EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interaction with patients and consumers

Overview of involvement in EMA activities during 2016

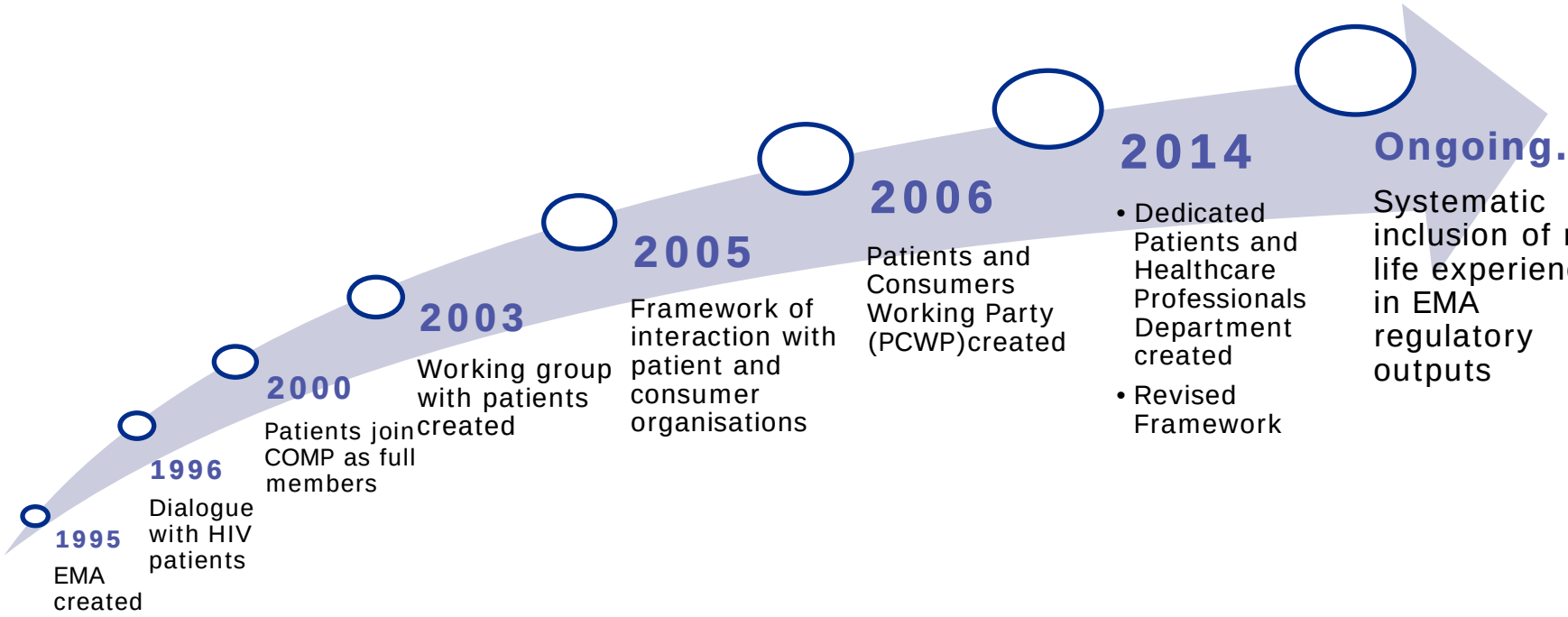
Presented by Nathalie Bere on 15 March 2017
Public engagement department, Stakeholders and Communication Division

