EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Towards rules of procedures for public hearings – an update

PCWP: meeting with all eligible organisations
11 December 2013

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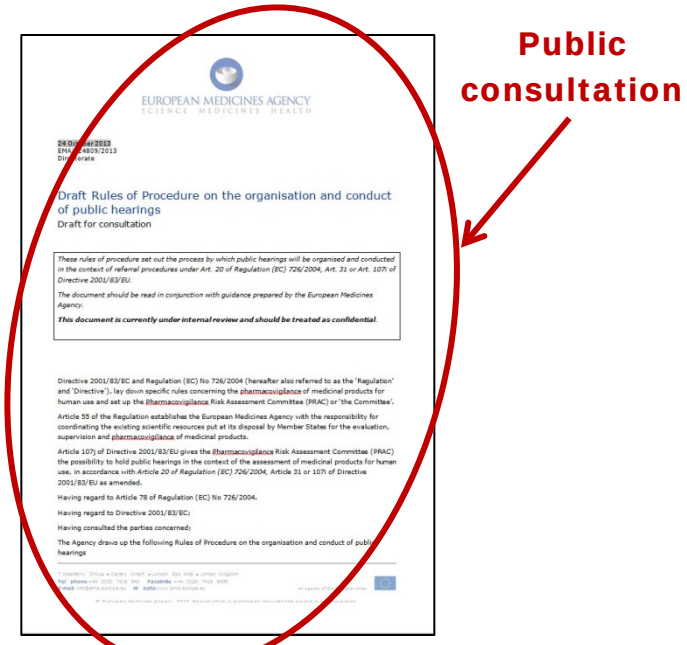
Rules of procedure and guidance

Rules of procedure

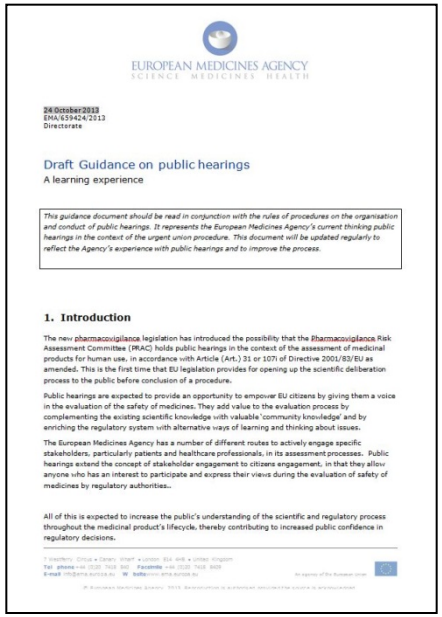
- Main principles and essential process steps
- Adopted in consultation with stakeholders



Public consultation

Guidance on practical aspects

- Sets out practical guidance
- Regular updates to reflect learning



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.

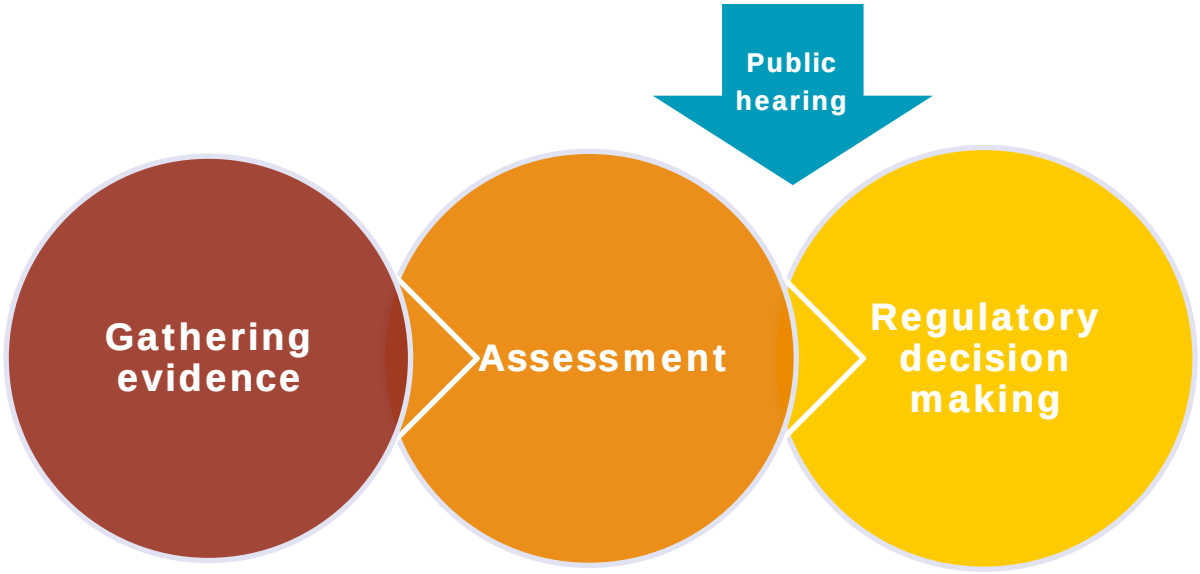
... a **channel** [for the PRAC] **to take the public's views and concerns into account**, particularly once all available data and evidence have been assessed and options for regulatory actions and risk management activities will need to be considered **in a wider public health context**.

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?



