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Stakeholders and Communication Division
European Medicines Agency

# 2025-2028 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

| **Chairpersons** | **Status** |
|---|---|
| EMA: Juan Garcia Burgos<br>PCWP: Marco Greco<br>HCPWP: Piotr Szymański | Adopted by PCWP and HCPWP on 30 April 2026<br>Tabled for information to CAT, CHMP, COMP, HMPC, PDCO, PRAC and CMDh in May 2026 |

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# Contents

# 1. Introduction

The PCWP and HCPWP are formal structures[1] within the European Medicines Agency (EMA), composed of representative organisations of patients, consumers and healthcare professionals (HCPs) and representatives from EMA Human Scientific Committees. They support and monitor the involvement of patients, consumers, healthcare professionals and their organisations in EMA activities and identify opportunities and challenges that may need special attention, particularly in the context of the respective frameworks[2].

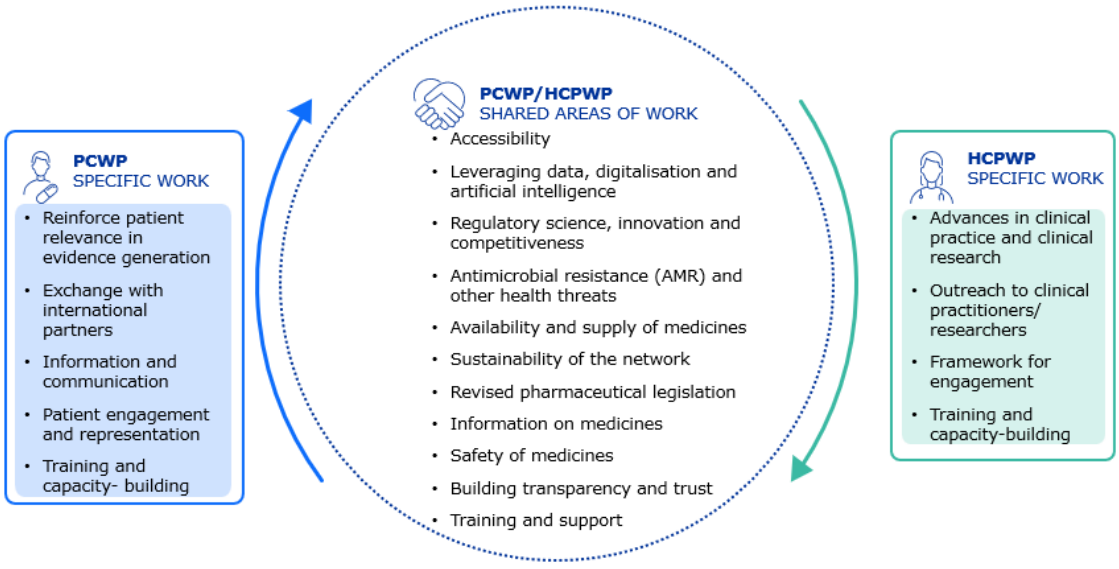
The working parties (WPs) serve as platforms for exchange and discussion between regulators and organisations on issues of common interest related to medicines, including vaccines, and medical devices. The WPs do not cover medicine-specific discussions or confidential aspects of ongoing regulatory procedures. The member organisations promote, through the communities they represent and their networks, a better understanding and awareness of the Agency's activities and foster involvement in European Union (EU)-wide initiatives.

The PCWP and HCPWP will participate at key stages of EMA initiatives, policy development and implementation as well as in other EMA activities including those aimed at supporting the implementation of the European Medicines Agencies Network Strategy to 2028 and EU legislation.

The WPs will identify topic co-leads and organisations' topic-specific interests, where needed.

The structure of this Joint Work Plan presents the work areas common to both WPs, followed by sections addressing the focus areas for each working party.

The work plan will be subject to annual reviews enabling refinement of proposed actions as necessary.

