EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of EMA's interaction with patients and consumers organisations (2014)

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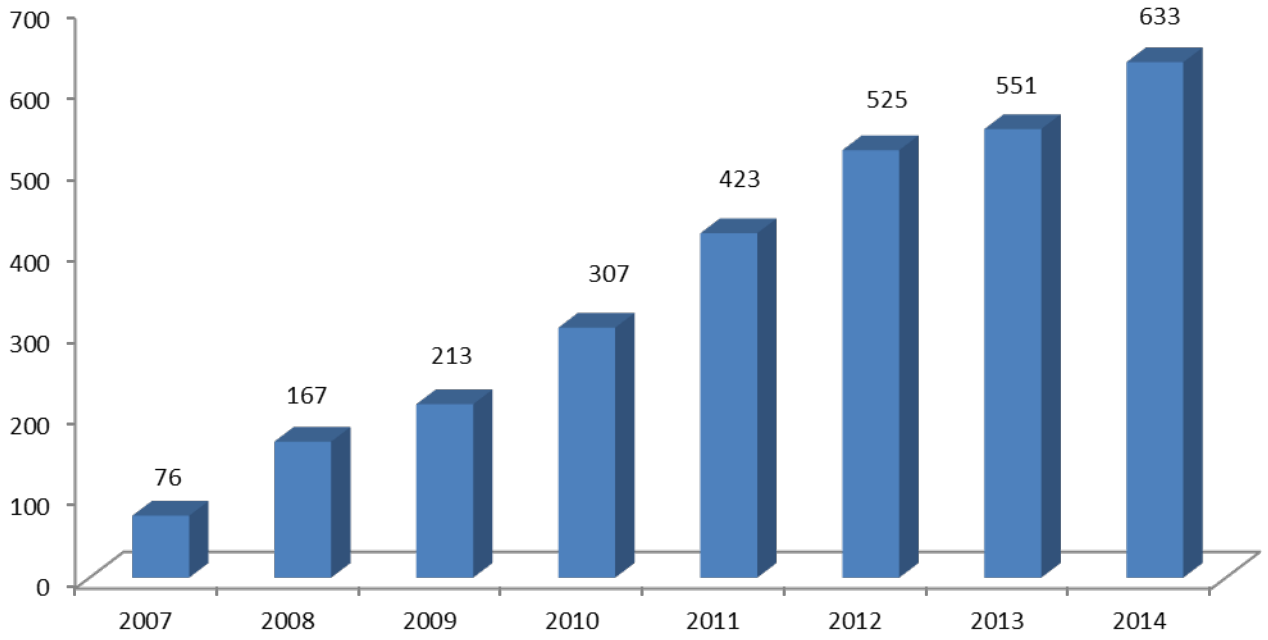
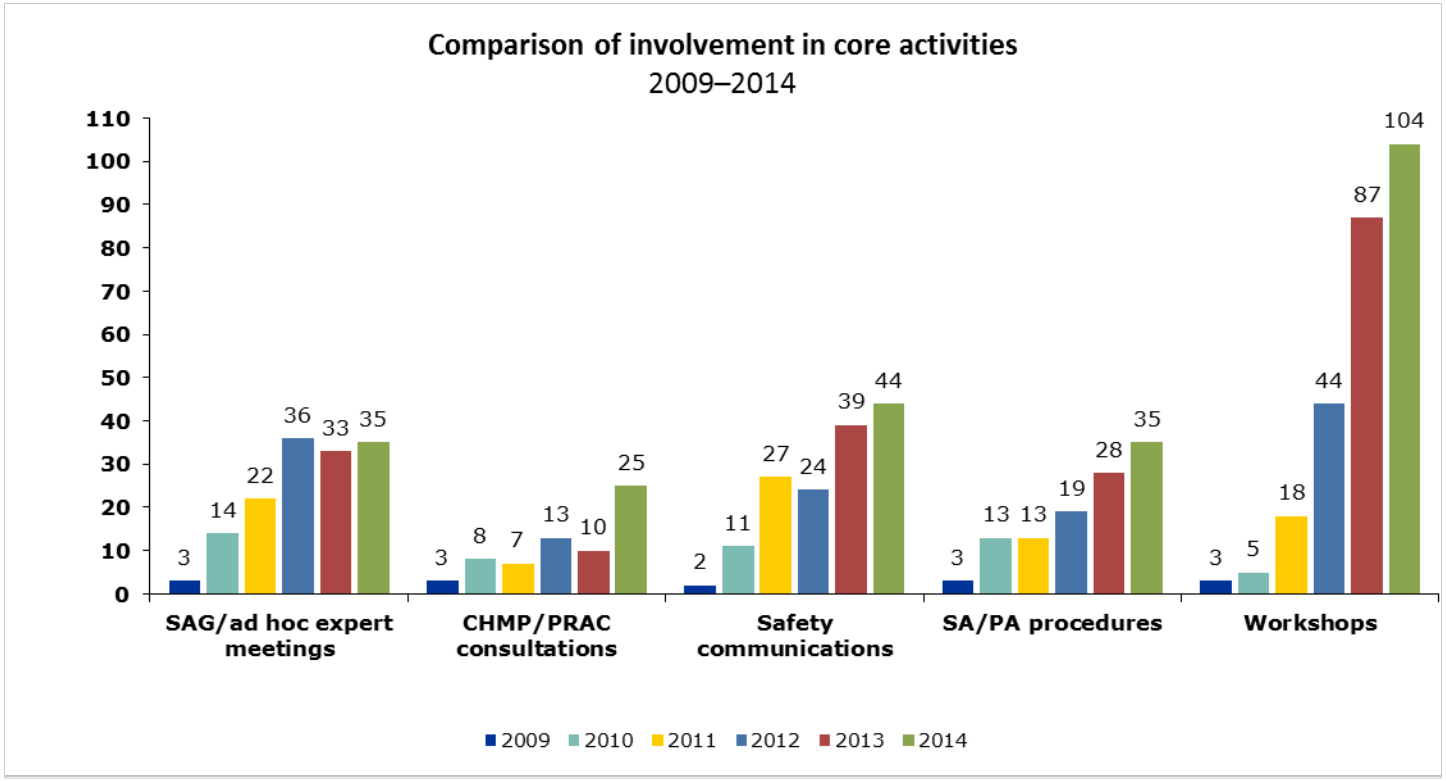
Introduction

