REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Lebanese Guideline on Good Pharmacovigilance Practices (LGVP)

Module III

Pharmacovigilance Inspections

Development Timeline of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline – Module III

Draft finalized by the Pharmacovigilance Working Group, Ministry of Public Health	June, 2025
Draft agreed by the Pharmacovigilance expert consultant	August, 2025
Draft adopted by the Quality Assurance for Pharmaceutical Products Program, Ministry of Public Health	September, 2025
Released for consultation	February, 2026
End of consultation	
Draft Revised by LNPVP Team	
Draft second revision by the LNPVP and the Pharmacovigilance expert consultant	
Draft finalized by the LNPVP Team	
Date for coming into effect	

Table of Contents

Module III – Pharmacovigilance Inspections

III.A. Introduction

This Module provides guidance on the planning, conduct, reporting, and follow-up of pharmacovigilance inspections in Lebanon and outlines the role of the different parties involved. General guidance is provided under III.B., while III.C. covers the overall operation of pharmacovigilance inspections in Lebanon.

To determine that marketing authorization holders comply with pharmacovigilance obligations established within Lebanon, and to facilitate compliance, the national competent authority concerned shall conduct, pharmacovigilance inspections of marketing authorization holders or service providers employed to fulfill marketing authorization holders' pharmacovigilance obligations. Such inspections shall be carried out by inspectors appointed by the national competent authority and empowered to inspect the premises, records, documents, and Pharmacovigilance System Master file (PSMF) and /or Pharmacovigilance Subsystem File (PSSF) of the marketing authorization holder or any service providers employed by the marketing authorization holder to perform the pharmacovigilance activities. In particular, marketing authorization holders are required to provide, on request, the pharmacovigilance system master file and /or pharmacovigilance subsystem file, which will be used to inform inspection conduct (see Module II).

The objectives of pharmacovigilance inspections are:

- To determine that the marketing authorization holder and/or its appointed service provider has personnel, systems, and facilities in place to meet their pharmacovigilance obligations; where pharmacovigilance activities are delegated, the marketing authorization holder shall retain overall responsibility and demonstrate sufficient oversight and control over all delegated responsibilities. This includes oversight of local affiliate performing pharmacovigilance activities, such as distributors and warehouses in Lebanon, where applicable. The competent authority may assess such oversight through inspection of the marketing authorization holder's PSMF and /or PSSF.
- To identify, record, and address non-compliance which may pose a risk to public health.
- To use the inspection results as a basis for enforcement action, where considered necessary.

For marketing authorization holders of products in Lebanon, it is the responsibility of the national competent authority to verify that the marketing authorization holder or its service provider, in case of subcontracted PV activities, satisfies the national pharmacovigilance requirements. The pharmacovigilance system master file, or a link to it, shall be located either where the main

pharmacovigilance activities of the marketing authorization holder are performed or where the qualified person responsible for pharmacovigilance/local safety person operates. The national competent authority may conduct pre-authorization inspections to verify the accuracy and successful implementation of the existing or proposed pharmacovigilance system.

Pharmacovigilance inspection programs will be implemented, which will include routine inspections scheduled according to a risk-based approach and will also incorporate “for cause” inspections, which have been triggered to examine suspected non-compliance or potential risks, usually with impact on a specific product(s).

The results of an inspection will be provided to the inspected entity, who will be given the opportunity to comment on any non-compliance identified. Any non-compliance should also be rectified by the marketing authorization holder in a timely manner through the implementation of a corrective and preventive action plan.

If the outcome of the inspection is that the marketing authorization holder does not comply with the pharmacovigilance obligations, the national competent authority concerned shall take the necessary measures to ensure that a marketing authorization holder is subject to effective, proportionate, and dissuasive penalties.

