EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Hearings

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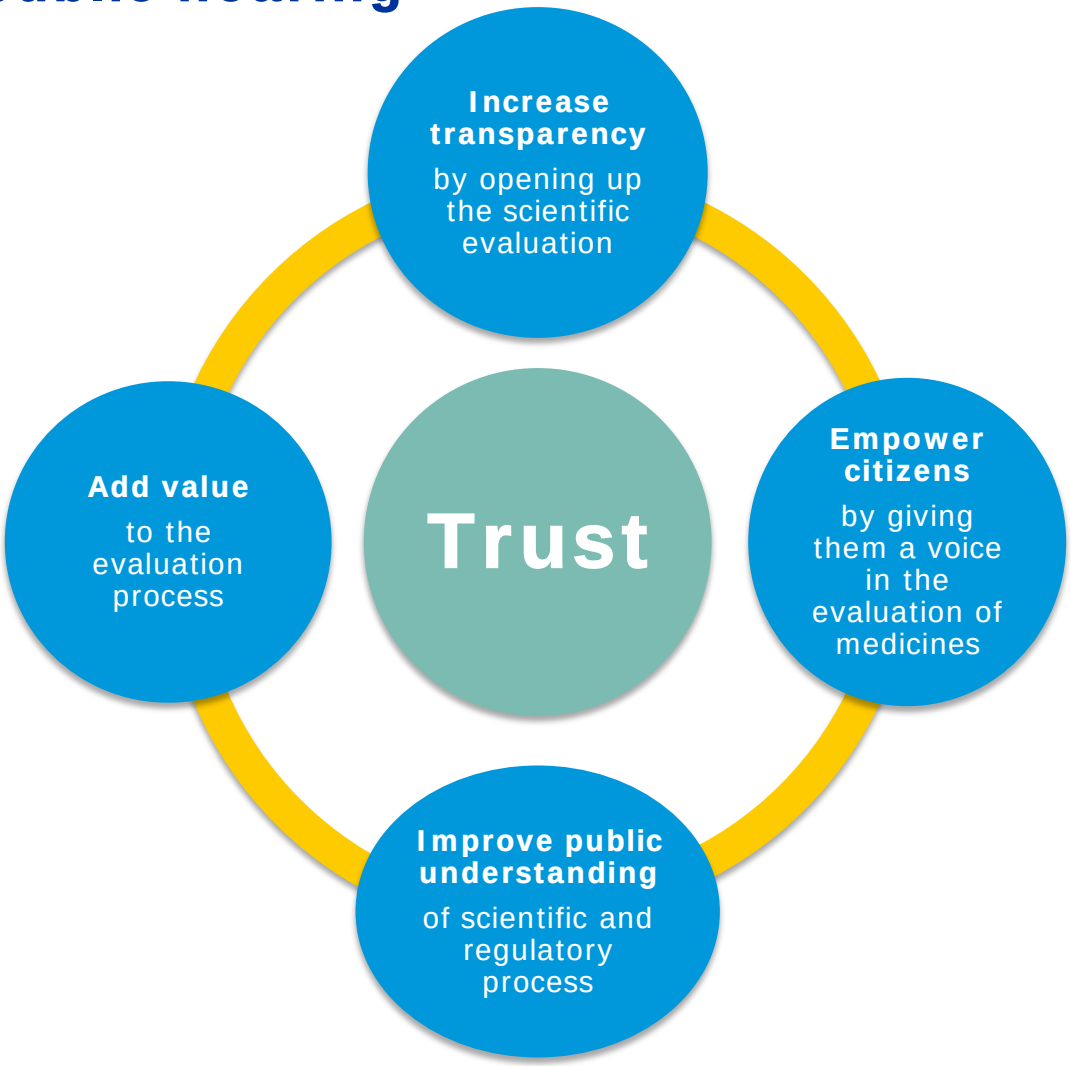
An agency of the European Union

Key principles

- Legal basis for Pharmacovigilance Risk Assessment Committee (PRAC) to hold public hearings in the context of safety referral procedures (Article 20, Article 31 or 107i)
- "Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee" available in all EU languages
- Public is invited to express its views, guided by a pre-defined set of questions
- Public hearings do not replace EMA's existing channels for engaging with patients and healthcare professionals in the assessment of medicines, such as written consultations and participation in EMA expert meetings during safety reviews.

