02 October 2025
EMA/307703/2025
Stakeholders and Communication Division

Meeting Summary - Patients and Consumers Working Party (PCWP) meeting

23 September 2025, hybrid meeting - WebEx/Room 2A

Co-Chairs: Juan Garcia-Burgos (EMA)

1. Welcome to 2025-2028 mandate and tour de table

1.1. Welcome and introduction / Health and safety information

Juan Garcia Burgos (EMA) opened the meeting, welcoming all participants in person and online to this first meeting of the new mandate.

1.2. Tour de table of PCWP members, alternates and observers

All working party members, organisations and committee members, were invited to introduce themselves at the start of this new mandate.

2. Election of PCWP co-chair

2.1. PCWP co-chair election proceedings

Following a brief presentation from both candidates and confirmation the required quorum was reached (21 eligible to vote), the voting was open.

Marco Greco (European Patients' Forum) was elected as the new co-chair to the PCWP for its 2025-2028 mandate after one round of voting. The election procedure was overseen by the EMA legal department. For more information, please see press release.

2.2. Nomination of observers to the HCPWP

Mehitabel Holler (European Heart Network) volunteered to be the observer to the HCPWP, which was agreed by all members of the PCWP.

3. Work plans for working parties

3.1. Discussion on draft work plan for 2025-2028

Ivana Silva (EMA) presented a proposal of the work plan for the mandate 2025-2028. She began by presenting the previous format and then displayed a new structure for the next workplan 2025-2028. The structure takes into consideration the overarching network (EMAN) strategy. The objective is to proceed a streamlined work plan that would include key actions such as communication, raising awareness, transparency and trust, and ensuring that the voices of these stakeholders are captured in EMA activities.

She presented the themes of the EMAN strategy that will influence the structure of the work plan along with the draft core activities that have been currently identified. The topics selected by the PCWP members for inclusion into the next work plan were also presented and a discussion followed where additional topics were highlighted by the working party members.

She concluded with a call for volunteers to join a small working group that will convene to contribute to the joint PCWP-HCPWP work plan (2025-2028). The dates for future meetings were also presented and will be included in the annex of the work plan. The work plan will be finalised in 2025 and presented to the working parties at a future meeting.

AOB

Inga Abed (EMA) presented an update on the upcoming public webinar on shortages taking place on 4 November 2025. This webinar targets patients, consumers and healthcare professionals and is one of several activities of shortages that will kick off in October.

Other activities include an influencer campaign on GLP-1 receptor agonists organised in collaboration with nine social media influencers, and a shortages campaign co-created with members of the eligible organisations. The aim of the webinar is to inform the public, patients and healthcare professionals about EU regulatory processes in place to manage shortages, showing stakeholders where to find information about shortages and providing information on what they can do when faced with shortages.

Eligible organisations are encouraged to register for the event (registration link was provided in the invitation email) and help promote the event amongst their extensive networks and call for people to follow the broadcast on the day.

Meeting Summary - Healthcare Professionals' Working Party (HCPWP) meeting

23 September 2025, hybrid meeting - WebEx/Room 2A

Co-Chairs: Juan Garcia-Burgos (EMA)

1. Welcome to 2025-2028 mandate and tour de table

1.1. Welcome and introduction / Health and safety information

Juan Garcia Burgos (EMA) opened the meeting, welcoming all participants in person and online to this first meeting of the new mandate.

1.2. Tour de table of HCPWP members, alternates and observers

All working party members, organisations and committee members, were invited to introduce themselves at the start of this new mandate.

2. Election of HCPWP co-chair

2.1. HCPWP co-chair election proceedings

Piotr Szymański (European Society of Cardiology) was elected as the new co-chair to the HCPWP for its 2025-2028 mandate after 2 rounds of voting. The election procedure was overseen by the EMA legal department. For more information, please see press release.

2.2. Nomination of observers to the PCWP

Elena Petelos (European Forum for Primary Care) volunteered to be the observer to the PCWP and Robin Doeswijk (European Hematology Association) volunteered to be the alternate, which was agreed by all members of the HCPWP.

3. Work plans for working parties

3.1. Discussion on draft work plan for 2025-2028

Ivana Silva (EMA) presented a proposal of the work plan for the mandate 2025-2028. She began by presenting the previous format and then displayed a new structure for the next workplan 2025-2028. The structure takes into consideration the overarching network (EMAN) strategy. The objective is to proceed a streamlined work plan that would include key actions such as communication, raising awareness, transparency and trust, and ensuring that the voices of these stakeholders are captured in EMA activities.

