31 April 2025
EMA/115618/2025
Stakeholders and Communication Division

Meeting Summary – joint PCWP/HCPWP meeting

1 April 2025, hybrid meeting - WebEx/Room 2A

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

1. Welcome and introduction

1.1. Welcome and introduction to joint meeting

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

1.2. EMA's 30th anniversary

Emer Cooke, EMA's Executive Director opened the first joint meeting of the year for the PCWP and HCPWP. This was also the last meeting of the current mandate where the co-chairs will be presiding and Emer thanked them for their valuable contributions in steering these important platforms. Emer also presented some of the activities planned around the celebrations of the 30th anniversary and invited the participants to visit the archive exhibition.

2. Regulatory science, innovation and competitiveness

2.1. Clinical trials update

Peter Arlett (EMA) set the scene focusing on the recently published paper 'Clinical evidence 2030: vision' emphasising how generating evidence to inform decision-making is critical for patients' accessing innovative treatments where there is a significant medical need. (see presentation)

The paper addresses 6 points central to the regulators' work: patient voice should guide every step of the way; evidence generation is planned and guided by purpose, data, knowledge and expertise; research question drives evidence choice and embraces spectrum of data and methods; clinical trials remain core but are smarter, better and faster; real world evidence is enabled, and its value is established; high transparency level underpins societal trust.

EMA is also aligned with WHO activities to strengthen clinical trials and contributing to Guidance for best practices for clinical trials.

The 3-year Clinical Trial Regulation (CTR) transition period ended on 30 January 2025 and more details on the activities supporting the transition and continued implementation of the regulation can be found in the ACT EU workplan 2025-2026.

The number of CT in the EU remain steady but the increase seen in other areas of the world, i.e. USA and China, has not been seen in the EU. Therefore, strengthening the EU clinical trial ecosystem remains a key priority where the ACT EU multistakeholder platform is at the core of EU clinical trials activities. These include: simplifying and modernising CTIS; enhancing harmonisation of clinical trials authorisations (CTR Collaborate); supporting collaboration with ethics committees (MedEthicsEU); supporting efforts to streamline trials of medicines and medical devices (COMBINE programme); implementing the ACT EU workplan.

2.2. ACT EU workplan 2025-2026

Laura Pioppo (EMA) provided an update on the ACT EU activities included in its workplan for 2025-2026 (see presentation).

Focus areas for 2025-2026 include overarching activities covering the ACT EU governance and the multi-stakeholder platform; operation of the CTR, including the implementation of the CTR, support the non-commercial sponsors and clinical trial safety; maximising impact of clinical trials through good clinical practice modernisation, consolidated advice on clinical trials and clinical trials methodologies.

There are still challenges related with the implementation of CTR and this remains the top priority. EMA is working closely with the regulatory Network on several fronts, including: RFI/RMS; timelines; risk-based approaches including low intervention clinical trials; methodological innovation; support investigator-initiated trial; regulation interface challenges of CTR/IVDR and MDR.

On a quarterly basis a document is published on the ACT EU website with an update on the CTR implementation.

Laura provided further details on the ongoing revision of CTR/CTIS training materials, with patient involvement (kick off meeting on 4 March) and the consultation with academia and SMEs to identify training needs. Information on the consolidated pilots on scientific and regulatory advice (SAWP-CTCG and Pre-CTA) and early feedback from applicants was shared.

The trial map was launched on 3 March 2025, with opening remarks also from patient and CTCG chair, participants were reminded of the main features of this tool and that although searches can only be done in English for the moment, more languages will come. EMA is seeking feedback to inform future versions of the map.

A discussion point was raised to be further addressed in upcoming meetings: how can this tool be further used (it is a nice tool but how can patients enrol and how can HCPs use it).

ACT EU is currently defining key performance indicators to measure attractiveness of the EU; faster access to treatments and impact of CTs to monitor the effectiveness of CTs in EU. Input to the indicators has been requested to the MSP advisory group and patient and HCP representatives have provided input on what could be considered to measure an impactful CT.

2.3. Feedback from ACT EU workshop on ICH E6 R3

Peter Twomey (EMA) and Kim Pietsch (EMA) provided an update on the ICH E6 R3 revision and the workshop held in February 2025 (see presentation). The principles and Annex 1 were finalised in January 2025, in EU, and the guideline comes into effect on the EU on 23 July 2025. Annex 2 (focusing on alternative trial types and technologies) is being further drafted in line with public consultation and is expected to be finalised in the second half of 2025 (ICH-E6(R3))

It was noted that up to 2,000 attendees joined the ACT EU workshop on ICH E6 R3 from 50 countries. Input from HCPs and patient representative groups significantly contributed to the event. The 'H' in ICH stands for harmonisation and thus not all viewpoints received via comments will be specified in the guidance and it is also acknowledged that one size does not fit all. Therefore, the successful implementation via initiatives such as training is key and critical. The meeting report summarising the high-level points discussed is being finalised ACT EU workshop on ICH E6 R3 (principles and Annex 1) | European Medicines Agency (EMA).

