15 March 2024
EMA/79367/2024
Stakeholders and Communication Division

Meeting summary - Joint Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting

27 and 28 February 2024, hybrid meeting - WebEx/Room 2A

Co-Chairs: Juan Garcia-Burgos (EMA), Marko Korenjak (PCWP) 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. Working party operations

1.1. Working party work plan – mid-mandate review

Ivana Silva (EMA) provided an overview of progress made on the work plan of the working parties as we have reached the mid-mandate point. Fifty-seven (57) actions were identified for 10 strategic areas and Ivana showed progress made by highlighting the key topic areas and the actions taken and associated achievements. She then discussed with the working parties how to address the remaining actions, to clarify those that are still needed and considerations for those remaining including their continued relevance, in light of new emerging strategic areas. Feedback was requested from the working parties on the progress of the work plan by mid-March. Please see presentation for further details.

1.2. Stakeholder Engagement report – overview

Maria Filancia (EMA) presented the 2022-2023 European Medicines Agency's biennial report on stakeholder engagement activities, expected to be published in Q2 2024. For the first time, the report provides a consolidated overview of all engagement activities that the Agency had with its key stakeholders' groups (patients/consumers, healthcare professionals, academia, industry EU trades). This report also includes a dedicated chapter of multistakeholder engagement therefore showing the Agency's commitment to promoting open dialogue across all stakeholders. There is also a highlight on the Regulatory Network's response to the COVID pandemic. In conclusion, the report recognises the critical role of each stakeholder groups and the value of both targeted and multi-stakeholder engagement activities. The report is expected to be published and available shortly after the March Management Board meeting. Please see presentation for further details.

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1.3. HMH (human medicines highlights) newsletter – new format

Kaisa Immonen (EMA) provided an overview of the renewed Human Medicines Highlights newsletter. The eligible organisations were surveyed, and volunteers were interviewed for input into the revamping of the newsletter. She demonstrated the new structure with a description of the topics and the option for reading the online version in different EU languages. The newsletter is a work in progress and development and planning of new content will continue. Current and new users are encouraged to sign up again (link) and to share their feedback with EMA. Please see presentation for further details.

2. Third party interventions

2.1 Third party contributions during ongoing assessments

Fabrizio Boccacci (EMA) presented the legal basis and background for third party interventions. A third party is defined as any legal or natural person who is not part of the ongoing regulatory procedure, and an intervention is any communication received by the Agency with which a third party shares any comments, data or observation regarding the medicinal products under assessment.

Pharmaceutical legislation does not explicitly foresee the possibility for a third party to intervene in regulatory procedures, which creates several challenges from a legal and regulatory perspective.

The aim of the presentation was to provide useful information on whether the Agency accepts interventions and how it handles such interventions received during ongoing regulatory procedures such as initial marketing authorisations, variations or referrals.

There are several aspects to consider in these cases, i) the bilateral nature of the marketing authorisation procedures that occur between the European Commission/EMA and the application/marketing authorisation holder (MAH), ii) EMA has a legal obligation to ensure a high level of human health protection and iii) the strict deadlines that pharmaceutical legislation imposes on the Agency and the European Commission for issuing a decision on a medicinal product.

Regulation (EC) No 726/2004 states in various provisions that all data potentially relevant for the adoption of a decision are shared by the applicant or MAH involved in a regulatory procedure. However, Article 168 of the Treaty on the Functioning of the European Union provides a clear obligation towards a high level of human health protection, which implies that if information is not shared by the applicant or MAH with the relevant scientific committee, then the Agency and the European Commission cannot disregard such information if brought by a third party. EU pharmaceutical legislation also provides strict deadlines for the adoption of the opinion on the marketing authorisation of a medicinal product in order to ensure that they are available to patients as soon as possible but also to ensure that the applicant / MAH receives an opinion within a predefined timeline.

