EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Working with patients and consumers

An agency of the European Union

Looking to the future

The involvement of patient representatives throughout many areas of the Agency's work is now well established and has proven to be extremely beneficial; they provide a crucial and unique 'real-life' perspective to the scientific discussions on medicines, which contributes to better outcomes within the regulatory process.

The Agency will continue to strengthen and streamline its collaboration with patients, and will:

- ensure support and training is provided and is tailored to the different activities;
- ensure that interactions take place in the most efficient manner, optimising patients expertise and time;
- work towards a more regular involvement in benefit risk evaluations;
- continue to strive for high-quality information on medicines written for patients who are consistently involved in the preparation of these documents.

The European Medicines Agency and patients, consumers and their organisations.

Overview

The European Medicines Agency has been engaging in dialogue with European patient and consumer organisations since it was established in 1995.

As users of the medicines that the Agency evaluates, patients and consumers have specific knowledge and expertise to offer. The EMA is committed to maintaining a strong relationship with these key stakeholders in the work of the Agency.

In 2005, the Agency's Management Board endorsed a framework for interaction between the EMA and patients and consumers and their organisations. In order to involve only the most appropriate organisations, the Agency has a set of eligibility criteria that need to be fulfilled prior to involvement in Agency activities.

All patients' and consumers' organisations are welcome to express an interest to work with the EMA.

The PCWP

In 2006, the Agency established a permanent "Patients and Consumers Working Party" (PCWP), which is a dedicated platform for exchange of information with the Agency and its scientific committees on matters of direct and indirect interest to patients in relation to medicines.

The PCWP meets four times a year, including joint meetings with its counterpart, the Working Party with Healthcare Professionals' Organisations (HCPWP), where issues of common interest are discussed.

Involvement of patients and consumers in the Agency's work

Patient representatives are formal members of:

- EMA's Management Board.
- Four of the Agency's scientific committees:
  - Committee for Orphan Medicinal Products (COMP);
  - Paediatric Committee (PDCO);
  - Committee for Advanced Therapies (CAT);
  - Pharmacovigilance Risk Assessment Committee (PRAC).

- Patients are also involved in a wide range of other EMA activities such as:
  - Participation in medicines evaluation with the scientific committees;
  - Participation in the provision of scientific advice given to pharmaceutical companies;
  - Participation in scientific advisory group (SAGs) and ad-hoc expert meetings;
  - Review of product information and EMA safety communications written for the general public;
  - Membership of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP);
  - Membership of the coordinating group for European Network of Paediatric Research (EnprEMA);
  - Membership of the EUCTR (European clinical trial database) information system expert group with stakeholders;
  - Participation in many workshops and conferences organised by the Agency.

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Further information

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