21 November 2024
EMA/526113/2024
Stakeholders and Communication Division

Meeting Summary - PCWP/HCPWP and all eligible organisations meeting

20 November 2024, hybrid meeting - WebEx/Room 1A

Co-Chairs: Juan Garcia-Burgos (EMA), Rosa Giuliani (HCPWP) and Marko Korenjak (PCWP)

1. 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.

2. Regulatory science, innovation and competitiveness

2.1. Clinical Trials in the EU: continuing the journey

Ana Zanoletty (EMA) provided a brief overview ACT EU initiative and the ongoing clinical trials activities in the EU.

The European Commission, EMA, and Heads of Medicines Agencies launched the 'Accelerating Clinical Trials in the European Union' (ACT EU) initiative in January 2022 to improve the clinical trials environment in the EU/EEA through harmonisation, innovation, and collaboration with stakeholders.

The success of clinical trials relies on a wide range of stakeholders and regular dialogue between all parties to identify and advance clinical trial methods, technology and science, as well as remove barriers to have more impactful clinical trials.

To promote collaboration across different stakeholder groups for the improvement of clinical trials in the EU, the ACT EU initiative has established a multistakeholder platform (MSP) aimed at improving the environment for clinical trials across the European Union (EU). The MSP is a key part of ACT EU, providing a platform for stakeholders to exchange views on all aspects of clinical research, through workshops, consultations and regular meetings of the MSP advisory group (MSP AG). The MSP AG meets regularly to provide strategic and operational advice to the ACT EU programme. Topics for discussion include clinical trial design, conduct, statistical analysis, proposals for regulation optimisation, transparency of data, and patient engagement. The group is composed of representatives from key stakeholder groups directly impacted by clinical trial-related activities in the EU.

The constant engagement with key stakeholder groups aims to accelerate the improvement of the clinical trials environment in the EU by streamlining processes, reducing administrative burdens and complexity, and fostering innovation in the way that clinical trials are designed, regulated and conducted. This will maximise their efficiency and utility for patients, enabling early access to new treatments in the EU.

Another key deliverable of this year has been the improvement of clinical trial transparency, including the revision of the CTIS transparency rules, which came into effect on 18th June 2024, along with the launch of a new, more user-friendly version of the CTIS website.

2.2. Feedback from ACT EU Multistakeholder Platform Annual Meeting

Ana Zanoletty (EMA) and Denis Lacombe (EORTC), stakeholder co-chair of the Multi-Stakeholder Platform advisory group (MSPAG), provided an update from the ACT EU Multistakeholder Platform Annual Meeting held on October 22nd.

For the first time, patients, healthcare professionals, academia, industry, regulators, and ethics committees were brought together to discuss stakeholder priorities for an improved environment.

The annual meeting of the MSP provided an opportunity to review ACT EU's key achievements of ACT EU since its inception and their impact on clinical research, discuss the current clinical trials landscape, including key initiatives, and the stakeholder needs for an improved environment. The meeting also focused on visualising what success would look like for different stakeholder groups in the future and discussed solutions that could accelerate change (see presentation).

During the meeting, stakeholders emphasised the need for true harmonisation, reduced administrative burdens across Member States, resource alignment, simplification, streamlined timelines for the assessment of trials, ensuring adequate funding and addressing legislative interplay between CTR/MDR/IVDR. Additionally, stakeholders recognised that ACT EU had implemented several initiatives such as MedEthicsEU, CTR Collaborate, and COMBINE that had positively impacted the clinical trial environment.

Key factors identified for success included increasing the availability, accessibility, and diversity of trials, innovating methodology approaches to make them more effective, reducing unnecessary burdens, and adjusting operational aspects to achieve harmonisation across different Member States. Finally, stakeholders emphasized the importance of continuing stakeholder engagement in order to build consensus around these priorities and work effectively towards improving clinical trials.

The eligible organisations were encouraged to visit the presentations from ACT EU Multistakeholder Platform Annual Meeting for more detailed information.

