EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interaction with patients and consumers

Overview of involvement in EMA activities during 2015

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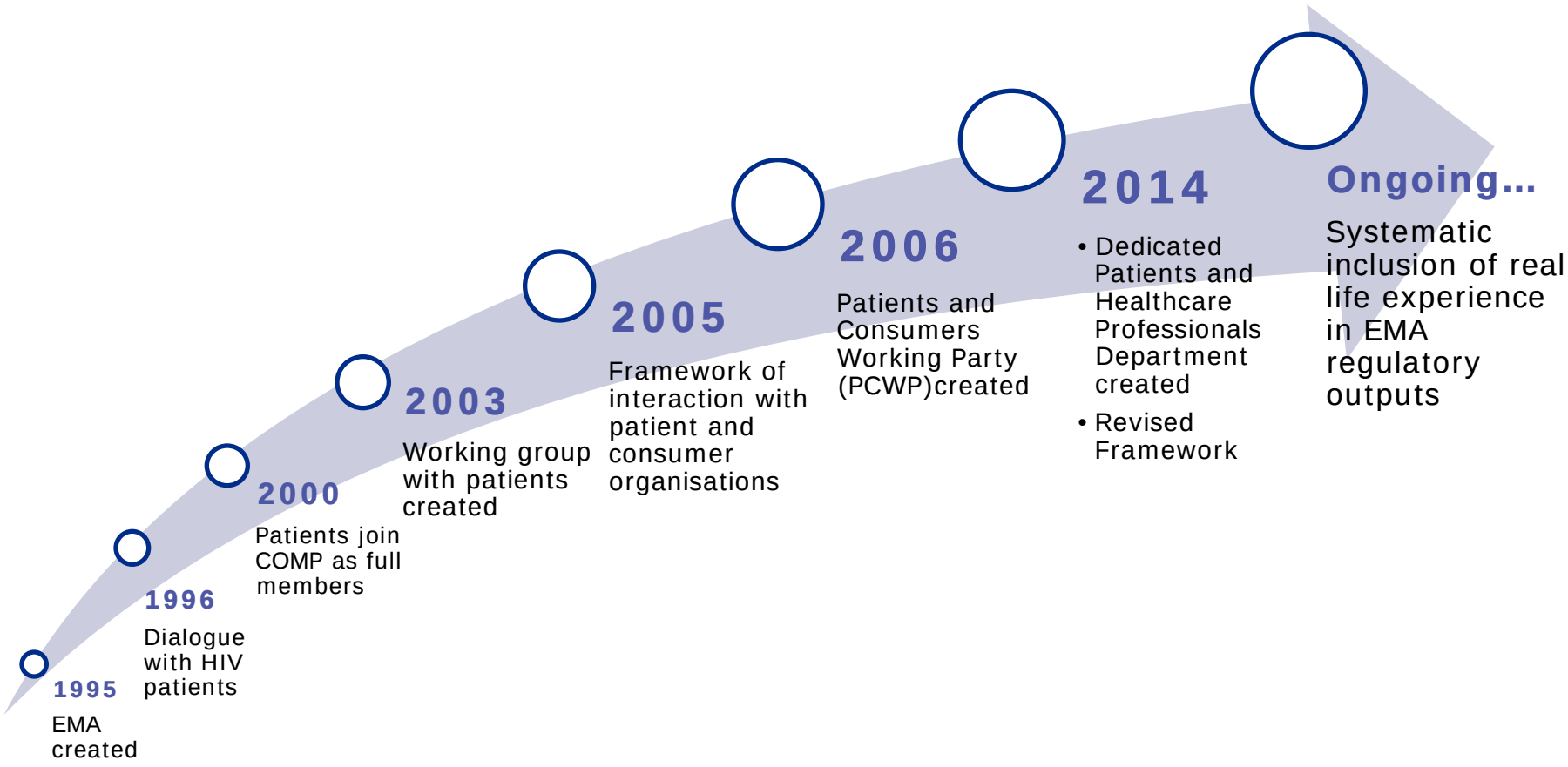
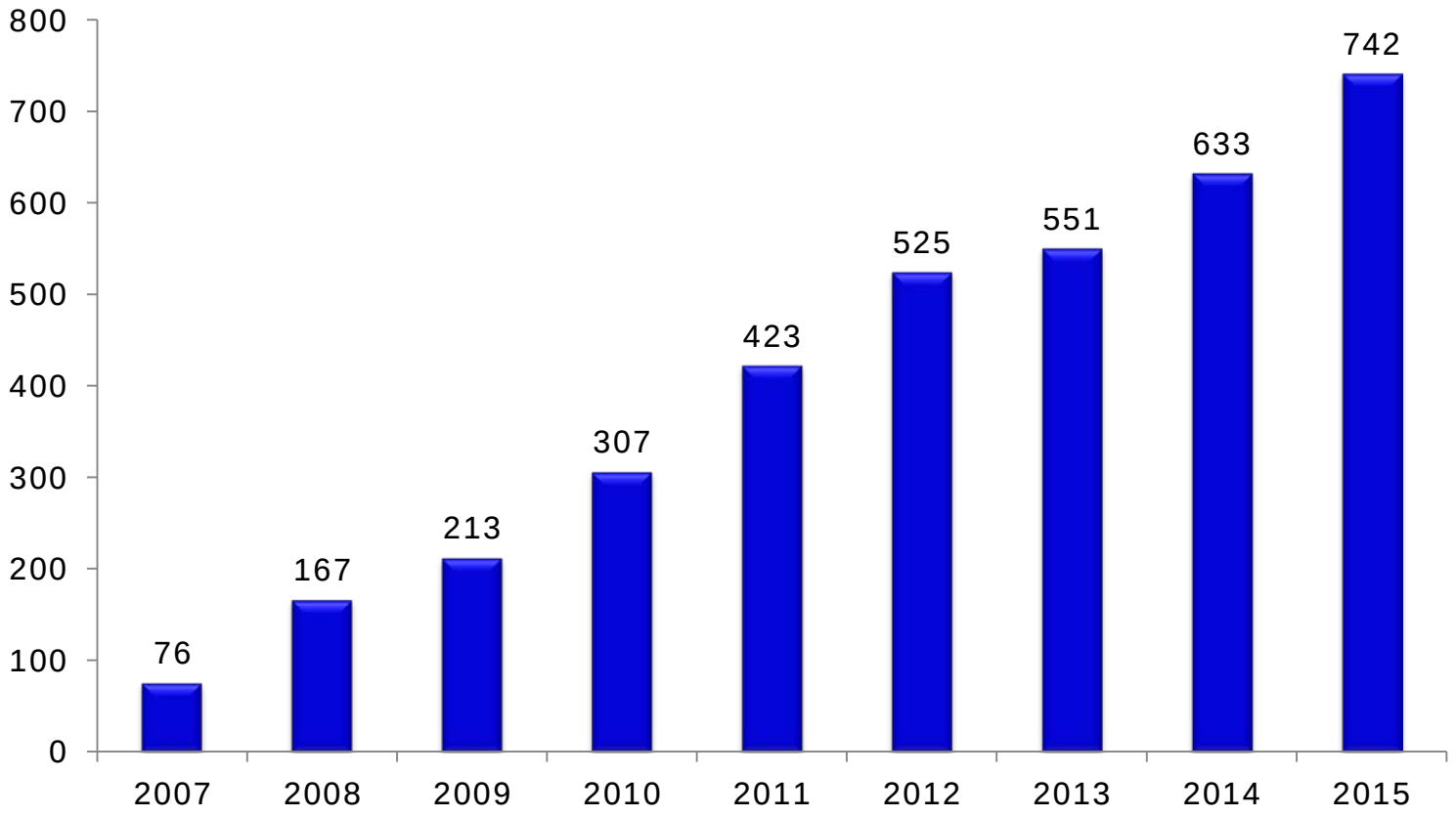
An agency of the European Union

