EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Involvement of patients in CHMP benefit-risk

Juan García Burgos

Purpose of this presentation

- Objective:
  - to establish framework/terms of references to facilitate involvement of patients in benefit-risk discussion and evaluation within the Agency's Committee for Medicinal Products for Human Use (CHMP) in a consistent, efficient way whenever it is appropriate.

Background - Rationale

- Confirmed added value of patient contribution
- Patient's main role not expected to be of a scientific nature - critical input based on their real-life experience of being affected by a disease and its current therapeutic environment
- Input necessary to achieve the best possible results within the regulatory process
- Confidence and trust in the regulatory process
- Higher levels of transparency
- Legal basis - Article 78 of Regulation (EC) Nº 726/2004

Scope

- Patients to be consulted in cases where it is anticipated that their involvement will bring added value to the CHMP discussion on benefit/risk
  - define clear criteria on 'when' (a priori) it would be beneficial to involve patients
  - describe the procedure by which this consultation can be implemented.

- Patients and consumers can be consulted, but will not take part in decision-making within the CHMP.

When patients should be involved?

- Request from CHMP to be considered:
  - When CHMP is likely to recommend the refusal of a new medicine in an area where there remains an unmet medical need;
  - When the CHMP is likely to recommend the withdrawal, suspension or revocation (or to restrict the indication) of an authorised medicine for which a significant impact in patient population is expected;
  - When a company informs of their intention to withdraw an authorised medicine;
  - When a possible shortage in supply/availability of a medicine is identified;

When patients should be involved? - 2

- Request from CHMP to be considered:
  - When CHMP is likely to recommend the refusal of a new medicine in an area where there remains an unmet medical need;
  - When there is a need to get advice on:
    - Specific information to be included in the Package Leaflet and its wording;
    - A Risk Management Plan and its feasibility in a "real life" environment (including feedback on its implementation).
  - To participate in Scientific Advisory Groups (SAG) / ad-hoc expert meetings
  - To participate in the work of the Scientific Advice Working Party
    - input on issues such as feasibility of a clinical trial design (e.g. availability of patients to enroll, acceptability of a comparator, endpoints, ethical issues).

When patients should be involved? - 3

- Request from patients' organisations:
  - In case a patient organisations addresses the CHMP on a specific issue
  - The CHMP will consider the matter and will decide whether further dialogue or interaction is necessary
  - In all cases the CHMP together with the EMA secretariat will respond in writing to the patient organisation

How patients will be involved?

- The EMA secretariat and/or CHMP will identify issues which may benefit from patient consultation (as per above criteria)
- Consultation will only be initiated following agreement by CHMP (via (Co)-Rap and CHMP Chair)

- Format:
  - Via teleconference
  - Participation in a meeting at the EMA

How patients will be involved? - 2

- Participation in a meeting at the EMA:
  - CHMP meeting
  - Meeting with (Co) Rapporteur and EMA secretariat in the margin of the CHMP meeting
  - SAG / Ad-hoc expert meeting (in practice, almost systematically)

Experience shows that consultation '***in writing'*** and by '***participation in SAGs'*** are the preferred options for involvement

Selection of patients

- Preferably 'eligible organisations'
  - EMA criteria is fulfilled
- If no eligible organisation is available or if interaction requested by the organisation, non-eligible can be considered
- Full transparency will apply in all cases
  - In terms of activities and funding

Training

- Training strategy in place
- Specific individual assistance available
- Sufficient background information to allow adequate understanding of the issue
- Introduction/induction pack

Monitoring

- Outcome of the interaction to be incorporated to the annual report
- To be presented to scientific committees and Management Board
- PCWP role in monitoring progress of overall interaction
- In all cases the patient contribution will be incorporated to the public assessment report and the patient organisation will be informed on the outcome

Thank you for your attention