



19 February 2026  
EMA/025717/2026  
Stakeholders and Communication Division

## Meeting Summary - PCWP/HCPWP joint meeting

3 February 2026, hybrid meeting – MS Teams/Room 1A

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

### 1. Revised pharmaceutical legislation

#### 1.1. Revised pharmaceutical legislation – outcome for EMA, patients and healthcare professionals

Lilia Luchianov and Anthony Rodiadis (DG Sante) presented an update on the revised EU pharmaceutical legislation. The revision introduces a modernised framework replacing 20-year-old rules, aiming to improve access to high-quality, safe, effective, and affordable medicines across Europe. The package merges existing orphan and paediatric regulations, simplifies regulatory structures, and aligns with broader initiatives such as the Critical Medicines Act and the Biotech Act. It is developed from a patient-centric perspective, and with strong competitiveness elements, aiming to increase availability of innovative treatments—including antimicrobials addressing AMR, rare-disease therapies, and paediatric medicines—while also strengthening EU capacity to prevent and manage medicine shortages and to future proof the EU pharmaceutical framework.

The reform delivers significant simplification and efficiency gains. Key measures include regulatory sandboxes for novel therapies, earlier and enhanced scientific support from EMA, phased reviews, broader use of real-world evidence, and reduced scientific assessment timelines. EMA's structure will be streamlined, with revised committee configurations and better use of expert resources. Patients and healthcare professionals will have voting rights in the CHMP and PRAC committees, and the creation of working groups will ensure broad expertise. Finally, KPIs and periodic reviews to monitor the legislation's effectiveness, including access benchmarks are being planned. The legislation is expected to be finalised in early 2026, enter into force later that year, and apply from 2028, with some provisions—such as AMR vouchers and sandboxes—applying earlier. Implementation will require extensive delegated and implementing acts beginning in 2026. Please see [presentation](#) for more information.

#### 1.2. What are the next steps for EMA under the revised pharmaceutical legislation: focus on stakeholders

Alexis Nolte (EMA) presented an EMA perspective on the implementation of the revised pharmaceutical legislation (NPL). He emphasised that the NPL represents a significant opportunity to reshape the way we work. The key elements of the legislation were outlined, which include creating a simpler and more innovation-friendly regulatory environment while strengthening safeguards against medicine shortages, reinforcing environmental protection and focusing on antimicrobial resistance.

He introduced the proposed governance structure for implementing the NPL, which includes existing EU network groups and stakeholder platforms for patients, healthcare professionals and the pharmaceutical industry. The governance has been designed with stakeholders in mind and reflects joint work across the EU regulatory network, with engagement channelled through existing structures and established stakeholder platforms.

Melanie Carr (EMA) explained how EMA plans to involve patients and healthcare professionals throughout the implementation process. This includes an EMA-EC joint high-level multi-stakeholder workshop once the legislation is published, ongoing engagement through PCWP/HCPWP meetings, and targeted consultations on specific implementation topics. She encouraged stakeholders to visit EMA's newly launched [NPL webpage](#) regularly to be kept updated, and to get involved in topic-specific webinars, public consultation process and via the PCWP and HCPWP. See [presentation](#) for more information.

## 2. Accessibility

### 2.1. From regulatory decision to health technology assessment: the new developments in Europe

Michael Berntgen (EMA) and Noemie Manent (EMA) set the scene regarding how the new Health Technology Assessment (HTA) regulation is shaping the collaboration between HTA bodies across Europe to perform joint assessment. While EU countries remain responsible for healthcare systems, the regulation establishes a formal regulatory-HTA interface to support joint work such as Joint Scientific Consultations (JSCs) and Joint Clinical Assessments (JCAs) for medicines and medical devices.

Noemie presented information regarding the implementing acts including how EMA and HTA bodies cooperate, share confidential information, coordinate timelines and identify experts. She also described that marketing authorisation applications and JCAs run in parallel, requiring aligned planning and timely sharing of clinical concerns and procedural updates. A list of the first products undergoing parallel assessment was shared. She concluded by presenting updates on parallel Joint Scientific Consultation (JSC) and Scientific Advice procedure. Information on the identification of expert patient and healthcare professionals and sharing with the HTA secretariat was presented, which was complemented by the next presentations. Finally she shared a joint [position paper](#) on evidence and uncertainties and encouraged participants to explore the [website](#) on HTA regulation implementation. For more information, see [presentation](#).

