EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication

2018-2019 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

Chairpersons	**Status**
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1. Meetings scheduled for 2018-2019

PCWP and HCPWP face-to-face meetings and some EMA stakeholder meetings directly relevant to the PCWP/HCPWP work plan are planned for the following dates:

- 17 and 18 April 2018 – Joint PCWP/HCPWP plenary meeting
- 24 September 2018 – 12th EMA stakeholder forum on the pharmacovigilance legislation
- 25 September 2018 – PCWP plenary meeting
- 26 September 2018 – HCPWP plenary meeting
- 8-9 November 2018 – HMA/EMA workshop on shortages and availability of medicines
- 20 November 2018 – Annual training day
- 21 November 2018 – Annual meeting with all eligible organisations
- 28-29 November 2018 – EC/EMA workshop on electronic EU product information (date to be announced)
- 5 and 6 March 2019 – Joint PCWP/HCPWP plenary meeting
- 4 June 2019 – PCWP plenary meeting (including election of co-chair)
- 5 June 2019 – HCPWP plenary meeting (including election of co-chair)
- 24 September 2019 – Joint PCWP/HCPWP workshop//information session on vaccines
- 25 September 2019 – Joint PCWP/HCPWP plenary meeting
- 19 November 2019 – Annual training day
- 20 November 2019 – Annual meeting with eligible organisations

The above mentioned dates may be modified as needed. Additional or replacement virtual meetings may be organised, as required. The location of meetings planned for 2019 will be confirmed as soon as possible in the context of EMA relocation to Amsterdam.

2. 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. They promote better understanding of the Agency's activities and involvement in European Union (EU)-wide initiatives.

The current work plan is structured around the main themes and objectives of the EMA multiannual programme to 2020 to which they will support. The working parties will concentrate on:

- Theme 1: Contributing to human health – objectives 1 to 4:
  - focus on key public-health priorities, including availability of medicines and antimicrobial resistance;
  - ensure timely access to new medicines for patients;
  - support patient-focused innovation and contribute to a vibrant life-sciences sector in Europe;
  - strengthen regulatory capability and transparency
- Theme 3: Optimising the operation of the European medicines agencies regulatory network – objectives 3 and 4:
  - ensure effective communication of and within the network;
  - strengthen links with other authorities and with other stakeholders.

PCWP and HCPWP will also keep scanning progress and developments in the context of the multiannual work programme to 2020 theme 4 "contributing to the global regulatory environment", as appropriate.

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 the next sections we will describe, for each of the objectives identified, the activities where the working parties will focus their efforts throughout 2018 and 2019. PCWP and HCPWP will agree on a process to identify topic co-leads and organisations' topic-specific interest.

The activities outlined in the work plan for 2018 have been agreed in view of the preparation for the Agency's relocation as a result of the UK's withdrawal from the EU and its impact on the Agency's business continuity. This may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency. Activities for 2019 will be revisited in Q4 of 2018.

3. PCWP / HCPWP shared areas of work

3.1. Focus on key public-health priorities, including availability of medicines and antimicrobial resistance

3.1.1. Supply issues and availability of new and well-established medicines

Expected outcome

- WPs are involved in HMA/EMA activities related to the implementation of strategies that help address issues regarding the availability of medicines, such as shortages or supply disruptions.

Work methodology

- Q1 2018 – WPs discuss how to support the HMA/EMA task force on availability of authorised medicines and the need to establish a joint topic group
- Q2-Q3 2018 – WPs reflect on how to enhance interaction with stakeholders for better management and communication of supply problems
- Q4 2018 – WPs provide feedback on proposed strategies for better managing shortages for medicines, including vaccines, by participating in the HMA/EMA workshop on shortages and availability of medicines
- 2019 – Topic will be covered as an agenda item for further information and discussion in joint PCWP/HCPWP plenary meetings

3.1.2. Antimicrobial resistance

Expected outcome

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

Work methodology

Priority activities

- Q1 2018 – WPs support dissemination of EMA's information session report amongst their members and through social media channels as well as provide feedback on its use as an information tool
- 2018/2019 – WPs serve as platforms to enable meaningful actions to be implemented and to cascade down information (e.g. EU-wide research projects; EU-based surveys/data collection exercises; European Antibiotics Awareness Day; joint training and capacity building initiatives)