Sharing of information and effective communication between pharmacovigilance **inspectors**, who conduct compliance inspections of systems and processes (including the PSMF and CAPAs), and **assessors**, who perform scientific and regulatory assessment of safety data (such as PSURs, signals, and RMPs), is essential to ensure appropriate prioritization and targeting of inspections, as well as proper follow-up and the formulation of recommendations on actions to be taken. Although inspectors and assessors operate with different competencies, workflows, and often different reporting lines, close collaboration between these functions is critical. To further enhance transparency, the competent authority may consider publishing biannual or annual pharmacovigilance inspection summary reports.

III.B. Structures and processes

III.B.1. Inspection types

III.B.1.1. System and product-related inspections

Pharmacovigilance system inspections are designed to review the procedures, systems, personnel, and facilities in place and determine their compliance with regulatory pharmacovigilance obligations.

As part of this review, product-specific examples may be used to demonstrate the operation of the pharmacovigilance system. Where pharmacovigilance tasks are subcontracted, inspections may also cover any service provider performing such activities in whole or in part on behalf of, or in conjunction with, the marketing authorization holder. These service providers shall be subject to audit by or on behalf of the marketing authorization holder and may be inspected by the national competent authority, irrespective of whether the obligation to agree to an audit or inspection is explicitly included in the subcontract. While the marketing authorization holder retains overall responsibility for pharmacovigilance compliance, shortcomings identified at the level of subcontracted service providers shall not compromise the conduct, scope, or effectiveness of audits and inspections.

Product-related pharmacovigilance inspections are primarily focused on product-related pharmacovigilance 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).

III.B.1.2. Routine and "for cause" pharmacovigilance inspections

Routine pharmacovigilance inspections are inspections scheduled in advance as part of inspection programs. There is no specific trigger to initiate these inspections, although a risk-based approach to optimize supervisory activities should be implemented. These inspections are usually system inspections but one or more specific products may be selected as examples to verify the implementation of the system and to provide practical evidence of its functioning and compliance. Particular concerns, e.g., raised by assessors, may also be included in the scope of a routine inspection, in order to investigate the specific issues.

For cause, pharmacovigilance inspections are undertaken when a trigger is recognized, and an inspection is considered an appropriate way to examine the issues. For cause inspections are more likely to focus on specific pharmacovigilance processes or to include an examination of identified compliance issues and their impact on a specific product. However, full system inspections may also be performed, resulting from a trigger. For-cause inspections may arise when, for example, one or more of the triggers listed below are identified (but are not limited to):

▪ **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 general public without giving prior or simultaneous notification to the national competent authorities, as applicable;
- non-compliance or product safety issues identified during the monitoring of pharmacovigilance activities by the national competent authorities;
- suspension or product withdrawal with no advance notice to the national competent authorities.

▪ **Reporting obligations (expedited and periodic):**

- delays or omissions in reporting;
- poor-quality or incomplete reports;
- inconsistencies between reports and other information sources.

▪ **Requests from the national competent authorities:**

- failure to provide the requested information or data within the deadline specified by the national competent authorities;
- poor-quality or inadequate provision of data to fulfil requests for information from the national competent authorities.

▪ **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 authorization;
- poor quality of reports requested as specific obligations.

▪ **Inspections:**

- 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, where applicable (GCP, GMP, GLP, and GSDP);
- inspection information received from other international authorities, which may highlight issues of non-compliance.

▪ **Other triggers:**

- 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

III.B.1.3. Pre-authorization inspections

Pre-authorization pharmacovigilance inspections are inspections performed before a marketing authorization is granted. These inspections are conducted with the intent of examining the existing or proposed pharmacovigilance system as the applicant has described it in support of the marketing authorization application. Pre-authorization inspections are not mandatory but may be requested in specific circumstances. Principles and procedures for requesting pre-authorization inspections should be developed to avoid performing unnecessary inspections, which may delay the granting of a marketing authorization. The following aspects shall be considered during the validation phase and/or early during the assessment phase:

- The applicant has not previously operated a pharmacovigilance system in Lebanon or is in the process of establishing a new pharmacovigilance system;
- Previous information (e.g., inspection history and non-compliance notifications or information from other authorities) indicates that the applicant has a poor history or culture of compliance. If the marketing authorization holder has a history of serious and/or persistent pharmacovigilance non-compliance, a pre-authorization pharmacovigilance inspection may be one mechanism to confirm that improvements have been made to the system before a new authorization is granted;
- Due to product-specific safety concerns, it may be considered appropriate to examine the applicant's ability:
  - to implement product-specific risk-minimization activities; or
  - to meet specific safety conditions which may be imposed; or
  - to manage routine pharmacovigilance for the product of concern (e.g., anticipated significant increase in adverse reaction reports compared to previous products).

