Healthcare Professionals' Working Party (HCPWP) meeting

27 June 2023

Co-Chairs: Juan Garcia Burgos (EMA) and Rosa Giuliani (HCPWP)

Welcome and introduction

Juan Garcia Burgos (EMA) opened the meeting, welcoming all participants in person and online as well as the Working Party co-chairs.

Opening remarks by the Executive Director

Emer Cooke, EMA Executive Director, applauded the commitment and hard work over the last decade that were fundamental to the development of the HCPWP as a key pillar of EMA's stakeholder engagement framework. She emphasised the uniqueness of both the HCPWP and the PCWP in providing a platform for dialogue and sharing of experience and good practices, and ultimately ensuring that the views of those the Agency works for are included in its work. She then looked to the future opportunities and challenges for the Agency and healthcare professionals, including ongoing implementation of the EU Clinical Trial Regulation and EMA's extended mandate, forthcoming legislation on the European Health Data Space and pharmaceuticals, and technological transformations in treating patients and collecting data on medicines' safety and effectiveness. These will lead to an even greater need for collaboration with healthcare professionals and other stakeholders, will transform areas such as personalised medicines, advanced therapies and medical devices. She also stressed the role of the working party in introducing new generations of healthcare professionals to the work of EMA and concluded with her wishes for a fruitful reflection on the future of the HCPWP (for more details see video).

1. The beginning of our journey

1.1. Setting the foundations towards healthcare professionals' engagement at EMA

Isabelle Moulon, who played a critical role in EMA regarding the development of interactions with patients, healthcare professionals and academia from 2004 and was the first EMA co-chair of the HCPWP from 2013 until 2017, set the scene by revisiting the history of EMA's engagement with healthcare professionals (HCPs). Following the creation of EMA, there was a strong push for patient involvement, which was formalised in the Orphan Regulation and led to the creation of a working party with patients and consumers. With HCPs there was no similar push, since they were already involved as experts and as scientific committee members. However, the need to create a working party with healthcare professionals was identified. To mirror work done with patients and consumers, EMA created an initial group of HCP organisations that was not immediately successful, but eventually the first framework of interaction was adopted in 2011 following further discussions with HCP organisations. The creation of the HCPWP, in turn, required work and support to organisations on the eligibility criteria which were unfamiliar to many at the time. Finally, the first meeting of the HCPWP took place on 5 June 2013 with 16 umbrella organisations and elected the first HCP co-chair, Gonzalo Calvo. Since then, the HCP organisations' engagement with EMA has

developed and become fundamental to the work of the Agency (for more details see video).

1.2. Perspectives from the former HCPWP co-chairs

Gonzalo Calvo, co-chair during the first and second mandates (2013-16 and 2016-19) recalled that in the beginning the HCP representatives' awareness and knowledge of medicines regulatory processes was very low, and an understanding of the rationale for engagement with EMA was not yet there. The experience was challenging but also very enriching, to create the right atmosphere to prompt discussions and create understanding about the importance of the regulatory framework for HCPs whilst also bringing the academic and regulatory worlds closer together. The HCPWP discussions became richer in time, and even more so once the HCPWP and PCWP started to have joint meetings (for more details see video).

Ulrich Jaeger, who co-chaired the HCPWP during its third mandate in 2019-22, shared the challenges experienced during this period when the HCPWP planned activities had to be reprioritised to focus on the COVID-19 pandemic. One of the HCPWP greatest achievements was to open a space for discussions with representative organisations and exchange knowledge and information between healthcare professionals and regulators. Equally important was to understand that only acting together, particularly with the PCWP, it will be possible to advance towards shared goals and achieve tangible things. Concrete topics such as harmonisation of guidelines for clinical trials, personalised medicines, access to medicines and real-world evidence require particular attention and more specific regulatory frameworks (for more details see video).

The floor was then opened to members of the working party for their perspectives (for more details see video). After their remarks, a slideshow displayed highlights of the HCPWP's work over the years.

Testimonials and anniversary messages from HCPWP members were also collected and can be viewed on the dedicated webpage of the 10 years of the HCPWP.

2. Where we are today

2.1. Remarks from the current HCPWP co-chairs

The next session kicked off with reflections from Rosa Giuliani, who currently co-chairs the HCPWP since 2022, and her EMA co-chair, Juan Garcia Burgos who took over from Isabelle Moulon in 2017.
Rosa Giuliani expressed her wish to maintain the HCPWP as a safe harbour for dialogue, sharing ideas and discussion and emphasised the momentum this WP can bring to current and future challenges and solutions. There are many topics already identified – with a strong focus on clinical trials and accessibility – where working together will be crucial. The knowledge healthcare professionals can bring to regulatory processes is based on daily clinical practice, their direct interaction with patients and their understanding of how science and good data shape regulatory decisions and support innovation. It is the HCPWP responsibility to nurture an environment where healthcare professionals working in different settings share their experiences and viewpoints and enrich the feedback it can provide to regulators as part of a circular model of interaction where patients, healthcare professionals and regulators interact at very early stages and continuously contribute to developing the science and innovation that support medicines regulation and ultimately patients' access to the treatments they need (for more details see video).