Activities subject to available resources

- Q2 2018 – WPs 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

3.1.3. Public health needs and priorities

Expected outcome

- WPs are more aware of regulatory initiatives addressing age and gender issues in medicines development and evaluation

Work methodology

Priority activities

- Q1 2018 – WPs are informed about the EC/EMA action plan to implement recommendations from the 10 year report on the paediatric regulation and provide feedback on proposed actions by participating in the EC/EMA multi-stakeholder workshop
- 2018/2019 – Relevant topics identified by PCWP, HCPWP and/or EMA will be covered as agenda items for information and discussion in joint PCWP/HCPWP plenary meetings, with special focus on gender-specific issues
- 2018/2019 – Nominated members of PCWP and HCPWP participate in the activities of the CHMP Geriatric Expert Group (GEG) and report to the WPs

Activities subject to available resources

- WPs identify members interested to discuss a proposal to develop a document outlining concerns related to age and gender issues in medicines development and evaluation

3.1.4. Public health emergencies

Expected outcome

- WPs coordinate effort to support patients and consumers to be better informed about the benefits and risks of vaccines

Work methodology

- 2018 – WPs discuss how to support vaccine confidence through improved communication on vaccines and how they are developed, approved and monitored
- Q3 2019 – Joint PCWP/HCPWP workshop/information session on vaccines

3.2. Ensure timely access to new beneficial and safe medicines for patients

3.2.1. Early access to medicines

Expected outcome

- WPs clarify their position towards the need to develop more concrete criteria to define "unmet medical need"
- WPs coordinate efforts to support patients and consumers to be better informed about the concept of "early access" (e.g. understanding notions of limited evidence; "presumed" vs "demonstrated" benefits, known and unknown safety risks)
- WPs are involved in activities aimed at stakeholder engagement in EMA/HTA collaboration

- WPs are more aware of and engaged with regulatory initiatives addressing the use of real-world evidence and patient registries in medicines evaluation
- Q1 2019 – WPs are updated on progress made by the Safe and Timely Access to Medicinal Products (STAMP) group on discussions on early access to medicines

Work methodology

Priority activities

- 2018/2019 – Topics will be covered as agenda items for information and discussion in PCWP/HCPWP plenary meetings
- Q1 2018 – WPs, through their topic group on digital media and health,
  - Identify points of concern from patients, consumers and healthcare professionals around generation and use of real world evidence (e.g. validity, reliability, transparency, security, ethics) in the evaluation and supervision of medicines
  - Reflect on how to address identified concerns and best communicate to patients, consumers and healthcare professionals in a clear and comprehensible manner
- Q1 2018 – WPs discuss how to support the implementation of the following actions in the EMA/EUnetHTA joint work plan 2017-2020:
  - Share respective practices and experiences related to the involvement of patients, consumers and healthcare professionals in assessment activities
  - Assess the feasibility of developing a shared pool/list of contacts
- 2018/2019 – WPs serve as platforms to facilitate meaningful interaction with European Reference Networks (ERNs)
- 2018 – WPs are informed on the Article 8.2 of Regulation 141/2000 to revise 10-year marketing exclusivity for orphan medicines
- 2019 – Reviewing existing materials and advise on initiatives to inform the public at large on the concept of “early access”

Activities subject to available resources

- WPs identify members interested in
  - Discussing how to inform European healthcare professionals and patients about compassionate use programmes authorised by national authorities, and how to facilitate the notification of such programmes by the authorities

3.2.2. Benefit-risk assessment

Expected outcome

- WPs are more aware of regulatory initiatives and legislation implementation activities relating to EMA procedures for benefit-risk assessment
- WPs are involved in EMA activities aimed at bringing input from patients, consumers and healthcare professionals into benefit-risk assessment

