EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

# Meeting summary - PCWP/HCPWP joint virtual meeting

21 and 22 September 2021

Co-Chairs: J. Garcia Burgos (EMA), K. Immonen (PCWP), U. Jäger (HCPWP) via WebEx

## 1. Welcome and introduction

### 1.1 Opening remarks

Juan Garcia-Burgos opened the meeting and welcomed all the participants.

Juan highlighted the focus of the meeting; the latest updates on COVID-19, update on pharmacovigilance activities with impact on healthcare and patient safety, update on the implementation of the Clinical Trials regulation, communication and stakeholder engagement plans for EMA's extended mandate, update on Big Data and DARWIN. Finally the meeting will also present an overview of working party topic prioritisation for 2022, with key dates and activities.

The co-chairs; Ulrich Jäger and Kaisa Immonen introduced themselves and welcomed the participants.

## 2. COVID-19 update

### 2.1 Update on vaccines and therapeutics

Marco Cavaleri (Head of Biological Health Threats and Vaccine Strategy), gave an update on EMA's activities related to COVID-19 vaccines and therapeutics since the last working party meeting in June (see presentation). He highlighted the latest information on vaccines and therapeutics development, assessment and authorisation, including those currently under rolling review and those likely to be authorised shortly. Aspects related to variants, booster and additional doses were also covered.

### 2.2 Safety surveillance

Georgy Genov (Head of Pharmacovigilance) provided an update after one year of safety surveillance (see presentation), including the number of adverse event reports (e.g. more reports received with 4 vaccines than all other centrally authorised products in 1 year), and how these reports are assessed within Eudravigilance. He also highlighted new strategies established to help tailor existing pharmacovigilance approaches, the intense work by the EMA's Safety Committee (PRAC) and its members, the unprecedented international collaboration, and the engagement with the public via the patient and healthcare professional members in EMA's COVID-19 Taskforce, the monthly vaccines safety updates, press conferences, public meetings and the PCWP & HCPWP.

The Working party will be kept up to date on COVID-19 developments and it was also announced that there will be a public meeting on COVID-19 vaccines and therapeutics on 25 November.

### 2.3 Results from user testing information materials on COVID-19 vaccines

Rosa Gonzalez-Quevedo (Public and Stakeholder Engagement) and Claudio Constantino (University of Palermo) explained how feedback received from patients and HCPs has provided valuable input to further improve clarity of information materials (see presentation). EMA and the University of Palermo carried out a survey of patients, consumers, HCPs and organisations to determine if key messages and figures are clear and understood, if any key information relevant for the audience is missing, the best content format and channels for dissemination for lay or professional audiences. The survey also explored perceptions/understandings on COVID-19 vaccination.
A publication with full results is currently being prepared.

## 3. Impact of pharmacovigilance activities on healthcare and patient safety

### 3.1 Enhancing engagement between PRAC and stakeholders PCWP/HCPWP

Priya Bahri (from the Pharmacovigilance office) presented the achievements and plans for evidence-based enhancement of PRAC engagement with patient communities and healthcare professional bodies regarding effective risk minimisation, in the context of the PRAC strategy on measuring the impact of pharmacovigilance activities (see presentation). These have led to the development of a proposal for PRAC 'points-to-consider' which aims:

- to support PRAC for systematic consideration of engagement options and questions to stakeholders;
- to achieve consistent, risk-proportionate and effective engagement;
- support to PRAC decision on risk minimisation measures (RMM).

EMA/PRAC are seeking input from PCWP/HCPWP on the proposed document prior to PRAC adoption and invited members to provide comments on the aspects addressed in the presentation. In addition, the identification of 2-3 PCWP/HCPWP members interested to join the PRAC engagement workstream further developing the 'points-to-consider' document was welcomed. PCWP/HCPWP will be further consulted on the pilot version of the document in 1/2Q2022.

### 3.2 Update on new guidance on risk minimisation measures (GVP modules XVI RMM)

Nuria Semis-Costa (EMA rapporteur for GVP XVI) and Thomas Goedecke (from the Pharmacovigilance office) presented the key aspects emerging from the public consultation launched in February 2021 for revision 3 of Module XVI on risk minimisation measures - selection of tools and effectiveness indicators and its new Addendum II on methods for effectiveness evaluation of risk minimisation measures (see presentation and presentation). Together, these two GVP documents are meant to clarify and enhance tools for risk minimisation measures and strengthen methods for studying the effectiveness of the implementation of risk minimisation measures and the possible need for adjustments of risk minimisation measures in the interest of patient safety. Guidance on the important collaboration with patient and healthcare representatives in the related regulatory processes is included too.

Once all comments from the public consultation have been assessed, this topic will return to PCWP/HCPWP and a separate dedicated call may be considered.

### 3.3 Direct Healthcare Professional Communications: reflection on publication and dissemination of DHPCs.

Morgane de Verdiere (EMA) presented current EMA practices for publication and dissemination of DHPCs (see presentation). Tiago Villanueva (European Union of General Practitioners, UEMO) outlined differences between Member States on how DHPCs are disseminated and made the case that DHPCs should be disseminated directly to GP's by email, post and/or social media; in his view, DHPCs should

be easy to find in the websites of NCAs and more research is needed on awareness and uptake of DHPCs among European GPs (see presentation). Jan de Belie (Pharmaceutical Group of the European Union's representative, PGEU) presented the results of a recent PGEU survey on Pharmacovigilance and Risk Minimisation focusing on the main findings and recommendations related with DHPCs from the community pharmacists' perspective (see presentation).

