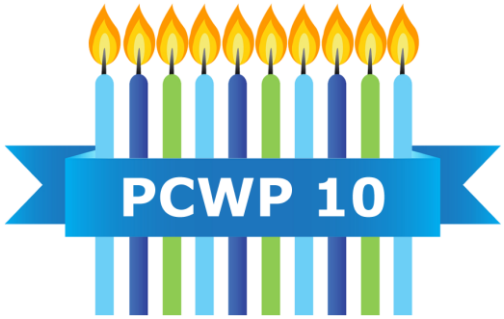
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP (2006-2016)

The original PCWP members describe the highlights and challenges of the last 10 years



Mary Baker
Ambassador
European Parkinson's Disease Association

EPDA
European Parkinson's Disease Association

"I well remember the first meeting of the Patient Board, a disparate group all delighted to be there but still pursuing our representative illnesses and our own agendas. After better understanding the work of the European Medicines Agency and under a good Chairman we became welded together into one strong voice combining passion and good sense. It was a privilege to participate and a real education to see the outcome of an integrated team within an efficient organisation. I wish you a very Happy Birthday."

W.H.J.M. Wim Wientjens

International Diabetes Federation, Europe

International Diabetes Federation

"I did start with my activities at EMA in 2003. On behalf of the International Diabetes Federation Europe. Having asthma since 1937 and diabetes since 1950 of course as a patient, but also very interested because of being a biochemist. Sometimes I knew the action of medicines better than the doctors who were prescribing these medicines. I got very inspired how EMA built during these years strong departments within patient health protection and strong departments within human medicines development and evaluation. And as member of the management board last years I was strongly involved in the necessary improvement of the departments within information and communications technology. The change in the strategy of EMA from risk-benefit into benefit-risk after many years of discussions was an important step by EMA and was strongly supported by us. Good interpretation of 'risk' as 'uncertainty' was very important. And in all discussions I was intrigued how 'statistics' and 'ethics' were always rather dangerous for correct conclusions, esp. for me as a patient and as a biochemist as well. Hopeful is that, after also many years of discussions, adaptive licensing and other methods are trying to bring medicines much faster to patients."

Ilaria Passarani

Head of the Food and Health Department,

BEUC – The European Consumer Organization

BEUC The European Consumer Organisation

"Openness, transparency and participation are pivotal elements in building people trust and confidence in the work of regulatory agencies. The European Medicines Agency patients and consumers working party is a successful example of stakeholders' involvement in the work of a public institution. Over the last 20 years the Agency put a lot of efforts and resources to ensure the PCWP collaboration was fruitful both for the Agency and for the organizations involved. The annual reports of the PCWP testify the added value of the EMA interaction with patients and consumers organizations and the concrete benefits it brought to the general public, for example in more reader friendly package leaflets. The PCWP is also a useful forum to exchanges views with representatives of patients and consumers organizations that represent a wide range of perspectives within the public health community. The main challenge for the PCWP will be to continue playing a key role within the Agency and to promote its work externally. The main challenge for EMA is to continue involving patients and consumers in its activities while remaining fully accountable in its role of promoting and protecting the health of all European citizens".

Jose Drabwell

IPOPI Chairperson,

International Patient Organisation for Primary Immunodeficiencies

Arriving at the impressive EMEA building in Westferry Circus all those years ago, I remember feeling incredibly nervous, because I was aware of how little I really knew and what to expect. I was after all just a patient with a rare disease, who was passionate about raising awareness and having the unique opportunity to learn, disseminate this information to other patients as well as maybe contributing to the discussions taking place during the EMEA meetings.

I know that our patients, not just in Europe but also in other parts of the world have been the recipients of crucial information about medicines and the regulations involved. Most of the original delegates were patients, parents, carers and some were paid staff of organisations. This has changed quite a lot over the last decade. Now the majority are paid members of staff. Some of the passion which was evident in the beginning has been lost.

