



Zambia Medicines Regulatory Authority

GUIDELINES FOR CONDUCTING VIGILANCE INSPECTIONS

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i. Abbreviations

CAPA	Corrective and Preventative Action
CIOMS	Council for International Organizations of Medicinal Sciences
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GLP	Good Laboratory Practices
GVP	Good Vigilance Practices
ICSR	Individual Case Safety Report
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
PASS	Post Authorisation Safety Study
PAES	Post Authorisation Efficacy Study
PSUR	Periodic Safety Update Report
PBRER	Periodic Benefit Risk Evaluation Report
RMP	Risk Management Plan
SOP	Standard Operating Procedures
QPPV	Qualified Person for Pharmacovigilance



ii. Definitions

In these guidelines, unless the context otherwise states: -

“Authority” means the Zambia Medicines Regulatory Authority

“Local responsible person” means a person residing in Zambia and appointed by a foreign based applicant to—

- a) submit an application, document and sample of products to the Authority on behalf of the applicant or holder of the marketing authorisation; and
- b) receive the decision of the Authority relating to the application on behalf of the applicant or holder of the marketing authorisation.
- c) implement the pharmacovigilance plan on behalf of the foreign holder of the marketing authorisation.

“Marketing Authorisation Holder” means a person to whom a medicinal product has been issued a market authorization and is responsible for all aspects of the medicinal product including quality, safety, efficacy and compliance with conditions of marketing authorization.

“Pharmacovigilance System Master File” means a document which describes the pharmacovigilance system for one or more products of the Marketing Authorisation Holder.

“Qualified Person for Pharmacovigilance” means an individual appointed by a Marketing Authorisation Holder and approved by the Authority as the person responsible for ensuring that the company (the MAH) meets its legal obligations in monitoring the safety of their products granted Marketing Authorisation in Zambia.

“Risk Management Plan” A systematic approach and set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to products, and the assessment of effectiveness of those interventions and how these risks will be communicated to the Authority and the general population.

In this guideline Pharmacovigilance and vigilance will be used interchangeably.

Version 1



1. Introduction

The Authority will conduct Vigilance inspections of a Marketing Authorisation Holder whose product has been granted Marketing Authorisation to ensure that they comply with vigilance regulatory obligations. Vigilance Inspections may be routine or unannounced (in the case of suspected non-compliance). The results of the inspection will be used to help the Marketing Authorisation Holder (MAH) improve compliance and may also be used as a basis for regulatory action. The scheduling and conduct of these inspections will be driven by routine programmes and risk analysis criteria.

2. Requirements

2.1 General Requirements

2.1.1. Vigilance Inspections

To ensure the MAH and the delegated local qualified person for Pharmacovigilance (QPPV) comply with Vigilance regulatory requirements and facilitate compliance, the Authority will conduct Vigilance inspections.

The inspection will be conducted at the site where Vigilance activities of a Marketing Authorisation Holder are undertaken.

2.1.2. Objectives of Vigilance Inspections

- a) To ensure compliance of the vigilance system with the legislation and guidelines provided by the Authority.
- b) To ensure that the MAH has personnel, systems and facilities in place to meet their vigilance obligations.
- c) To identify, record and address non-compliance which may pose a risk to patients and public health.
- d) To use the inspection results as a basis for appropriate regulatory action.



2.1.3. Types of Vigilance Inspections

a) Routine Inspections

These are scheduled inspections that MAH and qualified person for Pharmacovigilance will undergo at periods determined by the Authority. The frequency of routine inspections will be determined based on a risk analysis criterion.

MAH and local QPPV will be given advance notices of these inspections, at least 14 days prior to the inspection. These inspections will be aimed at identifying whether the MAHs have the personnel, systems and facilities in place to meet their vigilance regulatory obligations for products granted Marketing Authorisation.

