Pharmacovigilance Systems Master File (PSMF)

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Objectives of PSMF

- ***Describe*** the pharmacovigilance (PV) system
- ***Support/document*** PV system's compliance with the requirements
- ***Provides***:
  - information on
    - deficiencies in the system,
    - non-compliance with the requirements;
    - risks or actual failure in the conduct of specific PV aspects and
    - the action/measure taken
- ***Contribute*** to:
  - the fulfilment of supervisory responsibilities of the qualified personnel for PV activities (QPPV),
  - planning and conduct of internal audits and
  - external inspections/verification of compliance by the national competent authorities (NCAs)

Thereby, assuring PV system implementation and compliance in relation to the system.

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Structures and Process

Contents of PSMF

- Indexed with appropriate sections for efficient navigation
- Partitioned
  - Sections:
    1. QPPV
    2. MAH's organisational structure
    3. Safety data sources
    4. Computerised systems and databases
    5. PV processes
    6. PV system performance and
    7. Quality system
  - Annexes

SECTIONS

1. Qualified Person Responsible for PV (QPPV)

- A **description of the responsibilities** ensuring sufficient authority over the PV system that
  - promotes,
  - maintains and
  - improves compliance
- A summary **curriculum vitae** with the key information on the role
- Description of the qualifications, **experience** and registrations relevant to PV
- Proof of registration with the Eudravigilance database (EV-D)
- **Contact details** including name, postal, telephone, fax and e-mail and the usual working address
- Details of **back-up** arrangements to apply in his/her absence; and
- Contact information of national level PV person

A list of delegated tasks with respect to the personnel whom it is assigned to be part of the Annexes

2. MAH's Organisational Structure

- Clear overview of:
  - **company(ies)** involved,
  - the main **PV departments** and
  - the relationship(s) between organisations and operational units fulfilling PV obligations
- QPPV's position and sites for PV activities
- Details of the **links with other organisations**, such as contracting of PV activities and co-marketing agreements
- Description of any related contracts and agreements location and nature:
  - ***list/table*** - the parties involved, the **roles** undertaken and the concerned **product(s)** and **territories** and
  - ***organised*** according to
    - **service providers** (e.g. patient support programme providers, study data management etc.),
    - **commercial arrangements** (distributors, licensing partners, etc.) &
    - **other technical providers** (hosting of computer systems etc.)

At the request of NCAs and the Agency or during inspection and audit, the required information should be made available

3. Safety Data Sources

- **Description** of all responsible parties on a global basis in the form of:
  - **List** (Annexed):
    - describes the country, nature of the activity and the product(s)
    - a contact point (address, telephone and e-mail) for the site
  - **Flow diagrams**:
    - indicating the main stages, timeframes and parties involved and
    - description of the departments and/or third parties involved
- List that:
  - describes (on a worldwide basis)
    - the product(s),
    - the applicable country(ies),
    - the status of each study/programme, including ongoing studies/programmes as well as studies/programmes completed in the last two years
  - distinguishes between interventional and non-interventional studies and organised as per active substance

4. Computerised Systems and Databases

- Description of the **location, functionality and operational responsibility** used to receive, collate, record and report safety information
- Description of the **validation status** of key functionality aspects
- Summary of the aspects vital to PV compliance e.g. **change control, nature of testing, back-up procedures and electronic data repositories**
- For paper-based systems (e-system used only for expedited submission of ICSRs), description on:
  - data management ,
  - mechanisms used to assure the integrity and accessibility of the safety data, and
  - the collation of adverse drug reactions (ADRs) information

5. PV Process

- Description of:
  - the available **procedural documentation** (SOPs, manuals, etc.)
  - the **nature of the data** held (e.g. the type of case data retained for ICSRs) and
  - the **records management** (e.g. safety database, paper file at site of receipt)
- Description of the process, but not limited to:
  - continuous monitoring of product's **risk-benefit** profile(s)
  - risk **management system(s)** and monitoring of the outcome of risk minimisation measures
  - procedures for **ICSR collection, collation, follow-up, assessment** and **reporting**
  - **PSUR** scheduling, production and submission, if applicable;
  - **communication of safety concerns** to consumers, healthcare professionals (HCPs) and the NCAs;
  - **implementation of safety variations** to the summary of product characteristics and patient information leaflets

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5. PV Process (contd.)

- The description should be accompanied with:
  - A list (annexed) of applicable processes and comprises:
    - the procedural document reference number and title
    - effective date and
    - document type
- Clear identification of procedures pertaining to **service providers** and other third parties
- System for supporting appropriate and **timely decision making** and action in each area
- Information pertaining to any specific local procedures

6. PV System Performance

- Evidence of the ongoing monitoring and description of methods
- Information on:
  - the assessment methodology for ensuring correct reporting of ICSRs with figure/graphs showing the timeliness of reporting
  - description of the information provided by authorities regarding ICSR reporting quality, PSURs or other submissions
  - an overview of the methods used to ensure timeliness such as
    - safety variation submissions
    - PSUR reporting to the authorities
  - an overview of RMP commitments adherence, or other obligations or conditions of authorisation(s) relevant to PV
- Description and explanation of PV system performance target with a list of performance indicators alongside the results of actual performance measurements in the annexure

7. Quality Systems

- For document and record control
  - an overview of the procedures applied to other QS and PV records and documents
  - description of the arrangements for electronic and/or hardcopy versions archiving
- For procedural documents
  - A general description of
    - the types of documents such as SOP, manual etc.,
    - the applicability of the various documents at global, regional or local level, and
    - the controls that are applied to their accessibility, implementation and maintenance
  - Information about the documentation systems applied to those under the control of third parties
- Pertaining to training:
  - a description of the resource management i.e. the organisational chart
  - description providing explanation for training organized in relation to the relevance, personnel and site information
  - a summary description of training concepts along with location for training files

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7. Quality Systems (contd.)

- Pertaining to audit,
  - a list of specific procedures and processes that provides:
    - information about QA auditing of the PV system and
    - PV system audits with description of approach used to plan, reporting mechanism & timelines
  - for audit with significant findings provide associated note
    - brief description of CAPA plan associated with the finding, anticipated resolution date(s)
  - In the annex, provide list of audits conducted (last 5 years) with clarity on the ones with and without unresolved notes

8. Annexures

Annex A – QPPV
- The curriculum vitae of the QPPV and associated documents
- Contact details

Annex B – The Organisational Structure of the MAH
- The lists of contracts and agreements

Annex C – Sources of safety data
- Lists associated with the description of sources of safety data e.g. affiliates and third party contacts

Annex D – Computerised systems and Databases

Annex E – PV Process, and written procedures
- Lists of procedural documents

Annex F – PV System Performance
- Lists of performance indicators
- Current results of performance assessment in relation to the indicators

Annex G – Quality Systems
- Audit schedules
- List of audits conducted and completed

Annex H – Products
- List(s) of products covered by the PV system and any notes concerning the MAH per product

Annex I – Document and Record Control
- Logbook
- Documentation of history of changes for Annex contents, indexed accordingly

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Change Control, Logbook, Versions and Archiving

- All changes should be documented in the PSMF for the purpose of change control
- Though PSMF provides a description of the current PV system, especially for audit or inspection, but past functioning and scope of the PV system also important
- Logbook
  - should be used for recording the changes to the PSMF
  - should be such that it provide a history of change(s) along with their respective date and the nature
- A periodic review of the PSMF should be conducted in case it has remained unchanged for a period of time

Thank You