EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Public Hearings

Presented by: Nathalie Bere, Public Engagement Dept, Stakeholder and Communications Division

# Key principles

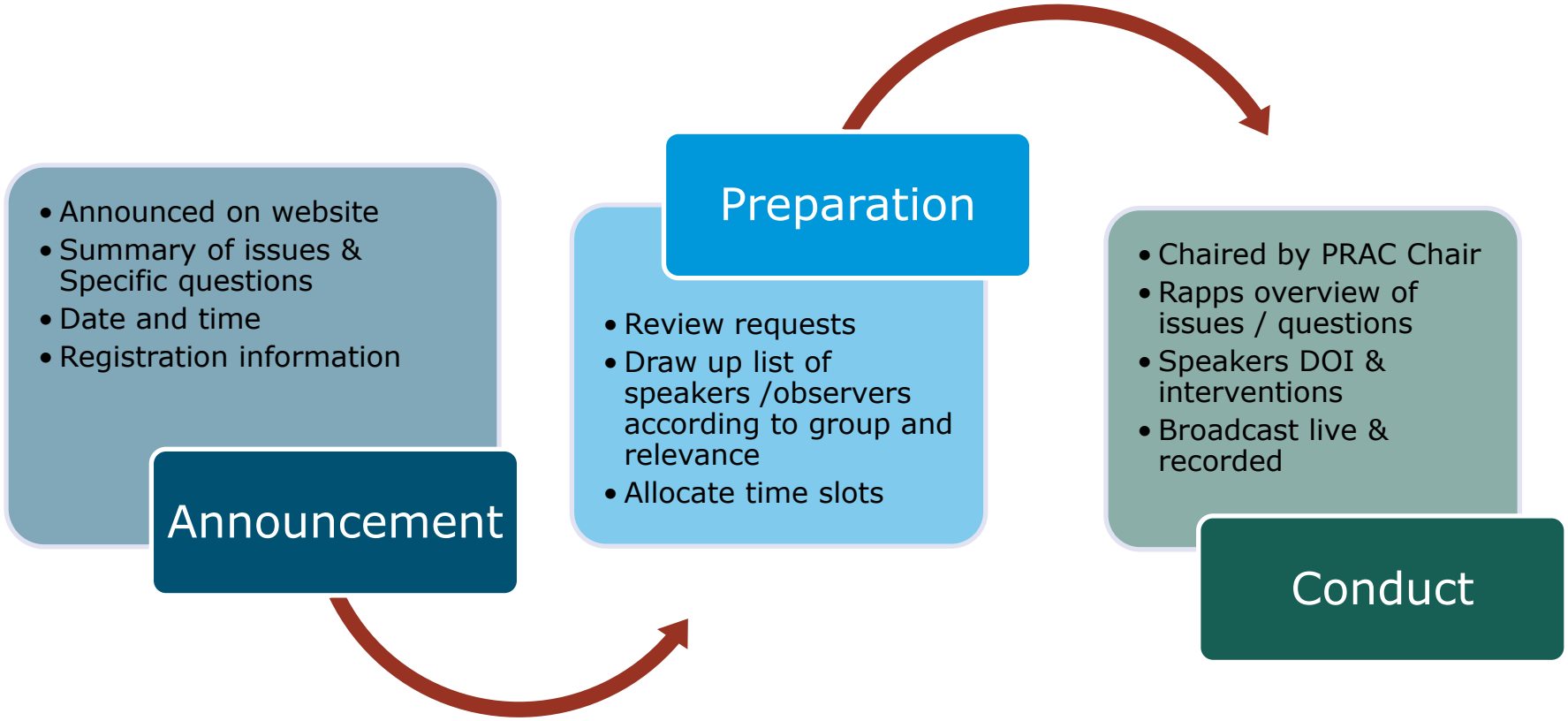
- PRAC can hold public hearings in the context of safety referral procedures (Article 20 of Regulation (EC) 726/2004, Article 31 or 107i of Directive 2001/83/EC)
- Public is invited to express its views, guided by a pre-defined set of questions
- Any member of the public can apply to attend as a speaker or an observer; if the number of requests is greater than can reasonably be accommodated only the most appropriate applications will be selected based on PRAC questions and focus of the hearing
- Public hearings complement 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

- At the start of each referral PRAC will consider need to hold a public hearing (can also decide later), 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
- Conducted in English
- If speakers unable to present in English, EMA can provide translation