- Overview of EMA activities where patients, consumers and their organisations have been involved throughout 2014
- Provides comparison to preceding years
- Will be included within the annual report for 2014, presented to the EMA Management Board and published on EMA website during 2015
- Usual high level of interaction between EMA and PCOs achieved during 2014

Overall number of patient & consumer involvement in EMA activities 2007–2014




Comparison of involvement in core activities
2009–2014
110
100
90
80
70
60
50
40
30
20
10
0
3
14
22
36
33
35
3
8
7
13
10
25
2
11
27
24
39
44
3
13
13
19
28
35
3
5
18
44
87
104
SAG/ad hoc expert meetings
CHMP/PRAC consultations
Safety communications
SA/PA procedures
Workshops
2009
2010
2011
2012
2013
2014

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
2007–2014

Members of committees :

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

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

Experts:

336 experts were involved in Agency activities in 2014, examples:

- CHMP oral explanation
- Scientific Advisory Group (SAG)/ad-hoc expert meetings
- Scientific Advice/Protocol Assistance procedures
- PRAC consultations
- Review of package leaflets
- Review of safety communications
- Review of EPAR summaries
- Participation in EMA annual training session

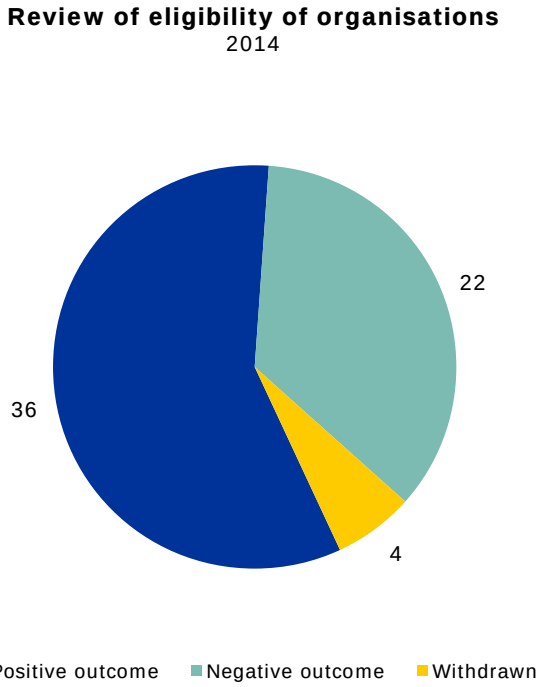
Representatives:

242 representatives of organisations were involved during 2014:

- Committee/EMA consultations
- Pharmacovigilance legislation forum
- Patient registries
- EMA policy on proactive publication of and access to clinical-trial data
- Pandemic preparedness
- WEB-Radr stakeholders survey
- Ad-hoc observers attending PCWP meetings
- Working groups
- Workshops

Eligible Organisations

- There are 36 eligible patient/consumer organisations working with the Agency. During 2014, 1 new organisation became eligible.

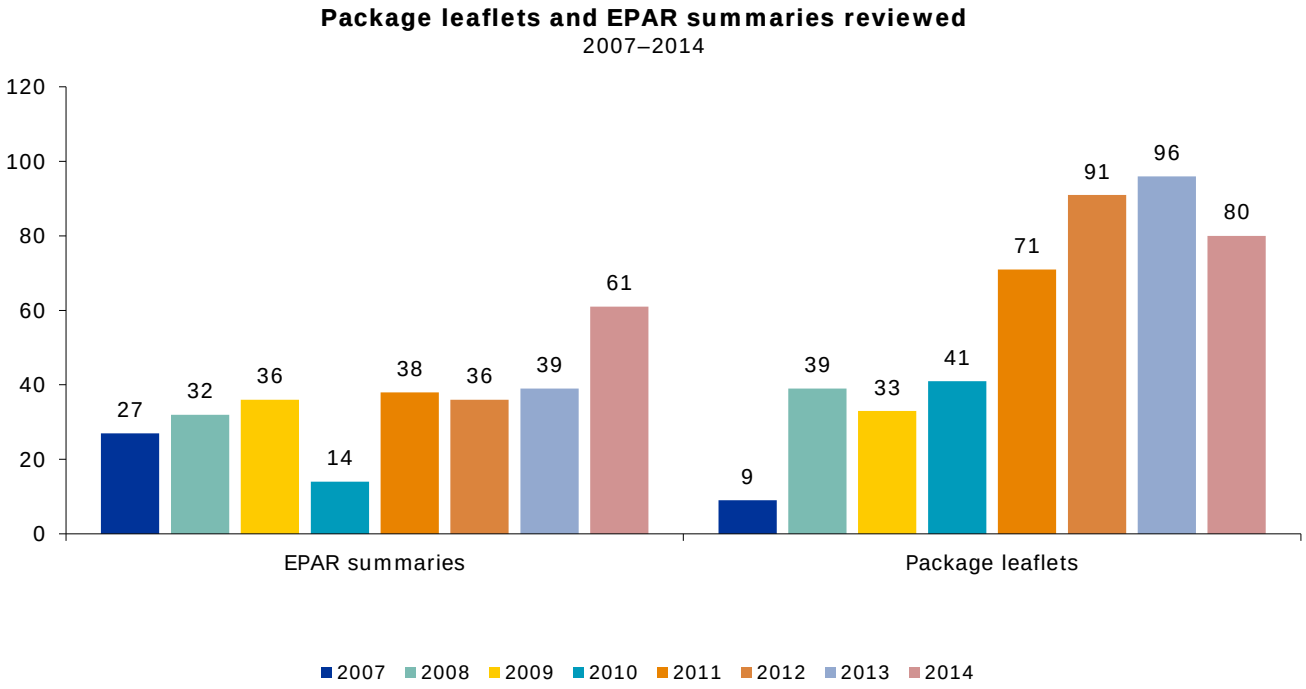


EMA Working Party with Patients & Consumers Organisations (PCWP)