These inspections may be requested with one or more specific products selected as examples for which specific information can be traced and verified through the various processes, to provide practical evidence of the functioning of the vigilance system of the MAH and their compliance with their regulatory obligations.

b) For cause inspections

These are unannounced inspections that are triggered by, for example, safety issues and/or suspected violations of legislation relating to safety monitoring of products. For cause or unannounced inspections will focus on specific vigilance processes or examination of identified compliance issues and their impact on a specific product. However, full system inspections may also be performed resulting from a trigger. Under these circumstances the MAH or the local QPPV will not be notified of these inspections in advance.

c) Re-inspections

A re-inspection will be conducted on a routine basis as part of a routine inspection programme. Risk factors will be assessed to prioritise re-inspections.



The scope of re-inspection will depend on the inspection history. It may include but not be limited to the following:

- i. A review of the corrective and preventive action(s) resulting from previous vigilance inspection;
- ii. A review of significant changes that have been made to the vigilance system since the last vigilance inspection;
- iii. A review of the process and/or issues not covered in the previous inspection;
- iv. Review of the whole vigilance system, especially if a long time has elapsed since the previous inspection.

Early re-inspection may take place where significant non-compliance has been identified or when the Authority has concerns regarding one or more of the above stated points.

d) System inspection

Vigilance system inspections are designed to review the procedures, systems, personnel, and facilities in place and determine their compliance with regulatory vigilance obligations. As part of this review, product specific examples may be used to demonstrate the operation of the vigilance system.

e) Product related inspections

Product-related vigilance inspections are primarily focused on product-related vigilance issues, including product-specific activities and documentation, rather than a general system review. Some aspects of the general system may still be examined as part of a product-related inspection (e.g. the system used for that product).

2.2 Specific Requirements

2.2.1 The Inspection Schedule

The Authority will carry out vigilance inspection of Marketing Authorisation Holders. The MAH will be inspected at least once every 4 years, subject to risk assessment. Routine inspections will



be separate from any “for cause” inspections, but if a “for cause” inspection takes place it may replace the need for a routine inspection, depending on its scope.

2.2.2 Inspection Planning and prioritisation

The Pharmacovigilance inspection planning will be based on a systematic and risk-based approach to enable the frequency, scope and breadth of inspections to be determined accordingly.

a) Factors for risk-based approach planning of routine inspections

Factors which may be taken into consideration, as appropriate, include, but are not limited to:

- i. **inspection related:**
 - compliance history identified during previous vigilance inspections or other types of inspections (GCP, GMP, GLP and GDP);
 - re-inspection date recommended by the inspectors or assessors due to a previous inspection;
- ii. **product related:**
 - product with additional vigilance activities or risk-minimisation activities;
 - authorisation with conditions associated with safety, e.g. requirement for post-authorisation safety studies (PASS);
 - product(s) with large sales volume, i.e. products associated with large patient exposure in Zambia;
 - product(s) with limited alternatives on the market;
- iii. **MAH related:**
 - MAH that has never been subject to a vigilance inspection;
 - MAH with many products on the market in Zambia;
 - resources available to the MAH for the vigilance activities they undertake;
 - MAH with no previous marketing authorisations in Zambia;
 - negative information and/or safety concerns raised by the Authority (i.e. GCP, GMP, GLP and GDP);
 - changes in the MAH organisation, such as mergers and acquisitions;
- iv. **pharmacovigilance system related:**



- MAH with sub-contracted pharmacovigilance activities and/or multiple firms employed to perform pharmacovigilance activities
- change of QPPV since the last inspection;
- changes to the pharmacovigilance safety database(s), which could include a change in the database itself or associated databases, the validation status of the database as well as information about transferred or migrated data;
- changes in contractual arrangements with pharmacovigilance service providers or the sites at which pharmacovigilance is conducted;
- delegation or transfer of pharmacovigilance system master file management.

b) Triggers of “For-cause inspections”

Unlike routine inspections; the “For-cause inspections” may arise when, for example, one or more of the triggers listed below are identified:

i. Risk-benefit balance of the product:

- change in the risk-benefit balance where further examination through an inspection is considered appropriate;
- delays or failure to identify or communicate a risk or a change in the risk-benefit balance;
- communication of information on pharmacovigilance concerns to the public without giving prior or simultaneous notification to the Authority, as applicable;
- non-compliance or product safety issues identified during the monitoring of pharmacovigilance activities by the Authority;
- suspension or product withdrawal with no advance notice to the Authority;

ii. Reporting obligations (expedited and periodic):

- delays or omissions in reporting;
- poor quality or incomplete reports;
- inconsistencies between reports and other information sources;
- failure to provide the requested information or data within the deadline specified by the Authority;
- poor quality or inadequate provision of data to fulfil requests for information from the Authority;

iii. Fulfilment of commitments:



- concerns about the status or fulfilment of risk management plan (RMP) commitments;
- delays or failure to carry out specific obligations relating to the monitoring of product safety, identified at the time of the marketing authorisation;
- poor quality of reports requested as specific obligations;
- delays in the implementation or inappropriate implementation of corrective and preventive actions;
- information such as non-compliance or product safety issues from other types of inspections (GCP, GMP, GLP and GDP);
- inspection information received from other authorities, which may highlight issues of noncompliance;

iv. **Other triggers may include but not limited to:**

- concerns following review of the pharmacovigilance system master file;
- non-inspection related information received from other authorities, which may highlight issues of non-compliance;
- other sources of information or complaints.

2.2.3 Announcement of inspections

Most inspections will be announced i.e. notified in advance to the party to be inspected, to ensure the availability of relevant individuals for the inspection. However, on occasion, it may be appropriate to conduct unannounced inspections or to announce an inspection at short notice (e.g. when the announcement could compromise the objectives of the inspection or when the inspection is conducted in a short timeframe due to urgent safety reasons).

2.2.4 Sites to be inspected

Any party carrying out vigilance activities in whole or in part, on behalf of, or in conjunction with the MAH may be inspected, to confirm their capability to support the MAH's compliance with pharmacovigilance obligations.

The sites to be inspected may be located within or outside Zambia. The latter might be appropriate where the main pharmacovigilance functions, databases and/or activities are located outside Zambia.



The type and number of sites to be inspected will be selected appropriately to ensure that the key objectives within the scope of the inspection are met.

2.2.5 Scope of the Inspection

The inspection scope will depend on the objectives of the inspection as well as the coverage of any previous inspections. The following elements will be considered when preparing the scope of the inspection, as applicable:

- information supplied in the Pharmacovigilance System Master File;
- information concerning the functioning of the pharmacovigilance system, e.g. compliance data available at the Authority;
- specific triggers;

It may be appropriate for additional data to be requested in advance of an inspection to select appropriate sites or clarify aspects of the pharmacovigilance system.

The pharmacovigilance inspections will include a review of the following elements, as appropriate:

a) Individual Case Safety Reports (ICSRs):

- collecting, receiving and exchanging reports - from all types of sources, sites and departments within the pharmacovigilance system, including from those firms employed to fulfil MAH's pharmacovigilance obligations and departments other than drug safety;
- assessment, including mechanisms for obtaining and recording reporter assessments, company application of event terms, seriousness, expectedness and causality. In addition to examples of ICSRs from within Zambia, examples of ICSRs reported from outside Zambia should be examined as part of this review (if applicable);
- follow-up and outcome recording, for example outcome of cases of exposure in pregnancy and medical confirmation of consumer reported events;
- reporting according to the requirements for various types of reported ICSRs, including onward reporting to the relevant bodies and timeliness of such reporting;
- record keeping and archiving for ICSRs;



b) Periodic Benefit Risk Evaluation Reports (PBRERs), as applicable:

- completeness and accuracy of the data included, appropriateness of decisions concerning data that are not included;
- addressing safety topics, providing relevant analyses and actions;
- formatting according to requirements;
- timeliness of submissions;
- ongoing safety evaluation use of all relevant sources of information for signal detection;
- appropriately applied methodology concerning analysis;
- appropriateness of investigations and follow-up actions, e.g. the implementation of recommendations following data review;
- implementation of the RMP, or other commitments, e.g. conditions of marketing authorisation;
- timely identification and provision of complete and accurate data to the competent authority(ies), in particular in response to specific requests for data;
- implementation of approved changes to safety communications and product information, including internal distribution and external publication;

c) Interventional (where appropriate) and non-interventional clinical trials:

- reporting suspected unexpected, serious adverse reactions (SUSARs);
- receiving, recording and assessing cases from interventional and non-interventional trials (see ICSRs);
- submission of study results and relevant safety information (e.g. development safety update reports (DSURs) and information included in PBRER), where applicable, PASS or post authorization efficacy studies (PAES) submissions, particularly when associated with specific obligations or RMP commitments;
- appropriate selection of reference safety information, maintenance of investigator brochures and patient information with respect to safety;
- the inclusion of study data in ongoing safety evaluation;



d) pharmacovigilance system:

- QPPV roles and responsibilities, e.g. access to the quality system, the pharmacovigilance system master file, performance metrics, audit and inspection reports, and their ability to take action to improve compliance;
- the roles and responsibilities of the MAH in relation to the pharmacovigilance system;
- accuracy, completeness and maintenance of the pharmacovigilance system master file;
- quality and adequacy of training, qualifications and experience of staff;
- coverage and adherence to the quality system in relation to pharmacovigilance, including quality control and quality assurance processes;
- fitness for purpose of computerised systems;
- contracts and agreements with all relevant parties appropriately reflect responsibilities and activities in the fulfilment of pharmacovigilance and are adhered to.

The inspection may include the system for the fulfilment of conditions of a marketing authorisation and the implementation of risk–minimization activities, as they relate to any of the above safety topics.

For cause inspections

The scope of the inspection will depend on the specific trigger(s). and may include but not limited to:

- QPPV involvement and awareness of product-specific issues;
- In-depth examination of processes, decision-making, communications and actions relating to a specific trigger and/or product.

If a “for cause” inspection has been or will be conducted in a similar timeframe as a routine one, it may replace the need for the planned routine inspection and the program will be revised to reflect this.

2.3 Phases of the Inspection Process

There are three main phases of each pharmacovigilance inspection:



2.3.1 Planning and Pre-inspection

A preliminary notification to the MAH or qualified person for pharmacovigilance about the scheduled inspection will be sent and pertinent documents to facilitate the inspection will be requested by the Authority, at least 14 days to the scheduled inspection date. The date for the inspection will be agreed with the local QPPV or the MAH, in the case of routine inspections.

The Authority may request the following documents prior to the inspection. This may include but not limited to:

- a) Pharmacovigilance System Master File (PSMF) to reflect Zambian Pharmacovigilance system including but not limited to human resource for pharmacovigilance, organizational chart for pharmacovigilance, contract agreements, job description of the local QPPV and other staff involved in pharmacovigilance, information relating to the local QPPV, SOPs, training records and training materials used for pharmacovigilance training and other work instructions. (*For details refer to Annex I*);
- b) Minutes of meetings specific to pharmacovigilance;
- c) Individual adverse reaction case files and CIOMS reports;
- d) Recent PSURs / PBRERs for products granted MA;
- e) Zambia specific RMPs for selected products when applicable;
- f) Line listings of adverse reaction reports;
- g) Evidence of investigations of pharmacovigilance related-issues;
- h) Evidence of mechanism for product recalls; and
- i) Evidence of a mechanism in place for periodic product reviews performed by manufacturing site.

2.3.2 Conduct of Inspection

The inspection may be conducted at the MAH's location or the local QPPV's location and if a sub-contracted organisation is involved in any pharmacovigilance activity, their site may also be



inspected by the Authority. The inspection will commence with an opening meeting and end with a closing meeting. The MAH may designate, in addition to the local QPPV, key personnel in the pharmacovigilance system to participate in these meetings.

