EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of EMA's interaction with patients and consumers during 2015

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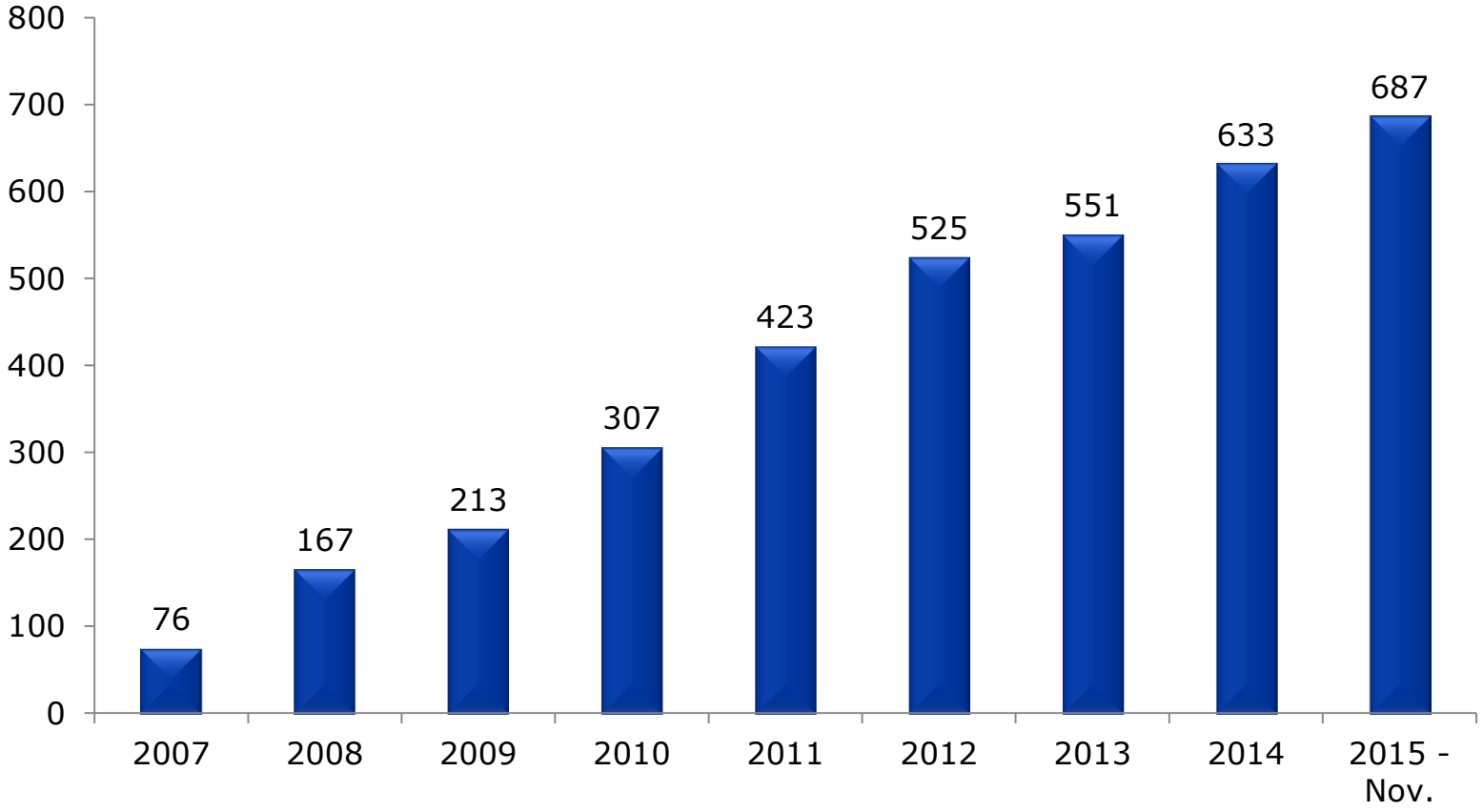
An agency of the European Union

