08 December 2025
EMA/364256/2025
Stakeholders and Communication Division

Meeting Summary - PCWP/HCPWP and all eligible organisations meeting

18 November 2025, hybrid meeting - WebEx/Room 2A

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

1. Welcome and opening remarks

1.1. Welcome and introduction / Health and safety information

Juan Garcia Burgos (EMA) welcomed all participants both in person and online to this first meeting of all eligible organisations under the new mandate (2025-2028) and with the new co-chairs elected in September.

1.2. Highlights of 2025

Melanie Carr (EMA) presented an overview of the highlights of 2025 that describe the continued engagement with patients and healthcare professionals, the different engagement methodologies, expansion of the PCWP and HCPWP from 22 to 25 members and election of the new co-chairs. Key events for 2025 included EMA's first public Open Day, the ACT EU platform meeting, publication of the much-anticipated patient experience data reflection paper, several activities related to shortages including a webinar and awareness-raising campaign and a quick guide to understand the restrictions of competing interests. The presentation concluded with a spotlight on engagement of patients and healthcare professionals in EMA activities. See presentation for more details.

1.3. Overview of the evolution of patient and healthcare professional engagement in EMA activities

Maria Mavris (EMA) provided an overview of the evolution of patient and healthcare professional engagement over the 30-year history of the EMA. She highlighted the increase in the number of scientific committees that include patients and healthcare professionals as full voting members and the increased engagement including creation of the PCWP and HCPWP with the corresponding frameworks. This was also complemented by the scientific meetings where patients and healthcare professionals are invited as experts to contribute their experience with living with a condition and its treatment and their review of documents destined for the public. See presentation for more details.

2. Update on New pharmaceutical legislation

2.1. New pharmaceutical legislation: timeline and EMA stakeholder engagement activities

Hilde Boone (EMA) provided an update on new pharmaceutical legislation which is in the final stages of negotiations between the European Parliament, Council, and European Commission, who are

aiming to reach agreement on the final text of the legislation and the directive by the end of the year. EMA has been working very closely with the European Commission throughout the whole process sharing any experience and technical input as needed, supporting the Commission with further explaining some of the proposals and providing feedback on certain amendments of the Parliament and the Council that are directly relevant to EMA.

Certain key elements for this audience are still under discussion such as the number of patient and healthcare professional members that are foreseen for the Pharmacovigilance and Risk Assessment Committee (PRAC) and Committee for Human Medicinal Products (CHMP), and their voting rights has not yet been decided upon. With respect to the start date for implementation of the new legislation, the timeframe also needs to be agreed, with the Commission proposal stating 18 months and the Council proposing 3 years, giving a range from end of 2027 or as late as mid-2029. EMA will work closely with European Commission, national competent authorities and all stakeholders to ensure that the transition will be as smooth and as efficient as possible.

Kristina Larsson (EMA) complemented with information on what is foreseen in the new pharmaceutical legislation regarding orphan medicines where orphan designations of medicines to treat rare diseases and incentives for developers of these medicines is described. However, no committee for orphans is mentioned and which 'body' will be responsible for the designation activities remains to be determined.

EMA is preparing for all possible outcomes and has discussed this extensively internally, as well as with the Committee for Orphan Medicinal Products (COMP) including definition of the escalation criteria for including experts such as patients and healthcare professionals. Some proposals include the creation of expert groups that can be finalised once the final text of the new pharmaceutical legislation is available. Stakeholder engagement has also been part of the discussion as the COMP has a long history of patient engagement both as members in the committee and disease-specific experts. The intention is to continue to capture the voice of these experts in any form necessary for the question being considered.

She went on to mention that the scientific advice activity will continue as no changes have been foreseen in the legislation. Patients will continue to be involved in scientific advice procedures via EMA therefore no change is expected in this regard. PRIME procedures that have been ongoing at EMA for several years have now been added to the new pharmaceutical legislation text.

Ralph Bax (EMA) explained that the Paediatric Committee (PDCO) has patient and healthcare professional representatives as members of the committee who bring their particular expertise to the discussions and participate in the assessments of Paediatric Investigation Plans (PIPs) and waivers. He said that consultation of more individual patient experts by the PDCO would be beneficial, however, consultation of patient organisations via surveys are already being conducted on a regular basis which brings a lot of additional important information and the relevant patient perspective.

With respect to the future, the paediatric regulation will remain in the new legislation and has even been strengthened. Regulators will be able to ask applicants directly to modify their paediatric investigation plans (PIP), e.g. if the scientific environment has changed since the original agreement of the PIP. A 'mechanism of action approach' is planned. In oncology, for example, where an adult disease that does not exist in children but where the mechanism of action of the medicine could be used to potentially treat a different paediatric cancer in the future, the applicant could be asked to provide a PIP in this respect. Some changes are also foreseen to the stepwise PIP approach that will make it easier to determine a PIP in complex situations.

He described situations where patients and healthcare professionals could be consulted in the future under the new pharmaceutical legislation. EMA's paediatric team works very closely with colleagues from the PDCO, and he emphasised that all expertise related to paediatric drug development needs to be maintained and even enhanced in the future.

