



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public hearings

Rules of Procedure on the organisation
and conduct of public hearings

Proposal under discussion

PCWP and HCPWP joint meeting
25 September 2013



Presented by: Monika Benstetter
Stakeholder & Communication Division

An agency of the European Union





Purpose of a public hearing

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.

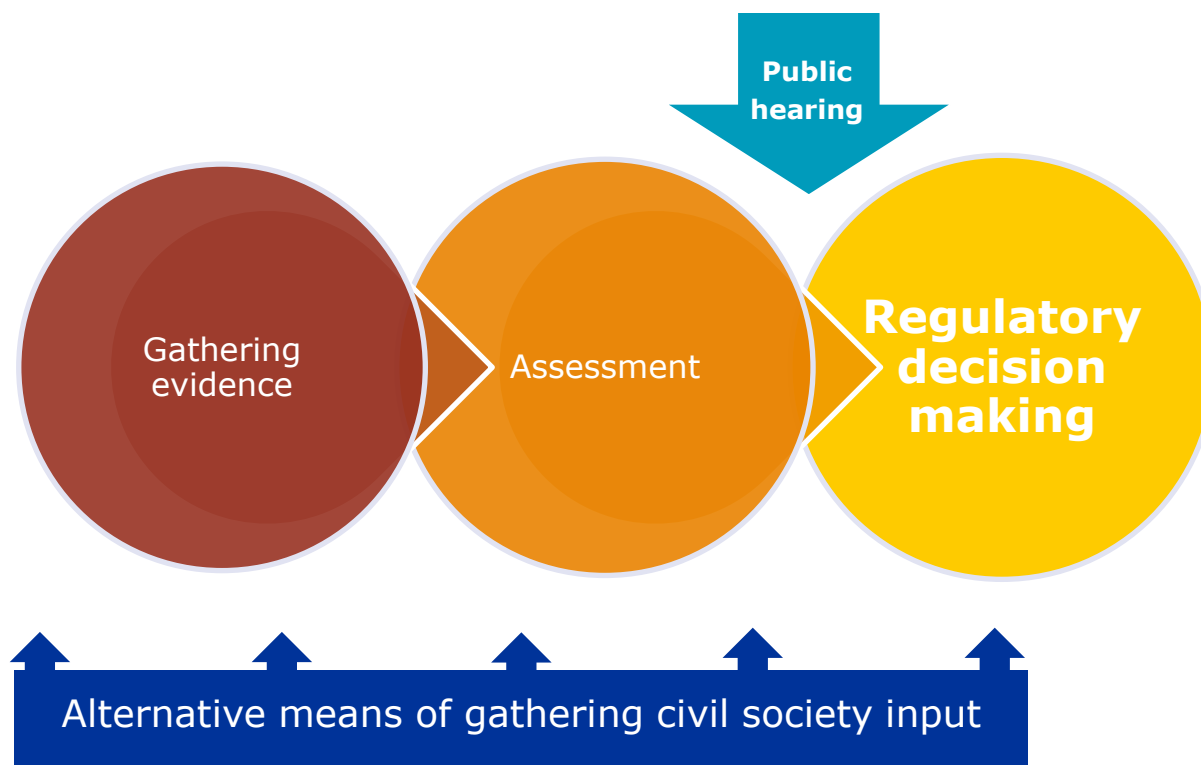


Aims of a public hearing





When to hold them?





Key principles

PRAC decides.

Case-by-case basis, in the context of certain referral procedures under Art. 31 or Art. 107i of Directive 2001/83/EU.

In English only.

Held as part of the monthly meetings of the PRAC.

The duration of a public hearing should not exceed three hours.

No reimbursement for speakers.

Public can both actively participate and also listen to the proceedings.

Rules will be regularly revised.