### 2.2. HTA Regulation – experience from the first year of implementation

Julie Spony (DG Sante) presented an overview of the first year of implementation of the EU Health Technology Assessment (HTA) Regulation, which entered into application on 12 January 2025. She highlighted the establishment of common frameworks and procedures for joint clinical assessments, joint scientific consultations, horizon scanning, and methodological development, all aimed at enabling high-quality, transparent, and evidence-based decision-making.

A Stakeholder Network was created that comprises 73 patient, healthcare professional and health technology developer organisations as well as other health related NGOs and informs the work of the HTA coordination group. She outlined the JCA and JSC activities of the first 12 months and described how the Stakeholder Network contributed to the identification of patients and clinicians as outlined the processes. Improvements to the process have been made that include guidance on the conflict-of-interest rules, creation of a dedicated IT helpdesk, and strengthened communication with patients and clinicians. Lessons learned emphasised the importance of sustained engagement, awareness-raising, supporting experts throughout their involvement, and collaborating with EMA.

Looking ahead, the focus is on learning from initial JCAs and JSCs, continuing to refine processes, and contributing to the evaluation of the HTA Regulation, which will feed into the European Commission's 2028 report to the Parliament and Council. Up-to-date information, key documents, and events will remain accessible via the HTA [website](#). For more information see [presentation](#).

### **2.3. Patient and healthcare professional perspectives from HTA stakeholder network**

Solene Jouan (EPF) began by emphasising the need to strengthen pathways for patient selection and refine mechanisms that support their contributions throughout Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs). This would contribute to an ongoing effort to ensure that patient perspectives are systematically and effectively incorporated within the new HTA Regulation framework.

The priorities for 2026 include better understanding of how conflict of interest (COI) rules impact patient involvement, receiving clearer information on how patient input is reflected in final HTA reports. Current activities include increasing awareness of the HTA Regulation through webinars and the future capacity-building on COI for patient organisations to ensure that interactions between the patient community and other stakeholders are built on mutual transparency, respect, autonomy and independence. In June, the European Patient's Forum (EPF) will also launch the EPF Barometer on patient involvement, which will include a section dedicated to HTA and patient involvement at the national level. This section will highlight best practices by countries and areas for improvement in this field.

She concluded by stating that successful patient involvement requires close cooperation with and learning from other stakeholders. However, financial support for patient organisations is essential to maintain momentum. See [presentation](#) for more details.

Robin Doeswijk (EHA) provided the perspective of medical societies such as the European Hematology Association (EHA) within the first year of EU HTA implementation. Their contribution included the identification of the best available clinical experts, offering structured scoping advice on PICO and raising broad awareness of the importance of the contributions of these experts to these procedures.

He highlighted several challenges including confidentiality constraints, tight timelines, limited clinician availability, COI eligibility issues, organisational readiness gaps, insufficient employer recognition, varying attitudes of HTA bodies, unclear training responsibilities, and risk of clinician demotivation. At the same time, several promising developments were identified, including improved structure and support for stakeholder involvement, constructive dialogue within the Stakeholder Network, pragmatic handling of COI, alignment between the HTA unit and EMA, motivated expert communities, and a growing recognition of medical societies' value. He concluded by describing how EHA organises itself to coordinate input and support the HTA process through its European Affairs "spider-like" function, reaching out to expert networks, and creating cross disciplinary partnerships.

# Meeting Summary - PCWP/HCPWP joint meeting

4 February 2026, hybrid meeting – MS Teams/Room 1A

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

## 3. Availability and supply

### 3.1. Next steps in the ECHA assessment of the PFAS universal restriction under REACH

Leonor Enes (EMA) began the presentation by describing the meeting held on 19 December, between EMA and a delegation from the AESGP, AnimalhealthEurope, EFPIA and Medicines for Europe. The purpose of the meeting was to discuss the potential impact of certain chemical and environmental policies on the availability of medicines for human and veterinary use. During the meeting, the industry provided an overview of ongoing activities, including an upcoming project under the Innovative Health Initiative (IHI) to assess the socio-economic impact of per- and polyfluoroalkyl substances (PFAS) restrictions and explore alternatives. The agency confirmed ongoing collaboration with the European Commission (EC) and the European Chemicals Agency (ECHA) and highlighted the importance of continued engagement and a possible future joint workshop.