She presented the themes of the EMAN strategy that will influence the structure of the work plan along with the draft core activities that have been currently identified. The topics selected by the HCPWP members for inclusion into the next work plan were also presented and a discussion followed where additional topics were highlighted by the working party members.

She concluded with a call for volunteers to join a small working group to convene to contribute to the joint PCWP-HCPWP work plan (2025-2028). The dates for future meetings were also presented and will be included in the annex of the work plan. The work plan will be finalised in 2025 and presented to the working parties at a future meeting.

4. Ongoing review of the Healthcare Professional engagement framework

4.1. Update of framework of interaction with HCPs

Ivana Silva (EMA) provided an update on the progress of the review of EMA's Framework of Engagement with Healthcare Professionals and their Organisations. Significant progress has been made with the establishment of a drafting group in February 2024. This group includes diverse representatives from various healthcare professional organisations. Key updates to the framework includes the description of the framework objectives in a format that lists the expected outcomes for EMA and for HCP organisations, alignment with the framework of engagement with patients and simplification of content, introduction of new definitions (e.g., "healthcare professionals"), recognition of the need to foster shared interests with academia and life sciences students, integration of veterinarians to support the One Health approach, and the inclusion of a monitoring and reporting section that incorporates agreed feedback survey methodologies, as outlined in EMA's Framework Strategy for External Communication and Stakeholder Engagement.

The draft framework for interaction with healthcare professionals is planned to be launched for consultation in October 2025. The aim is to have written endorsement of the Healthcare Professionals Working Party (HCPWP) by the end of 2025, followed by adoption by the Management Board in March 2026, and subsequent publication thereafter.

AOB

Inga Abed (EMA) presented an update on the upcoming public webinar on shortages taking place on 4 November 2025. This webinar targets patients, consumers and healthcare professionals and is one of several activities of shortages that will kick off in October.

Other activities include an influencer campaign on GLP-1 receptor agonists organised in collaboration with nine social media influencers, and a shortages campaign co-created with members of the eligible organisations. The aim of the webinar is to inform the public, patients and healthcare professionals about EU regulatory processes in place to manage shortages, showing stakeholders where to find information about shortages and providing information on what they can do when faced with shortages.

Eligible organisations are encouraged to register for the event (registration link was provided in the invitation email) and help promote the event amongst their extensive networks and call for people to follow the broadcast on the day.

Meeting Summary – joint PCWP/HCPWP meeting

24 September 2025, hybrid meeting - WebEx/Room 2A

Co-Chairs: Juan Garcia-Burgos (EMA), Marco Greco (PCWP) and Piotr Szymański (HCPWP)

1. EMA activities – an overview and update

1.1. Introduction to the assessment of medicines in the European Union

Bruno Sepodes (CHMP Chair, Infarmed) described the European Medicines Regulatory Network (EMRN) which is made up of EMA, the national competent authorities and the European Commission. He emphasised the EMA scientific committees and the work of the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh) for human medicines and CMDv for veterinary medicines. The benefits of the centralised procedure were illustrated as well as the evolution of the mandatory scope, which are medicines that must come through EMA for evaluation via the centralised procedure.

EMA's expert network encompassing regulators, patients and healthcare professionals was highlighted as one example of what works very well in the European system. The experts contribute to the work of the committees or working parties and along with international collaboration ensure a harmonised approach to facilitating the development of medicines globally. In addition to the evaluation of medicines, the many initiatives and activities to support research and innovation of medicines prior to submission of an application for marketing authorisation were described.

He mentioned the different actors involved in the evaluation process from EMA support staff and the product team along with the experts from the network and described the assessment process and timelines. Following CHMP assessment, the committee opinion, along with important annexes including patient information, is sent to the European Commission for final decision. Once on the market, EMA coordinates the safety monitoring of the medicines, which occurs via many different sources. Information that is collected is sent to the Pharmacovigilance and Risk Assessment Committee (PRAC) for assessment and for the committee to issue a recommendation, which is communicated to the EMRN.

He concluded by mentioning the bigger picture and the importance of trust and transparency in the regulatory system and network and the key role of platforms such as the PCWP and HCPWP.

This presentation was part of a webinar organised by EMA and Heads of Medicines Agencies (HMA) to explain how the EU regulatory system for medicines functions. This presentation can be found here and other presentations of the webinar can be found here.