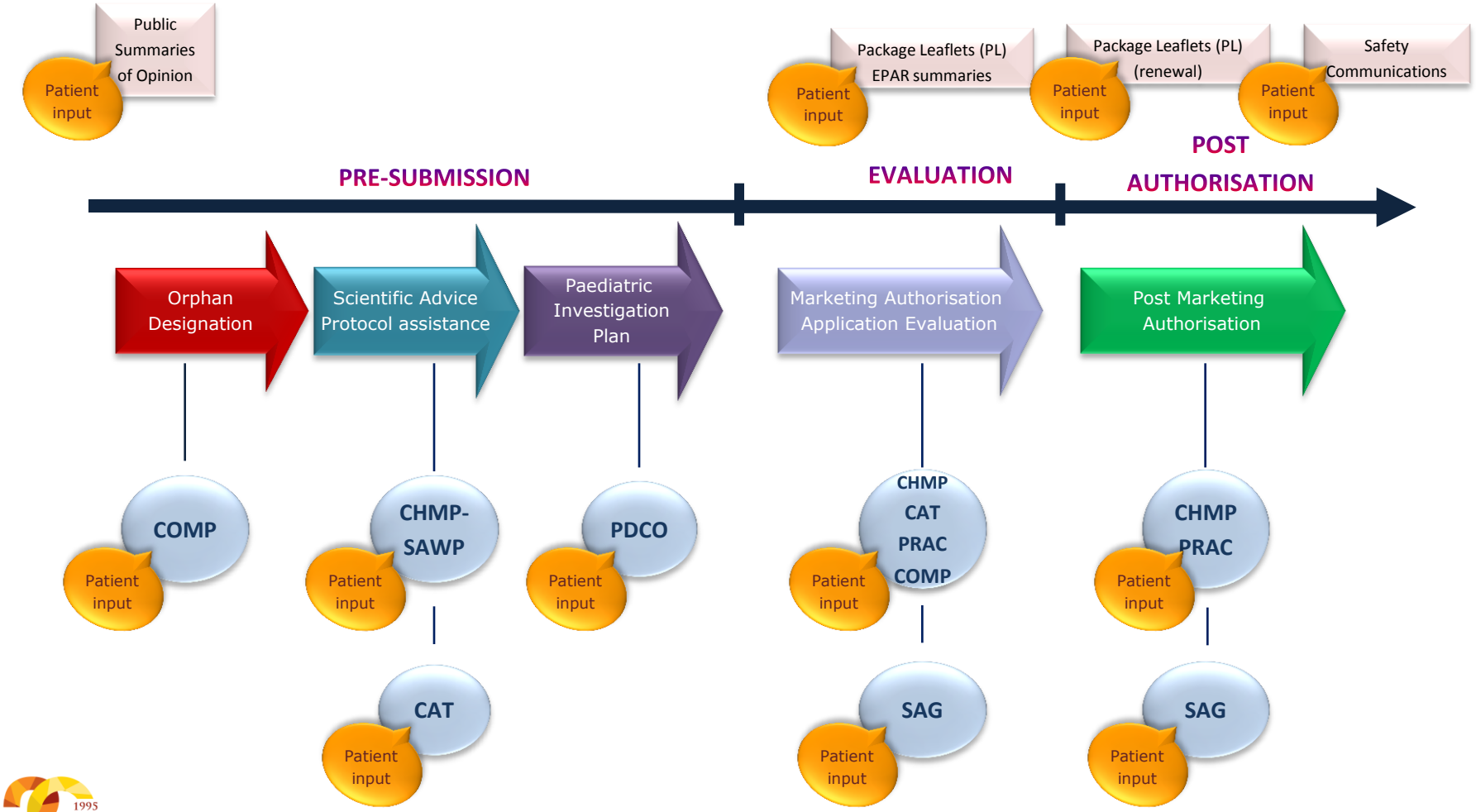
Introduction

- Overview of EMA activities where patients, consumers and their organisations have been involved throughout 2015
- Provides comparison to preceding years
- Will be included within the annual report for 2015, presented to the EMA Management Board and published on EMA website during 2016
- Consistent high level of interaction and collaboration between EMA and patients and consumers during 2015

