



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient engagement along the regulatory lifecycle

PCWP meeting
September 25, 2018

Presented by Nathalie Bere
Public Engagement Department, European Medicines Agency

An agency of the European Union



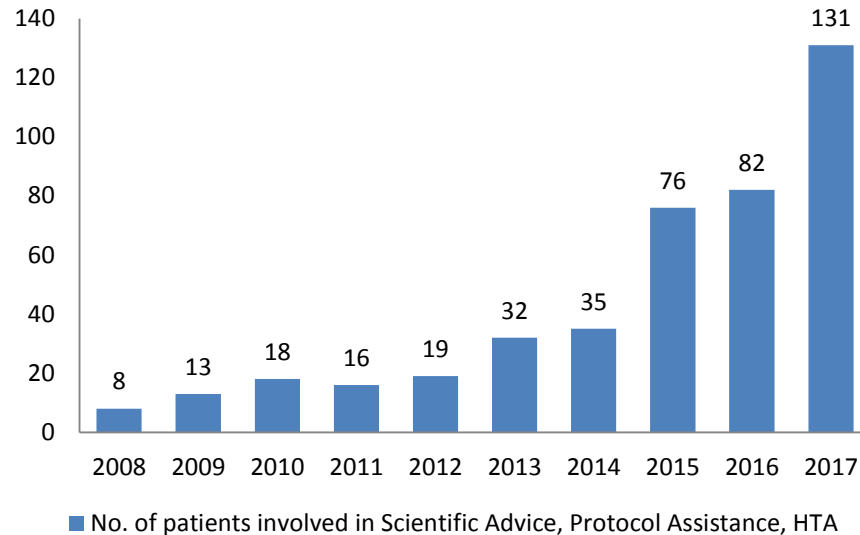
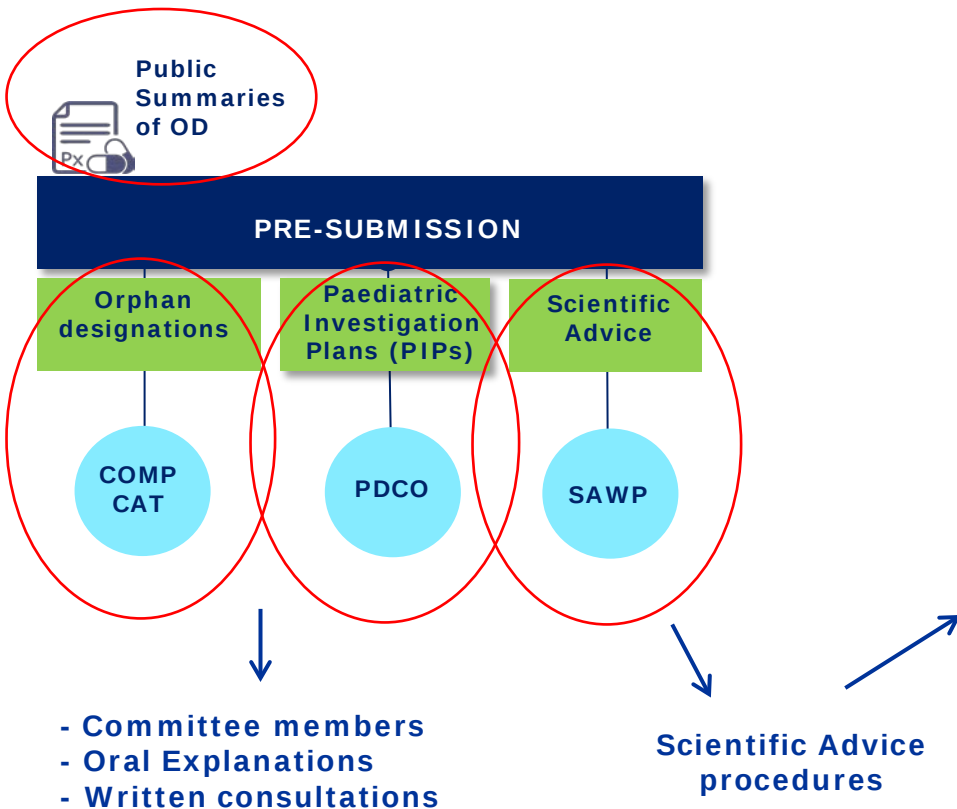