Many questions have been received, and EMA is looking into it and how these could inform additional communication materials. More training activities (including online) are under development.

Francois Houyez (Eurordis) underlined that PCWP and HCPWP provided their input to the principles and Annex 1. From the guideline to practice there are regulations in the middle – CTR, IVDR and others – and implementation is complex, but the sooner is done the quicker the narrative around how more difficult it is to conduct CTs in EU compared to other regions of the world can be overcome. Important to strengthen the role of patient organisations to support patient enrolment in clinical trials. The workshop was an opportunity to discuss on patient engagement methods in clinical trials, e.g. Community Advisory Board, and important new guidance on the consent form.

2.4. Update on Multistakeholder platform

Ana Zanoletty (EMA) presented acknowledging the role of the co-chairs Denis Lacombe (EORTC) and Maria Lamas (AEMPS) (see presentation).

The suggestion to have patient and HCP organisation representatives to come together in advance of MSP AG meetings and work together for preparation to the meeting was raised and this will be further explored.

A new organisation has joined the MSP AG – the European University Hospital Alliance. One patient organisation asked how they could become involved and there is openness from EMA to increase patient representation in the MSP AG.

Ana addressed what the MSP advisory group is involved in, including looking at the collection of problematic requests for information (RFIs) and see how these can inform making more information proactively available to support applicants. Creation of a focus group for the redesign of CTIS training and support material. Ad hoc consultation on recommendation on the use of auxiliary medicinal products in clinical trials. Last meeting of the MSP AG held on 12 March 2025. Dates for upcoming meetings were also shared.

3. Pharmacovigilance

3.1. Risk minimisation in healthcare – Updates on policy, practice, research and engagement. Risk minimisation in healthcare – Updates on policy, practice, research and engagement.

Priya Bahri (EMA) presented an update on EMA activities around the implementation of risk minimisation measures (RMM) in healthcare in collaboration with the working parties.

She described the two components of RMM, the first being the 'message' communicating both the risk and the action to be taken and the second being the 'tools' to disseminate the message and execute the action, such as the Summary of Product Characteristics (SmPC) and the Package Leaflet (PL). Additional RMM tools include patient cards, healthcare professional check lists or qualification systems for prescribing.

Four pillars (policies, processes, research and capacity-building) where engagement is needed to support the implementation of RMM in healthcare were presented.

The policy pillar describes the work done on the new pharma legislation and implementing regulation for better reporting on the implementation of RMM in periodic safety update reports (PSURs) as well as a reflection paper on the digital support to RMM. In 2024, the new GVP Module XVI guideline on RMM was published, which uses an implementation pathway that clarified what is in the regulatory remit and that RMM in healthcare includes further dissemination, knowledge adoption and behavioural change. Engagement with the patients and healthcare professionals is sought to improve RMM that are implementable and effective.

The traditional benefit-risk management cycle has been enlarged to include input from patient and healthcare professionals on the use of the product in healthcare. A distinction is made between a 'formative' approach and an 'evaluative' approach where the implementability (defined as the opportunity for RMM to be effective) of RMM is assessed upfront.

To support the policies mentioned above, processes are needed, and new templates are being developed, engagement events are currently in use and a webpage is being developed where links to RMM materials for different countries in different languages will be available. Processes also include working with the PRAC Risk Minimisation Alliance (PRISMA) group and both the PCWP and HCPWP.

The research pillar includes ongoing impact studies that look at issues with healthcare systems such as RMM control mechanisms and how these are initiated in different countries. In addition, two studies were described: one being a survey on integration of RMM into healthcare dispensing/prescribing software under PRISMA. The second study was on how RMM are integrated in clinical guidelines and conclusions included suggesting collaboration and monitoring of national implementation of RMM along with more educational programmes about pharmacovigilance.

The final pillar of capacity -building includes raising awareness by presenting at conferences and training initiatives of different stakeholders both within and outside the EU. A paper about the future of pharmacovigilance was published with the goal of the safe and effective use of medicines along with the trusted use that can support patient-centred healthcare.

Specifically, engagement of patient and healthcare professionals in RMM is needed in user testing of the materials created by the marketing authorisation holders and in the dissemination via different channels. The PRISMA group established in 2023 looks at RMM options from different perspectives. The group (previously described) includes HCP (general practitioners and pharmacists) and patients. The achievements of the PRISMA group were mentioned and can be seen in the slides. Priya concluded by stating that patient safety is a collaborative effort that EMA and PRAC seek to support by PRISMA and interacting with the PCWP and HCPWP (See presentation for more).

4. EMA policy on competing interests

4.1. Update on EMA policy on competing interests (policy 0044)

Zahra Hanaizi (EMA) presented the revised policy on competing interests that will be implemented from 1 May 2025 and reminded the audience of the context for undertaking this revision. She described the main changes to the policy, which had been shared for public consultation prior to adoption by EMA's Management Board in December 2024 and highlighted the changes that are relevant for this audience.

She provided an overview of the handling of past and current interests in pharmaceutical and medical device companies and in research organisations and concluded with information on the implementation and next steps, in particular regarding the need to update the declaration of interest in the Expert Management Tool.

