9 January 2023
EMA/775191/2021
Stakeholders and Communication Division

Meeting summary – PCWP/HCPWP annual meeting with all eligible organisations

15 November 2022, 09:00hrs to 17:00hrs – meeting room: 2A

Co-Chairs: Juan Garcia-Burgos (EMA) and Rosa Giuliani (HCPWP)

1. Introduction

1. **Opening remarks**

Juan Garcia-Burgos opened the meeting, welcomed all participants and highlighted the focus of the meeting. He explained that a new PCWP co-chair would be elected in December. The HCPWP co-chair, Rosa Giuliani, also welcomed all participants and gave her introductory remarks.

2. Patient involvement in medicines development and regulation

2.1 Report from EMA Multistakeholder Workshop on Patient Experience Data

Rosa Gonzalez-Quevedo (EMA) outlined the importance of patient experience data and the current state of play in the European Union. A multistakeholder workshop was held on 21 September and the objectives included reaching a common understanding of definitions of patient experience for different stakeholders, understanding the challenges and actions required for collecting and incorporating patient data into medicine's development and regulation and leveraging its use.

A multistakeholder approach to these objectives and next steps is needed as well as alignment and collaboration with the guidance work of ICH and the DARWIN EU project.

All presentations, recording and the summary report can be found here

2.2 CIOMS report on 'Patient involvement in the development, regulation and safe use of medicines'

François Houÿez (EURORDIS) presented the report on *Patient involvement in the development, regulation and safe use of medicines*. Patients were members of the working group responsible for the drafting along with regulators, industry, academia and international organisations. This report is a reference book on the matter, and the intention is to disseminate broadly, to collect any comments from reader, and to encourage ideas and suggestions for all actors who can benefit from involving patients. It can be downloaded as a free pdf and organisations are encouraged to further disseminate it amongst their networks.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Report: Patient involvement in the development, regulation and safe use of medicines

Lembit Rägo (CIOMS) complemented with information on the CIOMS (https://doi.org/10.56759/ocef1297) and ICH (https://doi.org/10.56759/eftb6868) glossaries. The glossaries have recommended definitions of terms used in pharmacovigilance and related drug development fields used by CIOMS and ICH working groups for informational and educational purposes. The glossaries will be periodically updated and can be useful to support training. CIOMS welcomes feedback on the glossaries.

3. Availability and accessibility of medicines

3.1 Task Force on availability of authorised medicines (TF AAM)

- Update on the TF AAM activities

Monica Dias (EMA) and Hugues Malonne (HMA) provided an update on the activities of the HMA/EMA Task Force, focussing on its new structure and composition, Work programme to 2025, updated terms of reference and 3-year mandate. Please refer to the presentation for more details.

This Task Force was established by EU regulators in 2016 to develop and coordinate actions for better prevention, identification, management of and communication on issues that can affect the availability of medicines, in order to improve continuity of supply of human and veterinary medicines across Europe.

- Reporting of shortages by organisations

Inga Abed (EMA) presented on the EMA plans to launch a pilot to explore the added value of shortage reports from EU eligible patient and healthcare professional organisations. Additional information is available in the supporting presentation. The idea of running such a pilot was well received by participants.

Organisations are invited to participate, and a specific call will be launched as a follow up of the meeting.

- Preparation for multistakeholder workshop in 2023

Monica Dias shared the rationale and preliminary outline for an HMA/EMA multistakeholder workshop on shortages to be held on 1-2 March 2023 (please refer to presentation). Participants welcomed the timely organisation of this workshop and pointed to the need to further work towards shifting from mitigation to prevention of shortages. Some participants highlighted the importance of discussing the impact of environmental policies on the availability of raw materials and medicines. Other participants suggested to use this opportunity to clarify the inter-institutional cooperation with HERA, the interactions with payers and the extent of EMA's remit for shortages of medical devices. A request was also made to consider a breakout session on biosimilars.