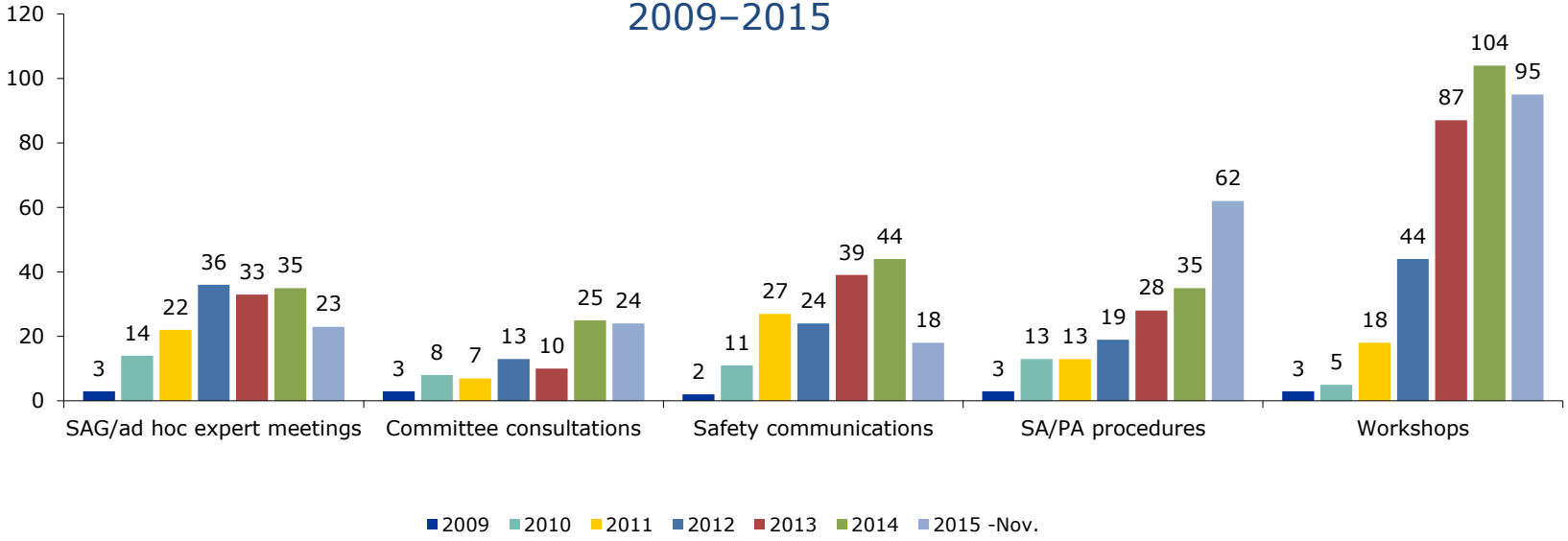
Overall number of patient/consumer involvement in EMA activities



