29 September 2022
EMA/792889/2022
Stakeholders and Communication Division

# PCWP/HCPWP joint meeting

22 September 2022

Chair: J. Garcia Burgos (EMA), Marilena Vrana (PCWP) and Rosa Giuliani (HCPWP)

## Welcome and introduction

Juan Garcia-Burgos (EMA) opened the meeting, welcoming all participants and congratulating the newly elected PCWP and HCPWP co-chairs.

## 1. Update on COVID-19 and Monkeypox

Marco Cavaleri (EMA) gave an update on EMA's activities related to COVID-19 vaccines and therapeutics since the last working party meeting in June. He highlighted the overall status of COVID-19 vaccines in the EU, including adapted vaccines for use as boosters. Three adapted COVID mRNA vaccines have been approved to better match current variants of concern: two bivalent original/Omicron BA.1 and one bivalent original/Omicron BA.4-5. EMA-ECDC has recommended additional booster doses in adults above 60 years of age, immunocompromised subjects, individuals with underlying conditions and pregnant women. Healthcare professionals should also be vaccinated with adapted vaccines. There are also other vaccines in the pipeline which may come to rapid approval to enlarge current portfolio of options.

He also explained the status of monkeypox vaccines and therapeutics in the EU. There is one vaccine and one antiviral treatment authorised for use against monkeypox disease in the EU. The monkeypox outbreak in Europe is now slowing down and plateauing in many countries. (See presentation).

## 2. Update on ongoing activities

### 2.1 Progress report on PCWP/HCPWP discussion on clinical trials and contribution to ICH guidance on good clinical practice

Piotr Szymanski (ESC) and Francois Houyez (EURORDIS) provided a progress report since the initial discussion held in June. (See presentation).

As agreed at the June meeting, points emerging from the discussion were organised against a selection of the ICH draft principles and presented for further discussion. More principles may require consideration following the discussion and additional follow up will take place in the context of a drafting group. A call for volunteers to support Francois and Piotr in the drafting group was organised between 8 and 15 September and additional volunteers can still join by 27 September.

A draft PCWP/HCPWP statement is expected to be prepared by end October/ early November and will be subject to PCWP/HCPWP consultation in writing during November/December. This will inform concrete input

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to be provided to ICH during the public consultation phase.

The start of the 6-month public consultation on the ICH E6(R3) GCP draft principles and Annex 1 is expected after the ICH meeting in Incheon/Korea (Mid Nov 2022). An EMA multistakeholder workshop is planned for Q1 2023 as part of the ACT EU (priority action 4) where more input will be collected and discussed.

The Concept paper for Annex 2 ICH E6(R3) GCP is expected in Q1 2023.

**2.2 Feedback from the ATMPs dedicated webinar on 28 June**

Due to interest following a presentation in the March joint PCWP/HCPWP, a webinar was held in the margin of the working party meetings to address topics such as manufacture of ATMPs (industrial versus hospital), obstacles to manufacture and a pilot to support academic developers.

A follow up survey with participants concluded that this format was very helpful and clarified the role of EMA in ATMP regulation. It was also helpful to hear from other patients and healthcare professionals. EMA will continue to explore this option. Presentations and recordings are linked in the presentation.

Regarding the pilot to support academic developers of ATMPs – a news item will be published on the EMA website in the next few weeks that will be shared with the PCWP/HCPWP. Any WP member who is developing candidate ATMP or is working in an academic centre developing such a product is welcome to contact Patrick.Celis@ema.europa.eu directly for information.

**2.3 Update on pharmacovigilance and new initiatives for risk minimisation**

Priya Bahri provided an update on new initiatives to enhance engagement with the safety committee, PRAC. Three activities were described and include i) the start of a commissioned study on integration of risk minimisation measures (RMM) in clinical guidelines with examples for five major disease areas, ii) an ongoing pilot of PRAC Risk Minimisation Alliance (PRISMA) involving patient and healthcare professional representatives and iii) the development of a reflection paper on digital support to risk minimisation in 2023. More information is available in the presentation.

## 3. Members' voice

**3.1 Consumer group surveys on drug shortages**

Ancel.la Santos (BEUC) presented the results of consumer surveys on medicine shortages carried out in Belgium, Spain, Italy, Portugal and Norway in 2019 and 2020. Medicine shortages are a growing public health problem in the European Union with rising shortage notifications and detrimental effect on consumers' health and their quality of life. Survey results can be found in the presentation.

**3.2 European Lung Health Group Policy Brief on medicines for rare diseases and children**

Isabel Proaño (EFA) presented the policy recommendations of the European Lung Health Group on the review of the Orphan medicinal products and paediatric legislations. The recommendations include calls for improved basic research in respiratory diseases, a framework to steer investment into unmet needs and the setup of a uniform and transparent regulatory and access pathway focused on delivering innovation quickly and equitably to patients. To read more about the recommendations, see presentation.

**3.3 The Asthma and COPD patients' digital journey in Europe, a survey report**

Isabel Proaño (EFA) presented results from interviews with 970 asthma and COPD patients conducted in 2021 from five countries with 50 questions on their views and use of digital health technologies for access, diagnosis, treatment, care as well as their expectations on health data and digital empowerment. The main results were presented with links to the full survey available.

## Wrap up / end of meeting

Before concluding the meeting, Juan Garcia-Burgos (EMA) reminded the working parties of the following points:

- **Perception survey – deadline for feedback by Friday, 30 September 2022**
  The aim of the survey is to collect feedback on EMA's external communication from patients, consumers, healthcare professionals, academics, media, pharmaceutical industry, and other regulators.
  https://www.ema.europa.eu/en/news/have-your-say-emas-communications-how-are-we-doing-0
  Members are invited to participate by 30 September

- **Biosimilar interchangeability**
  EMA and the Heads of Medicines Agencies (HMA) have issued a joint statement confirming that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or with an equivalent biosimilar. For more information, please refer to the news item
  This topic will be added in a future PCWP/HCPWP meeting.