Following an initial discussion, it was agreed that a dedicated brainstorming session should be organised on broader aspects of dissemination of information, together with NCAs, with the aim to come forward with concrete recommendations.

## 4. Clinical Trials

### 4.1 Clinical Trial Regulation and Clinical Trials Information System (CTIS) - what changes in 2022

Fergus Sweeney (Head of Clinical Studies and Manufacturing) provided an update on what is expected to change from 2022, when the Regulation becomes applicable (see presentation). The authorisation and oversight of clinical trials remains the responsibility of Member States**,** with EMA managing the Clinical Trials Information System (CTIS) and supervising content publication on the public website.

### 4.2 CTIS: functionalities and support for clinical trial sponsors, availability of clinical trial data to the public

Fia Westerholm (Data Analytics and Methods) presented EMA's work on CTIS related with support and information to sponsors, opportunities for engagement, and the public portal enabling access to clinical trial data (see presentation).
PCWP/HCPWP members will be kept up to date on the implementation of the Clinical Trials Regulation and the launch of the CTIS platform and their support in cascading information on planned CTIS training events will be welcomed.

## 5. Update on Big Data

### 5.1 Big Data Steering Group updated workplan and Clinical Trials Raw data project.

Francois Domergue presented the recently updated workplan of the Big Data Steering Group (August 2021) and also provided an update on the DARWIN EU project. He emphasised key progress to date and future highlights.
Eftychia Eirini Psarelli gave afterwards a presentation on EMA's clinical trials raw data project which aims to determine the regulatory benefit of access to raw data by building capacity and capability to receive, store, manage and analyse raw data. The project will put in place procedures and safeguards to process raw data, including clinical and non-clinical data, in accordance with data protection legislation (see presentation). There was a call for interest among the PCWP for a patient representative to join Advisory group on Raw Data (interested members to write directly to Eftychia).

### 5.2 Outcome of public consultation on the registry-based studies guideline

Further to the WPs involvement in the consultation phases of registry-based studies guideline in 2020, Xavier Kurz (Head of Data Analytics) provided an overview of the main comments emerging from the public consultation and how they have been reflected in the final text which is expected to be published in Q4 2021 (see presentation).

## 6. Looking ahead into 2022

### 6.1 PCWP/HCPWP workplan 2019-2022 and EMAN Strategy to 2025: topic prioritisation for

**2022**

Ivana Silva (from the Public and Stakeholder Engagement Department) provided an overview of activities in the WPs work plans that could be areas of focus for 2022 in alignment with the European Medicines Agencies Network strategy to 2025 (see presentation). These were considered during the discussion that followed, for prioritisation of topics and support to shaping the WPs' meetings in November 2021 as well as March and June 2022. Comments received during the discussion will also be used for drafting the high-level structure of the 2022-2025 PCWP/HCPWP work plan; the drafting and endorsement process of the work plan will follow the same approach as for the previous mandate.

### 6.2 Meetings for 2022 and related aspects; 6.3 New mandate 2022-2025 and co-chair elections; 6.4 Launch of annual re-assessment of eligibility

Nathalie Bere (from the Public and Stakeholder Engagement Department) presented on agreed dates for upcoming meetings and planned format (virtual/F2F) (see presentation). Members were informed of key timelines for the WPs' next mandate and co-chair elections and about the launch on 30 September of the annual re-assessment of eligibility, a pre-requisite to apply for the WPs' membership for the mandate 2022-2025. The launch call for the new PCWP/HCPWP mandate will be circulated to all eligible organisations in early March 2022.

## 7. Update on EMA's Extended mandate

### 7.1 Progress update

Hilde Boone (Head of Institutional and Policy) gave an update on the EC legal proposal for extending the mandate of EMA and how EMA is preparing for its implementation once finalised (see presentation).

### 7.2 Plans for communication and stakeholder engagement

Melanie Carr (Head of Stakeholders and Communication) outlined EMA's plans to communicate and engage with its external stakeholders and partners (see presentation).

PCWP/HCPWP members will be kept informed of progress on preparations for the implementation of the extended mandate as well as the plans for Communication and Stakeholders' Engagement.

## 8. AOB

### 8.1 Pronunciation of complex invented names

Alexios Skarlatos (Head of Labelling Office) explained that in the past months the EMA Name Review Group (NRG) identified a trend of increasingly complex invented names submitted by pharmaceutical companies. There is a concern that the correct identification of the medicine considering aspects of pronunciation may be impacted potentially increasing the risk of confusion and medication errors. The NRG would like to consult with interested PCWP/HCPWP members on issues related to readability and pronunciation and the proposed NRG guideline wording. A dedicated TC meeting will be organised.

### 8.2 Call for new members in MB, PRAC and CAT

Members were informed of the calls for expression of interest for new civil society representatives.

Link: https://ec.europa.eu/health/documents/public_call/call_index_en