The new form is now available, and all experts should have received an invitation to submit an updated declaration of interest. In addition, the Procedural guidance to scientific committees' members and experts on completing the European Medicines Agency's declaration of interests in the Experts Management Tool has been updated and provides information to help experts complete their declaration of interest. Please see presentation for more details.

5. European Medicines Agency Network (EMAN) Strategy

5.1. EMANS to 2028

Rui Ivo (HMA and newly elected EMA MB chair) and Melanie Car (EMA) presented on the update of the EMANS strategy to 2028. The development of the strategy included a number of steps including a public consultation phase and ended with its publication on 18 March 2025. A high-level overview of the comments received during the consultation phase was summarised per strategic focus areas as well as plans for implementation that will be reflected in the multiannual workplan to be published (see presentation).

One participant commented on the level of ambition to moving from mitigation to prevention of shortages and the expectation to go beyond identifying root causes of shortages as reflected in the strategy. It was clarified that many steps have already been taken and that concrete actions outlining the next steps for the network will be included in the workplan. Of note is that shortages continue to be a priority for the regulatory network and that this is acknowledged in the strategy with a separate focus area for availability and supply of medicines.

Another participant pointed out about the idea that all can be done without animal models and that it is important to find the right balance when implementing the 3Rs approach. The strategy is strengthening the idea of accelerating the pace of implementation to achieve the balance required for models facilitating reduction, replacement or refinement of use of animals in medicines development.

A clarification was also provided about the link with the European Health Data Space and the EMANS to 2028.

6. Product information

6.1. Update of the QRD template revision of the package leaflet

The ongoing revision of the QRD template started in September 2023, aiming to enhance the package leaflet. Monica Buch (EMA) provided an update on the revision of the QRD template and the upcoming public consultation. There will be two separate public consultations in parallel, with two different deadlines.

- The first consultation will address the potential inclusion of a "Key Information Section" in the package leaflet to gather the views of all interested stakeholders on its usefulness and added value. The evidence and views collected may help inform the decision on whether such a "key information section" in the package leaflet is needed and, if so, what type of information should be provided therein. This separate public consultation will be presented as an EU survey with a shorter deadline.
- The second consultation will focus on the revision of the QRD template, aiming to enhance the package leaflet. The main changes include. The main changes include: reorganisation of information, shortening of some sections (e.g. introductory bullets, optional table of contents), and the improvement and creation of some standard statements to be more patient friendly, and inclusion of a new optional section for instructions for use when these are too extensive or related to a medical device accompanying the medicine. This will be open for external consultation to all interested parties for five months.

Post-meeting note: EMA would like to invite all interested stakeholders to respond to both consultations:

Please note that these two consultations have different deadlines:

- The first consultation invites stakeholders' views on the added value of a "**key information section"** in the package leaflet. You can provide your views by answering an online survey. The deadline for completion is **31 May 2025**.
- The second consultation focuses on the draft revision of the QRD template. You can submit your views by completing the form available on the consultation website and sending it to qrd@ema.europa.eu. The deadline for comments is **31 August 2025.**

The input from patients, consumers and healthcare professionals on this consultation is extremely valuable.

6.2. Electronic product information (ePI) pilot and next steps

Elizabeth Scanlan (EMA) provided an update on the ePI project. ePI is defined as authorised, statutory product information for human medicines in a semi-structured format created using the EU ePI Common Standard. It is adapted for electronic handling and allows dissemination via the web, e-platforms and print. The benefits of ePI include facilitating use cases such as patients receiving information about their medicines through an app or video format, providing alerts for important updates about medicines, easier search and access to relevant information, rapid access to up-to-date information, especially in crisis situations, supporting accessibility for consumers with difficulties accessing paper package leaflets, streamlining management of shortages by providing electronic access to package leaflets, generating administrative efficiencies and supporting regulatory activities, and making searches for potential side effects more efficient.

The EMA's ePI team published a pilot report in December, marking a significant milestone. The pilot, which involved 23 companies and 5 regulators (EMA and the NCAs of Denmark, the Netherlands, Sweden and Spain), successfully created and published ePI in real-life regulatory procedures (both centralised and national). Despite areas for improvement, there were no blockers to ePI's inclusion in the regulatory procedure. The report also outlined recommendations for future actions in three categories: guidance, business processes, and the PLM portal. The team plans to initially implement ePI for centrally authorised products, followed by early adopter NCAs. The team is also working on a reflection paper on how patients should access ePI. The members were invited to refer to the Draft Reflection paper on linking to electronic product information (ePI) from EU medicine packages and to participate on the survey. Deadline for comments 30 June 2025.