The Agency only has 60 days to assess all the claims for a revaluation of an applicant/marketing authorisation holder. If in such a short deadline the relevant committee has to deal with third-party interventions, then this adds some complexity. Therefore, only those third-party interventions which are indispensable to ensure a high level of public health should be taken into account.

He described a well-known court case at the European Court of Justice, where the ECJ has the opportunity to express itself on the right of a third-party intervener. The principles defined by this judgement have been repeatedly confirmed by in other judgements and are summarised as i) information form a third party must be taken into account where such a course of action is indispensable to safeguard public health, ii) third parties cannot benefit from the same rights that are set up for the applicant/MAH but can submit data, which means that the intervener has the right to submit data or information but cannot stand in front of the committee and comment on the relevance of the data that

are submitted by them unlike the rights of the applicant/MAH who have the opportunity to comment on the assessment carried out by the relevant committee.

He concluded by summarising the principles stemming from the ECJ and those in the pharmaceutical legislation. See presentation for more information. The importance of having a procedure on how and when to submit data by third parties was emphasised, in addition the importance of bringing new evidence and not just submitting pleas was made in order to make more impactful contributions.

As EMA is in the process of elaborating detailed guidance on this matter, which will take recent experience into account and an update on this topic will be made to organisations later this year.

3. What is happening in cancer

3.1 Cancer Medicines as pathfinder

Francesco Pignatti (EMA) described the efforts EMA is making to identify and enable the approval of cancer medicines with significant potential to transform patient care.

Cancer medicines as a pathfinder was EMA's response to the pace of innovation and development in the oncology field to address high unmet medical need, where evidence generation is ever more complex and regulatory decisions more challenging, and to further maximise efficiency and increase capacity and support scientific quality in the assessment of these medicines. It is not a new tool, breakthrough designation or solution as such, but rather a program of initiatives to identify where existing regulatory tools can be improved and where they can be used to make an impact.

Although the focus is to do better in oncology, considering that this is the field with the largest volume of applications, there is an underlying ambition to identify learnings that can also be transferred to other areas. As part of collecting stakeholder and interested parties' input, Francesco also referred to the academia driven Cancer Medicines Forum, established in 2022 with the aim to explore how EMA can contribute towards addressing remaining uncertainties about the use of cancer medicines in clinical practice. Please see presentation for further details. A first public workshop of this Forum will take place on 5th April 2024. Francesco concluded with an invitation to all organisations to reach out to EMA to initiate further discussions.

3.2 Conversations on Cancer

Caroline Voltz (EMA) presented the FDA Oncology Center of Excellence 'Conversations on Cancer' initiative. Please see presentation for further details.

A participant commented that it would be important to reflect further on the concept of a global approach not just for drug development but also for healthcare systems and patient needs. Caroline clarified this was well noted and would be within the scope of discussions taking place at the level of the Cancer Medicines Forum.

Another participant suggested to have a conversation on immunotherapy (checkpoint inhibitors) as a next topic.

4 Update on progress with Patient Experience Data

4.1 Patient experience data reflection paper

Rosa Gonzalez-Quevedo (EMA) provided a status update on the reflection paper on the collection and use of patient experience data in the EU. The draft reflection paper may be finalised by mid-2024 and

will be subsequently released for public consultation. Working parties will be consulted before the finalisation of the draft. Please see presentation for further details.

In the Q&A, it was clarified that the EMA reflection paper will not provide methodological guidance or a guarantee that a MA application comprising PED will result in regulatory approval; rather, it will provide principles to developers and will give various examples on possible approaches. Developers will be encouraged to seek EMA scientific advice on their plans.

It was also clarified that PED is any data generated by patients (or carers) reflecting the patient experience and without interpretation of a clinician, including but not limited to PROs, and while such data is expected to be included as part of clinical trials in the future, it may also be real-world data used to support data from clinical trials. Third-party interventions can also be used to submit PED. Regarding the relevance of PED in pharmacovigilance, this including spontaneous patient reporting of suspected ADRs will also be within the scope. A point was made regarding data versus evidence, and that while high quality of data is important, the data also needs to substantiate evidence that is relevant to regulatory assessment. The paper will be aligned with other data-related initiatives such as the EHDS legislative proposal.

