Experience from patient observer in PhVWP

Second Stakeholder Forum on the implementation of the new Pharmacovigilance legislation : Albert van der Zeijden; London 17-06-2011

Why and why not?: Patient involvement in the PhVWP

- Why not: “I can not see what patients can add to the knowledge and expertise of the people already around the table”
- Unique expertise: living with a disease and understanding the role of a medicine in ones life
- Transparancy and building trust in society

The composition of a regular PhVWP meeting

- 3 days from Monday to Wednesday every month
- Constantly changing. Some 30 + items on particular medicines the first two days: signals, conclusions of assessment reports, CHMP questions , adoption of reports etc.
- Policy and regulatory affairs
- Side activities: Drafting groups, video-conference with FDA, working groups etc.

What can patients offer?

- Weighing benefits and risks of the use of medicines from the patients' perspective
- The readability of the EPAR's, PIL's and the tekst of packages
- Discussions about the need for a DHPC and the language of it
- Discussions about policy and regulatory issues

Assessment of the experiences

- The first meeting is kind of a nightmare: complexity of the agenda, jargon and missing the context. This is not just so for patients.
- Understanding the level of discussions is not a problem
- Patients and regulators benefit from each others knowledge.
- Gives an understanding of the patient centred way of working of the EMA

Some observations

- There is a lot of support , but a more systematic training would be helpful for newcomers. Task of the PCWP?
- Ideally patients should have experiences with regulatory bodies for a couple of years
- The experience showed that patients have an added value to the quality of the work of the PhVWP