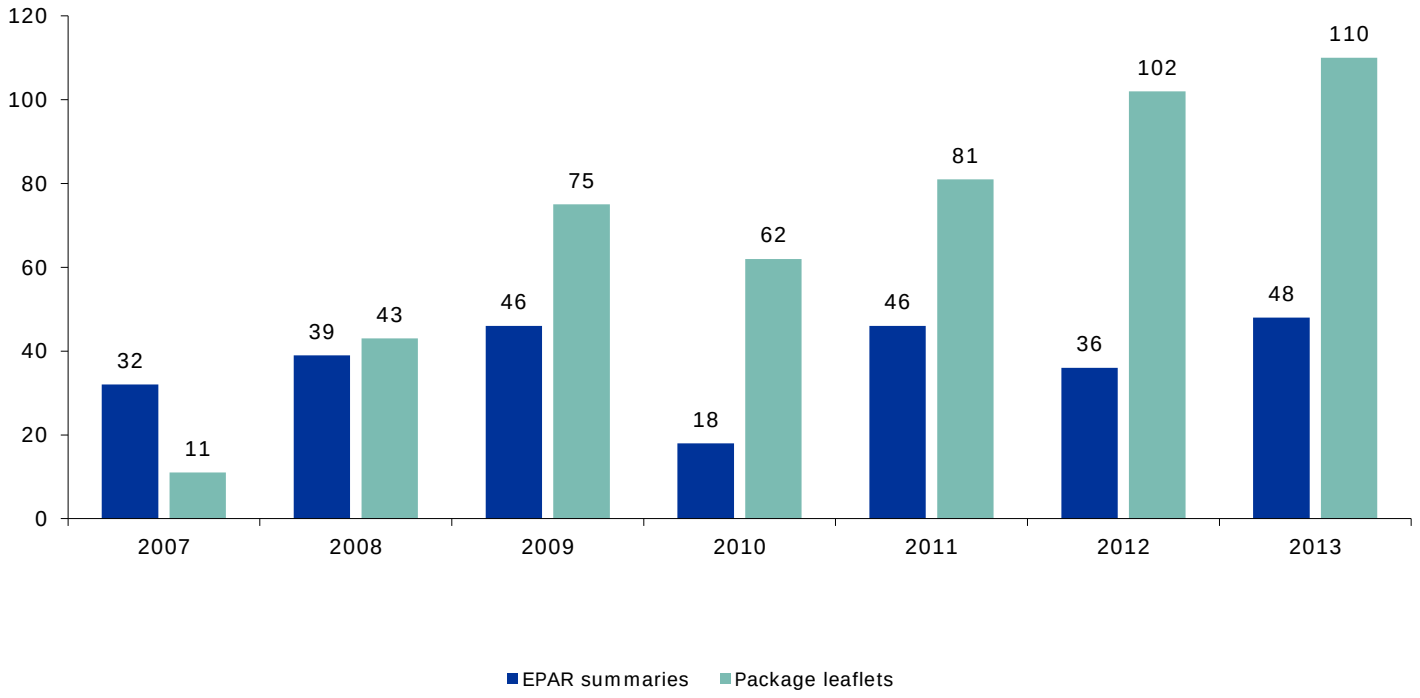
- SAG/ad-hoc expert meetings; 33 representatives (22 meetings);
- SA meetings; 28 representatives (now includes SA);
- PRAC consultations x 2 (8 Patient representatives);
- Review of package leaflets (110);
- Review of safety communications; (39);
- Review of EPAR summaries (48);
- Participation in EMA annual training session (63)

Representatives:

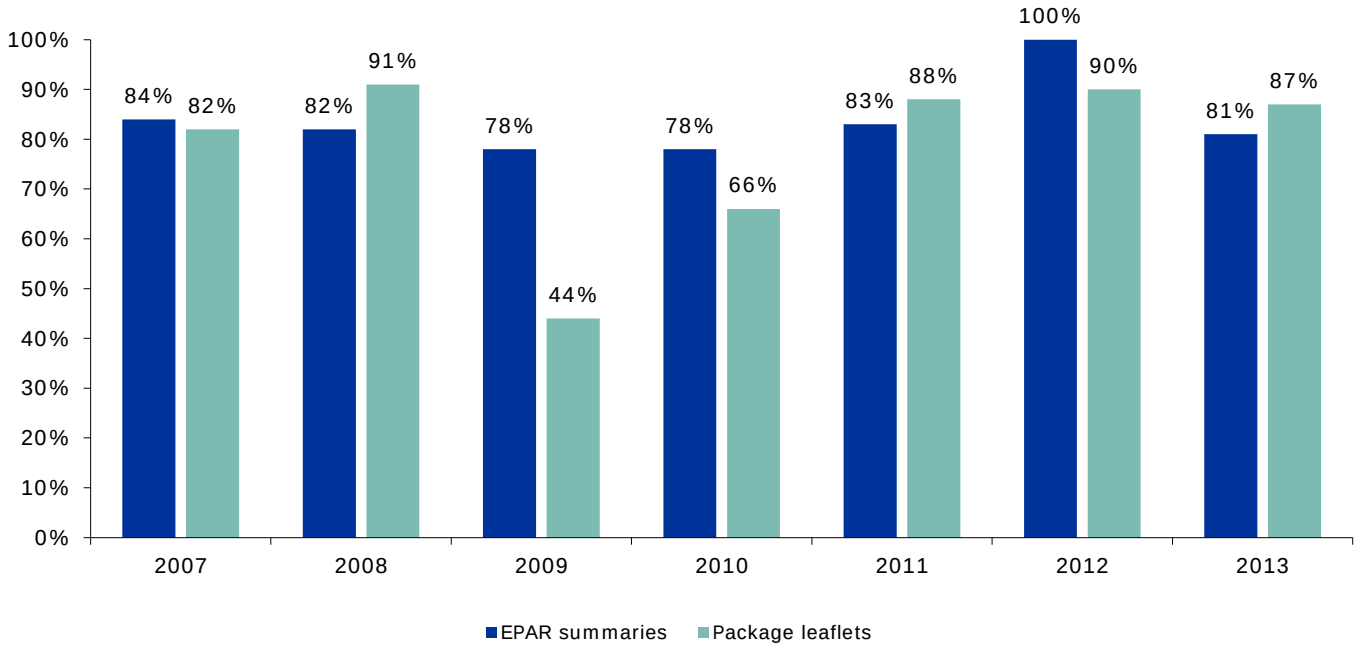
163 representatives of organisations were involved during 2013:

- CHMP consultation
- Pharmacovigilance legislation forum
- Working groups (e.g. funding of organisations, EudraCT)
- Ad-hoc observers attending PCWP meetings
- Workshops

Package leaflets and EPAR summaries sent for review
2007–2013

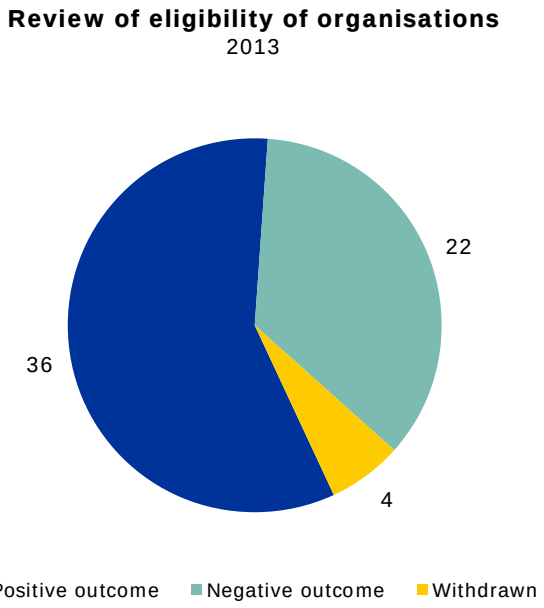


Percentage of package leaflets and EPAR summaries reviewed
2007–2013



Eligible Organisations

- There are 37 eligible patient/consumer organisations working with the Agency. During 2013, 4 new organisations became eligible.



EMA Working Party with Patients & Consumers Organisations (PCWP)

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

- 19 members and 18 alternates representing PCOs;
- 6 members from the EMA Scientific Committees;
- 1 member from the EMA secretariat;
- Observers from the CMD-h, HCP WP and MB.

Four PCWP meetings held during 2013; one with all 'eligible' organisations, two joint with the Healthcare Professionals' Working Party (HCP WP) and one-day training session.

PCWP representatives involved in many EU-wide initiatives

- 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 2013:

Increased involvement in **benefit / risk** evaluations

•**CHMP & PRAC consultations:** specific consultations with PCOs on medicines / issues under evaluation

•**SAG / expert meetings -** 33 patients participated as patient experts in 22 meetings - have provided unique information in terms of real life experiences and views.

•**Scientific Advice Working Party –** 28 patients' representatives participated as experts in specific scientific advice requests (16 for protocol assistance (orphan drugs).

Activities related to the implementation of the new pharmacovigilance legislation

- 1 **stakeholder meeting** (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 and launch

Involvement in EMA workshops/conferences

- Workshop on Conflicts of Interest Policy
- Clinical Trial advisory groups
- Workshop on medication errors
- Workshop on patient support and market research programmes
- Workshop on medicines shortages
- Workshop on the patient voice in benefit-risk assessment
- Workshop on clinical investigation of medicines for multiple sclerosis
- Workshop on biosimilars
- Workshop on Antimicrobial Resistance (AMR)

Challenges

- New member integration;
- Limited time, often not enough for allowing meaningful discussion;
- Managing group size, especially in joint meetings;
- Managing individuals' and organisations' sometimes conflicting expectations;
- Managing complex topics over several meetings in 3 month intervals

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.