An agency of the European Union

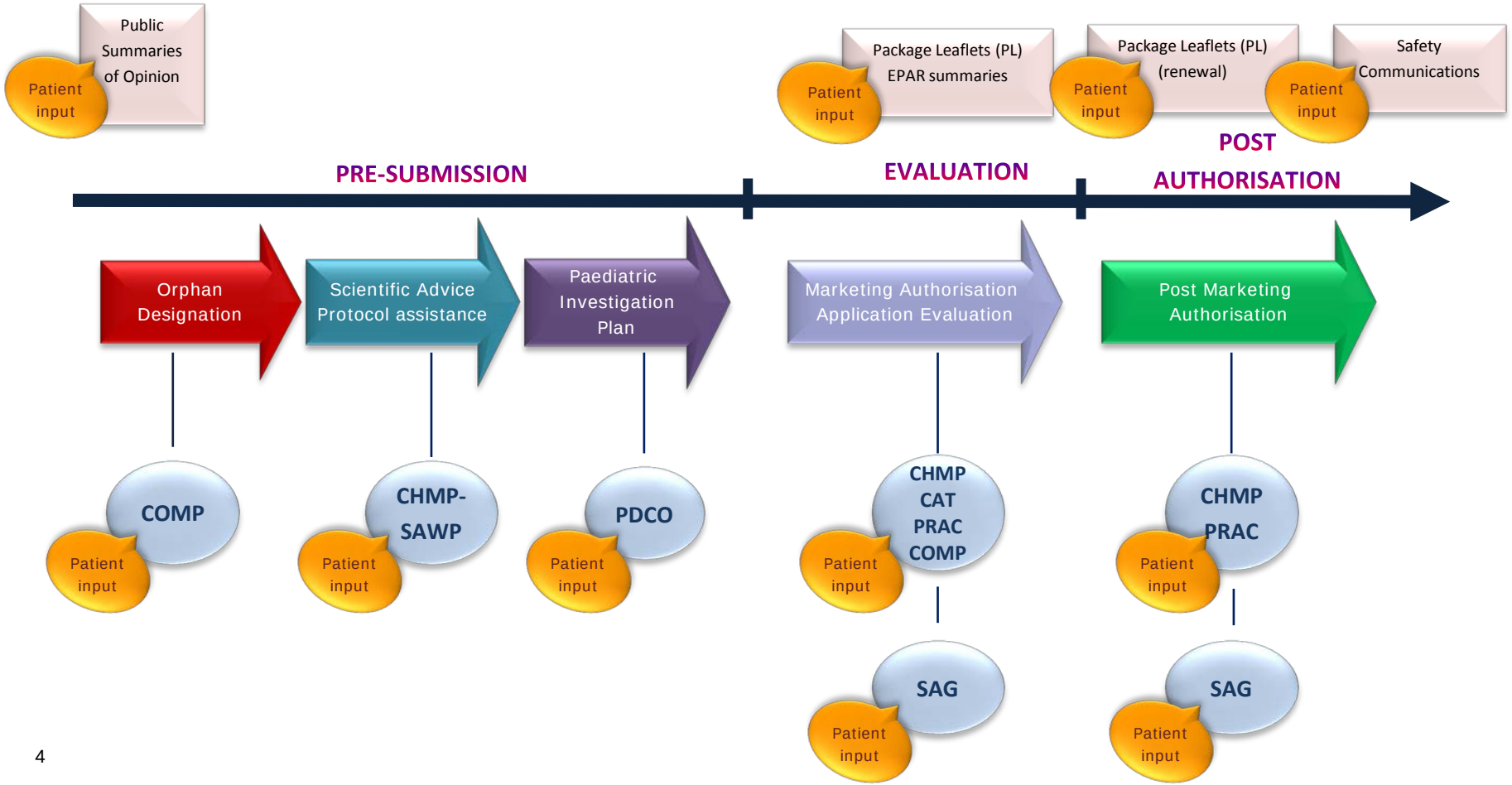
Contents

I. Patients and consumers involvement in EMA

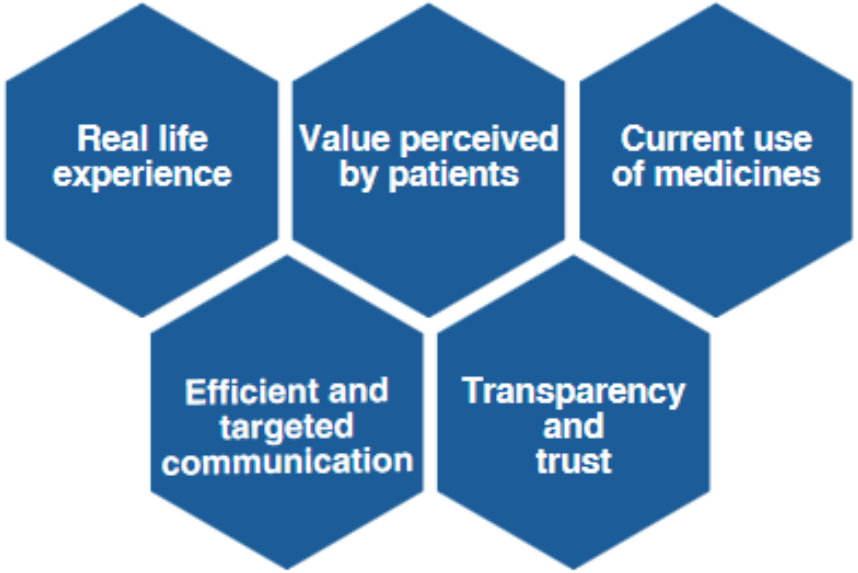
Interaction with patients: the EMA journey so far