4.2 Action plan (therapeutic area priorities), consultation and next steps – survey

Rosa Gonzalez-Quevedo (EMA) presented a project done in collaboration with Claire Espinasse (EMA) and collaborating expert Friederike Wilke (BARMER Statutory Health Insurance). It concerns an upcoming survey to understand perceptions, experiences and awareness of PED across therapeutic areas and stakeholders. The survey hopes to clarify the picture of PED and to understand gaps and unmet needs where PED could be useful to bring the needed evidence to develop new medicines. Please see presentation for further details.

Volunteers were identified to review the survey questionnaire before its launch, which is planned tentatively in Q2 2024.

5 Update on training resources

5.1 Update on the Network Training Centre

Esther Martinez (EMA) presented on the opening up of the EU Network Training Centre (EU NTC) to the PCWP/HCPWP members. The EU NTC is a joint initiative between EMA and HMA to facilitate the sharing of knowledge and strengthening the capacity within the network. Over the last 10 years, the NCA staff members have been the main target audience of the EU NTC, however, now the need to provide access to the training catalogue to a wider audience, including PCWP/HCPWP members, has been identified. The EU NTC governance was described with the strategic, tactical and operational levels explained.

The four strategic objectives of the EU NTC to 2025 include opening up to new audiences (the PCWP and HCPWP are the first stakeholders to receive this invitation) and then strengthening of the development of the curricula available, the services and tools available and the digital learning ecosystem. These objectives align with the priority areas for the EU NTC. Some of the available training courses cover the topics of advanced therapy medicinal products (ATMPs) clinical trials, pharmacovigilance and paediatrics). An annual planning cycle is undertaken which includes understanding the training needs as identified by the curriculum leads, identifying courses and working with the course owners for development of the material. Please see presentation for further details.

6 Policy on competing interests

6.1 EMA's policy on competing interests

Zahra Hanaizi (EMA) provided an update on the review of EMA's policy on the handling of competing interests with respect to involvement in certain activities in research organisations. The background to the revisions of Policy 44 was described and draft principles were presented. Overall, the principles are expected to provide a framework for a proportionate approach on the handling of these competing interests, while safeguarding the impartiality and independence with introduction of restrictions where (potential) competing interests are identified. Once final and adopted by the EMA Management Board, the revised policy will be published on EMA's corporate website.

7 Pharmacovigilance

7.1 Preparation of amendments to Commission Implementing Regulation 520/2012 on the performance of pharmacovigilance activities

Izabela Taborska (EC, DG Santé) presented the proposed amendments to the Commission Implementing Regulation 520/2012 on the performance of pharmacovigilance activities. These amendments are made in the frame of the Pharmaceutical Strategy for Europe, which is the opportunity for the Commission to evaluate and review the general pharmaceutical legislation, as well as to update and optimise existing implementing measures.

After a presentation of the legal and policy background on pharmacovigilance, Izabela outlined the main identified issues and possible solutions as foreseen in the revised text, which include:

- Subcontracting: clarifications around subcontracting by the marketing authorisation holder (MAH) to third parties and subcontracting between third parties for pharmacovigilance activities;
- EudraVigilance monitoring: based on the experience with the corresponding pilot project, it is now proposed that MAHs should monitor EudraVigilance not continuously but in the context of their obligation to monitor all sources of information;
- Transmission of suspected adverse reactions: the minimum requirements (reporter, patient, suspected adverse reaction and medicinal product concerned) will be applicable for all individual safety reports, not only for expedited reports, to improve quality of information;
- Digital Object Identifier: implemented to improve literature referencing;
- Post-authorisation safety studies: obligation to register post-authorisation safety studies electronically in the Register maintained by EMA, which is publicly available and searchable by class and active substance.