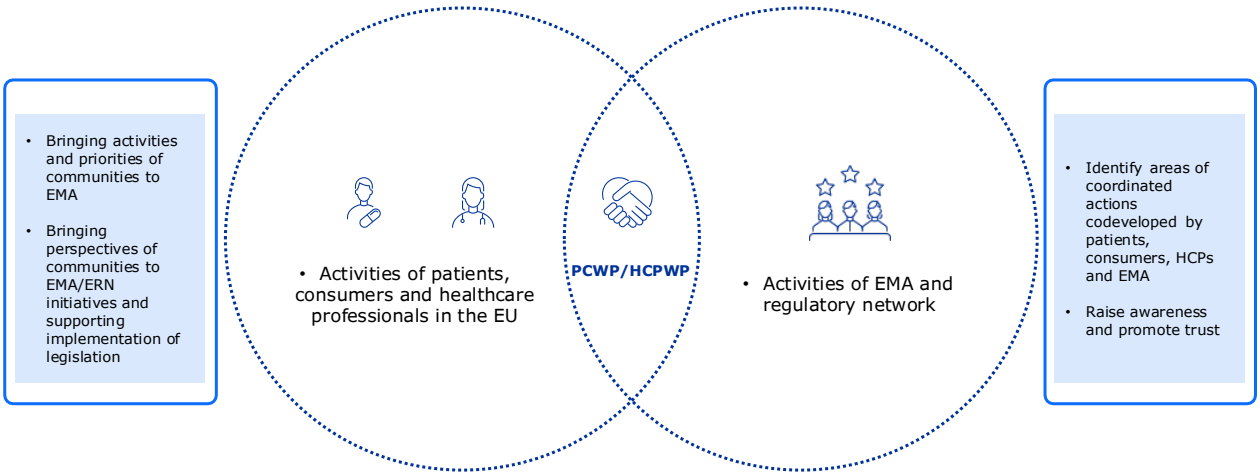



[1] https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/ema-pcwp-hcpwp-rules-procedure_update-en.pdf
[2] Engagement framework: EMA and patients, consumers and their organisations
Revised framework for interaction between the European Medicines Agency and healthcare professionals and their organisations

## Overarching objectives

The overarching objectives will be applied across strategic and core activities of the work plan. The member organisations of the WPs have a wealth of experience, expertise and knowledge of their stakeholders and part of their responsibility as a WP member is to share these activities and priorities. Similarly, EMA brings information from the regulatory network and shares updates and priorities. These objectives are described below:

- WPs to bring the perspective of their communities into EU/EMA initiatives and proposals
  - EMA and WPs together identify potential follow-up actions.
- EMA to bring the perspective of the European medicines regulatory network to the working parties
  - EMA and WPs together identify potential follow-up actions.
- WPs and EMA to reflect on advances in specific domains and initiatives and identify opportunities for coordinated action by,
  - capturing patients, consumers and healthcare professionals' interests and areas of work related to:
    - Medicines development and evaluation;
    - EMA's strategic goals and overall implementation of the European Medicines Agencies Network Strategy (EMANS) to 2028;
    - Revised pharmaceutical legislation and other relevant legislation.
  - continuously scanning and scoping topics for joint discussion (with inclusion of other stakeholder groups, as needed) and discussing potential need for actions from the WPs
- WPs and EMA to raise awareness, understanding and support communication, to promote trust and transparency.
  - Share practices on how WP members are promoting awareness and understanding of the mandate and work of EMA and the EU Medicines Regulatory Network.
  - Identify specific information needs within patient, consumer and healthcare professional communities.
  - Support the review of key messages and coordinate efforts for amplifying such messages.
- WP members to support the participation and contributions of patient and HCP representatives in EMA working groups such as EMA's Emergency Task Force (ETF), joint HMA-EMA Network Data Steering Group (NDSG), Accelerating Clinical Trials in the EU Multi-Stakeholder Platform Advisory Group (ACT EU MSP AG), the European Platform for Regulatory Science Research (EPRSR), and as observers on the Medicines/Devices shortages steering group (MSSG/MDSSG), among others.



