THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

LEBANON

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Prepared by
The Pharmacovigilance Team
at the Ministry of Public Health

OUTLINE

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B. Workshop Training: Pharmacovigilance Role in the CTD and Safety Surveillance

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From Theory to Practice: The Official Launch and Interactive Training on the Lebanese Good Pharmacovigilance Practices Guideline

I. SHARING THE KNOWLEDGE

A. INTRODUCTION TO PHARMACOVIGILANCE OPERATIONS: REPORTING AND DATA MANAGEMENT

As part of the Lebanese National Pharmacovigilance Program (LNPVP)'s educational activities, the Pharmacovigilance (PV) team conducted an onsite capacity building targeting healthcare professionals and aiming to promote the concept of PV.

The training session was held on February 26th, 2025 at the Sacre Coeur Hospital auditorium. The hospital's medical staff including nurses, residents, pharmacists, quality and safety persons have joined the session.

Under the title of "Introduction to Pharmacovigilance Operations: Reporting and Data Management", the 2-hour session introduced the staff to the scope of the LNPVP's operation and activities. The objectives were threefold:

- Introducing the concept of Pharmacovigilance
- Sharing the implementation steps and objectives of the Lebanese Pharmacovigilance Program
- Encouraging the reporting of the adverse events following the use of medications and vaccines.

Four presentations were provided by the PV team members revolving around the operations performed at the LNPVP, as detailed previously.

The aim was to share with participants what, when, where and how to report. And for a better understanding of the subsequent steps of data management, the handling of serious cases was also discussed. To close the loop, the audience were introduced to new reporting tools (VigiMobile e-Form and the e-Reporting e-Form).

I. SHARING THE KNOWLEDGE

A. INTRODUCTION TO PHARMACOVIGILANCE OPERATIONS: REPORTING AND DATA MANAGEMENT

The session was initiated and welcome remarks delivered by the Director of the Quality Assurance of Pharmaceutical Products Programs and the National Pharmacovigilance Program Coordinator Dr. Rita Karam, who introduced the Lebanese PV System with an opening presentation. She outlined the roadmap to the program's success, and acquainted the audience with its mission, vision and values. The implementation of the program from its activation in 2018 to its incorporation in the WHO Programme for International Drug Monitoring (WHO-PIDM) in 2021 was detailed. The program's partners, stakeholders, and activities were identified and shared.

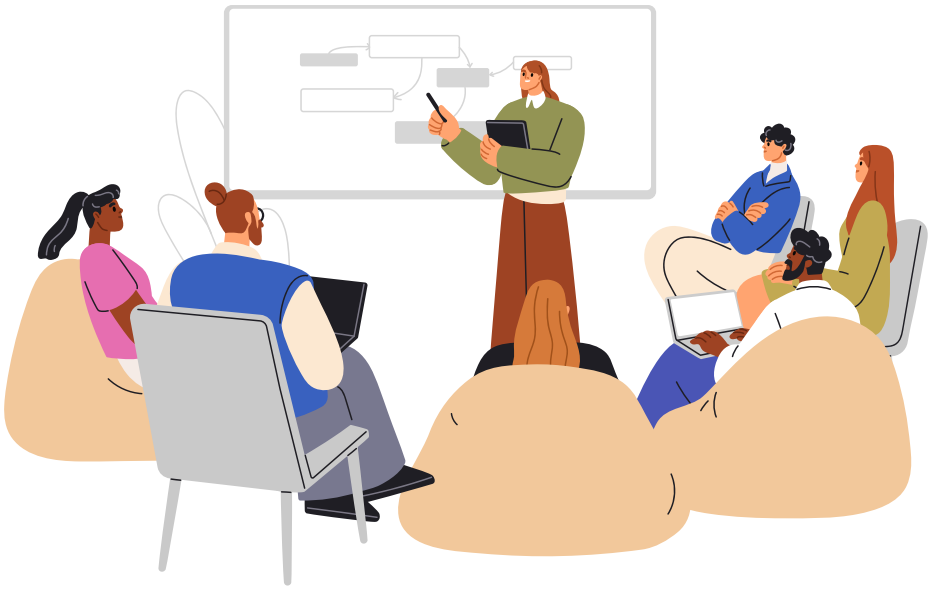
The audience was then reminded of the general concepts of PV by Dr. Abeer Zeitoun, the Senior Clinical and Technical Manager at the LNPVP, who presented a general overview on its importance and operations within healthcare systems worldwide. Dr. Zeitoun then acknowledged the important role that healthcare professionals play in the patient safety cycle.

