



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Collaboration with US FDA

Patient engagement

Maria Mavris, Patient liaison





EMA-FDA collaborations

20 years EU/US collaboration on medicines regulation

On 12 September 2003, the European Commission, European Medicines Agency (EMA) and the United States of America (USA) Food and Drug Administration (FDA) signed a **confidentiality arrangement** starting their successful collaboration in tackling public health challenges.



Milestones

European Commission, EMA and FDA sign Confidentiality Arrangement | 12 September 2003

First Cluster established in oncology | 2004

2005

First request from a company for Parallel Scientific Advice (PSA)

- EMA-FDA Good Clinical Practice (GCP) initiative starts
- First FDA Liaison arrives at EMA

2009

2010

- First EMA Liaison arrives at FDA
- Start of fellowship programme

2012

First Common Commentary on a paediatric development

EU-USA Mutual Recognition Agreement (MRA) for human medicines is signed

2017

2021

Latest two clusters established: Pregnancy and Lactation and Generic Drugs

2023

EU-USA MRA extended to veterinary medicines

Confidentiality arrangement
Permits the exchange of unredacted, commercially confidential information relating to regulatory and scientific processes, and thus facilitates collaboration between regulatory agencies.

Cluster
Regular and intensive exchange of information and collaboration between experts on a special topic or therapeutic area. Currently there are 31 established clusters. See [Cluster activities](#).

Parallel scientific advice (PSA)
Concurrent scientific advice from EMA and FDA on scientific issues during the development of human and veterinary medicines. See [General principles](#), [EMA-FDA scientific advice](#).

Liaison officials
Posted to the respective partner agency to facilitate collaboration and identify areas for further regulatory and scientific collaboration.

Fellowship programme
Short-term staff exchanges between EMA and FDA. See [Fellowships](#).

Common Commentary
Informal, non-binding comments on paediatric development plans submitted to both agencies. See: [Cluster activities](#).

EU/US mutual recognition agreement (MRA)
Allows EU and US authorities to rely on each other's good manufacturing practice (GMP) inspections for some types of medicines. See [Mutual recognition Agreements](#).

EMA | U.S. FOOD & DRUG ADMINISTRATION



Liaison officials

Posted to the respective partner agency to facilitate collaboration and identify areas for further regulatory and scientific collaboration.

FDA liaison to EMA – Katherine Tyner
 EMA liaison to FDA – Anabela Marcal



EMA-FDA Patient engagement cluster

Established: 2016 following fellowship exchange between EMA and FDA (2014 and 2015) and with support from liaisons

Meeting frequency: quarterly by teleconference

Participants: EMA, FDA – now includes Health Canada

The objective of the cluster is to share best practices on involving patients along the medicine's regulatory lifecycle, to further improve and extend both agencies' current activities in this area.

[Terms of reference for the European Medicines Agency / Food and Drug Administration cluster on patient engagement](#)



PCWP and Patient Engagement Collaborative (PEC)

Patient Engagement Collaborative (PEC)

- Hosted by Clinical Trials Transformation Initiative (CTTI) and supported by FDA's Patient Affairs
- Modeled on EMA's Patients' and Consumers' Working Party (PCWP)
- Inaugural group began in 2018
- Comprised of 16 wide-ranging representatives of the patient community (patients, caregivers, patient advocates)
- Serve 2-year terms

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patient-engagement-collaborative>



Patient Engagement
Collaborative

Representatives

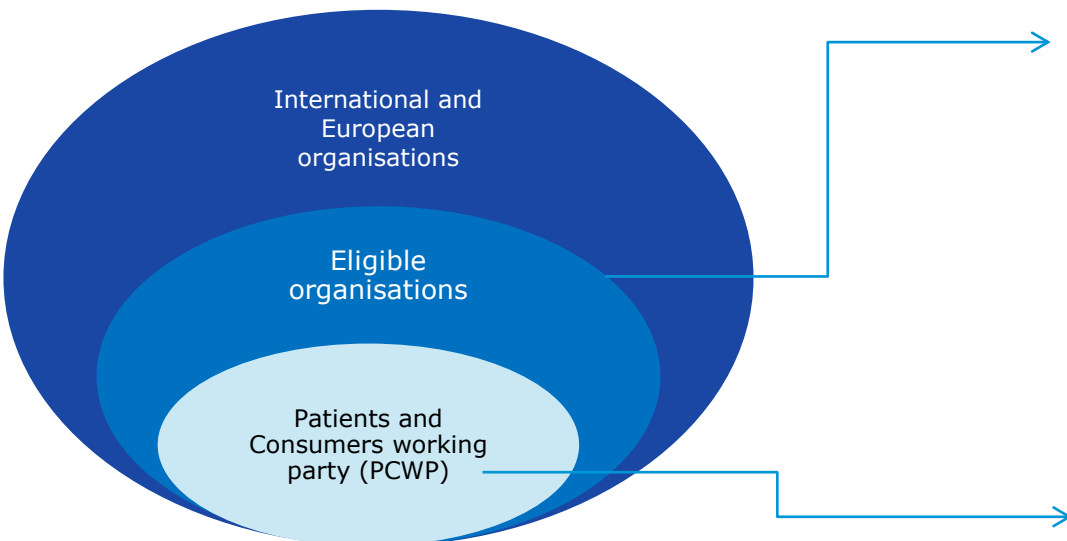
Representatives from the patient community include:

- Patients who have personal disease experience
- Caregivers who have personal experience supporting someone with a health condition (e.g., a parent, child, partner, family member or friend)
- Representatives from patient groups who have direct or indirect disease experience





Patients and Consumers Working Party (PCWP)





PCWP consists of 30 members:

- 22 representatives appointed from EMA's [eligible patients and consumers organisations](#);
- 6 representatives appointed by EMA's [scientific committees](#);
- 1 Chairperson elected from patient members (PCWP Co-Chair);
- 1 Chairperson nominated by EMA (EMA Co-Chair)
- [Mandate](#), [Rules of Procedure](#) and 3 year [Work Plan](#) developed together

Observers from:

- EMA [Management Board](#);
- [European Commission](#);
- [Healthcare Professionals Working Party](#) (HCPWP);

„All members' declarations of interests published in [European experts list](#).



Joint PCWP-PEC meetings

- 2021 focused on experiences on patient information and communication and youth engagement
- 2022 lessons learnt from COVID and emerging issues in patient engagement
- 2023 addressed the topic of decentralised clinical trials (DCT) and included speakers and patients from the US and the EU describing different perspectives and experiences of DCT.
- 2024 brought the topic of patient-reported outcomes with spotlights on two workshops followed by a panel discussion with representatives from PEC and PCWP



Thank you