6.3. EPF's statement information to patients

Solene Jouan from European Patients' Forum (EPF) began the presentation by emphasizing patients' right to access clear health information and highlighting the importance of the patient information leaflet (PIL) as a primary and essential source of information. EPF called for its improvement to meet patients' needs and urged the EU to consider the following recommendations:

1. Improving the content of the PIL to increase patient safety

EPF recommends adding a key information section to the leaflet to improve readability and accessibility. Studies show that the current PIL format is often inadequate due to complex language, medical jargon, and unclear presentation of side effects. Many patients do not read or understand the entire leaflet. The proposed key information section would include the following elements: indication and use, dosage and administration, undesirable effects and adverse reactions, contraindications and warnings, storage and disposal instructions, use in specific populations, and a disclaimer to read the full leaflet. This section should be written in lay language, avoid jargon, and feature standout formatting.

2. Complementing paper-based information with ePI

EPF advocates for electronic product information (ePI) to complement, not replace, paper-based information in medicine packages. Key considerations include accessibility, patient involvement in ePI design and testing, linking printed and digital formats, availability in all official EU languages, up-to-date regulator-approved information, and ensuring ePI does not collect personal data or navigation information.

3. A comprehensive health literacy strategy

EPF advocates for a comprehensive, EU-wide health literacy strategy for EU citizens. Recognising health literacy as a societal challenge, EPF emphasizes the need for coordinated action at all levels to strengthen prevention and improve all aspects of healthcare.

For further information, (see presentation) and EPF´s position statement

6.4. Joint statement on ePI

Diogo Texeira Pereira from the Standing Committee of European Doctors (CPME) presented a joint statement on ePI on behalf of the co-signatory organisations* (CPME, PGEU, BEUC, AGE, HOPE, AIM, EFN, EAHP, EPF), highlighting, in the context of the revision of the EU general pharmaceutical legislation**,** the importance of maintaining paper package leaflets (PL) while using electronic leaflets as a complementary tool.

The presentation began recognising the importance of the package leaflet as a key tool for information accessibility. Package leaflets provide patients with complete and unbiased information essential for their safety and effective medicine use. They also enhance health literacy and empower patients to make informed decisions about the medicines they take.

He highlighted the necessity of inclusivity, acknowledging that many individuals lack access to smartphones and/or the internet due to various factors including age, location, disability, health, income, religion, or social circumstances. Research showing that few consumers scan QR codes to access product information further demonstrates the need to keep printed medicine package leaflets.

The ePI offers opportunities to improve readability and meet specific patients' needs (such as those with impaired sight). However, there are cost implications as pharmacists and patients may need to print leaflets if they are not included in medicine packages.

It was stressed that strict compliance to the EU General Data Protection Regulation is essential for any platform accessing ePI. This should not compromise patient privacy: third-party links should not store personal information. It should be ensured that patient data is not used for commercial purposes or promotional activities.

The presentation reinforced the importance of maintaining paper package leaflets, and use electronic leaflets as a complementary tool to enhance accessibility and patient empowerment.

See presentation and read joint statement on ePI *(signed by the Standing Committee of European Doctors (CPME), the Pharmaceutical Group of the European Union (PGEU), the European Consumer Organisation (BEUC), AGE Platform Europe (AGE), the European Hospital and Healthcare Federation (HOPE), the International Association of Mutual Benefit Societies (AIM), the European Federation of Nurses Associations (EFN), the The European Association of Hospital Pharmacists (EAHP) and the European Patients' Forum (EPF)) for further information.

7. Availability of medicines. Shortages

7.1. Introduction to shortages topic

Monica Dias (EMA) introduced the topics to be covered in this session.

7.2. Discontinuation of the HMA/EMA Task Force on Availability of Authorised Medicines (TF AAM) and transition to Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and Medicine Shortages Single Point of Contact (SPOC) Working Party

Vanessa Bennett (EMA) gave an overview of the achievements of the Task Force since it was formed in 2016, when EU level collaborative and coordinated management of shortages was first formalised. TF-AAM was a supply and availability hub spearheading activities, including the creation of the EU Single Points of Contact (SPOC) network (now SPOC Working Party) and coordination of EU level actions and initiatives. A first EU-wide definition of shortage was agreed and a number of guidance documents were issued, including on communication to the public and to patient and healthcare professional organisations on the prevention of shortages of medicines for human use. Two multistakeholder workshops were also held. The changes driven by the TF-AAM and the European Medicines Regulatory Network were subsequently embedded in the legislation on EMA's extended mandate in 2022 and the proposed pharmaceutical legislation. Vanessa went on to explain, that while the Task Force is no longer active, key tasks are now integrated into the routine activities of MSSG, SPOC WP and the Working Group of Communication Professionals and will continue to be addressed in those fora. In the coming months EMA will publish a report of TF-AAM activities over the past eight years. For more details, please see the presentation.

7.3. Ongoing critical shortages

Klaus Kruttwig (EMA) informed the working parties of three ongoing shortages in the EU/EEA region: following hurricane Helena, the SPOC WP is closely monitoring shortage of IV solutions from several key suppliers; the second case focused on ongoing intermittent shortages of several oncology products; and EMA and the SPOC WP are assessing the supply situation for all insulin products in the EU/EEA due to the discontinuation of a subset of these products. For all the above, a regular dialogue with the marketing authorisation holders (MAH) is taking place. For more details, please see the presentation.

