30 September 2023
EMA/89221/2023
Stakeholders and Communication Division

PCWP/HCPWP joint meeting

19 and 20 September 2023

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

Welcome and introduction

Juan Garcia Burgos (EMA) opened the meeting, welcoming all participants in person and online as well as the Working Party co-chairs.

1. Patient and HCP representatives in EMA groups

Patients and healthcare professionals are part of many groups at EMA and provide the valuable perspective of their stakeholder group to the discussions. Representatives of three such groups (ETF, BDSG and MSSG) were invited to present the group they are involved in, its activities and their role within it.

The **Emergency Task Force (ETF)**, presented by Anita Simonds (ERS) and Jose Drabwell (IPOPI), is a multidisciplinary expert group established by Regulation (EU) No 2022/123 within the EMA in preparation for and during a health emergency to provide scientific advice and to review scientific data on medicinal products targeting the emergency, to provide recommendations with regards to the use of such medicinal products and to provide scientific support to facilitate clinical trials for such medicinal products. Rules of Procedure

The **HMA/EMA Joint Big Data Steering Group (BDSG),** presented by Ioana Agache (EAACI) and George Paliouras (WDO) serves as a strategic steering group on analysis and use of data that are received, analysed, or advised upon by the network. The initial scope of the activities of the BDSG was provided by the 2020 recommendations of the Big Data Task Force (10-priority recommendations) with one additional priority recommendation covering the veterinary domain. Mandate

The **Medicines Shortages Steering Group (MSSG)**, presented by Charlotte Roffiaen (EPHA) and Piera Polidori (EAHP) ensures a robust response to major events/public health emergencies, and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products or those related to the quality, safety and efficacy of medicinal products. Rules of Procedure.

Please see presentations for more information.

With an increase of EMA groups involving patients and HCP, a discussion followed on how to best support the members in these groups and how to ensure bilateral exchange of information with the PCWP and HCPWP. This topic will be further discussed with the working parties at future meetings.

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2. Crisis preparedness and management

2.1. Clinical trials in emergency situations

Manuela Mura (EMA) Scientific Officer, Health Threats and Vaccines Strategy described the role of the Emergency Task Force (ETF) in clinical trials in emergency situations and the initiative supported by EMA/HERA and the European Commission to organise a sustainable network of clinical trial sites to remain ready for potential emergencies. A Lessons-learned workshop on Clinical Trials in Public Health Emergencies, chaired by the Director General of SANTE for Health and Food Safety was held on 9 June 2023 with the objective of reviewing processes for clinical trials during emergencies, exploring actions to expedite approval and to define a more integrated framework for clinical trials during and in preparation for emergencies. She concluded by describing initiatives to make the European Union more attractive for investigational clinical research such as ACT EU and Vaccelerate. See presentation for more details.

3. Big Data

3.1. Big Data Steering Group updates

Denise Umuhire (EMA) Pharmacoepidemiology and RWE Specialist, focused on Patient Experience Data (PED) which is not yet systematically included in all aspects of medicines development and regulation. She highlighted the workshop on Patient Experience Data of September 2022 and a follow up meeting that took place in January 2023, which have led to PED being included in the workplan of the BDSG. Key actions of the workplan that involve patients and healthcare professionals were described. She outlined the short-, medium- and long-term approach for establishing the value of PED. See presentation for more details.

Kelly Plueschke (EMA) Scientific administrator, Real World Evidence talked about the workshop on the use of registries that will take place in February 2024 and asked for volunteers to work on scientific content.

Key BDSG events for this year include the Artificial Intelligence workshop (20-21 November 2023) and the Multistakeholder Big Data forum on 4 December 2023.