1.2. Overview of EMA 30th anniversary scientific conference

Steffen Thirstrup (EMA's Chief Medical Officer) described the scientific conference that took place on 25 June as part of EMA's 30th anniversary celebrations. More than 300 participants attended in person, and many were connected to the meeting online. The conference was opened by His Majesty King Willem-Alexander of the Netherlands with an opening speech. The scientific portion of the conference started with a presentation on the discovery of the GLP-1 hormone by Professor Jens Juul Holst. The conference continued with a look back over the 30 years from the first Executive Director, the patient's perspective as well as the difficult times faced by EMA during relocation and the COVID-19 pandemic. This naturally led to a look forward to imagining the future of science and regulation, what's next for biotechnology, AI and the reduction of animal testing, women's health

and gender equality. The European Commission presented the impact of One Health and the conference concluded with an EMA presentation on how to tackle the next pandemic. More information can be found on the event webpage. For more information, please see presentation.

1.3. EMA's first public Open Door Day

Maria Mavris (Patient liaison) presented EMA's first public Open Door Day. Taking place on the occasion of Europe Day, 9 May 2025, EMA welcomed members of the public to its premises in Amsterdam for the first time. This was the opportunity to describe the work of the Agency in clear language with topics ranging from the centralised process for authorisation, safety monitoring and One Health. Visitors were guided around the building by EMA staff member hosts and the visit concluded at the archive exhibition showcasing 30 years of EMA history. You can consult the agenda and presentations from the Open Day, see presentation.

1.4. Ongoing public consultation on biosimilar reflection paper

Steffen Thirstrup (EMA's Chief Medical Officer) reminded the audience of the scientific and regulatory background on biosimilars. He explained that when a company manufacturing a biological product would like to optimise their processes for manufacturing that international guidance exists to ensure the continued safety and efficacy of the product and that the marketing authorisation is maintained.

In 2004, biosimilar guidance was first created to support demonstration of the similarity of the 'biosimilar' to the originator product building on the same scientific/regulatory principle as applied to changes in manufacturing. Now with 20 years of biosimilar experience, discussions are ongoing on the necessity of comparator clinical studies to determine any differences between the biosimilar and the originator. The consideration of safety is first and foremost for regulators and developers of biosimilars are strongly encouraged to request scientific advice.

A multistakeholder workshop on a 'tailored clinical approach in biosimilar development' was held at EMA on 22 September to discuss the reflection paper on a 'tailored clinical approach in biosimilar development'. The reflection paper is open for public consultation until 30 September 2025. For more information, please see presentation.

2. Engagement with other stakeholder groups – Academia and Industry

2.1. Academia: outreach and engagement activities

Ralf Herold (EMA) presented the EMA activities geared to engage with academic researchers, describing the high-level framework of collaboration with academia and the broad set of support offerings for this specific stakeholder group (see presentation). He provided some examples of public engagement and sharing experience with academic researchers and developers, including the recent establishment of the European platform for advancing regulatory science research. Additional background was also provided on the systematic and strategic approach to advancing regulatory science. Furthermore, Academia briefing meetings and Collaboration management meetings are intended to welcoming researchers and developers from the academic sector, including not-for-profit entities and consortia or societies pursuing research to understand researchers' challenges but also EMA's scientific challenges, support on how to advance R&D capacities and have an opportunity to discuss regulatory aspects. Ralf concluded by explaining the scientific advice offered to academic developers to provide EU level advice on tests and trials necessary to demonstrate quality, safety and efficacy and on applicable scientific requirements for marketing authorisation.

During the discussion, it was mentioned that exploring ways to provide additional information to patient and HCP organisations about opportunities for research calls would be helpful. The point was

also made about how challenging it is to involve clinicians in discussions around conceptual aspects of regulatory science as it requires further awareness and capacity building supported beyond clinical learned societies and representative professional organisations, including hospitals and other healthcare facilities to free up time.

2.2. Small to medium-sized enterprises (SMEs): outreach and engagement activities

Helene Casaert (EMA) described the activities designed to support small, micro and medium-sized enterprises (SMEs) (see presentation). A dedicated SME office, established by the SME Regulation in 2005, provides dedicated advice, guidance and assistance to SMEs to support the development of medicines in the European Union (EU) and the European Economic Area (EEA). As of today, more than 2.000 SMEs are registered and supported by EMA. Support includes regulatory assistance, dedicated briefing meetings such as training activities.

Since 2021, EMA has also collaborated with the European Innovation Council (EIC) to identify support for Breakthrough Technologies and funding opportunities for start-ups and SMEs.

This year the SME office is celebrating 20 years and a roundtable with stakeholders will be organised on 17 October to review key achievements of the SME regulation and discuss challenges and next steps.