One thing that I was most proud of was the fact that I was able to introduce patients with a particular disease/conditions who were able to help with the work of the EMA and its scientific advice as this ultimately will have an impact directly on patients.

Since that first day at the Agency I have gained so much knowledge and have been fortunate to participate in workshops ranging from vCJD, ophthalmology, medication errors, vaccines and many more. The Agency's staff are incredibly professional and always friendly, which makes you feel really welcome and I would like to thank the EMA for giving me all these opportunities during the last ten years and hopefully I have been able to pass on some of the patient's perspectives on the various topics. It is wonderful to still be in the meetings with some of the original members of the PCWP.

The most significant achievement is the fact that after 10 years the patients/consumers are really looked upon as important contributors to the work of the EMA.

Christoph Thalheim

Director External Affairs

European MS Platform

EUROPEAN MULTIPLE SCLEROSIS PLATFORM

It is difficult to imagine that I have already been involved in the work of EMA as EMSP representative since the very first meeting of the PCWP in December 2006, chaired by Isabelle Moulon and the unforgotten Fritz Lekkerkerker.

I have learned something useful each time we worked within the PCWP and we tried hard each time to contribute actively (and sometimes controversially) to the discussion in order to make a win-win from all the meetings of the PCWP.

*The Open Letter of EMSP Board Member Allen to EMEA's Executive Director Thomas Lönngren, written in 2005 on the patient perspective of the benefit-risk ratio of Tysabri, was quoted repeatedly until today ("*I want to add life to my years, not necessarily years to my life!*") and has contributed to a correction of the wrong assumption that health care professionals can be used to learn about the "patients' opinion" in this sensitive field of prioritisation of therapy outcomes.*

The contributions by MS patients and MS patient advocates like myself to Scientific Advisory Group meetings related to MS were numerous and often a game changer.

Unsolicited ad-hoc activities by EMSP such as a European survey on patient need for Fampyra demonstrated that even such a patient-friendly authority as EMA/CHMP can take decisions which suggests a second thought in the light of patient data evidence - and fortunately EMA had the guts to correct such a decision in favour of patient benefit.

For concept of patient empowerment, EMEA/EMA has provided many positive signals since its' foundation; the creation of the EMEA CHMP Patient Organisation Working Group developing into the PCWP is probably the strongest and the most sustainable one.

After more than fifteen years of working as a European patient advocate I believe that I have a certain credibility when I consider EMA`s practice of patient and consumer involvement in its work as exemplary.

François Houÿez
Treatment Information and Access Director, Health Policy Advisor, EURORDIS

EURORDIS
Rare Diseases Europe

Patients and consumers who are members of the PCWP can be very satisfied by the fact that most of the initial recommendations made in 2004 in the domains of Pharmacovigilance, Transparency of the regulatory process, of the information, Product information, and Interaction between the EMA and the organisations were implemented by the EMA and the EU regulatory network.

And the work never finishes: a new Pharmacovigilance legislation was adopted in 2012, and its implementation is a fantastic opportunity for patients and consumers' organisations to play a greater role in the regulatory network. Transparency of the regulatory process is a "never ending story", with new issues coming in constantly.

Interactions are changing as new regulatory procedures are introduced (PRIME), new committees are formed (PDCO, CAT, PRAC), new pilots are launched (patients invited at CHMP oral explanation with the applicant).

Involving patients in the EMA activities requires a framework agreed by all parties, and also resources. Thanks to intensive discussions with all, the EMA Management Board endorsed and revised the framework for patients' involvement which is certainly a model for all agencies in the EU. Patients realise their views are taken into account, with equal credibility as other participants, to share their own experiences and knowledge. This principle of patients' advocacy is certainly achieved at the EMA.

Yet, the concerns patients had in the mid-90s are even more valid 20 years later: Member States established national rules and agencies to inform the reimbursement/coverage decision right in 1995 (HTA bodies), seen by most patients as a way to recoup sovereignty and control over new medicines approaching the healthcare system.