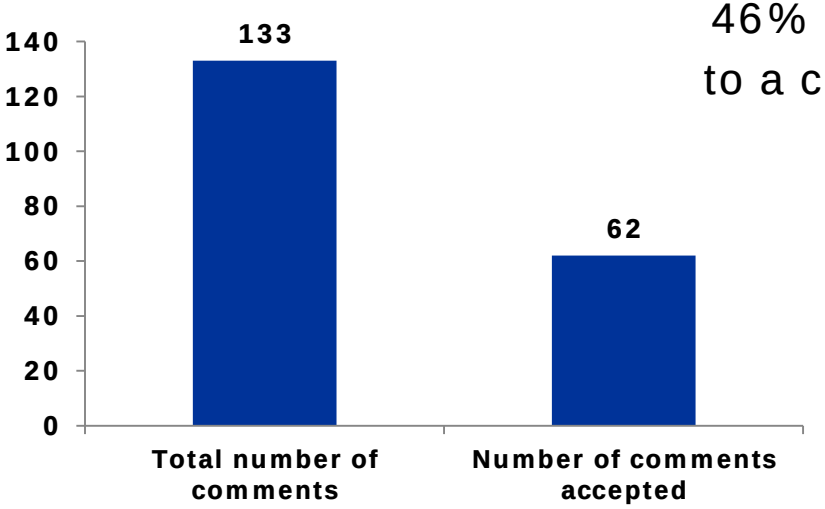
The PCWP continues to play a key role in the interaction between the EMA and PCOs.

- 19 members and 16 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.

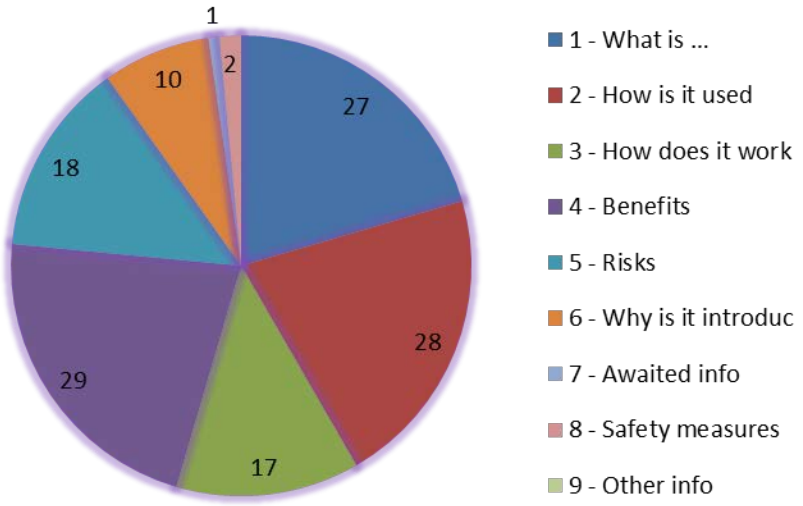
Four PCWP meetings held during 2014; one with all 'eligible' organisations, two joint with the Healthcare Professionals' Working Party (HCP WP) and one-day training session.


