



THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

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Prepared by
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I. A NEW MILESTONE

Official Launch of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline

Introduction

On **June 30, 2025**, the Lebanese National Pharmacovigilance Program (LNPVP), under the patronage and the presence of the **Minister of Public Health (MoPH)**, marked a key milestone with the official launch of the **Lebanese Good Pharmacovigilance Practices (LGVP) Guideline**.

The event, held at the MoPH premises, brought together stakeholders including: presidents of professional orders and syndicates, representatives of Marketing Authorization Holders, Pharma Group, local manufacturers and distributors, deans of professional schools, and MoPH leaders, staff and consultants; reflecting a shared commitment to advancing medication safety and strengthening Lebanon's regulatory framework.



The ceremony was opened by **Dr. Abeer Zeitoun**, the Clinical and Technical Manager of the LNPVP, who delivered the welcome address.

She emphasized the significance of the LGVP guideline as a product of years of technical dedication, institutional collaboration, and shared vision, calling it a testament to Lebanon's capacity to build a pharmacovigilance system that protects patients by design and not by chance.



I. A NEW MILESTONE

Official Launch of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline

Ministerial Address: A National Commitment to Patient Safety

In his keynote address, Minister of Public Health **Dr. Nasser Al-Din** emphasized that the launch of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline, marks a collective commitment to protecting public health.

He highlighted the Ministry's dual responsibility: ensuring the availability of medicines and guaranteeing their quality, particularly in light of recent concerns about counterfeit and substandard drugs.



The Minister reaffirmed that his mandate prioritizes two key pillars: hospitalization and medication, which require national collaboration beyond the Ministry alone. He credited partnerships with universities, professional bodies, the WHO, and the World Bank for the successful development of the LGVP.

Dr. Nasser Al-Din reiterated the Ministry's dedication to protecting citizens from drug-related harm through transparent and accountable pharmacovigilance. He also shared updates on the National Drug Agency and Central Laboratory projects, both progressing through necessary legal and preparatory stages.

Finally, he announced an upcoming national awareness campaign to educate the public on the importance of drug quality and the dangers of unauthorized medications, reaffirming that all initiatives aim to ensure access to safe, effective, and high-quality medicines for all Lebanese citizens.



I. A NEW MILESTONE

Official Launch of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline

Key Highlights

Dr. Rita Karam, Director of the National Pharmacovigilance Program, delivered a comprehensive overview of the LGVP's significance.

She presented the guideline as both a regulatory and strategic tool aimed at embedding pharmacovigilance within national policy and clinical practice.

Dr. Karam reviewed the LNPVP's achievements since its official launch in 2021, including the processing of more than 27,000 adverse event reports, the establishment of hospital focal points, the publication of safety bulletins, and ongoing stakeholder training.

She shared the program's roadmap for the coming three years, which includes policy advancement, stakeholder engagement, and the integration of pharmacovigilance into the structure of the future Lebanese Drug Authority (LDA).

Dr. Karam recognized the essential support of partners, including the World Health Organization, World Bank, Lebanese University, Pharma Group, Lebanese Pharmacovigilance Task Force, LPIA, SPIL, and the Order of Pharmacists.

Special acknowledgment was given to the core LNPVP team: **Dr. Abeer Zeitoun and Dr. Aya Ibrahim** for their exceptional dedication in sustaining and growing the program amid challenging circumstances.



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Dr. Bassam Badran, President of the Lebanese University, praised the academic sector's role in embedding pharmacovigilance in medical education.

He emphasized the importance of preparing future healthcare professionals to actively participate in patient safety efforts and recognized the contributions of Dr. Karam and Dr. Zeitoun in leading this national effort.



Dr. Abdinassir Abubakkar, The World Health Organization Representative in Lebanon, praised the Lebanese National Pharmacovigilance Program (LNPVP) for its outstanding performance in responding to the COVID-19 pandemic, highlighting its leadership among countries in establishing a strong pharmacovigilance system and regularly issuing safety reports on adverse events following COVID-19 vaccination, as well as during the Cholera outbreak.