Opportunities for involvement along the medicine lifecycle at EMA



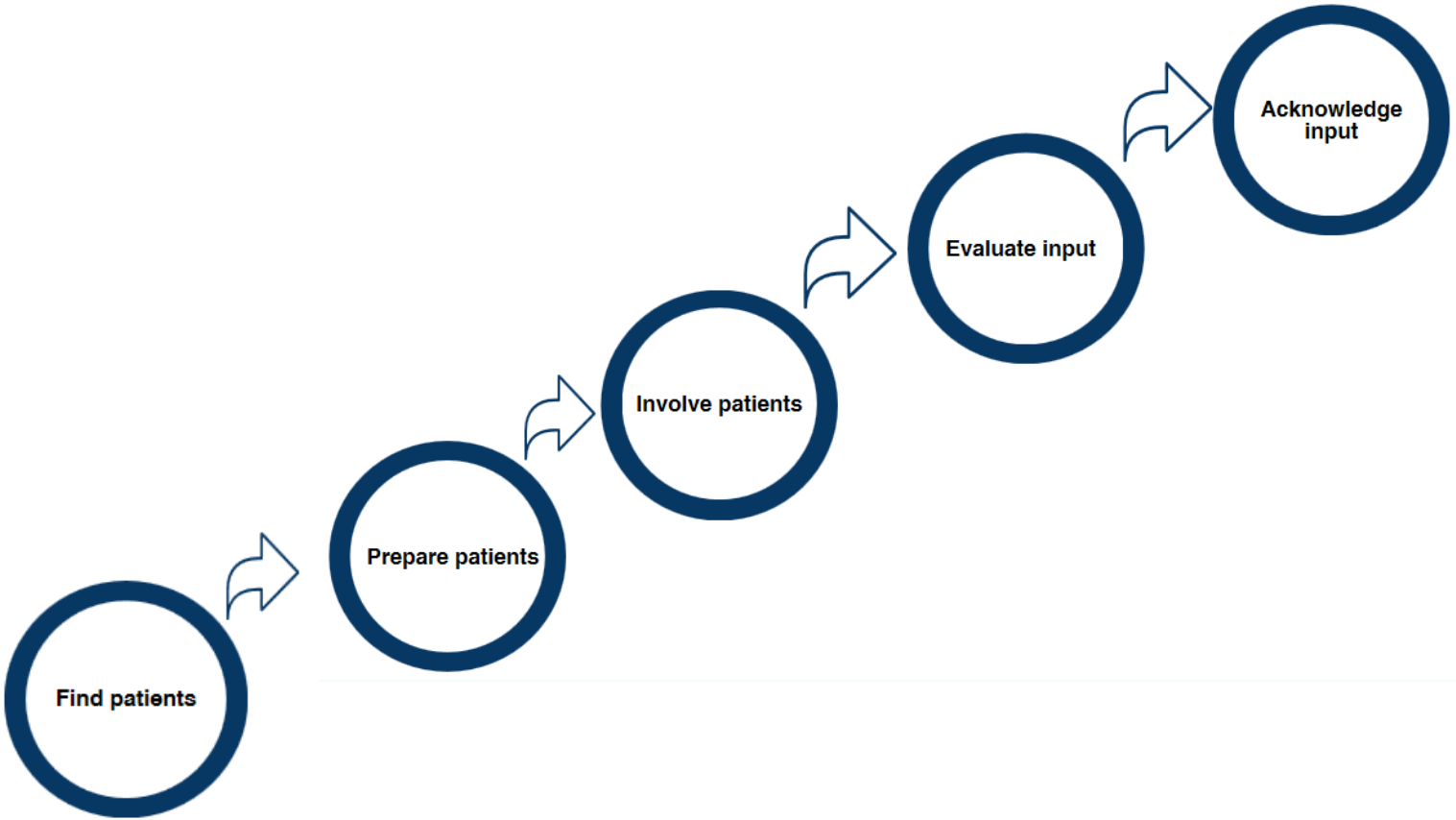
Benefits of patient involvement



"It is one of the success stories of EMA as only patients can really bring us the real benefit-risk assessment; they are entitled to teach us the added quality of life of any therapeutic approach"

