Template: Documentation for Preparation of a Supervisory Authority Pharmacovigilance Inspection
Last updated: August 2020

Points to consider

The description of the pharmacovigilance system should include clear information on the responsibilities and processes. For this purpose, diagrams or flowcharts may be placed in the body of this main document. **It is encouraged to refer to the PSMF (see 6.4), only additional information should be included in the main document.** Regarding the documents to be submitted, we ask you to use precise and short names (max. 30 characters, e.g. 2.6_CV_Deputy or 6.4_PSMF_AnnexA_CV_QPPV) and as few folder levels as possible.

Content and structure of the documentation

1. General information

1.1 Names and job titles of contact persons for the pharmacovigilance inspection, including telephone and fax numbers as well as e-mail addresses
1.2 Name and address of the premises to be inspected, including telephone and fax numbers
1.3 Name and address of the German office including telephone number(s) and website (if different from 1.2)
1.4 Name and address of the group / holding company including the website

2. Graduated Plan Officer (GPO, Stufenplanbeauftragter)

2.1 Name and job title of the GPO
2.2 Address of the premises where the GPO is permanently active
2.3 Name and job title of deputies of the GPO
2.4 Description of the back-up arrangement (see also 6.4)
2.5 Telephone, fax and "24/7" telephone numbers
2.6 CVs and job descriptions for the GPO and deputies

3. Brief description of changes to the company's structure

Recent acquisitions or fusions for the whole company, including the consequences for the pharmacovigilance system.

4. Pharmacovigilance system

4.1 Summary of the organisational structure of the pharmacovigilance system within the company group, especially with focus on the German site/affiliate (information on the sites within the company involved in pharmacovigilance and their relationship to the site to be inspected, including the main pharmacovigilance activities carried out at these sites)
4.2 Description of the pharmacovigilance activities of the German site(s) (in conjunction with the global pharmacovigilance unit), organisational charts/diagrams of the pharmacovigilance department(s) in Germany, including names and job titles. Please highlight the processes which are performed differently in Germany from the description in the PSMF for affiliates.
4.3 Description of the pharmacovigilance activities carried out by other departments in conjunction with the German pharmacovigilance department (e.g. medical information, product quality (e.g. product technical complaints), regulatory affairs)
4.4 Information on all activities and functions outsourced from the German unit that are directly or indirectly related to pharmacovigilance
4.5 Description of the flow of information and processing of safety-relevant data (ADR reports) from various sources from receipt to reporting to the competent authorities, illustrated in flowcharts where appropriate. It should be clearly depicted which activities are performed by the German unit and which ones by other units.

4.6 Description of the internal monitoring of reporting deadlines and regulatory requirements when recording drug risks, especially regarding the German site

4.7 Description of workflows for signal generation, risk-benefit assessment and modification of product information, especially regarding the German site

4.8 Presentation of the measures to be taken in the event of pharmacovigilance and quality defects or combined defects:

- Action plan
- Urgent Safety Restriction (USR), safety variation, Direct Healthcare Professional Communications (DHPC)
- Implementation of orders from graduated plan procedures, DHCPs / Rote Hand Briefe (“Red Hand Letter”)
- Information of competent authorities, healthcare professionals and the public
- Recall (complete, batch-related)

4.9 Pharmacovigilance tasks in which the Graduated Plan Officer is routinely involved

4.10 Tabular overview of the medicinal products for which additional risk minimisation measures have been imposed in the past 3 years in Germany and/or the EU (e.g. educational material, including updates) including overview of the specific risk minimisation measures

5. Electronic data acquisition systems

5.1 National data collection system

Detailed description of all computerised systems used at the German site for collection and evaluation of ADR reports from Germany. Interactions between the systems should be clarified, i.e. using diagrams

5.2 Data back-up and restoration of operational capability (disaster recovery) at the German site

Description of the (daily) data back-up, indication of whether "redundant" systems are present (e.g. are there independent database servers in different buildings or locations, which can take over the complete operation)

5.3 Previous situation:

Brief summary of the previous data collection systems for the collection, compilation and evaluation of ADR reports over the last 5 years

6. Quality management system

6.1 Brief description of quality management system at the German site, including:

- Responsibilities for internal audits of the pharmacovigilance system
- Retention time and storage of audit reports

6.2 Will the pharmacovigilance system be maintained in its current status for at least 6 months or are changes planned? If changes are planned, these should be described.

6.3 List of written procedures for pharmacovigilance (as a matrix table with the following elements: 1. legally required pharmacovigilance activity in keywords according to the implementing regulation and GVP; 2. SOP title; 3. version number; 4. date of entry into force), if not contained in Annex E of the PSMF

- Global
- Regional (EU), if applicable
- Local (Germany)

6.4 Copies of procedures and documents relating to the following topics must be attached:

- Information flow and processing of ADR reports from the spontaneous collection system from receipt to reporting to the competent authorities
- Follow-up of individual case reports
- Reporting of 15-day reports to the competent authority, including internal monitoring of expedited reporting dates
- Preparation of PSURs and submission
- Signal detection/trend analysis
- Action plan

- Template (or example) pharmacovigilance agreement between the pharmacovigilance unit (or global pharmacovigilance unit) to be inspected and pharmacovigilance service provider (e.g. service contract + service level agreement)
- Template (or example) pharmacovigilance agreement between the pharmacovigilance unit (or global pharmacovigilance unit) to be inspected and the licensing partner (e.g. licensing agreement + safety data exchange agreement)
- Template (or example) pharmacovigilance contract between the pharmacovigilance unit (or global pharmacovigilance unit) to be inspected and the sales organisation (or affiliate) (e.g. delineation of responsibilities agreement, PVAs/SDEAs)
- **Current** Pharmacovigilance System Master File (PSMF)
- Maintenance of the PSMF (PSMF SOP)
- Tasks of the QPPV (QPPV SOP)
- Back-up procedure QPPV - deputy QPPV (SOP)
- Tasks of the Graduated Plan Officer (StpB SOP)
- Back-up procedure for the Graduated Plan Officer - Deputy Graduated Plan Officer (SOP)
- Audit system in pharmacovigilance including risk-based approach (Audit SOP)
- Audit plan (German site)

7. Training system

Brief description of the training system in Germany for staff in key positions in the pharmacovigilance system, including information on success controls, the location of the documentation of the training, CVs and job descriptions

8. Archiving

Brief description of archiving of pharmacovigilance documents, including data protection and access authorisations, for the German site. If other companies have been commissioned with the archiving of pharmacovigilance documents, the names and addresses of these companies are to be stated (if divergent from global archiving system)

9. Drug-related safety issues

Details of all medicinal products withdrawn from the market for safety reasons in any country within the last 5 years, i.e. date of cessation of distribution or recall (initiated through regulatory authority or company), countries affected and nature of safety risk

10. Licensing agreements

List of all local (Germany) licence agreements with third parties concerning any medicinal products regardless of their current marketing status

11. Lists of medicinal products

11.1 List of standard marketing authorisations used in Germany according to § 36 (medicinal products, active substance(s), marketed yes/no)

11.2 List of local products (EU, with country indication), i.e. drugs authorised in individual countries, for which pharmacovigilance is carried out at the local site

Date, Name, Signature