Patient involvement along the medicine lifecycle at EMA



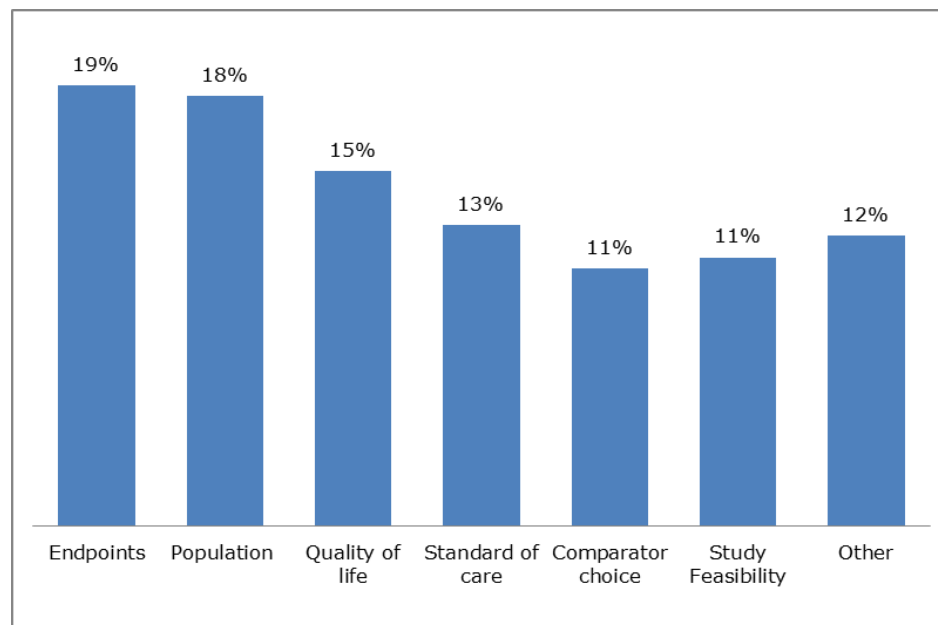
Patient input

Patient involvement along the medicine lifecycle at EMA

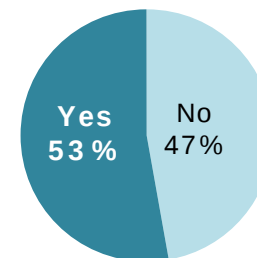




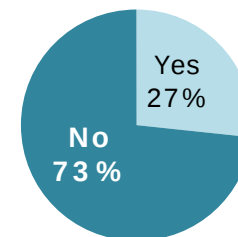
In which aspects of the development plan did the patient give input?



Did any of the patient's comments result in further reflection by the coordinators?

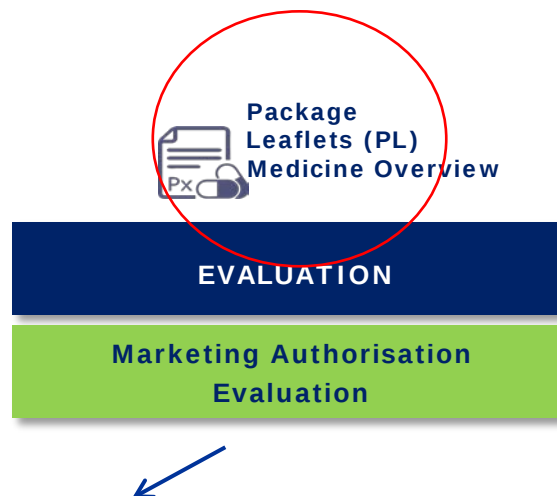


Did any of the patient's input result in a modification of the final advice letter?





Patient involvement along the medicine lifecycle at EMA

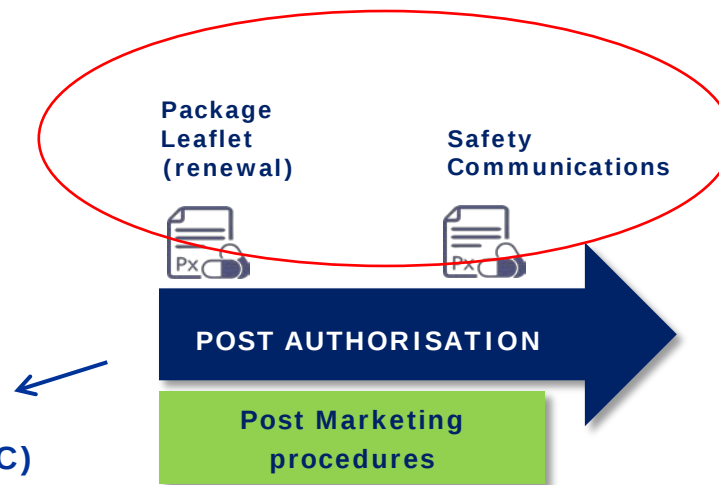


- Committee members (CAT/COMP/PRAC)
- SAG/ad-hoc expert meetings (CHMP/CAT)
- Oral Explanations (CHMP/COMP)
- Written consultations (all committees)