Guido Rasi

Stages of patient involvement



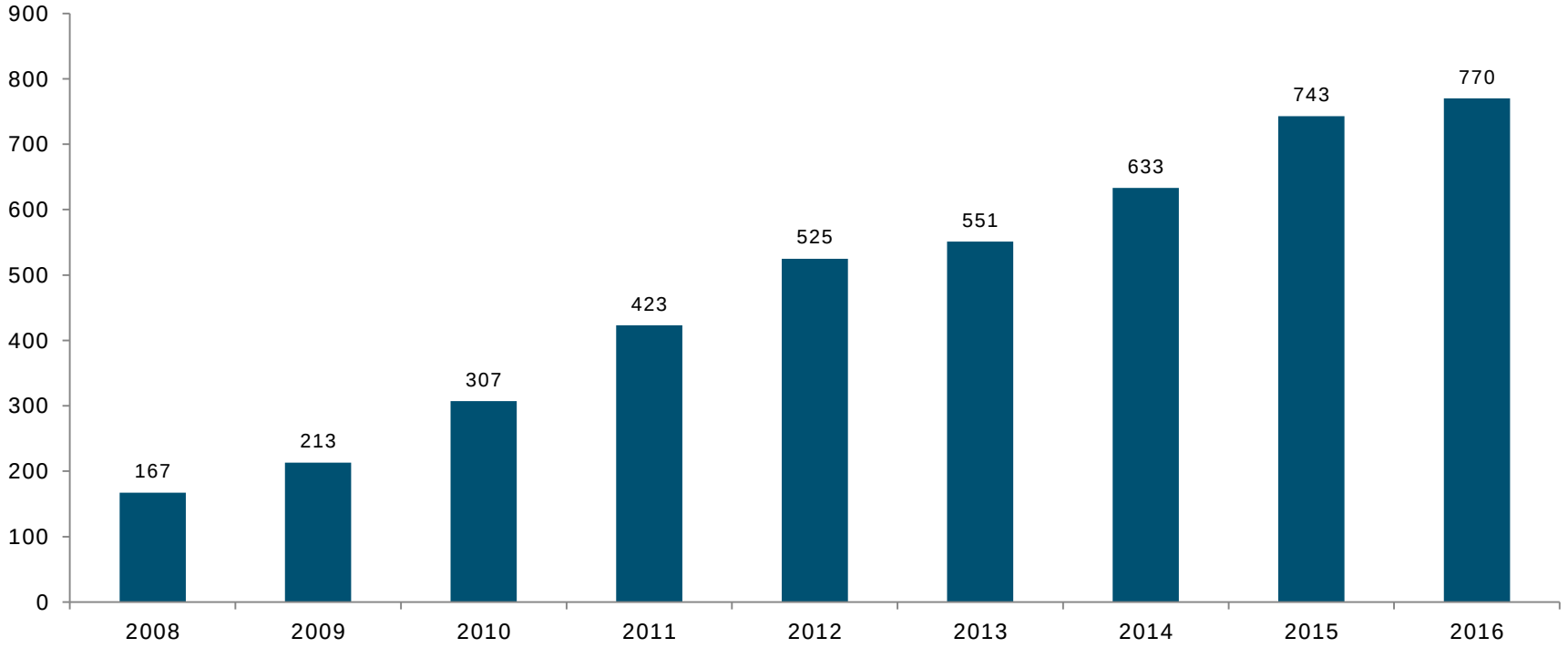
II. Types of representation

Types of representation

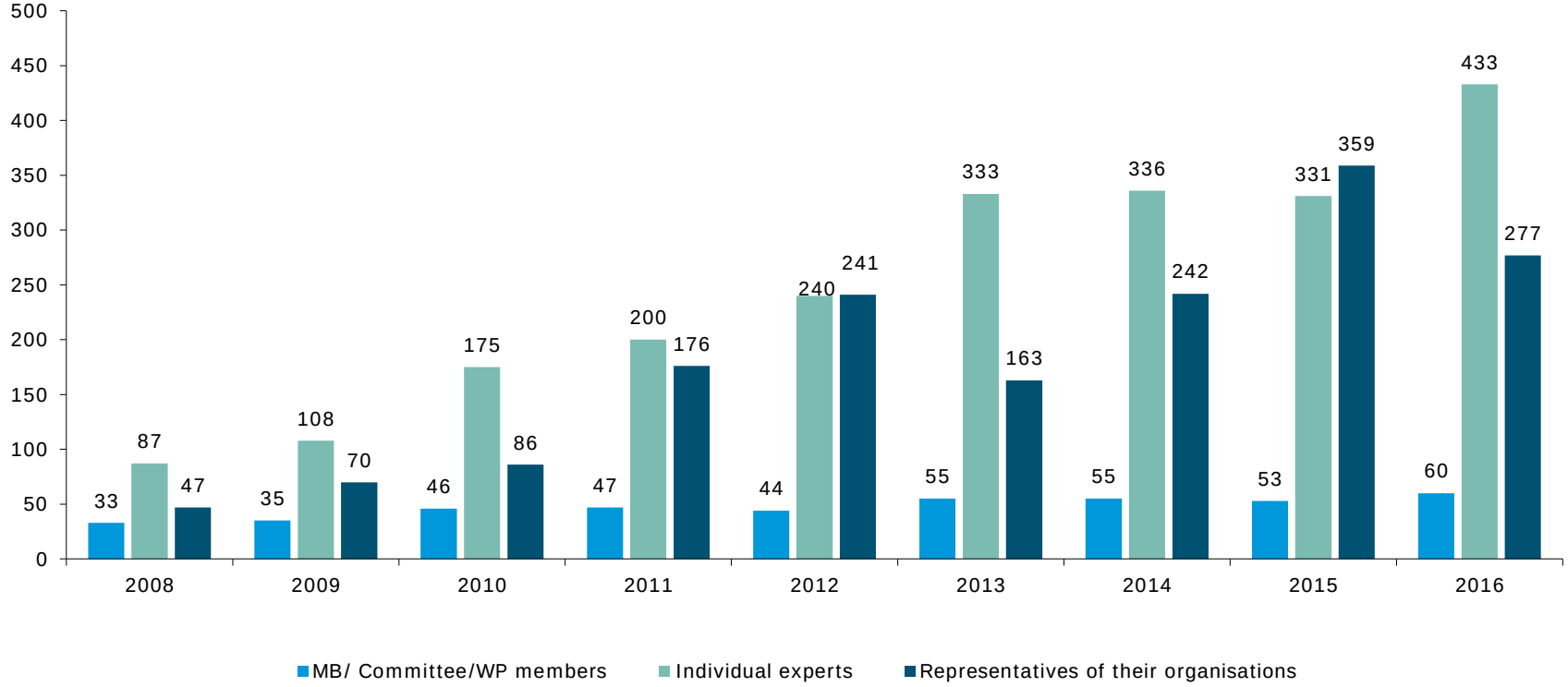
Patients representing *patients'* organisations	Management Board (MB) EMA Scientific Committee(s)
Patients representing *their* organisations	Patients' and Consumers' Working Party (PCWP) EMA consultations Workshops
Patients as *individual* experts	Scientific Advice Procedures Scientific Advisory / *ad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

III. Key figures in 2016

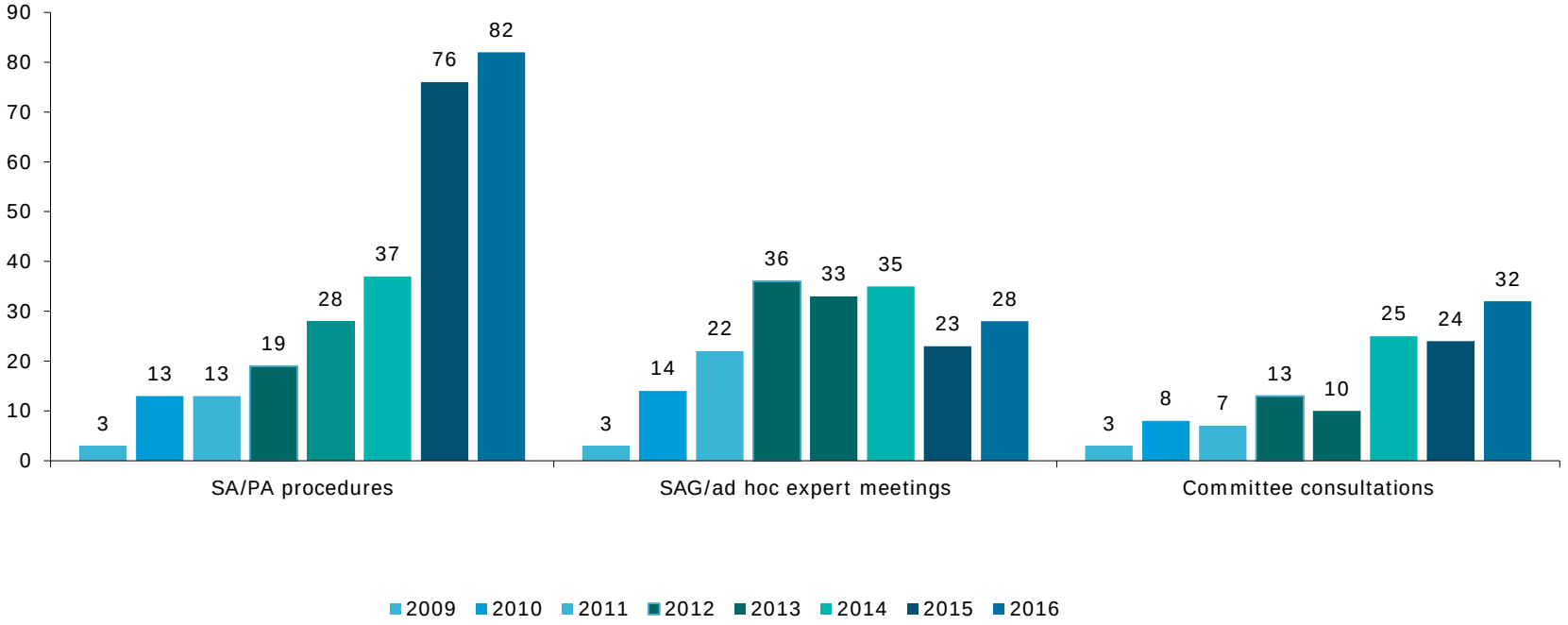
Patient and consumer involvement over the years