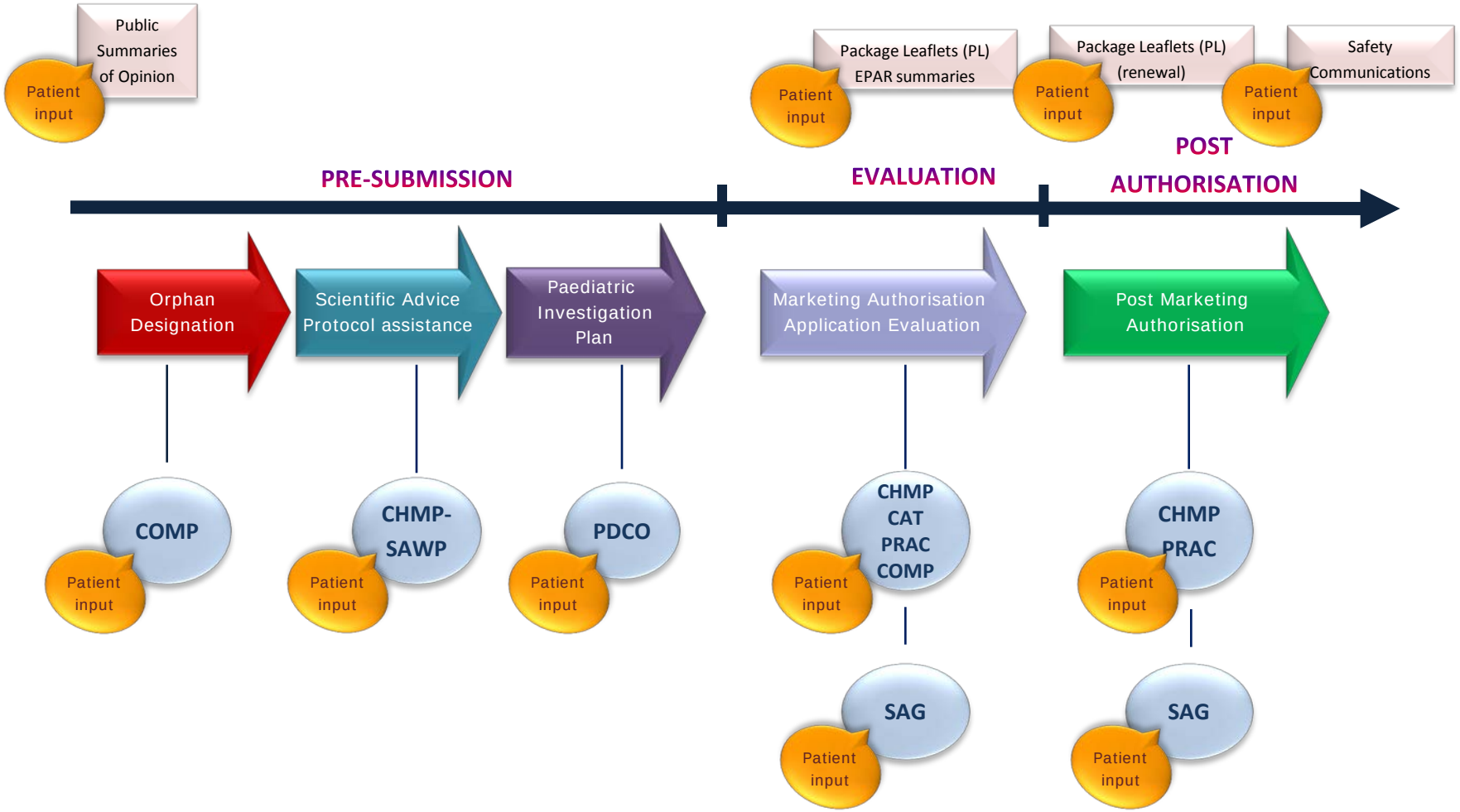
Interaction with patients: the EMA journey… so far



Patient and consumer involvement over the years..