7.4. European Shortages Monitoring Platform (ESMP) Update

Sofia Zastavnik (EMA) gave an update on the functionalities of the ESMP, a harmonised, transparent and collaborative IT platform to improve the prevention, monitoring and management of medicines shortages across the EU/EEA. The platform has a secure access interface for marketing authorisation holders and regulators and is designed to monitor every scenario with the criticality that the specific situation requires, from normal monitoring to close monitoring and preparedness, to crisis level. Calculations are done to evaluate each situation and whether supply will meet demand. EMA is currently working towards a harmonised reporting across the EU. The public interface of the ESMP provides access to shortage catalogues for ongoing and resolved critical shortages, i.e. those of critical medicines affecting or likely to affect more than one EU member state, with recommendations to patients, consumers and healthcare professionals. For more details, please see the presentation.

7.5. Webinar on shortages - patients and healthcare professionals

Inga Abed (EMA) notified the working parties of an upcoming public webinar to be held on 4 November 2025. Once more information is available, working parties and eligible organisations will be invited to attend the webinar and support in disseminating it to their members will be warmly welcomed.

8. Committee feedback

8.1. Updates from Scientific Committees

Committee for Orphan Medicinal Products (COMP)

Inês Alves (COMP member representing patients) and João Rocha (COMP member representing Portugal) co-presented updates from the COMP. Inês began by giving an overview of orphan designations for 2024 with 30 new conditions being designated. Nine applications were from academia and commented that it is good to see this trend increasing. The majority of opinions fell into following therapeutic areas: congenital, familial and genetic disorders. In 2024, there were 17 marketing authorisations granted for orphan medicinal products and 261 designations were covered by the marketing authorisations granted.

João continued and presented an overview of the 2025 COMP work plan. He described pre-existing and new initiatives and the related activities to support them. These included optimising the quality of initial and maintenance orphan designation by sharing COMP experience with stakeholders, exploring cases and process options for generation of real-world evidence in orphan designation decision making, maintaining and ensuring evidence standards in view of methods used to support significant benefit claims and ensuring consistency, transparency and quality of the ground of opinions. A new initiative is to develop guidance for appropriate methods to perform indirect comparisons by contributing to an analysis and coping exercise, explore the feasibility of adequate indirect comparisons and collaboration and knowledge sharing with HTA colleagues on the assessment of indirect comparisons.

He concluded with the topic of fostering patient involvement at the COMP by creating more robust engagement within the committee and identifying criteria for early patient engagement. This was complemented by Inês who described the initiative to increase and operationalise patient involvement (PI) at the COMP by defining potential criteria to identify early PI in orphan designation initial stage and maintenance and to pilot the use of the CollaboRARE tool (previously presented to the working parties). Another initiative under consideration is to include information about PI into the COMP report, which will potentially support developers/applicants about the relevance of patient involvement, which is all part of the COMP sharing available resources. (See presentation for more information).

Committee for Advanced Therapies (CAT)

Kerstin Sollerbrant (CAT member representing patients) began by presenting the committee members representing patients and then described their involvement in several projects listed in the 2025 workplan. In addition to contributing to the reflection paper on Patient Experience Data, other activities were described. The use of real-world data (RWD) to support regulatory decision-making. RWD encompasses natural history and patient treatment data from registries or other valid sources. To facilitate optimisation of clinical evidence generation in drug development programmes, it is desirable that evidence requirements address regulatory needs as well as those of other down-

stream decision makers. The third activity highlighted by Kerstin was to engage with different stakeholders including industry, academia, not-for-profit and patient organisations.

The CAT has used the occasions of the strategic review and learning meetings to focus on patient experience data and patient relevant outcome measures to talk about clinically meaningful measures for patients which will be continued on in the 2025 meeting. See presentation for more details.

Paediatric Committee (PDCO)

Johannes Taminiau (PDCO member representing Healthcare Professionals) reported on some of the key objectives of the 2025 work plan of the PDCO. These included the definition of strategies on how to approach paediatric investigation plans (PIPs) for identified therapeutic areas or certain paediatric developments. With the large number of medicines with different mechanisms of action and only a limited number of paediatric cancers a selection must be made. A multistakeholder paediatric oncology strategy forum is planned for Q3 2025 and the publication of the outcome of the workshop.

The stepwise PIP is being established as a permanent procedure after a successful pilot scheme.

The workplan describes the review of the experience from the new summary report and key elements forms to ensure their statistical robustness. Essential sections of the text submitted by applicants will be inserted into the summary report.

Implementation of the ICH E11A guideline on paediatric extrapolation is planned via the development of points to consider, to help with assessments of extrapolation, the development of training material and re-evaluation and improvement of reflection of extrapolation in PIP opinion. What cannot be extrapolated must be further defined and is essential for PIPs.

Finally the horizontal activities aimed at improving dialogue between PDCO and clinical trial assessors is planned to facilitate mutual understanding of the interplay between assessment or PIPs and clinical trials. Involvement of the PDCO in PIP-related CHMP procedures is planned in order to enhance dialogue.