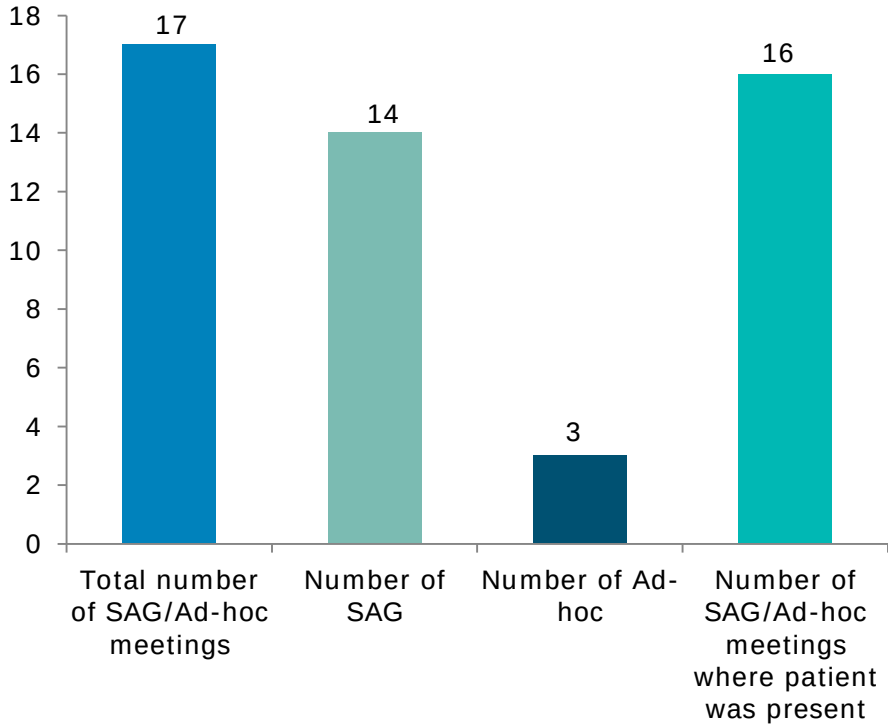
Involvement as committee / working party members, experts and representatives or organisations 2008-2016



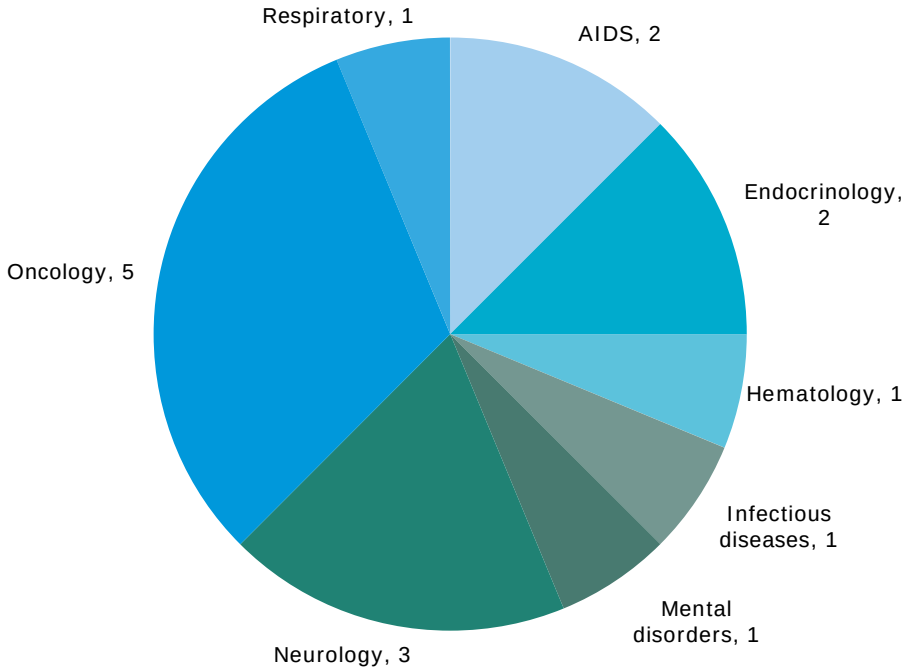
Involvement across different activities 2009-2016



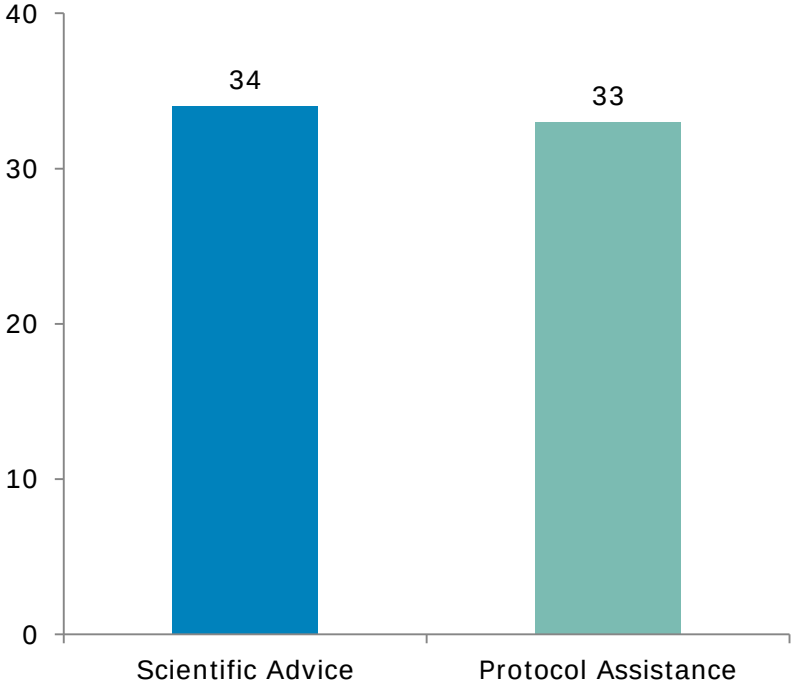
Number of SAGs / Ad-hoc including patient input



