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Stakeholders and Communication

Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2017

Chairpersons	Status
Isabelle Moulon (EMA)	Agreed by the PCWP on 20 September 2016

1. Meetings scheduled for 2017

- 14 March - Joint PCWP/Healthcare Professionals' Working Party (HCPWP) workshop on personalised medicine
- 15 March - Joint plenary meeting with HCPWP
- 27 June – PCWP plenary meeting
- 19 September – Joint PCWP/HCPWP session on antimicrobial resistance
- 20 September – Joint plenary meeting with HCPWP
- 21 November – Training session
- 22 November – Plenary with all eligible organisations

2. Introduction

The PCWP supports and monitors patients, consumers and their organisations' involvement throughout the Agency's activities. It identifies opportunities and challenges that may need special attention, particularly in the context of the framework of interaction.

The working party will continue to serve as a platform to promote better understanding of the Agency's activities and involvement in European Union (EU)-wide initiatives.

In June 2016 the PCWP started its new mandate for the period 2016-2019.

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Also in June 2016, the EMA multiannual work programme to 2020 was published, building on the EU Medicines Agencies Network Strategy to 2020 and outlining the main initiatives and activities that the Agency will undertake in the coming years, to support achievement of common goals.

The PCWP work plans for the mandate period will be structured around the main themes and objectives of the multiannual programme to 2020 that they will support. The working party will concentrate on theme 1 – contributing to human health – and theme 3 – optimising the operation of the network. More specifically, the following objectives will be pursued:

- 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 network - objectives 3 and 4:
  - ensure effective communication of and within the network;
  - strengthen links with other authorities and with other stakeholders.

The PCWP 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 party will continue to engage in consultations where patients'/consumers' input can bring added value to benefit-risk assessment and decision-making; contribute to EMA activities related with information on medicines and communication with patients/consumers; and support the continuous improvement of the operation of the pharmacovigilance system. As in previous years, the PCWP 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 PCWP will focus its efforts throughout 2017.

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

3.1. Antimicrobial resistance

- A PCWP/HCPWP dedicated information session on antimicrobial resistance (AMR) will be organised in September, aligned with the EMA communication plan on antimicrobial resistance. The aim is to:
  - continue to raise awareness of EMA's work and individual initiatives in the fight against AMR;
  - enhance understanding of how individual EMA initiatives in the human and veterinary areas fit into the broader picture of EMA's work in the fight against AMR;
  - enhance understanding of how EMA supports the overall European and global-level fight against AMR.

3.2. Public health needs and priorities

- Ensure that within appropriate discussions, the different needs of the specific populations are considered (e.g. older people, children, patients with rare diseases). In particular:
  - Provide input into the development of guidance for geriatric packaging and formulations and a Good Pharmacovigilance Practice (GVP) module on medicines used by the older population
  - Provide input into the development of a GVP module on medicines in pregnancy and breastfeeding.
- Contribute to a framework for involvement and consultation of young people in different EMA activities on paediatric medicines
- Contribute to the identification of experts through their organisations to participate in discussions on orphan designation within the COMP.

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

- Contribute to the implementation of the revised action plan regarding medicinal product supply shortages by promoting best practices on communication of shortages

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

4.1. Early access to medicines

- Follow the outcome of EMA's workshop on adaptive pathways;
- Discuss how to increase public understanding around EMA initiatives to promote early access to medicines, including the concept of 'adaptive pathways', the PRIME initiative, and the cooperation with health technology assessment (HTA) bodies and other regulatory agencies;
- Follow up and provide input as appropriate to the EMA initiatives on the use of real-world data and patient registries (also refer to 6.2.).

4.2. Benefit-risk assessment

- Contribute to increased involvement of stakeholders in relevant regulatory activities:
  - Continue to support the identification of experts through patients' and consumers' organisations within relevant therapeutic areas to provide input in 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;
  - Support participation of patients as members of committees;
  - Contribute to the implementation of methodologies for patients' input into benefit-risk discussions at CHMP plenaries.

5. Support patient-focused innovation and contribute to a vibrant life-sciences sector in Europe

5.1. Innovation

- Organise a workshop in March to create awareness about the areas where EMA is supporting personalised medicine. Discussions will take place on:
  - how patients'/healthcare professionals' expectations and concerns may be addressed by clearer communication from EMA to contribute to more informed discussions;
  - the types of initiatives that could be developed to promote dialogue and build upon the competences of different stakeholders in the personalised-medicine lifecycle.

