EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication

2019-2022 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 patients', consumers', healthcare professionals' and their organisations' involvement throughout the Agency's activities. They identify opportunities and challenges that may need special attention, particularly in the context of the respective frameworks of interaction.

The working parties (WPs) serve as platforms for exchange and discussion between regulators and organisations on issues of common interest which are 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 working parties will continue to engage in consultations where patients', consumers' and healthcare professionals' input can bring added value to benefit-risk assessment and decision-making; contribute to EMA activities related to information on medicines and communication with healthcare professionals and patients; and support the continuous improvement of the operation of the pharmacovigilance system. As in previous years, the PCWP and HCPWP will participate at key stages of EMA policy development and implementation as well as in other EMA initiatives aimed at supporting the implementation of EU legislation.

In addition, PCWP and HCPWP will be key platforms to gather input and contribute to recommendations identified as part of the Regulatory Science Strategy to 2025, in particular on those research areas where patient/consumer /HCP involvement or impact is expected to be high (e.g. RWE, patient preferences, educational topics on regulatory science, antimicrobial resistance (AMR), vaccines – see below for more details).

PCWP and HCPWP will agree on a process to identify topic co-leads and organisations' topic-specific interest, where needed.

The structure of this joint work plan presents firstly the areas of common work, followed by dedicated sections addressing the areas of particular focus 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

2.1. Medicines development and evaluation

Expected outcomes

- WPs involved in EMA activities aimed at bringing input from patients, consumers and healthcare professionals into medicine development and benefit-risk assessment
- WPs consulted on ways to ensure healthcare professionals, patients and consumers are better informed about current and emerging concepts and methodologies used in the development and evaluation of medicines

Work methodology

- Support identification of experts through patient and healthcare professional organisations to provide input within benefit-risk discussions, subject to application of EMA policy on the handling of competing interest,
- Members representing Scientific Committees to share evaluation highlights and relevant Committee initiatives, including development of new/revised regulatory guidelines, with WPs
- Provide input to discussions/initiatives exploring expanded collection of patient data for use in regulatory decision making (e.g. patient-centred clinical trial design, patient reported outcomes, quality of life measures, patient preferences) alongside traditional approaches
- WPs are involved in ICH (International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guideline updates specifically dealing with good clinical practice and general considerations for clinical studies, which includes consideration of the quality in the design and conduct of clinical studies across the product lifecycle
- Relevant topics identified by PCWP, HCPWP and/or EMA will be included as agenda items for information and discussion in joint PCWP/HCPWP plenary meetings
- Nominated members of PCWP and HCPWP participate in scientific committees' expert workshops
- In the context of EMA/EUnetHTA joint work plan 2017-2020, continue to share practices and experiences related to the involvement of patients, consumers and healthcare professionals in assessment activities
- Serve as a platform to facilitate meaningful interactions with European Reference Networks (ERNs), focusing on treatment of rare and complex diseases
- Review existing materials and advise on initiatives to inform the public of current and emerging concepts and methodologies used in the development and evaluation of medicines, such as personalised medicine; multi-investigational product trial design; data extrapolation; early access schemes; biological medicines; immunotherapy and drug repurposing
- Nominated members of PCWP and HCPWP participate in the CHMP Geriatric Expert Group (GEG) and report to the WPs

2.1.1. Digital health

Expected outcomes

- WPs are better informed on how digital health is impacting the regulatory environment for evaluation of medicines and engage with regulatory initiatives addressing the use and understanding of big data, artificial intelligence (AI), clinical trials data, real-world data, patient registries and m-health apps
- Increased understanding of the potential role of big data in accelerating medicines development and improving outcomes
- WPs promote the use of secure, privacy-centred/privacy-aware and ethical data sharing culture in collaboration with EU-wide initiatives
- Contribution to a common understanding of protection of personal data with the secondary use of healthcare data for medicines evaluation.
- Active engagement in EMA's work towards a regulatory system strengthened by efficient and secure integration of big data