The agenda together with the highlights of this meeting are published on [Meeting on the impact of chemical and environmental policies on the healthcare sector and availability of medicines | European Medicines Agency \(EMA\)](#).

Ricardo Mezzasalma (EMA) outlined the current status of examination of the PFAS restriction proposal under the EU's REACH Regulation. He explained that ECHA's Committee for Risk Assessment (RAC) is expected to adopt its opinion on PFAS risks between 2–6 March 2026. Following this, the Socio-Economic Analysis Committee (SEAC) will publish its draft opinion assessing the socio-economic impacts of the proposed restriction, shortly after its March meeting. A 60-day public consultation on the SEAC draft opinion will run from April to May 2026, using a structured EU Survey format. WP members were informed on how to participate in the consultation, which aims to collect inputs on the potential impacts of restricting the use of PFAS across different sectors and to provide concrete information about the availability and feasibility of alternative substances and technologies. Further information is available at: [ECHA topic page on PFAS](#). See [presentation](#) for more details.

### 3.2. How EMA manages shortage cases: step by step

Siofradh McMahon (EMA) presented to the group a detailed overview of the EU-level approach to manage and mitigate medicine shortages through a coordinated regulatory framework. Regulation (EU) 2022/123, implemented in 2022, established structured procedures for reporting shortages, coordinating crisis responses, and monitoring events that could lead to public health emergencies.

The regulation also established the Medicines Shortages Steering Group (MSSG), the Medicine Shortages Single Point of Contact (SPOC) Working Party, and the European Shortages Monitoring Platform (ESMP), all aimed at strengthening oversight and coordination across the EU. The MSSG is 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. All medicines are in scope of this work, regardless of route of authorisation.

The presentation outlined the process for escalating shortages from national to EU level and described how shortages of centrally authorised medicines are addressed. This process includes defining criteria for criticality, information flows, and the role of EMA in coordinating mitigation measures, communication, and, when applicable, escalation to the MSSG.

The MSSG toolkit of recommendations to address critical shortages was explained, including European and international cooperation, clear communication through shortage catalogues and public statements, active engagement with stakeholders such as industry, and measures to increase supply, controlled distribution, and the application of regulatory flexibilities.

Finally, the presentation emphasised that long-term prevention of medicine shortages requires broader policy initiatives beyond regulatory measures. Tools such as the Union List of Critical Medicines and vulnerability assessments will inform the upcoming Critical Medicines Act. This Act aims to facilitate EU-wide public procurement strategies, boost European manufacturing capacity, enable state aid, foster strategic partnerships, and promote international collaboration. These efforts are designed to shift the system from a reactive to a proactive approach, ensuring that critical medicines remain consistently available to patients across the European Union. See [presentation](#) for detailed information.

### **3.3. Update on Union list of critical medicines**

Siofradh McMahon (EMA) began with a reminder of the objectives and the scope of the Union list. The Union list of critical medicines identifies medicines that are critical for health systems across the EU/EEA and for which continuity of supply should always be guaranteed for European patients. The first annual review of the Union list of critical medicines was concluded in December 2025 and version 2.1 of the Union list was subsequently published on the [EMA website](#).

Additionally, in December 2025, MSSG adopted [the methodology for the annual update of the Union list of critical medicines](#), taking into account the feedback from Member States (MSs) and stakeholder groups. This document outlines the methodology, governance and criteria for identifying medicines to be added or removed from the Union list of critical medicines during the annual reviews. In addition, the document details the expected timelines and provides guidance on what information is needed to support a request for the review of a medicine to be added or removed from the Union list.

