EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 1
Transparency: Publication of Agendas and Minutes

Management Board
21 March 2012

Presented by: Noël Wathion
Head of Unit, Patient Health Protection

New Legislative Provisions

Article 26 of Regulation (EC) No 1235/2010 states that:

- the EMA shall make public by means of the European medicines web-portal the agendas and minutes of each of the Scientific Committees CHMP and PRAC and of the Coordination Group as regards pharmacovigilance activities

How to Implement? (1/8)

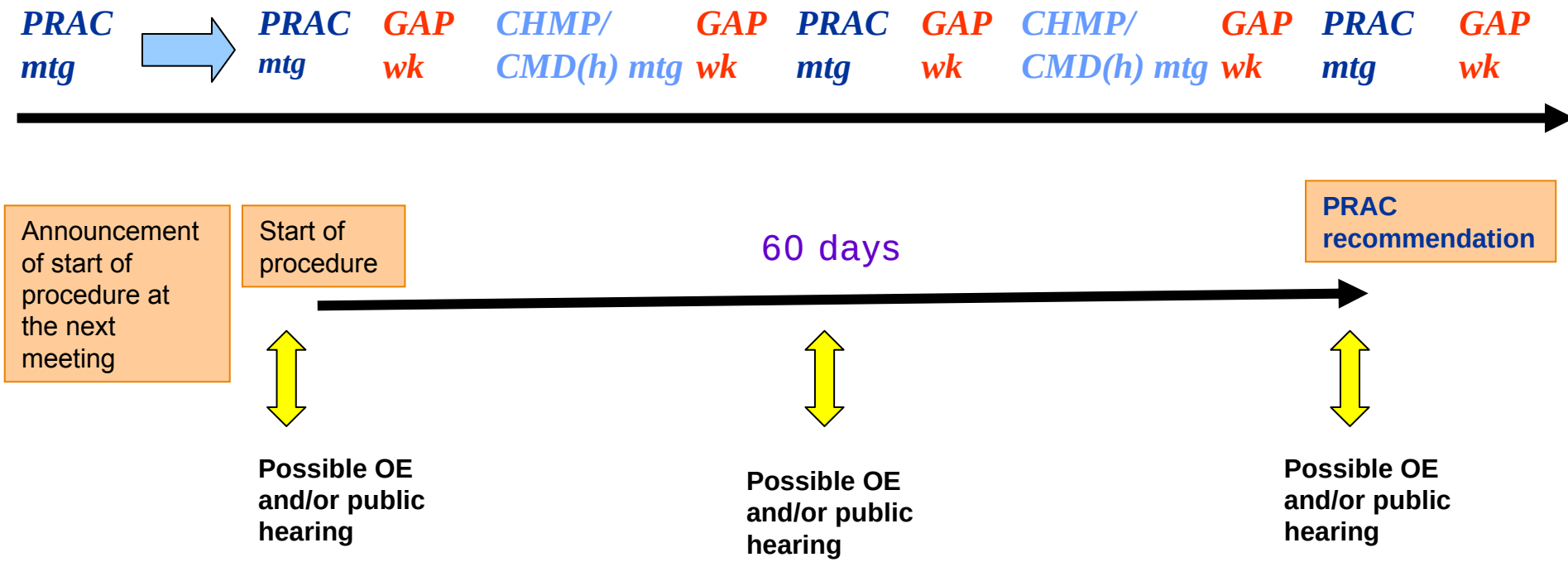
Timing of PRAC meetings:

- CHMP/CMD(h) shall rely on the scientific assessment and recommendations of the PRAC
- Proposal to leave gap of 1 week between PRAC and CHMP/CMD(h) meetings to contribute to the robustness of the outcome of the scientific review in terms of
  - Finalisation of the PRAC assessment and recommendation → enhanced quality of the PRAC output
  - Preparation of the CHMP/CMD(h) discussions (ensure sufficient review time at CHMP/CMD(h) level, facilitate interaction at national level between CHMP/CMD(h) and PRAC members)

  → facilitation of “Opinion”-making at CHMP/CMD(h)

