



When healthcare professionals came to the (working) party

Forewords by co-chairs of the working parties

PCWP co-chair: [David Haerry \(EATG\)](#)

The PCWP was established in December 2006 and its sister working party HCPWP is younger (created in 2013). As the agenda and work topics for both working parties are very similar, close collaboration and joint meetings made a lot of sense. Therefore, the two working parties worked very closely together during the mandate; 2013 to 2016.

For me as PCWP co-chair, this first meant having a lot more people in room than before, plus many unknown faces and organisations. It also meant that having enough discussion time was really essential, while keeping time became even more challenging.

We very quickly realised how beneficial the collaboration was for both sides. When a number of PCWP member organisations worked on recommendations regarding shortages in Europe, we were almost taken by surprise about how pertinent this topic was on the healthcare professional side. Looking back, I consider this initiative to have been the trigger for the current close collaboration.

Other areas where I have seen the collaboration as especially beneficial include:

- Adverse event reporting and regulatory decision-making in pharmacovigilance
- Health technology assessment (HTA) - EMA interaction
- Risk communication and communication in medicines
- Biosimilars
- Adaptive pathways pilot project
- EU study on off-label use

The overall experience may be similar as the when the patient organisations learnt to work with consumers. The interests and priorities may not always be identical. But learning about the specific issues of healthcare professionals helps the patients to better shape their expectations. Having both sides at the same table makes solutions more feasible and improvements more robust.

HCPWP co-chair: [Gonzalo Calvo \(EACPT\)](#)

Collaboration and enhancement of mutual understanding between patients, healthcare professionals and regulators is a must within the regulatory environment. After several years of informal collaboration the EMA took the initiative in 2013 to establish the healthcare professional working party (HCPWP), thus setting a formal framework of interaction with EMA as well as with patients, through the PCWP established years before. Both working parties frequently meet together, creating a unique enriching atmosphere to exchange ideas, share aspirations and sometimes confronting perspectives, which is an essential aspect to enrich opinions and broaden perspectives.

Both working parties now have a revised their frameworks of interaction, and initiatives exist to expand the collaboration to academia. Altogether, this new scenario should be the basis to consolidate actions leading to concrete results in terms of timely access to new safe and effective medicines; contribution to risk minimisation strategies; identification and prioritization of unmet needs; or communication strategies.

After three years of learning, we all (PCWP, HCPWP and EMA) face new challenges for this next mandate (2016-2019). Our path to 2019 should prioritise initiatives that crystallise this interaction in concrete achievements. This will not be minor task, but I am sure it will be achievable if we devote the same effort and enthusiasm that we have so far.

Coming together in the Working Parties led to opportunities for collaboration in other areas of common interest....

European Association of Hospital Pharmacists (EAHP)

As well as valuing the opportunities the European Medicines Agency provides to our organisation to make input and give perspective on their activities, EAHP also values the chance to hear and discuss viewpoints with counterpart healthcare professional organisations and patient associations.



Working Party meetings illuminate why others may view a regulatory issues differently from hospital pharmacists. However, perhaps even more often, they frequently bring to attention *shared* perspectives and concerns. At other times, conversations can even spark collaborations entirely outside of the Agency's consultative sphere.

Below are two testimonies from EAHP of collaborations that have to greater or lesser degrees, stemmed from our involvement with EMA's healthcare professional working party. One relates to collaboration firmly within the Agency's regulatory remit, and the other to a professional development initiative in which contacts formed via EMA's stakeholder network assisted collaboration.

Stakeholders collaborate on the topic of medicines shortages

Led by Rare Diseases Europe (EURORDIS), and assisted by a number of other healthcare professional and patient organisations, a stakeholder position paper on the topic of medicines shortages was published in 2013. This paper tackled the nature, causes and impact of medicines shortages Europe, and concluded with a series of recommendations not only to the European Medicines Agency, but also to the European Commission, pharmaceutical industry, governments and regulators.



The paper then established its own momentum, receiving the support of over 50 healthcare professional and patient organisations, and forming a basis for meetings with units of the European Commission and sections of the European Council of Ministers.

The paper continues to be a reference for the healthcare professional and patient perspective on this topic. This includes European Council of Minister conclusions (July 2015) on monitoring of shortages and EMA work streams (October 2015) in the area of definition and communication.

More information here: <http://download.eurordis.org.s3.amazonaws.com/documents/pdf/common-position-supply-shortages-final-10-2013.pdf>

The European Summit on Hospital Pharmacy May 2014

In 2014 EAHP determined to set out a new vision for the hospital pharmacy. This was to be conducted via a set of statements setting out the role of the hospital pharmacist across health service areas.

Building on the partnerships formed through EMA healthcare professional and patient and consumer working parties, EAHP made outreach to its partner associations on its professional development project.

Members of the working party were invited to contribute to the development and agreement of the statements via several rounds of Delphi consultation. In the final voting mechanism, votes by the hospital pharmacist constituency were equally weighted to those from other healthcare professional and patient associations.

EAHP was delighted by the outcome. Statements were made more robust and credible via the insights provided from other affected interest communities. For example, patient contributions helped to ensure the role of carers was given greater prominence within the statements. Meanwhile inputs from other healthcare professionals help to ensure the underlying multi-disciplinary nature of hospital pharmacist activity was given more attention in the surrounding descriptions of the statements.

As the Statements move into implementation phase, EAHP continues to keep the contributing organisations abreast of developments and keeps dialogue open on future partnership working towards their achievement.

More information here: <http://ejhp.bmj.com/content/21/5.toc>

European Association of Urology (EAU)



One of the core activities of the European Association of Urology (EAU) is the production of clinical urological guidelines. It is of crucial importance for their validity and uptake to ensure appropriate stakeholder involvement, which as primary partners must be patients and/or their representatives.

For the EAU Prostate Cancer Guidelines Panel the then PCWP Europa Uomo representative, Dr. Erik Briers, was approached with a request to join this group. Although EAU had already established contacts with Europa Uomo (now: EUomo), sharing discussions and meetings within the EMA framework proved most effective in identifying a candidate that could function effectively within this particular context. From our point of view, we could not have wished for a better arrangement, and we now look at a number of publications of which Dr. Briers is one of the co-authors (several more to deliver within the next 3-4 months).

This is clearly a first step only and the EAU already approached several other representatives from both the PCWP and HCPWP, as potential partners for a range of projects. As yet, none of these project delivered results just yet, but expectation is that in the course of 2016 this will change.

More information: <http://uroweb.org/guideline/prostate-cancer/> and <http://www.ncbi.nlm.nih.gov/pubmed/26691493>