EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Hearings

Second stakeholder forum on the implementation of the new Pharmacovigilance legislation, 17 June 2011

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Purpose

- Respond to public demands for more transparency of the scientific review process
- Give stakeholders a voice by enabling their participation in the scientific deliberation process
- Help to build trust in the Agency by opening up its procedures to the public
- Give access to public testimony or comment regarding therapeutic effects and clinical practice of medicines under investigation

Legal basis

Article 107j of Directive 2001/83/EU as amended

"Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern.

The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. The announcement shall specify the modalities of participation.

In the public hearing due regard shall be given to the therapeutic effect of the medicinal product."

What the EMA wants to achieve

A **participatory process** that allows **transparent interaction with stakeholders** and in which we aim to **obtain information** from the stakeholders that **adds value** to the assessment of medicines.

How do we get there?

- Stepwise implementation (Start with Art. 107 procedures)
- Learning from others (e.g. European Commission, FDA, other health authorities, other scientific bodies)
- Ongoing review and improvement of our process

Deliverables

- Criteria when to hold public hearings
- Rules of procedure on the organisation and conduct of public hearings
- A process for participation

Open questions

- Participation in the public hearing
- Advance notification
- Language regime

Open questions

- Access to hearing
- Use of broadcasting technology
- Requests for non-public hearings
- Follow-up to the hearing

Thank you!

Your ideas