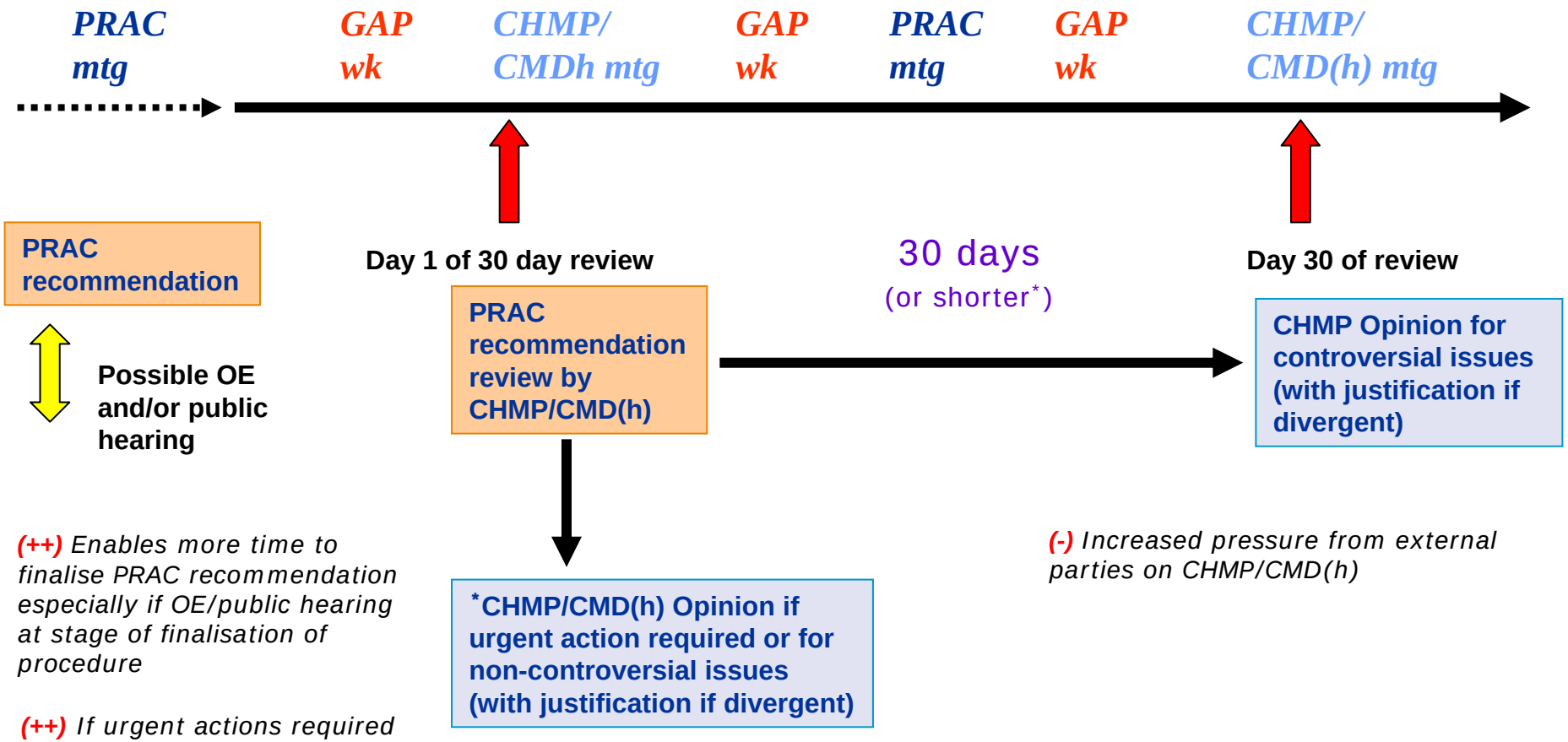
How to Implement? (2/8)

Urgent Union Procedure



How to Implement? (3/8)

Urgent Union Procedure



(++) Enables more time to finalise PRAC recommendation especially if OE/public hearing at stage of finalisation of procedure

(++) If urgent actions required CHMP/CMD(h) will be better prepared to act at their next meeting not using 30 day procedure

(-) Increased pressure from external parties on CHMP/CMD(h)

(-) Member States may act prior to CHMP/CMD(h) outcomes

How to Implement? (4/8)

Publication of agendas and minutes:

- Proposed to have a stepwise implementation starting with PRAC agendas and minutes
- In second phase (learning from experience) widening to CHMP and CMD(h) agendas and minutes

How to Implement? (5/8)

PRAC agendas:

- Only 1 agenda (for publication)
- Topics:
  - Always to be within a legal framework/procedure (includes signal detection)
  - No longer to be within an “informal” setting
  - Legacy of PhVWP to be addressed
- Content: respecting EMA policy on publication of information on ongoing evaluations + allowing for identification of the scope of the discussion
- Timing: publication around the time of the PRAC meeting but always prior to the start

How to Implement? (6/8)

PRAC minutes:

- Only 1 set of minutes (for publication)
- Topics:
  - Post-authorisation (including referrals):
    - Outcome of discussion in minutes to be published irrespective if the procedure is already finalised (overriding public health interest)
    - Still under discussion: RMPs in context of applications for new indications and line extensions
  - Pre-authorisation:
    - Outcome of discussion in minutes to be published once the procedure has been finalised (e.g. Commission Decision), unless there is an overriding public health interest (exception) (IT tool to be developed)

How to Implement? (7/8)

PRAC minutes (cont'd):

- Content:
  - Protection of CCI and personal data as per EMA/HMA recommendation on definitions in this field
  - Structured as follows: brief background of issue, summary of questions raised by the PRAC, conclusions reached by PRAC (including actions)
  - Personal reflections of PRAC members / views of PRAC members will not be minuted unless specifically requested (and subsequently published with identification of the persons concerned)
- Timing: publication once minutes have been adopted at the next meeting

How to Implement? (8/8)

Publication of other documents:

- In addition to publication of PRAC agendas and minutes, publication of outcome of PRAC discussions using Table of Decisions format in the week following the PRAC meeting and prior to the CHMP/CMD(h) meetings
- Full transparency on the outcome of the scientific review following finalisation by CHMP/CMD(h):
  - CHMP/CMD(h) Opinion/Position (integrated with updated PRAC Assessment Report)
  - PRAC Recommendation
  - Other relevant communication material: Press Release, Q&A, clarification in case of divergent views between PRAC and CHMP/CMD(h) (still under discussion)