



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Towards rules of procedures for public hearings

Eighth Stakeholders forum on the implementation of the
Pharmacovigilance legislation
15 September 2014

Presented by:

June Raine, Chair of the PRAC

Monika Benstetter, EMA Stakeholder and Communications Division





EMA's overall aim – **TRUST**

Increase transparency by opening up the scientific evaluation process

Empower EU citizens by giving them a voice in the evaluation of the safety of medicines

Improve the public's understanding of the scientific and regulatory process throughout the product's lifecycle

Add value to the evaluation process beyond existing channels of stakeholder engagement



Definition of public hearing

- ... a **forum** to which the **public is invited to express its views and concerns** on a **pre-defined set of questions on issues related to the safety**, whilst also considering the **therapeutic effects** of a particular medicine.
- ... a **channel** [for the PRAC] **to take the public's views and concerns into account**, particularly once all available data and evidence have been assessed and options for regulatory actions and risk management activities will need to be considered **in a wider public health context**.



Key principles

Decision for a public hearing taken on case-by-case basis, in the context of certain referral procedures (Art. 31 or Art. 107i of Directive 2001/83/EU).

In English only.

Held as **part of a PRAC meeting**.

Open to all members of the public.

Specific questions.

Public invited to **actively participate** and also **listen to** the proceedings.

Marketing authorisation holder(s) invited to **present their view**.



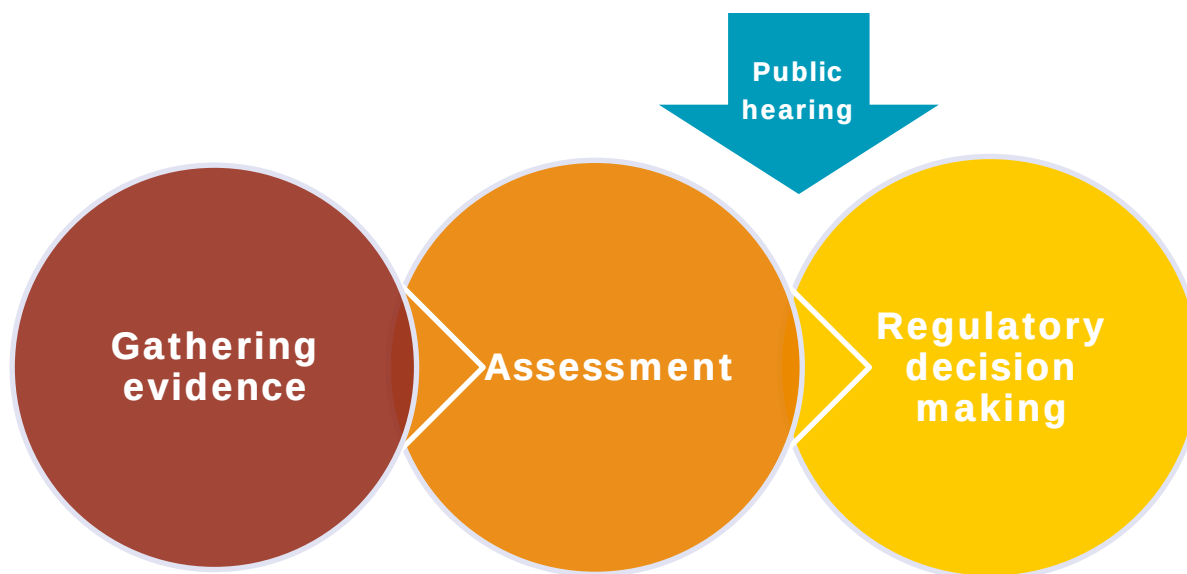
Purpose of a public hearing within referrals

To seek public opinion, suggestions and recommendations on the **acceptability of the risks** associated with the medicine/class of medicines concerned, particularly **in relation to its therapeutic effects and therapeutic alternatives** available, as well as on the **feasibility and acceptability of risk management and minimisation** activities.

To **inform the debate of the PRAC**, which continues to have the **sole responsibility for giving its scientific recommendation** on the safety of the medicine concerned.



When to hold a public hearing?





