



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA framework of interaction
with healthcare professionals:

10 YEARS
of implementation





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Public and Stakeholder Engagement

Who are the healthcare professionals interacting with EMA?

Doctors, pharmacists, nurses form part of EMA’s network of eligible organisations ensuring that the needs and concerns of a wide range of healthcare professionals and learned societies across Europe are represented via direct contact with EMA.

The ultimate goal is to bring on board organisations that represent different fields of clinical expertise and practitioners in Europe active within the broad spectrum of health care, including primary care.

Healthcare professionals are present in all aspects of medicines regulation as members of committees and expert groups, in addition to the specialists that are invited on specific issues. The perspective of the practicing clinician or community/hospital pharmacist or specialist nurse brings a beneficial viewpoint to the discussions.

Any not-for-profit organisation that fulfils EMA’s eligibility criteria is welcome to express its interest in [getting involved in the work of EMA](#).

In December 2021, [EMA’s network of eligible organisations](#) reached a total of 38 eligible organisations.



Eligible healthcare professionals' organisations



Full list of organisations provided in Annex 1



Steps leading to a framework of interaction

In 2004, the revised pharmaceutical legislation (Regulation (EC) No 726/2004) foresaw, for the first time, the inclusion of one representative of doctors' organisations in the EMA Management Board, leading to the appointment later on in September 2005 of Lisette Tiddens-Engwirda, then Secretary-General of the Standing Committee of European Doctors (CPME), as the first representative.

Still in 2004, the EMA initiated the drafting of a policy to involve patient and consumer groups, building upon several years of experience of interaction with these groups. It also released the EMEA Roadmap to 2010 for public consultation. The final roadmap was then published in March 2005, clearly identifying as a specific action to engage more fully in dialogue with healthcare professional organisations, academia, learned societies and other stakeholders. In September 2005, the EMA Management Board agreed to first finalise a framework for interaction with patient organisations due to the advanced state of play of preparations, which should then be followed closely by a framework for interaction with the organisations of healthcare professionals.

In 2006, EMA organised a first workshop¹ with healthcare professional organisations which led to the creation of an informal group. This group, co-chaired by Noel Wathion and Isabelle Moulon, ran for several years, as the precursor of what would become EMA Healthcare Professionals' Working Party (HCPWP), and was instrumental in developing the EMA interaction with healthcare professional organisations.

In 2011, a first formal [framework of interaction with healthcare professionals](#) was adopted by the EMA Management Board.

Key milestones

2011

- Adoption of framework by EMA's Management Board on 15 December 2011

2012

- The first group of 20 European organisations covering different areas of practice and expertise joined EMA's network of eligible healthcare professional organisations, following voluntary application and assessment of their compliance with EMA eligibility criteria

2013

- Establishment of EMA Healthcare Professionals' Working Party (HCPWP), a cross-human scientific committees' working party co-chaired by Gonzalo Calvo Rojas (HCPWP) and Isabelle Moulon (EMA) and composed of members appointed amongst eligible organisations and representatives from all EMA Human Scientific Committees. The HCPWP discusses issues of common interest between EMA and healthcare professionals.
- First joint workshop with PCWP, which was dedicated to the topic of patients' voice in the evaluation of medicines
- Further expansion and operation of the network of eligible organisations

2014

- PCWP/HCPWP workshop on regulatory and methodological standards to improve benefit-risk evaluation of medicines
- PCWP/HCPWP workshop on benefit-risk communication

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/12/WC500018171.pdf

- Publication of the first annual report on the progress of the interaction with healthcare professionals' organisations (final building block for the full implementation of the framework)
- Revision and implementation of EMA eligibility criteria
- Further expansion and operation of the network of eligible organisations

2015

- HCPWP topic group on developing EMA's collaboration with academia
- PCWP/HCPWP information session on biosimilars
- PCWP/HCPWP workshop on risk minimisation measures
- Further expansion and operation of the network of eligible organisations

2016

- PCWP/HCPWP session on communication and information on medicines
- PCWP/HCPWP workshop on social media
- HCPWP workshop on developing a framework of collaboration between EMA and academia
- EMA workshop on the collaboration with general practitioners/ family physicians
- Adoption of revised framework by EMA's Management Board to incorporate experience gained during first 5 years
- Further expansion and operation of the network of eligible organisations
- Second mandate of HCPWP initiated, with the number of members appointed amongst eligible organisations extended to 20 and co-chaired by Gonzalo Calvo Rojas (HCPWP) and Juan Garcia Burgos (EMA)