In most cases, a risk assessment based on a combination of product-specific and system-related issues should be performed before a pre-authorization pharmacovigilance inspection is requested.

If the outcome of the pre-authorization inspection raises concerns about the applicant's ability to comply with the national pharmacovigilance requirements, the following recommendations may be considered:

- non-approval of the marketing authorization;
- a re-inspection before approval of the marketing authorization to confirm that critical findings and recommendations have been addressed;
- granting of the marketing authorization with the recommendation to perform an early post-authorization pharmacovigilance inspection. In this case, the findings would influence the timing of an inspection conducted as part of the national routine program of pharmacovigilance inspections in Lebanon (see III.B.2), and the imposition of safety conditions on the marketing authorization.

III.B.1.4. Post-authorization inspections

Post-authorization pharmacovigilance inspections are inspections performed after a marketing authorization is granted and are intended to examine whether the marketing authorization holder complies with its pharmacovigilance obligations. They can be any of the types mentioned under III.B.1.1 and IIIB.1.2.

III.B.1.5. Announced and unannounced inspections

It is anticipated that the majority of inspections will be announced i.e., notified in advance to the inspected party, 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).

III.B.1.6. Re-inspections

A re-inspection may be conducted on a routine basis as part of a routine inspection program. Risk factors will be assessed in order to prioritize re-inspections. Early re-inspection may take place where significant non-compliance has been identified and where it is necessary to verify actions taken to address findings and to evaluate ongoing compliance with the obligations, including evaluation of changes in the pharmacovigilance system. Early re-inspection may also be appropriate when it is known from a previous inspection that the inspected party had failed to implement appropriate corrective and preventive actions in response to an earlier inspection.

III.B.1.7. Remote inspections

These are pharmacovigilance inspections performed by inspectors remote from the premises of the marketing authorization holder or service providers employed by the marketing authorization holder. Communication mechanisms such as the Internet or telephone may be used in the conduct of the inspection. For example, in cases where key sites for pharmacovigilance activities are located outside Lebanon or a service provider is not available at the actual inspection site, but it is feasible to arrange interviews of relevant staff and review of documentation, including the safety database, source documents, and pharmacovigilance system master file, via remote access. This approach may also be taken where there are logistical challenges to an on-site inspection during exceptional circumstances (e.g., a pandemic outbreak or travel restrictions). Such approaches are taken at the discretion of the inspectors and in agreement with the body commissioning the inspection. The logistical aspects of the remote inspection should be considered following liaison with the marketing authorization holder.

Where feasible, a remote inspection may lead to a visit to the inspection site if it is considered that the remote inspection has revealed issues that require on-site inspection or if the objectives of the inspection cannot be met by remote inspection.

III.B.2. Inspection planning

Pharmacovigilance inspection planning should be based on a systematic and risk-based approach to make the best use of surveillance and enforcement resources whilst maintaining a high level of public health protection. A risk-based approach to inspection planning will enable the frequency, scope, and breadth of inspections to be determined accordingly.

To ensure that inspection resources are used efficiently, the scheduling and conduct of inspections will be driven by the preparation of inspection programs. Sharing of information and communication between pharmacovigilance inspectors and assessors is important to ensure successful prioritization and targeting of these inspections.