3. Leveraging data, digitalisation and artificial intelligence

3.1. EU DARWIN studies:

- **Safety studies on GLP-1 receptor agonists (GLP-1 RAs).**
- **Frailty and polypharmacy among adults with selected cancers at the time of diagnosis.**

Daniel Morales (EMA) gave an overview of the role of RWE and DARWIN EU, its purpose and scope and showed its value through a discussion of two specific studies. The safety study on GLP-1 RAs and risk of suicidal ideation conducted as part of a signal assessment at PRAC did not suggest a causal association and no update to the product information was recommended. The study on frailty and polypharmacy explored real-world data within the DARWIN EU network to identify and describe cases of frailty and polypharmacy in people diagnosed with certain cancers. See presentation for more details.

4. Regulatory science, innovation and competitiveness

4.1. Updates on Cancer Medicines Forum (CMF)

Caroline Voltz-Girolt (EMA) provided an update on the Cancer Medicines Forum (CMF) and its mandate. EMA's Cancer Medicines Forum aims to help prioritise actions to fight cancer, in line with EMA's Regulatory Science Strategy to 2028 and academia collaboration matrix action plan.

Since March 2022, the CMF, co-chaired by EMA and the European Organisation for Research and Treatment of Cancer (EORTC), has been working to advance clinical research into optimising cancer treatments and foster high standards in cancer care within the European Union (EU). The CMF serves as a platform for sharing information and fostering communication on topics relating to treatment optimisation in oncology, with a specific focus on the post-authorisation phase.

The mandate and composition of the Cancer medicines Forum are listed on EMA website. The CMF meets quarterly, and the minutes of these meetings are published online. For more details, please refer to the EMA webpage. Since its establishment, the CMF has organised two workshops: the first in April 2024, and the second in November 2025 with industry stakeholders, focusing on cancer treatment optimisation and fostering collaboration between industry and academia. The presentation concluded with an overview of the next steps. See presentation for more details.

4.2. Update on ACT EU multistakeholder platform

Ana Zanoletty (EMA) began the presentation by providing an overview of the activities carried out by the ACT EU Multistakeholder Platform (MSP) in 2025. 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).

She outlined some of the activities that the MSP AG has been working on, including the re-design of CTIS training materials and TrialMap (translated into official EU and EEA languages), the establishment of the MSP AG focus group to incorporate stakeholder perspectives into the revision of the 2017 Recommendation paper on risk-proportionate approaches in clinical trials, monitoring of

the EU clinical trials environment against the ambition to make the EU a more attractive destination for clinical research (implementation of KPIs), CTR optimisation, CTCG patient involvement project, and the development of new training materials for the ICH E6(R3) guideline on Good Clinical Practice. For additional information, please refer to the presentation.

Following this, François Houyez (EURORDIS), one of the PCWP representatives on the Multistakeholder Platform Advisory Group (MSP AG), briefed participants on the six or seven key priorities identified by the group of patient advocates within the ACT EU initiative. These priorities include patient involvement in clinical trials (CTCG project), cross-border clinical trials, paediatric clinical trials, the artificial intelligence (AI) tools to facilitate trial participation, ethical and organisational considerations around new types of clinical trials (CTs) and new sites for CTs. Patient representatives with a particular interest in any of these key priority areas were encouraged to express their interest in contributing to these efforts. A key question raised was how patients organisations can contribute to making the EU more attractive for CTs and increasing patient interest in clinical research.

Denis Lacombe (EORTC), stakeholder co-chair of the Multi-Stakeholder Platform (MSP) Advisory Group, provided an update on the outcomes of the ACT EU Multi-Stakeholder Platform annual meeting. The event gathered over 500 participants, including representatives from patient organisations, academia, regulators, industry, and healthcare professionals. The goal of the meeting was to address how innovation can apply to different domains and drive progress towards making clinical research in the EU more efficient, patient-centred, and innovative to support ACT EU in delivering its mission. The stakeholders emphasised that while regulations are relatively static and take time to change, science and methodology evolve rapidly. How to reconciliate this difference requires agility in the forms and the methods how clinical research is addressed in Europe. Another major observation to be considered by ACT EU is the potential break between research and care. The current frameworks need to guarantee sustainable and constantly learning healthcare systems for greater patient centricity, addressing questions which are critical for patient in daily care. Addressing Patient Experience Data and patients' preferences are the next priorities. As data science and related methodology evolve, the stakeholders emphasised the potential but also the limits of AI in pushing forward the standards of clinical research. The evolution of the landscape also calls for innovation in ethics and more specifically in ethics review for new types of trials and technologies.

The presentation concluded with an outline of the next steps, accompanied by an invitation for all eligible organisations to reach out to the PCWP and HCPWP representatives at the MSP AG. These representatives are encouraged to bring forward topics and ideas for discussion at future MSP AG meetings. Open dialogue between stakeholders, regulators, and ethics bodies continues to be a fundamental pillar of ACT EU, and the critical involvement of patient and healthcare professional voices remains essential. For further details please refer to the presentation.