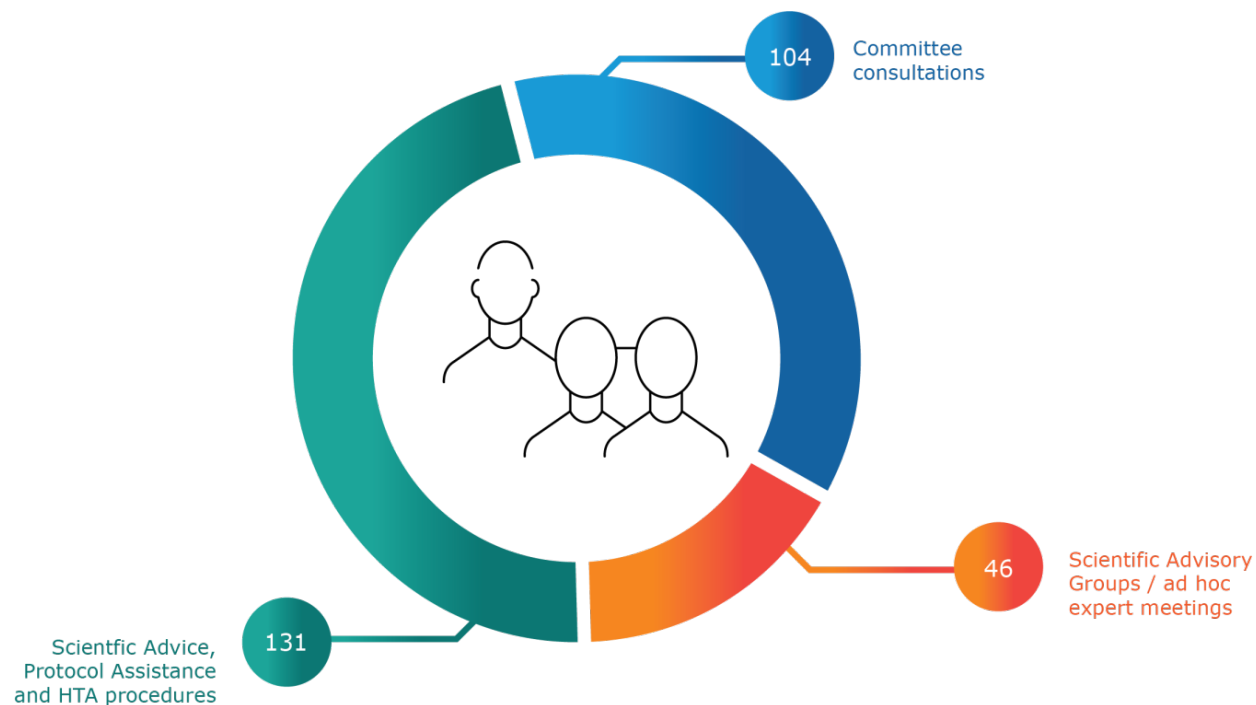
Patient involvement along the medicine lifecycle at EMA

- Committee members (CHMP/PRAC)
- SAG/ad-hoc expert meetings (CHMP/CAT/PRAC)
- Oral Explanations (CHMP/COMP/PRAC)
- Public hearings (PRAC)
- Written consultations (all committees)



