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Stakeholders and Communication

2022-2025 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

Chairpersons	**Status**
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1. Introduction

The PCWP and HCPWP are formal structures within EMA, composed of representative organisations of patients, consumers and healthcare professionals as well as representatives from all EMA Human Scientific Committees. They support and monitor the involvement of patients, consumers, healthcare professionals and their organisations in Agency activities. They identify opportunities and challenges that may need special attention, particularly in the context of the respective frameworks.

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

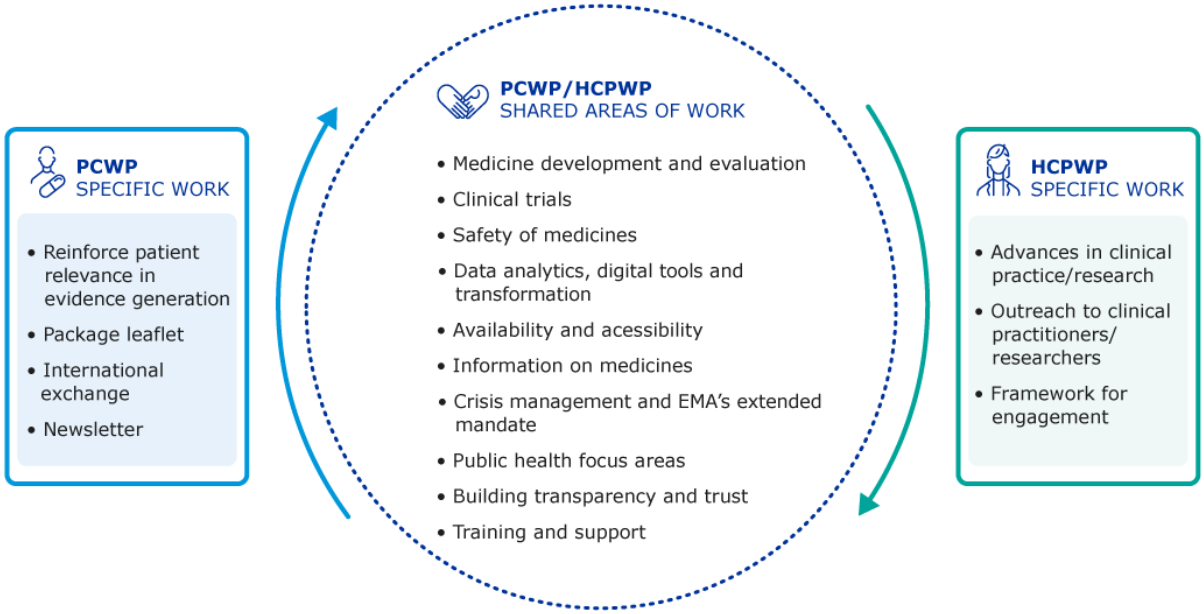
The PCWP and HCPWP will participate at key stages of EMA initiatives, policy development and implementation as well as in other EMA activities including those aimed at supporting the implementation of EU legislation (e.g. EMA's extended mandate, ACT EU, DARWIN, patient preferences, antimicrobial resistance, vaccines).

Particular attention will be paid to the revision of the EU general pharmaceuticals legislation and its implications for stakeholders.

PCWP and HCPWP will identify topic co-leads and organisations' topic-specific interest, where needed.

The structure of this joint work plan presents the work areas common to both working parties, 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.



2. PCWP/HCPWP shared areas of work

Overarching objectives

- Bring the patient, consumer and healthcare professional perspectives into EU/EMA initiatives and proposals
- Inform and reflect with EMA and WPs on advances in specific domains, initiatives and concerns of the respective stakeholder groups
- Raising awareness and supporting communication – trust and transparency

2.1. Medicines development and evaluation

Actions

- WPs kept regularly updated and provide input on current and emerging concepts and methodologies used in the development and evaluation of medicines (e.g. precision medicine, biomarkers, 'omics and ATMPs)
- WPs consulted throughout development and implementation of EMA initiatives, proposals and guidance (e.g. STAMP repurposing pilot; DARWIN EU; CTIS; ACT EU; CHMP pilot on early dialogue; patient experience data; pregnancy strategy; use of medicines in special populations (e.g. older people, pregnant and breastfeeding women, rare diseases); RSRN; PRIME; PRAC points-to-consider on engagement)
- Members representing scientific committees to share highlights and relevant committee initiatives with WPs
- WPs are involved in ICH guideline development and updates specifically dealing with good clinical practice (GCP) and patient-focused drug development (PFDD)
- WPs are involved in scientific guideline development and updates
- Relevant topics identified by WP members will be included as agenda items for information and discussion in plenary meetings
- WPs to identify knowledge gaps and awareness-raising needs to inform on current and emerging concepts and methodologies used in the development and evaluation of medicines
- WPs to participate in EMA's Cancer Medicines Forum
- WPs to be kept informed of relevant EMA actions that might arise in relation to the Healthier Together EU Non-Communicable Diseases Initiative

