16 April 2016
EMA/262673/2016
Media and Public Relations

Press release

Listening to the public's views on the safety of medicines

PRAC adopts rules of procedure on public hearings on selected safety reviews

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has adopted the final rules of procedure for public hearings to be held by the Committee. The rules of procedure describe the process and practical arrangements for the preparation, conduct and follow-up of public hearings.

As part of the implementation of these rules, the European Medicines Agency (EMA) will now organise an internal dry run exercise in order to test the process and procedures of public hearings. The dry run is scheduled to take place at the PRAC meeting in July 2016. Public hearings could take place as early as the fourth quarter of 2016, as soon as a relevant topic is identified.

Public hearings are a new tool for EMA to engage European Union (EU) citizens in the supervision of medicines and to listen to their views and experiences. The pharmacovigilance legislation has given the PRAC the possibility to hold public hearings as part of certain safety reviews of medicines, particularly in relation to their therapeutic effects and available therapeutic alternatives, as well as the feasibility and acceptance of proposed risk management and minimisation activities.

Contributions made by the public during a public hearing will be considered by the PRAC and inform the Committee's decision-making.

"Public hearings will enrich the scientific decision-making process on the safety of medicines," commented Noël Wathion, EMA's Deputy Executive Director. "Although we have many years of experience in involving patients and healthcare professionals in our work, public hearings are a new concept for EMA as they will open up the process of assessing medicines in the EU to the wider public for the first time."

Public hearings will be held on a case-by-case basis, where the Committee determines that collecting the views of the public would bring added value to its review. More details are outlined in the rules of procedure document.

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Background on public hearings

Public hearings allow the PRAC to access perspectives, knowledge and insights into the way medicines are used on the ground that would not otherwise be available to the Committee. They are expected to enrich the scientific assessment with new ways of learning and thinking about issues.

Existing channels of stakeholder engagement already invite the contribution of the public to the gathering of evidence from users of medicines to allow for better characterisation of benefits and risks of a medicine during the early stage of a safety review, e.g. through stakeholder submissions or through inclusion of patients and healthcare professionals in expert meetings. The value of a public hearing is considered to be greater in that phase of the process, where the PRAC has assessed the available scientific evidence from different sources and where different regulatory options to manage or minimise risks are considered in a wider public health context.

Draft rules of procedure were published by the Agency for comments in July 2014 and drew 200 comments from 22 stakeholder contributions representing 25 organisations. The rules were updated and revised in light of the comments received.

Today's adoption by the PRAC follows an endorsement of the rules of procedure by EMA's Management Board in March 2016.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The legal basis for public hearings is Article 107j of Directive 2001/83/EC which gives the PRAC the possibility to hold public hearings for safety reviews conducted by the Committee under Article 20 of Regulation (EC) No 726/2004, and Articles 31 or 107i of Directive 2001/83/EC.
3. The July 2016 PRAC meeting runs from 4-7 July.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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