Factors that may be taken into consideration, as appropriate, by the national competent authorities when establishing pharmacovigilance inspection programs include, but are not limited to:

- **Inspection related**:
  - compliance history identified during previous pharmacovigilance inspections or other types of inspections where appropriate (GCP, GMP, GLP, and GDP);
  - re-inspection date recommended by the inspectors or assessors as a result of a previous inspection.
- **Product related:**
  - product with additional pharmacovigilance activities or risk-minimization activities;
  - authorization with conditions associated with safety, e.g., requirement for post-authorization safety studies (PASS) or designation for additional monitoring;
  - product(s) with large sales volume, i.e., products associated with large patient exposure in Lebanon;
  - product(s) with limited alternatives in the marketplace.
- **Marketing authorization holder related:**
  - marketing authorization holder that has never been subject to a pharmacovigilance inspection;
  - marketing authorization holder with many products on the market in Lebanon;
  - resources available to the marketing authorization holder for the pharmacovigilance activities they undertake, including resources for the oversight and management of subcontracted pharmacovigilance activities*;*
  - marketing authorization holder with no previous marketing authorizations in Lebanon;

- negative information and/or safety concerns raised by the national competent authority, other bodies/competent authorities outside Lebanon, or other areas if applicable (i.e., GCP, GMP, GLP, and GDP);

- changes in the marketing authorization holder organization, such as mergers and acquisitions.

- **Pharmacovigilance system related:**

  - marketing authorization holder with sub-contracted pharmacovigilance activities (function of the qualified person responsible for pharmacovigilance (QPPV/LSR) in Lebanon, reporting of safety data, etc.) and/or multiple service providers employed to perform pharmacovigilance activities; where pharmacovigilance tasks are subcontracted, delegation arrangements, respective responsibilities, and audit and inspection arrangements shall be clearly documented. Service providers performing pharmacovigilance activities in whole or in part on behalf of, or in conjunction with, the marketing authorization holder shall agree to be audited by or on behalf of the marketing authorization holder and may be inspected by the national competent authority, irrespective of whether such obligations are explicitly included in the subcontract;

  - change of QPPV/local safety responsible (LSR) 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 the pharmacovigilance system master file management.

The national competent authority may solicit information from marketing authorization holders for risk-based inspection planning purposes if it is not readily available elsewhere.

III.B.3. Sites to be inspected

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

The sites to be inspected may be located in or outside Lebanon. However, where key pharmacovigilance activities, such as the main pharmacovigilance center, safety databases, or subcontracted pharmacovigilance activities, are located outside Lebanon, inspections of sites outside Lebanon may be considered on a case-by-case basis, where feasible and appropriate, and where it would otherwise be inefficient or not possible to confirm compliance from a site within Lebanon.

In such cases, the national competent authority may, where appropriate, rely on cooperation, information sharing, or coordination with other competent authorities, in accordance with applicable legal and administrative arrangements.

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

III.B.4. Inspection scope

The inspection scope will depend on the objectives of the inspection as well as the coverage of any previous inspections by the national competent authority and whether it is a system or product-related inspection (a description of the types of inspection, inspection triggers, and points to consider for the different types of inspection is provided in III.B.1).

The following elements should 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 from the national competent authority, such as the National Pharmacovigilance and Safety Reports database, reporting, and data quality audits;
- specific triggers (see III.B.1.2. for examples of triggers).

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

III.B.4.1. Routine pharmacovigilance inspections

Routine pharmacovigilance inspections should examine compliance with national competent authority legislation and guidance, and the scope of such inspections should include the following elements, as appropriate:

- **Individual Case Safety Reports (ICSRs):**
  - collecting, receiving, and exchanging reports from all types of sources, sites, and departments within the pharmacovigilance system, including from service providers employed to fulfill marketing authorization holders' 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 domestic ICSRs (from within Lebanon), examples of ICSRs reported from outside Lebanon should be examined as part of this review (if applicable and if requested);
  - follow-up and outcome recording, for example, the 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 national competent authority and the timeliness of such reporting;
  - record keeping and archiving for ICSRs;
- **Periodic Safety Update Reports (PSURs);**
  - 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 authorization;
- timely identification and provision of complete and accurate data to the national competent authority, 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;