WPs were reminded of the ongoing consultation phase for the second annual update of the Union list of critical medicines that was launched on 19 January 2026, which focuses specifically on requests for the inclusion or removal of medicines from the list, considering guidance included in the published methodology. All organisations were invited and strongly encouraged to provide their feedback using the designated Excel form, in line with the criteria for inclusion or removal as outlined in the published [methodology](#). Review requests should be submitted directly to the EMA MSSG secretariat by emailing the [mssgsecretariat@ema.europa.eu](mailto:mssgsecretariat@ema.europa.eu) mailbox by **Friday 27 March 2026**.

During the meeting, the workflow for the annual review of the Union list was outlined, including the criteria for triggering a review request (change in criticality of the therapeutic indication, change to the availability of appropriate alternatives, changes in the market dynamic, and historical critical shortages), as well as the associated timelines and next steps. For more detailed information, please refer to the [presentation](#).

### **3.4. Union List of Critical Medicines from the perspective of rare diseases**

François Houyez (EURORDIS) shared findings from a short analysis conducted of the Union List of Critical Medicines from the perspective of rare diseases (and some other diseases), raising some important questions about the list. The analysis showed that, while some rare disease medicines are included, many essential or life-prolonging treatments for conditions such as cystic fibrosis, multiple myeloma, Pompe disease are not. Looking at other diseases, modern HIV therapies are missing, while some less effective or outdated medicines remain included. The challenge of selecting among alternatives and the influence of national reimbursement policies was highlighted.

The appropriateness of the criteria was debated, pointing out the difficulty of screening more than 12,500 substances and the need to reach agreement among the 15 member states, which could result in a list that is more political than evidence based. The distinction between “critical” and “essential” medicines was discussed, with the Union list focused on structural vulnerabilities and shortages rather than clinical essentiality. The presentation concluded by emphasising that many medicines essential to patients might not be included in the list and calling for transparent mechanisms to allow patient groups and clinicians to request additions. Patients’ organisations were encouraged to assess their critical medicines with their learned societies and respond to the public consultation open until end of March 2026. Please see [presentation](#) for more details.

## 4. Sustainability of the network

### 4.1. Candidate countries observing EMA activities

Katre Rugo (EMA) presented how EMA collaborates with EU candidate countries through the Instrument for Pre-accession Assistance (IPA) programme. Target countries of the programme include Albania, Bosnia-Herzegovina, Kosovo, North Macedonia, Montenegro, Serbia, Türkiye, and activities are also extended to new candidates Georgia, Moldova and Ukraine. IPA programme’s main goal is to prepare these national competent authorities for future participation in the European Medicines Regulatory Network by helping them align their standards, regulatory practices, communication systems and information-exchange capabilities with those of the EU.

To achieve this, the IPA programme provides advanced training, access to EMA’s digital resources (including the EU Network Training Centre), and opportunities to observe selected EMA working groups. She concluded with a proposal to expand this collaboration by allowing candidate countries to participate as observers in PCWP/HCPWP meetings. This stepwise integration aims to support the broader EU enlargement strategy and strengthen regulatory cooperation. See [presentation](#) for more details.

## 5. Leveraging data and patient experience in evidence generation

### 5.1. ICH E22 guideline on general considerations for patient preference studies

Francesco Pignatti (EMA) gave an update on the draft International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E22 guideline, including its development, scope, and the importance of patient preference studies (PPS) in regulatory decision-making and a focus on global applicability. A lot of work is taking place in this area, and while impact on benefit-risk evaluation is not yet universally acknowledged, a recent EMA survey of regulators indicated that PPS do have an impact.

Input from stakeholders is currently being invited in a public consultation until 12 April 2026. A stakeholder webinar will take place on 6 February. For more details please see the [presentation](#). The consultation document and response template for EU feedback are available [here](#) and related information materials can be found on the [ICH website](#).

### 5.2. Patient perspective

François Houyez (EURORDIS) gave a patient perspective on the ICH work on patient preference studies (PPS). He showed through examples how PPS can gain insight into the trade-offs patients are willing to make between for example different kinds of side effects, and these views may be different from the views of other stakeholders. PPS allow for the collection of opinions from a broader patient

population, which can be particularly useful to support individual patient experts consulted by developers or regulators on complex questions. For more details, please see the [presentation](#).