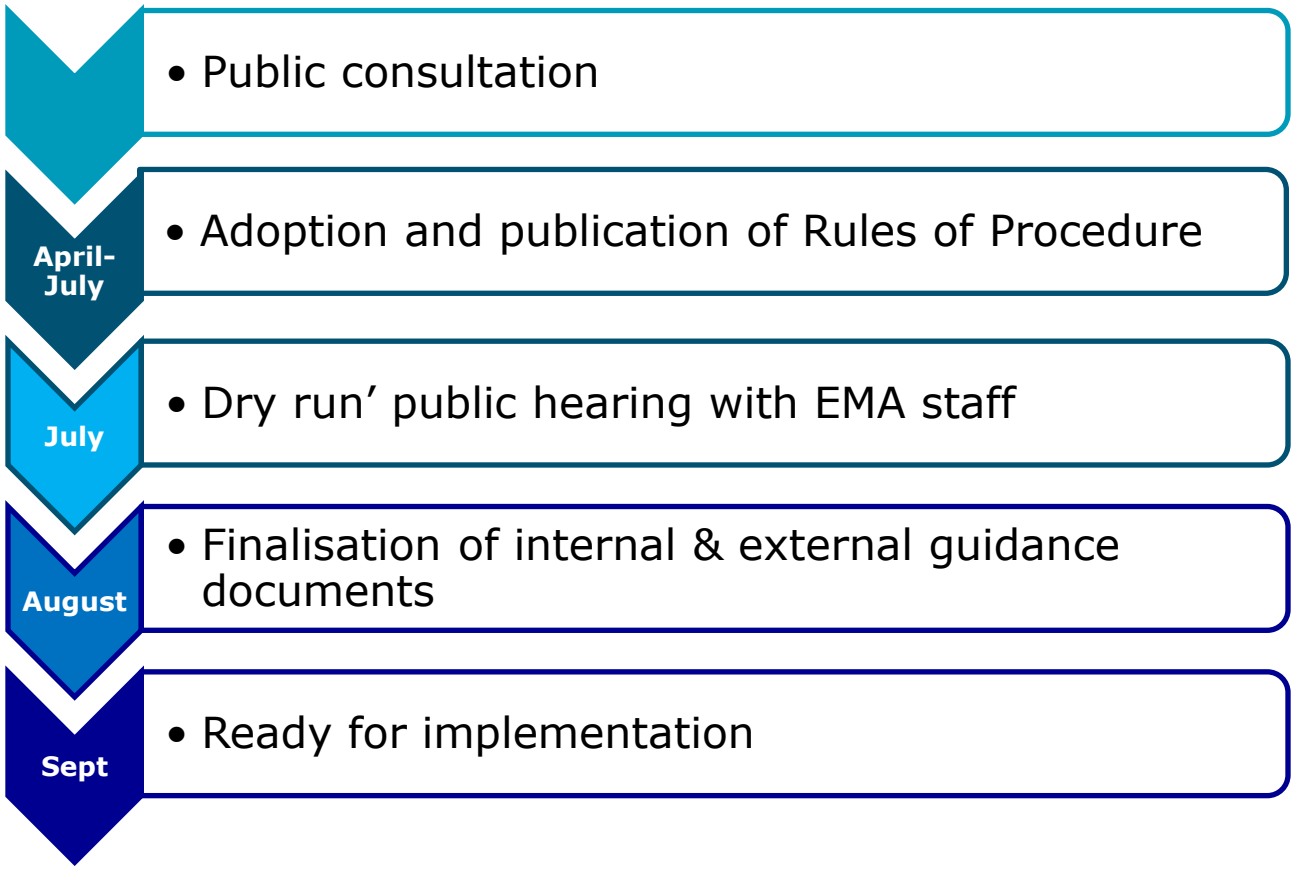
# Organisation of a public hearing



# Dry Run

- A dry run was held in July to prepare for possible scenarios, to fine-tune the process and finalise guidance for participants and PRAC members/EMA staff
- Approximately 75 EMA staff volunteered (speakers and observers)
  - → 5 speakers (3 patients, 1 industry, 1 healthcare professional)
  - → 60-65 observers
- Fictitious medicine used
- Overall conclusions and feedback confirmed that processes put in place generally worked well; some fine tuning is required but no major problems identified.

# Next steps


• Public consultation
April-July
• Adoption and publication of Rules of Procedure
July
• Dry run' public hearing with EMA staff
August
• Finalisation of internal & external guidance documents
Sept
• Ready for implementation