Guidelines on Reporting of Pharmacovigilance Inspections

1. Introduction

The pharmacovigilance inspection report may be used after a pharmacovigilance inspection to report the registration/authorization holder's status of compliance with the requirements to appropriate units within the Ministry, or to determine the further steps to be taken, if necessary, to improve compliance, or as basis for regulatory action.

The inspections will be coordinated by the relevant unit, and carried out by an appropriate inspection unit, established based on the nature of the inspection involved.

2. Preparing the Inspection Report

An inspection report is prepared for each department/site inspected. All major or critical findings noted for the departments/sites inspected will be addressed in this document, along with an assessment of the impact of the findings and recommendations on the action that needs to be taken. If the inspectors identify urgent critical findings when conducting the inspection or during preparation of the report, they may notify the situation to the relevant unit within the Ministry before submitting the inspection report.

In certain circumstances, preparing a single report may be appropriate for two or more sites, even if each have undergone separate inspections (e.g., a specific process of a registration/authorization holder is inspected at two or more sites worldwide, but consolidating the findings of the inspections is found useful since they relate to the elements of the same process). However, this should be indicated and a rationale therefor given in the inspection report.

3. Inspection Report

The minimum information that must be contained in the inspection report is outlined in Appendix 1.

The inspection report is prepared according to a common format and should be completed within thirty days of concluding the inspection. Where the inspectors require the parties inspected to submit information the inspectors see relevant for the completion of the report, the report preparation time may be extended for a further thirty days after receipt of the last document requested. The inspection team will have completed examining, interpreting, and approving the content of their inspection report within the above timeframes.

The registration/authorization holder should give his response to the Ministry within thirty days on major factual errors, points of disagreement, or remedial actions to be taken. If no response is received within the prescribed timeframe, this should be noted in a supplement, appended with the report. The inspectors will examine the registration/authorization holder's response within ten days, and prepare a supplement indicating whether these are acceptable along with their impact, if any, on the original inspection findings.

The inspection report will be signed by all inspectors who are on the inspection team.

3.1 Content of the Inspection Report

The inspection report should be evaluated for compliance with the current regulations. The validity and reliability of the data submitted should be evaluated in accordance with the scope of the inspection and issues identified in the request for the inspection.

The compliance of the pharmacovigilance system with the regulatory requirements and the adherence of the parties inspected to the described system should be evaluated.

The inspection report should include at least the following essential items:

- Administrative information on what was inspected, where, when and who was present.
- Scope and reasons for the inspection.
- Reference texts and documents for the inspection.
- Summary of the organization of the registration/authorization holder's system, along with an overview of the system, the function of the qualified person for product safety, the processing and reporting of adverse event/reaction data, trend analyses/signal generation, the databases used, the organization of quality assurance and quality control and the archiving.
- Documents reviewed prior to and during the inspection.
- Status of compliance with currently applicable regulations and guidelines.
- An indication of any opportunity given to the registration/authorization holder to comment, whether and when these comments were received, and whether or not these were accepted.

The above items should be clarified in the inspection report, and the findings classified as minor, major or critical, with reference made to each regulatory provision to which each finding relates.

The inspection report will contain an evaluation of the significance of any non-compliances and a summary of the major and critical findings. The report should also contain a conclusion on whether the pharmacovigilance system complies with current regulations and guidelines, and whether a risk for public health exists; where multiple sites inspected, this may be included in the inspection overview. In case of deficiencies, a recommendation should be given, taking into account their nature, on the need for the registration/authorization holder to implement a corrective and preventive action plan and the need for an inspection to evaluate the implementation of such plan.

3.2 Preparing and Forwarding the Inspection Report

The inspection report should be prepared within the above timeframes, signed, and forwarded to the relevant unit within the Ministry the latest within seventy days of concluding the inspection.

The inspection report is sent to the registration/authorization holder and/or to the party inspected in line with the applicable regulatory requirements and the objectives of the inspection. The inspection report may be sent to other institutions and/or organizations, if necessary.

Appendix – 1: MINIMUM DATA AND DOCUMENTS REQUIRED IN THE INSPECTION REPORT

1. Administrative Information

a) Registration/authorization holder details.
b) Products
c) Inspection team details.

2. General Information

a) Reason for the inspection.

3. Description of Inspection and Findings

a) Conduct of the inspection.
b) Persons met during inspection.
c) Findings related to the pharmacovigilance system and the product.
d) Function of the qualified person for product safety:
   - *i. Job description*
   - *ii. Qualification certificates*
   - *iii. Training*
   - *iv. Deputizing*
e) Organizational structure
   - *i. Pharmacovigilance system*
   - *ii. Interactions with business partners and subcontractors*
   - *iii. Interactions with other departments of the company (e.g., Clinical Trials, Quality).*
f) Standard Operating Procedures
g) Personnel
   - *i. Job description.*
   - *ii. Qualification certificates.*
   - *iii. Training.*
h) Databases.
i) Adverse event/reaction reports:
   - *i. General overview of ADR (Adverse Reaction) reports.*
   - *ii. Periodic safety update report/National report.*
   - *iii. Overview of clinical trial safety data and post-approval safety surveillance study reports, if available.*
   - *iv. Procedures for trend analysis/signal generation.*
j) Quality control and quality assurance
   - *i. Quality control.*
   - *ii. Quality assurance.*
k) Archiving

4. Summary and Evaluation of Findings and Conclusions

a) Summary of findings.
b) Conclusions.
c) Recommendations.
d) Conclusions based on the responses received from the party inspected.

5. Signature and Date

6. Appendices

a) Responses relating to the registration/authorization holder, if provided, and the comments from the inspectors on the responses.
b) References.
c) Documents requested prior to, during, and after the inspection.
d) Other appendices as required.