THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

LEBANON

ISSUE 10

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Prepared by
The Pharmacovigilance Team
at the Ministry of Public Health

OUTLINE

I. Sharing the Knowledge

Exploring Pharmacovigilance from Theory to Practice

As part of the Lebanese National Pharmacovigilance Program (LNPVP) educational activities, the Pharmacovigilance (PV) team provided an educational training session to the 5th-year Bachelor's degree pharmacy students and Pharm-D students at Lebanese American University (LAU). The training session took place on January 22nd, 2024, at the LAU Byblos Campus, with a total attendance of 50 students.

Titled "Exploring Pharmacovigilance: Theory and Practice", the two-hour session introduced the pharmacy students to the PV landscape in Lebanon, offering insights into its daily activities and operations.

The offered presentations provided a global perspective on pharmacovigilance, followed by a comprehensive explanation of the adverse event reporting process. Special attention was given to the handling procedures for Adverse Events Following Immunization (AEFIs) and Adverse Drug Reactions (ADRs) in Lebanon.

The session was concluded with a hands-on practice of essential PV definitions and terminologies for data entry. This was reinforced by an interactive discussion on real-life cases of AEFIs/ADRs received by the LNPVP.

II. Stay Vigilant, Stay Safe

Lebanese Good Pharmacovigilance Practices Guidelines Public Consultation

The Lebanese Good Pharmacovigilance Practices guidelines were launched at the first annual Pharmacovigilance Conference in September 2023. Following a structured public consultation process divided into three phases, the Modules were sequentially released on the MoPH website online.

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

Phase I

- **Introductory Note:** Legal basis and structure of pharmacovigilance guideline
- **Module I:** Pharmacovigilance systems and their quality systems
- **Module VI:** Collection, management, and submission of reports of suspected adverse reactions to medicinal products

Phase II

- **Module II:** Pharmacovigilance System Master File (PSMF) and Pharmacovigilance Sub-System File (PSSF)
- **Module V:** Risk Management Systems
- **Module XVI:** Risk minimization measures-selection of tools and effectiveness indicators

Phase III

- **Module VII:** Periodic Safety Update Report (PSUR)
- **Module VIII:** Post-Authorization Safety Studies (PASS)
- **Module XV:** Safety communication

II. Stay Vigilant, Stay Safe

Lebanese Good Pharmacovigilance Practices Guidelines Public Consultation

Deadlines for National and Multinational Market Authorization Holders (MAHs), local agents, and other companies were set for the three phases as follows:

Phase I

October 16th, 2023 → January 16th, 2024

Phase II

November 16th, 2023 → March 16th, 2024

Phase III

December 16th, 2023 → April 16th, 2024

A committee of internal and external experts is currently reviewing the received comments on the released Modules from the national and international MAHs, Local agents, and other companies. An updated version of the Modules will be posted on the MoPH website.

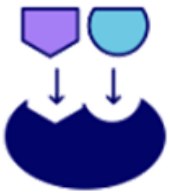
III. Knowledge Corner

A. Expand your vocabulary

1.What is an Adverse Event Following Immunization (AEFII)?

An adverse event following immunization (AEFI) is defined as any untoward medical occurrence following immunization that does not necessarily have a causal relationship to the vaccine.

2.What are the types of AEFIs?

	**Vaccine Product Related Reaction:** Caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.
	**Immunization error-related reaction:** Caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer.
	**Vaccine quality defect-related reaction:** Caused by inappropriate vaccine handling, prescribing or administration.
	**Immunization anxiety-related reaction:** An AEFI arising from anxiety about the immunization.
	**Coincidental event:** An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

https://www.who.int/

III. Knowledge Corner

B. VigiMobile

VIGIMOBILE

Report Adverse Events Following Immunization

The Lebanese National Pharmacovigilance Program is working in collaboration with the WHO-UMC for the development of the new AEFI reporting tool "VigiMobile".

