



20 years of the PCWP

Patients and Consumers Working Party (PCWP) meeting

30 June 2026, 13:30 – 17:30 (CEST)

Meeting room 2A, EMA, Amsterdam / MS Teams

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

Opening remarks by the Executive Director

Emer Cooke (EMA) welcomed all participants and officially opened the anniversary meeting. She acknowledged the importance of the PCWP within EMA, Europe and internationally and commented on the commitment and hard work of the working party that contributed to its success. She described the PCWP as a key platform for EMA consultation of organisations to ensure their voices are captured in Agency activities. Looking ahead, she stressed that the implementation of the revised EU pharmaceutical legislation offers an important opportunity to further strengthen patient-centred regulation, including through the participation of patient and healthcare professional representatives in the CHMP, while reaffirming EMA's commitment to integrating patient expertise throughout the regulatory process. See recording for more details.

Welcome and introduction / Health and safety

Juan Garcia Burgos (EMA) also welcomed participants online and in person and described the structure of the meeting.

1. Where it all began

1.1. Journey of the PCWP

Melanie Carr (EMA) presented the past 20 years of the PCWP and reflected on two decades of commitment, collaboration and progress in strengthening patient and consumer involvement in medicines regulation. She paid tribute to former co-chairs from EMA and the working party as well as to the PCWP secretariat, all of whom helped shape the working party over the years.

Over the past 20 years, the PCWP has played a pivotal role in ensuring that patient and consumer perspectives are embedded in many EMA activities. Among its major achievements was its support for public hearings that help to bring patient experiences directly into discussions on the benefits and risks of medicines. The working party has also contributed extensively to patient information initiatives, including package leaflets, electronic product information, training materials and communication campaigns. Its members have supported EMA committees, contributed to work on patient experience data, participated in international collaborations and provided valuable expertise during the COVID-19 pandemic response.

Melanie also highlighted the evolution of both the PCWP and EMA over the years, marked by changing locations, growing international recognition and increasingly influential patient engagement activities. In conclusion, Melanie thanked all past and present members, acknowledged their commitment, dedication and collective achievements, while expressing confidence that the strong partnership between patients, consumers and regulators will continue to flourish in the decade ahead. See [presentation](#) and recording for more details.

1.2. The first interactions of patients with EMA

François Houÿez (EURORDIS) reflected on a pivotal moment in the history of patient involvement at EMA, describing how patient advocates successfully made the case for meaningful participation in the regulatory process. Using the HIV/AIDS community as an example, he showed how early interactions with the CPMP (now CHMP) demonstrated that patients could contribute not only lived experience but also valuable scientific knowledge and evidence. These exchanges marked a shift from patients being passive observers to becoming trusted partners in regulatory science. He emphasised that this collaboration helped shape more efficient approaches to medicines evaluation and contributed to transparent decision-making. More broadly, these first interactions demonstrated the value of high-quality dialogue between patients and regulators, laying the foundations for the structured patient engagement that is now an integral part of EMA's work. See [presentation](#) and recording for more details.

This perspective was complemented by Fernando de Andres Trelles (AEMPS) who at the time was a member of the committee. Fernando reflected on the transformative impact of the early interactions between patients and regulators at EMA. He recalled how these meetings challenged regulators' assumptions by demonstrating that patients not only brought lived experience but also an understanding of the scientific and methodological issues underpinning medicines evaluation. The dialogue helped regulators recognise the value of patient expertise, contributed to more pragmatic and timely regulatory decision-making, and influenced the evolution of approaches to assessing and approving treatments. He also highlighted how the nature of patient-regulator discussions matured over time, evolving to broader questions of benefit-risk assessment and patient safety and showed the importance of maintaining continuous dialogue, as patient perspectives and regulatory challenges evolve. Concluding, he stressed the importance of sustained, independent patient involvement in regulatory activities and praised the PCWP for its lasting contribution to the EMA's work. See [presentation](#) and recording for more details.

1.3. PCWP: a model of interaction

Frits Lekkerkerker (consultant, former CHMP member) reflected on the origins of structured patient involvement at EMA, recalling how a workshop in [2002](#) led to the creation of a joint working group bringing together patient organisations, EMA staff and CHMP members. At the time, many regulators were sceptical about the value patients could bring to scientific and regulatory discussions, believing that medicines evaluation should remain the domain of experts. However, through a series of meetings focused on topics such as transparency, pharmacovigilance and communication with the public, patient representatives demonstrated a high level of competence and engagement. This experience helped change attitudes within the CHMP and showed that patients and their organisations could make meaningful contributions to regulatory decision-making.

He also highlighted several foundational principles that emerged from these early discussions and continue to shape patient involvement today. These included the importance of ensuring the independence and transparency of patient organisations, recognising patients as experts who can contribute directly to scientific discussions, and acknowledging the significant voluntary effort required from patient representatives. Examples of patient participation in scientific advisory groups further reinforced the value of patient expertise and helped build acceptance of patient involvement across the regulatory system. Looking back, Frits described the establishment of the PCWP as a major milestone in the evolution of EMA's approach, expressing satisfaction at seeing patient participation become an integral and widely accepted part of the Agency's work over the past two decades.

Nikos Dedes (EATG) complemented by talking about the early years of the PCWP and the factors that enabled patient involvement to become embedded in both the scientific work and governance of EMA. He highlighted how feedback from the early workshops and working group discussions helped shape legislative changes between 2004 and 2006, supported by committed regulators and patient advocates who believed patients should participate on an equal footing in regulatory discussions. He also noted that these developments took place during a period when greater transparency and public engagement were becoming increasingly important, following major public health events and changes within the European Union.

