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

Meeting Summary - HCPWP plenary meeting

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

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

Welcome and opening remarks

Juan Garcia Burgos (EMA) opened the meeting, welcoming the HCPWP participants in person and online.

1. Ongoing review of the Healthcare Professionals engagement framework

1.1. Update of engagement framework: EMA and healthcare professionals and their organisations

Ivana Silva (EMA) provided an update on the progress of the framework for interaction with healthcare professionals (HCPs) and the proposed next steps. Key updates to the framework include alignment with the framework of engagement with patients and simplification of content, inclusion of additional definitions, recognition of the need to foster shared interests with academia and life sciences students, integration of veterinary professionals to support the One Health approach, and the inclusion of feedback survey methodologies, as foreseen in EMA's Framework Strategy for External Communication and Stakeholder Engagement. Furthermore, the framework will be supplemented by a standalone document, outlining the framework's objectives in a structured format, listing the expected outcomes for both EMA and healthcare professional organisations. The final draft of the framework will be shared with the HCPWP for final written consultation and endorsement in Q2/Q3 2026. The framework is then expected to be adopted by the Management Board in Q3/Q4 2026, followed by its official publication.

2. Work plans for working parties

2.1. Update on the joint PCWP/HCPWP workplan (2025-2028) and discussion on HCPWP specific work

The HCPWP was informed that the mature draft workplan will be circulated for final consultation and endorsement to PCWP and HCPWP by end Feb 2026.

3. 5-year of the policy officer's group (POG)

3.1. Overview of the 5-year journey and activities of the POG

Maria Bonafonte (EMA) provided an overview of the 5-year journey of the Healthcare Professionals' Policy Officers' Group (HCP POG), which was established to complement the HCPWP by enabling broader participation from eligible healthcare professional organisations. Marking its fifth year in 2026, the group has grown significantly, with 60 representatives by 2025, and held five virtual meetings throughout the year, each lasting 1.5 hours. The HCP POG serves as a valuable tool for stakeholder listening and for strengthening early engagement with all eligible healthcare professional organisations through policy officers. It provides a forum for the EMA to share high-level updates on ongoing work and strategic priorities, enables eligible organisations to provide input and raise issues or concerns with the EMA at an earlier stage, facilitates the identification of common needs, and creates opportunities for organisations to explore new areas of collaboration.

An overview of the meeting topics discussed over the past two years was shared, alongside the areas of interest for organisations in 2026. For more details, please refer to the presentation.

3.2. Update on HCP POG drafting group on shortages

The presentation focused on the progress made by the HCP POG drafting group on shortages and the next steps. See presentation for further information.

4. Members' voice

4.1. Selecting outcomes that are relevant to patients and health care professionals for trials

The European Respiratory Society (ERS) presented on core outcome sets (COS), developed in collaboration with patients, to improve the relevance and comparability of clinical trials.

The presentation highlighted the critical role of selecting appropriate outcomes in clinical trials for understanding treatment effects, comparing development studies, and supporting regulatory and health technology assessment (HTA) decision-making. However, trials often measure inconsistent outcomes using varying methods and frequently omit outcomes important to patients and healthcare professionals, such as symptom burden and daily functioning. This heterogeneity in trial outcomes limits comparability, interpretability and regulatory decision-making.

COS are standardised, agreed set of minimum outcomes that should be measured and reported in all trials for a specific condition. They are developed through evidence-informed, global, multistakeholder consensus processes—often using Delphi surveys—to ensure that outcomes reflect what matters most to patients and clinicians.

Examples of COS developed and endorsed within respiratory medicine were shared, including work supported by the ERS, with close collaboration with COMET and in-house methodological expertise to maintain methodological rigour and promote uptake.

For regulators and HTA bodies, COS offer the potential to reduce uncertainty by ensuring consistent, relevant, and comparable outcomes across trials, while preserving flexibility for innovation.

The presentation concluded by emphasising the importance of aligning COS with regulatory expectations and involving regulators early in their development to enhance their usefulness and adoption in clinical development programs. See presentation for further details.

Link: Core outcome sets, developed collaboratively with patients, can improve the relevance and comparability of clinical trials.

4.2. ESC's reflections on the identification of critical medicines

The presentation by the European Society of Cardiology (ESC) provides reflections on Union List of Critical Medicines and the annual review process, focusing on how healthcare professionals (HCPs) can be better involved. The ESC raised concerns regarding the limited participation of HCPs, lack of transparency in the assessment process, and the absence of a structured feedback mechanism, all of which hinder the integration of comprehensive clinical input.

The ESC outlined several key issues with the current approach:

- Limited transparency: HCPs are not provided with sufficient insight into why certain medicines are prioritised, leading to uncertainty about their clinical relevance.
- Information gaps: HCPs involvement occurs too late in the process, with limited access to key information from Member States' assessments (e.g., therapeutic relevance and available alternatives).
- Weak feedback mechanisms: The absence of a robust feedback loop reduces the impact and depth of HCPs contributions.

As an example of these issues, the ESC highlighted the exclusion of some beta blockers from the list, despite their clinical importance, illustrating a disconnect between guideline-recommended therapies and medicines classified as critical. The ESC called for the inclusion of up-to-date clinical guidelines in the assessment process to better align the list with current clinical practices. See presentation for further information.

AOB

N/A