Opportunities for Patient involvement along the medicine lifecycle at EMA



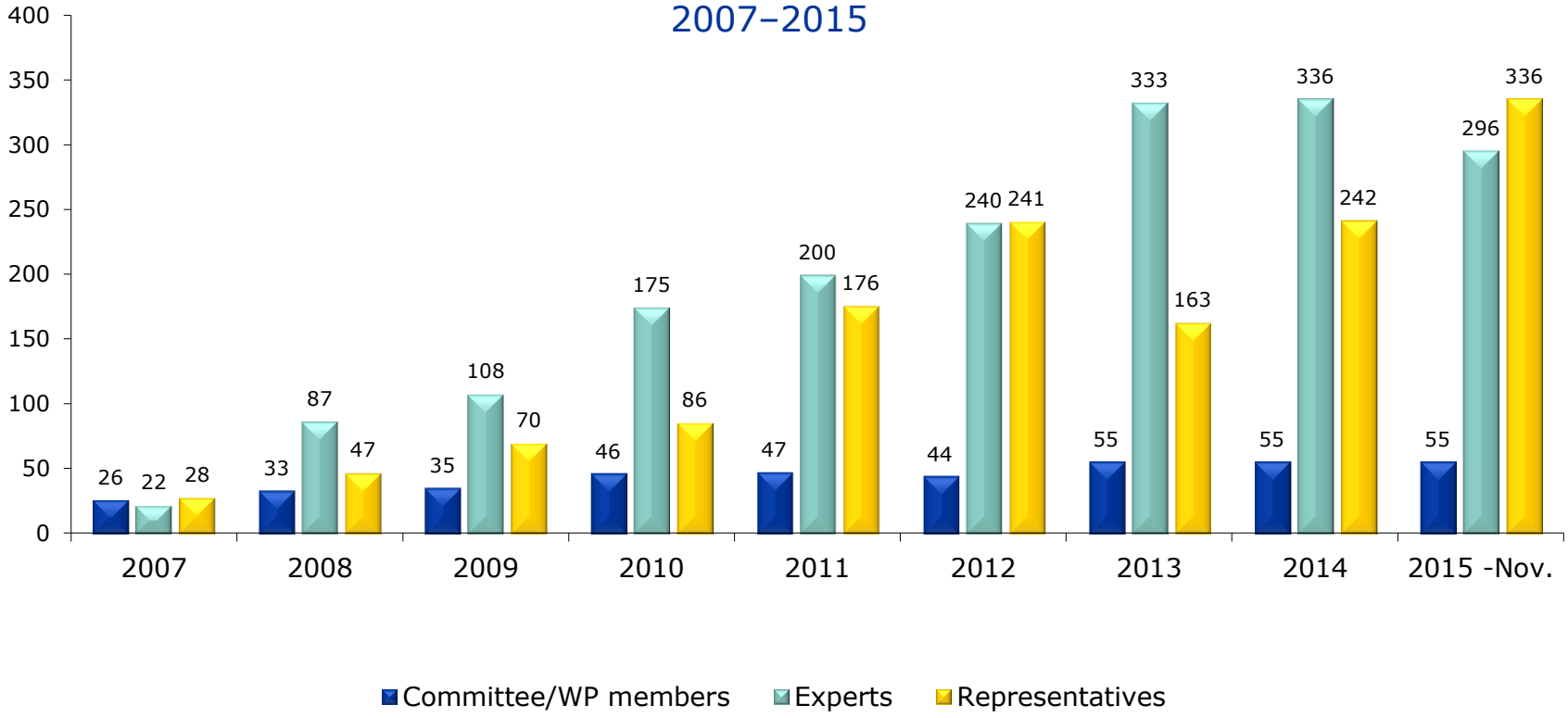
Comparison of involvement in core activities
2009–2015



Activities can be categorised in three different ways:

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

Involvement as committee/WP members, experts and representatives of organisations
2007–2015



Members :

- EMA Management Board (MB)
- Committee for Orphan medicines (COMP)
- Committee for paediatric medicines (PDCO)
- Committee for advanced therapies (CAT)
- Pharmacovigilance Risk Assessment Committee (PRAC)

Individual experts; Examples during 2015:

- Scientific Advice/Protocol Assistance procedures (some with HTAs*)
- Scientific Advisory Group (SAG)/ad-hoc expert meetings
- Committee consultations
- CHMP oral explanations
- Review of package leaflets
- Review of safety communications
- Review of EPAR summaries

* HTA = health technology assessment

Representatives of organisations; examples during 2015:

- 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

EMA Working Party with Patients & Consumers Organisations (PCWP)

The PCWP plays 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, HCPWP and MB.

Five PCWP meetings;

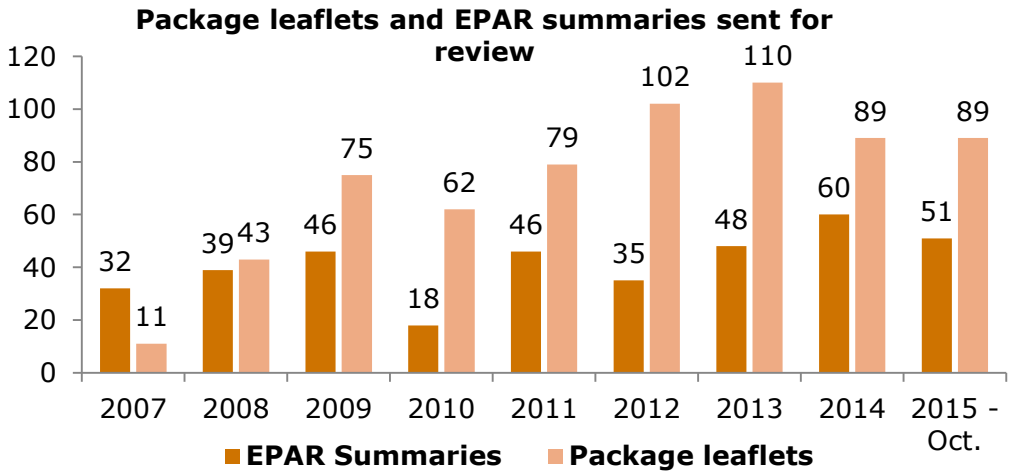
- one plenary meeting,
- two joint meetings with the HCPWP (including a dedicated session on "Biosimilars" and a workshop on "Risk minimisation tools")
- one with all eligible organisations
- one-day training session