4.3. General update on ACT EU

Laura Pioppo (EMA) provided a general update on ACT EU. ACT EU, established in 2022 is a joint initiative by the European Commission (EC), the Heads of Medicines Agencies (HMA), and the EMA, with a vision of achieving better, faster and smarter clinical trials in the EU.

To monitor progress towards the goal of making the European Union (EU) a more attractive destination for clinical research and improving timely access to innovative medicines for patients, three benefits have been identified: increased attractiveness of the EU for clinical research, faster patient access to treatments, and the delivery of impactful clinical trials. Two benefits will be monitored with Key Performance Indicators (KPIs) measured against targets. These targets and KPIs

will support the ongoing evaluation of advancements and enable adjustments to ensure Europe remains at the forefront of scientific innovation.

An overview of the ACT EU workplan for 2025–2026 was provided, outlining the priorities and deliverables for the short and medium term.

The plan focuses on key priority actions, including the implementation and operation of the Clinical Trials Regulation, maximising the impact of clinical trials, addressing clinical trials in public health emergencies, enhancing the design and conduct of high-quality clinical trials, as well as key underpinning activities. For more details, please refer to the presentation.

4.4. A patient's quest to the magical land of clinical trials: is there a yellow brick road?

The European Alliance for Vision Research and Ophthalmology (EU-EYE) presented insights into the pathways patients navigate to access clinical trials, the challenges and risks they encounter, and the factors influencing their decisions to participate. Key challenges include the overwhelming number of online resources and the use of complex medical terminology and eligibility criteria, which can significantly hinder patient understanding, as well as multiple national/regional databases/registries and jurisdictions. Additionally, issues related to digital equity pose barriers to accessing clinical trial information and impede participant recruitment. The presentation highlighted the need for paradigm shifts in how stakeholders view their traditional roles and related frameworks and emphasised the importance of fostering collaboration among stakeholders to develop transparent and reliable pathways that enable patients to make informed decisions about participating in clinical trials. For more detailed information, please refer to the presentation.

5. Work plans for working parties

5.1. Update on work plans for working parties

Ivana Silva (EMA) gave a progress update on the drafting of the working parties' joint work plan for the period 2025-2028, highlighting the initial input received from the group of PCWP and HCPWP volunteers who joined the drafting group.

A broader discussion took place to collect additional feedback. Participants underlined the importance of ensuring an active approach with actions that stimulate collaboration between EMA and organisations. Participants also expressed a preference to keep a comprehensive listing of topics whilst suggesting concise, prioritised action items are clearly identified in the workplan, to better manage expectations and resources.

In particular, the involvement of young people in health information, the integration of aging populations into regulatory assessments as a cross-cutting element rather than a special population category, and the improved access and awareness of real-world data among stakeholders, particularly in relation to safety signals and adverse reactions, were stressed as areas where the working parties could identify more specific actions.

A revised draft workplan will be circulated in December for written comments with the expected endorsement by the working parties in Q1 2026.

6. Training activities

6.1. Annual training 2026 - for patients, consumers and healthcare professionals involved in medicines-related activities at EMA

Kaisa Immonen (EMA) gave an update on the annual training day 2026, which is planned to be held on 23 September. The training is aimed at individuals who may become involved as experts in EMA

activities. Topics will include scientific advice, document reviews, and an introduction to the Paediatric Committee (PDCO). A call for interest will be circulated to eligible patient, consumer and HCP organisations in Q1/Q2 2026, and organisations will be invited to nominate one person for the training. See presentation for more details.

6.2. Training material on Scientific Advice

Liese Barbier (EMA) presented a new training resource on the EMA scientific advice process. This training is targeted at academic stakeholders to encourage researchers and developers from the academic sector to advance development. The modular training includes an overview of the process, as well as guidance on how to prepare and make most effective use of scientific advice. The resources will be publicly available and are expected to be published in early 2026. See presentation for more details.

7. International EMA activities

7.1. Overview on international EMA activities and update on African Medicines Agency

Martin Harvey-Allchurch (EMA) began his overview of the activities of EMA in the international team with a quote from the EU Global Health Strategy (2022) that described strengths in collaboration of bodies such as EMA and ECDC within the EU region that would in turn strengthen collaboration with similar bodies in the African region.

Looking at the benefits of international engagement for patients and healthcare professionals, these include faster and broader access to medicines, improved quality and safety of medicines, better crisis preparedness and response capacity, exchange of global scientific knowledge and promotion of EMA's stakeholder engagement model.

To build on these collaborations, EMA operates in partnership with the European Commission at bilateral and multilateral levels with confidentiality arrangements and mutual recognition agreements. In addition, EMA has seconded staff from both US FDA and the Japanese PMDA at its premises in Amsterdam and an EMA staff member at FDA. This direct engagement is vital and there are 32 clusters operating on various topics with regular exchanges. EMA also participates as part of the EU delegation in multilateral fora that includes ICH.

Main engagements and collaborations are with trusted partners that reach as far as Australia and increasingly with Africa, Asia, North and South America and Europe. The different key activities that occur with the different regions were described. He described four reliance pathways, when and how they are used. These include EU-Medicines4all, the WHO Collaborative Registration Procedure, the OPEN pathway and the EMA/WHO post-approval reliance pilots. For more information, please see presentation.