4. Medicine shortages

4.1. Results from surveys on medicine shortages

Stephanie Marschler (EMA) Trainee in Stakeholders Engagement Department presented the results of surveys sent to patients and healthcare professionals to gain insight into how they were informed about the shortages of amoxicillin, Ozempic and Visudyne, which resources they then consulted and an open question on which information they required but could not find. The surveys to patients were conducted in all official EU languages. Inga Abed (EMA) Medical writer, Medical and Health Information presented results of a survey conducted with National competent authorities (NCAs) on their communication practices on the shortages of the same medicines. The surveys were carried out on behalf of HMA-EMA task force on availability of authorised medicines. Conclusions of the surveys include that shortage catalogues play a key role in communication provided by regulators. They are used as a confirmatory source by HCP however use by patients is lower indicating a need to raise awareness of these catalogues and the PCWP and HCPWP are requested to assist. Please see presentation for more information.

4.2. EU list of critical medicines

Joao Francisco Ferreira (EMA), Medicines and Medical Devices Shortages Specialist, presented an update on the development of the "EU list of critical medicines" under the joint HMA/EMA Joint Task Force on Availability of authorised medicines for Human and veterinary use (TF AAM).

This builds on work already done during the European Commission's Structured Dialogue in 2021, which included patient and HCP organisations.

He described the objectives and scope of the EU list of critical medicines along with the methodology and criteria adopted by the EMA/HMA TF-AAM methodology on 29 June 2023 that takes into account two criteria: 1. therapeutic importance, and 2. availability of alternatives". The methodology allows Member States to list medicines in three categories: 1. "critical medicine", 2. "at-risk medicine", or 3. "other medicine".

This work has begun and will be carried out in two phases:

Phase 1: publication of a first version based on existing, published national lists of critical medicines or lists currently under development in the EU/EEA countries; Phase 1 started in August and the first version of the list will be published by the end of 2023.

Phase 2: review of medicines in therapeutic groups of major interest, with subsequent version releases.

In conclusion, continued engagement with patients, consumers and HCP is planned with a follow up to be presented in the November PCWP/HCPWP meeting with all eligible organisations. For more information, please see presentation.

4.3. Update on preparedness activities

Emilija Matelytė (EMA) Medicines and Medical Devices Shortages Officer, presented an update on preparedness activities for medicine shortages building on the information shared by Monica Dias (EMA) Head of Supply and Availability of Medicines and Devices, in June 2023.

At the beginning of the year, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Board of DG HERA agreed on the need to prepare for the upcoming autumn and winter season. Therefore, a joint EMA/HERA exercise was launched to identify any gaps between supply and demand of a subset of antibiotics to understand whether any shortfalls could be expected in the autumn and winter season of 2023-2024.

An overview of the exercise as well as the outcomes were described. Based on the findings of the exercise, MSSG issued recommendations for proactive actions to be undertaken by all stakeholders. This also includes the prudent use of antibiotics and the need to avoid stockpiling by all stakeholders, amongst others. For more information, please see presentation.

5. Patient information on medicines

5.1. Publication on 'Communication of anticancer drug benefits and related uncertainties to patients and clinicians'

Courtney Davis (HAI) presented a study recently published in the BMJ and sponsored by HAI, which compared information in the assessment reports (EPARS) of a number of authorised medicines for cancer with the product information (SmPC and PL). The results highlighted some gaps in what information from the EPAR is reflected in the product information. It also showed how patients can misunderstand regulatory information. The study points to some good practices that could be used in the review of the QRD template that has now started (see topic 5.2.). Several aspects of the findings could be applicable to other health conditions.

In the discussion it was pointed out that healthcare professionals, too, sometimes use package leaflets for information. Another comment on the inclusion of information on benefits was that at the time of the marketing authorisation, some benefits are not yet captured and emerge post-authorisation. Juan Garcia confirmed that the 'key information section' or 'fact box' will be considered during the review of the QRD template. Please see the presentation for more details. The published article is available here.