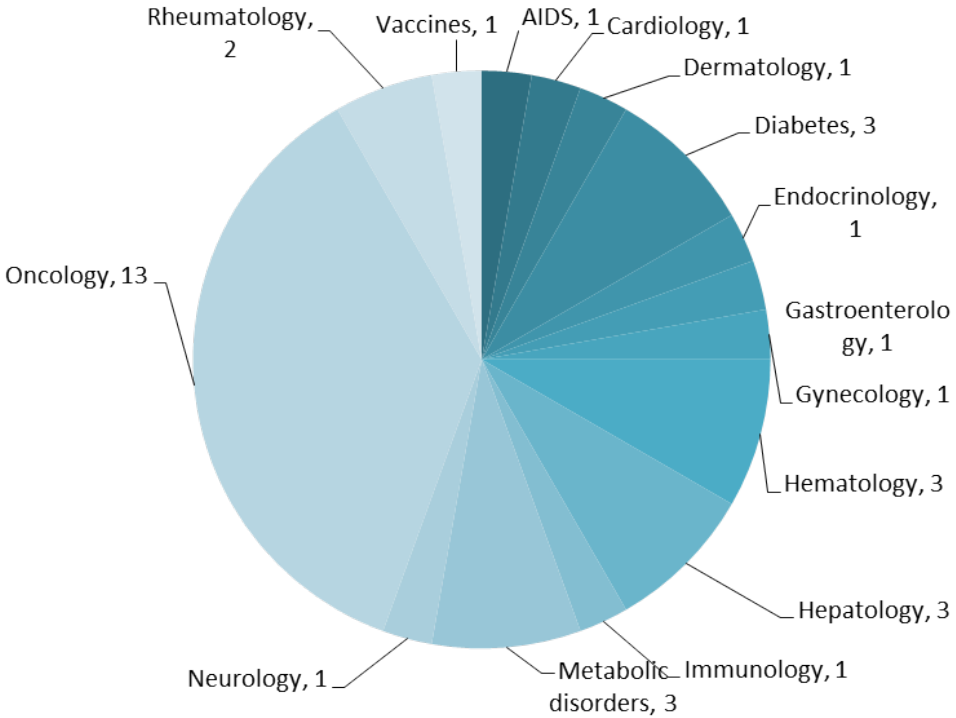
Frequency of therapeutic areas of SAG / Ad-hoc meetings