2.2. Clinical trials

Actions:

- WPs updated on implementation of the Clinical Trials Information (CTIS) system in context of Clinical Trials (CT) Regulation
  - WPs involved in the development and update of recommendations on reporting clinical trials

- WPs to identify and discuss issues around CT in a dedicated session (e.g. continued access to trial medicines, lay summaries for publication, informed consent and ethical requirements, ensuring representative patient samples, comparison against standard treatment, selection of endpoints and surrogate validation)
- WPs participation in workshop on ICH GCP E6 (R3) and follow up actions
- WPs informed of and involved in ACT EU multi-stakeholder platform
- WPs updated on progress of relaunch of EMA's policy on the publication of clinical data (policy 0070)

2.3. Safety of medicines

Actions

- WPs contribute to *EMA/Pharmacovigilance Risk Assessment Committee (PRAC) strategy on impact of pharmacovigilance activities* and continue enhancement of patient and healthcare professional involvement in PRAC activities, in particular the Engagement Workstream on risk minimisation measures and the points-to-consider on engagement.
- WPs to further support engagement of patients and healthcare professionals in regulatory pharmacovigilance by:
  - Providing input in the finalisation of the revision of EMA GVP Module XVI on risk minimisation measures (RMMs)
  - Discussing any case studies related to safety concerns and possible RMMs implementation
  - Contributing to a reflection on how to enhance impact of safety communications
  - Identifying knowledge and awareness gaps and providing relevant information to WPs

  - Continuing to increase awareness on adverse drug reactions (ADR) reporting by healthcare professionals and patients/consumers

2.4. Data analytics, digital tools and digital transformation

Actions:

- Continue WP collaborations on Big Data initiatives:
  - representatives on the Big Data Steering Group and the DARWIN EU Advisory Board
  - participation in the annual multi-stakeholder forum and in relevant workshops (e.g. data quality, RWE analytics)
  - consultation on data protection Q&A
- WPs to be kept informed of progress and to provide input into next phases of electronic product information (ePI) set-up project (see 2.6.1.)
- WPs to promote awareness and provide input on the use of public interface of Clinical Trials Information System (CTIS) (see 2.2.)
- WPs to contribute to discussions on collection of real-world data from healthcare professionals and patients

2.5. Availability and accessibility of medicines

Actions:

- WPs to be informed of progress and provide input, as needed, to the Heads of Medicines Agencies (HMA)/EMA task force on availability of medicines (TFAAM), with a particular focus on:
  - deliverables to improve prevention, management and reporting of shortages and their causes, and
  - multi-stakeholder workshop and webinar on shortages, public communication and transparency (e.g. workshop report and recommendations, shortages catalogue
  - use of 'Good practice guidance for patient and healthcare professional organisations on the prevention of shortages'
- WPs to contribute to the implementation of the Communication and Stakeholders' Engagement Plan on EMA's extended mandate for medicines and medical device shortages (see also 2.7.):
  - Observers on the Medicines/Medical Devices shortages steering group (MSSG/ MDSSG)
  - Provide input to development of the EU shortages monitoring platform and the lists of critical medicines and medical devices
- WPs to be kept informed and discuss progress of ongoing initiatives, such as biosimilars, repurposing of medicines, compassionate use and expanded access programmes, aimed at facilitating access to medicines;
- WPs regularly updated on EMA's collaboration with HTA bodies (including EMA/EUnetHTA21 joint work plan (2021-2023))
- WPs to identify knowledge and awareness gaps on HTA bodies' and EMA's practices and provide relevant information to WPs

2.6. Information on medicines

2.6.1. EU product information

Actions:

- WPs continue to support EMA in the implementation of EMA Action Plan to improve Product Information and user-testing
- WP to be kept informed of progress and to provide input into next phases of electronic product information (ePI) set-up project (see 2.2.)

2.6.2. EMA communications and information on medicines for patients and healthcare professionals

Actions:

- WP to help identify volunteers through their organisations to review and user-test EMA communication materials and advise on contextualisation of information to support health literacy
- WPs to disseminate EMA communications through their organisations' websites and other channels
- WPs to advise on organisations' needs and preferences for EMA communication materials

2.7. Crisis management and EMA's Extended Mandate

Actions:

- WPs to be regularly kept informed of implementation of EMA's extended mandate
- WPs updated about the work of the expert panels on medical devices
- WPs to contribute to the implementation of the Communication and Stakeholders' Engagement Plan on EMA's extended mandate including:
  - WPs to participate in multi-stakeholder workshop on extended mandate
  - Members of EMA's Emergency Task Force (ETF)
  - Observers on the Medicines/Devices shortages steering group (MSSG/ MDSSG)
  - Provide input to development of the EU shortages monitoring platform

    (see also 2.3.)

