THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

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Prepared by:
The Pharmacovigilance Team at the Ministry of Public Health

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I. SHARING THE KNOWLEDGE

From Theory to Practice: Interactive Training on the Lebanese Good Pharmacovigilance Practices (GVP) Guideline

SciencePro Academy organized a two-day training on 27–28 November 2025 dedicated to advancing the effective implementation of the Lebanese Good Pharmacovigilance Practices (LGVP).

The LNPVP was invited as a key speaker, bringing substantial expertise across the LGVP modules and regulatory expectations.

This two-day training brought together key experts and representatives from national bodies to strengthen pharmacovigilance practices and enhance collaboration across stakeholders.

Contributions from industry and external experts enriched the sessions, including perspectives from Roche, Boehringer Ingelheim, Sanofi, KBP-Biomak, SPIL, and independent consultants. Topics covered safety communications, DHPCs, PSURs, PBRERs, PASS implementation, outsourcing models, and case management challenges.

I. SHARING THE KNOWLEDGE

From Theory to Practice: Interactive Training on the Lebanese Good Pharmacovigilance Practices (GVP) Guideline

Day 1 Moderator: Dr. Amani Ghadban , LPG Representative

Opening by Science Pro:

Dr. Rony Abboud (VP – Development and Compliance at Science Pro) started the session by introducing the training program and outlining its objectives, emphasizing its role in strengthening pharmacovigilance capacity. He also highlighted the importance of each module and set the stage for an interactive and practical learning experience.

Dr. Rita Karam, Director of the National Pharmacovigilance Program, delivered an in-depth progress update on the Lebanese GVP Guideline. Her presentation focused on strengthening the national pharmacovigilance quality system, advancing the PSMF and PSSF framework, enhancing Risk Management Plans, and supporting additional risk minimization measures.

Dr. Abeer Zeitoun delivered a comprehensive walkthrough of LGVP Module XV on Safety Communications, highlighting harmonized messaging, timely dissemination, regulatory alignment, and stakeholder feedback integration.

I. SHARING THE KNOWLEDGE

From Theory to Practice: Interactive Training on the Lebanese Good Pharmacovigilance Practices (GVP) Guideline

Dr. Aya Ibrahim presented LGVP Module VI on the collection, management, and submission of suspected adverse reaction reports, focusing on reporting quality, timelines, data management, and stakeholder responsibilities.

Day 2 Moderator: Dr. Randa Aoun, LPIA Representative

Dr. Abeer Zeitoun presented LGVP Module VII on Periodic Safety Update Reports (PSURs), focusing on report objectives, content structure, benefit–risk assessment, and regulatory compliance.

Dr. Aya Ibrahim delivered LGVP Module VIII on Post-Authorization Safety Studies (PASS), highlighting study design, methodological transparency, feasibility considerations, and national expectations.

For more details, refer to the briefing:

https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/Training%20on%20the%20Lebanese%20Good%20Pharmacovigilance%20Practices%20(LGVP)%20%E2%80%93%20November%202025.pdf

II. ANNOUNCEMENT

A. Audit and Inspection Modules – Public Consultation

The National Pharmacovigilance Program is pleased to announce the release of the Pharmacovigilance Audit and Inspection Modules for the public consultation phase as part of the national implementation of the Lebanese Guideline on Good Pharmacovigilance Practices (LGVP). The public consultation will take place from the start of February 2026 till the end of April 2026.

JOIN US !

FEBRUARY-APRIL, 2026

The Audit and Inspection Modules cover key areas such as:

- Pharmacovigilance system organization and governance
- Risk management systems
- Individual Case Safety Report (ICSR) management
- Quality management systems and corrective actions

The public consultation is intended to:

- Review the proposed modules
- Provide scientific and operational feedback
- Contribute to enhancing clarity, feasibility, and alignment with real-world practice
- Engage national and multinational/other companies Marketing Authorization Holders (MAHs), service providers, and drug distributors

II. ANNOUNCEMENT

B. ISoP Medication Errors Prevention Hackathon

We truly honored to share that our team was selected among the top three winning teams in the **ISoP Medication Errors Prevention Hackathon**: a powerful global initiative uniting minds and expertise to reimagine the future of medication safety.