In a third presentation, Dr.Zeitoun. defined terminologies used to distinguish between what is being reported. A useful overview of the available reporting means was then provided. Finally, she gave an insight on the program's workflow when handling the received cases.

I. SHARING THE KNOWLEDGE

A. INTRODUCTION TO PHARMACOVIGILANCE OPERATIONS: REPORTING AND DATA MANAGEMENT

The final presentation was delivered by Dr. Aya Ibrahim, a Senior PV Officer. The objective of this presentation was to equip the staff with the skills to develop high-quality case reports. The presentation included a detailed breakdown of each section of the case report. Dr. Ibrahim explained how to correctly report the drug suspected to be related to the observed reaction, supported by practical cases. The Medical Dictionary for Regulatory Activities (MedDRA) term was then explained along with its hierarchy and how to use it. Several examples elaborating on the importance of using the correct MedDRA were provided. And finally, two videos were provided on how to use the VigiMobile e-Form and e-Reporting e-Form. She guided the participants on the steps to follow to submit a case report using these tools.

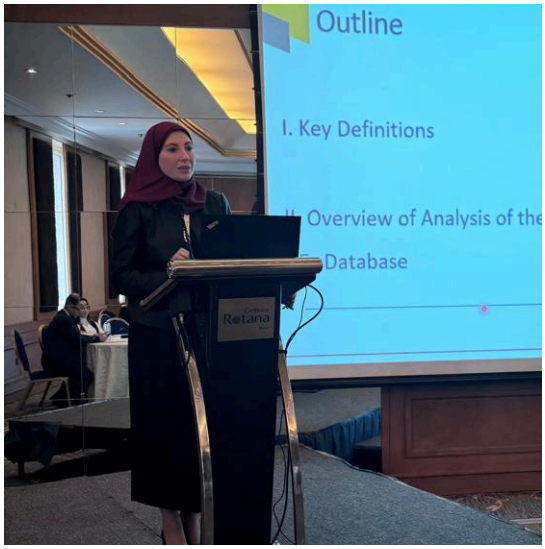


I. SHARING THE KNOWLEDGE

B. PHARMACOVIGILANCE ROLE IN THE CTD AND SAFETY SURVEILLANCE

In line with continuing efforts to strengthen the Pharmacovigilance (PV) knowledge, the LNPVP team was invited to deliver two presentations during the training program titled "CTD Module 3 and 5: Comprehensive Training in Drug Dossier Submission and Review Process for Regulatory Professionals," held on the 5th and 6th of March 2025, and organized by Science-Pro Academy. The objective of the training was to equip participants with the necessary knowledge to prepare and submit a complete drug CTD file. The PV sessions focused on strengthening participants' understanding of drug safety monitoring and enhancing regulatory compliance practices.

The first presentation, entitled “Descriptive Analysis of the National Adverse Event Database in Lebanon”, was delivered by Dr. Abeer Zeitoun. She focused on the analysis of Adverse Drug Event (ADE) data collected between 2018 and 2024. This session highlighted key trends, patterns, and outcomes within the national ADE database, with insightful comparisons to regional and global benchmarks. The analysis not only highlighted the progress in pharmacovigilance reporting but also identified areas requiring targeted improvements. Emphasis was placed on using evidence-based data to guide public health decisions and improve patient safety outcomes.