He concluded by describing the objective of increasing interactions with stakeholders (including patients and public) to raise awareness of the work of the committee.

Committee for Herbal Medicinal Products (HMPC)

An Lê (HMPC member representing France) presented the objectives of a communication initiative of the HMPC that is an ongoing part of the committee's workplan. The committee has focused on what to communicate, how and to whom. To explore this they conducted a study of the websites of the national agencies, worked on a new draft of the assessment report summary for the public (ASRP) and aimed to publish information on the status of the different products to differentiate herbal medicines from other medicines.
They conducted a 15-question survey among 28 national competent authorities on what is available on their websites about herbal medicines, the level of scientific information available and how the HMPC activities are reported among Member States. The conclusion was that information about herbal medicines is limited at the national level, more focused on regulatory aspect, but some information for patients and healthcare professionals exists. There was limited scientific communication on HMPC activities, which was targeted primarily to the scientific community and not to the general public. The Dutch and Swedish websites helped in the identification of best practices to inform on the best use of herbal medicines, to focus on safety, interactions and status. These websites present clear and condensed information through clear language, short videos and images.

The new ARSP templates were built on national experiences above as well as a survey of university students. Survey results indicated that respondents valued clear and readable information, use of colours and images, information on types of preparations to name a few. Based on this feedback a

draft has been created and endorsed by the committee. The new template was presented that includes a statement that this document is not the summary of product characteristics or the package leaflet but rather an assessment report for the public based on the scientific bibliographical work. Additional sections include the types of preparations, efficacy, interest in the use of the medicines and precautions for their use. The example of the Valerian root ARSP was presented.

An invitation to the working parties was made for any comments on the new ARSP template, which is currently dedicated to patients, on the presentation of the document or communication. See presentation for more information.

AOB

There was no other business raised.

Meeting Summary – joint PCWP/HCPWP meeting

2 April 2025, hybrid meeting - WebEx/Room 2A

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

9. Leveraging data, digitalisation and artificial intelligence

9.1. Data Analysis and Real World Interrogation Network (DARWIN EU)-three years of a journey

Andrej Segec (EMA DARWIN EU® Project manager) provided an update on the establishment and operation of DARWIN EU. The vision of the EMA when DARWIN EU® was designed was to enable the use of Real-world evidence (RWE) in regulatory decisions thought medicinal product life-cycle. After three years, this vision is now in action to support EU regulatory decisions.

During the first phase of the network, 10 data partners from 8 European countries were included covering approximately 26 million active patients. The network has since expanded to 30 data partners from 16 European countries, covering approximately 180 million active patients. In parallel, the number of studies initiated have increased from 4 studies initiated in 2022 to approximately 100 studies estimated to be initiated in 2025.

By 2030, the vision is to have clinical evidence generation further guided by the patient voice and informed by existing data and knowledge; study design being driven by research questions to be addressed; clinical trials being more efficient and impactful; real-world evidence (RWE) use enabled and its value fully established; and trust built through transparency. Applying these six principles for clinical evidence generation will result in increased efficiency and effectiveness for research and development in Europe, enable better data-driven decision making and accelerate patient access to medicines.

Randomised clinical trials (RCTs) are the mainstay for providing drug efficacy and safety information to regulators. However, the value of Real World Data (RWD) is increasingly acknowledged for transforming, accelerating, and de-risking decision-making processes. RWD improves the efficiency in the design and conduct of trials and increases public health impact. At the time of marketing authorisation, RWD contextualises study results and ensures the generalisability of results to the target population. It is very valuable in post-authorisation procedures for long-term supervision of the benefit-risk balance.

Andrej provided an overview of the RWE experience report 2023-2024 , which summarises the achievements and progress made to date. He also presented various examples of recently completed studies supporting regulatory decision making on medicines. For more details, see presentation.

9.2. Update Patients experience data – reflection paper

Kaisa Immonen (EMA) gave an update on the reflection paper on patient experience data (PED), a key deliverable of the Agency's PED initiative originating in a 2022 multistakeholder workshop. PED is welcomed as an important contribution to the totality of evidence and are working collaboratively to enable its broader use in regulatory decision-making. The reflection paper will provide a general EU framework and principles, rather than specific methodological guidance, and encourages medicine developers and other stakeholders to collect PED using reliable and validated methodologies. Developers will be encouraged to come to EMA for scientific advice or qualification opinion. Following internal consultation in early 2025, the reflection paper is planned to be released for public consultation in Q4 2025. Comments were already received from some PCWP/HCPWP members and further input will be welcomed. For more details please see the presentation.

9.3. Public and stakeholder interventions during medicines evaluation

Kaisa Immonen (EMA) presented the topic for discussion and feedback from the working parties. The added value of patients, consumers and healthcare professionals' input has been demonstrated over many years of engagement, and EMA has established methodologies for consulting these groups at several points along the regulatory pathway of a medicine. However, sometimes, evaluation can take longer than anticipated for various reasons which EMA is unable to communicate externally, or the rationale for a negative conclusion to a scientific evaluation may be challenging to explain. It was discussed what actions could potentially be taken together to raise awareness of how the assessment process works and what kinds of interventions are helpful and not helpful, with the recognition that EMA must always remain open to listening to the concerns of stakeholders.