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

- reporting suspected unexpected serious adverse reactions (SUSARs) and non-interventional study cases according to the national regulations;
- 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 PSURs), 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, where applicable;
- the inclusion of study data in ongoing safety evaluation;

▪ **Pharmacovigilance system:**

- QPPV/LSR 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 marketing authorization holder 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 concerning pharmacovigilance, including quality control and quality assurance processes;
- fitness for the purpose of computerized systems;
- contracts and agreements with all relevant parties appropriately reflect responsibilities and activities in the fulfillment of pharmacovigilance, and are adhered to.

As a general approach, a marketing authorization holder should be inspected based on risk-based considerations, but it is recommended to routinely inspect the MAH at least once every 4 years.

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

III.B.4.2. For cause inspections

The scope of the inspection will depend on the specific trigger(s). Some, but not all of the elements listed in III.B.4.1 and below, may be relevant:

- QPPV/LSR 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.

III.B.4.3. Re-inspections

For the scope of a re-inspection, the following aspects should be considered:

- review of the status of the system and/or corrective and preventive action plan(s) resulting from previous pharmacovigilance inspection(s);
- review of significant changes that have been made to the pharmacovigilance system since the last pharmacovigilance inspection (e.g., changes in the pharmacovigilance database, company mergers or acquisitions, significant changes in contracted activities, changes in QPPV/LSR as appropriate);
- review of process and/or product-specific issues identified from the assessment of information provided by the marketing authorization holder, or not covered in a prior inspection.

The scope of re-inspection will depend on the inspection history. It may be appropriate to conduct a complete system review, for example, if a long time has elapsed since the previous inspection, in which case the elements listed in III.B.4.1. may be considered for the inspection scope, as appropriate.

III.B.5. Inspection process

Pharmacovigilance inspections should be planned, coordinated, conducted, reported on, followed up on, and documented in accordance with national inspection procedures.

The pharmacovigilance inspection procedure will cover at least the following processes:

- sharing of information;
- Inspection planning;
- pre-authorization inspections;
- coordination of pharmacovigilance inspections in Lebanon (where applicable), including coordination within the national competent authority and with the Ministry of Public Health inspection department, and, where relevant, with other national bodies involved in pharmacovigilance, medicines regulation, or public health oversight, in order to ensure consistency, avoid duplication, and support effective inspection follow-up;
- coordination of inspections involving sites or contractors located outside Lebanon (where applicable), which may include cooperation, information exchange, or coordination with other competent authorities, in accordance with applicable legal and administrative arrangements);
- preparation of pharmacovigilance inspections;
- conduct of pharmacovigilance inspections;
- reporting of pharmacovigilance inspections and inspection follow-up;
- communication and prioritization of pharmacovigilance inspections and findings;
- interaction with the national pharmacovigilance committee (if applicable) in relation to inspections and their follow-up;
- record-keeping and archiving of documents obtained or resulting from pharmacovigilance inspections;
- unannounced inspections;

- sanctions and enforcement in case of serious non-compliance;
- recommendations on the training and experience of inspectors performing pharmacovigilance inspections.

These procedures will be revised and updated as deemed necessary. New procedures may also be developed when the need is identified with the inspection process.

III.B.6. 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:

- review of the marketing authorization holder's corrective and preventive action plan;
- review of the periodic progress reports, when deemed necessary;
- re-inspection to assess appropriate implementation of the corrective and preventive action plan;
- requests for submission of previously un-submitted data; submission of variations, e.g., to amend product information; submission of impact analyses, e.g., following review of data that were not previously considered during routine signal detection activities;
- requests for issuing safety communications, including amendments of marketing and/or advertising information;
- requests for a meeting with the marketing authorization holder to discuss the deficiencies, the impact of the deficiencies, and action plans;
- other product-related actions depending on the impact of the deficiencies and the outcome of follow-up actions (this may include recalls or actions relating to the marketing authorizations or clinical trial authorizations).

