EMA

Public engagement highlights of 2018

EMA's Public Engagement Department was set up to facilitate the involvement of patients, consumers, healthcare professionals (HCPs) and academics in the work of the Agency

Public Hearing

In 2018, EMA held its second public hearing to gather insights into patients' and healthcare professionals' experiences with quinolone- and fluoroquinolone-containing medicines.

A total of 69 participants attended:

- 40 patients/patient representatives
- 14 healthcare professionals/academics
- 13 pharmaceutical industry
- 2 media

Participants explained the impact of their wide-ranging and often life-changing symptoms, and highlighted that patients did not get sufficient information about the risks. Suggestions were made on restricting use, improved information, and better communication, management and research. There was a follow-up meeting to refine the proposals, which contributed significantly to the final PRAC recommendations.

See the press release here

See the referral page here

PCWP/HCPWP

The Patients' and Consumers' and Healthcare Professionals' working parties held two joint meetings in 2018:

April included a focus on digital media and health
September highlighted the Regulatory Science to 2025
December was the first virtual meeting due to EMA's relocation

Stakeholder involvement

Patient contribution to EMA's work

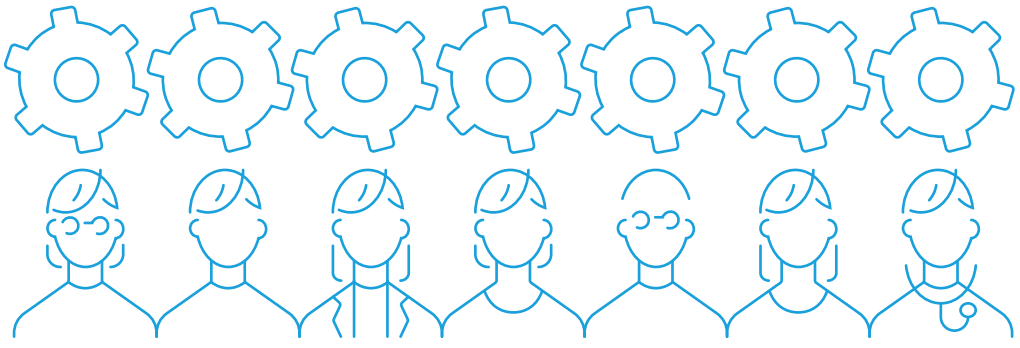
107 Scientific advice procedures (SA)
37 Scientific Advisory Groups (SAG)
112 Consultations
178 Review of documents

34 medicine overviews (with comments)
→ **17** Medicine overviews changed (50%)

HCP contribution to EMA's work

31 Scientific Advisory Groups (SAG)
47 Consultations
80 Review of documents

In 2018, 20% of all cases of interaction with HCPs involved a general practitioner



Workshops

European Reference Networks (ERN) explored reinforcement of EMA and ERN efforts to encourage and facilitate research into new treatments for rare and low-prevalence complex diseases and engagement of ERN in EMA activities.

Availability of authorised medicines brought together all stakeholders to contribute to the work of the HMA/EMA taskforce on availability of authorised medicines. This taskforce was established for better prevention, identification, management and communication of availability issues.

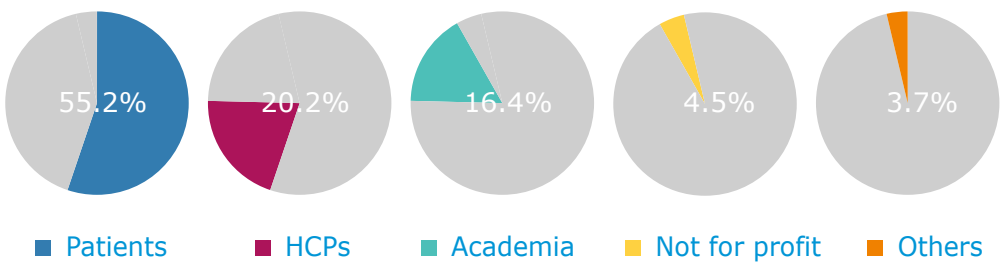
Electronic product information (ePI) was the focus of a multi-stakeholder workshop, organised jointly by EMA-HMA-EC to draft key principles to guide the development and use of ePI in the EU.

Regulatory awareness session aimed at academics, NGO staff and regulators and provided insight into the functioning of the EU regulatory network, the role and work of EMA and interactions with scientific experts and stakeholders.

EU-Innovation network of regulators addressed challenges and opportunities to boost the success of development programmes and clinical studies. The discussion covered national and EU initiatives and aimed at finding ways to work together to support new medicines and innovative healthcare solutions.

Queries

Queries received in 2018 by affiliation



Queries received in 2018, by topic

71% of queries received responses within 1 week
93% of respondees were satisfied to very satisfied with the service provided