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SCIENCE MEDICINES HEALTH

PRAC interaction with SAWP

PASS pilot and other consultations

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SAWP secretariat

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An agency of the European Union

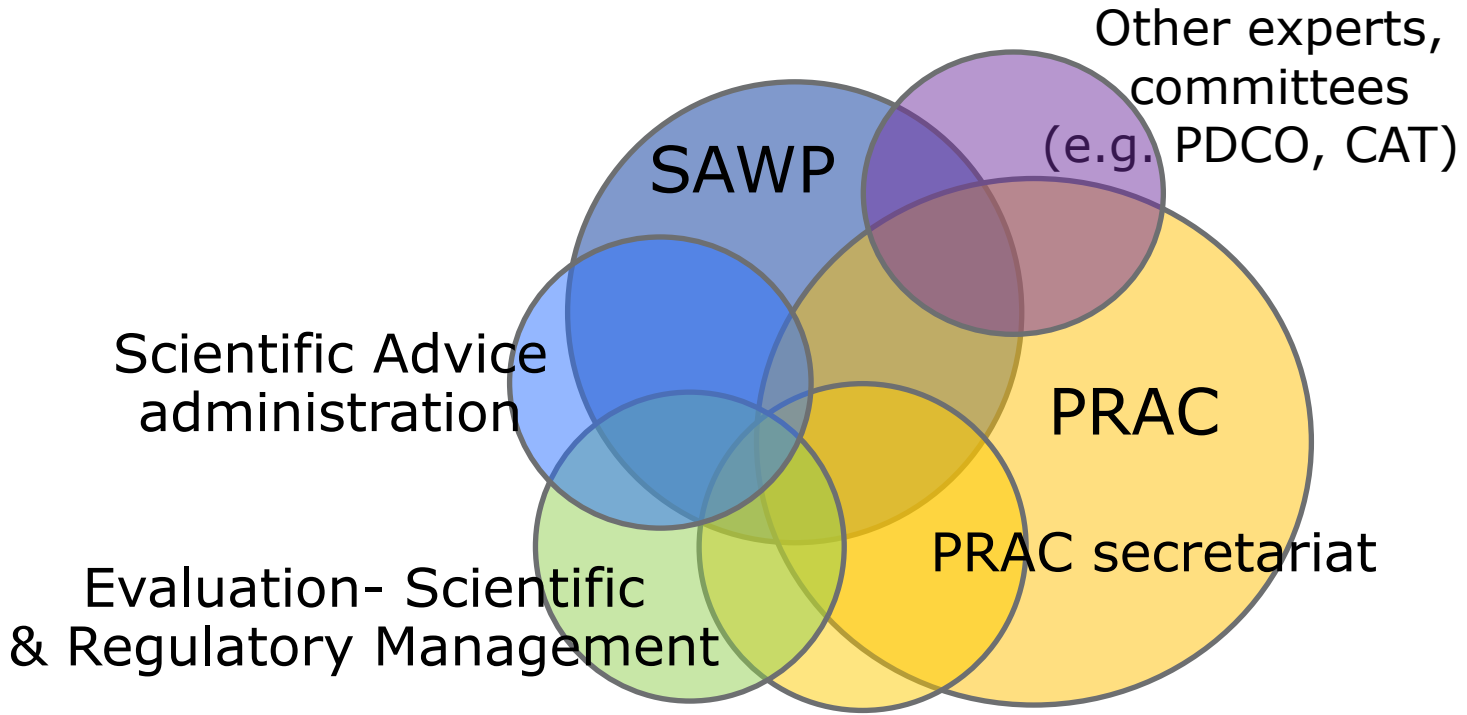
Overview

- PASS pilot – overview, interactions, procedure, progress
- Scientific advice requests with PRAC consultation – rationale, criteria, procedural elements

PASS pilot - overview

- Requests for EMA scientific advice to protocols for non-imposed Post Authorisation Safety Studies (PASS) i.e. studies required to investigate a safety concern or evaluate the effectiveness of risk minimisation activities
- PRAC involvement
  - Committee level involvement in all relevant procedures
  - PRAC Rapporteur always to be involved for a given procedure
  - PRAC/SAWP joint delegates
  - PRAC formally considers and endorses scientific advice relating to PASS
- Scientific advice is voluntary, fees levied