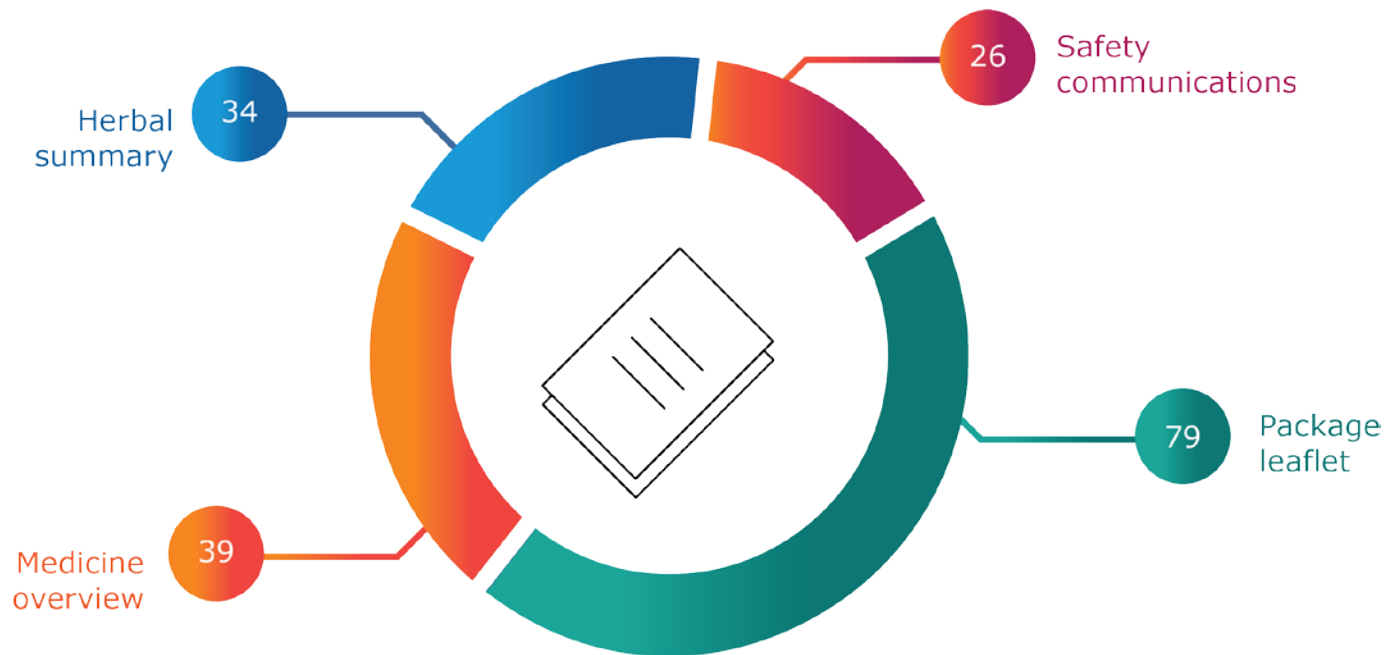


Patients involved in scientific meetings (2017)