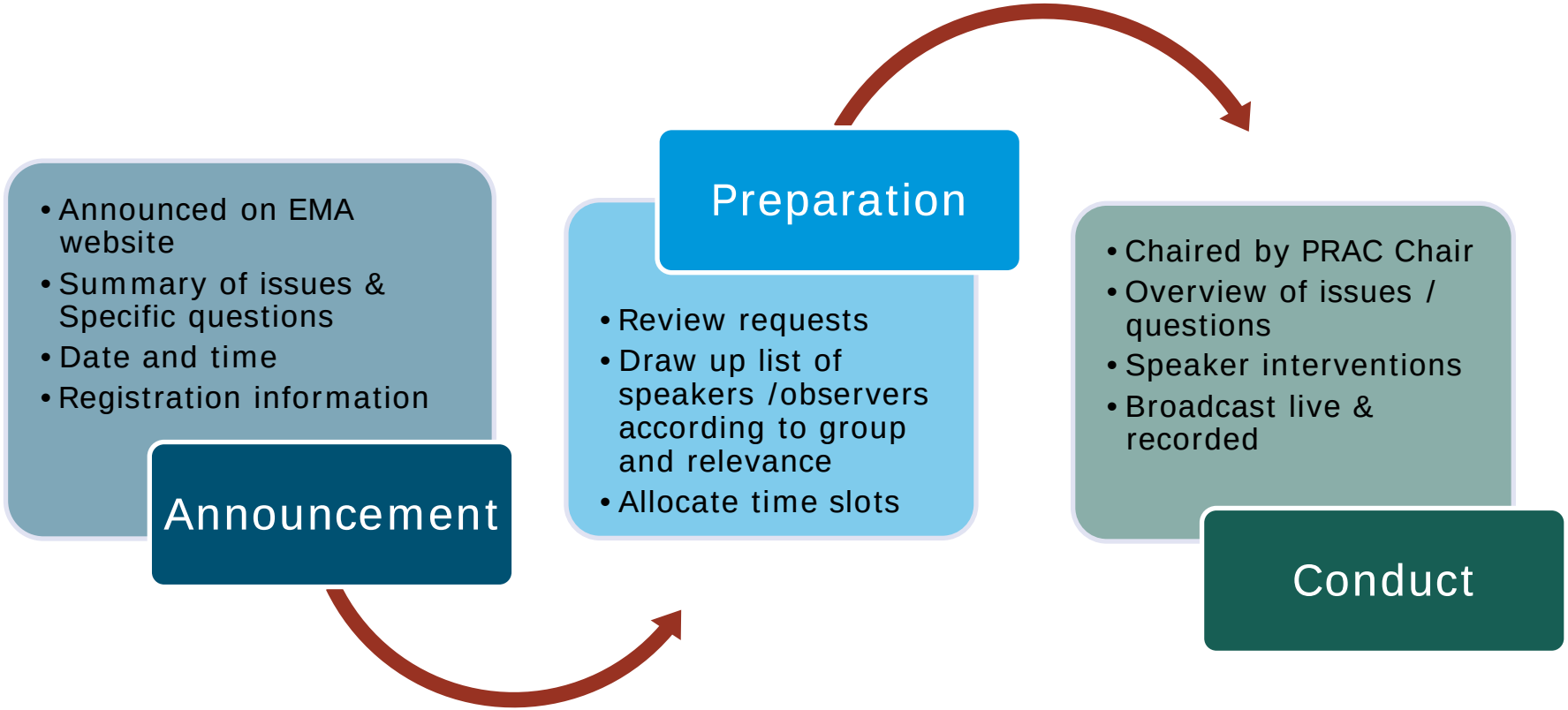
Aims of a public hearing



Key characteristics

- PRAC will consider the need to hold a public hearing, based on;
  - Feasibility in light of urgency of matter
  - Nature and extent of safety concern
  - Therapeutic effect of medicine and availability of alternatives
  - Potential impact of regulatory actions
  - Level of public interest
- Any member of the public can apply to attend as a speaker or observer;
  - ➢ if number of requests is greater than can be accommodated only the most appropriate applications will be selected, based on PRAC questions and focus of the hearing
- Conducted in English; if speakers unable to present in English, EMA will provide translation

Organisation of a public hearing



Preparations for public hearings

- A dry run was held in July to prepare for possible scenarios, to fine-tune the process and finalise Approximately 75 EMA staff volunteered (speakers and observers) / fictitious medicine
- Overall conclusions and feedback confirmed that processes put in place generally worked well; some fine tuning is required but no major problems identified
- Guidance prepared for public and for PRAC members/EMA staff
- EMA/PRAC is now ready to hold public hearings