Work methodology

- Through a joint topic group on digital health, identify points of concern around generation and use of real-world data in the evaluation and supervision of medicines and how these may be addressed and communicated
- Participating in discussion and providing feedback on EMA communications and messages on big data
- Supporting awareness measures on the need for systematic collection of information on disease, treatments and outcomes
- Supporting dissemination of relevant educational materials through patient/HCP organisations
- Regular updates and exchanges on the work of the HMA/EMA joint big data task force

2.1.2. Safety of medicines

Expected outcome

- WPs are involved in EMA activities aimed at strengthening patients' and healthcare professionals' engagement and communication, to support the operation of the EU pharmacovigilance system for human medicines
- WPs are involved in activities aimed at gathering input from patients and healthcare professionals via public hearings and other means such as written consultations

Work methodology

- Follow EMA/Pharmacovigilance Risk Assessment Committee (PRAC) work on measuring the impact of pharmacovigilance activities and contribute to continued strengthening of patient and healthcare professionals involvement in PRAC activities where appropriate
- Support further engagement of patients and healthcare professionals in regulatory pharmacovigilance, in particular by:

  - Fostering early engagement of healthcare professionals and patients in risk minimisation in the next revision of EMA GVP Module XVI on risk minimisation measures (RMMs)
  - Responding to requests where real world evidence gaps have been identified in relation to a safety concern under investigation and on the possible RMM
  - Contributing to a reflection on how to enhance impact of safety communications (see also 2.2.2)
  - Understanding how severity of ADRs is analysed in relation to benefit-risk assessment
- Nominated members of PCWP and HCPWP participate and support the annual EMA Stakeholder Forum on the pharmacovigilance legislation
- Explore options to collaborate with the European Food Safety Authority (EFSA) to organise a joint discussion between EFSA/EMA to address borderline products and how to work together to inform the public on the risks

2.2. Information on medicines

2.2.1. EU product information

Expected outcome

- WPs will continue to provide key input into the implementation of EMA's action plan to improve the product information (PI)
- A more accessible Summary of Product Characteristics (SmPC) and package leaflet (PL) that provides more tailored information to patients and HCPs

Work methodology

- Support EMA in the implementation of EMA Action Plan to improve Product Information and user-testing
- Contribute to improving content and readability of the PL (see also 3.2)
- Contribute to discussions on potential introduction of key facts in the PL
- Participate in consultations on implementation of electronic product information (ePI) for EU medicines
- Participate in consultation on promoting best practice examples of PI

2.2.2. EMA communications and medicines information for patients and healthcare professionals

Expected outcome

- Dissemination network harnessed to cascade targeted messages (e.g. EMA safety communications) from EMA to relevant patients and HCPs
- Availability and use of medicines information on the EMA website widely promoted
- Patient/HCP-targeted information from EMA meets the audiences' information needs

Work methodology

- Help identify volunteers through patient and healthcare professional organisations to review product-related communication materials
- Support EMA in disseminating EMA communications through patient/HCP organisation websites and other channels
- Better understand organisations' needs and preferences for communication materials
- Help identify patients/HCPs for user-testing of communication materials
- Contribute to discussions on EMA communication processes and practices

2.2.3. Access to clinical data

Expected outcome

- WPs are involved in activities related with the implementation of the Clinical Trials (CT) Regulation
- WPs are involved in activities related with the implementation of the clinical data publication policy

Work methodology

- Follow progress made with the implementation of the Clinical Trials Information (CTIS) system, including its public module of the system (lay summary results) and provide input as needed
- WPs are informed about progress made in relation to the anonymisation of clinical reports in the context of EMA's policy on the publication of clinical data and planning around consultations as need

2.3. Building trust and developing methodology

Expected outcome

- WPs revisit and further implement actions to improve understanding of EMA processes in general and to increase visibility about stakeholder engagement in those processes
- Increased awareness about EMA's frameworks of interaction with patients, consumers, healthcare professionals and academia