The second presentation, entitled “Pharmacovigilance in the CTD: Monitoring Drug Safety and Compliance”, was delivered by Dr. Aya Ibrahim. She addressed the important role of pharmacovigilance within the Common Technical Document (CTD). Dr. Ibrahim provided a detailed introduction to pharmacovigilance in regulatory contexts, explained the correct placement of pharmacovigilance documents within the CTD, and elaborated on the significance of maintaining robust safety documentation.

II. A NEW MILESTONE

RECENT PUBLICATION OF THE NATIONAL PV TEAM

Journal of Pharmaceutical Policy and Practice

Taylor & Francis
Taylor & Francis Group

J Pharm Policy Pract. 2025 Mar 14;18(1):2473014. doi: 10.1080/20523211.2025.2473014

Rita Karam [a,b,c], Sarah Reda El Sayed [a], Aya Ibrahim [a], Joya-Maria Karam [d], Souheil Hallit [e,f,g], Abeer Zeitoun

A study entitled “Descriptive analysis of the national drug adverse events (AEs) database in Lebanon,” which highlights the safety and effectiveness of the registered medicinal products in Lebanon, was published on the 14th of March 2025 in the Journal of Pharmaceutical Policy and Practice.

Aim of the study: A retrospective analysis-based study that describes collected national AE cases for all marketed medications, as well as medications in the pre-marketed phase, as part of clinical studies in Lebanon.

Duration of the study: Data were spontaneously received from Marketing Authorisation Holders (MAHs) between 2018 and 2023.

Key factors examined included the age, gender, and adverse events experienced by individuals who received the vaccine.

The results showed that Lebanon, a country that suffers from a turbulent economic and health context, was able to implement a PV system and operate with efficiency while evaluating a 5-year worth of ICSR reports. The dissemination of this information promotes stakeholder awareness by encouraging a collaborative approach among patients, healthcare providers, and regulatory authorities in Lebanon. However, further research is warranted to investigate factors contributing to MEs in Lebanon.

READ MORE AT:

DOI: 10.1080/20523211.2025.2473014

III. EMPOWER YOUR SAFETY

THE GOOD PHARMACOVIGILANCE PRACTICES GUIDELINE (GVP)

Foundations, Evolution, Importance, Adaptation

1. Foundations of GVP: A Regulatory Backbone

1960's

The concept of pharmacovigilance was formally recognized following global drug safety incidents, most notably the thalidomide tragedy in the 1960s, which highlighted the need for a robust drug monitoring system. In response, national and international regulatory bodies began laying the groundwork for structured safety surveillance.

1994 - 2010

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use **(ICH)** has published a series of Efficacy Guidelines aimed at harmonizing the collection, reporting, and analysis of clinical safety data across different regulatory regions. Among these, the guidelines E2A, E2B, E2C, E2E, and E2F are specifically focused on pharmacovigilance and clinical safety reporting.

https://www.ich.org/page/ich-guidelines

2012

In the European Union, Good Pharmacovigilance Practices (GVP) were officially introduced in **July 2012** by the **European Medicines Agency (EMA)**, following the release of updated pharmacovigilance legislation—Directive 2010/84/EU and Regulation (EU) No 1235/2010. These GVP modules offer comprehensive guidance for marketing authorization holders (MAHs), national competent authorities, and the EMA on fulfilling pharmacovigilance obligations. While the EMA led the establishment of GVP within the EU, the harmonization of pharmacovigilance standards has been further supported by the International Council for Harmonisation (ICH).

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

https://www..ema.europa.eu

III. EMPOWER YOUR SAFETY

THE GOOD PHARMACOVIGILANCE PRACTICES GUIDELINE (GVP)

Foundations, Evolution, Importance, Adaptation

2015

In order to cope with these changes and to unify guidelines and performance of PV activities across the Arab world, Arab ministers of health came to a common decree (number 7) in their 37th regular meeting in **March 2012**. Countries such as Saudi Arabia, Egypt, Jordan, Morocco, Oman, Tunisia, and the United Arab Emirates have contributed to the development of the Arab guidelines based on the EMA's GVP modules. The guidelines were drafted to meet the needs of the region.

