26 September 2014
EMA/578072/2014
Press Office

Press release

Patients to discuss benefit-risk evaluation of medicines with the Committee for Medicinal Products for Human Use

EMA launches pilot project to integrate patients' unique and critical views into CHMP discussions

The European Medicines Agency (EMA) has launched a pilot project to involve patients in the assessment of the benefits and risks of medicines in its Committee for Medicinal Products for Human Use (CHMP).

Listening to patients enriches the scientific assessment of a medicine with new ways of thinking about benefit and risk from the patient perspective. This pilot project marks the next step in bringing patients' views and values to the assessment of medicines throughout their lifecycle.

"As patients live with their condition on a day-to-day basis, their views on the therapeutic effect of a medicine and its impact on their quality of life - particularly when these are balanced against the risks - may differ from those of other stakeholders," says Guido Rasi, EMA Executive Director. "Involving patients in CHMP discussions brings the patients' voice into the decision-making process and ultimately contributes to the safe and rational use of medicines."

The CHMP is responsible for conducting the initial assessment of medicines for which a Europe-wide marketing authorisation is sought. Assessing whether the benefits of a medicine outweigh its risks lies at the heart of this authorisation process.

As part of the pilot project, patients will be invited to present their views on medicines under review for which there is an unmet medical need and where the Committee is still undecided. Patients may also be invited to give their views in cases where the Committee is considering whether to recommend the maintenance, suspension or revocation of a marketing authorisation, or a restriction of indication of an authorised medicine.

The pilot project will explore how patients can be involved systematically and effectively in oral explanations at the CHMP. A document outlining the main principles of the project is available here. This pilot project stems from a wider EMA strategy to better involve patients in the Agency's activities.

The first medicine to be included in the pilot project contains the active substance afamelanotide. It is intended for the treatment of erythropoietic protoporphyria (EPP), a rare genetic blood disorder which

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

causes intolerance to light. Between five to ten thousand patients worldwide have EPP. There is currently no authorised medicine for this condition.

At the September meeting of the CHMP, two patients with EPP shared their experiences of living with the condition and answered specific questions from the Committee. Their inputs will be considered by the CHMP as part of its assessment of afamelanotide.

Inviting patients to participate in the CHMP is also an opportunity to increase patient awareness of the CHMP's deliberations and makes the assessment process of medicines more transparent.

The pilot project will run for at least one year to allow a full assessment of the feasibility of involving patients in CHMP oral explanations. A report on the experience gained will be presented to the CHMP at the end of the pilot phase and will address issues including organisational aspects, feedback from the CHMP and patients involved, lessons learned and areas for improvement, as well as a proposal for full implementation of the project.

Pilot project reflects EMA emphasis on involvement of patients in scientific evaluation of medicines

The pilot project is in line with the work programme of the CHMP which recommends further integrating patients' views in the assessment of benefits and risks of medicines. It also reflects the Agency's continued emphasis on stakeholder involvement. Although this is the first time that patients have been invited to participate directly in discussions on the benefits and risk of medicines at the CHMP, patient representatives are already involved in many other activities, e.g., in the capacity of:

- full members of the Pharmacovigilance Risk Assessment Committee (PRAC), Paediatric Committee (PDCO), Committee for Advanced Therapies (CAT) and Committee for Orphan Medicinal Products (COMP);
- experts within Scientific Advice procedures;
- experts in the various scientific advisory groups (SAGs), which provide specialised advice to the Agency's scientific committees on the benefit-risk evaluation of specific types of medicines or treatments;
- members of the Patients' and Consumers' Working Party (PCWP), through which they provide recommendations to the Agency and its human scientific committees on all matters of interest to patients in relation to medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu
3. Afamelanotide is still under evaluation by the CHMP.

Contact our press officers

Monika Benstetter or Martin Harvey

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu