



Framework of EMA interaction with patients' and consumers' organisations

- Adopted by the Management Board in 2006
- Objectives:
 - Creation of the EMA Patients' and Consumers' Working Party (PCWP)
 - Implementation of the recommendations made by the Working Group with PCOs: transparency, product information, interaction with Committees, pharmacovigilance
- The objectives have been fulfilled:
 - PCWP in operation since December 2006
 - Recommendations have been implemented in the 4 identified areas
 - Annual report presented every year to the MB including the outcome of a satisfaction questionnaire



Reflection paper on the further involvement of patients and consumers in the Agency's activities

Baseline: the work achieved has established the agendas toward systematic interaction and involvement of patients and consumers at different level of the Agency work, particularly in information and communication activities

Objective: identify questions to be addressed:

1. The role that patients and consumers are to play in scientific committees.
To which extend patients should be involved in benefit/risk considerations
2. The Agency should provide support to patients participating in the Agency's activities including:
 - Training
 - Financial support

Outcome: - Role of patients in Committees
- Proposal to involve patients – benefit/risk
- Training strategy
- Concept of double daily allowance



Revised framework of interaction

Objectives:

- Give the full picture of the interaction with patients and consumers under one umbrella document
- Identify any gaps and areas for improvement:
 - Further develop trainings?
 - Better communicate on the EMA interaction with PCOs?
 - In Europe – involvement of NCAs / organisations
 - At international level
 - Involvement in research projects?
 - Financial support (based on workload versus participation in meetings)
 - Role of patient at an early stage of development (SA/HTA)

Propose a way forward:

- Open further to the general public?
 - Information-communication
 - Getting feedback – public hearing
 - Use of social media
 - In this context clarify the role of PCO