EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient engagement – the EMA experience

Partnerships Meet-up (Lygature), 29 October, Utrecht

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An agency of the European Union

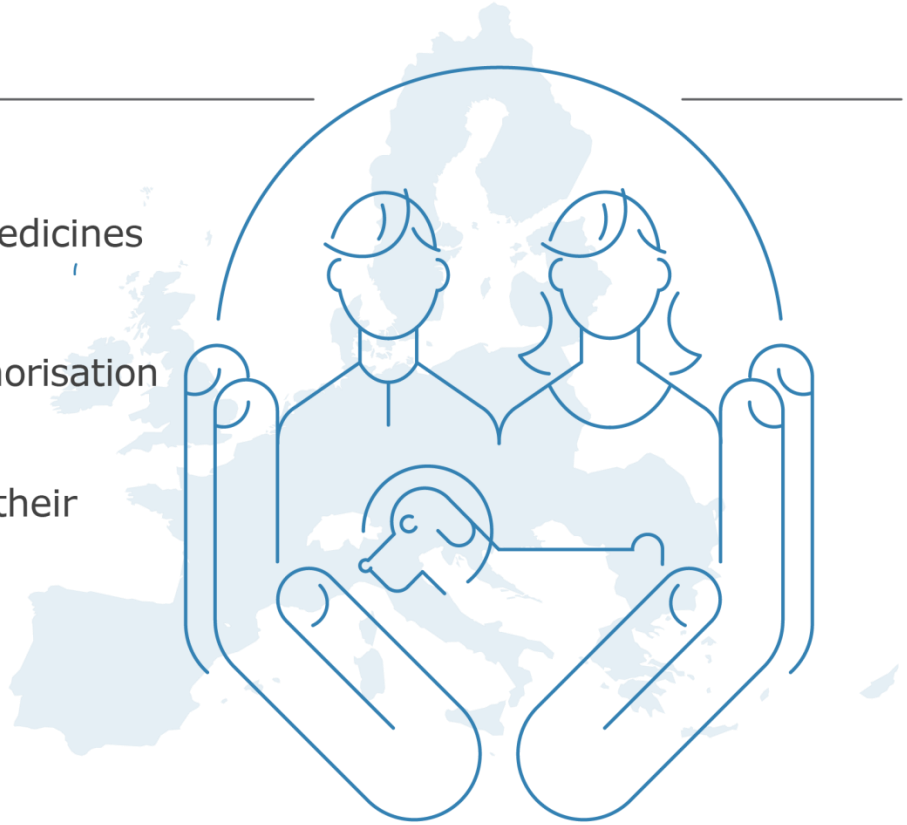
The European Medicines Agency (EMA)

EUROPEAN MEDICINES AGENCY

What we do

Protect human and animal health

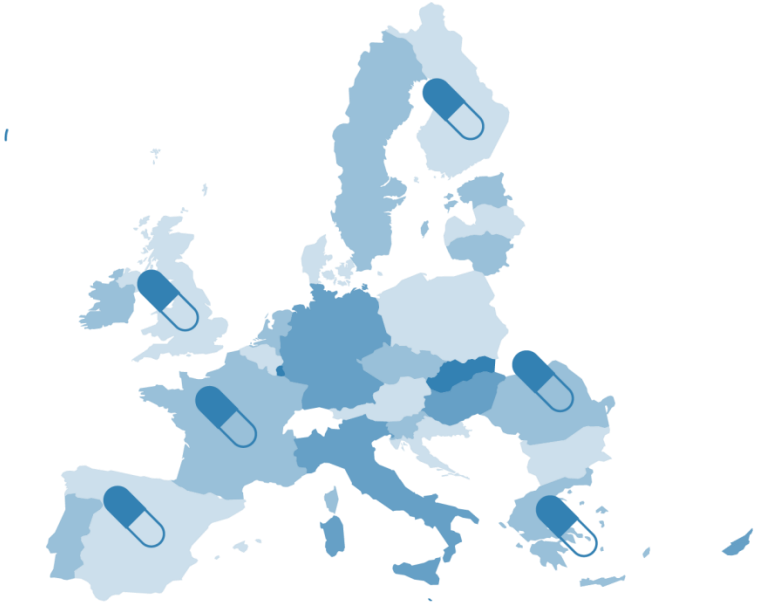
- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- ABC XΨΩ Provide reliable information on human and veterinary medicines to patients and healthcare professionals



How are medicines approved?