Decision to hold a public hearing

Proposal for a public hearing

- Referral procedures in accordance with Art. 20 of Regulation (EC) 726/2004, Art. 31 or Art. 107i of Directive 2001/83/EC
- Proposal to hold a public hearing – can be submitted by any PRAC member
- Content of proposal
 - Purpose of the public hearing (what is intended to be achieved?)
 - Specific questions on which public opinion should be sought
 - Any additional information as appropriate

Evaluating the need

- Who: PRAC

Agreement to hold a public hearing

- Who: PRAC
 - By consensus
 - Or by majority vote



Modalities of participation

Participants
can attend
**in person
to speak**

Participants
can submit
their
contribution
in writing

Participants
can watch a
**live video-
stream**



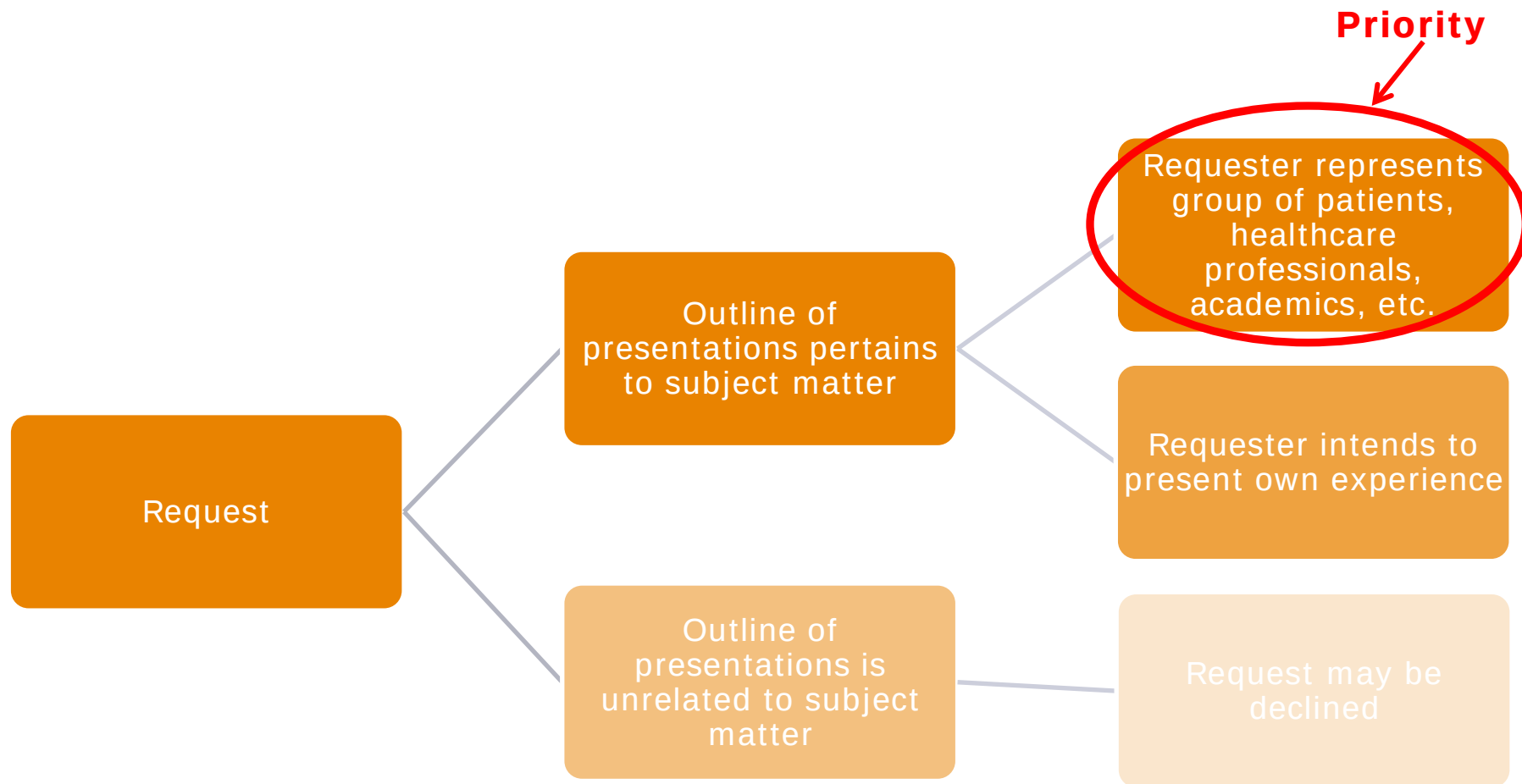
EMA organisation of a public hearing

Before the hearing



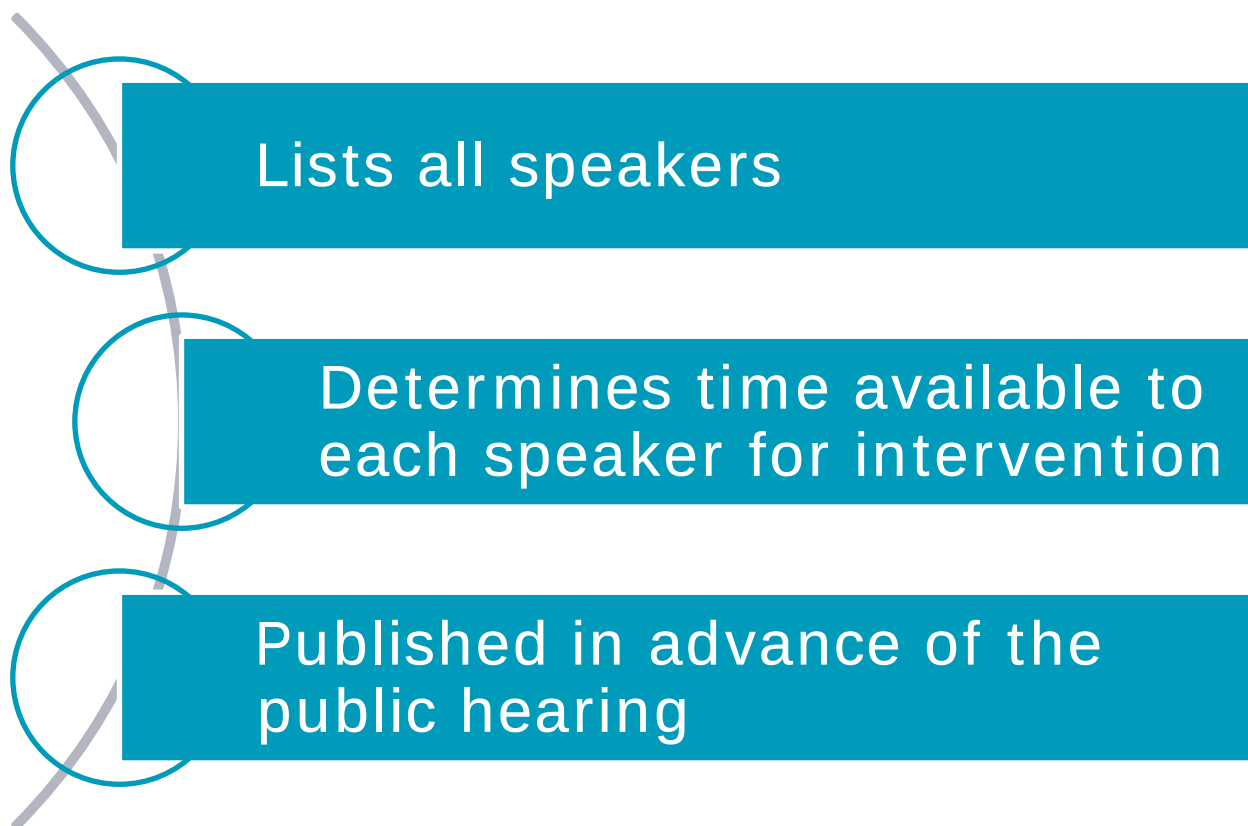


Review of participation requests





Draft agenda





Conducting a hearing

Chair: PRAC chair or vice-chair

Attendance of the Committee

Registration

Opening presentations by Rapp and Co-Rapp

Interventions made one-by-one