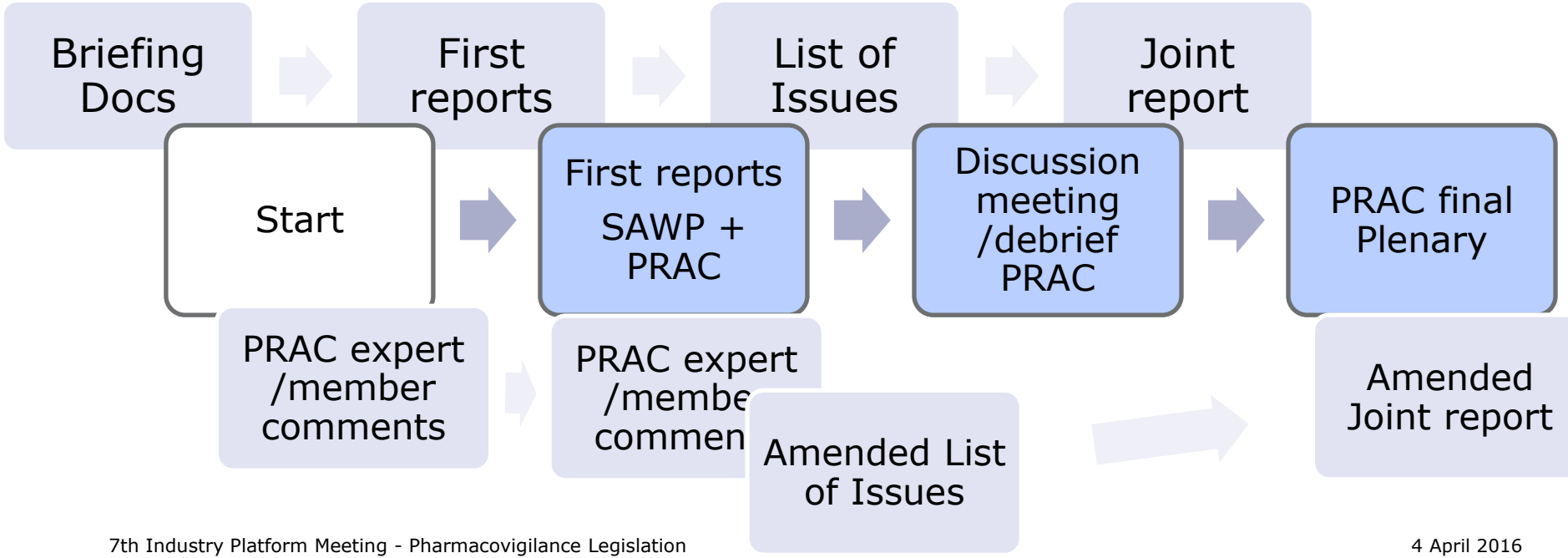
Scientific advice interactions on PASS requests



- Final advice will be endorsed by PRAC after discussion at PRAC plenary
- Adoption of final advice by CHMP via a written procedure

PASS pilot - procedure

- PRAC Committee level contribution
- PRAC plenary discussion at every stage



PASS pilot - progress

- 12 month pilot was launched in July 2015
- First joint PRAC/SAWP member / alternate nominated (DK)
- Two SA requests for PASS – scientific advice finalised in March 2016

PASS pilot - Published information

EMA website: PASS- questions and answers
10. Scientific advice for safety studies NEW July 2015
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000134.jsp&mid=WC0b01ac058066e979

Scientific advice general guidance

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000049.jsp&mid=WC0b01ac05800229b9

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

Consultation of PRAC by SAWP

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Rationale

Scientific Advice procedures where PRAC input would be valued (e.g. RMP)

- Bring in PRAC expertise - outputs richer and better advice
- Facilitating life-cycle advice on medicines
- Fostering inter-disciplinary/committee thinking
- Stimulate proactive PhV planning

PRAC work-plan 2016: Life-cycle approach to pharmacovigilance and risk management

- Early highlighting of any identified concerns
- To shape evidence generation at an early stage
- To emphasise the importance of proactive planning of pharmacovigilance

Proposed criteria for PRAC consultation

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Main topics identified : PV planning and risk minimisation activities

- Pre-authorisation advice on Risk Management Plans
- Procedures making reference to post-authorisation data collection to address a safety issue or to further investigate potential risks
- Adaptive pathways / PRIME
- Additional evidence generation and multi-stakeholder (HTA) advice including registry planning
- Opinion/advice on safety biomarkers

Criteria under discussion / can be revised with experience

PRAC consultation procedural elements

- PRAC peer reviewer – PRAC Rapporteur, if exists
- Focus: PRAC peer reviewer making written comments on first reports prepared by the SAWP coordinators
- PRAC peer reviewer selects topics/questions for PRAC plenary discussion
- PRAC endorsement of the comments at the plenary meeting (after discussion of first reports at the same SAWP/PRAC meeting)

Conclusion

New interactions between SAWP and PRAC

✓ Scientific advice on PASS protocols

✓ Interdisciplinary advice for issues relevant to pharmacovigilance

EMA team

D-DS SCA Scientific advice - Anna Tavridou / Viola Macolic Sarinic / Jane Moseley / Spiros Vamvakas / Olivia Capanna

E-SR ECV– Risk Management - Giampiero Mazzaglia / Michael Berntgen

PRAC secretariat - Margaux Philippe / Geraldine Portier

C-CS-SCS Scientific Committee Support Department - Sheila Kennedy

P-PH Pharmacovigilance – Peter Arlett

D- RD-REA Regulatory affairs – Maria Boulos / Sonia Ribero

Thank you for your attention

Further information

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PASS pilot - roles

- **SAWP coordinators** can be
  - MS of PRAC/CHMP Rapporteur
  - PRAC/SAWP joint delegate
- **SAWP peer reviewer** (SAWP member or PRAC/SAWP joint delegate)
- **PRAC expert** (should be PRAC Rapporteur if MS not already involved as coordinator)

Consultation process

- Under discussion
- PRAC Committee level contribution