Work methodology

- 2018/2019 – WP members representing Scientific Committees inform about evaluation highlights and relevant Committee initiatives, including development of new/ revised regulatory guidelines
- 2018/2019 – WPs monitor the process for identification of experts through patient and healthcare professional organisations to provide input within benefit-risk discussions, including, for example:
  - Participation in scientific advisory groups and ad-hoc expert group meetings
  - Responses to calls for ad-hoc consultations from committees and their working parties
- 2018/2019 – WP members are involved in discussions/initiatives exploring expanded collection of patient data for use in regulatory decision making (see more information under section 4.3)
  - WPs are updated on ongoing research of use of Patient Preferences Elicitations (e.g. IMI PREFER project, EMA initiatives)
  - WPs reflect on initiatives that could support patient co-leadership in collaborative studies exploring additional approaches to include patient data (e.g. patient reported outcomes and quality of life measures) alongside traditional approaches
- 2018/2019 – Nominated members of PCWP and HCPWP participate in Scientific committees' expert workshops

3.3. Support patient-focused innovation

3.3.1. Innovation

Expected outcome

- WPs become a port of call 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
- WPs are more aware of how digital media and health is shaping the regulatory environment for authorisation and monitoring of medicines

Work methodology

Priority activities

- Q1 2018 – Joint PCWP/HCPWP meeting includes a day themed around digital media and health
- 2018/2019 – WPs serve as platforms to share ideas and enable meaningful interaction with academia
- 2018/2019 – Foster PCWP and HCPWP participation in the strategic development of EMA workshop agendas and objectives
- Q1 2019 – WPs are updated on progress made by the International Consortium for Personalised Medicines (IC-PERMED)
- Q1 2019 – WPs are updated on progress made by the Safe and Timely Access to Medicinal Products (STAMP) group on discussions on re-purposing

Activities subject to available resources

- WPs identify members interested to
  - Review existing materials and advise on initiatives to inform the public at large on the concept of "personalised medicine"
  - Discuss what constitutes innovation in medicines development and evaluation from a healthcare professional and patient perspective and how WPs can support communication, education and engagement
  - Identify topics where patients' and healthcare professionals' organisations could play a role in increasing awareness of models/methodologies used in medicine development (e.g. multi-investigational product trial design (multi-factorial design); data extrapolation; small populations)
- Reflect on how to build better understanding around biological medicines, immunotherapy, and other areas of special focus in medicines pipeline
- Highlights from the EU–Innovation network to be covered as an agenda item for information and discussion in PCWP/HCPWP plenary meetings

3.4. Strengthen regulatory capability and transparency

3.4.1. Pharmacovigilance

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

Work methodology

Priority activities

- Q1 2018 – WPs are consulted about next steps on the basis of the findings of the survey about awareness of the "additional monitoring" concept
- Q1 2018 – WPs are informed of the findings of the WebrADR project, and future developments and perspective
- Q1 2018 – WPs, through their topic group on digital media and health,
  - Identify points of concern from patients and healthcare professionals around mHealth apps for real world clinical use (e.g. validity, reliability, transparency, interoperability, safety, effectiveness and efficacy)
  - Reflect on the need for a guideline for patients on how to assess open mHealth apps and solutions: privacy, transparency, usability
- 2018/2019 – WPs are informed of EMA/PRAC work on measuring the impact of pharmacovigilance activities
- 2018/2019 – WPs are informed of lessons learnt from the first PRAC public hearing, discuss and endorse recommendations

- 2018/2019 – WPs support early engagement of healthcare professionals and patients in risk minimisation and provide input on the best way to do so in the next revision of EMA GVP Module XVI on risk minimisation measures (RMMs)
- 2018/2019 – WPs explore how patients could look at acceptability and efficacy of proposed RMM aimed specifically to patients
- 2018/2019 – Nominated members of PCWP and HCPWP participate and support the annual EMA Stakeholder Forum on the pharmacovigilance legislation

Activities subject to available resources

- WPs provide input on activities related to better communicating concepts and pharmacovigilance activities to the general public (e.g. related to personalised medicine)
- Organise a joint discussion between EFSA/EMA at a PCWP/HCPWP meeting addressing borderline products and how to work together to inform the public on the risks