He concluded by stating that health in the EU is strongly linked with health outside the EU. Working to improve the EU population's health cannot be done without interacting with international partners. EMA's unique way of working is highly valued internationally. What we do is leveraged outside of the EU through reliance mechanisms, transparency, and information sharing. International engagement has a significant impact on global health benefiting both patients and health-care professionals.

8. Members' voice

8.1. Patient and consumer organisations

Mehitabel Holler (EHN) provided an update on developments in the cardiovascular field, focusing on the forthcoming EU Cardiovascular Health Plan, which the European Commission is expected to launch by the end of 2025. The plan is intended as a comprehensive framework addressing prevention, screening, and care.

She noted the strong interest surrounding this initiative and stressed the need for broad engagement across the community, including patients, researchers, and civil society. Mehitabel highlighted the fact that the initiative should not be conceived as a mere disease-specific strategy, drawing attention to several shared persistent challenges that the plan aims to address, such as the underrepresentation of women in research, the need for aligned prevention priorities, and ongoing risk factors like unhealthy diets, alcohol consumption, and tobacco use. She outlined the ongoing work of the European Heart Network (EHN), including the creation, together with the European Society of Cardiology (ESC), of the European Alliance for Cardiovascular Health (EACH). The Alliance has developed a roadmap designed to inform the European Commission's preparation of the plan.

Strengthening engagement with younger people, who are increasingly affected by cardiovascular diseases, is also a priority. Within EHN, this work is being advanced through a dedicated youth-focused working group.

EHN also continues to support its national member heart foundations in preparing for the implementation of the future EU Cardiovascular Health Plan and has published its own set of priorities to guide this work. Mehitabel concluded by spotlighting the EACH cardiovascular health summit. See presentation for more details.

8.2. Healthcare professional organisations

- **Aligning policies with real-world medical needs: the bridging role of HCPOs in the EMA–ECHA regulatory overlap.**

On August 20, 2025, the European Chemicals Agency (ECHA) published an updated proposal to restrict per- and polyfluoroalkyl substances (PFAS) under the EU's REACH Regulation, following public consultations that were conducted between March and September 2023. The primary aim of this proposal is to reduce PFAS emissions into the environment and enhance the safety of products and processes for both people and the planet.

The European Alliance for Vision Research and Ophthalmology (EU EYE) presented key insights and the implications of the application of this restriction on per- and polyfluoroalkyl substances (PFAS) made by European Chemicals Agency (ECHA), with a particular focus on its potential impact on the field of ophthalmology.

It was highlighted that multiple medical devices and products currently used in ophthalmology contain PFAS. Furthermore, special attention was given to the potential impact of this restriction on PFAS used as tamponade agents in vitreoretinal (VR) surgery. At present, there are no feasible alternatives for these agents, and such a restriction could compromise the quality of care for patients affected by vitreoretinal diseases, thereby result significantly increasing the risk of blindness or severe vision impairment. In addition, the case of PFAS in ophthalmology highlights a complex regulatory challenge that crosses boundaries between the EU Medical Device Regulation (MDR) and the REACH Regulation.

During the public consultation on the restriction proposal, more than 5,600 comments were submitted to ECHA, many of which highlighted the potential challenges and consequences across the various fields of application, including ophthalmic clinical practice. EU EYE and the European Society of Retina Specialists (EURETINA) submitted their own comments to ECHA to highlight the dramatic negative impact and the unmet clinical need that could arise from the restriction, and to request a

derogation from PFAS restriction for use in ophthalmology. In addition, EURETINA developed recommendations aimed at minimising the emission and use of PFAS-containing ocular endotamponades and promoting a more environmentally friendly practice.

Furthermore, a restriction on PFAS could increase the vulnerability of supply chains, exacerbate supply chain disruptions and increase the risk of product shortages, further jeopardising the timely delivery of critical ophthalmic treatments.

The presentation illustrates the importance of collaborating with healthcare professionals to make meaningful regulatory decisions and to translate regulatory decisions into clinical practice.

- **Presentation of EFPC and ongoing work for women's health and interprofessional collaboration.**

The European Forum for Primary Care (EFPC) showcased ongoing efforts in the area of women's health, with a strong emphasis on promoting collaboration among professionals, including partnerships with other organisations such as the European Midwives Association.

Women's health and safety remain critical priorities for achieving gender equality and building resilient health systems across Europe. Although progress has been made, significant challenges persist in several key areas. Women continue to be excluded or underrepresented in biomedical research and clinical trials, creating potential risks to their health and safety. Gender and sex differences are often overlooked in study designs, leading to inaccurate assumptions about how men and women respond to medicines. While EU regulations on clinical trials require gender issues to be considered, their implementation is weak and focuses mainly on pregnant and breastfeeding women. Furthermore, there is a lack of robust EU-wide strategies to systematically study gender differences in the effects of medicines, despite evidence that these differences can significantly influence treatment outcomes. This research gap, particularly on the effects of contraceptives, antidepressants and other medicines, limits the ability to provide safe and effective healthcare for women. The presentation concluded with a compelling call to action, urging organisations to foster synergies, leverage complementarities, and engage in coordinated efforts to advance centralised initiatives for women's health.

