EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good Vigilance Practice

Module VIII- Post-authorisation safety studies

4th Stakeholder Forum

Xavier Kurz

Post-authorisation safety study

Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

Post-authorisation safety study

Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

Post-authorisation safety study

Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

Post-authorisation safety study

Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.

Objectives of a PASS may include:

- to characterise the safety profile of a medicine
- to provide reassurance about the absence of a safety concern related to a specific adverse reaction
- to investigate potential or identified risks
- to evaluate risks of a medicinal product used in authorised indications by patient groups not studied in the pre-authorisation phase
- to assess patterns of drug utilisation and use of the medicinal product that may have an impact on its safety
- to evaluate the effectiveness of a risk minimisation activity

Post-authorisation safety study

- Clinical trial
- Non-interventional study

The MAH has the responsability to ensure that the PASS is not a clinical trial.

If the PASS is a clinical trial, Directive 2001/20/EC and Volume 10 of The Rules Governing Medicinal Products in the European Union shall apply.

GVP Module VIII mainly applies to non-interventional trials

PASS may be initiated, managed or financed by a MAH:

- Voluntarily
- Pursuant to an obligation imposed by a competent authority
  - as a condition to the granting of the marketing authorisation, or
  - after the granting of a marketing authorisation if there are concerns about the risks of the authorised medicinal product

Obligation is a condition to the marketing autorisation.

Obligation duly justified based on benefit-risk considerations.

Close oversight

Structure of Module VIII

- To provide a general guidance and requirements for any non-interventional PASS conducted by marketing authorisation holders, whether voluntarily or pursuant to obligations (section VIII.B)

- To describe the procedure for imposing an interventional or non-interventional PASS as an obligation, and describe the specific requirements that apply to non-interventional PASS conducted by marketing authorisation holders pursuant to such obligation (section VIII.C)

Structure of Module VIII

- To provide a general guidance and requirements for any non-interventional PASS conducted by marketing authorisation holders, whether voluntarily or pursuant to obligations (section VIII.B)

- To describe the procedure for imposing an interventional or non-interventional PASS as an obligation, and describe the specific requirements that apply to non-interventional PASS conducted by marketing authorisation holders pursuant to such obligation (section VIII.C)

General guidance and requirements (section VIII.B)

Guiding principles:

- Scientific standards
- Transparency
- Harmonisation
- Quality control

General guidance and requirements (section VIII.B)

- Applies to all PASS
- Level of enforcement depends on type of studies and topics
  - Requirements based on Dir. Art 107m of Directive apply to all studies
  - Requirements based on Dir. Art IM Art 107n to 107q and IM Annex IV apply only to studies imposed as an obligation
  - Some requirements for studies imposed as an obligation are recommended for studies voluntarily initiated by MAHs (eg. format of study protocol and final study report)
  - Some recommendations apply to all studies (eg. registration of studies in European registry of PASS)

General guidance and requirements (section VIII.B)

General principles

- Objectives of PASS
- Consideration to relevant scientific guidance
- Investigators qualified by education, training and experience
- Research contract
  - compliance to regulatory requirements
  - investigator's scientific expertise to be excercised
  - ENCePP CoC recommended

General guidance and requirements (section VIII.B)

Study protocols

- Transmission to relevant competent authorities
- Involvement of QPPV
- Registration into EU public registry of PASS
- Format and content
- Change control
    - substantial amendments

General guidance and requirements (section VIII.B)

Reporting of pharmacovigilance data

- data relevant to the risk benefit balance
- expedited reporting of serious ADRs
    - cross-reference to Module VI

General guidance and requirements (section VIII.B)

Study reports

- Progress reports
  - may be requested before study commences or any time during study conduct – timing to be agreed
- Final study report
  - to be submitted as soon as possible after finalisation within 12 months
  - transmission to competent authorities
  - format and content
- Publication of results by investigators
- Submission of published study results

General guidance and requirements (section VIII.B)

Data protection

Quality systems, audit and inspections

Study registration

Impact on risk management system

Next step

To assess Member States' preferences in case of optional transmission of information

eg. transmission of study protocols/progress reports/final reports to NCAs where the product under study is authorised

eg. channel for transmission of information (study registration in EU register of PASS?)

Questions ?