3.4.2. Transparency

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

Priority activities

- Q2 2018 – WPs are informed about progress made with the implementation of the EU CT Portal and Database, including the public module of the system
- 2018/2019 – Nominated members of PCWP and HCPWP participate in the EU clinical trials portal and Union database meetings with Stakeholders
- Q2 2018 – 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 subsequent planning around consultation with stakeholders on the publication of individual patient data
- Q2 2018 – WPs are informed about the revised Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products

Activities subject to available resources

- Invite independent organisations that carry out systematic reviews of clinical trials and use regulatory documents from EMA to give a presentation to the WPs and explain the usefulness of this information in medicines reviews

3.5. Ensure effective communication within the EU medicines regulatory network

3.5.1. Building and maintain trust of civil society

Expected outcome

- WPs revisit and further implement actions to increase visibility about stakeholder engagement at EMA
- WPs are involved in activities aimed at bringing input from patients and healthcare professionals into public hearings

Work methodology

Priority activities

- Q2 2018 – WPs are informed of current practice for public reporting of stakeholder engagement and provide input on ways to enhance transparency (e.g. in SA, PRIME, SAGs)
- Q2 2018 – WPs agree on ways to improve visibility of WP meetings
- 2018/2019 – Discuss a training strategy, including possible series of webinars: "the cycle of drug development", "pharmacovigilance throughout the medicine lifecycle", "benefit-risk assessment", "product information"
- 2018/2019 – WPs help to disseminate information about public hearings
- 2018/2019 – WPs provide feedback on EMA's work to produce information materials for patients and healthcare professionals as needed

Activities subject to available resources

- WPs discuss potential areas for improvement on the basis of lessons learnt from public hearings
- WPs are updated on experience with Policy 0040 (handling of competing interests of scientific committees' members and experts), compliance and procedure for selecting experts and provide input on potential areas for improvement
- WPs reflect on what could be impact indicators of EMA pubic engagement activities

3.5.2. Cross-EU communication about medicines

Expected outcome

- WPs are involved in the implementation of EMA's action plan to improve the product information (PI) for EU medicines on the basis of the recommendations from the EC assessment report on current shortcomings in the summary of product characteristics and the package leaflet
- WPs are involved in the development of information materials targeting patients, consumers and healthcare professionals
- WPs coordinate effort to support healthcare professionals, patients and consumers have access to comprehensive, quality and tailored information on medicines

Work methodology

Priority activities

- Q1 2018 – WPs participate in EMA's mapping exercise of on-going initiatives for electronic EU product information
- Q1 2018 – WPs discuss results of mapping exercise and provide feedback on aspects to take into account in the EC/EMA workshop on key principles for the use of electronic formats

- Q3 2018 – WPs participate in EC/EMA workshop and discuss how electronic or digital means can be used to improve accessibility to medicines' information by patients and healthcare professionals
- 2018/2019 – WPs monitor the process for identification of experts through patient and healthcare professional organisations to review product-related communication materials
- 2018-2019 – WPs help disseminate EMA's communications on medicines through their networks, including the newly introduced publication of OMARs (Orphan maintenance assessment report)
- 2018-2019 – WPs are consulted on activities aimed at improving understanding of how biological medicines, including biosimilars, are assessed and approved in the EU
- 2019 – WPs provide feedback on proposals emerging from the EC/EMA workshop

Activities subject to available resources

- WPs are informed about how to find information on the EMA website (webinar following new release of EMA corporate website)
- WPs clarify their position on the need to introduce "Talking Points" in SmPC for healthcare professionals to know how to communicate complex information when discussing with their patients

3.6. Strengthen links with other authorities and stakeholders

3.6.1. Collaboration with stakeholders

Expected outcome

- Increased awareness about EMA's frameworks of interaction with patients, consumers, healthcare professionals and academia
- WPs coordinate efforts to maintain meaningful collaboration with patient, consumer and healthcare professional organisations throughout EMA relocation to new host country