Vigilance inspections will consist mainly of the following:

- a) **Opening meeting:** held between the inspection team and the local QPPV of the MAH being inspected
- b) **Collecting and verifying information:** depending on the type and scope of the inspection, this includes:
 - review of relevant documents;
 - review of processes
 - examination of computer systems;
 - conduct of interviews;
 - review of internal and external communication
- c) **Closing meeting:** held at the end of the inspection, between the inspection team and the local QPPV of the inspected MAH.

2.3.3 Reporting on Inspection

In general, preliminary findings will be communicated at the closing meeting. An inspection report is then prepared and reviewed internally to ensure consistency of classification of deficiencies prior to issue of the final report. The report is sent to the local responsible person or MAH, usually within 30 days of the site visit or the date of the provision of the last document requested. It should be noted that the factual matter contained in the inspection report relates only to those things that the inspection team sees and hears during the inspection process.

Deficiencies found during the Authority's vigilance inspections will be graded as follows:

- i. **Critical:** A deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable regulations and guidelines.
Deficiencies classified as critical may include a pattern of deviations classified as major.



A critical deficiency also occurs when a MAH or local representative is observed to have engaged in fraud, misrepresentation or falsification of data.

- ii. **Major:** A deficiency in pharmacovigilance systems, practices or processes that could potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable regulations and guidelines.

Deficiencies classified as major may include a pattern of deviations classified as minor.

- iii. **Minor:** A deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the whole pharmacovigilance system or process and/or the rights, safety or well-being of patients.

Deficiencies from a previous inspection that have not been addressed as required can be upgraded to a higher grade.

2.3.4 Inspection follow-up

When non-compliance with pharmacovigilance obligations is identified during an inspection, follow-up will be required until a corrective and preventive action plan is completed. The following follow-up actions should be considered, as appropriate:

- i. requests for a meeting with the MAH to discuss the deficiencies, the impact of the deficiencies and action plans;
- ii. review of the MAH's corrective and preventive action plan;
- iii. review of the periodic progress reports, when deemed necessary;
- iv. re-inspection to assess appropriate implementation of the corrective and preventive action plan;
- v. requests for submission of previously un-submitted data; submission of impact analyses, e.g. following review of data that were not previously considered during routine signal detection activities;



2.3.5 Responding to Findings

Following the issue of the inspection report, the MAH is requested to respond to any deficiencies identified and to provide the Authority with an appropriate Corrective and Preventive Action (CAPA) within 30 days or a deadline to be determined by the Authority based on the criticality or risk of non-compliance identified.

The MAH may be required to provide reports and where necessary evidence of the progress and completion of the action plan. There may be re-inspection at an appropriate time to verify the progress and success of these remedial actions.

Note that, in some circumstances, the MAH may be required to take immediate action to address a critical or major finding, for the protection of public health and safety.

Where required, evidence of completion of all CAPAs should be submitted to the Authority not later than 30 days following their completion.

2.4 Record Management and Archiving

The MAH and delegated local qualified person for pharmacovigilance should ensure that Vigilance data is maintained in a secure area (dedicated for that purpose) and the data should be stored to ensure:

- i. Limited access to data
- ii. Protection of confidentiality of patients
- iii. Protection of information
- iv. Easy retrieval

Documents must be stored in secured location to protect them from hazards (i.e. rodents, flood, fire). Vigilance data should be stored throughout the life cycle of the product.



