REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Lebanese Guideline on Good Pharmacovigilance Practices (LGVP)

Version 1

2023

Ministry of Public Health, Republic of Lebanon

Lebanese National Pharmacovigilance Program

Lebanese Guideline on Good Pharmacovigilance Practices (LGVP)

Guideline for Marketing Authorization Holders in Lebanon

Version 1

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Introductory note

Background on the LGVP guideline

This guideline represents the first initiative to formulate the Guideline on Good Pharmacovigilance Practices (GVP) exclusively designed for Lebanon. This first draft, denoted as Version 1, is organized into modules, placing special emphasis on eight modules that cover prioritized topics.

This first version is set to undergo a period of public consultation and is expected to be released in Lebanon in the first quarter of 2024. Following this consultation, the modules will be finalized within the governance structure, addressing the comments from stakeholders, and then published by the MoPH.

This guideline draws substantial inspiration from international and regional references. With the strategic objectives to harmonize with global developments in pharmacovigilance practices and regulations, this guideline was greatly adopted from the European Good Pharmacovigilance Practices (EU GVP) guidelines, which exhibit high compatibility with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines.

In addition to the international perspective, this guideline was tailored from the Guideline on Good Pharmacovigilance Practices for Arab Countries to fit the Lebanese pharmacovigilance landscape.

Objectives of the LGVP guideline

Pharmacovigilance has been defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

This guideline aims to provide Marketing Authorization Holders of medicinal products in Lebanon with needed information on the requirements, procedures, roles, and activities in the field of pharmacovigilance. It further describes the responsibilities and obligations of MAHs to build a pharmacovigilance system to collate and evaluate data on suspected adverse reactions.

Legal basis, scope and process for GVP in Lebanon

In Lebanon, the Lebanese Ministry of Public Health (MoPH) is currently the national competent authority responsible for granting marketing authorizations and supervising medicinal products, including the conduct of pharmacovigilance activities.

The legal framework for pharmacovigilance of medicinal products in Lebanon was initiated by the issuing of regulations # 180 and #181 in 2021, which have the primary aim to strengthen and rationalize pharmacovigilance and increase patient safety (https://www.moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon#collapse_1).

Through these legislations, the MoPH imposes responsibility for pharmacovigilance, together with specific obligations on MAHs (i.e. in terms of tasks and responsibilities).

It should be noted that within the context of this guideline the term "national competent authority" consistently pertains to the Lebanese MoPH, which serves as the principal entity responsible for overseeing and ensuring the safety of pharmaceutical products in Lebanon.

Structure of the LGVP guideline

The GVP guideline is structured into Modules that address various essential pharmacovigilance processes. Recognizing the interconnection between distinct yet interrelated pharmacovigilance activities, each GVP Module in this guideline focuses on a key pharmacovigilance process.

Each drafted module has been prepared by a team of experts from the Lebanese National Pharmacovigilance Program (LNPVP), taking into account comments collected from external consultants and previous stakeholder meetings.

This first version of the GVP guidelines specifically pertains to the Modules indicated in bold font type. The remaining planned modules are currently in the developmental phase and will be the subject of subsequent public consultations.

- **Introductory Note: Legal basis and structure of pharmacovigilance guideline**
- **Module I: Pharmacovigilance systems and their quality systems**
- **Module II: Pharmacovigilance System Master File (PSMF)**
- Module III: Pharmacovigilance inspections

- Module IV: Pharmacovigilance audits
- **Module V: Risk management systems**
- **Module VI: Collection, management and submission of reports of suspected adverse reactions to medicinal products**
- **Module VII: Periodic Safety Update Reports (PSUR)**
- **Module VIII: Post-Authorization Safety Studies (PASS)**
- Module IX: Signal management
- Module X: Additional monitoring
- **Module XV: Safety communication**
- **Module XVI: Risk minimization measures: selection of tool and effectiveness indicators**

It is pertinent to observe that, owing to the adoption of the EU GVP's Module classification and numbering system in this current guideline, Modules XI, XII, XIII, and XIV remain unallocated, as their intended subject matter has been covered by alternative guidance documents published on the EMA's website.
However, the original numbering for the remaining modules remains unchanged.
(https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices#final-gvp-modules-section).

Marketing Authorization Holders operating in Lebanon are required to establish and maintain a comprehensive pharmacovigilance system that encompasses the documentation and implementation of the Modules listed above.
It is expected from MAHs to comply with these forthcoming Modules as they become available, ensuring their pharmacovigilance systems remain up to date and aligned with evolving regulatory requirements.
Within each Module, when applicable:

- **Section A** provides introduction to the legal, technical and scientific context of the respective process.
- **Section B** gives guidance which reflects scientific and regulatory approaches, formats and standards agreed on internationally, or where such formal agreements or expert consensus do not

exist. Section B describes approaches which are considered in line with general current thinking in the field.

- **Section C** focuses on the specifics of applying the approaches, formats and standards, and other aspects of operating the respective process in Lebanon.

Format and general requirements

In instances where there is a necessity to submit any document as mandated by the guidelines, the submitted files must conform to the following prescribed requirements:

- For documents to be submitted in electronic format to the national competent authority in the context of this guideline; these documents should be consistent with the headings described in the relevant GVP Module, and indexed in a manner to allow easy navigation to the contents.
- For document sections where there is no applicable content, those sections or annexes that are provided should still be named according to the format described in the relevant Module (i.e. without renaming or renumbering). The section/annex in question should not be omitted, but should rather simply be described as “Not applicable”.

The ultimate responsibility for the fulfillment of all pharmacovigilance tasks and responsibilities and the quality and integrity of the pharmacovigilance system always remains with the MAH. This guidance therefore seeks to ensure that MAHs are fulfilling their principal role in the safety monitoring of their medical products in Lebanon.

Working group

The Good Pharmacovigilance Practices Guideline for Lebanon have been developed with the collaborative efforts of various individuals and stakeholders. The success of this initiative would not have been possible without the tireless efforts of those involved.

The invaluable knowledge, expertise, and efforts of the Pharmacovigilance team at the Quality Assurance for Pharmaceutical Products Program (QAPPP) - Ministry of Public Health, throughout the development of these guidelines are appreciated. Their extensive experience in pharmacovigilance practices and regulations have been instrumental in ensuring the completeness and accuracy of the guidelines.

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