EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role of patients as members of EMA scientific committees

Background

- The purpose of this paper is to define the role of patients within the different scientific committees of the EMA, focusing in particular on their role as members of such committees.
- The term ‘patient’ refers to any individual who has been appointed member of an EMA scientific committee to represent the views and interests of patients in such committee.
- Gives guidance to those patient representatives who are looking for nomination as member of a committee at the EMA;
- It addresses not only the work of the patients when they attend the committee but also the work involved outside of the committee and other related aspects.

Community legislation

In accordance with legislation, participation as members/ alternates of scientific committees has been implemented as follows:

COMP - 3 members representing patients' organisations

PDCO - 3 members / 3 alternates representing patients' Organisations

CAT - 2 members and 2 alternates representing patients' organisation

PhVWP – Observers have attend (pilot phase)

PRAC – legislation comes into force as of July 2012

Participation

Analysis of current experience to date, four different ways in which the patients can participate within the scientific committees can be distinguished:

- **Members** (and alternates)
- **Observers**
- **Experts**
- **Representatives** of a specific organisation

All must maintain confidentiality, declare any interest and abide by the EMA code of conduct.

Role and added value of patients as members of scientific committees

- Act in the same way as all other members
- Patient's main role however is not expected to be of a scientific nature.
- The added value: bring a unique and critical input based on their real-life experience of being affected by a disease and its current therapeutic environment.
- This element fills a gap which other committee members (so-called scientific experts) cannot fill, and which has proven necessary to achieve the best possible results within the regulatory process.

Role and added value of patients as members of scientific committees

- Reflecting on real-life implications of regulatory decisions.
- Helping and assisting in decision making so that the best decision is taken.
- Increasing transparency and building confidence and trust in the regulatory process.
- Ensuring credibility by guarantying that scientific regulatory bodies act for the benefit of society.
- ask for changes in the system to improve reliability.
- Representing patients' interests and providing a "patient perspective" view, on behalf of those directly affected by regulatory decisions.

Role and added value of patients as members of scientific committees

- Bringing experience of the disease and/or identifying patients with experience of the disease.
- Reflecting about the risk that patients are prepared to take.
- Identifying potential topics which may require or benefit from additional patient consultation.
- Actively contributing to patient information and communication.
- Ensure that patients and patient's organisations can access useful and understandable information.

Role and added value of patients as members of scientific committees

- Disseminating committees' outcomes
- Bringing specific expertise from a patient communication-perspective
- Contribution to the decision on when to communicate.
- Ensuring that information in any document prepared by the committee for patients and the general public is clear and understandable by the target audience (e.g. wording of package leaflet, Q&As, etc).
- Advising and supporting regulators on the feasibility of planned investigations (e.g. for paediatric investigation plans (PIP), orphan designation, risk management plan, etc).

Role and added value of patients as members of scientific committees

- Guarantee that scientific opinions address patient needs and that there is a rational and adequate use of incentives (e.g. in orphan designation) for the benefit of patients.
- Advising and supporting regulators in its dialogue with industry and other stakeholders when identifying areas of medical need for target research.
- Contributing, in a general capacity, to public health (raising awareness of the impact of regulatory decisions) in the context of their organisation.

Participation

Independently of the way in which patients participate, four different areas of patient contribution have been identified regarding specific discussions:

Expertise: convey a combination of specific education, training or professional experience

Experience: convey practical disease knowledge obtained from direct contact with the disease (affected person or close contact with affected person)

Participation

Advocacy: act on behalf of the affected patients in defence of their rights; provide patient-oriented public health / healthcare policy perspective

Empowerment: participate in decision-making process within the committee; having access to information and process on behalf of patients

Challenges

- Scientific/regulatory discussion - adequate preparation is necessary.
- patients with some background on medicines regulation may find participation less demanding *(support?)*
- Management of pre-mail documentation; participants learnt to select those topics which would be of more interest to them.
- Same resources not available as for other delegates, both in terms of available time and access to information.
- The general workload of some meetings does not always allow time to advocate a patient perspective.

Workload

Usually membership of an EMA scientific committee is for a period of 3 years, which may be renewed.

The duration of meetings is as follows:

- **COMP** – 2 to 3 day meeting per month (11 meetings per year).
- **PDCO** – 3 day meeting per month (12 meetings per year).
- **CAT** – 2 day meeting per month (11 meetings per year).
- **PhVWP** – 3 day meeting per month (11 meetings per year).

Workload

- 4 days per month preparation and follow-up work;

- Time should be allocated to share, discuss and disseminate ‘non-confidential’ information within the organisation and to other stakeholders.

- The meeting attendance and work can be shared between the member and the alternate (with good communication to avoid discontinuity).

Thank You…

Any questions?