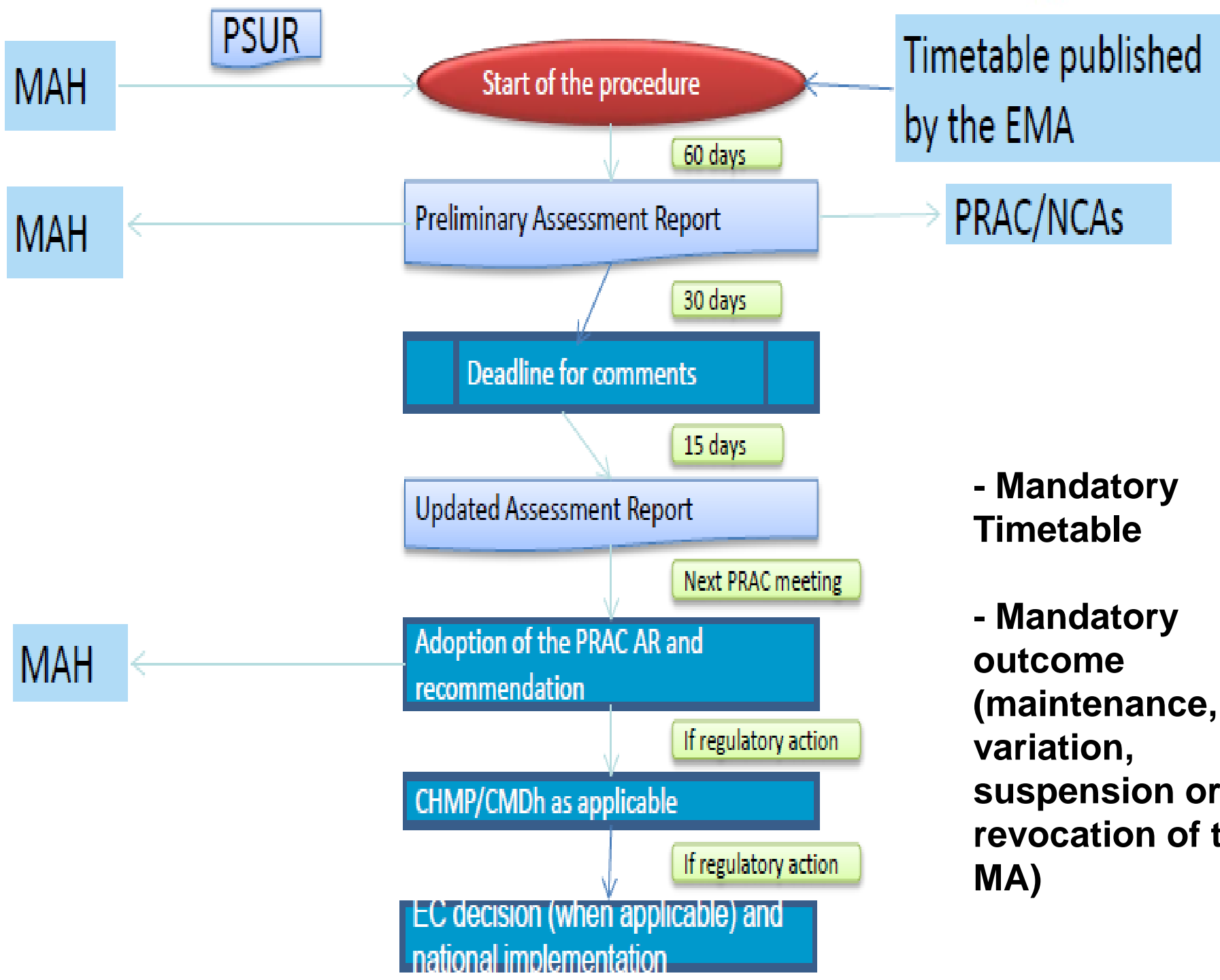


# PSUSA – Assessment aspects

## *Stakeholders meeting*

*Margarida Guimarães – PT PRAC Member  
March 2015*



**- Mandatory Timetable**

**- Mandatory outcome (maintenance, variation, suspension or revocation of the MA)**

# PSUR Assessment

## Main points for discussion

- **Preparation phase**
  - provide good initial presentation of data
    - ➔ avoid requests for discussion of individual cases
  - good signal and risk evaluation ➔ essential as this in a way replaced the previous discussion of case narratives in the old PSURs
  - ongoing studies findings
  - RMM effectiveness assessment
- **Comments phase - responses within the 30 days**

# PSUR Assessment

## Outcomes

***Based on the evaluation of the cumulative safety data and the B/R analysis, the MAH shall draw conclusions in the PSUR as to the need for changes and/or actions***

- Updates to the Product Information
  - wording proposal
  - translations into all EU official languages of wording
- MA Annex II conditions updates
- RMP updates
- Requests for next PSUR
- Solve issue within the procedures to avoid follow-up measures (LEGs...)

**Publication of the PRAC recommendations**



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Please see also:

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