6. Strengthen regulatory capability and transparency

6.1. Regulatory capability

- Follow the outcome of the EMA workshop on impact of pharmacovigilance activities, with a particular focus on actions targeting stakeholder engagement:
  - Using public hearings as a case study for measuring stakeholder engagement (also refer to 7.1.);
  - Assess methods to measure trust and how they can be applied to pharmacovigilance activities;
  - Stimulating patients' and consumers' participation in surveys intended to assess the impact of pharmacovigilance activities for specific medicines;
- Revisit the outcomes of EMA's 2015 workshop on risk minimisation measures and the findings/recommendations from the dedicated HCPWP topic group to identify areas of focus for the period 2017-2019, in close collaboration with the Pharmacovigilance Risk Assessment Committee (PRAC).

6.2. Transparency

- Provide input to the draft reflection paper on making individual patient data from clinical trials available.
- Support EMA's initiatives to achieve its vision for real world evidence:
  - Provide input to the stakeholder engagement strategy;
  - Follow the outcome of the workshops organised in 2016 on social media, mHealth/apps (IMI-WEBrADR project) and big data and contributing with expertise as required, through the continued work of the HCPWP/PCWP topic group on digital health and media (the former topic group on social media);
  - Continue to follow and support as needed the EMA Patient Registry Initiative launched in September 2015;
- Continue to follow up and support, as needed, the implementation of the EMA policy on publication of clinical data for medicinal products for human use and the provisions of the Clinical Trials Regulation regarding the transparency and availability of clinical trial data.

7. Ensure effective communication of and within the network

7.1. Building / maintaining trust of civil society

- Support the Agency in the implementation of public hearings, particularly focusing on raising awareness and understanding of this additional transparency tool;
- Follow the outcome of the social media workshop held in 2016, in order to contribute to the implementation of EMA's social media strategy;
- Support the implementation of the EMA crisis communication plan, in the event of any crisis, to ensure coherent and consistent messages to the public.

7.2. Cross-EU communication about medicines

- Support the EMA activities to improve information on benefit-risk
  - Ensure effective and consistent communication about medicines;
  - Review of EMA communication materials (i.e. package leaflets, EPAR summaries, safety communication, public summary of opinions of orphans, herbal summaries)
- Contribute to EMA communication perception surveys as appropriate;
- Provide input into relevant actions carried out by the EMA to assess the impact of its communications;
- Building on the PCWP/HCPWP information session on biosimilars organised in March 2015, support the implementation of the EMA action plan on biosimilars by reviewing/user testing specific communication materials and contributing to their wider dissemination
- Contribute to discussions on the European medicines web portal.

8. Strengthen links with other stakeholders

8.1. Collaboration with stakeholders

- Promote participation in workshops and conferences by supporting the identification of the most appropriate candidates to participate, including when appropriate, speakers who can address specific topics
- Increase collaboration with civil society representatives through the continued and expanded involvement of patients/consumers when appropriate along the lifecycle of medicines regulation (CHMP plenaries, young people, individual patient database)
- Share best practices through regular feedback from working party members at plenary meetings on initiatives and activities relevant to topics covered within PCWP;
- Maintain close interaction with healthcare professionals:
  - Organise two joint HCPWP-PCWP meetings: 1) Dedicated session on AMR; 2) Workshop on personalised medicine;
  - Regular attendance of one PCWP representative as an observer at HCPWP meetings and vice-versa.

- Contribute to the activities of EMA research networks:
  - Involvement of a PCWP member in the coordinating group of the European Paediatric Research Network at EMA (EnprEMA) and participation in its annual workshop;
  - Involvement of a PCWP member in the coordinating group of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

9. Organisational matters

9.1. Implementation of eligibility criteria

- Review experience gained throughout 2015-2016;
- Initiate reflection on available options for simplifying (re-)evaluation procedures.

9.2. Identification of topics to be addressed by members

- Identify possible topics that could be closely followed and reported directly by PCWP members during its plenary meetings;
- Conclude the work of ongoing topic groups and reflect on the need to initiate new ones (e.g. older people).

9.3. Training and awareness-raising

- Provide training and support to patients and consumers in line with the adopted training strategy
- Monitor and adapt, if necessary, the in-house training session depending on requirements

9.4. Monitoring and reporting

- Monitor the involvement of patients/consumers and their organisations in the Agency's activities and the implementation of the action plan of the framework for interaction.
- Endorse, in conjunction with the HCPWP, an annual report on the progress of the interaction to be presented to the Management Board.