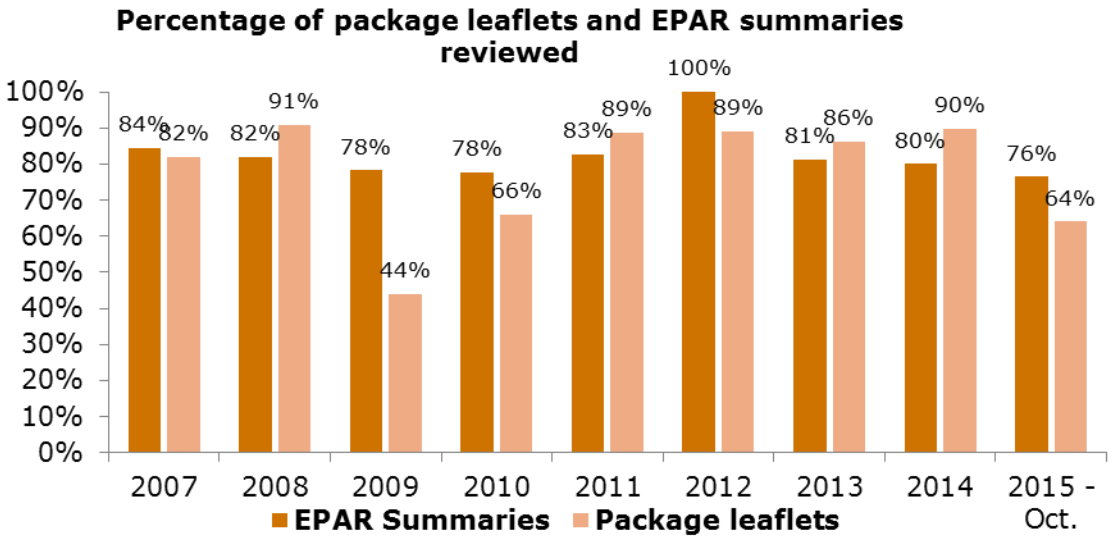
PCWP representatives involved in many EU-wide initiatives

- 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
- ADVANCE project;
- WEB-RADR

Involvement in EMA workshops/conferences

- Workshop on biosimilars
- Science, Medicines, Health: Patients at the heart of future innovation conference
- Duchene (DMD) workshop
- Workshop on chordoma as a model for very rare cancers
- DIA Info Day on Post-Authorisation Studies
- Webinar: Implementation of EMA policy on publication of clinical data
- EMA workshop on the development of new medicines for the treatment of ulcerative colitis and Crohn's disease
- Workshop on haemophilia registries
- Implement. policy on access to clinical data
- ADAPT SMART kick-off meeting
- Follow-up stakeholder meeting on the implementation of EMA policy on publication of clinical data
- 9th Stakeholder Platform meeting
- Joint EFGCP-DIA-EMA paediatric conference
- Lunchtime talk and debate: 'Involving young people in the evaluation of medicines for children'
- EMA workshop on shortages
- Anticoagulants workshop


Package leaflets and EPAR summaries sent for review
120
100
80
60
40
20
0
32
11
39
43
46
75
18
62
46
79
35
102
48
110
60
89
51
89
2007
2008
2009
2010
2011
2012
2013
2014
2015 - Oct.
EPAR Summaries
Package leaflets