He highlighted the program's rapid development. Finally, **Dr. Abubakkar** congratulated the Ministry of Public Health and the PV team for their professionalism and dedication.

Mrs. Farah Asfahani, the World Bank representative, expressed in her speech the outstanding performance of the LNPVP's team and their ability to operate during the COVID -19 pandemic despite infrastructure and financial challenges. She also praised the launch of the LGVP Guideline as a major regulatory advancement, noting that national guidelines are essential for enforcing standards, ensuring accountability, and protecting public health investments. She reassured on the World Bank's ongoing support for health system strengthening and policy modernization in Lebanon.



I. A NEW MILESTONE

Official Launch of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline

Moving Forward

With the LGVP guideline as a foundation, Lebanon is set to institutionalize pharmacovigilance practices, ensure transparent and accountable reporting systems, and embed patient safety at the heart of its healthcare system. This launch marks not just the release of a guideline, but the beginning of a collective national commitment to protect every patient, every day.

Let the LGVP stand as a symbol of what Lebanon can achieve when expertise, collaboration, and purpose come together.

The ceremony concluded with a cake-cutting and cocktail reception, symbolizing the collective success of all those involved in the development and launch of the LGVP.



II. ANNOUNCEMENTS

Call for Participation: Med Safety Week 2025

The Lebanese National Pharmacovigilance Program (LNPVP) is proud to announce its participation in MedSafety Week 2025, taking place from November 3 to 9, 2025.

This global initiative, coordinated by the Uppsala Monitoring Centre (UMC) and supported by the World Health Organization (WHO), brings together national medicines regulatory authorities, healthcare professionals, patients, and the pharmaceutical industry to raise awareness about the critical importance of reporting Adverse Drug Reactions (ADRs).

For one week, stakeholders join forces to spread the campaign across the globe. They do this by sharing #MedSafetyWeek materials on their social media channels and via live events in university professional schools, hospitals, pharmacies, and other public spaces.

Participants in 2024



II. ANNOUNCEMENTS

Call for Participation: Med Safety Week 2025

Under the theme “Every Report Counts”, this year's campaign highlights how every contribution, no matter how small, plays a vital role in ensuring medicine safety.

The LNPVP invites healthcare professionals, academia, community pharmacists, hospitals, and the general public to take part in this important week through a wide range of activities, including:



Disseminating educational materials and videos



Hosting awareness sessions and workshops



Engaging directly in ADR reporting through the VigiMobile e-Form available on the Ministry of Public Health website

By encouraging open dialogue and active involvement, MedSafety Week 2025 aims to empower all stakeholders in the medication safety ecosystem. Together, let's promote a culture of vigilance because every report truly does count.



Join us in strengthening pharmacovigilance efforts. For details on how to participate, kindly contact the LNPVP Team (**Before September 15, 2025**) at:



+961 1 830 255/254



**pv.moph@gmail.com
pv@moph.gov.lb**

III. EMPOWER YOUR SAFETY

Abridged Patient Medication Information

Abridged Patient Medication Information (aPMI) is a simplified version of the full patient information leaflet designed to provide essential, easy-to-understand information about a medicine for patients and caregivers. Its purpose is to improve patient understanding and promote safe, effective, and informed use of medications.

A. The starting point

The concept of abridged or simplified patient medication information has evolved globally, but it gained formal structure and momentum through:

 Health Canada and the Therapeutic Goods Administration (TGA) of Australia, which developed Consumer Medicine Information (CMI).

 World Health Organization (WHO) has long encouraged simplified patient communication tools in their access to medicines and pharmacovigilance guidance.

 ISoP (International Society of Pharmacovigilance) supports abridged Patient Medication Information (aPMI) through advocacy, research, and risk-communication best practices, though it does not regulate aPMI directly.

B. aPMI Drafting

Abridged or simplified PMIs are usually:

- Drafted by the Marketing Authorization Holder (MAH) or pharmaceutical company often with input from regulatory agencies for review or approval.
- Ideally tested with patient groups (user-testing or readability testing) to ensure comprehension.
- Drafted by medical writers or regulatory affairs professionals, often in collaboration with pharmacovigilance teams for safety information.

