

Detailed Description of the Pharmacovigilance System for Parallel Imported Products

These requirements must be satisfied for all Standard and Complex Parallel Import Licences (including those submitted before the additional types were introduced) and for Simple Parallel Import licences where the UK reference product marketing authorisation has been cancelled.

Reference: Volume 9A of the Rules Governing Medicinal Products in the European Union: Guidelines on Pharmacovigilance for Medicinal Products for Human Use:

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol9_en.htm

2. Detailed Description of the Pharmacovigilance System

2.1. Location in the Marketing Authorisation Application

The detailed description of the pharmacovigilance system, including the proof of the availability of the services of the QPPV and the proof that the parallel import licence holder has the necessary means for the collection and notification of any adverse reaction, should be provided.

2.2. Statement of the Parallel Import Licence Holder and the Qualified Person for Pharmacovigilance (QPPV) Regarding their Availability and the Means for the Notification of Adverse Reactions

The statement, including the signature of the licence holder and of the QPPV, and confirming the availability of the services of the QPPV and of the necessary means for the collection and notification of any adverse reaction occurring either in the Community or in a third country must be provided.

2.3. Elements of the Detailed description of the Pharmacovigilance System

2.3.a. Qualified Person Responsible for Pharmacovigilance

The company's **QPPV name**, the address and contact details.

A summary **CV** of the QPPV should be provided (as appendix).

A summary **job description** of the QPPV should be provided (as appendix).

The description of the **back-up procedure** in the absence of the QPPV (e.g. deputy QPPV, 24/7 telephone cover, drug safety hotline, other back-up procedure in place) should be included.

The name and contact details of the deputy QPPV and a CV depicting their experience in pharmacovigilance.

2.3.b. Organisation

Company's **units and other organisations** should be listed where principal EEA and global pharmacovigilance activities are undertaken (location of the QPPV and fulfilment of related responsibilities, main location of the safety database, collection and management of adverse events, reporting (expedited, electronic, periodic) to the local/regional national authorities, medical review and assessment, ASPR/PSUR generation, signal detection, risk management, pharmacovigilance training, etc.).

The **point(s) in Community** where pharmacovigilance data (ICSRs, PSURs and global pharmacovigilance data) are accessible should be listed.

A high level organisation chart depicting an overview of the global and EEA pharmacovigilance units and the relationships between them and other departments/units/contractors/internal quality assurance. The chart should clearly show the position of the QPPV in the pharmacovigilance system of the company (no names).

A flow chart indicating the flow of safety reports from various sources (from licence holder, affiliates, contract organisations) and of different types from the receipt of the safety information to the final stage of reporting to the applicable regulatory authorities must be provided. A timeline for the individual stages of the process should be shown.

2.3.c. Documented procedures

The company should provide details of the **written procedures/SOPs/working instructions/policies/guidelines** addressing the following pharmacovigilance activities. Where procedures are in preparation, this should be indicated with a deadline for their finalisation.

- The activities of the QPPV and the back-up procedure to apply in their absence;
- The collection, processing (including data entry and data management), quality control, coding, classification, medical review and reporting of ICSRs:
 - Reports of different types:
 - Organised data collection schemes (solicited), unsolicited, clinical trials, literature
 - The process should ensure that reports from different sources are captured:
 - EEA and third countries, healthcare professionals, sales and marketing personnel, other Marketing Authorisation Holder personnel, licensing partners, Competent Authorities, compassionate use, patients, others;
- The follow-up of reports for missing information and for information on the progress and outcome of the case(s);
- Detection of duplicate reports;
- Expedited reporting;
- Electronic reporting;
- Periodic Safety Update Reports (PSURs):
 - The preparation, processing, quality control, review (including medical review) and reporting;

- Global pharmacovigilance activities applying to all products: Continuous monitoring of the safety profile of authorised medicinal products (product-specific risk management systems and pharmacovigilance planning are covered in Chapter I.3.):
 - Signal detection and review,
 - Risk-benefit assessment;
 - Reporting and communication notifying Competent Authorities and healthcare professionals of changes to the risk-benefit balance of products, etc;
- Interaction between safety issues and product defects;
- Responses to requests for information from regulatory authorities;
- Handling of urgent safety restrictions and safety variations;
- Meeting commitments to Competent Authorities in relation to a marketing authorisation;
- Global pharmacovigilance activities applying to all products (signal detection, evaluation, reporting, communication etc.);
- Management and use of databases or other recording systems;
- Internal audit of the pharmacovigilance system;
- Training;
- Archiving.

Where there is no procedure in place, a description of how the activity is performed should be provided.

2.3.d. Databases

The listing of global **safety databases**/electronic data collection systems and their brief functional description (collection, tracking, processing of safety information received from different sources, generation of regulatory reports, safety signal analysis, coding, medical review, triage of adverse events, generation of E2B files, electronic submission of the ICSRs to the NCAs, etc.) shall be provided.

Statement regarding the **validation status** of the databases must be included.

Statement confirming that the electronic system, including the components of electronic reporting, is compliant with the **ICH internationally agreed standards for electronic reporting** to the Competent Authorities [E2B (M2)] must be provided.

Copy of the **QPPV's registration with the EudraVigilance** database must be enclosed (as an attachment).

The indication of the **responsibility for the safe operation**, maintenance and upgrades of the database is to be provided along with an indication of their location.

2.3.e. Contractual Arrangements with Other Persons or Organisations Involved in the Fulfilment of Pharmacovigilance Obligations

Major **subcontracting arrangements for the conduct of pharmacovigilance activities** (role of the QPPV, electronic reporting of ICSRs, safety database, signal detection,

compilation of PSURs, etc.) and the principal organisations to which these are outsourced shall be described. An example is given below:

Activity	Agreement in place	responsible company/subcontractor
e.g. expedited reporting if ICSRs, submission of PSURs, pharmacovigilance audits, literature review, archiving of documents, etc.		e.g. company, organisation, sub-contractor, vendor, etc.

The nature of the agreements with the co-marketing partners and contractors for pharmacovigilance activities must be indicated.

The company's **co-licensing and co-marketing arrangements in the EEA** and identification of major responsibilities should be given.

If co-licensing, co-marketing and subcontracting activities are product-specific, these have to be summarised in a **product-specific addendum**.

2.3.f. Training

A brief description of training provided to the pharmacovigilance and non-pharmacovigilance staff shall be given. The department/unit/sub-contractor/vendor, etc., responsible for pharmacovigilance training should be identified and the review period for pharmacovigilance training should be stated.

The global/regional safety **location, headquarters**, etc. responsible for filing and maintenance of personal training files containing training records, CVs and job descriptions should be named.

2.3.g. Documentation

The main locations where different types of pharmacovigilance documentation are stored should be described. An example is given below:

Type of documentation	Location	Type of storage
e.g. SAE forms and related documents, ICSRs from clinical trials, pregnancy forms, spontaneous reports, quality assurance (SOPs), PSURs, etc.		e.g. paper, electronic, microfiche, CD.

Detail of retention time for archived materials should be specified along with the procedures for back up. Detail of the security aspect of the storage and the level of access should be provided.

2.3.h. Quality Management System

The quality management system of the company should be described. This should specify what the organisational roles and responsibilities for pharmacovigilance activities and documentation are. The measures taken for ensuring corrective and preventative action and who is responsible for this should be provided.

The responsibility for quality assurance and pharmacovigilance system auditing (including subcontractors) should also be given, and a description provided for how internal and external auditing is performed and how often.