Following intra- and inter-service consultations, the draft will be published for comments on the European Commission website, with the standard timeline for consultation of 4 weeks. The aim is to go for adoption Q2 2024.

Please see presentation for further details.

Post-meeting note: it was confirmed that a range of line listings of individual case reports of suspected adverse reactions can be produced from the public EudraVigilance access. There are also predefined query options for the numbers of reported suspected adverse reaction cases by system organ class or over time. However, there is no option to see the numbers of cases by SOC over time. The ADR website offers 18 different possibilities to visualise the data stratified in different parameters. For further

information on the possible visualisations, the Web report user guide EN (adrreports.eu) can be consulted.

7.2 Risk minimisation for patient safety – update on policies and practices

Priya Bahri (EMA) provided an update on policies and practices for risk minimisation for patient safety.

EMA initiatives include strengthening guidance to MAH and competent authorities; enhancing engagement with patient and healthcare professional representatives; and investing in research.

Priya highlighted themes of the revisions made to Module XVI of the EU Good Pharmacovigilance Practices (EU-GVP) on risk minimisation measures (RMM), including the implementation pathway, which is divided between the regulatory remit and the healthcare systems remit. Opportunities for engagement of patient and healthcare professional representatives include the following:

- Provide input on RMM options, their implementability and target audiences;
- Contribute to designing/tailoring to target audiences, user-testing and planning for implementation of RMM in healthcare;
- Support the dissemination of RMM via multiple channels and further implementation in healthcare;
- Advise and participate in the evaluation of RMM.

Priya then provided an update on the EMA's safety committee pilot working group called Pharmacovigilance Risk Assessment Committee(PRAC) Risk Minimisation Alliance (PRISMA) group, which looks at RMM options from the perspective of patient and healthcare professionals representatives. The group meets once a month after the PRAC meeting. PRISMA achievements under the pilot (July 2022 – December 2023) were summarised. These included proposals on PRAC lists of questions to stakeholders regarding RMM and for competent authorities in support of RMM implementation, conduct of surveys and development of a new patient journey-based PRISMA discussion framework.

Plans for PRISMA for 2024 include the following:

- Report on survey on integration of RMM in dispensing and prescribing software with proposals for potential opportunities for collaboration;
- Proposal for an EMA webpage on RMM with links to the webpages of national competent authorities for access to RMM materials;
- Mapping of RMM tools and their enablers, using and further developing the PRISMA discussion framework.

Priya also provided an update on the Implementation of EU risk minimisation measures for medicinal products in clinical guidelines (EMA-commissioned research 2022-2023), for which the abstract is already published. Preliminary findings show that RMMs are integrated in clinical guidelines, if at all within their scope, in very limited manner. Please see presentation for further details.

8 Feedback from Patient and HCP representatives in EMA groups

8.1 European Network of Paediatric Research at EMA (Enpr-EMA)

Gunter Egger (EMA) presented the European network of paediatric research at the EMA (Enpr-EMA), which has its legal basis in the European Paediatric Regulation. Enpr-EMA was launched in 2011 and has grown to an umbrella network of more than 50 members worldwide (with different categories of memberships).

The mission of the network is to support the conduct of paediatric clinical trials with the ultimate goal of increasing the availability of paediatric medicines. It provides a mutual platform for dialogue to build up competency at the European level, supporting the formation of new networks. Interactions with PDCO and advice on the development of PIPs are also part of the scope.

Enpr-EMA also acts as a contact point for industry to facilitate conduct of clinical trials. Enpr-EMA however does not fund studies, nor act as a CRO for study management.

Enpr-EMA organises an annual workshop; the next one is planned for October 2nd, 2024, with a draft agenda planned to be published before the EMA's committees' summer recess.

