Pharmacovigilance Systems Master File (PSMF)

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PATH
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/measures 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.
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
- OPPV’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:
  - listable - 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 NCA(s);
  - implementation of safety variations to the summary of product characteristics and patient information leaflets
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
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

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<tr>
<th>Annex A - QPPV</th>
<th>Annex B - The Organisational Structure of the MAH</th>
<th>Annex C - Sources of safety data</th>
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</table>
| • The curriculum vitae of the QPPV and associated documents  
• Contract details | • The lists of contracts and agreements | • Lists associated with the description of sources of safety data e.g., affiliates and third-party contacts |

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<tr>
<th>Annex D - Computerised systems and Databases</th>
<th>Annex F - PV Process, and written procedures</th>
<th>Annex F - PV System Performance</th>
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<tr>
<td>• Lists of procedural documents</td>
<td>• Current results of performance assessment in relation to the indicators</td>
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|---------------------------|-------------------|------------------------------------|
| • Audit schedules  
• List of audits conducted and completed | • List(s) of products covered by the PV system and any notes concerning the MAH per product | • Logbook  
• Documentation of history of changes for Annex contents, indexed accordingly |
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, past functioning and scope of the PV system are also important.

- Logbook:
  - Should be used for recording the changes to the PSMF.
  - Should be such that it provides 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