Meeting Summary - PCWP/HCPWP and all eligible organisations meeting

19 November 2025, hybrid meeting - WebEx/Room 2A

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

9. Availability and supply of medicines

9.1. Critical Medicines Act

Vanessa Bennett (EMA) provided an overview of the key measures included in the Commission's Proposal for a Critical Medicines Act (CMA) and its current status.

The European Commission proposed CMA aims to strengthen the EU pharmaceutical industry by boosting investment in EU-based manufacturing capacity, reducing reliance on third-party manufacturers outside the EU, and diversifying supply chains to enhance resilience. It also introduces public procurement-related measures to strengthen supply chains and leverage aggregated demand for products.

The CMA complements the ongoing revision of the pharmaceutical legislation and the enhanced role of the EMA in managing medicine shortages and ensuring security of supply of critical medicines. It contributes to the European Health Union's goal of ensuring that all EU patients have timely access to the medicines they need. The Act considers extensive stakeholders feedback obtained through the European Commission's Structured Dialogue and Critical Medicines Alliance initiatives.

The Critical Medicines Act negotiations are currently ongoing, with the European Parliament and the Council working on their respective positions. The final text is expected to be adopted in 2026.

The scope of the CMA includes critical medicines identified on the Union's critical medicines list, with certain provisions relying on the identification of supply vulnerabilities under the proposed pharmaceutical legislation. Additionally, for certain provisions, the Act extends to 'medicines of common interest' in cases of market failure—specifically, issues affecting multiple Member States.

The key elements of the CMA include:

- The establishment of "**Strategic Projects**" to promote and facilitate investments aimed at strengthening manufacturing capacity in the EU for critical medicines and substances.
- **Public procurement** to incentivise diversification and resilience in the supply chain.
- **Collaborative procurement** among EU Member States to address disparities in the availability of and access to critical medicines and other medicines of common interest.
- **Strategic partnerships** to support supply chain diversification and reduce dependencies on single suppliers.

For further information see the presentation and refer to Proposal for a Critical Medicines Act and Questions and answers on the Critical Medicines Act.

9.2. Introduction to shortages topic

Monica Dias (EMA) provided an overview on the activities of the Medicine Shortages Steering Group (MSSG) and the SPOC (Single Point of Contact) Working Party. The MSSG plays a key role in ensuring a robust response to major events or public health emergencies, and in coordinating associated actions within the Union in relation to the supply of medicinal products.

The MSSG is also responsible for monitoring critical shortages that could lead to a major event or public health emergency. It is supported by the SPOC WP, which identifies and reports potential supply issues in the EU. The MSSG annual activity report, together with the minutes of the SPOC WP and MSSG meetings, are available to the public.

In 2025, the MSSG actively monitored several critical shortages and coordinated preparedness activities to ensure the security of the medicine supply. Key areas included the monitoring of antibiotic supply situation for the upcoming autumn/winter season 2025/26. This involved collaborating with key marketing authorisation holders to assess the anticipated supply of a subset of antibiotics, liaising with international regulators in the southern hemisphere, and re-launching a social media campaign to promote the prudent use of antibiotics.

The MSSG continues to monitor and mitigate critical shortages through various mechanisms, including issuing recommendations to apply certain regulatory flexibilities where appropriate. The Voluntary Solidarity Mechanism (VSM) can also be triggered, as last resort, in case of critical shortages. It was used to successfully manage 13 cases of critical shortages to date.

During this year, the MSSG has also issued recommendations for vulnerabilities in the supply chain of Anti-D immunoglobulins and radiopharmaceuticals. Close interaction with relevant stakeholders was instrumental in informing the drafting of the MSSG's recommendations.

In October 2024, the MSSG adopted the Medicine Shortages Communication (MSC) process, a procedure to inform healthcare professionals about critical shortages not related to quality, safety, or efficacy issues, such as commercial withdrawals, manufacturing disruptions, or unexpected demand increases. The MSC was implemented through a pilot programme which started in October 2024. See EMA MSC webpage. See presentation for more details.

9.3. Update on the Union list of critical medicines

Siofradh McMahon (EMA) began with 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.

The Methodology to identify critical medicines for the "Union List of critical medicines" document outlines the process used to develop the list as agreed upon by Member States. Critical medicines are selected based on a risk assessment that evaluates their importance to public health—referred to as medicinal product criticality. Medicines are assessed based on two key criteria: their therapeutic indication and the availability of appropriate alternatives.

Eligible organisations were informed about the first annual update of the Union List of Critical Medicines. The second version of the Union List, published on 16 December 2024, includes more than 270 critical medicines. This list represents a significant step towards ensuring supply security and preventing shortages of critical medicines across the EU.

The annual review process of the Union List was initiated by the EMA in July 2025, with Member States submitting requests for the classification of certain active substances based on changes in market dynamics or medicinal product availability. National Competent Authorities (NCAs) and Ministries of Health reviewed and classified approximately 61 active substance groups proposed for consideration.