PRAC 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 pubic 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

Evaluating the need for a public hearing

Nature and extent of the safety concern	Risk attitudes	Therapeutic effect
Impact of possible regulatory actions	Impact on scientific decision-making	Expressed public interest
Trust	Scientific complexity	Use of resource

Modalities of participation

Participants can attend **in person to speak**

Participants can submit their contribution **in writing**

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

Organisation of a public hearing
Before the hearing

Announcement of the public hearing

- A **summary of the** safety concern
- A **list of specific questions**
- Information on **date, time and location** of the public hearing
- **Registration information**
- Information on how to **submit written contributions**
- Contact email address and phone number
- Information about **live-broadcast/ webstream**

Submitting a request to speak

- **Name** & **Affiliation** (e.g. patient, carer, physician, etc....)
- Name of the **organisation/group** he or she is representing if applicable
- Contact information
- **outline of the planned presentation/intervention**, specifically how it addresses the questions on which the PRAC is seeking public opinion
- **Declaration of interest** pertaining to the medicine(s) to be discussed at the public hearing.

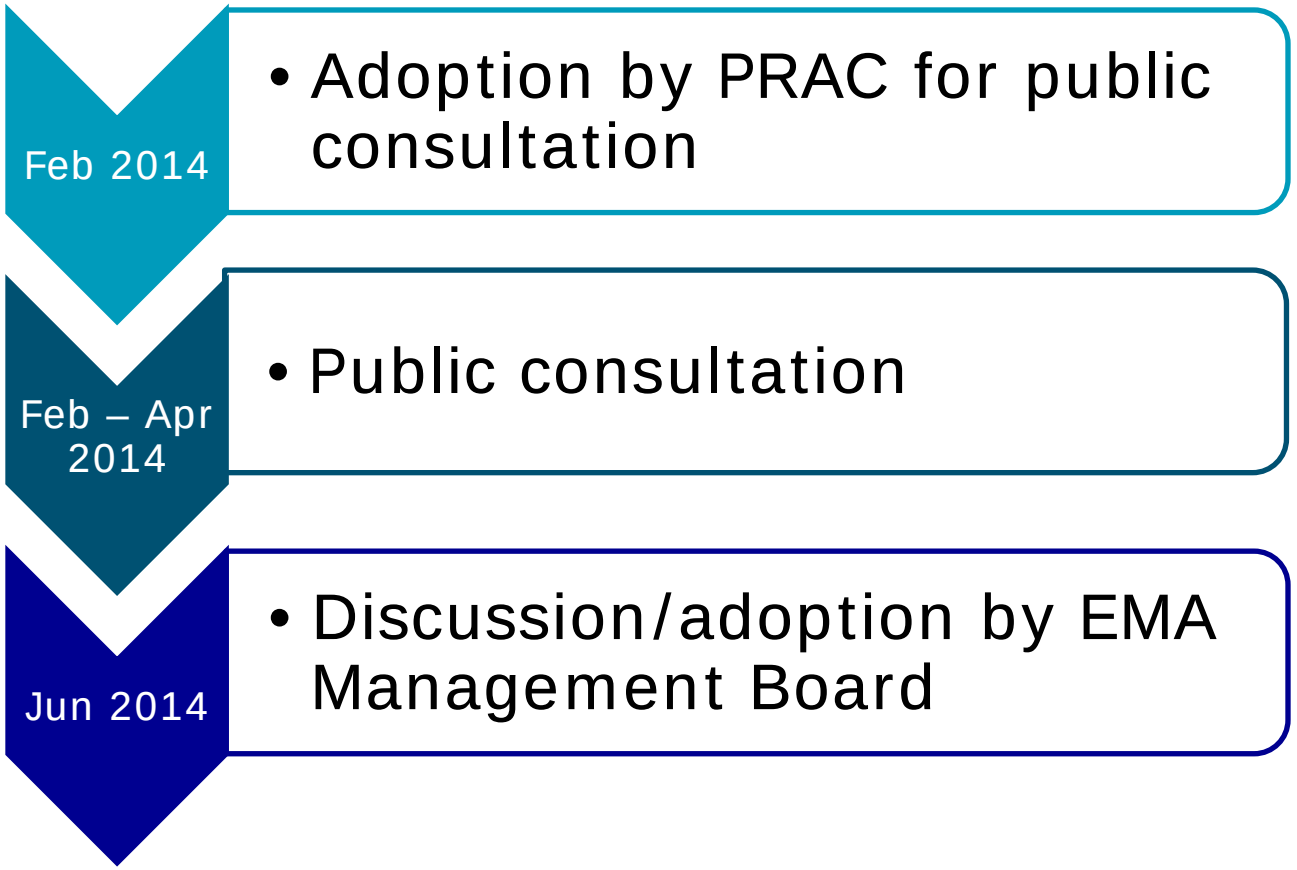
Review of requests to speak

- All requests will be **reviewed**.
- Efforts to **accommodate all speaking requests**
- Speaking requests may be **declined only if clearly unrelated to subject matter** of pubic hearing
- **Priority to speakers representing groups, organisations or institutions**
- **Confirmation** of attendance as a speaker **at least 10 days in advance** of the public hearing

Conducting a hearing

- Chair: PRAC chair or vice-chair
- Attendance of the Committee
- 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

Suggested next steps



Thank you for your input and ideas.

Any further thoughts or comments? Please send an email to:

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