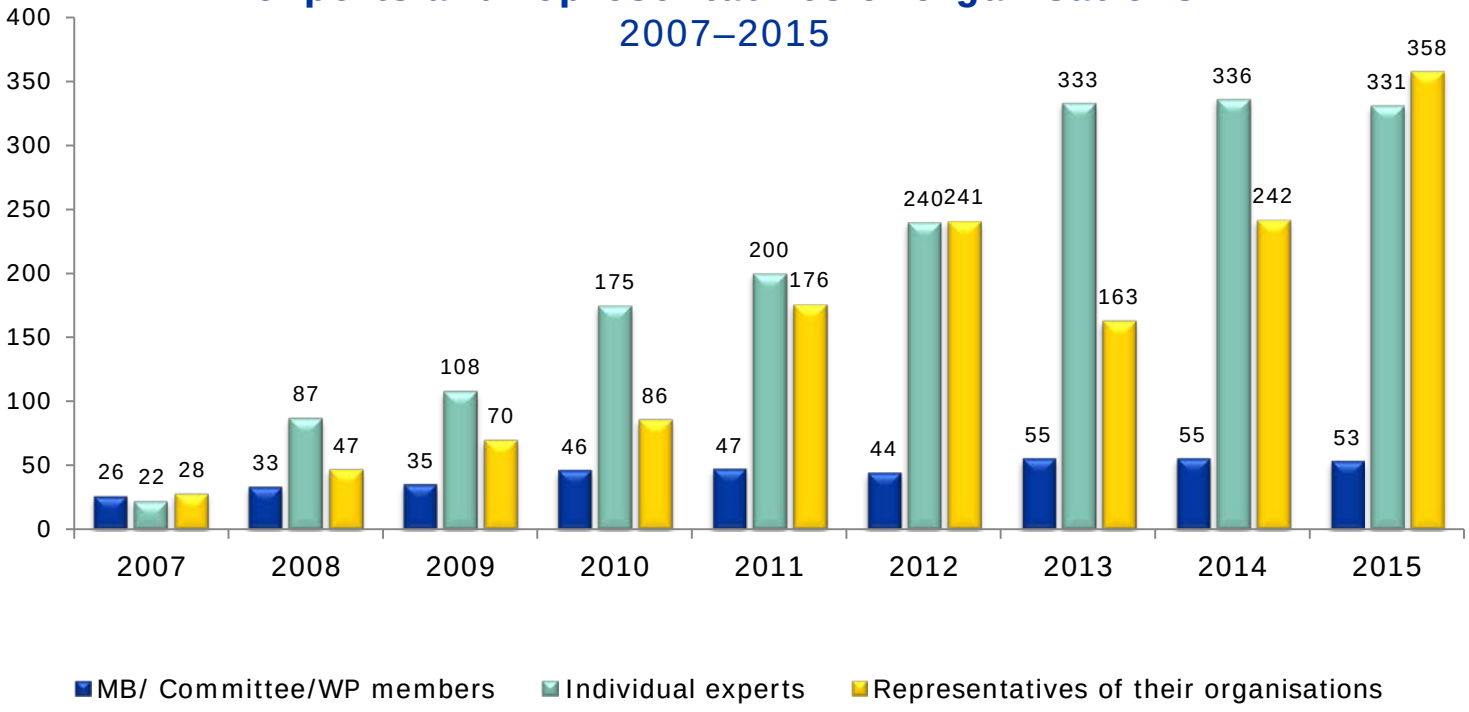
Opportunities for involvement along the medicine lifecycle at EMA



