EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Incorporating patient views during EMA's evaluation of benefit-risk of medicines

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Purpose

- Identify the situations in which we should seek patient input – those which bring added value.
- Define what is expected from patients (patient values and utilities).
- Define a process to make this happen.

Background

- Past experience: patients add value to scientific process (enriching the quality of opinion, build trust);
- Proper structure to achieve this is still missing;
- EMA reorganisation: one of the key elements reflecting the Agency's renewed focus;
- 2013 CHMP work programme;
- Openness and transparency.

Legal basis

Article 78 of Regulation (EC) no 726/2004

Scope

- Specific focus on CHMP and PRAC (benefit-risk evaluation);

But also:

- SAGs, Ad-hoc expert groups
- Scientific Advice Working Party (SAWP)

- Principles of the proposal should apply to all committees and areas of EMA’s work.

Expected contribution from patients

- Patients' role – not expected to be scientific;
- Bring unique and critical input;
- Based on real-life experience;
- Filling a gap - necessary to achieve the best results in regulatory process;
- Add openness, transparency and trust.

Ways of participation for patients

- Members
- Observers;
- Experts;
- Representatives of an organisation.

At what stage to involve patients? (1)

- Refusal of a new medicine in an area of unmet medical need;
- Withdrawal and suspension of marketing authorisation for which significant impact on patient population is expected;
- When companies inform of their intention to withdraw a medicine already authorised;
- When a shortage is anticipated;

At what stage to involve patients? (2)

- When advice is needed on:
  - Risk management plan (e.g. feasibility);
  - Package leaflet;
  - Any information on benefit-risk addressed to patients;
  - Any safety announcement.
- To participate in SAGs/ ad-hoc expert meetings;
- To participate in SAWP;
- To address specific request from patients/ patient organisations.

How patients should be involved?

- Upon above criteria;
- Consultation to be initiated after agreement by the Committee;
- Contribution to be acknowledged (referenced in AR).
- For the sake of efficiency, PRAC comes first.

Format of the interaction

- In writing;
- Via teleconference;
- Participation in meetings:
  - Scientific committee: PRAC & CHMP;
  - Meeting with (Co)-Rapporteur (margin of PRAC/CHMP);
  - SAG/ Ad-hoc expert group meeting;
  - SAWP meeting.

Source of patients

- Reference to EMA “eligible organisations”;
- Other means (non-eligible organisations, other bodies etc.);
- Any organisation involved should be fully transparent;
- Any expert should sign a DoI and a confidentiality undertaking.

Training and support

- Patient and Consumer Working Party (PCWP);
- Training strategy:
  - 'patient-friendly' background information;
  - On-line 'information pack';
  - General information on EMA's work;
  - Specific information to the type of activity (e.g. SAG, scientific advice etc.)
  - Personalised assistance from EMA staff always available.

Monitoring

- Patient involvement on benefit-risk to be included in the Annual Report (presented to the Management Board).

- Satisfaction questionnaire and KPIs.