2.8. Public health focus areas

2.8.1. Antimicrobial resistance

Actions:

- WPs to promote guidance on antimicrobial use and the Agency's approach to antimicrobial resistance in the environment and increase stakeholder understanding of new antimicrobials
- WPs to participate in multi-stakeholder workshop on AMR and contribute to any discussions on alternative models for the development of new antibiotics
- WPs to contribute to any activities related to European Antibiotic Awareness Day (EAAD)

2.8.2. Vaccines

Actions:

- WPs to continue to contribute to the creation and user-testing of materials and combatting misinformation to increase vaccine confidence
- WPs to participate in joint PCWP/HCPWP workshop on vaccines in 2024

2.9. Building transparency and trust

Actions:

- WPs informed and provide input to:
  - initiatives intended to communicate the science behind EMA decisions, particularly on areas of high public health priority (e.g. vaccines)
  - development of information materials and awareness raising campaigns targeting patients, consumers and healthcare professionals
- WPs to stimulate reciprocal transfer of knowledge between member organisations, EMA and international partners to develop specific dialogue on topics of common interest

- WPs to promote awareness of EMA’s stakeholder database and benefits of registration (e.g. targeted communications, invitations for workshops)
- WPs to continue to create awareness of EMA's Regulatory science research needs

2.10. Training and support

Actions:

- WPs to be updated and to provide input to training materials supporting involvement in EMA activities, considering the training strategy for patients, consumers, healthcare professionals and academia
- Induction training for new PCWP/HCPWP members

3. PCWP specific work

3.1. Reinforce patient relevance in evidence generation

Actions:

- WP to review analysis of outcome of CHMP pilot on early dialogue with patient organisations
- WP to review pilot proposal for disease-specific focus groups
- WP to participate in workshop on enhancing the patient voice in the development and authorisation of medicines; Q2 2022
- WP informed of potential use of patient preferences in decision making
- WP involved in ICH guideline development and updates specifically dealing with good clinical practice (GCP) and patient-focused drug development (PFDD) (see 2.1.)
- WP to explore complementary methodologies for the collection and use of patient data (e.g. real world evidence, patient-reported outcomes (PROs), patient preferences) for medicine's development, assessment and monitoring
- WP to provide input on best ways to communicate on benefit-risk assessments, and the various marketing authorisation options (e.g. conditional, exceptional circumstances).

3.2. Package leaflet

Actions:

- WP to provide input to support implementation of EMA's action plan to improve the product information (PI)
- WP to be kept updated on progress of implementation, in particular ePI

3.3. Exchange with international stakeholders

- WP to join annual meeting with FDA's CTTI/Patient Engagement Collaborative and identify topics for discussion

3.4. Newsletter

- WPs to review and contribute to proposed enhancements of current newsletter (HMH) with patient-relevant information

4. HCPWP specific work

4.1. Advances in clinical practice and clinical research

Actions:

- WP to identify topics to be addressed for the 2022-2025 period and discuss how HCPWP and the healthcare professionals policy officers group (HCP POG) can support development of concrete deliverables
- WP to reflect on current practices for communication and uptake of risk minimisation measures by healthcare professionals
- WP to reflect on further engagement with primary care focused organisations in EMA activities

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

4.3. Framework for engagement

Actions

- WP to reflect on need to revise the framework, and if needed, initiate revision

Annex 1: Meetings scheduled for 2022-2025 mandate (tbc)

- 01 - 02 June 2022 – Virtual Joint PCWP/HCPWP meeting (start new mandate) including dedicated session on clinical trials
- 15 July 2022 Joint PCWP – FDA CTTI meeting
- 21 September 2022 – Workshop on patient data
- 22 September 2022 – individual plenary PCWP/HCPWP (elections of co-chairs) + Joint PCWP/HCPWP plenary
- 15 November 2022 – PCWP/HCPWP annual meeting with eligible organisations
- 02 March 2023 – Multi-stakeholder workshop on shortages
- 03 March 2023 – Joint PCWP/HCPWP plenary meeting
- 27 and 28 June 2023 – individual plenary PCWP/HCPWP + Joint PCWP/HCPWP meeting
- 19 and 20 September 2023 – Joint PCWP/HCPWP plenary meeting
- 14 November 2023 – Multi-stakeholder workshop on antimicrobial resistance (AMR)
- 15 November 2023 – PCWP/HCPWP annual meeting with eligible organisations
- 27 and 28 February 2024 – Joint PCWP/HCPWP plenary meeting
- 04 and 05 June 2024 – Joint PCWP/HCPWP – Plenary PCWP/HCPWP meeting each
- 24 and 25 September 2024 – Joint PCWP/HCPWP plenary meeting
- 20 November 2024 – Annual meeting with eligible organisations
- February/March 2025 – Joint PCWP/HCPWP plenary meeting

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