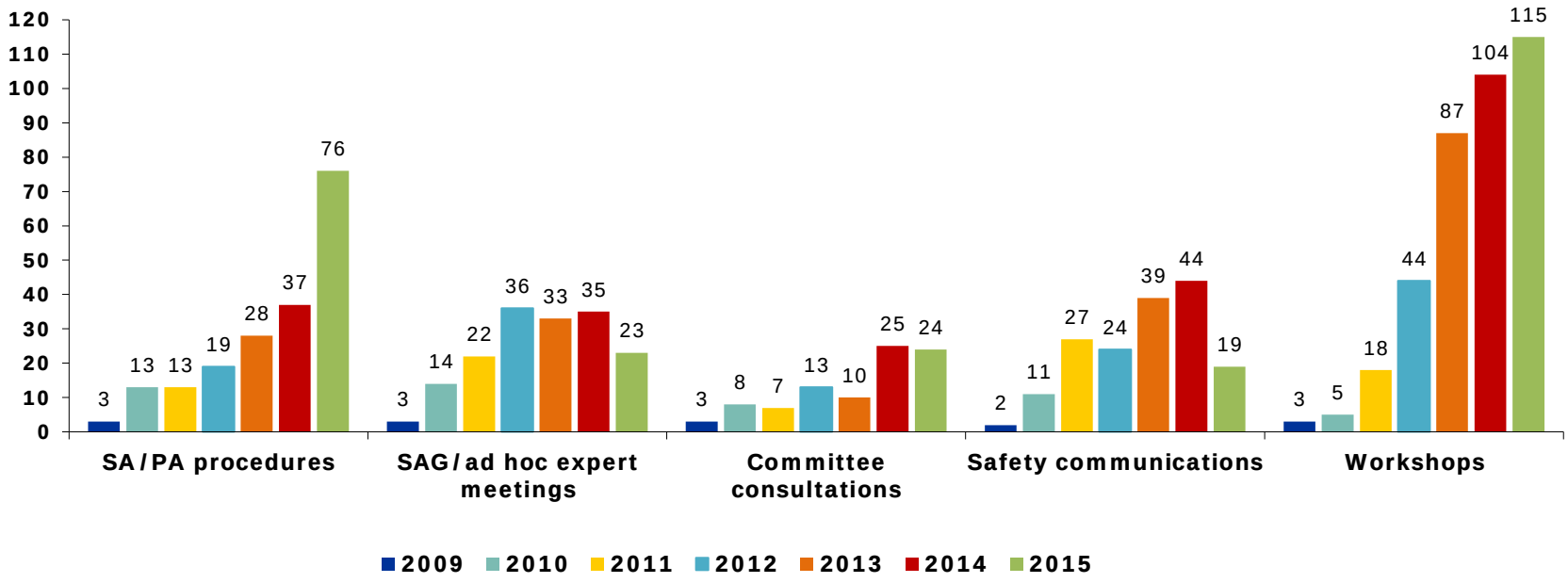
Categories of patient participation:

Patients representing *patients'* organisations	• Management Board • EMA Scientific Committee(s)
Patients representing *their* organisations	• Patients' and Consumers' Working Party (PCWP) • EMA consultations • Workshops
Patients as *individual* experts	• Scientific Advice / Protocol Assistance Procedures • Scientific Advisory / *ad hoc* expert Groups • Scientific committee consultations • Review of documents

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



Comparison of involvement across different activities



The revised framework of interaction ; Action Plan

- **Maintain the network of patients and consumers organisations**

- **Establish a pool of experts**:
  - Continue to identify patients/consumers through network
  - Identify gaps in expertise
  - Publish a call for expression of interests

- **Promote participation at key milestones during lifecycle of medicines**:
  - Ensure early involvement in development of medicines
  - Patients involvement in benefit/risk evaluation at CHMP; develop processes to capture patients' input

- **Build capacity**:
  - Explore means to increase awareness on medicines evaluation
  - Gather feedback and streamline provision of EMA training
  - Conduct a reflection on providing further support to enable patient involvement

- **Monitor and increase transparency on involvement of patients, consumers and organisations in EMA**:
  - Establish system for regular collection of quantitative and qualitative data for monitoring and reporting purposes
  - Explore methodologies to measure the impact of patients' involvement on regulatory outcomes
  - Acknowledge and promote visibility of patient/consumer organisations input provided in Agency activities

Eligible organisations: patients/consumers

Patients representing patients' organisations

Members of :

- EMA Management Board (MB)

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

Patients representing their organisations

EMA Working Party with Patients & Consumers Organisations (PCWP)

- 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

Patients representing their organisations (Cont.)