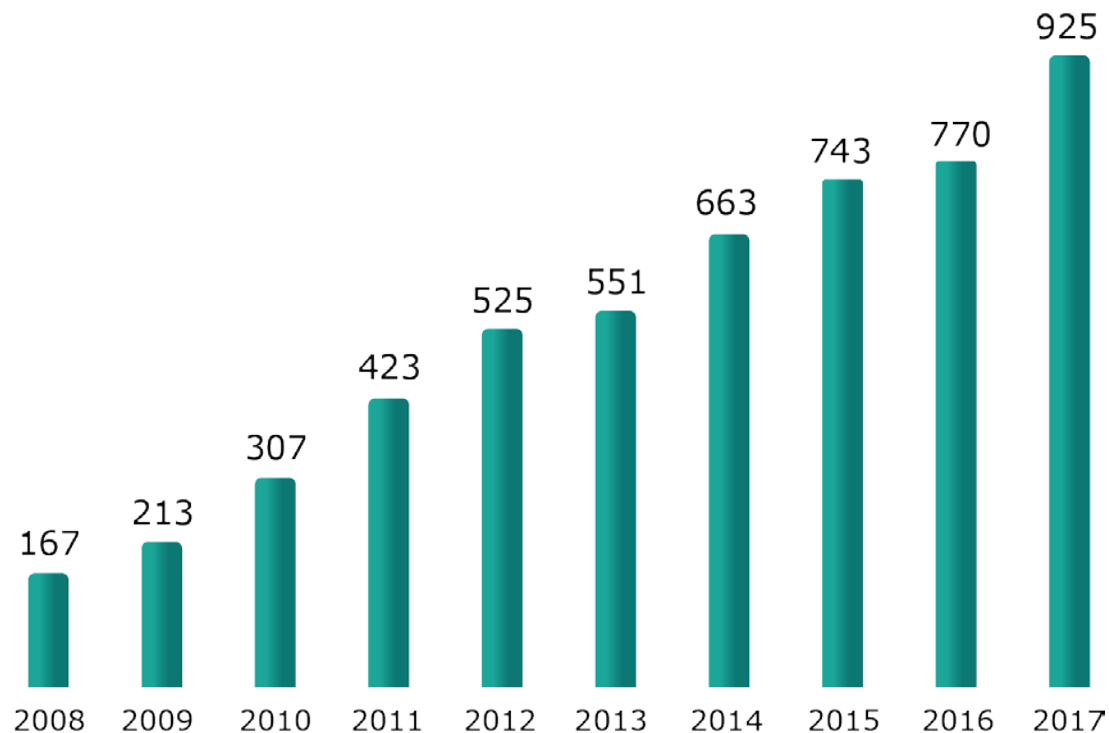


Patients review of documents (2017)



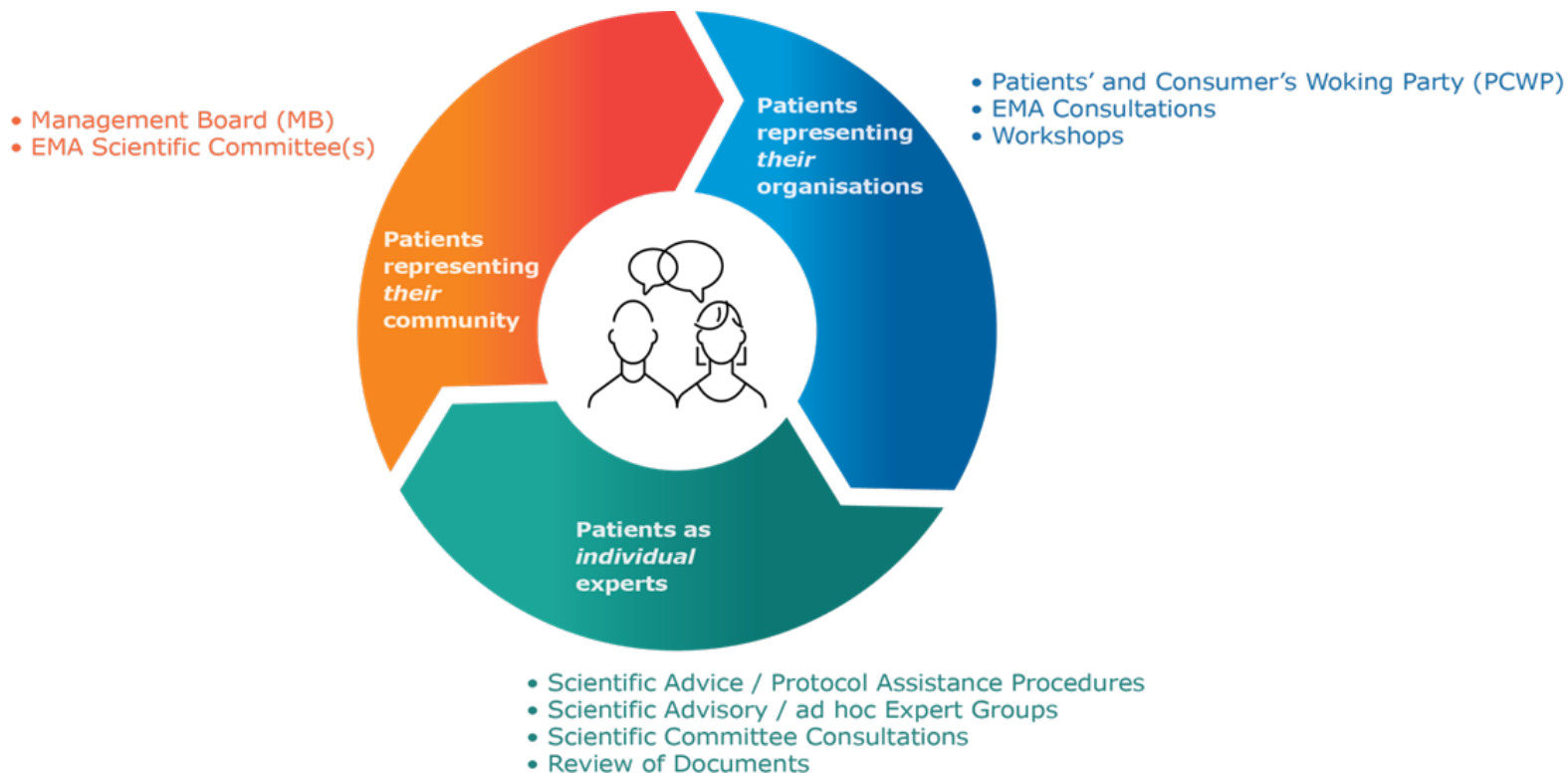


Patient Involvement in all EMA activities (2008 – 2017)