Our project, “Application of Human Factors to Design a Standardized Label for IV Infusions,” was more than just a hackathon challenge. It was a mission. A mission to design a meaningful, practical solution that could one day help prevent avoidable medication errors and protect patients around the world.

A heartfelt thank you to the International Society of Pharmacovigilance (ISoP) team especially Angela Caro-Rojas FISoP for creating the space, platform, and inspiration that made this journey possible.

Here’s to innovation, collaboration, and the shared belief that even small improvements can save lives.

🥉 **Team 3:** Application of Human Factors to Design a Standardised Label for IV infusions

Team Lead: Abeer Zeitoun (Lebanon) | Members: Rabih Dabliz, Aya Ibrahim, Mina Sodad, Meriem Kerrar, Diallo Mamadou Madio, Uzu Maki

III. STAY VIGILANT, STAY SAFE

MedSafety Week

November 3rd till 9th 2025

OVERVIEW

MedSafety Week is a global medicine-safety awareness campaign led by the Uppsala Monitoring Centre (UMC) to promote the reporting of side effects and strengthen a culture of pharmacovigilance. From 3–9 November 2025, stakeholders worldwide united under the theme “We can all help make medicines safer.” The Lebanese National Pharmacovigilance Program (LNPVP) actively participated in the campaign through a comprehensive social media strategy and academic engagement with five Lebanese schools of pharmacy.

LNPVP SOCIAL MEDIA CAMPAIGN

- The LNPVP shared UMC-provided campaign materials, including social media cards, flyers, and animated videos, across Facebook, Instagram, X, and LinkedIn. Adding to this poll questions were used to increase engagement.
- In parallel, locally tailored flyers, short videos, and graphics were produced to address the Lebanese context. A coordinated campaign was run through the Ministry of Public Health platforms and the LNPVP LinkedIn page.

The objectives were to raise public awareness of adverse drug reactions (ADRs), encourage reporting through national tools, and strengthen pharmacovigilance culture among future healthcare professionals.

III. STAY VIGILANT, STAY SAFE

MedSafety Week

ACADEMIC ENGAGEMENT

To deepen outreach, the LNPVP invited five schools of pharmacy to participate:

- Lebanese University (LU)
- Lebanese American University (LAU)
- Lebanese International University (LIU)
- Beirut Arab University (BAU)
- Saint Joseph University (USJ)

The LNPVP provided print-ready materials, educational videos, local content, and flexibility for each institution to design its own activities.

Schools of pharmacy, in collaboration with the LNPVP, organized awareness campaigns focused on Adverse Drug Reaction (ADR) reporting and safe medication use. Posters, flyers, small lectures, and video presentations were shared across the faculty.

For more details, refer to the briefing:
https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/Training%20on%20the%20Lebanese%20Good%20Pharmacovigilance%20Practices%20(LGVP)%20%E2%80%93%20November%202025.pdf

IV. KNOWLEDGE CORNER

Pharmacovigilance in Special Population

Children and Women of Childbearing Age

Addressing the Challenge of Limited Safety Data

Children and women of childbearing age represent vulnerable populations in pharmacotherapy, where clinical trial data are often limited, and real-world pharmacovigilance plays a critical role in identifying and managing medicine-related risks.

1. Pediatric Population

Why Safety Data Are Limited

- Children are frequently excluded from pre-authorization clinical trials
- Ethical and methodological constraints limit pediatric studies
- Off-label use of medicines is common in pediatrics

Common Pediatric Safety Concerns

- Dose-related toxicity due to weight-based dosing errors
- Central nervous system effects (e.g., sedation, behavioral changes)
- Growth and development impacts, which may appear only after long-term exposure

Healthcare professionals are encouraged to report all suspected ADRs in children, even if the reaction is already known, as pediatric-specific patterns may differ from those in adults.