Number of SA / PA meetings including patient input

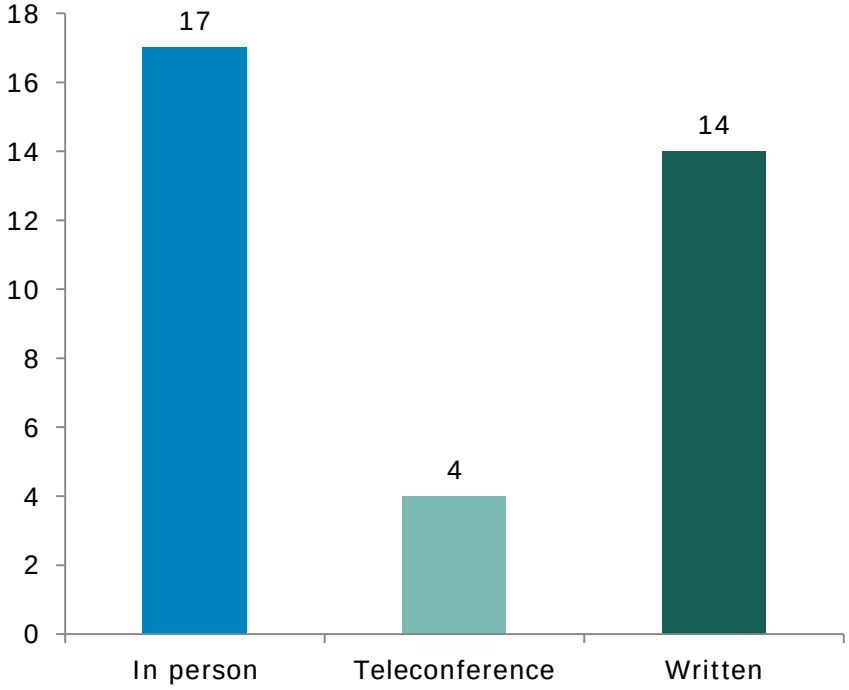


Frequency of therapeutic areas of SA meetings

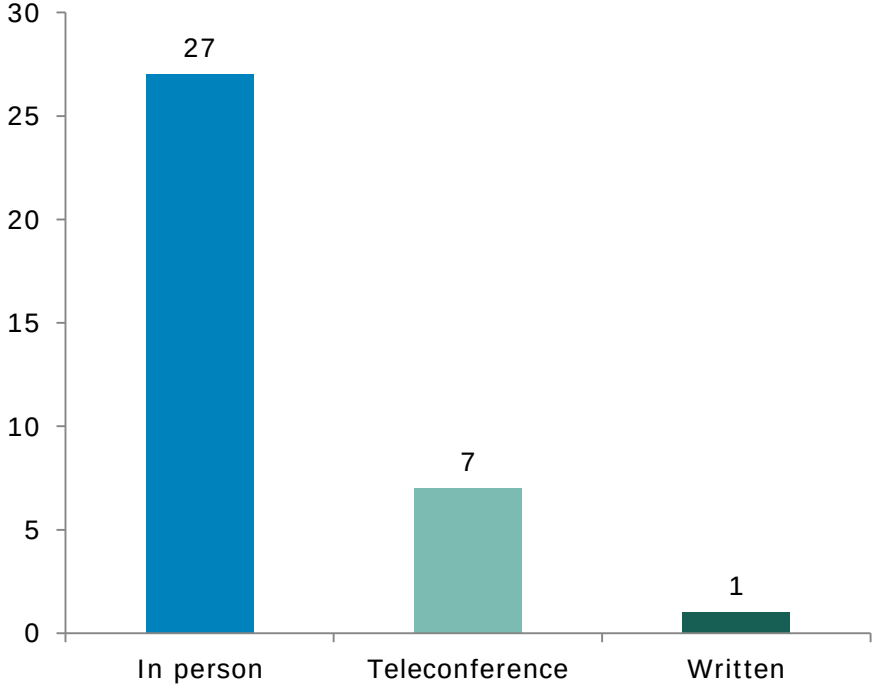


Distribution of participation type in Scientific Advice and Protocol Assistance

Scientific advice



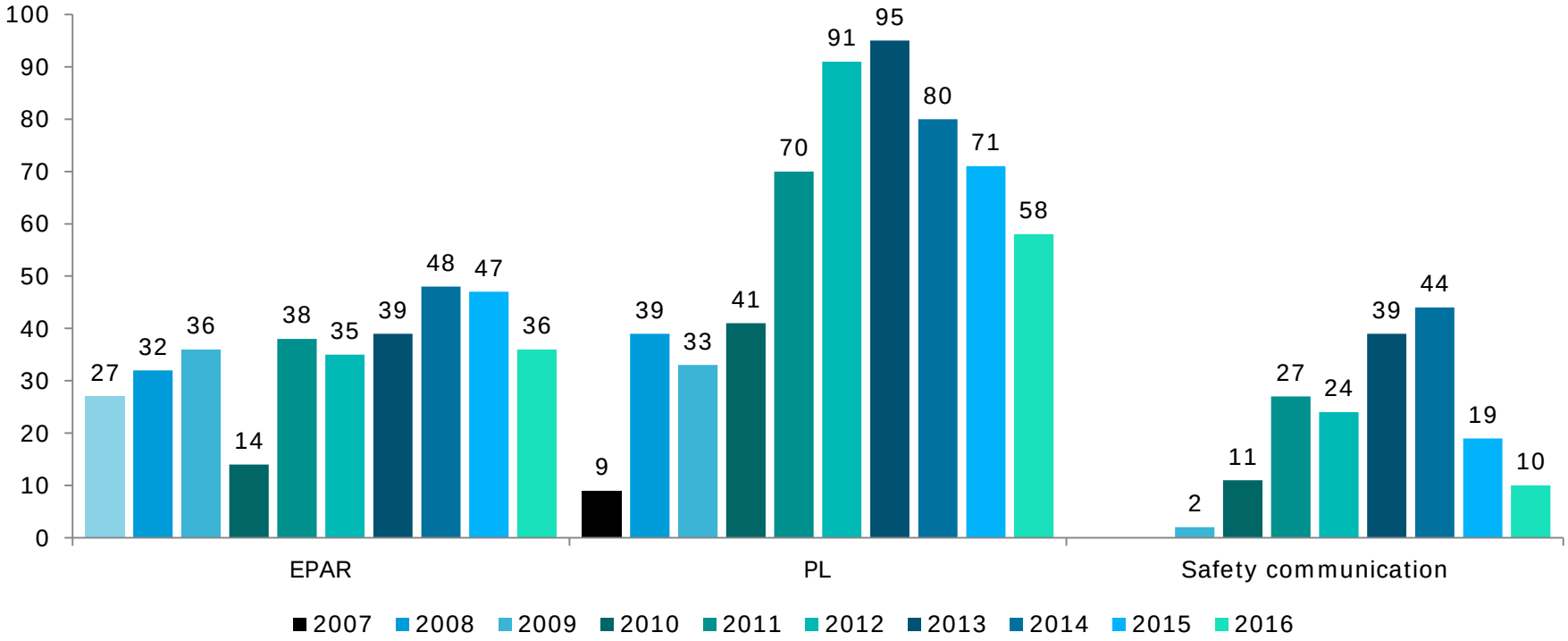
Protocol assistance



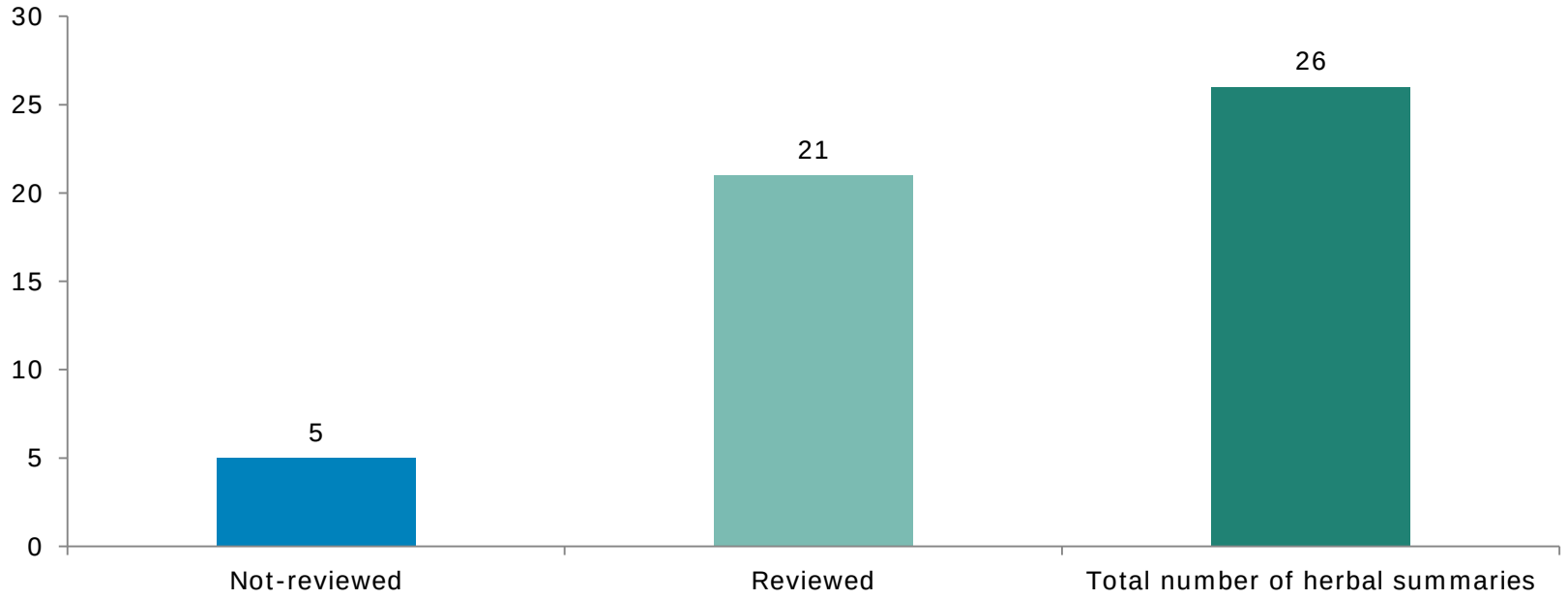
EMA Scientific Committee consultations in 2016 (examples)