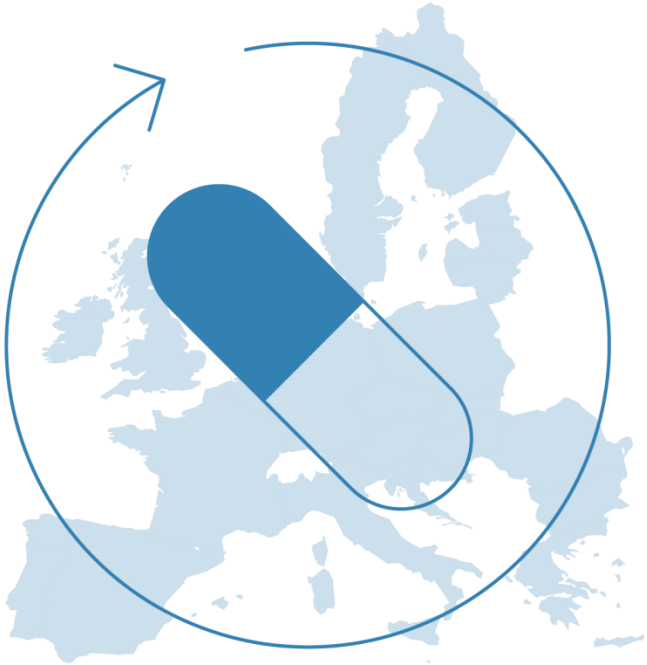
Different authorisation routes: one set of common rules

Centralised procedure (via EMA)



National procedures (via Member States)

Which medicines are approved through the centralised procedure?



- Human medicines containing new active substances for the treatment of HIV/AIDS cancer, diabetes, neurodegenerative diseases, auto-immune, and other immune dysfunctions, and viral diseases
- Medicines derived from biotechnology processes, such as genetic engineering
- Advanced therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- Officially designated 'orphan medicines' (medicines used for rare human diseases)
- Veterinary medicines for use as growth or yield enhancers

EMA stakeholder engagement

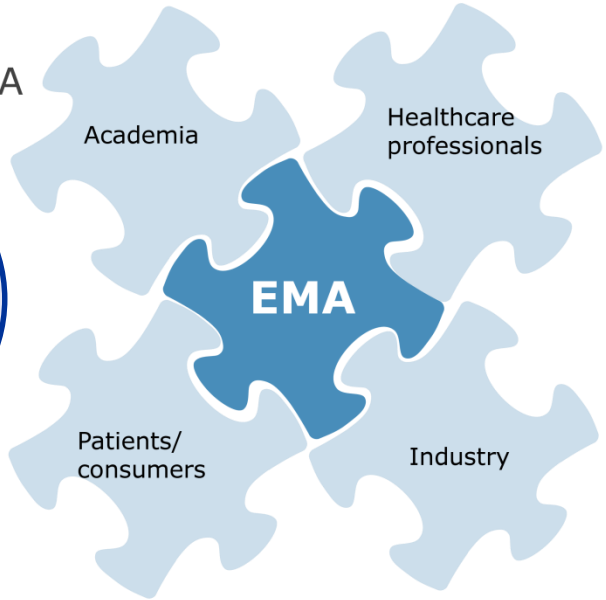
Promoting multi-stakeholder discussions

- Engage and involve stakeholders in EMA activities
- Enable stakeholders to share relevant issues with EMA

- Provide reliable, targe
- Enhance understandi
  network
- Increase transparency a

