EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Non-Imposed PASS Protocols

## A new option with Scientific Advice

Presented by Jane Moseley on 13 March 2015
Scientific officer/Scientific Advice

# Overview

- High level view of proposal and rationale
- Scientific advice working party - overview
- Next steps

# New approach

- Opening requests for EMA scientific advice to protocols for non-imposed Post Authorisation Safety Studies (PASS)
- Building in PRAC review in the process

Imposed PASS protocols – respect formal procedures under articles 107n–q Dir 2001/83/EC as amended

# Added value of scientific advice approach

- Will have strong PRAC–SAWP interaction
- **Benefits / opportunities / strategic interest**
  - **Lifecycle approach**
  - **Integration of Safety, Quality, Efficacy and Pharmacovigilance planning**
  - **Optimise product development**
  - **Bridge observational/non-observational studies**

# Added value of scientific advice approach

- Will facilitate potential **efficiency gains** across the system whilst maintaining adequate oversight
- More **intensive interaction** with the MAH (within the procedure) than what happens at PRAC
- Allows additional **experts, Follow up advices**
- **Early and/or late** protocol development
- Pre a**nd/or** post-authorisation

# PASS categories in focus

- Category3: ‘Required to investigate a safety concern in the RMP or to evaluate the effectiveness of risk’

- Category 4: Other studies conducted by MAH which may provide safety information but are not considered to be of significant importance in investigating a safety concern or the effectiveness of risk minimisation activities

# Final protocols

- Final protocols for category 3 studies required by the PRAC will continue to be submitted to PRAC

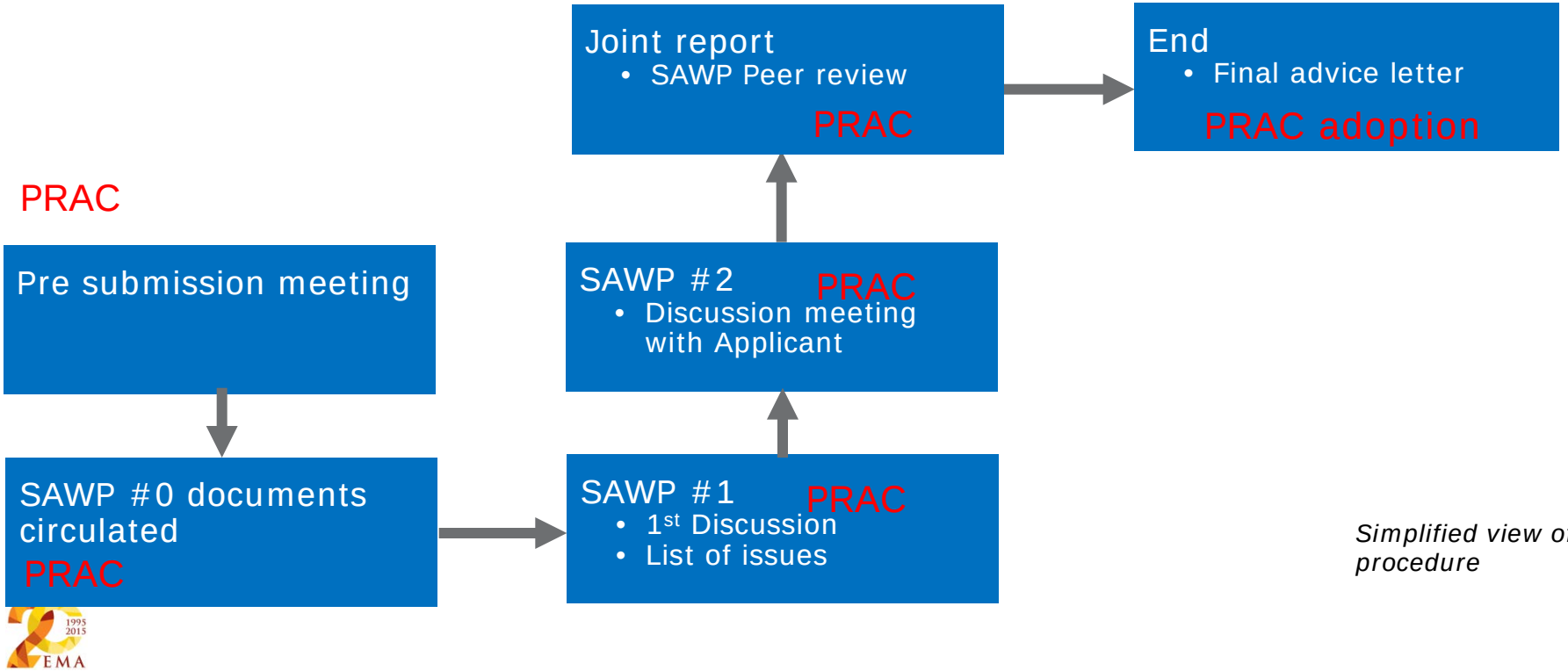
# Procedural elements

- Scientific advice is voluntary, fees levied
- Proposed procedure systematically involves PRAC for protocols submitted to Scientific Advice
- PRAC formally considers and adopts scientific advice relating to PASS
- All scientific advice documents  will be available to the full PRAC.
- PRAC will be invited to comment during the procedure.

# Timing

- 40 or 70 day procedures
- Briefing document +Letter of intent submitted according to published Scientific Advice deadlines
- Allows possible presubmission TC
- Lead time ( Submission to start of procedure)
  - No presubmission 3 weeks
  - With presubmission 7 weeks

# Presubmission and 70 day procedure with committee interaction



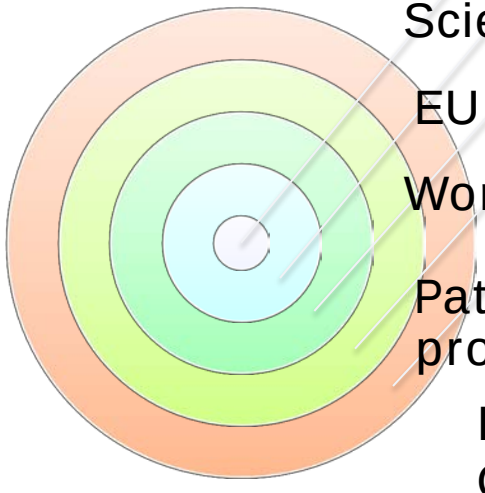

*Simplified view of procedure*

# Information on SAWP

- Submission by letter of intent to scientificadvice@EMA.europa.eu with briefing document and annexes
- Published timelines
- Briefing document template
- Contact point scientificadvice@ema.europa.eu

# Scientific Advice Working Party (SAWP)

NEW- 2 joint PRAC –SAWP members with pharmepi expertise



Multidisciplinary expert group

Scientific secretariat

EU Regulatory network/experts

Working parties and Committees

Patient & health care professional organisations

HTAs
Other regulators
Additional external experts

# Pilot

1. Pilot of 12 months for the new procedure to be undertaken
2. SA PASS can be submitted Q3
3. Joint SAWP PRAC membership (based on study design expertise)
4. Procedural details to be elaborated further
5. Further communications/guidance to be made available shortly

# Conclusion

New option for advice on PASS protocols

**Benefits / opportunities**

**Strategic interest and efficiency gains**

# Thank you for your attention

## Further information

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