2.3. Industry associations: outreach and engagement activities

Maria Filancia (EMA) provided an overview of how EMA engages with pharmaceutical industry organisations, following the structured approach defined in the specific framework for interactions with this stakeholder group (see presentation). Maria described more in detail the role of the Industry Standing Group (ISG), established in 2022. The ISG enables regular dialogue with industry stakeholders on strategic topics relating to human, veterinary medicines and medical devices. Moreover, annual bilateral meetings are also organised upon request from pharmaceutical industry associations: the purpose is to exchange views and promote dialogue on high level and strategic topics of common interest, including business priorities and pipeline forecast and specific challenges or proposals from the organisation. Another area of engagement includes platform meetings with representatives of the pharmaceutical industry to address operational aspects linked to research and development for medicines, the centralised marketing authorisation procedure and pharmacovigilance.

3. Communication activities at EMA

3.1. Communication materials on safety monitoring of medicines: engagement with stakeholders

Violeta Pashova (EMA) began the presentation by explaining that, due to the high demand for information, questions, concerns, and occasional misunderstandings from patients and healthcare professionals about how the safety of medicines is monitored and ensured within the EU, EMA is developing new communication materials on medicines safety monitoring.

The materials aim to explain, in clear and accessible language, how EMA and EU Member States continuously monitor the safety of medicines and take appropriate action when needed. The planned formats include a booklet, videos, infographics, and other communication materials, which will be made available on the EMA's corporate website and promoted via its social media channels. EMA will also reach out to partner organisations to encourage them to amplify key messages through their channels. The primary target audiences include the general public, patients, caregivers, consumers,

healthcare professionals and their respective organisations. Translations into all EU languages are envisaged.

Stephanie Cohen (EMA) highlighted the key topics identified for inclusion in the content, provided an update on the progress of the project, and outlined the next steps. As part of the development process, EMA consulted a small group of patients and healthcare professionals, collected their feedback on the topics covered in the booklet, and their input has been taken into account (see presentation).

Members welcomed the initiative and expressed their willingness to provide additional comments.

The publication of some of these materials is planned around *#MedSafetyWeek* (November 3–9, 2025) to seize upon this opportunity to promote the materials. EMA will notify the group upon the publication of the communication materials on medicine safety monitoring to request support for their further dissemination.

3.2. Risk minimisation measures webpage: what you can find

Priya Bahri (EMA) presented the new EMA's webpage (see presentation) on risk minimisation measures (RMM). The webpage provides comprehensive information on what RMMs are, relevant guidelines, and links to national repositories containing additional RMM resources for concerned medicinal products in each country's official language.

To access the webpage, visit Risk minimisation measures (RMM) | European Medicines Agency (EMA) or search online using the keyword "EMA RMM".

4. EMA feedback surveys

4.1. EMA surveys of organisation satisfaction

Ivana Silva (EMA) presented the background of EMA satisfaction and communication perception surveys since 2008 (see presentation). Currently, communication perception surveys are sent to all stakeholders and focus on external communications; while they include some elements of engagement, they do not reflect all aspects covered in the satisfaction surveys, which are sent to eligible organisations. Satisfaction surveys have consistently had positive results but low participation rates. A co-creation approach was agreed in 2023, and EMA has been reflecting on the type of survey that would best capture most important aspects and to encourage participation. The aim is also to streamline communication and engagement elements into one biennial feedback survey. A call for volunteers was made to join a small group for the reflection and shaping of the survey.

5. Update on activities related to pregnancy and lactation

5.1. New GVP guidance on minimising embryo-fetal risks of medicines

Priya Bahri (EMA) presented the new GVP guidance on risk minimisation measures (RMM) for medicines with embryo-fetal risks, published on 28 August 2025 (see the guideline). The guideline provides information on the regulatory options for RMM actions to be taken by patients and healthcare professionals to avoid in utero-exposure and on the points-to-consider for selecting additional RMM tools or demanding a pregnancy prevention programme (PPP). Priya explained the public consultation and aspects emerging from the consultation and how these were reflected in the guideline. From the discussion, it emerged the suggestion to take the discussion further on how to

handle different risk levels during stages of pregnancy and implications for clinical guidance. For more information, please see presentation.

6. Committee feedback

CMDh: Jikta Vokrouhlická provided an overview of the Coordination Group for Mutual Recognition and Decentralised Procedures – human (CMDh), which is a unique network of cooperation between the national competent authorities (NCAs). More about the coordination group can be found here.