# 2. PCWP/HCPWP shared areas of work

## *2.1. Strategic activities – EMANS to 2028*

### 2.1.1. Accessibility

**Actions**

- WPs to be regularly updated on:
  - EMA's collaboration with European Commission's Health Technology Assessment (HTA) unit on implementation of the HTA regulation;
  - European Commission's progress on the implementation of the HTA regulation and engagement with their stakeholder network in joint scientific consultations (JSC) and joint clinical assessments (JCA);
  - Implementation of EMANS to 2028 activities related to multistakeholder engagement on the concept of unmet medical needs and involvement of patients and carers in parallel joint scientific consultations (JSCs).

### 2.1.2. Leveraging data, digitalisation and artificial intelligence

**Actions**

- WPs to be regularly updated on the activities related to:
  - Network Data Steering Group (NDSG) work plan, with contributions from the nominated patient and healthcare professional association representatives in the NDSG;
  - DARWIN EU and the generation and delivery of valid and reliable real-world evidence (RWE) via, with contributions from the nominated patient and healthcare professional association representatives in the DARWIN EU Advisory Board;
  - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (EnCePP) activities and outputs with contributions from stakeholders in the steering group;
  - European Health Data Space (EHDS).
- WPs to continue being engaged in the development and communication of artificial intelligence (AI) guidance to support the medicines lifecycle.
- WPs to be updated on the progress of the implementation of the reflection paper on patient experience data and identify any areas for further action.
- WPs to be updated and consulted on ICH E22 scientific guideline on General considerations for patient preference studies.

### 2.1.3. Regulatory science, innovation and competitiveness

**Actions**

- WPs to be involved and actively contribute to exchanges and engagement activities with all stakeholders including academia, patients, healthcare professionals and industry working on the development of innovative medicines and medical devices, novel technologies and methodologies, with the aim to support innovation for public and animal health.
- WPs to be involved in and contribute to discussions on best practices, recommendations and strategic activities for the integration and adaptation of scientific and technological advances in the development of medicines, with the aim to bridge the gap between scientific research and its practical application.
- WPs regularly updated on and involved in:
  - the implementation of the ACT EU objectives and workplan, with input from WP members represented in the ACT EU multistakeholder platform advisory group;

- the activities of EMA's Cancer Medicines Forum;
- the work of the EPRSR, with input from the respective WPs' representatives;
- EMA work addressing non-animal methods and novel manufacturing technologies intended to facilitate more sustainable practices in medicines development and manufacturing.

- WPs to identify and discuss issues related to clinical trials in alignment with ACT EU priorities such as patient-oriented research, integrate stakeholders' input into trial design and product development, use of AI in clinical development, digitalisation, ethics and innovative trial.
- WPs involved in discussions with stakeholders on specific areas of unmet medical needs, rare diseases, developments in the field of advanced therapy medicinal products (including tissue engineered products), cardiovascular health in the EU, chronic conditions and multimorbidity, and the use of medicines in special populations (e.g. paediatric and geriatric population, pregnant and breastfeeding women, and young people).

### 2.1.4. Antimicrobial resistance (AMR) and other health threats

**Actions**

- WPs regularly updated on:
  - Emergency Task Force (ETF) activities, with input from the nominated PCWP and HCPWP representatives at ETF;
  - EMA/HMA activities intended to strengthen preparedness for health threats and public health emergency.
- WPs to discuss concrete ways to contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach, to preserve existing therapeutic options, including antibiotics, antiparasitic and antifungal agents.
- WPs to contribute to EMA annual communication campaign on European Antibiotic Awareness Day (EAAD).
- WPs to collaborate in campaigns aimed to face infodemic and support communication during crisis situations.
- WPs to contribute to EMA's planned initiatives aimed at increasing vaccine confidence, building vaccine science literacy and combating vaccine-related mis-disinformation.

### 2.1.5. Availability and supply of medicines

**Actions**

- WPs to be regularly updated on and engage in discussions regarding the progress of ongoing initiatives:
  - Medicines Shortages Steering Group (MSSG) activities, with input from the nominated observers;
  - Medicines Shortages Single Point of Contact (SPOC) Working Party main activities aimed at enhancing the availability of medicines to safeguard public health;
  - Ongoing critical shortages escalated for EU coordinated actions;
  - On the Union list of critical medicines.
- WPs to be kept informed on EMA activities intended to improve transparency and communication on medicine shortages such as MSSG annual activity report and EMA shortage catalogue.
- WPs to be kept informed and discuss progress of ongoing initiatives, such as biosimilars and repurposing of medicines aimed at facilitating access to medicines.
- WPs to contribute to coordinated campaigns for greater public awareness of the dangers posed by falsified medicines.

