EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2014
EMA/372554/2014 – rev. 1
Stakeholders & Communication Division

Pilot phase to involve patients in benefit/risk discussions at CHMP meetings

Background

As previously highlighted, the added value of including patients' perspectives within EMA benefit/risk considerations has been demonstrated many times; however it is felt that this can be further enriched by ensuring assessments performed by the CHMP are able to take into account patients' views on a more regular basis. This is in line with the CHMP work programme which recommends further integrating patients' values in the benefit/risk assessment and reflects the Agency's emphasis on stakeholder involvement.

Patient representatives are involved in benefit-risk evaluations through participation in SAG/ad-hoc expert group meetings and scientific advice/protocol assistance procedures. Building on this, it is proposed to invite patients to participate in specific B/R discussions at CHMP meetings, initially during a pilot phase which would explore how this could occur to maximal effect, as detailed below.

When should patients be invited to join CHMP?

- Patients will be invited to participate during product-specific oral explanations where their involvement can bring added value to the benefit/risk discussion.
- The Rapporteurs and EMA team leaders will decide on a case-by-case basis whether a specific oral explanation would benefit from the involvement of patients:

  When the questions refer to benefit/risk aspects;

  - When the CHMP is still undecided on a marketing authorisation application for a new medicinal product in an area where there remains an unmet medical need and would like to assess the impact of their recommendation on the relevant patient population;
  - When the PRAC and/or the CHMP would like to assess the impact of their recommendation, to maintain, suspend, revoke a marketing authorisation, or to restrict the indication of an authorised medicine, on the relevant patient population.
- The need to involve patients should be discussed as early as possible and confirmed (or not) when an oral explanation is deemed necessary.

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Which patients should be invited?

- Patients (or carers) with personal experience and knowledge of the particular disease/condition under evaluation will be invited to participate. They will be selected depending on the relevance of their experience on the topic for discussion, and only invited following assessment of any potential conflicts of interest.
- Patients will be contacted via the EMA network of eligible patient organisations, other European or national organisations or individuals who have expressed an interest to participate in the Agency's work.
- As much as possible, patients will be selected from across Europe, bearing in mind that they would need to be able to understand and communicate in English.
- The patients will be accompanied by a 'mentor'; a patient representative experienced in EMA procedures (likely a PCWP member) who would provide appropriate support. The same mentor will be invited each time, with the option of an alternate.

How many patients should be invited?

- At least two patients will be invited to participate in each identified oral explanation, in addition to the mentor as mentioned above.

How should patients join the discussion?

- Patients who participate will give their views and may participate actively in the discussions; including the possibility to ask questions to the company. They will however not take part in any decision-making process (no voting rights).
- Patients may join the meeting for the briefing by the rapporteurs, followed by the company presentation and subsequent Q&A session. They may also remain for the discussion and conclusions, but would leave prior to voting.
- Patients would be given the option to remain in a separate meeting room and follow the oral explanation by video link if they prefer, joining the CHMP for the subsequent discussion.
- If a patient is not able to travel, there is also the possibility to join via teleconference or to provide comments in writing beforehand.
- 'Rules of participation' will be prepared and given to each patient prior to involvement. These rules will highlight that they present their individual views and not those of any organisation.

What CHMP documents should be provided to the patients?

- Patients will be provided with the List of Outstanding Issues, draft Summary of Product Characteristics and Package Leaflet (more documents, e.g. assessment reports, could be provided on request).
- Wherever appropriate, the Rapporteurs will include specific questions in advance to be addressed by the patients.

What support will be provided to the patients?

- In addition to the support provided by the patient "mentor", the EMA will provide appropriate support to each patient who is invited to participate; they will receive written and personal guidance to ensure they understand the work of the EMA and the CHMP, the issues for discussion, as well as a clear definition of their expected role.

How will potential conflicts of interest and confidentiality aspects be handled?

- Every patient will be required to complete a declaration of interest / confidentiality agreement prior to formal invitation. They undergo screening for conflicts of interest in the same manner as all other experts.
- Patients must adhere to the confidentiality of the documentation they receive and the discussions they partake in. They participate as individuals and should not discuss the documents received with others.

What is the duration of the pilot phase?

- It is proposed that the pilot phase should last at least one year to fully assess the feasibility of involving patients within CHMP oral explanations.

How will the pilot phase be evaluated?

- Following each patient's participation, an evaluation questionnaire will be sent to the patients involved, the relevant rapporteurs and to the CHMP topic leaders for their feedback in order to assess the impact and contribution of the patients.
- An outcome report will be presented to the CHMP at the end of the pilot phase, and will address:
  - Organisational aspects
  - Feedback from CHMP and from patients involved
  - Lessons learned / areas for improvement
  - Proposal for full implementation