2020 Public engagement highlights

Annual overview of the involvement of patients and healthcare professionals (HCP) in the work of the European Medicines Agency (EMA)

Engagement during a health crisis

In response to the COVID-19 pandemic, EMA has taken specific actions to accelerate the development and availability of treatments and vaccines for COVID-19. There was a corresponding increase in communication and transparency as well as outreach to stakeholders.

- A COVID-19 EMA pandemic Task Force has been established where representatives from patient and healthcare professional organisations are included.

- A public meeting was organised to keep the public informed and explain the regulatory processes for the development, evaluation, approval and safety monitoring of COVID-19 vaccines in the EU.

- Information materials on COVID-19 vaccines:

  o Key Facts developed with input from patients and healthcare professionals
  o Information on how COVID-19 vaccines are being developed, approved & monitored in the EU
  o Information on studies needed to approve COVID-19 vaccines

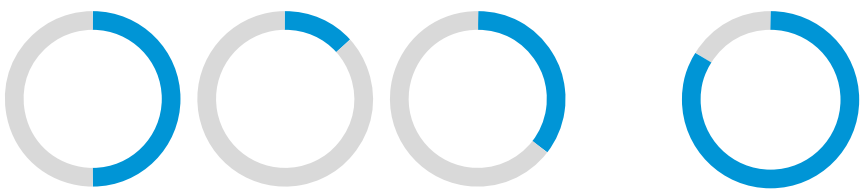
During the pandemic, normal engagement activities have been maintained as far as possible.

Working party meetings

March focused on the European Medicines Agencies Strategy
June EMA COVID-19 response, medicine shortages and data protection
October training on review of documents for patients and navigating targetted information for healthcare professionals
November Updated information on COVID response

Queries

Queries received* in 2020 by affiliation:



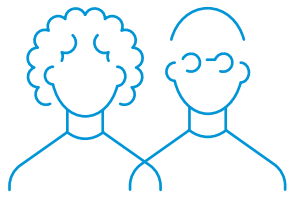
49.7% Patients
12.8% HCPs
31% Academia
82.7% Respondents to our survey were satisfied/very satisfied with the service provided

Queries by topic:

COVID-19 Availability Chloroquine Nurown Kaftrio ALS Vaccines

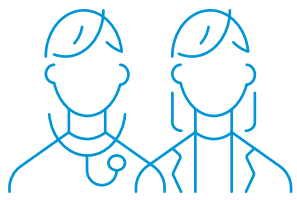
* representing 28% of total queries to EMA

Stakeholder involvement in medicines



Patient contribution to EMA's work

Scientific Advice procedures	**102**
Scientific Advisory Groups	**42**
Committee consultations	**228**
Review of documents	**203**



HCP contribution to EMA's work

Scientific Advice/Advisory Groups	**40**
Committee consultations	**29**
Review of documents	**46**

Key events

EMA's new Executive Director
Emer Cooke was appointed as new Executive Director of the Agency by the EMA Management Board and took up office on 16 November 2020 for a five-year renewable mandate.

Meeting on risk minimisation measures
Early engagement with patients and HCPs in risk minimisation will provide additional insight on the feasibility of the proposals in the revision of good pharmacovigilance practices (GVP) module. This is the first time for such early engagement in a revision of this kind.

ICH good clinical practice workshop
Views and experiences of patients, HCPs and clinical researchers were gathered on clinical trials and applying good clinical practice (GCP). This was in preparation for the revision of the ICH E6 good clinical practice (GCP) guideline.

Benefit-risk of medicines used during pregnancy and breastfeeding
In Europe, few medicines are licensed specifically for use in pregnancy and breastfeeding. The PCWP and HCPWP discussed the development and implementation of EMA's strategy for better information on benefits and risks of medicines in pregnancy and breastfeeding and how to obtain evidence on medicine use and safety.

GDPR in health and secondary use of data for medicines and public health
The European Commission's work on the European Health Data Space was shown and a discussion followed on the development of a framework and code of conduct on the processing of personal data in the health sector as well as the application of GDPR in the health sector and the secondary use of health data.

25 Years of EMA: building, learning and adapting to new challenges
EMA reached the milestone of 25 years in 2020. This workshop addressed key achievements and learnings and elaborates on key strategic areas for the future. Watch video.