### **5.3. Enhancing transparency and discoverability: HMA-EMA Catalogues of real-world data (RWD) sources and studies**

Katerina-Christina Deli (EMA) gave an overview and update on the catalogues first presented to PCWP/HCPWP members in 2024, explaining their structure, functionalities, and use cases for patients, healthcare professionals, and researchers. The catalogues were launched to promote transparency, ensure discoverability of RWD sources and enhance understanding of RWE supporting regulatory decisions. The catalogues are continuously improved based on user feedback, with recent enhancements including better search, notifications, and dashboards. Data holders and investigators are encouraged to contribute information on data sources and studies in the catalogues. For more details, please see the [presentation](#).

### **5.4. Emerging topics from the Patient Experience Data (PED) reflection paper consultation**

Rosa Gonzalez-Quevedo (EMA) gave an update on the public consultation that closed on 31 January. Comments were received on all sections, with information on the number of comments received from different stakeholders and some examples of comments to provide an initial flavour while a full analysis of the consultation responses is ongoing. Responses highlighted the value of the reflection paper as a consolidation of current thinking while some stakeholders called for more practical guidance, clearer definitions and international harmonisation of terminology and methods. For more details please see the [presentation](#).

### **5.5. Feedback from surveys in PED priority areas**

Claire Espinasse (EMA), Friederike Wilke (Barmer – Statutory Health Insurance) and Florence Borrelly-Konyakhin (EMA) presented preliminary results from the multistakeholder survey on patient experience data (PED), which was sent to all eligible organisations in September 2025. A total of 233 respondents completed the survey, with the majority being healthcare professionals and researchers (111), followed by patients (75). The main objectives of the survey are to gain a better understanding of key stakeholders' experiences with the use of PED across therapeutic areas, and to compare the findings between stakeholder groups and therapeutic domains. It was highlighted that the responses will help inform and support the finalisation of the reflection paper. For more details, please see the [presentation](#).

### **5.6. PED in non-interventional studies containing real world data**

Denise Umuhire (EMA) and Diogo Almeida (University of Lisbon) presented a review of the use of PED from non-interventional studies submitted to the EMA, detailing methodology, findings, and recommendations for future practice. Between 2018 and 2023, 250 applications with RWD were submitted with around 18% of them including PED. PED use was most frequently seen in the post-authorisation setting, often involving patient-reported outcomes. Patient registries were a common data source for PED. Recommendations include early stakeholder dialogue, robust study designs with clear objectives, and leveraging patient registries. New guidance, e.g. the PED reflection paper and ICH guidelines, is expected to further encourage use of PED and a follow-up review is planned in five years' time. For more details, please see the [presentation](#).

## 6. Multistakeholder workshops

### 6.1. Feedback from the HMA/EMA multistakeholder workshop on artificial intelligence

Luis Pinheiro (EMA) presented feedback from the EMA/HMA multistakeholder workshop on Artificial Intelligence (AI) that took place on Thursday 20 and Friday 21 November 2025. There was great interest in this topic with numerous attendees in person and online. He outlined the key topics of the workshop and spotlighted talks by patient organisations that had developed their own AI tools. The workshop [report](#) is now available. Luis concluded with the priorities for the 2026 AI workplan that include international harmonisation, regulatory guidance and regulatory sandboxes. Please see [presentation](#) for more details.

### 6.2. Information on workshop for medicines and medical devices in the cardiovascular field.

Ivana Silva (EMA) informed the group about an upcoming multistakeholder workshop on medicines and medical devices in the cardiovascular field that will take place on 1-2 July 2026. She explained the overall objective of the workshop is to enhance understanding among stakeholders on the interplay of regulation and innovation in medicines and medical devices, providing a space for interdisciplinary discussions on clinical gaps, development challenges and regulatory strategies, advancing CV prevention and treatment in the overlapping fields of diabetes, obesity and lipid disorders, and also on the role of real-world data, and digitalisation and AI in CV innovation. The workshop is EMA's contribution to the EU Safe Hearts Plan. An outline of the agenda was provided, and more information will be available on the EMA website. See [presentation](#) for more information.

## AOB

- A call for volunteers was made regarding the establishment of an expert group on vaccine confidence.
- The 20<sup>th</sup> anniversary of the PCWP will be celebrated in June 2026.
- Training on Data Quality and Omics Data was made available to working party members via the EU network training centre.