2.5 Responsibilities of Marketing Authorisation Holder

The Marketing Authorisation Holders and delegated qualified person for pharmacovigilance will be subject to Vigilance inspections. The responsibilities of the MAH in relation to Vigilance inspections include but are not limited to the following:

- a) to always be inspection ready as inspections may be unannounced;
- b) to maintain and make available to the inspectors on request, no later than 7 days after the receipt of a request, the Pharmaco(Vigilance) System Master File;
- c) to ensure that the sites selected for inspection, which may include firms sub-contracted by the MAH to perform pharmacovigilance activities, are ready to be inspected before the inspection is performed;
- d) to make available to the inspectors any information and/or documentation required for the preparation of the inspection within the deadline given or during the conduct of the inspection;
- e) to ensure that relevant staff involved in pharmacovigilance activities or related activities are present and available during the inspection for interviews or clarification of issues identified;
- f) to ensure that relevant pharmacovigilance data is accessible; and
- g) to ensure that appropriate and timely corrective and preventive action plans are implemented to address findings observed during an inspection, with appropriate prioritisation of critical and/or major findings.



3. References

1. Ghana FDA Guidelines for conducting Pharmacovigilance Inspections
 2. EMA Guideline on good pharmacovigilance practices (GVP) Module III, Pharmacovigilance inspections
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4. Annex I: Format for the Pharmacovigilance System Master File

Cover page

- The name of the MAH
- The date of preparation and last update

Section I: Administrative Information

A signed statement that the local responsible person or the MAH has the necessary means to fulfill the tasks and responsibilities listed in the underlisted references:

- Medicines and Allied Substances Act No. 3 of 2013
- Regulations on safety monitoring of medicines
- Guidelines for Qualified Person for Pharmacovigilance
- Guidelines for Reporting Adverse Reaction
- Guidelines for Conducting Pharmacovigilance Inspections
- Guidelines for Safety Monitoring of Medicinal Products

Section II: The local QPPV

- The details of the QPPV, i.e. name and contact details (address, telephone number, fax number, email)
- The Curriculum Vitae (CV) of the QPPV
- The job description of the QPPV
- The proof that the QPPV has attended a pharmacovigilance training and other training programmes
- The proof that the QPPV has been officially designated
- Back-up procedure to apply in the absence of the QPPV and the training provided for the backup
- A signed contract/agreement between the local responsible person or the MAH and the QPPV
- The list of tasks that has been delegated by the QPPV and to whom these have been delegated



Section III: The organizational structure of the MAH

- The description of the organizational structure of the MAH relevant to pharmacovigilance showing the position of the QPPV in the organisation.
- Diagrams showing the organizational charts.
- Any pharmacovigilance related activities performed by third parties.
- Description of co-marketing agreements and contracts of pharmacovigilance activities, if any.
- List of product(s) for which the QPPV is responsible.

Section IV: Sources of Safety Data

- Inflow of adverse reaction reports and safety information.
- Description of the stages involved in the processing of ICSRs including the timelines for submission to regulatory authorities including the Authority.
- Outflow of safety data to the Authority and other regulatory agencies.
- List of the sources of safety data, including but not limited to spontaneous reports, study sources, including any studies, registries, surveillance or support programmes sponsored by the MAH.

Section V: Computerised systems and databases

- Description of the functionality and operational responsibility for computerised systems and databases used to receive, collate, record and report safety information and an assessment of their fitness for purpose.
- Responsibility for the operation of the database and the type of training to be provided to staff involved in the database operations.
- Validation, maintenance, backup and access control.
- Management of the data for paper-based systems should be described and mechanisms used to assure the integrity and accessibility of the safety data, and particularly the collation of information about adverse reactions.

Section VI: Pharmacovigilance processes



- The list of standard operating procedures
 - Details of all the current standard operating procedures relating to pharmacovigilance which are expected including but not limited to the following:
 1. Archiving and retrieval
 2. Corrective and Preventive Action (CAPA) processes for pharmacovigilance
 3. Causality assessment, if applicable
 4. Coding of Individual Case Safety Reports (ICSRs), if applicable
 5. Communication of safety concerns to patients/consumers, healthcare professionals and regulatory authorities
 6. Complaint handling
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7. Deviation Documentation
 8. Escalation of safety issues
 9. Handling of substandard and falsified medicinal products
 10. Internal audits
 11. Literature searches (scientific and lay media)
 12. Management of pharmacovigilance inspections
 13. Manual handling of ICSRs, if applicable
 14. ICSR collection, collation, follow up, assessment and reporting
 15. Review and submission of regulatory documents (e.g. PSURs/PBRERs, RMPs)
 16. Signal generation
 17. SOP for SOPs
 18. Training
 19. Implementation of safety variations to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL), if applicable