Key Features of VigiMobile:

- No sign-up procedure
- Data entry can be done while offline
- Requires very little data per report for transfer
- Possible to save copies of sent reports on the device

SOON WILL BE AVAILABLE ON

IV. Exchanging the Experience

GCC Regulatory Affairs Pharma Summit 2024

GCC Regulatory Affairs Pharma Summit

Mövenpick Grand Al Bustan, Dubai, UAE

April, 24, 2024

9:30 AM

Journey to GVP Excellence in Lebanon

Our Speakers:

Dr. Abeer Zeitoun

Clinical and Technical Manager at he National Pharmacovigilance Program in Lebanon

Dr. Rita karam

Focal Point, Manager and Coordinator of the National Pharmacovigilance Program in Lebanon

IV. Exchanging the Experience

GCC Regulatory Affairs Pharma Summit 2024

GCC Regulatory Affairs Pharma Summit is an annual event that provides a platform for pharmaceutical regulatory experts and industry professionals in the GCC region to share insights and discuss the latest updates in the pharmaceutical regulations.

The LNPVP team, represented by Dr. Rita Karam and Dr. Abeer Zeitoun participated in the GCC Regulatory Affairs Pharma Summit with a presentation entitled “Journey Towards Pharmacovigilance Excellence in Lebanon”.

Part I of the presentation entitled “Drafting and Implementing the Lebanese Good Pharmacovigilance Practices Guideline (LGVP)” was delivered by Pr. Rita Karam. She highlighted the significance of the Pharmacovigilance Program in Lebanon in safeguarding public health.

Pr. Karam outlined the program development and how it collaboratively works with the pharmacovigilance stakeholders to achieve a safer use of medicine. She explained how the program followed the international and regional GVP guidelines, to draft the Lebanese Good Pharmacovigilance Practice (LGVP) version. The LGVP guideline provides a tailored, structured approach aligned with Lebanon's healthcare system, empowering stakeholders to implement effective pharmacovigilance strategies.

Pr. Karam highlighted the LGVP's role in preparing companies to be compliant with upcoming regulations.
This partnership between the public and private sectors enhances commitment to transparency, collaboration, and ensuring the safety and efficacy of pharmaceutical products.

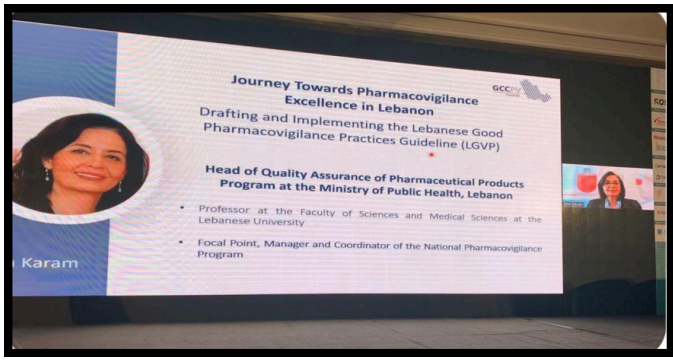
IV. Exchanging the Experience

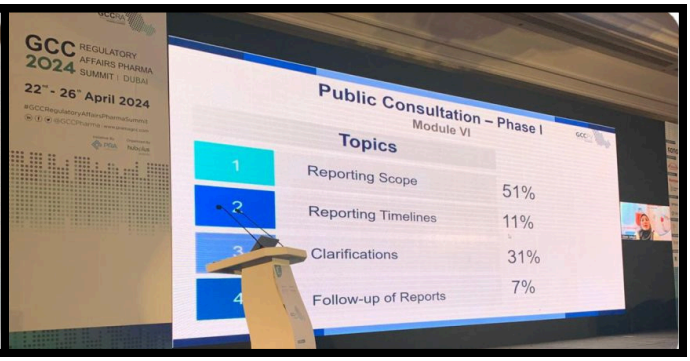
GCC Regulatory Affairs Pharma Summit 2024

Part II of the presentation entitled “Drafting and Implementing the LGVP Guideline” was presented by Dr. Abeer Zeitoun. She introduced the audience to the official launching of the guideline during the "First Annual Lebanese Pharmacovigilance Conference," marking a significant step towards enhancing drug safety and monitoring practices in Lebanon.

She emphasized the strategic approach that guided the dissemination of the guideline, highlighting the adoption of a modular and sequential release strategy for public consultation.

Dr. Zeitoun outlined the specific focus on Modules I and VI, detailing comments and actions taken within these modules. Looking ahead to 2024, the outline maps plans for national implementation to ensure effective pharmacovigilance practices.





PV Team Members at The MoPH

Pr. Rita Karam
Dr. Abeer Zeitoun
Dr. Aya Ibrahim
Dr. Myriam Watfa