III. EMPOWER YOUR SAFETY

Abridged Patient Medication Information

C. aPMI Purpose and Importance

- **Enhances Patient Safety:** Ensures patients understand how to use their medication properly, reducing misuse and adverse events.
- **Supports Adherence:** Clear instructions help patients follow dosing schedules correctly.

D. Key Features of aPMI



1. Lay Language:

aPMIs are written in simple, non-technical language that is accessible to the general public, including people with limited health literacy.



2. Essential Content Only:

It summarizes the most critical points from the full leaflet:

- What is the medicine used for
- How to use it
- Common side effects
- Warnings and precautions
- Storage instructions
- When to seek medical help



3. User-Friendly Format:

Often formatted in bullet points or Q&A style, and may include pictograms or icons for clarity.



4. Short and Concise:

Typically one to two pages long, focusing on practical information a patient needs to take the medicine safely.

IV. TESTIMONIALS



Nazira Hamadeh Jammaz
Chief Regulatory, Safety & Quality Officer
Mersaco

“As the Local Safety Responsible at Mersaco, I would like to extend my sincere appreciation and full support for the Lebanese National Pharmacovigilance Program, initiated and led by the Lebanese Ministry of Public Health.

In the face of immense national challenges, the commitment to patient safety has remained unwavering, thanks to the outstanding leadership of the Ministry’s Pharmacovigilance team: Dr. Rita Karam, Dr. Abir Zayton, and Dr. Aya Ibrahim. Their professionalism, scientific dedication, and genuine care for public health have transformed what was once an ambition into a functioning, impactful system.

Pharmacovigilance is more than a regulatory obligation, it is a moral and ethical responsibility that directly influences lives. The national program has created a much needed platform for collective vigilance and transparent reporting for better health outcomes in Lebanon.

The MOH Pharmacovigilance team continues to lead with clarity, integrity, and a spirit of collaboration. Their work reflects a national commitment to safety, science, and humanity.

At Mersaco, we stand in full alignment with this mission. We remain committed to actively contributing to the strengthening of the national PV system and to working hand in hand with the MOH to protect patients.

With gratitude and professional respect.”

IV. TESTIMONIALS



Amani Ghadban
Country Safety Head NEMA at Johnson & Johnson
& Pharmacovigilance Taskforce Lead at Lebanon Pharma Group

“Pharmacovigilance is a fundamental component of effective healthcare systems worldwide. A robust national pharmacovigilance program at the Lebanon Ministry of Public Health is essential for ensuring that patients receive not only the most effective treatments but also the highest safety standards. It can quickly identify and address safety concerns, promptly alert healthcare providers and patients, and implement necessary regulatory measures and risk minimization strategies in a timely manner.

An empowered national pharmacovigilance program in Lebanon goes beyond merely collecting and monitoring adverse events; it represents a commitment to delivering safe, effective, and high-quality care to every patient.

By prioritizing patient safety, we can foster trust in our healthcare system and enhance the overall well-being of our community.”

IV. TESTIMONIALS



Badiaa Masri
Levant PV Manager & Senior CRA
2628 Medical, Regulatory & Quality
Novo Nordisk Pharma SARL Lebanon

"I want to express my appreciation for Lebanon's national pharmacovigilance program. This initiative is crucial in ensuring the safety and well-being of patients, helping HCPs to better understand the safety of our products in a real-world setup. The dedication of the local health authority to monitor and address adverse drug reactions instills confidence in both healthcare providers and the public. Despite the constant struggles and scarce resources, the national pharmacovigilance team not only managed to launch the national pharmacovigilance program but was able to develop it throughout the years. Thank you for your ongoing commitment to patient safety and quality care."

PV Team Members at The MoPH

Dr. Rita Karam

Dr. Abeer Zeitoun

Dr. Aya Ibrahim

Stay Vigilant
Stay Safe
Report



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ابقَ آمِنًا
بَلِّغْ