A key milestone was the publication of the "Arab Guidelines for Good Pharmacovigilance Practices" in **July 2015** by the **Arab League's Arab Harmonization Working Party (AHWP)**, which aims to unify pharmacovigilance requirements across the region.

These efforts reflect a growing recognition of the importance of drug safety and harmonized regulatory oversight in improving patient outcomes in the Arab world.

Guideline on good pharmacovigilance practices (GVP) For Arab Countries, Guideline for Marketing Authorization Holders, Version 3. https://who-umc.org/media/164038/the-good-pharmacovigilance-practice-for-arab-countries-v3-12-2015.pdf

2025

As for **Lebanon**, in **January 2023**, the Lebanese National Pharmacovigilance Program **(LNPVP)** initiated the drafting of the Lebanese Good Pharmacovigilance Practices (GVP) guideline, aiming to establish a standardized framework for PV activities in the country. This guideline was released for public consultation, allowing Marketing Authorization Holders (MAHs) and pharmaceutical companies to review and provide feedback on the proposed modules. An introductory training was conducted in **September 2023** to familiarize stakeholders with the content of the modules. In 2024, following the conclusion of the consultation period, the LNPVP started organizing focused training sessions on LGVP modules. In 2025, the LNPVP will conclude this structured training process. **June 2025** will mark the official launch of the LGVP, marking a critical milestone in strengthening the national PV system.

https://www.moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon#/en/view/70479/lebanese-guideline-on-good-pharmacovigilance-practices-lgvp-

III. EMPOWER YOUR SAFETY

THE GOOD PHARMACOVIGILANCE PRACTICES GUIDELINE (GVP)

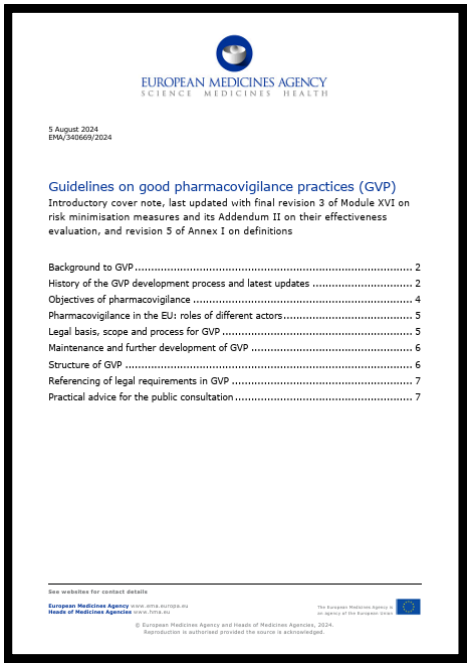
Foundations, Evolution, Importance, Adaptation

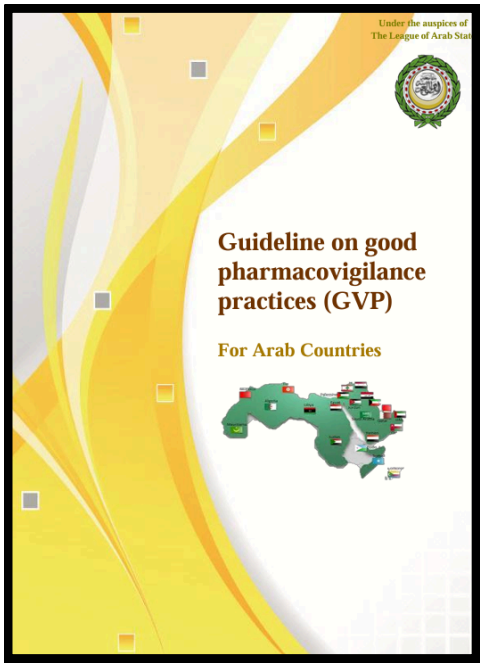
2. The Important Role of GVP in Drug Safety