2.3. Update on the Clinical Trial Information System (CTIS) public portal

Francesca Scotti provided an update on the latest improvements made to the new CTIS public portal, following up on the previous PCWP/HCPWP meeting held on 2-3 July. New features were introduced on the CTIS public portal on 20 September 2024, following a thorough consultation with stakeholders, including patients and healthcare professionals. The enhanced portal aims to benefit the public by making it easier to search for publicly available information on clinical trials in the EU and EEA. The updates included advanced search functionality, including searching per recruitment status in a specific country, the ability to download search results and all published information and documents for a specific clinical trial, subscribe to a certain search, as well as changes to the user interface that make the portal more user-friendly for patients and healthcare professionals. The list of search results is now translated in every European language and clearly displays the most important information, including the recruitment status and locations for each trial.

In addition, every trial page now displays a dedicated section on 'Locations and contact points' for anyone who wishes to get in touch with the healthcare professionals at the trial locations or with the sponsor. There is more extensive information on the 'Summary' page, such as the main objective of the trial and its estimated duration, a dedicated section with all available trial documents, a section with 'Full trial information' which is easier to consult, as well as documents with layperson explanations of the fields in each section.

These changes enable stakeholder faster and more efficient access to clinical trial information, including patients and healthcare professionals, reduce the burden to CTIS users and help promote the conduct of clinical research in the EU/EEA. A demonstration of the portal was then presented.

2.4. The ACT EU trial map: a dashboard for patients

IJsbrand den Rooijen (EMA) presented a new trial map dashboard currently under development, designed to facilitate the access to clinical trial information based on CTIS public data, specifically for patients. The trial map dashboard allows users to search for clinical trials by medical condition and view trial sites on a map. This tool was developed in response to requests from patient organisations for better ways to interface with CTIS data during the ACT EU Clinical Trials Analytics workshop on clinical trials held in January 2024.

EMA plans to make the tool publicly available by mid-February 2025 and hold a webinar afterward.

2.5. Full relaunch of Clinical Data Publication

Karen Quigley (EMA) provided an update on the publication of clinical data for medicines (see presentation). EMA has resumed its clinical data publication activities (policy 0070). Under this policy, EMA publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure.

Since September 2023, all initial marketing authorisation applications for new active substances and medicines authorised for COVID-19 have been subject to publication on the Clinical Data Portal. The next step will be the full relaunch of clinical data publication for all new marketing authorisation applications, line extensions and major clinical Type II variations (extension of indications), except for all biosimilars, hybrids and generics, regardless of whether they receive a positive or negative opinion, or whether the application is withdrawn. This is expected to happen in Q2 2025.

EMA has implemented several changes to improve the efficiency of the clinical data publication process. These include implementing an EMA tracking tool to establish a list of documents in scope, sending invitation letters with detailed information about early request packages, offering pre-submission meetings to assist with package preparation and anonymization strategies. Additionally, updated Q&A guidance has been published to address practical questions related to procedural matters such as timelines, commercially confidential information, and the anonymization process. An external guidance document is currently under review and will be published in early 2025. Furthermore, EMA has collaborated with Health Canada to align processes. For more details, please see the presentation.

3. Medical devices

3.1. Overview of EMA activities in the area of medical devices

Silvy da Rocha Dias (EMA) provided an update on EMA activities in the area of medical devices. She described the roles and responsibility of EMA, such as the CHMP-related procedures, which include medicines in combination with medical devices, companion diagnostics, ancillary medicinal substances and systemically absorbed substances in consultation with Notified Bodies (NB). EMA has also acquired the role of the secretariat of the medical device shortages steering group (MDSSG) to ensure a response to supply issues of medical device issues during a public health emergency and secretariat support to the medical device expert panels on high-risk medical devices and in vitro diagnostics. The role of the expert panels is to provide an opinion and a view to the NB on the conformity assessment of the high-risk medical devices and in vitro diagnostics.

High-risk medical devices are defined as implantable class III devices such as pacemakers, joint replacement and breast implants as well as infusion pumps and ventilators. High-risk in vitro diagnostics (IVD) are class D devices, intended for the detection of transmissible agents and certain blood groups.

She described the structure of the medical device expert panels and their role in providing ~~an~~ opinions and views for the NB to support scientific conformity assessment. The opinions and views are publicly available. In addition, the expert panels also play an advisory role to the manufacturers on high-risk medical devices and to the European Commission and the medical device coordination group (MDCG) on the safety and performance of any type of device.

A pilot on advice to medical device manufacturers was launched last year and will close end 2024 with full implementation planned in 2025. The remit is for the class III high risk devices and to help manufacturers with clinical evidence generation and clinical investigations and their development plans. For more information see presentation.