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

Patients also contribute to **EU-wide initiatives** where EMA is involved such as:

- Enpr-EMA - European Network of Paediatric Research at the European Medicines Agency
- ENCePP - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
- WEB-RADR - Recognising Adverse Drug Reactions

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
- 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
- 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
- Workshop to clarify concept/demonstrating of significant benefit of orphan medicines
- EMA 20th anniversary event: The view from the sharp end: what patients and healthcare professionals can do for us
- IMI ADVANCE project

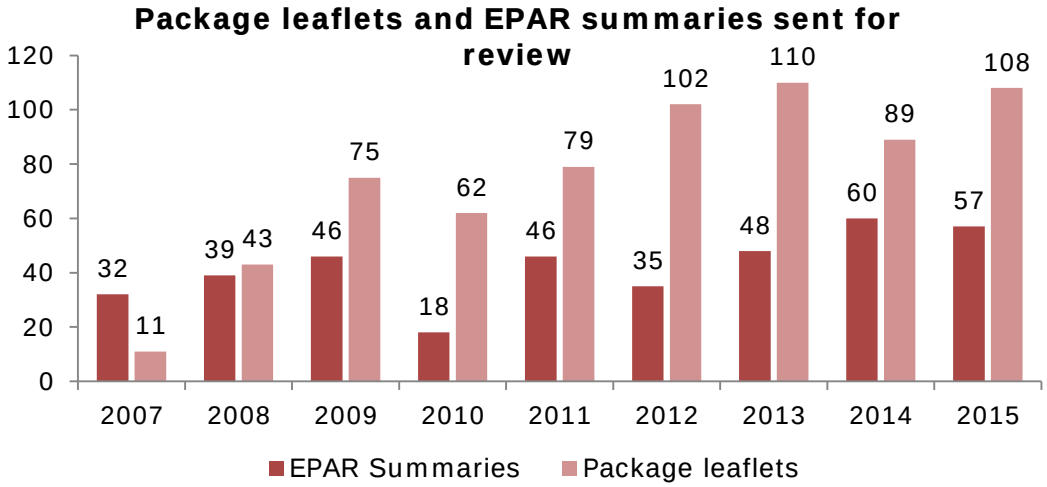
Patients as individual experts

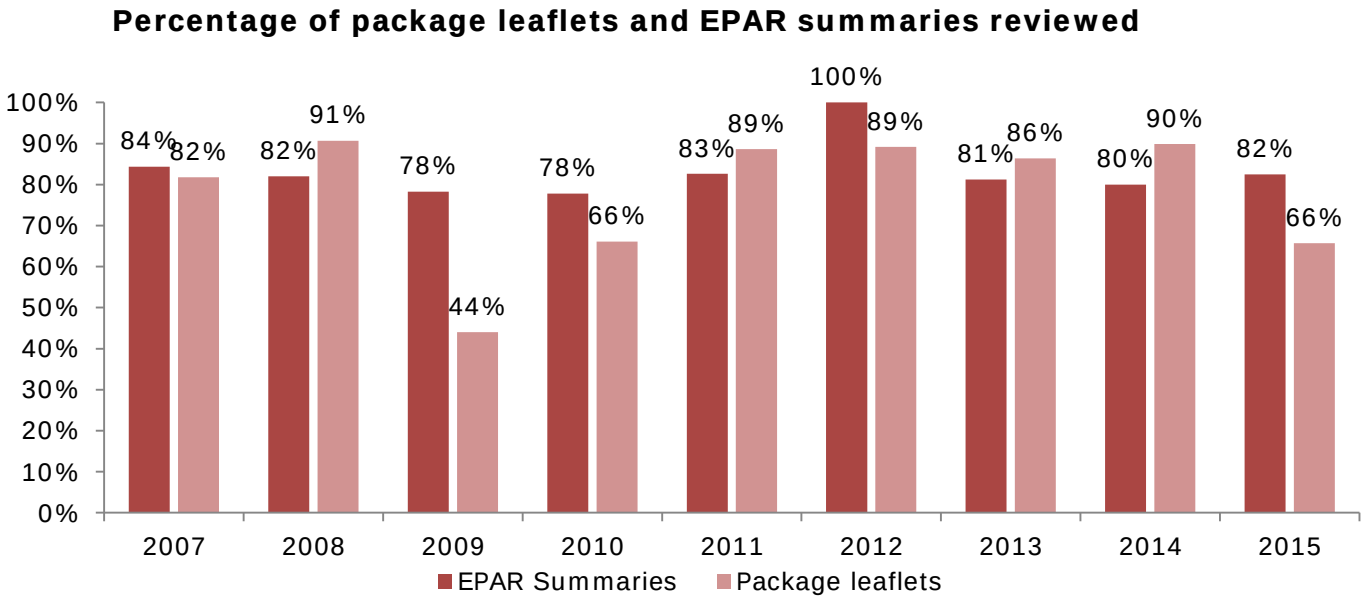
Medicines' development:

- Participation in scientific advice/protocol assistance procedures

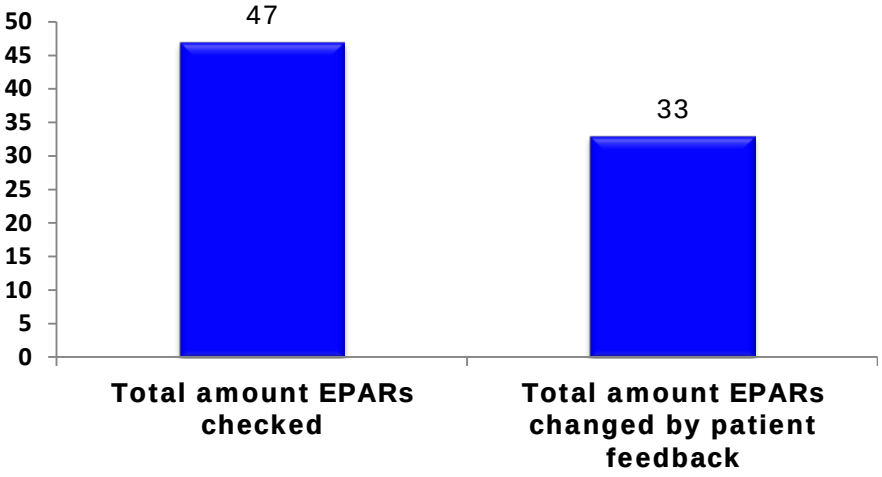
Benefit / risk evaluations:

- Participation in scientific advisory / ad-hoc expert group meetings (SAGs) convened by CHMP or PRAC
- Respond to ad-hoc consultations on assessment of medicines from all Committees
- Review information on medicines: Package leaflets, EPAR summaries, safety communications (Q&As) and soon herbal summaries