10. Reflection from PCWP and HCPWP co-chairs

10.1. End of mandate comments from PCWP and HCPWP Co Chairs engagement.

The chairs provided their reflections from their mandate of the past three years.

Marko Korenjak (PCWP co-chair) began by describing his motivation for applying to be co-chair and his experiences as well as insights into improvements for the next mandate. He emphasised that asking questions can lead the discussion in unknown and informative directions.

Rosa Giuliani (HCPWP co-chair) then shared with her reflections as co-chair of the HCPWP. She expressed that she learnt a lot as a healthcare professional and felt very enriched by the discussions. They both recommended the experience of co-chairs to the working party members for the next mandate.

10.2. Call for new mandate 2025-2028

Ivana Silva (EMA) described the expansion of both working parties from 22 members to 25 after agreement from all of the human scientific committees. The corresponding mandate and rules of procedure have been updated to reflect the change. Maria Bonafonte (EMA) followed up by presenting the timeline for eligible organisations to apply to the respective working parties for the new mandate. (see presentation)

10.3. Information on election of Co-Chairs

Maria Mavris (EMA) presented information related to the election of the new co-chairs. This will happen once the working party memberships have been decided and the representatives named for each working party. The role and responsibilities were described ahead of the elections that will take place in September 2025.

10.4. Highlights of PCWP/HCPWP 2023-2025 mandate

A short video of the highlights of the mandate was presented.

11. Information ecosystem management

11.1. Stakeholder listening pilot and 11.2. Update on misinformation framework activities

Sophie Labbe (EMA), Rosa Gonzalez-Quevedo (EMA) and Margarita Gkrava (EMA) presented on ongoing activities to establish and information ecosystem management process aiming to better and systematically capture stakeholders' needs, expectations, concerns and experience to inform organisational decision-making and the Agency's strategy (see presentation).

There are two projects in a pilot phase addressing aspects of misinformation management (where a more immediate action is needed) and stakeholder listening (to anticipate issues in a more proactive manner).

The pilot on misinformation management is testing EMA processes with a case study on Respiratory Syncytial Virus (RSV) vaccines, gathering retrospective insights on the 2024-2025 cold season. The goal is to develop an EMA integrated process for infodemic insights, adapting existing guidelines to EMA’s specific mandate.

The pilot on stakeholder listening has taken Long COVID as case study. The objectives are to identify key scientific evidence, concerns and information gaps on Long COVID, explore the use of stakeholder listening as source of Patient Experience Data on Long COVID, and evaluate the use of stakeholder listening to support key EMA activities.

A discussion followed on the overall process, on the research questions for the Long COVID pilot and what other misinformation issues beyond the RSV pilot could be potentially considered for further engagement.

EMA secretariat will follow up with a call for expressions of interests from organisation to engage more closely in the ongoing pilots and further report in an upcoming PCWP/HCPWP meeting. All members were invited to also highlight what aspects they would like to prioritise as follow up to the two pilots.

12. Communication activities

12.1. Update on communication campaigns

Giulia Gabrielli (EMA) and Camelia Enachioiu (EMA) provided an update on communication campaigns. Giulia began by presenting the communication plans for 2025. The campaign on Fake Medicines was launched earlier in the year and future campaigns included European immunisation week, GLP-1 influencer campaign and a campaign on shortages co-created with some members of the working parties. Each campaign was described along with the various communication tools and

supporting documents used to amplify the important messages. The working party members were encouraged to actively disseminate the information.

Camelia highlighted the communications approach around the European Immunisation Week with key messaging around promoting information on vaccine-preventable diseases starting with measles and human papillomavirus (HPV). EMA's communications team will use video quizzes for the first time, which will be filmed on the streets of Amsterdam with the aim of promoting the need to be informed about vaccination. She then described the first influencer campaign on GLP-1 medicines, which will involve around 15 European-based influencers who represent groups such as doctors and health specialists. The social media platforms that will be covered include YouTube, Instagram, Facebook, and TikTok, and as EMA is not present on all of these platforms, the campaign will help to reach new audiences. In the case of the GLP-1 campaign, the intention is to reach out to young people and lay audiences to inform and advise them that these are serious medicines and not a quick solution for weight loss. The message is around responsible use rather than shortages. Continuing on the topic of fighting medicine shortages, the final campaign for 2025, PCWP and HCPWP members have already contributed, and the call is still open for more contributions. The co-created campaign showcases the work that is going on at the EU level to fight medicine shortages and includes regulators, national agencies, patient and healthcare professional organisations. In this context, key stories are being collected from these organisations as well as from EMA and national competent authorities and include video testimonials, pictures and quotes that will all be included on a dedicated webpage on the corporate website. For more information, see presentation.