Percentage of package leaflets and EPAR summaries reviewed
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
84%
82%
82%
91%
78%
44%
78%
66%
83%
89%
100%
89%
81%
86%
80%
90%
76%
64%
2007
2008
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2011
2012
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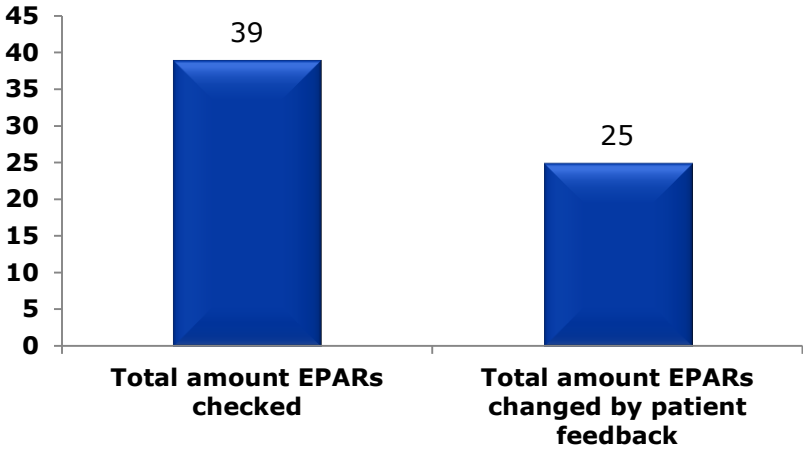
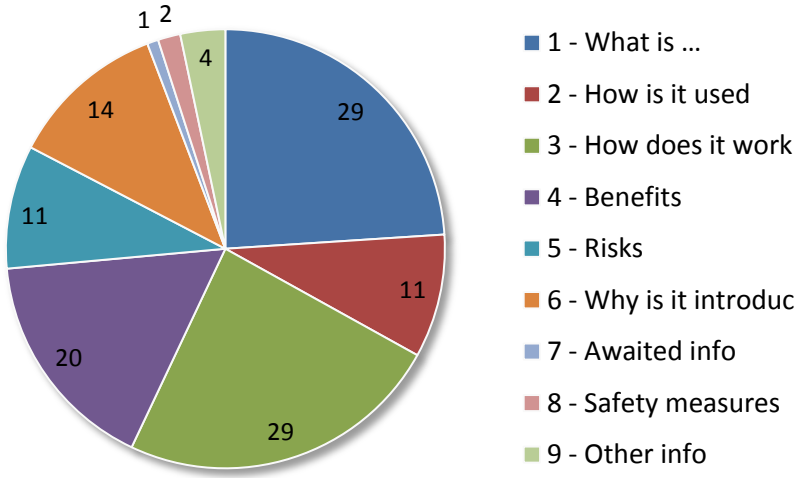
2014
2015 - Oct.
EPAR Summaries
Package leaflets

Feedback on comments received; EPAR summaries



64% of EPARs adjusted due to feedback by patients



Eligible organisations: patients/consumers

Topic groups

1. Measure impact of patient involvement (2 TC held)
2. Acknowledge and promote visibility of patient input in the Agency's activities (3 TC held)
3. Training (2 TC held)
4. Social media (4 TC held, face to face meeting planned)
5. Involvement of young people – children (2 TC held)

Ongoing initiatives

- Pilot project to involve patients in CHMP plenary discussions
  - 3 cases so far
- Elicitation of B/R preferences
  - Pilot study with melanoma / myeloma patients
  - Larger study planned 1Q 2016
- Enhanced training materials
  - 'EMA basics' short videos
  - Info-sheets
  - Improvements to webpages dedicated to patients

Conclusion

- The involvement of PCOs continues to be extremely beneficial;
- They are a recognised and integral part of the Agency's work with opportunities for input along the lifecycle of the medicines development
- With the passing years, their involvement not only continues to expand, but also evolves ensuring it occurs in the most optimal manner possible
- We will continue to look to enhance and improve involvement wherever needed / feasible
- This interaction allows patients to engage with the EMA to share their real-life experience and knowledge which ultimately contributes to the quality of the decision-making process
- We look forward to a continued mutually beneficial collaboration during 2016!