Three categories of patient representation





Flexible engagement methodologies



Expert meeting



Conference calls



In writing



Surveys



Committee meetings



Preference Elicitation



Vital support for patients participation



Annual
training
day



Info-sheets



Videos; EMA basics



Webpages



One-to-one
personalised support

Where do the patients come from?

Network of organisations and individual patients:

- 36 EU organisations representing EU patients / consumers, published on the EMA website - must meet eligibility criteria
- 440 individuals registered in EMA database

Application form for patient
& consumer organisations



Eligibility criteria to be fulfilled by
patient, consumer organisations



Declaration of interests / confidentiality
agreement



Patients and Consumers Working Party (PCWP)





Monitoring and measuring

- Questionnaires sent to patients who participate
- Proposals for improvements proposed accordingly
- Annual report to EMA Management Board

Patients and consumers

17 questions

Questionnaire sent to:
248 patients and consumers

Number of responses:
95/248

Response rate:
38%



Healthcare professionals

15 questions

Questionnaire sent to:
144 HCP

Number of responses:
44

Response rate:
34%

Feedback

- Meeting minutes
- Thank you acknowledgement
- Comments taken into account



Annual reports
with
summaries of
feedback

Importance of engaging with patients in EMA

- Engagement with patients:
 - Brings the everyday aspects of living with a disease into the scientific discussions and helps bridge the gap between clinical trial data and real world data
 - Improves transparency and trust
 - Increases understanding and dissemination of EMA outcomes
- ALL perspectives are crucial and have ultimately resulted in more meaningful decisions for all concerned.



Public hearing

Quinolone and Fluoroquinolone medicines

13 June 2018

Getting input from the public to better understand and manage serious and persistent side effects with these antibiotics

120 Applications (55 speakers / 65 observers)

23 speakers selected, within 21 speaker slots, from 11 EU MS

Quinolone / fluoroquinolone Public hearing; outcome

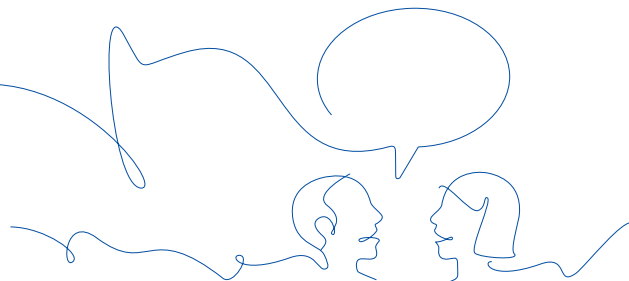
Important information / themes raised:

- Symptoms life-changing and wide ranging
- Patients not given enough information about risks
- Healthcare professionals generally unaware of range and severity of possible symptoms

Key proposals gathered during the hearing:

- Restrict use
- Improve education for healthcare professionals
- Improve communication and information and encourage further research
- Improve management of side effects
- Consider how certain foods affect patients' symptoms

➤ Input shaped questions for subsequent expert meetings





Challenges

- Finding suitable patients (e.g. language barrier, availability)
- Ensuring training to facilitate and enhance participation
- Managing potential conflicts of interest
- Representativeness
- Avoid missed opportunities





How to address challenges; Next steps

- Finding suitable patients (e.g. language barrier, availability)
 - Increase network of patients and organisations
- Ensuring training to facilitate and enhance participation
 - Encourage & enhance current training (EMA/EU)
- Managing potential conflicts of interest
 - Increase understanding and awareness among patient community
- Representativeness
 - Implement complementary methods to gather wider patient data; e.g. further research on preference elicitation, organise disease specific focus groups, reflection paper
- Avoid missed opportunities
 - Let us know of any ongoing evaluations which may benefit having patient input



Any questions?



Nathalie Bere
Public Engagement Department

maria.mavris@ema.europa.eu
www.ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550

Send a question via our website www.ema.europa.eu/contact