



26 September 2019  
EMA/527554/2019  
Stakeholders and Communication Division

## Meeting summary - Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) joint meeting

25 September 2019, 09:00hrs to 16:00hrs

Co-Chairs: Juan Garcia Burgos (EMA), Kaisa Immonen (PCWP), Ulrich Jäger via Adobe (HCPWP)

### PCWP/HCPWP joint meeting

#### Highlights of previous mandate

EMA presented the highlights of the previous PCWP and HCPWP mandate.

#### 1. Public health focus areas - vaccines

##### 1.1 Council recommendation on vaccine preventable diseases

I. de la Mata (EC) presented the objectives, state of play and actions at EU and member states level following the [Council recommendation on vaccine preventable diseases](#), dated 7 December 2018 (see [presentation](#)). Ms de la Mata highlighted the importance of combatting vaccines hesitancy and presented tools and campaigns to address the myths around vaccination. For more information on the European Commission's work on vaccination visit the following links:

[https://ec.europa.eu/health/vaccination/overview\\_en](https://ec.europa.eu/health/vaccination/overview_en)

[https://ec.europa.eu/health/sites/health/files/vaccination/docs/2019-2022\\_roadmap\\_en.pdf](https://ec.europa.eu/health/sites/health/files/vaccination/docs/2019-2022_roadmap_en.pdf)

##### 1.2 Vaccination portal

In line with the [Council recommendation on vaccine preventable diseases](#), J. Kinsman (ECDC) presented the development of the European Vaccination Information Portal and its main features (see [presentation](#)). He asked for feedback on specific questions and invited those interested to also provide their input after the soft launch in December 2019 in preparation for its official launch on 20 April 2020.

PCWP and HCPWP members highlighted the importance of aligning the information provided in the portal with the information provided at national level.

In order to disseminate the portal as much as possible members suggested to use key internet engine tools to reference to the portal's link.



ECDC asked specific question to PCWP and HCPWP on the development of the European Vaccination Information Portal.

### 1.3 Towards an EMA vaccine outreach strategy

M. Carr (EMA) provided an update on work ongoing within EMA to develop a vaccine outreach strategy, which aims to increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and allow the EU public and healthcare professionals to take well-informed vaccination decisions. M. Carr identified opportunities for collaboration with PCWP and HCPWP in this area (see [presentation](#)).

Participants commented on the different proposals as well as practical aspects for dissemination of the information on vaccines and stressed the importance of a consistent approach (see actions agreed).

During the discussion, PCWP/HCPWP highlighted the need to use multiple dissemination channels in order to achieve maximum coverage (e.g. traditional TV, Social Media).

The need to invest more resources in education was also highlighted.

#### Actions:

- PCWP and HCPWP Members to provide input on questions raised by ECDC on the development of a European Vaccination Information Portal by 10 October 2019
- PCWP and HCPWP Members interested in joining a PCWP/HCPWP topic group to collaborate in the development and implementation of EMA vaccines outreach strategy to contact [PCWPsecretariat@ema.europa.eu](mailto:PCWPsecretariat@ema.europa.eu) or [HCPsecretariat@ema.europa.eu](mailto:HCPsecretariat@ema.europa.eu) by 10 October 2019

Areas of work would include support to development and user-testing of materials; discussion on dissemination channels; identifying challenges and knowledge gaps

- EMA to organise a workshop on vaccines in 2021 as per the PCWP/HCPWP work plan 2019-2022

## 2. Medicines development and evaluation

### 2.1 Impact of pharmacovigilance activities

S. Straus (PRAC chair) gave an overview of the work of the Pharmacovigilance Risk Assessment Committee (PRAC) and its changing landscape. She covered PRAC involvement with HCP and PCOs highlighting the [Valproate](#) case study (see [presentation](#)).

P. Arlett (EMA) complemented and presented the EudraVigilance database, a system for managing and analysing information on suspected adverse reactions to medicines (see [presentation](#)). He also discussed the move to using real world data to support decision making. The [2019-2022 PCWP-HCPWP work-plan](#) specifically includes cooperation with HCP and PCO in the field of reporting of suspected adverse reactions to medicines and real world evidence.

During the discussion it was stressed that it will be important to work with PCWP/HCPWP to see where and how improvements can be made within Pharmacovigilance.

#### Actions:

- Proposals presented by Peter Arlett and Sabine Straus will be discussed further as part of the implementation of the PCWP/HCPWP work plan 2019-2022, including aspects related with data sharing (GDPR application to health research; data anonymization; patient data processing within the eHealth Digital Health Infrastructure and the need for EU funding for platforms to access and analyse electronic healthcare data).

## 2.2 STAMP initiative on medicines repurposing

C. Bouygues (EMA) presented the Safe and Timely Access to Medicines for Patients (STAMP) initiative on a proposal for a repurposing framework for not-for profit organisations and academia; repurposing challenges and the scope and objectives of the proposed repurposing framework (see [presentation](#)).

F. Houyez (EURORDIS) presented the Commission Expert Group on STAMP proposal for the repurposing of off-patent medicines and open call for “champions” within patients or healthcare professionals organisations. He highlighted some outstanding issues to monitor and raised questions to regulators (see [presentation](#)).

### Action:

- EMA will prepare a response to questions raised by F. Houyez in his presentation and will share with the WPs

## 3. Committee feedback

- COMP D. Duarte, T. Leest (COMP) [presentation](#)
- PRAC V. Hivert, R. Anderson (PRAC) [presentation](#)
- CAT R. Pochet, B. Gansbacher (CAT)
- CHMP F. Ventura (CHMP) [presentation](#)
- PDCO D. Athanasiou (PDCO)
- HMPC S. Bager (HMPC) [presentation](#)

## 4. Brainstorming for EMA 25th anniversary

### 3.1 Initial ideas for PCWP/HCPWP dedicated meeting in Feb/Mar 2020

The following dates and events were announced:

On 26 January will be EMA's 25<sup>th</sup> anniversary, there will be several events throughout the year to mark this anniversary that will include aspects of looking ahead.

Members were invited to share ideas on how this event can be ‘celebrated’, especially during the 3-4 March: PCWP/HCPWP meeting as well as the potential to hold an open day in May.

### Action:

- Members interested in joining a small PCWP/HCPWP group to elaborate further on the ideas gathered during the brainstorming to contact [PCWPsecretariat@ema.europa.eu](mailto:PCWPsecretariat@ema.europa.eu) or [HCPsecretariat@ema.europa.eu](mailto:HCPsecretariat@ema.europa.eu) by 10 October 2019