What is the point of authorisation medicines for human use, if this use is not made possible? Efforts to bring together regulators and HTA doers / payers are essential to reconcile patients with the evaluators of both types.

Nikos Dedes

Vice Chair Board of Directors

EATG - European AIDS Treatment Group

It is with a great sense of pride and an equal measure of nostalgia that I pay tribute to the early days of the PCWP. On its 10th anniversary I look back to the beginning and the EATG was there when EMA opened its doors in 1995. This was a period when things were changing and the contributions of the patients was critical. The other preeminent patient group to engage with the EMA was EURORDIS and the work of Yann Le Cam secured patient representatives in the COMP, which created an experience within the EMA of the usefulness of the interactions with patients and led to a number of workshops with patient organisations in May 2002 followed by the creation of the working group of patients and consumers in May 2003.

A critical meeting took place in December 2004 which led to changes in the roadmap of the EMA and these outcomes were taken to the EMA Management Board. During this period, we identified the four main topics; transparency, information on medicines, pharmacovigilance and interaction with the committees on which we wanted to work. We also determined eligibility criteria that needed to be filled by patients in order to work with the EMA.

In September 2005, the Management Board supported these suggestions and stated that the interactions with stakeholders was an integral part of the Agency's mission and one of its core activities which led to the creation of the PCWP in December of 2006.

I close by paying tribute to one person who above all other supported and enabled the patients and citizens of Europe to play a growing in significance role inside EMA. All of us will be indebted to you forever. Isabelle Moulon!

Albert van der Zeijden

International Alliance of Patients' Organizations (IAPO)

International Alliance of Patients' Organizations
A global voice for patients

Ten years is a reason to look back and celebrate and a nice number of years for reflection. The question is: "Did it add something that we have to celebrate".

A Working Group started 3 years earlier under the leadership of Isabelle Moulon and Frits Lekkerkerker. The Working Party started with a Framework of Interaction, which was very ambitious. In the minutes of the Working Group the European Commission it is cited: "the European Commission considered the framework as very broad in some areas, e.g. network at the level of EU Regulatory Activities in the field of medical information and asked to focus only on those aspects which refer to the EMEA."

Yes, we were ambitious but I do not believe that any of us could have imagined that in a few years the PCWP would have realised all its recommendations to the EMEA and most of those to the European Commission. More recently we have seen that a growing number of national competent authorities are also implementing these recommendations.

This was only possible because there were enough people within the EMA workforce who believed in the power of patient involvement in regulatory activities. The reasoning for this early involvement was that it could contribute to transparency and to public trust. Most members of the Scientific Committees did not see the involvement of patients as an additional value for the quality of their decisions, but it paved the way to meet each other and to learn from each other.

My personal experience as a patient observer at the Pharmacovigilance Working Party of the CHMP was that the members told me that at the start they did not see the value of the involvement of patients in their discussions but that they had learned that patients' comments can lead to better outcomes of the considerations. As patients we learned where our input can have a really an added value. Now we see it as norm that patients are involved in regulatory decision making processes at all levels of the process. This is the success of all those members who dedicated their time and their efforts the past ten years, but it is certainly the success of all those EMA people who believed in the need and the added value of involvement of patients and consumers in their regulatory activities. I give credit to EMA for taking responsibility with its activities to involve patients, thus becoming the leading organisation with respect to meaningful involvement of patients and consumers now even more than 10 years ago. The real strength of the current EMA model is not that they started this process, but that they are constantly evaluating the process and improving it.

To conclude: 10 Years is a good moment for a celebration, but an even better reason for congratulations is the successes we have booked together, paving the road for the following decades, building on these successes. For all of is it was and will be an honour to contribute.


Ioannis Natsis
EPHA
Christoph Thalheim
EHSP
Jean Georges
AE


Francois Houyez
EURORDIS


PCWP 10


Nikos Dedes
EMA MB


Nikos Dedes
EATG