2.2. Where is science, technology and medicines regulation heading to?

Anthony Humphreys, Head of EMA's Regulatory Science and innovation Task Force, gave an overview of developments in science and regulation. He stressed the importance of collaboration between academia, developers, regulators, patients and HCPs in an evolving landscape. He outlined the forthcoming reform of the EU pharmaceutical legislation and the tools included in the Commission's proposals to support innovation. He also touched on the proposals to modify EMA's structure, with notably HCPs and patients becoming full members of the CHMP. For more details, see the presentation and video.

2.2. The importance of stakeholders' engagement to support implementation of the European Medicines Agencies Network Strategy

Juan Garcia Burgos presented on the added value of engagement with HCPs and how this fits into the EMA's wider multi-stakeholder engagement framework. HCPs bring multi-disciplinary expertise from a range of therapeutic and practice areas, covering detailed scientific input, clinical care, policy and strategic topics. He outlined the opportunities of adopting a multi-stakeholder approach, such as achieving common understanding and collaboration, encouraging the interface between clinical research and clinical practice, a richer input on issues of common concern, transparency and trust. Bilateral and multi-stakeholder HCP engagement are complementary and needed. For more details, see the presentation and video.

During the Q&A that followed, members highlighted the importance of not only supporting innovation but also creating the environment to use such innovation. To that end, it is highly relevant to understand what the place of new medicines and new indications in the context of clinical reality is, to follow what happens once a new medicine in on the market, and study what are the conditions for optimisation and discontinuation of treatment. Members also emphasised the need to gain a better understanding of the use of biomarkers and to use clinically relevant endpoints, identified together with patients and healthcare professionals, that go beyond efficacy and support effectiveness. It was suggested to explore how the HCPWP could have a role in encouraging putting academic trials to the service of clinical practice and include it by design in the process of medicines development and access as a way to create a better intersection and articulation with the innovation originating from the pharmaceutical industry.

It was also pointed out that medicines' development is changing dramatically and at a very fast pace. Mathematicians, biophysicists, and AI experts are bringing new approaches, non-traditional investors have entered the healthcare and medicines innovation ecosystem, development timelines are being compressed and traditional approaches such as population-based trials may no longer provide the framework needed to develop individualised therapies. There is a need to understand how regulators, and stakeholders overall, are preparing to face these changes and again the HCPWP can be a platform to catalyse discussions and contribute to a more agile and dynamic way to organise expertise in specific areas.

Members also stressed that as data generation expands and diversifies, particular in the real-world context, it is very important to involve patients and healthcare professionals in defining the criteria for data quality and relevance for clinical decisions.

In relation to the pharmaceutical legislation review, members raised more specific questions which EMA will share with the EC.

3. Looking ahead

3.1. EMA perception survey

Christopher Gadd, Head of Online Communication, presented the results of the 2022 EMA communication perception survey. This survey is targeted towards all stakeholders and partners and aims to gauge general perception, identify communication challenges and opportunities, and support continuous improvement. The results highlight the importance and generally high satisfaction of EMA communication resources to respondents and a perception of EMA as a transparent and open organisation. Areas of improvement could include further tailoring of communications, increasing awareness and use of some communication tools, improving the website and making more resources available in languages other than English. For more details, see the presentation and video. The full survey report is available.

During the discussion that followed, members expressed different views with some suggesting that to

increase dissemination and re-use of EMA's content and materials by healthcare professional organisations and learned societies a more tailored approach per therapeutic area would be needed and others favouring to continue the more general, non-selective approach. Members also encouraged to continue working closely at HMA level with national competent authorities in the translation and dissemination of communications and surveys.

3.2. Results from satisfaction survey

Giulia Gabrielli, Patient Liaison, presented the results of the 2023 satisfaction survey with HCP organisations. In 2023, all eligible organisations were surveyed (previously only HCPOs). The results indicate a high level of satisfaction with the responding organisations' engagement with EMA and with being an eligible organisation. The rating of current priorities confirms the continued relevance of priorities identified from past interactions and of EMA's priorities and work. For more details, see the presentation and video.

3.3. Reflection on the need to review EMA's framework of engagement with healthcare professionals and their organisations

Ivana Silva, Healthcare Professionals Liaison, presented the rationale for a review of the framework for interaction with HCPs, last revised in 2016. A "points to consider" document had been circulated to the working party members in advance. For more details, see the presentation and video.

During the discussion that followed, members welcomed the idea of engaging with European students' associations as a way of reaching out to future generations of healthcare professionals and academics and suggested also considering how to strengthen interactions with universities. In addition, members raised the question whether more specific objectives would need to be established depending on the type and profile of the organisations.

HCPWP members were invited to complete the written consultation on the need to review the framework of engagement.

Any other business

The working party was informed that the Committee for Medicinal Products for Human Use (CHMP) will be drafting a guidance document on information to be included in the SmPC under section 5.1 "Pharmacodynamic properties" and would like to consult the HCPWP on some specific questions. Members were invited to complete a written consultation by 11 September. This may be followed up by further discussion in the WP, if needed, to explore if a consensus view is feasible.

At the close of the meeting participants were invited to join the HCPWP 10th anniversary celebration.