Questions were raised regarding the consultation of patients by the expert panels and their willingness was voiced along with the need for training and preparation. Another question on the HTA regulation (HTAR) and the role of the expert panels on medical devices as described in the HTAR implementing act.

3.2. Expert panel support for orphan medical devices

Michael Vogl (EMA) provided a presentation on the guidance on how orphan devices can be handled to ensure that they will stay / that they will come to the EU market, which was adopted by the Medical Device Coordination Group (MDCG) in June 2024. He described the challenges faced by medical device developers and clinicians, which was addressed in part by the Clinical Evaluation of Orphan Medical Devices guidance developed by the MDCG. This guidance also defines criteria for medical devices to be regarded as 'orphan'. This guidance also sets out two new roles for the expert panels: early-stage and late-stage advice, which represent the first time that advice can be provided at the EU-level and not only at the national level. The first 'early-stage' consists of confirming the status of a device as orphan and to advise specifically on the limitations for the orphan device in the proposed clinical strategy and investigations. The later stage includes confirming orphan status with specific mechanism and to advise NB and manufacturers on the appropriateness of the data set.

He described the content and showed the processes for requesting both early and late-stage advice by the manufacturers and the NBs, who can also request late-stage advice to the expert panels. He concluded by showing the tentative timelines proposed for this pilot. See presentation for more details.

4. Leveraging data, digitalisation and artificial intelligence

4.1. HMA/EMA joint Big Data Steering Group (BDSG) ongoing activities

François Domergue and Denise Umuhire presented an update on the HMA/EMA Big Data Steering Group activities and highlights of recent activities. Among these were that DARWIN EU® is now operational and has become the main RWE generation pathway for studies to support regulatory decisions. Forty studies are completed or ongoing, including studies to inform vaccine safety and effectiveness and public health emergencies. The HMA/EMA catalogues of real-world data sources and non-interventional studies were launched earlier this year, improving discoverability of data sources and transparency on non-interventional studies in EU; and the BDSG published its second interim report on experience gained in conducting studies with RWD. Feedback on feasibility and utility of raw data analysis has been positive and EMA has extended the pilot to gather more

insights. Recently, expert reports were published on mobile health (mHealth) data and social media data investigating their potential utility for regulatory decision-making and the related challenges.

A public consultation is forthcoming on real-world data quality before end of 2024 and will be communicated to eligible organisations. A survey on stakeholder communication and engagement is currently open for input until the end of 2024. Eligible organisations are encouraged to give input to these.

At the end of this year, the BDSG and the Network Data Board (EU NDB) will be unified into one governance group, the Network Data Steering Group (NDSG). A call for interest for patient and HCP representatives was shared with the eligible organisations. For more information, please see presentation, which includes written input from the patient and HCP members of the BGSD, George Paliouras and Ioanna Agache.

4.2. Patients experience data – reflection paper and upcoming consultation

Rosa Gonzalez-Quevedo reiterated the background to the patient experience data (PED) initiative and gave an update on recent developments. During 2024, two key deliverables have been under development, namely the draft reflection paper and work on improving transparency on the use of PED in regulatory assessment. The reflection paper which will outline an EU approach to PED in the EU. It will provide an overview of possible data sources and methodologies to collect PED and will include reflections on factors affecting implementation of PED, such as challenges related to methodology, data quality, trust and acceptance. It will not provide methodological guidance and medicine developers will be encouraged to seek scientific advice concerning their development plans for PED. The draft paper is expected to be released for public consultation in Q1 2025.

Regarding transparency, the CHMP has undertaken a review of the assessment report template, and as part of this review changes have been made to ensure different types of PED can be more clearly identified and included in the report. The new template will be implemented in 2025. For more information, please see the presentation.

4.3. Artificial Intelligence multi-annual workplan update

Luis Pinheiro gave an update on the HMA/EMA workplan on AI, under the BDSG, which will become the Network Data Steering Group from next year. Among the highlights were a revision of the reflection paper on AI, which was concluded and the final paper published in September. Likewise, the guiding principles on AI, targeted specifically at regulators, were published; and a multistakeholder workshop on AI held on 5 November. These workshops provide an opportunity for stakeholders to comment on the workplan and their feedback will inform further shaping and prioritising of the activities. Training modules on AI for the Network Training Centre (EU NTC) have been delivered, and EU and international collaborations and communications with stakeholders are an ongoing priority. Preparations to support the implementation of the AI Act are ongoing; the implementation of this legislation will take some time and will be layered. Development of AI guidance in future activities and a roadmap on research priorities are in progress and planned to be published in 2025. For more information, please see the presentation.