Much of the work of Enpr-EMA is carried out in ad hoc working groups. Noteworthy achievements include the following publications:

- Guidance for collaboration between networks and industry, advising when to best contact networks;
- Information on informed consent/assent requirements in Europe;
- Guidance on clinical trial preparedness, including when to contact stakeholder groups to get input on the study design;
- Information on repurposing of products used off-label in paediatrics (more than half of the prescriptions in the paediatric group are off-label).

Current Enpr-EMA activities include the development a recommendation paper on the quality criteria for paediatric clinical trial sites; the establishment of a working group strengthening the role of paediatric research nurses across EU/EEA; the promotion of inclusion of paediatric patients in trials across borders; and the development of a global guidance on the clinical trial approval process (including ethics opinion) across jurisdictions. Enpr-EMA also collaborates with ACT EU on several initiatives.

In the frame of the new pharmaceutical legislation, Article 95 of the proposed Regulation, it is proposed to widen the scope of Enpr-EMA and give it an even more active role in the network, promising exciting developments for the network.

Jose Drabwell (IPOPI), PCWP member to Enpr-EMA, described her role within Enpr-EMA. Jose's role included identifying experts such as clinical research nurses; making the group aware of initiatives on decentralised clinical trials; and gathering information about the use of Artificial Intelligence in hospitals.

Please see presentation for further details.

8.2 Review of the package leaflet template

- Update on the QRD subgroup

Monica Buch (EMA) provided an update from the QRD subgroup on the package leaflet template review. Following a first consultation survey of stakeholders in late 2023, a second survey is currently open to seek views on the potential inclusion of a key information section and presentation of the benefits of a medicine. The survey was extended until 7 March 2024.

The draft template, once agreed by the subgroup, will be presented to the QRD plenary meeting, tentatively in June 2024, which will adopt a final proposal for public consultation. The aim is to hold a multistakeholder workshop once the public consultation is closed and feedback received has been analysed. User testing the new template will also be considered. The timings of these activities will be confirmed. Please see presentation for further details.

- Feedback from patient, consumer and HCP members of the subgroup

Loris Brunetta (TIF) on behalf of Courtney Davis (HAI) gave the perspective of the patient, consumer and HCP representatives within the QRD subgroup, which include also Jorge Batista (PGEU). Please see presentation for further details.

9 Ongoing EMA activities

9.1 Update on crisis activities: Outcome of Long COVID workshop – EMA and patient perspectives

Stephanie Buchholz (EMA) summarised the main workshop outcomes and next steps from the EMA perspective.

The workshop took place on 17 November 2023 and was well attended by multiple stakeholders. The meeting addressed the complexity of Long-COVID and focused on study design for future treatments.

The main outcome of the workshop was that double-blinded, randomised clinical studies should be initiated as soon as possible and that collaborative efforts are needed to facilitate and initiate coordination of platforms studies in the EU, to better coordinate EU cohorts, and to establish EU patients registries. Real world evidence was also discussed during the workshop. To ensure consistency of the patient population and comparability and interpretability of the data, there was consensus that an agreed operational case definition of Long-COVID and/or an ICD-10 definition for diagnosis across Europe is needed.

The workshop also addressed paediatric aspects and animal models.

There was consensus that treatment should be prioritised over prevention, and that patients with the most severe clinical manifestations should be addressed first. Two options for primary endpoints were discussed during the workshop: Patient Reported Outcomes (PROs) and biomarkers. PROs are presently considered to be a viable option to establish efficacy in clinical trials and experts recommended to use already well-known, disease specific PROs, which should be adapted for Long-COVID. For biomarkers there is presently insufficient evidence to use them as surrogate endpoint for clinical efficacy, however, they could be useful to enrich the patient population and to confirm the biological plausibility of the drug.

In conclusion, patients are in need of treatments now and initiation of clinical studies should not be delayed, and should be a priority on the EU public health agenda. EMA will publish the summary report, submit a publication and organise a follow-up workshop. Please see presentation for further details.