In October 2025, stakeholders were consulted on the outcomes of the Member States' review. Sixteen stakeholder groups provided feedback, and a summary of their input, along with the review outcomes, was presented. It was clarified that no additional active substance groups could be considered for inclusion or removal at this stage.

A subsequent call for input on this topic will be circulated to stakeholders in early 2026 as part of the consultation for the next annual update (2026).

The publication of the Union list of critical medicines (v2.1) is expected in December 2025.

Organisations will be informed about the upcoming consultation phase in January 2026, as part of the second annual update. Stakeholder consultations in early 2026 will focus specifically on requests for inclusion or removal of medicines in the Union List of Critical Medicines. All organisations are invited and strongly encouraged to submit their feedback by the end of March 2026. Exact dates will be confirmed when the consultation is launched, and a template will be provided to streamline request submissions. Stakeholder contributions are critical for evaluating the importance of medicines and refining the list during future updates. See presentation for more details.

9.4. Results of the Shortage Prevention and Mitigation Plans (SPP/SMP) pilot

Maria Jesus Alcaraz (EMA) provided eligible organisations with an update on the initial results of the Shortage Prevention and Mitigation Plans (SPP/SMP) pilot and outline the next steps, including the publication of the pilot report.

The MSSG launched a six-month pilot phase in December 2024, following the release of the SPMP templates in June 2024, to support marketing authorisation holders and competent authorities in implementing Shortage Prevention and Mitigation Plans in anticipation of the new pharmaceutical legislation. The pilot concluded in September 2025. However, EMA would be able to request additional SPPs and SMPs as per SPOC WP/MSSG request.

The pilot programme was designed to assist companies in developing and implementing Shortage Prevention Plans (SPPs) and Shortage Mitigation Plans (SMPs) while testing the effectiveness of the newly developed templates. Feedback collected during the pilot phase highlighted the need for additional guidance and further refinement of the templates to ensure that the data provided is fit for purpose in identifying and addressing supply chain vulnerabilities. A report on the pilot is expected to be published by the end of 2025.

It was clarified that further amendments to the templates will be considered once the final text of the revised pharmaceutical legislation will be published. For further information see the presentation.

9.5. Ongoing critical shortages

Klaus Kruttwig (EMA) highlighted the role of the Single Point of Contact Working Party (SPOC WP) and the Medicine Shortages Steering Group (MSSG) in addressing four ongoing critical medicine shortages in the EU/EEA, each stemming from different root causes. Klaus explained how the SPOC WP assessed the supply situation for these medicines and closely monitors the supply and availability situation. A further outline of the individual actions taken to mitigate critical shortages through various mechanisms was provided, including maintaining regular dialogue with the respective marketing authorisation holders (MAHs).

Additionally, Klaus provided an update on the activities carried out in preparation for the autumn/winter 2025/2026 season. These included engaging with key marketing MAHs of specific critical antibiotics to assess the expected supply and identifying potential bottlenecks of critical antibiotics.

In addition, further details on the collaboration with international regulators in the southern hemisphere, and a recently launched social media campaign to promote the prudent use of antibiotics were presented. For more details, please see the presentation.

9.6. EAHP Survey on the shortages of medicines and medical devices

Despoina Makridaki (European Association of Hospital Pharmacists-EAHP) provided an overview of the Shortages Surveys carried out by EAHP since 2012, announcing the upcoming publication of the 2025 Shortages Survey findings.

The EAHP is committed to addressing medicine and medical device shortages across Europe by gathering insights from hospital pharmacists, patients, and other healthcare professionals to support preventive and mitigation measures in current and future legislation. This year's survey places particular emphasis on medical device shortages, the role of compounding in managing shortages, and the use of national and European critical medicines lists. For more details, please see the presentation.

Post-meeting note: See below the link to EAHP's final report published on 27th Nov 2025.
FINAL_EAHP-2025-Shortages-Survey-Report.pdf

9.7. EMA-HMA repurposing pilot report

Christelle Bouygues (EMA) presented the findings of the repurposing pilot that was conducted in collaboration with the EU regulatory network. The pilot originated from an initiative of the European Commission with the STAMP expert group, which proposed a framework whose aim was to provide support to not-for-profit organisations (NFP) and academia in generating and/or gathering data in accordance with regulatory standards to facilitate the regulatory recognition of new indication for well-established, authorised medicines. The draft framework led to a pilot with several national competent authorities (NCAs) that aimed to support not-for-profit organisations and academia to present their proposed repurposing project to regulatory authorities and seek scientific advice, either nationally or at EMA.

The pilot consisted of four phases: submission of candidates, selection of projects, tailored support including scientific advice and post-scientific advice. The objectives included the identification and characteristics of repurposing projects in the pilot, the analysis of the benefits of the customised support to NFP and academia, the evaluation of the added value of scientific advice and finally the exploration of the marketing authorisation holder engagement and the feasibility of using EMA's real world evidence pathways.

A total of 40 candidate applications were submitted to both EMA and NCAs, and nine were selected for the pilot based on public health benefit criteria and the scientific evidence provided, while also taking into account the available incentives. The regulatory support went beyond the standard scientific advice process and included an introductory meeting with academia and EMA staff, which served as an opportunity to discuss the project and to highlight points that would merit to be covered in the SA briefing document. It was then followed by several rounds of review to refine the briefing document, and a debriefing meeting with the scientific advice working party coordinators after the advice was issued.