Sharing of information and communication within the national competent authority, including among staff involved in pharmacovigilance inspection and assessment activities, is important for the proper follow-up of inspections and the formulation of appropriate recommendations on actions to be taken.

III.B.7. Regulatory actions and sanctions

According to the national legislation and regulations, in order to protect public health, the national competent authorities are obliged to ensure compliance with pharmacovigilance obligations. When non-compliance with pharmacovigilance obligations is detected, the necessary action will be judged on a case-by-case basis. What action is taken will depend on the potential negative public health impact of the non-compliance(s), but any instance of non-compliance may be considered for enforcement action. The national competent authority shall take the necessary measures to ensure that a marketing authorization holder is subject to effective, proportionate, and dissuasive penalties. Moreover, financial penalties may be imposed on the holders of marketing authorizations to ensure the enforcement of certain obligations connected with marketing authorizations for medicinal products. In the event of non-compliance, possible regulatory options include the following, in accordance with guidance and, as applicable, rules set in legislation:

▪ **Education and facilitation:** the national competent authority may communicate with marketing authorization holder representatives (e.g. in a meeting) to summarize the identified non-compliances, to clarify the legal requirements and the expectations of the regulator, and to review the marketing authorization holder's proposals for corrective and preventive actions;

▪ **Inspection:** non-compliant marketing authorization holders may be inspected to determine the extent of non-compliance and then re-inspected to ensure that compliance is achieved;

▪ **Warning letter, non-compliance statement, or infringement notice:** these are instruments that national competent authorities may issue stating the legislation and guideline(s) that have been breached, reminding marketing authorization holders of their pharmacovigilance obligations, or specifying the steps that the marketing authorization holder must take and the timeframe within which to rectify the non-compliance and prevent further non-compliance;

▪ The national competent authority may consider making public a list of marketing authorization holders found to be seriously or persistently non-compliant;

▪ **Actions against a marketing authorization or authorization application, e.g.:**

- Urgent Safety Restriction;
- variation of the marketing authorization;
- suspension or revocation of the marketing authorization;

- delays in the approval of new marketing authorization applications until corrective and preventive actions have been implemented, or the addition of safety conditions to new authorizations;
- requests for pre-authorization inspections;

▪ **Product recalls,** e.g. where important safety warnings have been omitted from product information;

▪ **Action relating to marketing or advertising information;**

▪ **Amendments or suspension of clinical trials** due to product-specific safety issues;

▪ **Financial or administrative penalties** may be considered in the future, subject to the establishment of an appropriate legal and regulatory framework;

▪ **Referral for criminal prosecution** with the possibility of imprisonment (in accordance with national legislation).

III.B.8. Record management and archiving

The principles and requirements to be followed will be described in the procedure on Record Keeping and Archiving of Documents Obtained or Resulting from the Pharmacovigilance Inspections referred to in III.B.5.

III.B.9. Qualification and training of inspectors

Inspectors who are involved in the conduct of pharmacovigilance inspections requested by the national competent authority should be officials of, or appointed by, the national competent authority in accordance with national regulations and follow the provisions of the national competent authority.

It is recommended that inspectors are appointed based on their experience (especially in pharmacovigilance) and the minimum requirements defined by the national competent authority. In addition, consideration should be given to the recommendations for training and experience described in the pharmacovigilance inspection procedures.

The inspectors should undergo training to the extent necessary to ensure their competence in the skills required for preparing, conducting, and reporting inspections. They should also be trained in pharmacovigilance processes and requirements in such a way that they are able, if not acquired by their experience, to comprehend the different aspects of a pharmacovigilance system.

Documented processes should be in place in order to ensure that inspection competencies are maintained. In particular, inspectors should be kept updated with the current status of pharmacovigilance legislation and guidance.

Training and experience should be documented individually and evaluated according to the requirements of the applicable quality system of the concerned competent authority.