Chantal Britt (Long COVID Europe) provided the patient perspective on the workshop outcome.

Long COVID has a large prevalence and poor prognosis. Exertion intolerance, post-exertional malaise, and orthostatic intolerance are the most debilitating symptoms that should be focused on for the development of treatments. Biomarkers in line with main disease mechanisms should also be a research priority, while studies on psychosomatic theses should not be supported.

Due to the fact that randomised clinical trials may take too long to yield results, patients plead for the use of existing research infrastructures and adaptive trial platforms to conduct faster pilot trials on repurposed therapies in parallel with RCTs.

Some already marketed drugs, e.g. anticoagulants, anti-inflammatory, antivirals, may be useful to relieve some symptoms, and their off-label use should be expedited and investigated in clinical trials as long as there is no approved treatment.

Patient representatives should be involved from the start in all research efforts and funding decisions. The planned clinical trials must use decentralised features to allow for enrolment severely affected

patients. Focus should be on non-hospitalised long COVID patient subtypes where we lack data, and not only hospitalised post-acute COVID-19 patients. Please see presentation for further details.

9.2 ACT EU: summary of recent workshops and establishment of the Multistakeholder Platform (MSP) Advisory Groups

Ana Zanoletty (EMA) provided an update on the progress of the ACT EU initiative, which was launched two years ago, in parallel of the entry into application of the Clinical Trials Regulation (CTR) and launch of the Clinical Trials Information System (CTIS). Ana outlined the complex and evolving regulatory landscape, which includes amongst others international collaborations, EU Health Data Space, MDR and IVDR, real world evidence and Artificial Intelligence, etc. The 11 ACT EU priority actions were listed and the following areas highlighted:

- Support of non-commercial sponsors, with the intention of increasing the number of non-commercial multinational clinical trials: support activities include mapping existing initiatives at national/EU level; optimising regulatory helpdesk, leveraging national initiatives; and targeted CTR/CTIS support (handholding).
- Clinical trial analytics workshop, held on 26-26 January 2024: the workshop report is expected to be published by the end of March 2024. The workshop highlighted a real desire for access to more detailed and up to date clinical trials data by the stakeholders. Priorities for the different stakeholder groups were discussed during dedicated break out sessions. The outcome of the workshop will support the ACT EU steering group in their funding calls, to make research priorities a reality.
- Consolidated scientific advice pilots, with two scientific advice pilots in scope:
    - 1) Scientific Avice Working Party (SAWP) – Clinical Trials Coordination Group (CTCG): scientific focus, with discussion of topics of common interest for clinical trial applications (CTAs) and marketing authorisation application (MAA);
    - 2) CTCG pre-CTA advice: focus on technical/administrative aspects.

Both pilots should be launched towards the end of April 2024, with dedicated trainings and webinars organised.

- Clinical trial methodology guidance workshop, held on 23 November 2023: the workshop covered various topics including complex trials, paediatric trials and pragmatic trials, focusing on patient needs. The workshop report and subsequent deliverables, including a roadmap, are under preparation.

Two projects not directly under the ACT EU umbrella were also presented:

- CTR Collaborate project, under the remit of the CTCG, which aims to optimise alignment between national competent authorities (NCAs) and ethics bodies;
- MedEthics EU, an initiative from ethics committees in cooperation with the European Commission, which will strengthen cooperation between EU ethics committees, facilitate exchange of experience, provide training, and integrate ethics in the European Medicines Regulatory Network. The kick-off meeting occurred recently.

Maria Filancia (EMA) then provided an update on the establishment of the Multi Stakeholder Platform (MSP) Advisory Group (AG). The MSP concept developed into 3 elements: 1) multi-stakeholder workshops organised under ACT EU; 2) stakeholder engagement tools including consultations and surveys; 3) MSP Advisory Group, formed by key stakeholder groups representatives, with an aim of providing strategic and operational advice on activities linked to the ACT EU workplan.