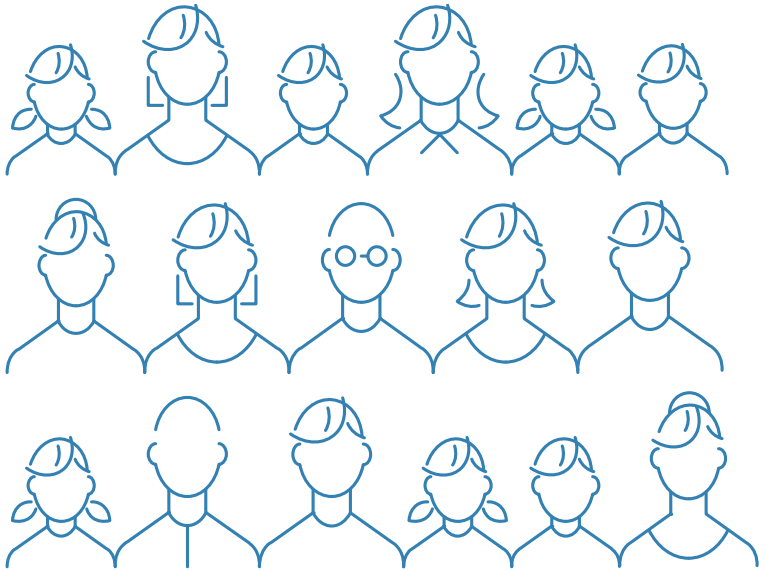
- Use stakeholder relations to further support EMA's strategic priorities

Together foster scientific excellence in the evaluation and supervision of medicines, for the benefit of EU public health

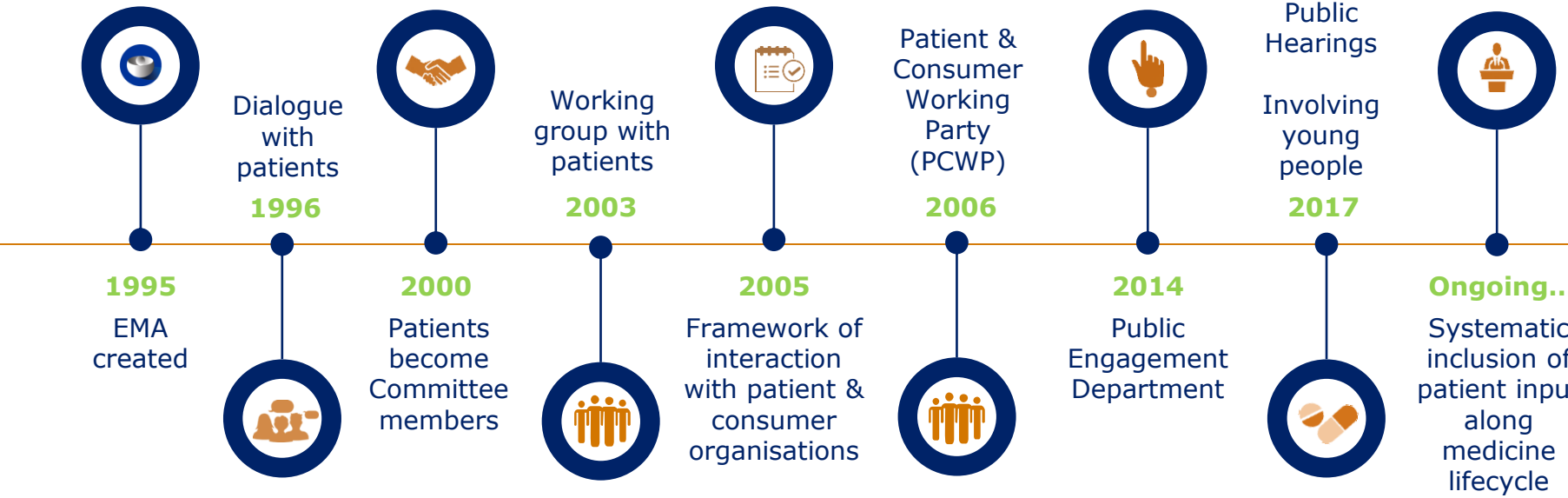


Patient engagement:

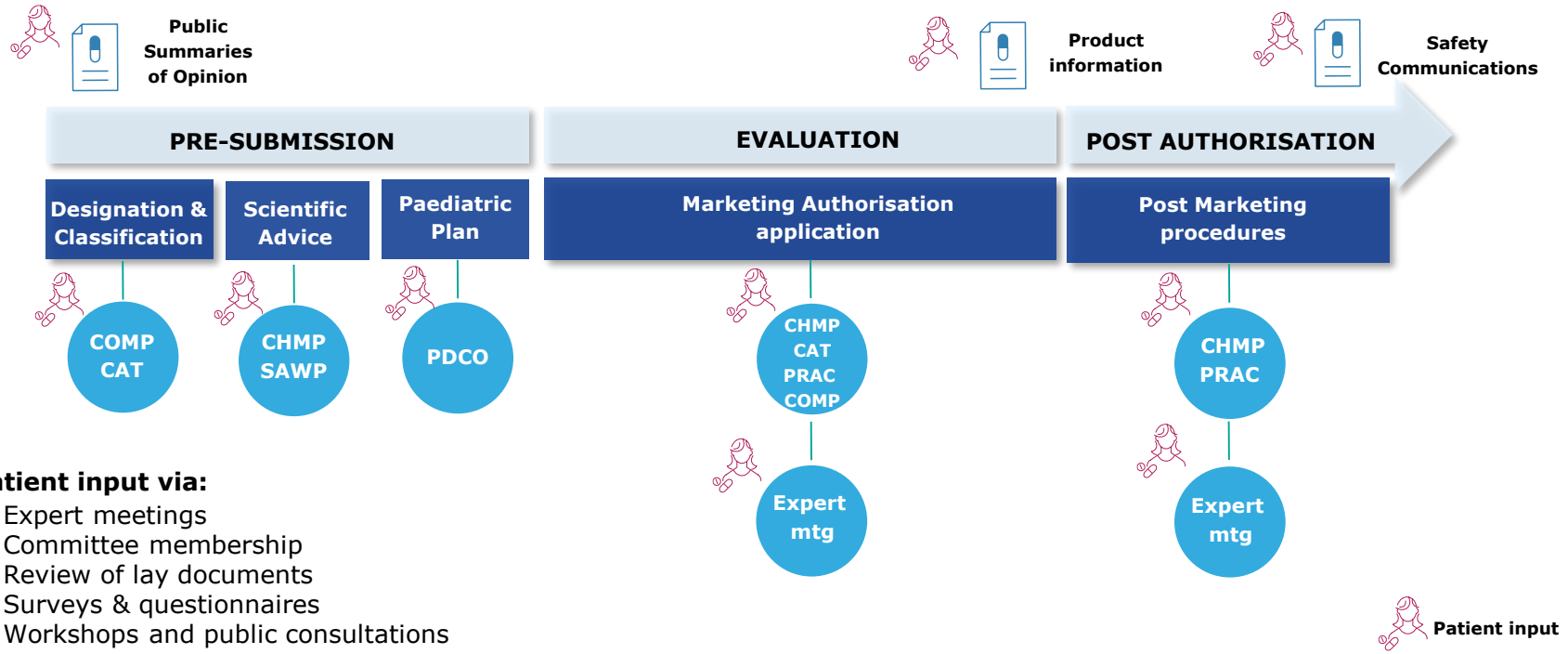
- Integral element of EMA activities



Interaction with patients: a progressive journey…



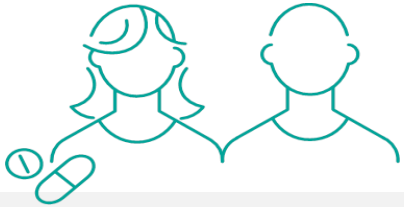
The patient voice along the medicine lifecycle

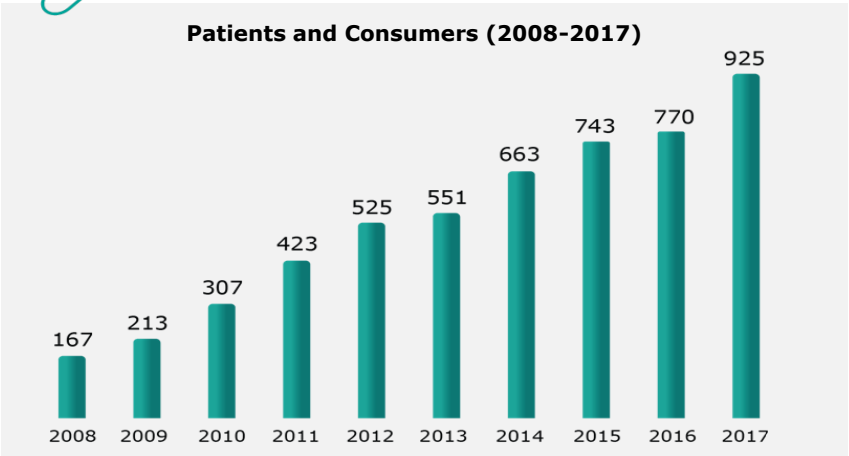


Patient input via:

- Expert meetings
- Committee membership
- Review of lay documents
- Surveys & questionnaires
- Workshops and public consultations

Increasing involvement in EMA activities





Increasing patient networks

- Any **organisation** representing EU patients or consumers may express an interest to work with the Agency, (must meet eligibility criteria : application form on EMA website)
- Any **individual** patient or carer can register to work with the EMA (application form on EMA website)

Individual expert database

Register as **Patient expert**

Eligible organisations: patients/consumers

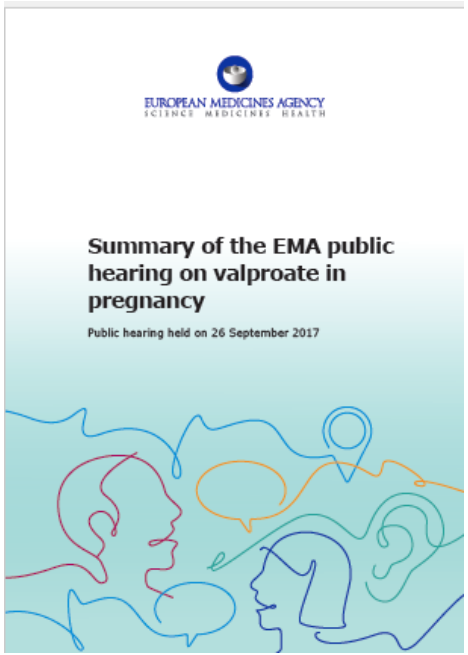
Different ways patients engage:

Representing their *community*	*Management Board* *EMA Scientific Committee Members*
Representing their *organisations*	*Working Party (PCWP or HCPWP)* *EMA consultations* *Workshops*
Individual experts	*Scientific Advice / Protocol Assistance Procedures* *Scientific Advisory/ad hoc expert Groups* *Scientific Committee consultations* *Review of documents*

- All organisations must comply with EMA eligibility criteria
- All individuals must complete a competing interest declaration and confidentiality undertaking

Public hearings; listening to all stakeholders..

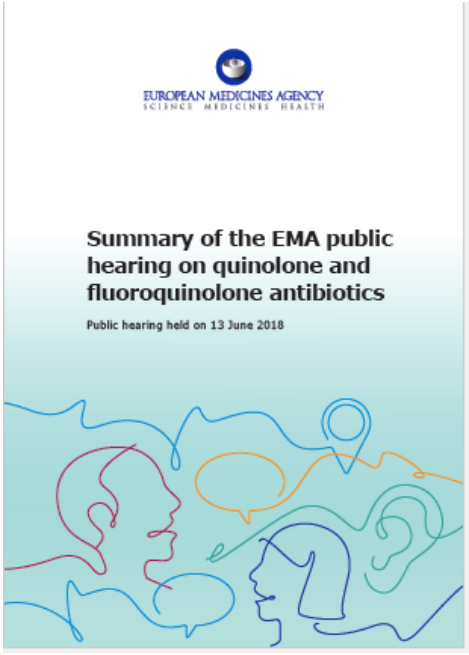
Aim: how to minimise the risk of harm from valproate to unborn babies



Proposals taken into account

Restricted use
Education materials
Communication campaign
Labelling/packaging
Encourage further research

Aim: how to raise awareness on extent of side effects



Learn by experience!