### 2.1.6. Sustainability of the network

**Actions**

- WPs to be consulted on the development of a communication approach to promptly identify and proactively address false narratives, to support more proactive engagement with misinformation.
- WPs and EMA to contribute to raising awareness of EMA's open call for patient and healthcare professional experts to be involved in EMA activities and be remunerated.
- WP to reflect upon identification of young patients and professionals to be trained in EMA activities to support capacity building and bring them into the regulatory environment.

### 2.1.7. Revised pharmaceutical legislation

**Actions**

- WPs will be instrumental in supporting the implementation of the revised pharmaceutical legislation and ensuring the views of patients and healthcare professionals are considered.
- WPs will be regularly updated on EMA/HMA implementation plan of the revised pharmaceutical legislation.
- Support to patient and HCP observers to CHMP in preparation for membership in future committee.

## *2.2. Core activities*

### 2.2.1. Information on medicines

**Actions**

- WPs to contribute to the development of information materials and awareness raising campaigns targeting patients, consumers and healthcare professionals.
- WPs to assist in identifying volunteers from their respective organisations to review and user-test EMA communication materials, as well as to provide advice on contextualising information to enhance health literacy.
- WPs to facilitate the cascade of information prepared by EMA, with the ultimate goal of promoting patient safety and ensuring the optimal and rational use of medicines throughout the patient journey.
- WPs to continue supporting EMA in the implementation of EMA's action plan to improve Product Information and user-testing, which includes the electronic product information (ePI) project and the QRD template review to enhance readability of the package leaflet.
- WPs to be kept informed of progress and to provide input into next phases of electronic product information (ePI).
- WPs to reflect on and discuss effective strategies for addressing issues related to ecosystem management and identify ways to collaborate on topics related to misinformation.

### 2.2.2. Safety of medicines

**Actions**

- WPs to contribute to EMA/Pharmacovigilance Risk Assessment Committee (PRAC) strategy on impact of pharmacovigilance activities, in particular the workstream on risk minimisation measures.
- WPs to further support engagement of patients and healthcare professionals in regulatory pharmacovigilance by:
  - Identifying knowledge and awareness gaps and providing relevant information to WPs;

- Providing input for the development of a reflection paper on the use of digital tools to support risk minimisation measures (RMMs);
- Providing input on the revision of relevant Good Pharmacovigilance Practices (GVP) guidelines, such as module P. I (rev.1) on 'Product- or population-specific considerations: Vaccines for prophylaxis against infectious diseases';
- Continuing to increase awareness on adverse drug reactions (ADRs) reporting by healthcare professionals and patients/consumers;
- Contributing to a reflection on how to enhance impact of safety communications.

- WPs to continue to contribute to EMA's communication materials on safety monitoring of medicines, including vaccines.

### 2.2.3. Building transparency and trust

**Actions**

- EMA will keep WP updated on activities where WP volunteers are requested and WPs to provide support for the identification of volunteers for these activities.
- WPs to identify knowledge gaps and awareness-raising needs on regulatory aspects related to the development and evaluation of medicines for EMA to address in meetings or via the creation of educational materials.
- WPs and EMA to stimulate reciprocal transfer of knowledge between WP member organisations, EMA and international partners to develop dialogue on topics of common interest, by sharing current initiatives in the 'members voice' section.

### 2.2.4. Training and support

**Actions**

- WPs to be updated on initiatives for training at EMA.
- WP to provide input to training materials designed to support the involvement of experts in EMA activities, taking into account the training strategy for patients, consumers, healthcare professionals and academia.
- Support capacity building by bringing young patients and professionals into the regulatory environment through training activities.

# 3. PCWP specific work

## *3.1. Reinforce patient relevance in evidence generation*

**Actions**

- WP to explore how patient organisations can be involved in collecting and using patient experience data (including patient preferences) for use in regulatory decision making and identification of training needs.
- WP to provide input on best practices for communication and transparency regarding regulatory outcomes.