The stakeholders call for expression of interest was presented at the September 2023 PCWP/HCPWP meeting and formally launched in October 2023. 21 permanent as well as ad hoc representatives were appointed by the ACT EU Steering Group. The full list was published on the ACT EU website. As outlined in the concept paper, and in order to enable the dialogue, ACT EU regulatory partners, ethics committee representatives, and other experts from regulatory bodies where needed attend the meetings of the group.

The MSP AG's first inaugural meeting scheduled for March 20th will be the opportunity for permanent members to get to know each other, discuss and agree on the group mandate, and launch the call for interest for stakeholder co-chair (limited to non-commercial organisations). Next activities include planning of the next MSP annual meeting, launch of scientific advice pilots, CTIS workshop on best practices for transitioning trials to CTR, workshop on methodology guidance in clinical trials, workshop on ICH E6 R3, and ACT EU annual matrix meeting. Please see presentation for further details.

For more information: https://accelerating-clinical-trials.europa.eu/index_en; acteu@ema.europa.eu

9.3 Data discoverability: HMA-EMA Catalogues of Real-World Data sources and studies

In early 2024, EMA launched the HMA-EMA catalogues of real-world data (RWD) sources and studies which describe RWD sources and studies through a set of collected metadata to help pharmaceutical companies and researchers identify and use such data when investigating the use, safety, and effectiveness of medicines. The catalogues will replace the current ENCePP Resources Database and the EU PAS Register offering an improved, more efficient service for researchers, regulators, and pharmaceutical companies alike.

The catalogues aim to promote transparency and build trust in observational research and encourage the use of good practices.

In the context of the Big Data Steering Group (BDSG) workplan 2023-2025, the EMA-HMA catalogues fall under the third priority recommendation: Data Discoverability.

As the catalogues are published, EMA would like to engage patient, consumer and healthcare professional organisations to contribute to the mapping of existing data sources (e.g. patient registries) by inviting them to populate the catalogues. The next steps also include identifying, from the new catalogue of data sources, which data sources capture patient experience data and to define opportunities, challenges, and quality considerations (including harmonisation and use of CDMs). A multistakeholder webinar was held on 4 March 2024. Please see presentation for further details.

10 Shortages

10.1 Next phase to complete and extend the Union list of critical medicines

Joao Francisco Ferreira (EMA) described the launch of Phase 2 of the Union list of critical medicines. A targeted consultation with stakeholder groups will be launched in March 2024 to identify missing substances and to flag critical medicines subject to review by Member States in Phase 2 (throughout 2024). The outcome of the 2nd version of the list will be shared with stakeholder groups in Q4 2024. Please see presentation for further details.

Charlotte Roffiaen (EPHA, MSSG) underlined the importance to review the list to ensure critically important substances are not missing from the list. During the first iteration entire categories were missing. She added that although the list will be used for regulatory purposes and to check the supply chain vulnerability this would not mean that all substances' production would be relocated to Europe.

10.2 Update on shortage of glucagon-like peptide-1 receptor agonists (GLP-1 RAs)

Klaus Kruttwig (EMA) and Romana Micovcakova (EMA) provided an update on the shortage of GLP-1 Ras, including shortages of Ozempic (semaglutide) that have been ongoing since 2022. There are also shortages of Victoza (liraglutide) and other GLP-1 RAs. They elaborated further on the current mitigation and shortage management activities for these medicines. Please see presentation for further details.

PCWP and HCPWP were asked about their experience with one of the MAH's mitigation measure – limitation of the supply of the starting dose for Ozempic (0.25 mg), which is expected to limit the initiation of new patients, to mitigate the increasing demand on the maintenance doses (Ozempic 0.5 mg and 1 mg).

EMA is monitoring national information campaigns and collaborating at an international level on this matter.

AOB

A Multi-Stakeholder Workshop on Psychedelics will take place on 16-17 April 2024. The workshop will be broadcast live, and the recording will be made available after the event.