Marketing authorisation holders are given opportunity to present their view

Clarification requests from the PRAC

Chair concludes the hearing



Impact on PRAC opinion

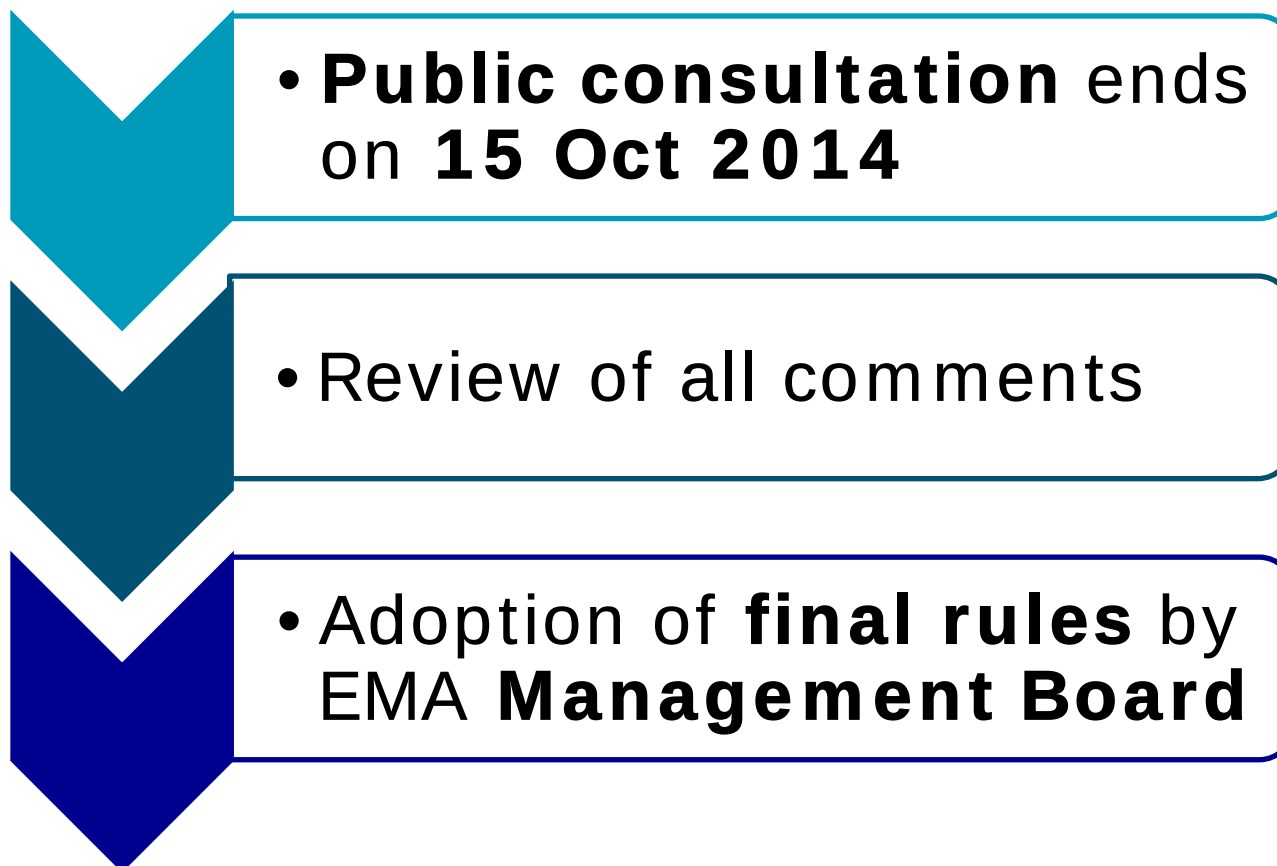
Public hearings

- inform the deliberations of the PRAC
- considered by PRAC when giving recommendation

Assessment report reflects how the outcome of the public hearing has impacted **decision-making**.



Next steps





Public consultation until 15 October 2014

Submit your comments to
public-hearings@ema.europa.eu



Thank you for your attention.