In the discussion, there was positive feedback on the revised version of the AI reflection paper. There was a question on terminology for technologies using AI; it was commented that EMA is looking into possible areas where we can converge with other regulators on terminology and mapping those areas where convergence is not possible for legal or other reasons. As for differences between member states, this is complicated and the AI Act preparatory group is working to gain an understanding of the application of some provisions of the AI Act in various areas, for example how research exemptions might apply to e.g. pharmacovigilance activities. There will be further updates.

5. Availability and supply of medicines

5.1. Introduction to shortages topic

Monica Dias (EMA) provided a brief introduction on shortages activities and upcoming milestones. She began with EU-level coordination that includes the medicines shortages SPOC working party and the MSSG who continue their work in putting in place mitigating measures to address critical shortages and where possible to prevent shortages. In this regard, the impact of major events such as natural disasters on the availability of medicines due to potential supply disruption continues to be monitored. With the approach of winter, EMA along with other regulatory authorities have been monitoring the supply of antibiotics by interacting with key suppliers for the European market. The situation appears to be stable and only one critical shortage has been signalled to date, which has been addressed with the support of EMA.

The European Shortage Monitoring Platform (ESMP) go-live is planned for end of November for routine reporting for centrally authorised products with training ongoing for marketing authorisation holders to ensure that they are adequately prepared to report shortages to EMA. The full go-live is February 2025 with the extension of the platform to crisis and MSSG led reporting for companies and national competent authorities.

A new procedure called the MSSG Solidarity Mechanism has been established where a Member State experiencing a critical shortage can temporarily seek assistance from other Member States and six cases have been launched to date and all concluded successfully.

Finally, through the use of Shortage Prevention/Mitigation Plans (SPMP), the aim is to move toward prevention of shortages. EMA is launching a pilot to implement the shortage prevention plan (SPP) and shortage mitigation plan (SMP). The main objectives of the pilot are to facilitate the harmonised implementation of the SPP and SMPs by MAHs and Competent Authorities (CAs) and to collect information from industry on the use of the templates and identify any challenges. See presentation for more details.

5.2. Update on the publication of version 2 of the Union list of critical medicines

Joao Ferreira (EMA) began with a quick recap of the timeline and the activities to date related to the union list of critical medicines, followed by a reminder of the objectives and the scope of the union list. The purpose of the list is primarily to help ensure availability of critical medicines in the EU healthcare systems using a series of measures to enable supply security in Europe. This is not a list of shortages but a list of critical medicines that need to have a guaranteed supply in healthcare systems. In terms future actions, through EMA's SPOC working party and the MSSG, monitoring of medicines on the list will continue and there are a series of established measures that regulators have in place to monitor shortages. This year, new recommendations were issued from the MSSG to strengthen supply chains of critical medicines. From the industrial capacity/support perspective, DG GROW and HERA performed an analysis of the supply chain vulnerabilities of a first group of critical medicines in the union list. The Critical Medicines Alliance is also developing industrial policy recommendations that include support to industry on increasing or scaling up manufacturing capacity and from a financial perspective.

Looking ahead to the future implications for the union list, the new pharmaceutical legislation on the future use of the Union list, and the conclusion to these discussions is awaited. A critical medicines act is a key priority of the next Commission's mandate.

Phase 1 of the implementation of the union list concluded last year and Phase 2 is ongoing and nearly finalised. In Phase 2, the data sources included a targeted stakeholder consultation that was

held between March and May 2024. The two main objectives of the consultation were i) for stakeholder organisations to flag medicines that they believed to be critical in alignment with the published methodology and to identify additional medicines that were not reviewed by the regulatory network that had to be taken into consideration. He provided details of the analysis and feedback received from the different stakeholders who commented on methodology, in particular on publication transparency and on policy measures that concern regulatory aspects. He then described the distribution of the different active substance groups identified and how they were classified.