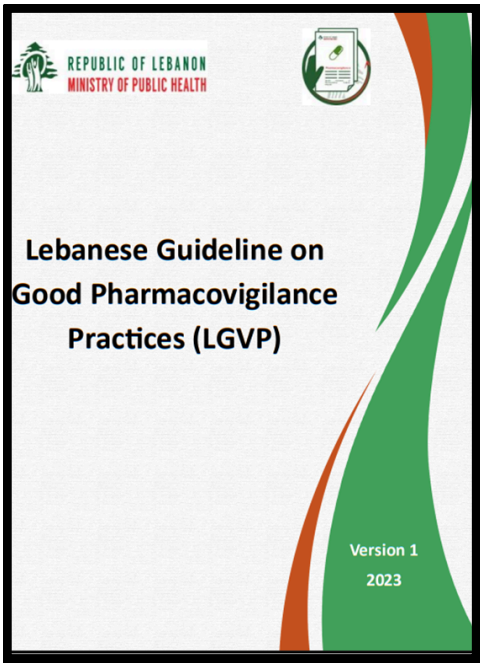
The primary objective of GVP is patient safety and ensuring regulatory compliance. In addition to ensuring that the benefits of a medicinal product continue to outweigh its risks.

In practice, this translates into **real-world safety actions** such as:

- Labeling changes after signal detection
- Market withdrawals of unsafe products
- Updated guidance to healthcare professionals and patients
- Rapid communication of emerging risks during pandemics or global health crises

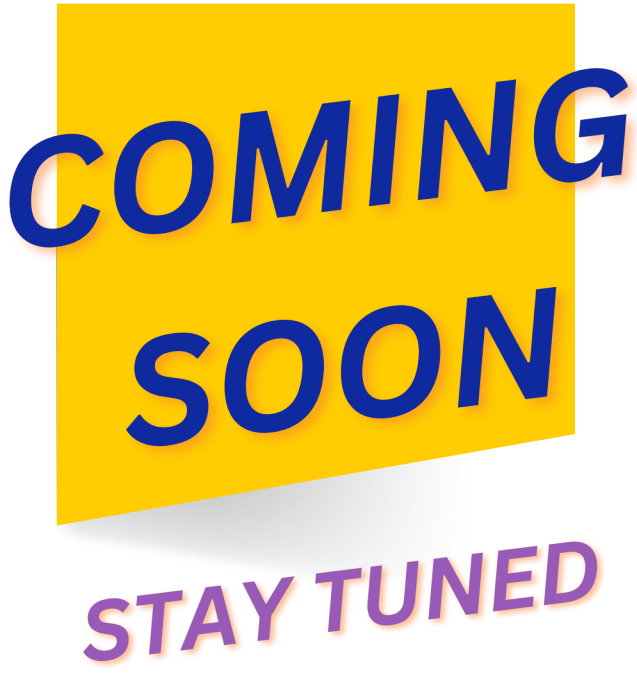






IV. ANNOUNCEMENT

FROM THEORY TO PRACTICE: THE OFFICIAL LAUNCH AND INTERACTIVE TRAINING ON THE LEBANESE GOOD PHARMACOVIGILANCE PRACTICES GUIDELINE



24th and 25th June, 2025

Under the patronage and in the presence of the **Minister of Public Health**, a specialized workshop titled “From Theory to Practice: The Official Launch and Interactive Training on the Lebanese Good Pharmacovigilance Practices Guideline” will mark the official announcement of the LGVP’s effective implementation.

The training will provide an in-depth exploration of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline, equipping participants with a thorough understanding of PV regulations and expectations in Lebanon.

PV Team Members at The MoPH

Dr. Rita Karam

Dr. Abeer Zeitoun

Dr. Aya Ibrahim

Stay Vigilant
Stay Safe
Report

ابقَ يقظًا
ابقَ آمنًا
بلِّغ