Work methodology

- WPs are informed and, where possible, provide input to initiatives intended to communicate the science behind EMA decisions, particularly on areas of high public health priority where it is needed to educate the public on regulatory science (e.g. vaccines)
- Explore ways to enhance how patient and healthcare professional input is documented within EMA regulatory outcomes (i.e. recommendations / assessment reports) (see also 3.4)
- WPs are involved in the development of information materials and awareness raising campaigns targeting patients, consumers and healthcare professionals
- Continue to reflect on ways to enhance transparency and build better public understanding of regulatory decisions
- Develop an overarching training strategy, including possible series of webinars addressing "the cycle of medicines' development", "pharmacovigilance throughout the medicine lifecycle", "benefit-risk assessment", "product information"

- Help to disseminate EMA information and provide feedback on relevance, usefulness and best dissemination practices
- WPs are updated on experience with Policy 44 (handling of competing interests of scientific committees' members and experts), compliance and procedure for selecting experts and provide input on potential areas for improvement
- Help to raise awareness about EMA's frameworks of interaction with patients, consumers, healthcare professionals and academia to expand EMA stakeholders' database
- Serve as a platform to:
  - share ideas and enable meaningful interaction (e.g. EU-wide research projects and initiatives; EU-based surveys/data collection exercises; European Antibiotics Awareness Day; supporting vaccine confidence, joint training and capacity building initiatives)
  - exchange knowledge and practices with National Competent Authorities (NCAs) within the EU and other regions of the world as well as with other EU-Agencies
- Contribute to and endorse a revised format of the annual report on public engagement activities
- Revisit satisfaction survey amongst patients/consumers/HCPs involved in product-related activities prior to 2020 survey launch

2.4. Public health focus areas

2.4.1. Supply issues and availability of medicines

Expected outcome

- WPs are involved in EMA activities related to the implementation of strategies that help address issues regarding the availability of medicines
- Patients/consumers/HCPs are better informed about shortages

Work methodology

- Serve as a platform to share practices and initiatives addressing availability of medicines
- In the context of the Heads of Medicines (HMA)/EMA task force on availability of medicines, follow progress and provide input as needed, with a particular focus on deliverables to improve prevention, reporting of shortages including their causes, public communication and transparency
- Follow and provide input as needed into EMA activities aimed to strengthen collaboration with Health Technology Assessment (HTA) and payers

2.4.2. Antimicrobial resistance

Expected outcome

- WPs coordinate effort to support healthcare professionals, patients and consumers to be more aware about the problem of antimicrobial resistance and empowered to use antibiotics prudently

Work methodology

- Survey members on their information needs and expectations related to EMA-prepared information

- Identify members interested to review existing EMA materials and advise how EMA could further inform the public at large as well as specific populations with different information needs on the risks of antimicrobial resistance
- Continue joint efforts with the European Centre for Disease Prevention and Control (ECDC), in particular by:
  - Early engagement in European Antibiotic Awareness Day (EAAD) related activities
  - Exploring options for a joint session as a follow up to the one organised in September 2017

2.4.3. Vaccines

Expected outcome

- Increased vaccine confidence through strengthening trustworthy information on vaccines and empowering healthcare professionals and patient/consumers groups to become advocates of the science underpinning vaccines' approval and safety monitoring

Work methodology

- Support efforts to ensure healthcare professionals, patients and consumers are better informed about the benefits and risks of vaccines
- Provide input in the creation and user-testing of materials
- Help disseminate these materials and amplify public health messages
- Joint PCWP/HCPWP workshop on vaccines in 2021

3. PCWP specific work

3.1. Patient data generation

Expected outcome

- Increase collection and use of patient data (e.g. clinical trials, real world evidence, patient-reported outcomes (PROs), patient preferences). See also 2.1.1.