She provided a comparison of medicines authorised via the centralised procedures and those via the NCAs and described the MRI product index where details on medicines authorised via the mutual recognition/decentralised procedures (MRP/DCP) can be found. The composition of the CMDh, collaboration with EMA and the agenda structure were described along with transparency measures such as the publication of the agenda, minutes and press releases. She concluded by describing five main priority areas and focused on the optimisation of communication and relationships with interested parties and stakeholders, such as the patients, consumers and healthcare professional organisations and could be facilitated via the PCWP and HCPWP.

Nina Malvick continued with a focus on the current work of the Coordination Group in particular, safeguarding public health. A sub-group exists that is dedicated to working on safety who prioritise transparency in light of the numerous national procedures for the authorisation of medicines. How to improve outreach to patients, healthcare professionals, pharma industry and national agencies with this information is currently being explored. Further, CMDh cooperates with PRAC on safety issues for nationally authorised products and outcomes such as direct healthcare professional communication (DHPC), patient card, risk minimisation measures and product information updates are considered. In addition to safety, all updated information needs to be shared with users and prescribers of medicines. While not directly involved with medicine shortages, CMDh can implement precautionary measures to try to prevent shortages. They concluded by explaining that input to the new pharmaceutical legislation occurs via the NCAs however CMDh has discussed various aspects including innovation, preventing dis-harmonisation, facilitating digitalisation and repurposing. For more information, please see presentation.

CHMP: Ewa Bałkowiec-Iskra and Ingrid Wang presented an overview of CHMP activities where patients, consumers and healthcare professionals have contributed such as scientific advice/ protocol assistance, early dialogue with patients and healthcare professional organisations, scientific advisory and ad hoc expert groups and oral explanations. Ewa emphasised the role of patients and the important aspect of patient-relevant outcomes, lived experience and patient experience to these regulatory processes. The numbers of interactions of both patients and healthcare professionals were shown however she stressed that the collaboration and the impact of their participation was the more important element for the assessment. For more information, please see presentation.

This was followed by Ingrid who provided data on the interactions with healthcare professionals and the CHMP where the numbers also include the core group of the healthcare professionals who make up the core group of the scientific advisory and ad hoc expert groups. She concluded with some data on the CHMP opinions of 2025 including some of the positive opinions for 2025 to date.

PRAC: Roberto Frontini began by explaining that a new chair and vice chair have been elected since the last feedback. PRAC is creating a repository of responses to ensure harmonisation of answers to requesters, as well as the text of Summary of Product Characteristics (SmPC). The PRAC also looks at groups of medicines; if a relevant number of medicines has elicited an alert in this group, then the committee will look at the whole group and information will be shared.

Two recent referral cases were described that outlined the work of the committee, the importance of international collaboration and the evidence that is considered for the PRAC recommendations.

7. Patient Experience Data

7.1. Update on patient experience data reflection paper

Rosa Gonzalez-Quevedo presented the Agency's work on patient experience data, including the development of a reflection paper on this topic. Following adoption by PRAC and CHMP, the paper has been published for a 4-month public consultation on 29 September. Members are encouraged to submit feedback by 31 January 2026. Rosa also briefly presented the updated template of the CHMP assessment report, which now includes some improvements regarding how to reflect PED. The new template has been implemented in Q1 2025 and once enough procedures have been completed using this, EMA is planning to evaluate whether the changes contribute to increased transparency among stakeholders. EMA has also launched a survey to understand the use of PED within different therapeutic areas, and member organisations were encouraged to respond to this survey as well as share it with their networks, by 19 October. For more information, see presentation.

AOB

The PCWP and HCPWP were updated on the following topics:

Launch of annual eligibility re-assessment – launched on 15 September, **deadline to submit 31 October**.

Survey for AI workplan – overview of survey and timelines to be shared by team (Luis Pinheiro) for stakeholder input. The responses to the survey will help determine the AI priorities for EMA. The survey opens on 29 September and closes on 17 October, please see presentation.

Link to survey: https://ec.europa.eu/eusurvey/runner/AI-Priorities-Stakeholder-Survey

Information on competing interests

Handling competing interests

- Procedural guidance
- Fact Sheet (NEW)

Upcoming events

ACT EU multi-stakeholder platform annual meeting

22 October 2024 (09:30-17:00)

EMA event page and Draft agenda for webinar on shortages

Public webinar on shortages: putting patients first

4 November 2025 (14:00-16:00)

EMA event page and Draft agenda for webinar on shortages

HMA-EMA annual multistakeholder data forum

9 December 2025 (09:30-17:30)

EMA event page

Multistakeholder workshop on Patient Registries for Alzheimer's Disease

15 December 2025

EMA event page