The Phase 2 distribution of medicines per pharmacotherapeutic group was presented. In terms of projected figures, there are approximately 28 substances that will end up in this version 2, which will bring the total to 270 active substance groups in the core version. He concluded by stating that that further union list operations will need to align with the outcome of the new pharmaceutical legislation and that regular updates to the union list will be necessary. See presentation for more details.

5.3. Update on the new Medicine Shortage Communication (MSC) process and template

Joao Ferreira (EMA) presented the new Medicine Shortages Communication (MSCs) process and template to be issued for shortage situations without any associated quality, safety or efficacy issues under MSSG governance. This will streamline the process and ensure adequate and targeted communication with healthcare professionals in the event of critical shortages linked to commercial reasons, increased demand and supply capacity. The proposed template together with the communication plan were presented to all eligible organisations (see presentation).

MSSG is rolling out the new MSC process and template from October 2024 through a six-month pilot (until March 2025), allowing marketing authorisation holders (MAHs) and national competent authorities (NCAs) to familiarise themselves with the new template. The pilot phase aims to identify potential implementation and dissemination issues at the national level and adjust the template and process prior to full implementation in April-May 2025. For all other communications, including quality, safety or efficacy issues affecting supply or availability, the current Direct Healthcare Professional Communications (DHPC) process will remind unchanged, under remit CHMP/CMDh.

5.4. Feedback on the Single Point of Contact (SPOC) Working Party activities on Glucagon-Like Peptide-1 (GLP-1) receptor agonists shortage management

Klaus Kruttwig (EMA) provided a brief summary of ongoing activitites in relation to the coordination, monitoring and mitigation of the shortages of Glucagon-Like Peptide-1 (GLP-1) receptor agonists (RAs). To this end, a specific subgroup involving clinical experts on insulin products and GLP-1 RAs has been established.

One expert group is focusing on the results of the DARWIN EU - Drug Utilisation Study on GLP-1 receptor agonists. The Darwin EU study aims to understand prescription patterns, the characteristics of patients prescribed with a GLP-1 RA medicinal product and how these have changed over the past ten years. This will help to contextualise the determinants that might be driving demand for GLP-1 RA and also to have other information on the observed shortage of medicines, including exploring comparative trends in prescription of other medicinal products used in diabetes and for weight management, as well as patterns of off-label use. The final report is expected to be published in December 2024. A follow up study is planned to be conducted in 2025.

The second expert group is discussing potential therapeutic alternatives and clinical implications in case of (potential/actual) shortages of insulins and GLP-1 RA. Following the communication of the discontinuation of selected insulin products over the next two years, among other measures, a clinical expert group has been established to discuss the implications on patient care, including switching options. The first meeting was held on 18 November 2024, where the main topics

discussed included the impact of discontinuation on patient treatment, understanding challenges and concerns associated with switching patients to vial presentations in the event of discontinuation of pen presentations, options for switching to alternative products, and understanding whether healthcare professionals have already been notified in individual countries. The next steps will focus on further analysis of the impact of the discontinuation of these insulin products on the availability of insulins for patients, supporting EU/EEA countries in assessing the impact, further evaluate the clinical parameters to be considered for switching to alternative medicinal products, and conduct communication activities to inform patients and healthcare professionals. See presentation for more details.

6. Communication activities at EMA

6.1. Setting the scene

Monika Benstetter introduced herself as new Head of EMA's communications department and introduced some of the activities of the department, which include the corporate website (www.ema.europa.eu), media relations, EMA's social media accounts, visual design, campaigns to highlight specific issues and communication planning and monitoring.

The ambition of the team is to communicate with impact, which means producing high quality, accessible content with clear calls to action that is tailored to the needs of the audiences and offered in different formats and disseminated through different channels relevant for the stakeholders. This is followed by an evaluation of the successes and lessons learnt.

She then described a selection of communication initiatives that include antibiotics awareness campaign, a media seminar on shortages, framework for mis- and dis-information, a communication perception survey and launch of a key user group for the corporate website.

She concluded by describing the framework to address misinformation with a call to action to the stakeholders. The framework is based on three pillars, the first being 'infodemic insights' where processes for social listening and misinformation management can be employed in the case of an acute public health event. The second pillar is 'collaboration', which is about building bridges with regulatory partners and communities to share best practices and possibly campaigns and the third is 'building trust in public health efforts' that support building trust in EMA and science through targeted actions.