Looking back at the discussions that shaped the first working group and working party, the speaker emphasised the guiding principle of “nothing about us without us” and the belief that patients should have a meaningful role in decisions affecting their health. They recalled that patient organisations quickly established themselves as credible and constructive partners, contributing thoughtful scientific perspectives rather than simply advocating for quicker access to medicines. This helped build trust between regulators and patients and laid the foundations for the collaborative approach to patient engagement that remains a central part of EMA’s work today. See recording for more details.

1.4. Panel discussion with speakers and past chairs

A panel consisting of former PCWP co-chairs; Nikos Dedes, Lise Murphy, David Haerry, and Kaisa Immonen was asked a series of questions relating to their perceptions of what was the meaningful impact of the PCWP, how the working party helped patient perspectives gain credibility within a regulatory agency such as EMA and how could the PCWP influence the way patient and consumer voices were heard within EMA. This lively discussion was complimented with comments by former PCWG co-chair Frits Lekkerkerker. See recording for more details.

2. Patients at EMA today

2.1. Patients at EMA

Steffen Thirstrup (EMA) reflected on his long experience in medicines regulation and highlighted how patient involvement has become a defining strength of the European regulatory system. Drawing on his experience as a regulator, he described how interactions with patients have transformed regulatory thinking, particularly by demonstrating that patients may assess benefits and risks differently from regulators and healthcare professionals. He recalled a significant discussion on a multiple sclerosis treatment, where patient representatives made a compelling case for maintaining access to a medicine despite serious risks, provided that adequate risk minimisation measures were in place. For him, this illustrated the unique and essential perspective that patients bring to regulatory decision-making.

Looking at the present and future, he emphasised that patient engagement is now embedded throughout the medicines’ lifecycle, from scientific advice to marketing authorisation, safety monitoring and governance. He welcomed the forthcoming inclusion of patient representatives in the CHMP under the revised pharmaceutical legislation and stressed that patient expertise would continue to play an important role in the future regulatory framework, even as some committee structures evolve. Highlighting the broad involvement of patients across EMA committees, expert groups, task forces and strategic initiatives, he described patient engagement as one of Europe’s major achievements in medicines regulation and expressed confidence that this partnership will continue to grow and strengthen in the years ahead. See [presentation](#) and recording for more details.

3. The best is still to come

3.1. PCWP and the next ten years: reflections from the co-chairs

In this session chaired by Ivana Silva (EMA) Marco Greco (EPF) and Juan Garcia Burgos (EMA) as co-chairs of the PCWP were asked to address the question *'Looking ahead ten years, what should success look like for collaboration between the PCWP, committees, and the wider EMA network under the new pharmaceutical framework ?'*

Looking ahead to the next decade, Marco Greco stressed that the achievements of patient involvement at EMA should not be taken for granted. He emphasised that maintaining and strengthening the current model will require continued collaboration, mutual support and ongoing investment from both patient organisations and regulators. In his view, one of the greatest successes of the past 20 years has been the transformation of patient representatives into recognised experts who contribute meaningfully to regulatory discussions while retaining the human perspective that makes their contribution unique. He highlighted the importance of preserving this balance in an increasingly complex and fast-changing environment shaped by developments such as artificial intelligence, evolving legislation and new communication challenges.

Marco also underlined the need to ensure the long-term sustainability of the system. Key priorities for the future include embedding patient involvement consistently across all levels of the European regulatory network, including national agencies; securing adequate funding and resources for patient organisations; and investing in the training and development of future generations of patient advocates. Above all, he expressed the hope that, ten years from now, there will no longer be a perceived divide between patients and regulators, but rather a shared partnership in which patient perspectives are fully integrated into every aspect of medicines regulation.

Juan Garcia Burgos agreed that patient engagement at EMA represents a major success story, having evolved from consultation towards fully structured and meaningful participation in regulatory decision-making. Looking ahead, he stressed the importance of consolidating these achievements and ensuring they remain resilient in a rapidly changing environment. He welcomed the forthcoming inclusion of patient representatives in the CHMP under the new pharmaceutical legislation as a significant step towards completing the integration of patients into the regulatory system.

Juan identified several areas where further progress is needed over the next decade. These include making patient experience data a routine and influential part of medicines development and evaluation, broadening the diversity of patient representation by engaging more national organisations, and increasing transparency about how patient input contributes to regulatory decisions. He also highlighted the importance of ensuring the long-term sustainability of patient engagement through adequate resources, capacity building and succession planning. In his view, the future challenge is not to reinvent the current model, but to strengthen and adapt it so that patient involvement continues to add value and remains an integral part of the regulatory process.

3.2. Panel discussion with CHMP, PRAC and MB chairs

A panel consisting of the Management Board Chair Rui Santos Ivo, CHMP Chair Bruno Sepodes, PRAC chair Ulla Wändel Liminga, HCPWP co-chair Piotr Szymanski and PCWP co-chair Juan Garcia Burgos was asked their perspectives on the future role that patients will play under the new pharmaceutical legislation in their respective groups. Advice on onboarding patients to committees was shared as well as a view on the continued successful collaboration of the PCWP and HCPWP. See recording for more details.

3.3. Closing remarks

Juan Garcia Burgos celebrated the fact that patient engagement is now firmly embedded in the EU regulatory system and recognised Europe's leadership in this area. While acknowledging the significant progress achieved over the past 20 years, he stressed that continued collaboration between patients and regulators will be essential to meet future challenges and build on this success. He thanked all participants and everyone who contributed to this journey over the 20 years of the PCWP and expressed confidence in the continued growth and impact of patient involvement in the years ahead.