An analysis was conducted on the added value of the scientific advice outcome and was determined based on the extent of the recommendations. Some challenges included the identification of meaningful endpoints, defining patient populations and when products were used in combination identifying the effects of the investigational product.

Lessons learnt from the pilot showed that the customised regulatory meetings were beneficial but required significant resources. Scientific advice was important to academia in terms of providing a better understanding of what evidence is necessary to facilitate generation of data expected to meet

the regulatory standards to support an application for a new indication. Academia is encouraged to come and engage with regulators as early as possible.

The next steps include continued support for the projects selected which most of them are still in the development phase and for any future repurposing projects, scientific advice remains the main route for support. Furthermore, in their support to researchers and developers from the academic sector, EMA will continue to offer a suite of measures, as appropriate to each specific case. There is also a need to increase the real-world evidence footprint in the repurposing activities.

To improve uptake by applicants and MAHs, Industry Associations are encouraged to facilitate connections between not-for-profit organisations and their member companies. Finally, the new pharmaceutical legislation may bring policy changes to support repurposing by proposing a new pathway for academia to bring their projects to the CHMP and, as appropriate, for MAHs to obtain additional data protection. See presentation for more details.

10. Communication activities at EMA

10.1. Update on EMA's communication campaigns

Giulia Gabrielli (EMA) presented the outcomes from the two big social media campaigns that were run this year: the GLP-1 campaign #HealthNotHype, created in partnership with selected content creators to promote safe and responsible use of GLP-1 medicines; and the campaign on shortages #ItTakesATeam, co-created with the PCWP and HCPWP that aims to highlight the role of different stakeholders in supporting patients in case of a shortage. Both campaigns were launched in November, and their impact will be evaluated at the end of the year. See presentation for more details.

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

Stephanie Cohen (EMA) provided an update of the communication materials on the safety monitoring of medicines, an activity that was performed in collaboration with representatives of patient and healthcare professional organisations. These stakeholders reviewed the plan and the content and ensured that the content was clear and helpful, their input confirmed the direction of travel for this booklet.

A dedicated webpage for this activity has been created that features the EMA booklet on the Safety of Medicines, which takes the reader through the lifecycle of a medicine with a focus on the importance of reporting suspected side effects covering raising awareness of reporting tools at national level, how to report and who can report.

Actions that can be taken are also described, based on the diverse range of data sources that are continuously analysed to identify new safety information. The booklet explains how new data are assessed and highlights the actions that can be taken to address the issue. A section is dedicated to how patients and healthcare professionals are consulted throughout the assessment of safety issues including the review of communications to the public.

Violeta Pashova (EMA) then updated the group on the dissemination and promotion of the materials, which were published during Medicine Safety Week using the momentum gathered to launch a campaign on this topic. The main objective of the campaign was for the key messages to reach those who need them and diverse channels, such as social media channels, targeted mailing, the Human Medicines Highlights newsletter and key meetings, were used to disseminate as broadly as possible. EMA will continue to promote the materials, create videos on safety monitoring of medicines, and develop an interactive digital version of the booklet, which will also be translated into

all EU languages. Monitoring of the use of the published materials will continue to ensure that that best practices will be captured for future materials. See presentation for more information.

11. Update on activities related to pregnancy and lactation

11.1. Gender equality in women's health – the forgotten priority

Corine de Vries (EMA) presentation emphasised that gender equality in women's health remains an overlooked priority. Despite progress in healthcare, disparities persist in addressing women's specific health needs, particularly in clinical research, which require renewed focus and action. See presentation for more details.

While regulatory frameworks aim to ensure representation of the anticipated user population, pregnant and breastfeeding women remain significantly underrepresented in clinical trials. The exclusion of these populations poses risks as uncontrolled real-world exposure to medicines can be more harmful than structured research. Past tragedies involving drugs like thalidomide and valproic acid illustrate the consequences of inadequate testing during pregnancy. Diseases such as diabetes, epilepsy, and autoimmune disorders pose significant risks to both mother and child if not properly managed, reinforcing the need for evidence-based treatment strategies. EMA advocates for a paradigm shift that balances treatment needs with uncertainties, emphasising that a healthy child begins with a healthy mother.

Looking forward, EMA proposes strengthening benefit-risk information throughout the product life cycle, improving transparency, and leveraging tools like the Clinical Trials Information System (CTIS) and trial maps to facilitate inclusion. Global regulatory collaboration, stakeholder engagement, and new guidelines such as ICH E21 aim to ensure appropriate inclusion of pregnant and breastfeeding individuals in trials. The ultimate goal is to generate robust data for informed decision-making, reduce reliance on assumptions, and enhance safety for women and their children across all stages of healthcare.

As part of the discussion, it was noted that limited feedback was received from patients and healthcare professionals during the public consultation phase of the ICH 21 guideline. Eligible organisations are welcome to refer to the published draft ICH E21 guideline on inclusion of pregnant and breastfeeding individuals in clinical trials – Scientific guideline and the overview of comments received during the public consultation phase.