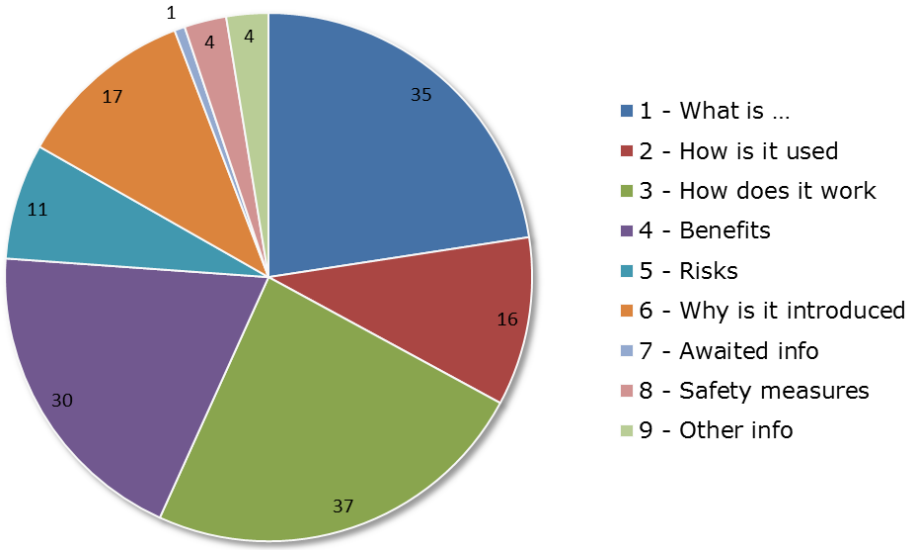

Package leaflets and EPAR summaries sent for review
120
100
80
60
40
20
0
32
11
39
43
46
75
18
62
46
79
35
102
48
110
60
89
57
108
2007
2008
2009
2010
2011
2012
2013
2014
2015
EPAR Summaries
Package leaflets


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%
82%
66%
2007
2008
2009
2010
2011
2012
2013
2014
2015
EPAR Summaries
Package leaflets

Feedback on comments received; EPAR summaries



62% of EPARs adjusted due to feedback by patients



Ongoing initiatives

- **Pilot project to involve patients in CHMP plenary discussions**
  - 3 cases so far; ongoing
- **Elicitation of B/R preferences**
  - Pilot study with melanoma / myeloma patients
  - Expanded study 2016
- **Enhanced training materials**
  - 'EMA basics' short videos
  - Info-sheets
  - Improvements to webpages dedicated to patients
- **Topic groups**
  - Measure impact/value of patient involvement
  - Acknowledge and promote visibility of patient input in the Agency's activities
  - Training and support to patients
  - Social media
  - Involvement of young people

Continued to raise awareness

Participation in conferences

- EATG stakeholders meeting, Brussels
- Giving patients a voice - Federal Joint Committee, Berlin
- PROTECT Final Symposium, EMA
- Eurordis rare disease day media event
- LSE conference - Pharmaceutical Policy: Pricing, access and reimbursement, London
- EFPIA 50 year anniversary of EU pharmaceutical legislation, Brussels
- Newcastle University – Workshop: Participants not subjects – engaging patients and families in paediatric clinical research
- DIA Euromeeting-Paris
- Melanoma (MPNE) 2015 conference - Brussels
- Myeloma Patients Europe annual meeting - Dubrovnik
- University of Copenhagen: Patient Involvement in medicines development and approvals
- Eurordis summer school - Barcelona
- EUPATI Advisory Board meeting - Berlin
- CIRS patient Engagement workshop - UK
- EUPATI training course for patients - Barcelona
- WONCA conference - Istanbul
- ISPOR roundtable - Milan
- FT global pharmaceutical and Biotechnology conference - London
- EUnetHTA-EMA meeting - Copenhagen
- Invitation to participate and advise on workshop on stem cell therapies and gene therapies (Genetic Alliance UK/Wellcome Trust - Medical Research Council Cambridge Stem Cell Institute)
- Joint EMA-EBE (European Biopharmaceutical Enterprises) seminar

Conclusion

- The involvement of PCOs continues to be extremely beneficial;
- Patients 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 expands, but evolves to ensure it occurs in the most optimal manner possible
- We will continue to look to enhance and improve involvement wherever feasible
- We look forward to a continued mutually beneficial collaboration during 2016!