After Three Years of PRAC

The Patients Perspective

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- What we learned in the past three years
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- Areas and priorities for improvement

Five principles of patient centred healthcare

- IAPO's vision: Patient centred healthcare throughout the world
- 2006: IAPO's declaration on patient centred healthcare: 5 principles

1. Respect and support for the individual patient, their wants, preferences, values, needs and rights
2. Choice and empowerment
3. **Meaningful patient involvement in all health policies**
4. Access and support
5. Information that is accurate, relevant and comprehensive

The phenomenology of the concept patient

- Different connotations of the concept
- A patient is everyone entering the health care system with a medical question
- A patient is a person with a long term medical condition, a chronic illness with a disabling impact on his daily life.
- This changes the perspective from I want cure to I ask support
- These are the people who can add to the already available qualities of the other PRAC members

Why do we need patients at the PRAC

- Transparency
- Building public trust
- Strongly restricted by confidentiality agreement: For the patients you start as one of us and the membership makes you one of them
- Better quality of decisions by the inclusion of the otherwise not available perspective of the chronic patient

What did I learn?

- Had the advantage of 3 years pharmacovigilance working party
- Can be a chain between the PRAC/EMA and the public/patients in general and patients' organisations
- Labeling with an organisation (IAPO) is misleading
- You are not there to compete with regulators and other experts at their realm of expertise
- Understand where your intervention can have an additional value

Areas of improvement/setting the scene

- Patients are members like all members
- EMA the leading organisation with the implementation of meaningful involvement
- EMA is built as a cooperative organisation of representatives of National Competent Authorities
- The rules of the game has been set before the involvement of patients
- To treat patients in all cases in the same way as the members of NCA's does not lead to the best use of their capacities

Areas of improvement/the differences

- NCO members are working in large organisations
- They are aquinted with the regulatory work from the start
- They work in teams and can consult their teammates
- The patient is isolated from his colleague patients (confidentiality agreement)
- He has no background as a regulator
- He cannot consult other patients but his alternate

Priorities for the future

- Introduction to the EU regulatory system, the organisation of EMA in general and the PRAC in particular
- Support of the EMA organisation for the patient representative. What do they expect of me and what can I expect of them
- Compensation for patient representatives for loss of income during PRAC activities
- More patients involved in the PRAC as observers or members: to verify the position of the member and to build future successors