Although the public consultation is now closed there will be further opportunities for engagement, including a global multistakeholder workshop to present the high-level of comments received and direction of travel.

Any additional comments from PCWP and HCPWP members will be accepted and should be sent to public-engagement@ema.europa.eu by Friday 30 January 2026, so that EMA can coordinate collection of input from eligible organisations**.** Publication of the final guideline is expected by end of 2027.

12. Product information

12.1. Update on the QRD template – revision of the package leaflet

The ongoing revision of the QRD template began in September 2023, with the objective of improving the package leaflet. On 11 April 2025, two public consultations were launched simultaneously. The public consultation on the revision of the QRD v11 template was open to all interested parties for five months and concluded at the end of August 2025.

A total of 800 comments were received from 40 different stakeholders, including pharmacist associations, industry representatives, NCAs, service providers, individual respondents, public medicines organisations, medication safety organisations, and ePI product team.

Monica Buch explained that once the comments have been fully analysed and the QRD subgroup and QRD group have agreed on the final changes to the QRD v11 template, the possibility of holding a multi-stakeholder workshop will be considered. The date for these activities is yet to be confirmed.

In addition, Monica Buch provided an update on the results of the EU survey on the potential inclusion of a "Key Information section" in the package leaflet. This survey was open for public consultation until the end of May 2025, with the aim of gathering opinions from all stakeholders on the usefulness and added value of such a section. A total of 561 responses were received from patients, consumers, healthcare professionals, industry, academia and other stakeholders, of which 413 were in favour (357 supported inclusion in all medicines and 56 supported inclusion in certain medicines) and 133 were against. She presented a summary of the comments received, including the key arguments both for and against the proposal and, if in favour, what specific information it should contain. See presentation for more details. The results were shared with the European Commission (EC) in late June for consideration. Eligible organisations will be informed of the next steps in the process.

12.2. Effect of a key information section in European patient leaflets on expectations about new medicines: results from an online, randomised controlled trial

Avi Cherla (London School of Economics, Harvard Medical School) and Huseyin Naci (London School of Economics) presented the main findings of a study funded by King's College London, coauthored with Courtney Davis (King's College London). The study consisted of an online randomised controlled trial comparing the impact of two different versions of a "Key Information section" included in the package leaflet (PL) of a cancer medicine approved for advanced kidney cancer, with a control version (the standard PL for this medicine).

The objective of the study was to evaluate the effect of these two different formats and contents of the "Key Information section" (one with only qualitative statements and another incorporating both qualitative and quantitative information) on the accuracy of individuals' treatment expectations, their perception of the magnitude of the medicine´s benefits and side effects, as well as their satisfaction with the package leaflet.

12.3. Medicine overviews: survey on target audience awareness and satisfaction

Catriona Ester (EMA) presented the results of a survey and series of interviews with patients and healthcare professionals where the objective was to evaluate the usefulness of EMA's plain language summaries of medicines (also known as 'medicine overviews'). The medicine overviews are structured in a question-and-answer format and are reviewed by patients for clarity prior to publication on EMA's website in all EU languages.

The purpose of the survey was to ask whether these documents reach the audience they are intended for and whether they meet the user needs. Several questions were asked around where stakeholders look for information online, whether they are aware that EMA publishes medicine overviews, which elements of the medicine overview are the most helpful and how they use the overviews. The surveys were followed up with small focus group discussions and interviews.

A total of 411 responses were received that included 276 patients and 135 healthcare professionals, primarily from European countries.

When looking for medicine-related information online, patients reported that they tend to consult national or local health authority websites first, closely followed by the EMA website and that they most commonly look for information about potential side effects or treatment options.

Part of the consultation included sharing a medicine overview and asking whether they had previously used a medicine overview: the majority (76% patients and 62% healthcare professionals) had not used one and this was mainly due to a lack of awareness. Conversely, those who did use medicine overviews reported doing so because they found the medicine overview provided reliable information and, quick access to key information, and also helped patients make informed treatment decisions and gave healthcare professionals access to the latest regulatory updates.

Findings from focus groups and interviews were consistent with those from the survey, demonstrating that while the content and language are satisfactory, awareness of the medicine overviews needs to be increased. EMA will focus on increasing awareness of the medicine overviews, clarifying where additional relevant information and translations can be found by making this clearer on the medicine's page and will explore the possibility of incorporating visual elements and a website navigation guide for patients. See presentation for more details.

13. Update on Human Medicines Highlights (HMH)

13.1. One year of revamped HMH newsletter

Kaisa Immonen (EMA) presented the revamped Human Medicines Highlights newsletter, which was launched in May 2025. The objective was to create a newsletter that would meet the needs of its target audience – patients, consumers and HCPs and their representative organisations – and become a go-to channel for receiving information, thus reducing the burden of email communications. The reach of the newsletter has grown to just over 3,000 subscribers to date, compared with around 900 for the old newsletter. EMA will launch an evaluation of the new Human Medicines Highlights in early 2026 to understand what is working well and what could still be improved. Eligible organisations and all subscribers are welcome to send feedback and comments at any time to public-engagement@ema.europa.eu.