EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 January 2022
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Stakeholders and Communication Division

Meeting summary - Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations

24 November 2021

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

Welcome and introduction

1.1 Opening remarks

Juan Garcia-Burgos opened the meeting, welcomed all participants and highlighted the focus of the meeting. The co-chairs, Ulrich Jäger and Kaisa Immonen, also welcomed all participants and gave their introductory remarks.

1. Update on ongoing initiatives

1.1 European collaboration between regulators and Health Technology Assessment (HTA) bodies

With the completion of EUnetHTA Joint Action (JA) 3, EMA's cooperation with HTA bodies will continue in the context of the new EUnetHTA21 consortium as well as the new Heads of Agencies group (HAG) of European HTA bodies (HAG). Michael Berntgen (EMA) and Bruno Sepodes (CHMP) presented on what are the priority areas for cooperation and how these are expected to support transitioning into the future legal framework – the HTA regulation (see video and presentation). It was agreed to continue addressing this topic in upcoming PCWP/HCPWP meetings.

1.2 ICH E8 Guideline on general considerations for clinical studies

Fergus Sweeney (EMA) presented the topic and Spiros Vamvakas (EMA) then took over to provide an update on progress made with ICH GCP E8(R1) on general consideration for clinical trials, particularly focusing on aspects related with patient engagement (see video and presentation). The guideline was published in October 2021 and will come into effect in April 2022. Everyone involved in the conduct of clinical trials is advised to read this guideline. Members are invited to promote awareness amongst their networks.

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1.3 Implementation of the clinical trials regulation

Pieter Vankeerberghen (EMA) provided an update on what is expected to change from 2022, when the Clinical Trials Regulation becomes applicable and CTIS will go live. The authorisation and oversight of clinical trials remains the responsibility of Member States**,** with EMA managing CTIS and supervising content publication on the public website (see video and presentation). Members will be kept up to date on the continuous implementation of CTIS and can find related training material in the following links:

- Clinical Trials Information System (CTIS): online modular training programme | European Medicines Agency (europa.eu)
- Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS | European Medicines Agency (europa.eu)

1.4 Medicine repurposing pilot project

César Hernández García (HMA) and Christelle Bouygues (EMA) gave an overview of the medicine repurposing pilot project (see video and presentation). The key aims are to facilitate the regulatory recognition of new indications for well-established, authorised medicines, outline the process to support not-for-profit organisations and academia and to help champions present their proposed repurposing project to regulatory authorities and seek advice. The pilot went live at the end of October and there is a Q&A document on EMAs website here.

The Working parties will be informed of the pilot outcome in due course.

2. Capturing challenges and priorities for 2021 and beyond

2.1 Civil society members in EMA scientific committees: an overview

Maria Mavris (EMA) gave a presentation on Civil society members in EMA scientific committees, including a historical overview of the committees' civil society memberships, the nomination process by the EC and the role of the members (see video and presentation). She also explained the support that is provided to the members by the EMA engagement team, including regular meetings and a dedicated contact point. Members will be kept up to date on activities of civil society members and the relevant annual meetings.

2.2. Future challenges and key priorities for patient and healthcare professionals' organisations

Ulrich Jäger, presenting on behalf of both HCPWP and PCWP co-chairs, shared the preliminary results of a survey which had been sent to all eligible patient and healthcare professional organisations prior to the meeting. The aim of the survey was to gather feedback from organisations on their top three priorities to 2025 (within the remit of EMAN Strategy to 2025) with the top three associated challenges. The survey also asked how these can be addressed within PCWP and HCPWP and what topics they feel should be re-prioritised. A lot of rich information was gathered from many organisations, as well as a productive post presentation slido poll and discussion.

It was agreed that EMA will further review all the feedback received and will consider how and where it can translate into actions and priorities to be incorporated into the next working parties' workplan. This will then be re-discussed at the next working party meetings in March and June 2022.

3. AOB

- The meeting dates for 2022 were presented and shared in the post mail
- The update of the framework of Engagement with patients and consumers was presented and working party members were given until 13 December for any comments.
- Members were encouraged to disseminate information on EMA's fourth Public stakeholder meeting on COVID-19 vaccines and therapeutics in the EU held on 25 November
- It was highlighted that the 10-year anniversary of the Framework of Interaction with healthcare professionals was taking place on 15 December, with some relevant publications on the day here