EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Seal studies and imposed PASS: compliance and disclosure measures

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Two separate aspects

1. ENCePP Seal studies: compliance to requirements
2. Post-authorisation safety studies (PASS) imposed as an obligation: publication of study protocols and study reports

ENCePP Seal studies

41 studies with ENCePP Seal

→ 20 : Date of final study report < 01/11/2016

→ 9 : No study report uploaded.

Critical issue of credibility for the Seal, ENCePP, and EMA

Objective is not to have as many ENCePP Seal studies as possible but to identify studies (and investigators) following good practice of independence and transparency.

ENCePP Seal studies

Primary investigator to be contacted for 27 Seal studies with date of final report <01/11/2016 and not uploaded

Request to upload study protocol and study report within **one month**, unless reasoned justification.

If not done: Seal removed

PASS imposed as a legal obligation by a regulatory authority (RMP category 1)

- Legal obligation to MAH to register the study in a public study register – obligation applies at the time of study report
- Legal obligation to MAH as regards the format of the study protocol, study report and abstract of study report
- Recommendations in Good pharmacovigilance practices, Module VIII
  - MAH to register the study in the EU PAS register
  - MAH to upload the study protocol prior to start of data collection or data extraction
  - MAH to upload study report within two weeks of finalisation

PASS imposed as a legal obligation by a regulatory authority (RMP category 1)

- Article 26(1)(h) of Regulation (EC) No 726/2004 requires the Agency to make public "*protocols and public abstracts of results of the post-authorisation safety studies referred to Articles 107n and 107p of Directive 2001/83/EC*". (= studies imposed as an obligation)
- PASS protocols and full study reports may in principle be publicly available via the Agency's obligation to provide access to documents under Regulation (EC) No 1049/2001 (subject to the exceptions set out in Article 4) (this is applicable to all studies)

PASS imposed as a legal obligation by a regulatory authority (RMP category 1)

MAH to be strongly encouraged to upload in the EU PAS register the PASS protocols and results of imposed PASS by *1 month* after PRAC recommendation.

MAH to be informed that after this deadline the Agency will otherwise upload the protocols and public abstracts of results into the EU PAS Register on its own initiative in order to fulfil its legal obligations under Art 26(1)(h) of Regulation (EC) No 726/2004, unless alternative timelines are agreed.

Questions?