III.B.10. Quality management of the pharmacovigilance inspection process

The quality of the pharmacovigilance inspection process is managed by the national competent authorities and covered by their pharmacovigilance systems and associated quality systems, meaning that the process is also subject to audit. Guidance on the establishment and maintenance of a quality-assured pharmacovigilance system is provided in Module I.

III.C. Operation of pharmacovigilance inspections in Lebanon

III.C.1. Role of the national competent authority

The national competent authority should establish the legal and administrative framework within which pharmacovigilance inspections operate, including the definition of the rights of inspectors for inspecting pharmacovigilance sites and access to pharmacovigilance data.

The national competent authority should provide sufficient resources and appoint adequately qualified inspectors to ensure effective determination of compliance with good pharmacovigilance practice. The inspector(s) appointed may be accompanied, when needed, by expert(s) on relevant areas.

Pharmacovigilance inspections should be planned, coordinated, conducted, reported on, followed up on, and documented in accordance with national inspection procedures. The scheduling and conduct of these inspections will be driven by the preparation of inspection programs based on a systematic and risk-based approach as outlined in III.B.2.

III.C.1.1. Inspection Programs

A program for routine inspections of authorized products in Lebanon will be determined by the national competent authority. These inspections will be prioritized based on the potential risk to public health, considering the factors listed in III.B.5. As a general approach, a marketing authorization holder should be inspected based on risk-based considerations, but it is recommended to routinely inspect MAH at least once every 4 years.

If the same pharmacovigilance system is used for a variety of authorizations, then the results of a competent authority inspection may apply to all products covered by that system. This routine inspection program will be separate from any "for-cause" inspections, but if a "for-cause" inspection takes place it may replace the need for one under this program, dependent on its scope.

The national competent authority is also responsible for the planning and coordination of pharmacovigilance inspections in order to ensure compliance with the national legislation and to verify the effectiveness of the marketing authorization holder's pharmacovigilance system.

Based on the information from other inspections, the national competent authority will prioritize the inspections in its program and will use the information for the preparation of an appropriate scope for the inspection. For example, the national competent authority may seek to verify the fulfillment of requirements concerning the implementation of specific risk-minimization measures, communications concerning safety, locally conducted safety studies, or issues linked to national healthcare systems. A broader examination of pharmacovigilance applied to particular products of national interest may also be appropriate.

Deficiencies are classified by the assessed risk level and may vary depending on the nature of the medicine. In some circumstances, an otherwise major deficiency may be categorized as critical. A deficiency reported after a previous inspection and not corrected may be given a higher classification.

III.C.1.2. Cooperation and Sharing of Information

The national competent authority may, where appropriate, engage in cooperation and information sharing related to pharmacovigilance inspections, with the objective of supporting effective inspection planning, avoiding unnecessary duplication of activities, and promoting the exchange of good practices. Such cooperation may include informal information exchange, training activities, or

experience sharing, subject to feasibility and in accordance with applicable national legal and administrative arrangements.

III.C.2. Role of the Marketing Authorization Holders and Applicants

Marketing authorization holders with authorized products and applicants who have submitted new applications are subject to pharmacovigilance inspections (see III.B.1). Therefore, both have responsibilities in relation to inspections, including but not limited to the following:

- Always be inspection-ready as inspections may be unannounced.
- To maintain and make available to the inspectors on request, no later than 14 days after The receipt of a request, the pharmacovigilance system master file, and /or PSSF.
- To ensure that the sites selected for inspection, which may include service providers employed by the marketing authorization holder (such as service providers) to perform pharmacovigilance activities, agree to be inspected before the inspection is performed.
- 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.
- 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.
- To ensure that relevant pharmacovigilance data is accessible
- To ensure that appropriate and timely corrective and preventive action plans are implemented to address findings observed during an inspection, with appropriate prioritization of critical and/or major findings.

III.C.3. Inspection Fees

For pharmacovigilance inspections, inspection fees and related expenses may be applicable in accordance with national laws and regulations, where such provisions are established**.**