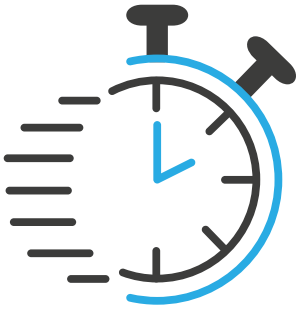
Reference: https://pubmed.ncbi.nlm.nih.gov/29598957/

IV. KNOWLEDGE CORNER

Pharmacovigilance in Special Population

Children and Women of Childbearing Age

2. Women of Childbearing Age



Why Safety Data Are Limited

- Pregnant women are routinely excluded from clinical trials
- Safety data often rely on post-marketing reports, pregnancy registries, and observational studies

Common Pediatric Safety Concerns

- Timing of exposure (especially first trimester)
- Dose and duration of treatment
- Concomitant medications

Despite these limitations, medication exposure before or during pregnancy may lead to:

- Teratogenic effects
- Pregnancy complications
- Neonatal adverse outcomes

➡ Suspected ADRs related to pregnancy, breastfeeding, fertility, or fetal outcomes should always be reported, even in cases of uncertainty, as signal detection relies on cumulative data.

Reference: https://pubmed.ncbi.nlm.nih.gov/38907172/

IV. KNOWLEDGE CORNER

Pharmacovigilance in Special Population

Children and Women of Childbearing Age

3. The Role of Pharmacovigilance in Low-Data Populations

For both pediatric patients and women of childbearing age, “every report counts”.

Pharmacovigilance systems depend on:

High-quality Individual Case Safety Reports (ICSRs)

Detailed patient characteristics (age, gestational age, weight)

Clear description of outcomes

Strengthening ADR reporting in these populations supports:

Earlier signal detection

Evidence-based regulatory decisions

Safer use of medicines in routine practice

➡ Healthcare professionals are reminded that the lack of certainty should never prevent reporting.

V. TESTIMONIALS

Mrs. Martine Abikhalil – KBP Biomak

“Thankfully, we now have the LGVP guidelines, which will place us on the international stage and align us with global pharmacovigilance regulations followed by pharmaceutical companies.”

V. TESTIMONIALS

Dr. Randa Aoun - LPIA Representative

“I would like to congratulate the LNPVP at the Ministry of Public Health for the great effort and significant work invested in developing and preparing the LGVP guideline.”

V. TESTIMONIALS

Sara Bahr, Near East and UAE Patient Safety Lead at Boehringer Ingelheim

“I had the privilege of working closely with the LNPVP (Lebanon National Pharmacovigilance Program) team during the workshop designed to train the pharmaceutical companies, distributors, and service providers in Lebanon to ensure effective GVP implementation. The team’s leadership and commitment position them as a role-model for other regulatory bodies across the region. I truly value their proactive mindset, collaborative spirit, and dedication to learning from global regulatory experiences and engaging leading experts which were clearly evident in the well-organized GVP workshops. I would like to sincerely thank Dr. Rita Karam, Dr. Abeer Zeitoun, and Dr. Aya Ibrahim for their tremendous efforts.”

V. TESTIMONIALS

Amira Shehata - Pfizer - Country Safety Lead

“I was pleased to attend the recent two day training (From Theory to Practice- Interactive Training on the Lebanese Good Pharmacovigilance Practices (LGVP) guideline). The sessions were highly insightful, providing much needed clarity on the new regulatory expectations and practical steps for implementation ahead of the 2026 timeline.

I truly valued the constructive face to face discussions with Dr. Rita Karam, Dr. Abeer Zeitoun, and Dr. Aya Ibrahim. Their expertise, openness, and commitment to building a robust national PV framework were evident throughout. I also had the opportunity to share relevant experience from Egypt, which enriched our exchanges.

This training was timely, well delivered, and instrumental in preparing stakeholders for the upcoming transition. I look forward to continued collaboration with the Lebanese PV Program team.”

PV Team Members at The MoPH

Dr. Rita Karam

Dr. Abeer Zeitoun

Dr. Aya Ibrahim

Stay Vigilant
Stay Safe
Report

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بلِّغ