20. Risk management system(s) and monitoring of the outcome of risk minimisation measures

Section VII: Pharmacovigilance system performance

Evidence of ongoing monitoring of performance of the pharmacovigilance system including compliance of the main outputs of pharmacovigilance should be described. The description of monitoring methods should include but not limited to the following:

1. An explanation of how the correct reporting of ICSRs is assessed. In the annex, figures/graphs should be provided to show the timeliness of 7-day and 28-day reporting over the past year;
2. A description of any metrics used to monitor the quality of submissions and performance of pharmacovigilance. This should include information provided by competent authorities regarding the quality of ICSR reporting, PSURs or other submissions;
3. Where applicable, an overview of the methods used to ensure timeliness of safety variation submissions compared to internal and competent authority deadlines, including the tracking of required safety variations that have been identified but not yet been submitted; and
4. Where applicable, an overview of adherence to risk management plan commitments, or other obligations or conditions of marketing authorisation(s) relevant to pharmacovigilance.

Targets for the performance of the pharmacovigilance system shall be described and explained and a list of performance indicators must be provided.

Section VIII: Pharmacovigilance Quality system

The pharmacovigilance quality system should include the following:

- *General Overview*

A general description of the quality management system should be provided, in terms of the structure of the organization and the application of the quality to pharmacovigilance.



- *Document and Record Control*

There should be a description of the archiving arrangements for electronic and/or hardcopy versions of the pharmacovigilance system master file, as well as an overview of the procedures applied to other quality system and pharmacovigilance records and documents.

- *Procedural documents*

The description of the types of documents used in pharmacovigilance (standards, operating procedures, work instructions etc) should be provided. The applicability of the various documents at global, regional or local level within the organisation, and the controls that are applied to their accessibility, implementation and maintenance should be described.

A list of specific procedures and processes related to the pharmacovigilance activities and interfaces with other functions, with details of how the procedures can be accessed must be provided.

- *Training*

Qualification and records of training for members of staff in the pharmacovigilance Departments of the local responsible person or the MAH and any individual that may receive safety reports, including employees of local distributors. Updated training materials and records of training programmes should be provided including assessment of the effectiveness of the training programmes as an Annex in the PSMF.

- *Auditing*

Information about quality assurance auditing of the pharmacovigilance system should be included in the PSMF.

A description of the approach used to plan audits of the pharmacovigilance system and the reporting mechanism and timelines should be provided, with a current list of the scheduled and completed audits concerning the pharmacovigilance system maintained in the annex to the PSMF. This list should describe the date(s) (of conduct and of report), scope and completion status of audits of third parties including local distributors. Where there are findings during the audit, the CAPA plans for addressing these should be included in the Annex.

As a means of managing the pharmacovigilance system, and providing a basis for audit or inspection, the PSMF should also describe the process for recording, managing and resolving



deviations from the quality system. The master file shall also document deviations from pharmacovigilance procedures, their impact and management until resolved.

Section IX: Annex to the PSMF

An annex to the PSMF shall contain but not limited to the following documents:

1. A list of products covered by the pharmacovigilance system master file including the name of the product, the name of the active substance(s).
2. list of written policies and procedures for the purpose of complying with the Authority's pharmacovigilance requirements.
3. A list of tasks that have been delegated by the QPPV.
4. A list of all completed audits, for a period of five years, and a list of audit schedules.
5. Where applicable, a list of performance indicators.
6. Updated training materials and records of the training should be provided including assessment of the effectiveness of the training programmes.
7. Pharmacovigilance agreement between the MAH and QPPV.



5. Amendment Sheet

Date identified	Amendment identified by	Short description of the changes proposed to the document	Review of proposed amendment