- Risk minimisation measures for HIV PrEP. (CHMP/PRAC)
- Melanoma medicine - educational material (CxMP)
- HIV-1 brochure for individuals/reminder card (PRAC)
- Risk minimisation of medication errors with new diabetes medicine (PRAC)
- Wording (class labelling revision HIV medicines) (CxMP)

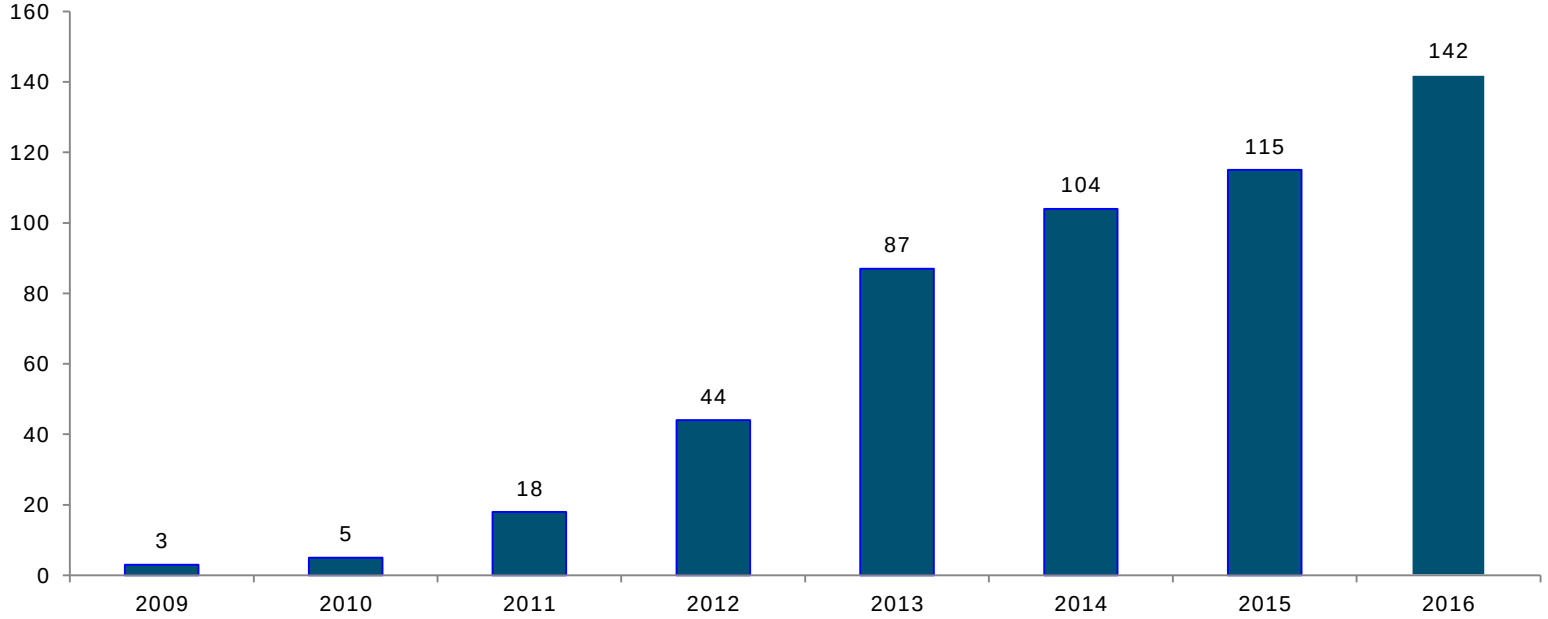
Review of EPAR, PL and Safety communication



Herbal summary review: March - December



Involvement in workshops 2009-2016



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Patient participated in all 22 workshops & conferences organised by EMA in 2016

HIGHLIGHTS

- EMA workshop on extrapolation of efficacy and safety in medicine development across age groups
- EMA multi-stakeholder workshop on Advanced Therapy Products
- DIA Information Day on Medication Errors
- Registries meeting
- Big data workshop
- Workshop on adaptive pathways

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EMA participated in 16 stakeholder meetings last year

HIGHLIGHTS

- Action Duchenne international conference
- DIA Euromeeting, Hamburg, Germany
- ECTRIMS-EMA-EMSP meeting
- IAPO seventh patients congress, London
- ICAN summit, Barcelona
- IMI workshop on patient engagement strategy, Brussels
- IASLC 17th World conference on Lung Cancer, Vienna
- 8th European Conference on Rare Diseases & Orphan Products, Scotland

Training

- EUPATI Face-To-Face session, Barcelona, Spain
- EURORDIS summer school, Barcelona

Highlights of the year

- **Pilot project to involve patients in CHMP plenary discussions**
  - Completed; report pending
- **Elicitation of Benefit/Risk patient preferences**
  - Larger study with myeloma patients
- **Enhanced training materials**
  - ‘EMA basics’ short videos
  - Info-sheets
- **Topic groups**
  - Social media
  - Training
  - Involvement of young people
- **Public hearings**
  - Preparations, including dry run

Challenges

- Finding suitable patients (e.g. language barrier, availability),
- Ensuring comprehensive, tailored support to facilitate and enhance participation,
- Provide a clear definition of patients role in the different activities to manage expectations from all angles,
- Managing potential conflicts of interest,
- Representation – how to also gather information from a larger group,
- How to measure the value / impact of patients,
- Process of review of documents needs to be looked at.

IV. Conclusion

Conclusion and way forward

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- 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 2017!

Thank you for your attention

Nathalie Bere

Acknowledgement: Ivan Sebest

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