Any further suggestions to be sent to the Secretariat by 30 November.

- Update on EU guidance on shortage prevention and communication to the public

Inga Abed reminded the audience of the aim and scope of this guidance and shared the results of an awareness survey conducted prior to the meeting (refer to presentation for more details).

Organisations are kindly asked to promote the single point of entry to shortage information to increase awareness.

3.2 Access to medicines

- "Sequential decision making": how regulatory and HTA activities interconnect under the

new HTA Regulation

Valentina Barbuto (Policy Officer from DG Sante) set the scene by describing the background to the Health Technology Assessment (HTA) regulation and the timeline of implementation. She referred to the anticipated interactions with patients and healthcare professionals and concluded by emphasising the importance of co-creation of this new system and working together towards inclusivity and transparency to ensure secure and smooth implementation.

Michael Berntgen (EMA) followed this introduction with a background of the collaboration between regulators and HTA bodies at the European level and illustrated with specific examples. He then explained how collaboration is embedded in the new HTA regulation and indicated the transversal elements in the new Regulation that would facilitate such work. Finally, he emphasised the joint EMA/EUnetHTA21 workplan and concluded that discussions across decision-makers are crucial to better guide on evidence requirements throughout the medicine's lifecycle, including post-authorisation evidence. The value of value of collaboration at the regulatory/HTA interface as well as with all stakeholders was emphasised and there are multiple opportunities to progress evidence methodologies to facilitate the design of development plans and support assessment work, within the respective remits.

- The delivery under the EMA/EUnetHTA 21 work plan: focus on engagement with patients and HCPs

Anne Willemsen (ZIN, EUnetHTA21) explained the different mandates of HTA and regulators and introduced participants to EUnetHTA 21 that will support the implementation of the HTA regulation. She stressed the continuous collaboration between EMA and EUnetHTA21 and then handed over to Stephanie Said (G-BA, EUnetHTA 21) who confirmed that the contribution of patients and clinical experts is of high value and helps to contextualise the needs and experiences of those who are either affected by a particular disease or are dealing with it in their daily lives.

A question-and-answer session was moderated by Daniel Ritter (G-BA, EUnetHTA 21) and Maggie Galbraith (HAS, EUnetHTA 21).

The session closed with a discussion of the role of patients and healthcare professionals at the regulatory/HTA intersection as well as their experiences and challenges in terms of access to medicines in health care systems and identification of topics where EMA/HTA cooperation could help. To complement this discussion, organisations were invited to complete a survey to gather further input.

4. Antimicrobial resistance and other emerging health threats

4.1 Lessons learnt from COVID-19

Melanie Carr (EMA) gave a presentation addressing the impact of COVID-19 on medicine regulatory activities, the focus areas of lessons learnt, some preliminary conclusions and priority areas for future (please refer to the presentation).
Participants were invited to share comments/suggestions for follow up action by 7 December.

4.2 Preparation for multistakeholder workshop on AMR in 2023

Radu Botgros (EMA) provided an overview of EMA activities related with antimicrobial resistance and shared the initial scope for a multistakeholder workshop on AMR to be organised on 14 November 2023 (see presentation). Participants welcomed the opportunity to provide early input into the programme of the workshop and praised the scoping of the workshop under the One Health approach. The need to consider all microbial agents was acknowledged but focus on antibiotics was preferred. Some participants underlined the importance of bringing different stakeholders around the table, including

funding institutions as incentives are a critical aspect of the discussion and expected to be addressed in the context of the review of the pharmaceutical legislation. Participants expressed a preference to have a workshop focusing on what EMA can do whilst having ECDC and other intuitions contributing to the discussion. Some participants requested that environmental aspects were considered in the shaping up of the programme as well as addressing the prudent use of antibiotics.

Any further suggestions for be sent to the Secretariat by 7 December.

A draft agenda will be prepared and shared at an upcoming PCWP/HCWPW meeting.

Wrap up / end of meeting

No other business was suggested.