Work methodology

- Explore complementary methodologies to collect patient data for medicine's development, assessment and monitoring in ways that ensures high quality and with a full alignment with EU's data protection framework
- Continue drafting reflection paper on 'enhancing the importance of the patient data in the development of innovative medicines'
- Explore methodologies for organising disease specific focus groups. Plan for first pilot focus group by 2Q 2020
- Inform and consult when needed on activities related to the implementation of the EMA principles for the involvement of young people

3.2. Package leaflet

Expected outcome

- Provide key input into PL-specific actions within EMA's action plan to improve the product information (PI)
- Improved package leaflet that better serves patient needs including supporting the needs of a wide range of diverse patient groups (e.g. visually impaired)

Work methodology

- Contribute to PL-specific actions as defined above in section 2.2.1
- Provide input to help regulators progress towards a more accessible product information
- Contribute to improving patient input in user testing of PL

3.3. Patient/consumer reporting of ADRs

Expected outcome

- Increased awareness of patients and consumers organisations on direct patient adverse drug reactions (ADR) reporting and on the information that can be found in Eudravigilance

Work methodology

- Discuss how to increase awareness amongst patient and consumer organisations about ADR reporting and Eudravigilance data

3.4. Visibility of the patient contribution in EMA activities

Expected outcome

- Increased awareness on how EMA involves patients and consumers within its activities, including how and when they provide input to EMA medicine assessments.

Work methodology

- Explore how to enhance visibility of patient engagement in EMA processes, especially within benefit-risk discussions (see also 2.3)
- Determine how the input of patients is reflected within EMAs scientific recommendations (e.g. assessment reports) and how this could be enhanced.

3.5. Framework of interaction

- Reflect on need to revise the framework, and if needed, initiate revision
- Contribute and endorse update of the action plan of the framework

3.6. Training and support

- Provide input to training materials supporting patient involvement in EMA activities, taking into account the overall EMA training strategy for public engagement with patients, consumers, healthcare professionals and academia

4. HCPWP specific work

4.1. Advances in clinical practice

Expected outcome

- WP is abreast of advances in clinical practice related with innovative medicines and treatments
- WP coordinate effort to support uptake of risk minimisation measures by healthcare professionals

Work methodology

- Define a methodology for prioritising and addressing topics in the form of reflection papers, workshops and discussion points at HCPWP meetings
- On the basis of the agreed methodology, agree on topics to be addressed for the 2020-2022 period and expected deliverables
- Reflect on current practices for communication and uptake of risk minimisation measures by healthcare professionals
- Reflect on an action plan to develop interaction with primary care focused organisations in EMA activities

4.2. Outreach to clinical practitioners/researchers

Expected outcome

- Increased outreach to young clinical researchers and practitioners
- Strengthened engagement of healthcare professionals in EMA activities

Work methodology

- Discuss how to promote inclusion of young clinical researchers and practitioners in EMA activities
- Analyse options for recognition of EMA activities within CME/CPD for healthcare professionals involved in the work of EMA
- Contribute to and support the development of EMA training strategy for public engagement with patients, consumers, healthcare professionals and academia
- Inform of developments related to the implementation of EMA framework of collaboration with academia

4.3. Framework of interaction

- Contribute and endorse update of the action plan of the framework

Annex 1: Meetings scheduled for 2019-2022 mandate (tbc)

- 26 June 2019 – Virtual Joint PCWP/HCPWP meeting (start new mandate)
- 24/25 September 2019 - Joint PCWP/HCPWP plenary meeting (including elections of co-chairs)
- 20 November 2019 – Annual meeting with eligible organisations
- February/March 2020 – Joint plenary meeting
- June 2020 – Joint PCWP/HCPWP
- September 2020 – Plenary PCWP/HCPWP meeting each
- November/December 2020 – Annual training day
- November/December 2020 – Annual meeting with eligible organisations
- February/March 2021 – Joint plenary meeting & workshop
- June 2021 – Joint PCWP/HCPWP September 2021 – Plenary PCWP/HCPWP meeting each
- November/December 2021 – Annual training day
- November/December 2021 – Annual meeting with eligible organisations
- February/March 2022 – Joint plenary meeting

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