## *3.2. Exchange with international partners*

**Actions**

- WP to be informed of the exchanges in the EMA-FDA-HC Patient Engagement Cluster.
- WP to join annual meetings with FDA's Clinical Trials Transformation Initiative (CTTI)/Patient Engagement Collaborative and identify topics for discussion.
- WP to be informed of updates regarding the African Medicines Agency (AMA) and stakeholder engagement in particular.

## *3.3. Information and communication*

- WP to be kept informed on ongoing updates to the medicine overview template to improve access to information relevant to patients.

## *3.4. Patient engagement and representation*

**Actions**

- WP to discuss how to best ensure inclusion of the patient voice in regulatory processes and how to capture their impact (e.g. navigating competing interests, experts' management tool, remuneration etc).
- WP to discuss how they engage with young patients and how to best support their participation.

## *3.5. Training and capacity-building*

- EMA and WP to explore training needs and gaps and how EMA could make use of different formats and technologies to deliver training in an accessible manner.

# 4. HCPWP specific work

## 4.1. Advances in clinical practice and clinical research

**Actions**

- WP to identify topics to be addressed during the 2025-2028 period and discuss how the WP and the healthcare professionals' policy officers' group (HCP POG) can support development of concrete deliverables.
- WP to explore synergies and identify specific focus areas of common interest among healthcare professional organisations, learned societies, and academia, to uncover and foster opportunities for enhanced collaboration.
- WP consulted on best ways to contribute to improving RWD evidence generation in clinical practice to support regulatory decision-making.
- WP to provide input on current practices for communication including uptake of risk minimisation measures (RMMs) by healthcare professionals.
- Provide expert input to the development of guidance on the use of AI in pharmacovigilance.
- WP to provide expert input on the EU landscape of RMMs integration in dispensing and prescribing software, and related topics as background to the development of a concept paper on digital tools supporting RMMs.
- WP to reflect on further engagement with primary care focused organisations in EMA activities.
- WP to continue discussing the inclusion of patient-relevant outcomes in clinical research to strengthen the clinical applicability of regulatory decisions.
- WP involved in AMR-relevant activities, including EMA activities on harmonising SmPCs of old antibiotics.

## 4.2. Outreach to clinical practitioners/researchers

**Actions**

- WP to discuss how to promote inclusion of young clinical researchers and practitioners in EMA activities.
- WP to be informed of developments related to the implementation of EMA framework of collaboration with academia.
- WP to discuss collaboration with academia that can support development of clinical practice guidelines with the aim of bridging the gap between scientific research and its practical application.
- WP to reflect on ways to enhance the impact of safety communications and continue collaborating with EMA to promote broader outreach of safety communications with significant clinical impact.

## 4.3. Framework for engagement

**Actions**

- WP to be consulted on the revision of the framework.
- WP to stimulate and monitor engagement of member organisations in the implementation of the framework.

## 4.4. Training and capacity-building

- EMA and WP to explore training needs and gaps and how EMA could make use of different formats and technologies to deliver training in an accessible manner.

# Annex 1: Meetings scheduled for 2025-2028 mandate

- 2025
  - PCWP/HCPWP plenaries and joint meeting – 23-24 September
  - PCWP/HCPWP joint meetings will all eligible –18-19 November

- 2026
  - PCWP/HCPWP joint meetings –3-4 February
  - PCWP/HCPWP plenaries and joint meeting –30 June–1 July
  - PCWP/HCPWP joint meetings will all eligible – 20-21 October

- 2027
  - PCWP/HCPWP joint meetings – 2-3 March
  - PCWP/HCPWP plenaries and joint meeting – 1-2 June
  - PCWP/HCPWP joint meetings will all eligible – 19– 20 October

- 2028
  - PCWP/HCPWP joint meetings – either 1-2 March (Wednesday - Thursday) or 28-29 March
  - PCWP/HCPWP plenaries and joint meeting – 19-20 September
  - PCWP/HCPWP joint meetings will all eligible – 21-22 November

The above-mentioned dates may be modified as needed. Additional or replacement virtual meetings may be organised, as required.