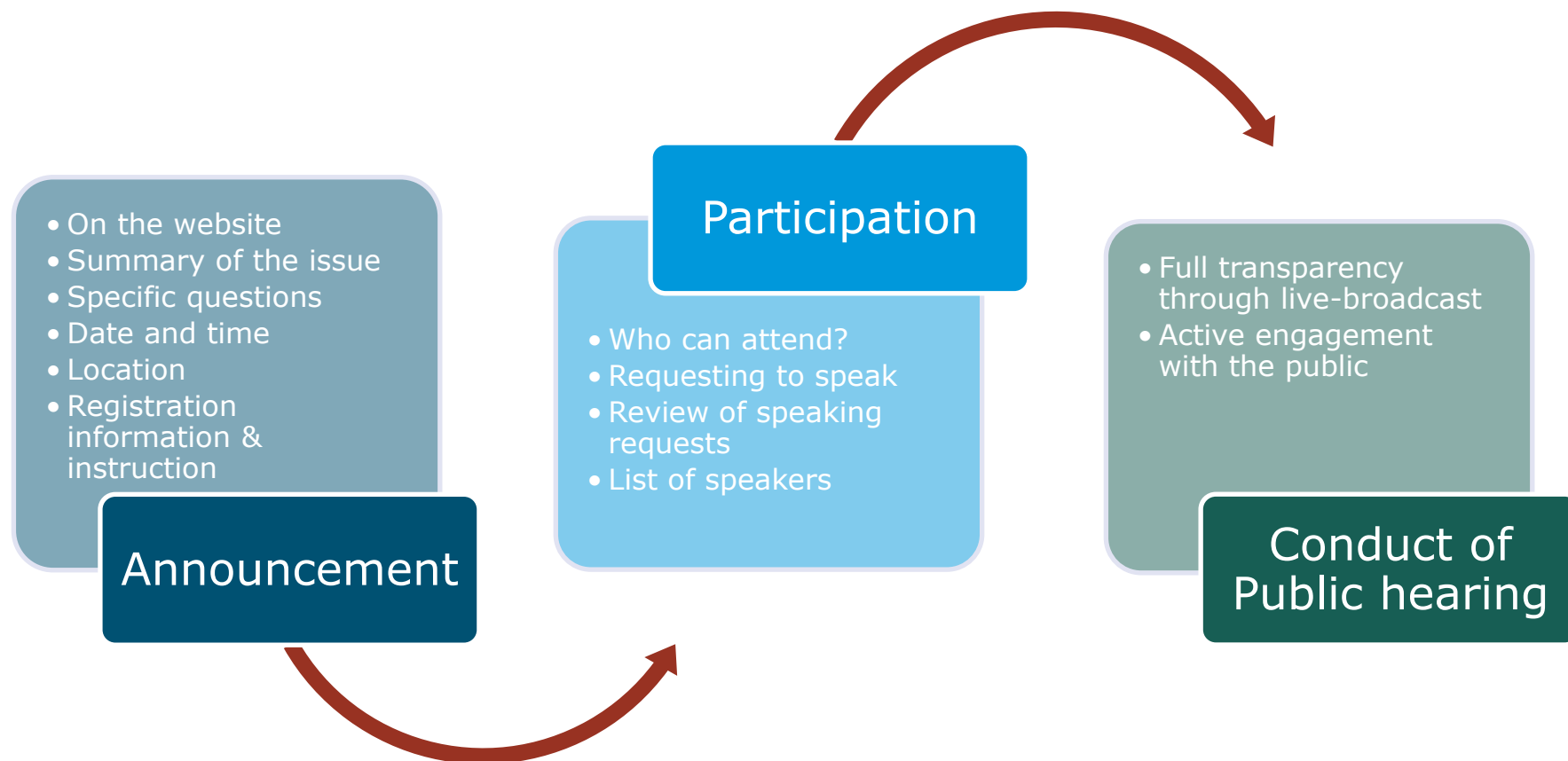


Evaluating the need for a public hearing





Organisation of a public hearing





Rules of procedure – journey ahead

- **Adoption of the Draft Rules** of Procedure on the organisation and conduct of public hearings **by PRAC**
- **Public consultation**
- **Adoption of Rules of Procedure** by EMA **Management Board**
- Entry into effect



Your involvement

- Discussion of the proposed draft rules prior to adoption by PRAC
- Expression of interest invited to participate in a small working group
- Working group to be convened via teleconference (est. 2 meetings over the next 6 weeks)

Interested? Please send an email with your contact details to monika.benstetter@ema.europa.eu by Friday, 27 September.

Any comments on the draft Rules can be sent to the same email address by 7 October 2013.