EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA DEVELOP INNOVATE ADVANCE

PSUR roadmap

Achieving a common understanding of the PSUR single assessment in Europe

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Disclaimer

Recap – where it started (1)

New Pharmacovigilance Legislation

- adopted in 2010
- entered into force 2012: Establishment of PRAC and NEW PSUR procedure

"In the light of the experience acquired and following an assessment by the Commission of the Union system of pharmacovigilance, it has become clear that it is necessary to take measures in order to improve the operation of Union law on the pharmacovigilance of medicinal products for human use."

Recap – where it started (2)

ICH E2C(R2): periodic benefit risk evaluation report (PBRER)

- Concept paper 2010
- Finalised Guideline November 2012

"Optimise the lifecycle benefit risk of medicines for the promotion and protection of public health by establishing a modular and improved approach to the documentation of safety information, risk evaluation, risk minimisation and benefit risk evaluation, including how these are evaluated and planned."

What happened next

- Establishment of PRAC
- Implementation of the ‘new’ PSUR procedure
- Finalisation of GVP VII
- Expansion to NAPs only PSUR single assessment
- …

→ Focus on implementation/change management

→ Experience was starting to be gained

→ **Feedback from Industry** via October 2014 PhV Industry platform meeting

Issues for action highlighted by industry

- Bring Periodic Benefit/Risk Evaluation report (PBRER) spirit into everyday review/assessment practice (review assessor template c.f. ICH; publish ICH Q&A; agree/come to a common understanding as regards granularity needed in PBRERs)
- If safety topic review negative then close; if safety topic for ongoing monitoring in PSURs – justify and make time limited
- Don’t use PSUR as repository for all regulatory requests
- Make requests realistic and proportionate if included in preliminary assessment report
- Consider **PRAC procedure document** to drive up standards and consistency

PRAC and CMDh reflection on points raised by Industry

Need to have a common understanding within the network as platform for common understanding between network and industry

→ Need to build this consensus within the regulators: **PSUR roadmap**

- Creation of a PSUR action group (PRAC and CMDh members)
- Scoping paper for dedicated workshop
- PRAC/CMDh common understanding of optimal use of the single assessment for old substances – Workshop in January 2016
- Drafting and Finalisation of PRAC/CMDh working document on common understanding in May 2016

Implementation of the PSUR roadmap

- Q&A for assessors
- Explanatory note for industry on GVP VII – PSUR

→ Presentation today

Next steps:

- Consultation with industry stakeholder associations on explanatory note via PV industry platform meeting (Jan 2017)
- Joint assessors' & industry training (2017)
- Initiate revision of GVP VII (2017)

Initiatives to address Industry's concerns

- Advisory Group for the EU reference date (EURD) list (GPAG – established)
- PRAC Assessors' trainings with a focus on single assessment
- Review and refinement of the assessment report template (ongoing)

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Thank you for your attention

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