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I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for the preparation, review, approval, update, submission and storage of a Pharmacovigilance System Master File (PSMF) at PharmExpert LLC (Pharmex).

II. SCOPE

This procedure shall apply to the preparation and maintenance process of PSMF outsourced by Marketing Authorization Holders (MAH) to Pharmex in line with the agreement.

III. RESPONSIBILITIES

Role	Responsibility
Senior Pharmacovigilance Specialist (SPVS)	• Preparation and updating of the PSMF • Assigning unique issuance and version number to PSMF • Preparation and submission of notification letter • Submission of PSMF to RA
The Head of Pharmacovigilance Department (HPVD)	• To assure this procedure is followed, remains consistent with current practices • Review and approval of the PSMF
Quality Assurance Manager (QAM)	• Ensure limited access to draft of PSMF • Compliance monitoring
MAH's Qualified Person Responsible for Pharmacovigilance (QPPV)	• Review and approval of PSMF

IV. DEFINITIONS

Abbreviations used in the text are spelled out on its first mention.

Pharmacovigilance System Master File (PSMF) − a detailed description of the pharmacovigilance (PV) system used by the MAH with respect to one or more authorised medicinal products.

For terms and definitions refer to the SOP-QA-003 «Pharmacovigilance Glossary».

V. PROCEDURE

A. General specification

1. MAH's responsibility

a) The MAH has to operate a PV System for the fulfilment of his legal responsibilities.

b) PSMF as a detailed description of the PV System used by the MAH in order to ensure safety and documents the compliance with the legal PV requirements.

c) The PSMF allows for the proper planning and execution of the MAH's PV System audits, as well as inspections of the Regulatory Authority (RA), allow full traceability of changes which makes it possible to make an overall assessment by the RA at the authorization and post-marketing authorization stages.

d) The PSMF shall be located either at the site where main PV activities are performed or at the site where the QPPV operates.

e) The PSMF can be in paper or electronic format.

2. The sections of the PSMF:

I. QPPV
II. MAH's organizational structure
III. Safety data sources
IV. Computerized systems and databases
V. PV processes
VI. PV system performance
VII. Quality system
VIII. Annexes

B. Process

Process Stages and Steps
1. PMSF Preparation
SPVS: a) For preparation of a new PSMF use the subfolders: «drafts», «under review» and «released». Folder path: <QA/Document development/PSMF preparation>. b) Use the «PSMF Template» (R01T-SOP-QA-006). c) Request from the MAH's QPPV information and documents needed to complete the «PSMF Template». **Note.** Timeline for PSMF preparation and revision is specified in the agreement signed with the Client. d) Ensure that all received information, documents are complete and valid in accordance with regulatory requirements.

PHARMACOVIGILANCE SYSTEM MASTER-FILE

PSMF-XYZ-MMYY

MARKETING AUTHORISATION HOLDER'S NAME AND ADDRESS:
<Name>
<Address>
<E-mail address> (contact person)
NAME AND CONTACT DETAILS OF THE QPPV:
<Name>
<Address>
<Telephone number>
<Fax number>
<E-mail address>
NAME OF OTHER CONCERNED MAH(s) (*sharing the pharmacovigilance system*) (*if applicable*)
LIST OF PSMFs FOR THE MAH (*concerning products with a different pharmacovigilance system*)
DATE OF PREPARATION/LAST UPDATE:
SIGNATURE:

1. PHARMACOVIGILANCE PROCESSES AND WRITTEN PROCEDURES

1.1. The continuous monitoring of the risk-benefit balance of the medicinal product(s)

1.2. Collection, assessment and reporting of individual case safety reports

1.3. Transmission of safety data to CA

1.4. Operation of the risk management system(s)

1.5. Planning, drafting and submission of periodic safety update reports

1.6. Procedures for communicating safety concerns and safety variations

1.7. Implementation of safety variations to the instruction for medical use

A description of data handling and records for the performance of pharmacovigilance, covering the following aspects shall be included (but not limited to):

- continuous monitoring of medicinal product risk-benefit profile(s), result of evaluation, decision making process for taking appropriate measures; signal generation, its detection and evaluation, list of standard operating procedures, instructions, working instructions concerning safety database outputs, interactions with other organization departments of the applicant, etc;

- risk management system(s) and monitoring of the outcome of risk minimisation measures. Several organization departments of the applicant may be involved in this area and interactions should be defined in SOP or agreements;

- ICSR collection, collation, follow-up, assessment and reporting. The procedures applied to this area should clarify what are central and what are local activities;

- PSUR scheduling, production and submission;

- communication of safety concerns to consumers, healthcare professionals and the authorized body;

- implementation of safety variations to the instruction for medical use. Procedures should cover both internal and external communications on safety issues.

The description must be accompanied by the list of SOPs, instructions, working instructions related to compliance management, as well as interfaces with other functions, which include (but are not limited to) the roles and responsibilities of the QPPV/LQPPV, responding to authorized body requests for information, scientific and medical literature searching, safety database change control, safety data exchange agreements, safety data archiving, pharmacovigilance auditing, quality control and training. The list, which may be located in the Annexes, should comprise the reference number, title, effective date and document type (for all SOP, instructions, work instructions etc.). Procedures belonging to service providers and other third parties should be clearly identified.