2017

- PCWP/HCPWP information session on antimicrobial resistance
- PCWP/HCPWP workshop on personalised medicines: role of patients, consumers and healthcare professionals
- Further expansion and operation of the network of eligible organisations
- First public hearing

2018

- Revision and implementation of EMA eligibility criteria
- Further expansion and operation of the network of eligible organisations
- Second public hearing

2019

- Publication of joint statement of collaboration with general practitioners
- Further expansion and operation of the network of eligible organisations
- Third mandate of HCPWP initiated, with the number of members appointed amongst eligible organisations extended to 22 and co-chaired by Ulrich Jaeger (HCPWP) and Juan Garcia Burgos (EMA)
- Publication of first joint PCWP/HCPWP 3-year work plan

2020

- ICH E6(R3) good clinical practice workshop with PCWP and HCPWP

- PCWP/HCPWP workshop on benefit-risk of medicines used during pregnancy and breastfeeding
- PCWP/HCPWP workshop on the application of GDPR in the area of health and secondary use of data for medicines and public health purposes
- further expansion and operation of the network of eligible organisations
- PCWP/HCPWP COVID-19 updates
- HCP representative joins HMA/EMA Big Data Steering Group

2021

- PCWP/HCPWP COVID-19 updates
- First satisfaction survey to eligible organisations
- Pilot to step up engagement with eligible organisations through the creation of a Healthcare professional organisations policy officers' group (HCP POG)
- Further expansion and operation of the network of eligible organisations
- HCP representative joins DARWIN-EU Advisory Board

Future direction

Overall, the framework is solidly based on the regular interaction with a network of European healthcare professionals' organisations, aiming to:

- Support the Agency in order to access the best possible **independent expertise in clinical practice**, to incorporate the real-world experience into drug development, benefit/risk evaluation and monitoring;
- Contribute to a more efficient and targeted **communication** to healthcare professionals, which can facilitate the transfer of information along the patient journey as a mean to promote patient safety and optimal use of medicines;
- Enhance healthcare professionals' organisations' **understanding** of the role and activities of the EU medicines Regulatory Network.

Future direction of EMA's interaction with healthcare professional organisations and learned societies will continue to be aligned with EMA's regulatory science strategy to 2025 and the European Medicines Agencies Network strategy to 2025.

Advances in adaptive design for clinical trials, personalised medicine, more extended use of real-world evidence, and the public availability of clinical data will provide additional opportunities for engaging with healthcare professionals in the interface of clinical research and clinical practice. For such engagement to become a reality the Agency sees healthcare professional organisations and learned societies as relevant intermediaries able to facilitate relations with the wider community of healthcare professionals across the EU (i.e. individual members and/or national associations).

EMA is fully committed to continue working closely together with its ever-expanding network of eligible organisations. As always, EMA remains open to learn and understand the wider issues affecting healthcare professionals and explore further ways of engaging with them in the context of its activities and wider ecosystem of stakeholders and partners.

Annex 1

Eligible healthcare professionals' organisations:

- Biomedical Alliance in Europe
- Council of European Dentists
- European Academy of Allergy and Clinical Immunology
- European Academy of Neurology
- European Academy of Paediatrics
- European Alliance for Vision Research and Ophthalmology
- European Alliance of Associations for Rheumatology
- European Association for Clinical Pharmacology and Therapeutics
- European Association for the Study of Diabetes e.V.
- European Association for the Study of the Liver
- European Association of Hospital Pharmacists
- European Association of Urology
- European College of Neuropsychopharmacology
- European Committee for Treatment and Research in Multiple Sclerosis
- European Federation of Internal Medicine
- European Forum for Primary Care
- European Geriatric Medicine Society
- European Headache Federation
- European Hematology Association
- European Organisation for Research and Treatment of Cancer
- European Psychiatric Association
- European Public Health Association
- European Respiratory Society
- European Society for Medical Oncology
- European Society for Organ Transplantation (ESOT)
- European Society of Cardiology
- European Society of Contraception and Reproductive Health (ESC)
- European Society of Endocrinology
- European Society of Oncology Pharmacy
- European Society of Radiology
- European Specialist Nurses Organisation (ESNO)
- European Union of General Practitioners
- Health Care Without Harm Europe AISBL
- International League Against Epilepsy
- Pharmaceutical Group of the European Union
- Standing Committee of European Doctors
- Stichting WONCA Europe
- United European Gastroenterology