Focusing on the first pillar, infodemic insights, the objective is to establish a validated methodology to help detect misinformation or false narratives and address them. This will consist of systematic monitoring of social media conversations, queries to EMA from the public and insights from partners and stakeholders, followed by analysis of the information to assess risks and prioritise actions to address concerns or fill information gaps.

EMA plans to pilot this process through a case study involving recently authorised therapeutics and vaccines to protect against Respiratory Syncytial Virus (RSV). The pilot aims to identify knowledge gaps early and to deal with any misinformation that could negatively impact public health. Stakeholders are invited to share any information or insights on concerns, false narratives or disinformation in relation to RSV vaccines and therapeutics with press@ema.europa.eu. (See presentation for more details).

6.2. 'Communicating about shortages' campaign

Giulia Gabrielli (EMA) began by presenting a broad overview of the work of the communications team regarding shortages, which is relevant to all of EMA's stakeholders including the pharmaceutical industry, patients and healthcare professionals. There is therefore a need to tailor

the messaging to a broad audience and an overview of the messages that were created was presented. Journalists also represent an important audience as they are an important amplifier of information and can impact patient and consumer behaviour. Direct communication with journalists to explain the different elements related to shortages is essential and a media seminar was planned for the same week. Four work packages were described that would use an integrated approach to address the issue of shortages more broadly taking into consideration the different goals and messages using multiple tools, channels and partners.

She also provided an overview of what had been done around individual shortages such as GLP-1 receptor agonists with several activities that complemented both the MSSG recommendations and GLP-1 shortages workshop such as a press briefing with EMA's executive director, Instagram live interview and social media video-based approach, to capture the interest of a younger audience.

Laure Herold (EMA) talked about enhancing collaboration with the eligible organisations, in particular those who responded to a survey to help to identify the topic of shortages for a co-created campaign with EMA. The steps taken so far were described along with the challenges that included the diversity of the organisations involved, the risk of the message being too abstract to name a few. Opportunities were also highlighted such as the possibility of reaching a broader audience as well as gaining insight into different points of view and access to additional knowledge. The conclusion of these reflections was that the target audience of this joint campaign were individual patients and consumers as well as the networks of organisations accessible via the participating organisations.

The proposal for this joint campaign is Fighting medicine shortages: it takes a team, which demonstrates the collaboration of key actors. The purpose is to highlight the work of the patient and consumers and to bring consistency to the narrative around shortages. The key messages of the campaign were described along with how the campaign will be delivered, such as a page on the EMA corporate website, a production package with key messages and visual identity and a dissemination package. The next steps were presented. See presentation for more details.

6.3. Findings of communication perception survey 2024

Violeta Pashova (EMA) presented the preliminary results of the Communication Perception Survey, with a focus on key findings, stakeholder views, areas for improvement and next steps. The survey is run every two years to assess how EMA's external communications are valued and perceived by our partners and stakeholders. There were 87 questions that covered topics such as EMA's external communications, its openness and transparency as well as stakeholder engagement, making any feedback received very helpful to establish baselines and targets to measure progress, analyse trends and further improve EMA's communication and engagement activities and outputs.

The survey results demonstrated high awareness of EMA's key working areas, communication activities, and channels and overall satisfaction with EMA's external communications remains high. Areas for improvement and preliminary recommendations were identified that will be used to inform EMA's future communication planning and goals. Once the analysis has been finalised, the results of the perception survey will be made public on the EMA website.

6.4. 'Key User Group' for EMA corporate website

Inês Matos (EMA) presented a project called the 'Key User Group' for the EMA corporate website. This is a platform through which the main users of EMA's corporate website can engage in an open discussion with the team responsible for its maintenance and continuous improvement (Online communication service, S-CO-ONL). After a period of inactivity due to the pandemic, the Key User Group will resume its activities in 2025 with the main objectives being to hear feedback from the main users of the website and to exchange ideas on how to improve it. The Key User Group

meetings also provide an opportunity to learn more about planned improvements. EMA is currently seeking to extend participation to one patient, one consumer and two healthcare professionals. Those who are interested in joining it or to get more details, can contact S-CO-ONL via email (newwebsite@ema.europa.eu). The team will be able to share the Terms of Reference in the coming weeks. See presentation for more details.

7. AOB

Key dates and activities for 2025 were presented.