5.2. Revision of QRD template for package leaflet (PL) improvement

Monica Buch and Alexios Skarlatos (EMA) gave an overview of the new initiative to review the QRD template for product information on human medicines. QRD refers to the fact that the template is developed and maintained by EMA's Working Group on Quality Review of Documents. As Monica explained, the template has undergone several minor updates but few major changes since its creation in 1996, the last major revision having been in 2011. The current initiative follows up on the European Commission's recommendations from its 2017 report on shortcomings in product information and the EMA's action plan, the implementation of which was delayed due to Brexit and the Business Continuity Plan in the following years. EMA is already progressing on electronic product information (e-PIL) formats, but the current revision will focus on the content of the document. Room for improvement was identified in shortening the leaflet, improving its readability, possible inclusion of 'key information', focus on patient-relevant content, and enhancing patient input into and user-testing of leaflets. The project started in June 2023 with the creation of a working sub-group of the QRD group. This includes nine national members, relevant EMA staff, and representatives of patients, consumers and healthcare professionals. The project is envisaged to be completed by end of 2024, and Monica explained the steps that will be followed. For more information see the presentation.

In the discussion part, it was clarified that the review mainly focuses on the PL, but the QRD sub-group will also consider changes to the SmPC if they can be made without a review of the official European Commission SmPC guideline. After the meeting, a call for interest to participate was circulated and three representatives were selected to the working group. The wider group will also be involved in further steps.

6. Clinical trials

6.1. ICH E21 Concept paper on inclusion of pregnant and breastfeeding individuals in clinical trials

Corinne de Vries (EMA) presented a new ICH concept paper E21 on "Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials" that was published in June 2023. She recalled a clear message from a PCWP/HCPWP workshop on safe use of medicines during pregnancy and breastfeeding (2020) to generate more data on the benefits and risks of medicines in pregnant and breastfeeding women throughout a medicine's lifecycle, and to change the routine exclusion of pregnant and breastfeeding women from clinical trials. As a case study, Corinne spoke about the COVID-19 vaccine trials. See the presentation for more details.

In the discussion, ethical implications of some potential solutions were raised. Corinne explained that ethicists are being consulted and the objective is not to encourage or incentivise women to participate for reasons like financial gain or better care, but to shift the approach from exclusion to inclusion unless there are reasons not to. A question was raised about having more information on pre-clinical research, for example the use of biomarkers to predict toxicity, better baseline risk information, and randomisation strategies by gender in case different medicines are tested in a platform trial. Corinne said the pre-clinical guidance was revised a year ago and is not being reopened but for example comparator groups and baseline risk information are being considered. She welcomed the point on randomisation and also said following up women who become pregnant during trials is an opportunity to use routinely collected health data.

6.2. ACT EU Multi-stakeholder platform (MSP) advisory group update

Ana Zanoletty (EMA) gave an overview of the ACT EU MSP and Maria Filancia (EMA) explained the call for interest to participate in the advisory group, reminding the working groups that the advisory group is only one part of the MSP and there will be other opportunities to contribute such as multistakeholder events. See the presentation for more details. More information about ACT EU and the MSP can be found on the dedicated page on the ACT EU website.

In answer to a question about tasks, Maria explained that a concept paper on the MSP is currently being updated and will be published with the call for expression of interest so it can be a reference point, and there is also the ACT EU annual plan. The advisory group will provide more focused discussion on the revision of the work plan, check if the initiative is going in the right direction, and if stakeholders identify other priorities. The stakeholders will also advise on which expertise needs to be included in future multistakeholder events, and there will be the option to form topic groups if needed.

Following the meeting, the ACT EU multi stakeholder platform concept paper was published and the expression of interest for the MSP advisory group was launched. Targeted emails were sent to all concerned stakeholders. The call is closing on the 24th of November. For more details: Multi-stakeholder platform (europa.eu).