13. One Health approach

13.1. Cross-agency One Health Task Force – a framework for action

Ana Vidal (EMA) presented on one of the initiatives EMA is currently involved with together with 4 other EU agencies to advance the One Health approach (see presentation). This approach aims to be better able to prevent, predict, detect, and respond to health threats.

Ana outlined the One Health policy landscape at both international and EC levels and briefly introduced the activities of the recently formed "cross-agency One Health task force", a collaboration between EMA, ECDC, EFSA, ECHA and EEA. This task force has developed a framework for action, published in May 2024, with the aim *to* facilitate strategic coordination in the implementation of the One Health approach, promote a One Health-driven research agenda, enhance capacity building on One Health, strengthen One Health stakeholders' engagement and support the development of partnerships through joint One Health activities.

AMR is one of the most known case studies of the One Health approach but there are others, and the ambition is to create a path from concept to practice working in more collaborative ways across sectors to enable a change of mindset to be better able to detect, prevent, prepare, and respond to health threats.

One participant raised the topic of pharmaceuticals in the environment and how to address 'green' manufacturing. Another pointed to the relevance of the One Health approach in the EU Global Health strategy.

Overall, members welcomed the presentation and the inclusion of updates on the task force activities in upcoming meetings.

14. Members' voice

14.1. Patient organisations - 10-year experience of patient involvement EMA, opportunities, challenges and learnings for meaningful patient involvement

Dimitrios Athanasiou and Elizabeth Vroom of the World Duchenne Organisation (WDO) presented their experience, challenges and learnings regarding their interactions with EMA. WDO has 47 members in 39 countries, was established 20 years ago and has activities in research, advocacy, regulatory and policy areas, which were described in the presentation.

The involvement, commitment and investment of WDO in EMA regulatory procedures was described and ranged from scientific advice, scientific advisory groups to CHMP oral explanations. An important reflection was made on the future of meaningful patient involvement in light of the changing regulatory landscape. The challenges of patient involvement were described and included limited representation, resource constraints, timing of receipt of documents, need for training and consistent engagement to name a few. It is important to acknowledge that knowledge gaps exist of both sides of the table. They concluded with ideas for the way forward to optimise the opportunities for patient engagement and a call for recognition of their expertise based on lived experience. See presentation for more information.

14.2. HCP organisation - Risks on the misuse of medicines

Jorge Batista from the Pharmaceutical Group of the European Union (PGEU) presented the challenges and risks linked with the misuse of medicines, highlighting recent occurrences on potential misuse of paracetamol among teenagers. He explained that although the media could be amplifying the importance of a few isolated cases and therefore causality for a trend was difficult to establish (for reference, Euractiv). PGEU urged stakeholders to be vigilant as medicines such as paracetamol are widely available without a prescription and in different settings beyond pharmacies, and can cause severe health issues if misused (liver damage, bleeding, brain damage and even death).

The European Consumer Organisation (BEUC) was aware about this possibly fake challenge and pointed out that the European Commission had opened an investigation focusing on the platform's protection of children, and encouraged the PCOs and HCPOs to bring similar harmful challenges to the attention of the authorities for their investigation, especially in digital platforms.

There was a discussion on enhancing control over over-the-counter medications, with some advocating for better monitoring through electronic health records, though these are not available in all Member States.

From a pharmacovigilance perspective, Belgium, as the Lead Member State monitoring the safety of paracetamol, informed the WP about steps taken via the national and European network of Pharmacovigilance following the alert from the Belgian Poison Center in January. Based on all the data available at that moment in time, it was concluded that no signal of paracetamol overdose related to any social media challenge could be identified yet. In addition, no concerning trends were emerging from the available data on the recently published DARWIN EU® report on paracetamol prescribing and overdose in Europe (see RWD catalogue link).

It was concluded that, despite no evidence being found in this particular case, misinformation in healthcare poses significant challenges to patient safety and public health via different social media. Patients, consumers, and healthcare professionals play a crucial role in staying vigilant, monitoring, preventing and reporting harmful campaigns.

14.3. Preparing future roles for patients and HCP in EMA committees PRAC-CHMP

François Houÿez (EURORDIS) presented a reflection on how to prepare for the inclusion of civil society in the future CHMP and PRAC committees. He began by describing the main role of the CHMP and the evolution of the diversity and complexity of the workload of the committee. The proposed changes under the general pharmaceutical legislation could lead to increased complexity for the CHMP as they may absorb some of the activities of other committees.

With regards to patients, they are regularly consulted by EMA for scientific meetings however there is little understanding of the potential future situation as described in the different articles of the proposed new legislation.

He described the possible roles for patients appointed to the CHMP, which would likely not include acting as rapporteur and presented comments from patients who were consulted on this subject (see presentation for more details). He concluded with a proposal to include patients and healthcare professionals from the PCWP and HCPWP to act as observers on the CHMP, as was done with the Pharmacovigilance Working Group (prior to creation of the PRAC) to highlight important committee tasks, to report back to the working parties on the estimated workload and recommendations to help share the workload and provide best input. This observation phase, if CHMP and PRAC approve, could start in 2025 to best prepare for possible legislative changes.

AOB

There was no other business raised.