Package leaflets and EPAR summaries reviewed
2007–2014
120
100
80
60
40
20
0
27
32
36
14
38
36
39
61
9
39
33
41
71
91
96
80
EPAR summaries
Package leaflets
2007
2008
2009
2010
2011
2012
2013
2014

Feedback on comments received; EPAR summaries

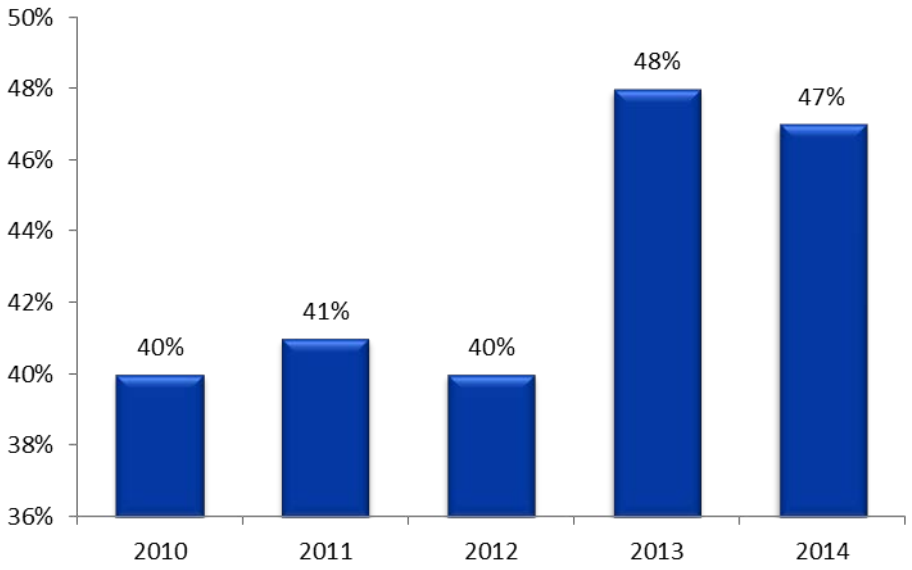


46% of comments led to a change in the text



Scientific advice – influence of patients on outcome

(comments included in final advice)



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
- ADVANCE project; patients involved

Involvement in EMA workshops/conferences

- Workshop on B/R (PCWP/HCPWP)
- EMA/DIA Eudravigilance Information Day
- Clinical trial portal and union database stakeholders meeting
- 6th Enpr-EMA Workshop (Paediatric Network)
- 8th Stakeholder Forum PhV leg
- Workshop on Risk Communication (PCWP/HCPWP)
- Clinical trial portal and union database stakeholders meeting
- Regulatory workshop on clinical trials designs in Neuromyelitis optica and spectrum disorders (NMO)
- ADVANCE WP1 Workshop (Revised framework for development of influenza vaccines)
- Clinical trials stakeholder meeting
- Workshop on Alzheimer's Disease
- WEB RADR (IMI project) workshop
- Development pathways workshop for advanced therapy medicinal products

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.

Written consultations, example…

Humalog / Liprolog - Extension of indication : concerns regarding introduction of a new high strength and how to ensure its safe and correct use

- Consultation with patients to obtain input on how best to minimise potential risk of medication errors
  - Input received prompted the PRAC & CHMP to request further changes to the labelling (differentiations of strengths).
  - The MAH subsequently amended the labelling and other measurements in the risk minimisation plan.

Face to face consultations, example…

Article 31 referral procedure - review of Valproate ; PRAC review of new information on risk of long-term developmental problems in children whose mothers took Valproate

- Patient meeting– included epilepsy, bipolar disorder and migraine patient organisations and organisations representing the patients, families and carers affected by valproate
  - Very constructive exchange of information; patients shared their personal experiences and provided input on how best to raise awareness for all concerned; in turn allowed PRAC to explain the assessment process
  - The need to consult with HCPs was very much emphasised by patients
- PRAC also initiated consultation with relevant HCPs organisations to obtain information on communication, awareness & understanding of risks
  - Valuable input will be taken forward by the PRAC in reaching its recommendation

Face to face consultations, example…

Article 107i referral procedure – methadone – PRAC review into misuse of oral methadone containing povidone leading to ADRs

- Patient expert participated in expert group meeting;
  - provided valuable information on current use and misuse of oral methadone, adherence to therapies and views of associated risks,