EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on implementation of public hearings at the PRAC

Ninth Stakeholder forum on the Pharmacovigilance legislation
15 September 2015

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An agency of the European Union

Overview of comments received

- **200** comments from 25 organisations[1]
  - patients organisations (6)
  - learned societies/academia (6)
  - pharmaceutical industry associations (12, including two individual pharmaceutical companies)
  - media organisations (1)

[1] One joint contribution came from 4 organisations

Introduction: Key characteristics of public hearings at the PRAC (1/2)

- Draft RoP state:
  - Aim of public hearing is to **hear the public's view** on:
    - The acceptability of the risks of a medicine, in relation to its therapeutic effects and therapeutic alternatives available
    - The feasibility and acceptability of risk management/minimisation activities
  - Public hearings are:
    - Conducted in English only
    - Are open to all members of the public (advance registration is needed) who can either participate actively or attend as observers

Introduction: Key characteristics of public hearings at the PRAC (2/2)

- Draft RoP state (cont'd):
  - PRAC takes the decision to hold a public hearing on a case-by-case basis
  - PRAC agrees on a list of questions on which information from the public during the public hearing is sought
  - A system to accommodate as many speakers as possible
    - Priority will first be given to speakers representing civil society
  - The hearing is broadcast and a recording of the meeting will be published
  - The information gathered in the public hearing will inform the PRAC debate

About the rules of procedures (RoPs) for public hearings

- Provide a definition of public hearings at PRAC and set out general principles and rules
- Details will be made available in guidance documents
- Guidance documents will be updated regularly to reflect learnings from experience with public hearings

An overview of major comments received

- On the definition and purpose of public hearings:
  - Calls for the public hearing to include a debate (either a debate between the speakers and the PRAC during the public hearing; or participants listen to the PRAC debate following the public hearing)
  - Public hearings to focus on victims' testimonies
- On the involvement of marketing authorisation holders (MAHs) during a public hearing
- On the language regime
  - Translation of the RoP and other supporting documentation into the official EU languages requested
  - Interpretation/translation requested so that participation can be in the official EU languages other than English

An overview of major comments received contd…

- On the criteria for evaluating the need for public hearings
  - Comments made relate to either delete all or some of the criteria
- On transparency of PRAC decision to hold public hearings
- On the selection of speakers when requests to speak exceed the capacity of the meeting room:
  - Concerns around how the priority of certain speakers will be determined, including the proposed lottery system
- On reimbursement for patient representatives
- On timelines for public hearings in the RoP

Next steps

- Comments and proposed responses discussed with PRAC, HMA, Management Board
- Comments require impact assessment, which is under preparation
- Preparation of additional material to assist implementation:
  - Guidance document to accompany the Rules of Procedures
  - Training plan
  - Communications plan
- Entry into force of revised Rules of Procedures for PRAC public hearings after obtaining favourable opinion of the European Commission and the Management Board.

Thank you for your attention

Further information

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