7. EMA communications

7.1. Social media strategy

Camelia Enachioiu (EMA) gave a presentation on the social media strategy (see the presentation for more details). In the discussion, there was a question whether EMA may sometimes create unnecessary panic with negative information, given this is perceived more strongly than positive (e.g. myocardial side effects of vaccines). Camelia emphasised that the aim is to be transparent and offer the correct information, rather than negative or positive. In the absence of correct information, misinformation would fill the gap. She acknowledged that on social media, attention spans are short and emotional are sticker, and therefore more effort could be put into conveying technical scientific information better for lay people and use rich media formats that 'stick' more. Regarding reaching central eastern Europe more effectively, there was a question about Telegram. This is not included as a potential channel at the moment but EMA is keeping a close eye on possible benefits and disadvantages of embracing new platforms. To a question about facebook, frequently used by patients like a support group, it was stated that currently EMA will not be present on facebook for reasons related to the algorithm and human resources needed to manage a page and interactions.

Answers to questions submitted via the chat:

- EMA regularly uses audience insights such as questions to LinkedIn Live and comments on posts to identify trends in interests, misinformation or disinformation. EMA uses a professional tool, as well as the platforms themselves to get input. More false narratives are seen on Twitter, Reddit and Facebook around vaccines compared to Linkedin.
- EMA is following European Commission guidelines regarding X (Twitter) and for now continues to be present and share newsworthy content. Engaging directly with users on X is time-consuming and has no positive effect, despite arguments and facts presented, and for this reason EMA stopped doing this.
- User-testing of videos and graphics has been done for some of EMA's information materials when time allowed for it.
- EMA is still producing physical information materials although less than before. There are also efforts in place to make the website as accessible as possible for people with for example visual impairments.

7.2. Mis- and disinformation

Sophie Labbe (EMA) started by distinguishing between misinformation (false information shared unintentionally) and disinformation (false information spread intentionally) and explained that "prebunking" is considered a very effective complementary tool to debunking false information: it is about educating people to identify misinformation, check the facts, check trusted sources, and to ensure correct facts are available. A range of actions go hand in hand. For example regarding vaccine safety, many people drew false conclusions from the available data because it was hard to understand, while there were also deliberate cases of disinformation, use of false logos and so on. EMA addressed some concerns proactively on its website and had frequent contact with the media and a fact-checking

workshop with journalists. The EU vaccination information portal has a useful video on how to check sources before sharing information. Sophie said that whenever there is a new topic, there is a new wave of mis- and disinformation. EMA's framework approach shown in the presentation includes monitoring and actions along the spectrum (before – during – after mis and disinformation spread), recognising that no single action or organisation can solve the issue. She invited first reactions and comments from the participants. For more information see presentation.

One commenter said that even if a message appears to be lay-friendly, it is not always and whether EMA consults with patients or consumers to user-test messages. In response Sophie acknowledged that this has indeed been done in the past, but it could be done more often. Another question was on the role of NCAs and language. Coordination with NCAs is at the heart of EMA's operating model and there is currently an initiative ongoing on lessons learnt from the pandemic with the involvement of communication counterparts in NCAs. Collaboration with NCAs, but also stakeholders, is necessary to address the limitations of English language. In response to a question about whether individuals or organisations can report misinformation to EMA, Sophie said this would be valuable and will be explored to find the best way. Regarding young people, EMA's presence on Instagram can be useful, and all major other social media platforms EMA uses professional tools for monitoring and social listening and follows these daily. In conclusion to the discussion, Juan Garcia said working in partnership with stakeholders is important and EMA would reflect internally and follow up in a future meeting with a more mature proposal.

The details of a joint press briefing of EMA and ECDC on 21 September on preparations for the autumn-winter season were shared after the meeting. The recording of the briefing is available.

8. Working party updates

Update from PCWP-PEC joint meeting

The PCWP has met annually with the Patient Engagement Collaborative (PEC), created by the FDA in conjunction with the CTTI, for three years discussing on topics of joint interest such as patient information, youth engagement, lessons learnt from COVID and decentralised clinical trials. More information can be found Patients' and Consumers' Working Party meetings | European Medicines Agency (europa.eu)

Finalisation of the joint PCWP-HCPWP position on ICH6 (R3) GCP

It was confirmed that an agreement had been reached on a joint position of both working parties on the ICH E6(R3) GCP guideline review and this would be submitted in the context of the ongoing public consultation. More information on ICH guidelines can be found here.