Work methodology

Priority activities

- 2018/2019 – WPs help to raise awareness about EMA's frameworks of interaction with patients, consumers, healthcare professionals and academia to expand EMA's stakeholders database
- 2018/2019 – WPs help disseminate EMA's communications and contribute to give visibility to EMA's WPs work and activities
- 2018/2019 – WPs serve as platforms 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; joint training and capacity building initiatives)
- 2018/2019 – WPs serve as platforms to enable stakeholder engagement in EMA/HTA collaboration
- 2018/2019 – WPs serve as platforms to enable meaningful interaction with the European Reference Networks (ERNs), the European Paediatric Research Network at EMA (EnprEMA) and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

- Q1 2018 – WPs endorse 2017 annual report on the interaction with patients, consumers, healthcare professionals and academia to be presented to the Management Board
- Q1 2019 – WPs endorse 2018 annual report on the interaction with patients, consumers, healthcare professionals and academia to be presented to the Management Board

Activities subject to available resources

- Stimulate the exchange of knowledge and practices with National Competent Authorities (NCAs) and other regions of the world as well as with other EU-Agencies.

3.7. Organisational matters

3.7.1. Implementation of eligibility criteria

Expected outcome

- Patient and consumer organisations comply with eligibility requirements and adhere to streamlined eligibility process

Work methodology

- Q1/Q2 2018 – WPs participate in webinar dedicated to streamlined eligibility process
- Q4 2019 – WPs reflect on outcome of random checks and revise process if needed

3.7.2. Mandates and rules of procedure

Expected outcome

- WPs operate under a revised mandate and rules of procedure

Work methodology

- 2018 – WPs adopt revised mandates and rules of procedure
- 2019 – WPs mandate for 2019-2021 and election of co-chairs to be organised following revised rules of procedure

4. Other PCWP specific work

4.1. Package leaflet

Expected outcome

- Improved package leaflet

Work methodology

- 2018/2019 – Develop recommendations on the inclusion of warnings on the prudent use of antibiotics in the package leaflets of medicines
- 2018/2019 – Make recommendations for EMA medicines overview for Advanced Therapy Medicinal Products (ATMPs)

- 2019 – PCWP is consulted on actions focusing on:
  - how to make the package leaflet easier to understand for EU citizens
  - updating the EU guidance available for companies to prepare the package leaflet
  - strengthening patients' input during the preparation of the package leaflet

4.2. Pharmacovigilance

Expected outcome

- Increased awareness of patients and consumers organisations on the information that can be found in Eudravigilance
- WP to gain a better understanding of which type of risk minimisation measures can be proposed for which risks

Work methodology

- 2018 – WP identifies members interested to
  - Analyse data available in Eudravigilance and comment on the adrreports.eu web site
  - Discuss how to increase awareness amongst patient and consumer organisations about Eudravigilance

4.3. Visibility of the patient contribution in procedures/documents

Expected outcome

- Increased visibility of patient contribution in procedures/ documents

Work methodology

- Q3 2018 – Organise a PCWP information session on patient and consumer engagement in benefit-risk discussions at CHMP, scientific advice, PRIME and adaptive pathways
- 2018/2019 – Propose adding a reference to patient input in the EPAR; to highlight when patients were consulted (SA, SAG, CHMP oral explanation, PRAC) and how (meeting at EMA, in writing,…)
- 2018/2019 – Propose adding a standard sentence to the package leaflet or medicines overview (formerly known as EPAR summary) or other public documents when documents are reviewed by patients and consumers

5. Other HCPWP specific work

5.1. 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

- Q3 2018 – Organise a HCPWP session to learn about scientific and regulatory challenges to be overcome before innovative products can be brought to the market (e.g. cancer immunotherapies)
- 2018/2019 – WP clarifies the role of regulatory stakeholders in clinical guidelines
- 2018/2019 – WP reflects on current practices for communication and uptake of risk minimisation measures by healthcare professionals
- 2018/2019 – WP reflects on an action plan to develop interaction with primary care focused organisations in EMA activities

5.2. Education and clinical research

Expected outcome

- Increased outreach to young clinical researchers and practitioners

Work methodology

- Q2 2018 – Organise a HCPWP session to share practices on how regulatory sciences are being included in fellowships and young researchers training (e.g. ESMO, EHA)
- WP discuss how to promote inclusion of young clinical researchers and practitioners in EMA activities