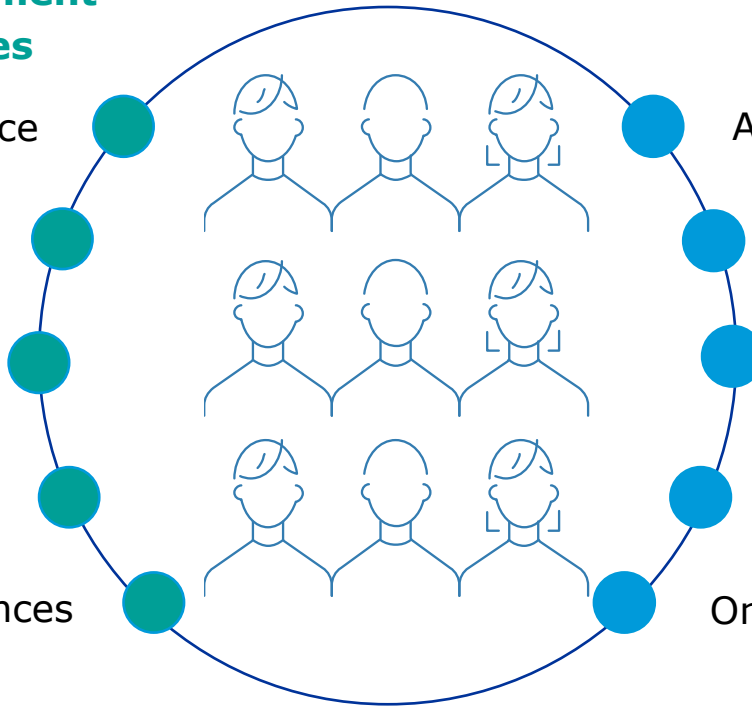
Be flexible!

Vital elements

One size does not fit all!

Flexible engagement methodologies

- Face to face
- In writing
- Committee meetings
- Surveys
- Patient preferences



Appropriate support and training

- Annual training day
- Info-sheets
- Videos
- Webpages
- One-to-one personalised support

Monitoring and measuring is part of the process

Optimal methodology?

Mutually beneficial?

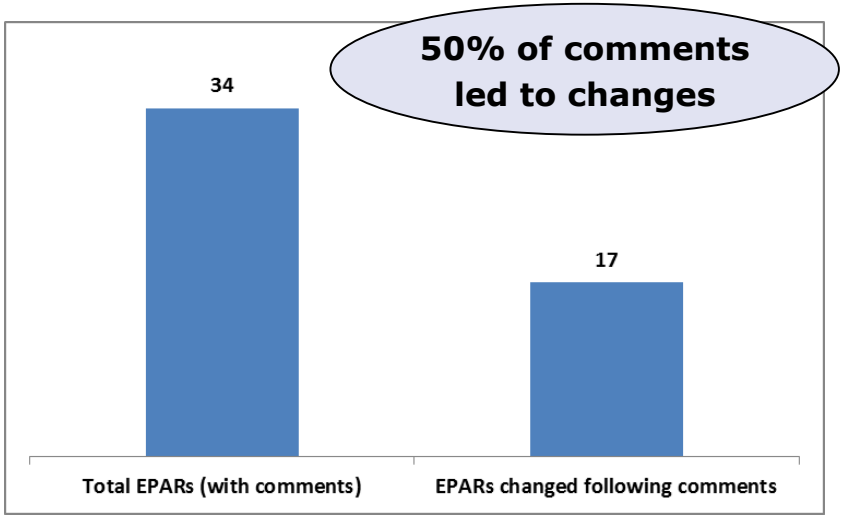
Feedback

- Meeting minutes/report
- Thank you acknowledgement
- Show when input is taken into account

Monitoring and measuring

- Questionnaires sent to patients and assessors who participate
- Leads to proposals for improvement
- Continuous monitoring
- Demonstrate value

Review of documents



Learnings

- Engaging with patients;
  - brings **everyday aspects of living with a disease** into scientific discussions
  - helps **bridge the gap** between clinical trial data and real world data
  - increases **transparency**, **awareness** and **understanding**
- Initiate engagement in a **stepwise approach**; **learn together** what format works best;
  - **Define roles** - manage expectations – give feedback
  - Ensure engagement is **mutually beneficial**
- **Everyone** has a role to play to ensure engagement happens
- Engaging with patients leads to **more meaningful outcomes** for everyone!

Patient engagement; where next?

Today:

- Added value of patient input into regulatory decision making has been demonstrated

Challenges: **Resources**, **Independence** and **Representability**

Tomorrow (as highlighted in RSS to 2025):

- Systematic input throughout the product life-span
- Robust assessment of independence; a) 'eligibility' criteria; b) conflict of interests policy
- Increased patient data generation; support/conduct patient data collection (e.g. preference studies, quality of life and patient-reported outcomes, use of big-data technologies)
- A strengthened regulatory system that can efficiently integrate evidence from RWD into its assessments

Questions?

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