REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

LEBANON

ISSUE 8

October 2023

Prepared by
The Pharmacovigilance Team
at the Ministry of Public Health

OUTLINE

I Sharing the Knowledge

1st Annual Lebanese Pharmacovigilance Conference

II Stay Vigilant, Stay Safe

1. **Pre-conference Courses:**

- **Course 1: Pharmacovigilance and the Marketing Authorization Holders: Introduction to the Lebanese Good Pharmacovigilance Practices Guideline (LGVP Guideline)**
- **Course 2: Patient and Medication Safety System: Optimizing Healthcare Systems Safety Operation**

2. **Hospital Pharmacovigilance Focal Point Capacity Building**

III Guiding Safety

Launching of the Lebanese Good Pharmacovigilance Practices Guideline

I. Sharing the Knowledge

1st Annual Lebanese Pharmacovigilance Conference

On September 30th 2023, the Lebanese National Pharmacovigilance Program at the Ministry of Public Health, marked one of its milestones by holding the 1st Annual Lebanese Pharmacovigilance Conference titled “Exploring Pharmacovigilance in The MENA Region and Shaping the Good Pharmacovigilance Practices”. The conference was hosted by the Lebanese American University, Byblos campus, under the patronage and presence of His Excellency Dr. Firass Al Abiad, the Minister of Public Health.

The event hosted pharmacovigilance experts from Egypt, Jordan, Iraq, UAE, and Switzerland. In addition to pharmacovigilance representatives of national and international pharmaceutical companies, university professors, and students.

Among the distinguished guests who attended the conference: Prof. Bassam Badran - President of the Lebanese University; Dr. Shanti Pal – Team Lead - World Health Organization (WHO) Headquarter - Geneva; Dr. Abdinasir Abubakar - WHO Representative – Lebanon Country Office; Dr. Omar Al Rifai - WHO Pharmacovigilance Focal Point; Dr. Walid Ammar – MoPH Former Director; and Dr. Naser Alsharif - Dean of the School of Pharmacy - LAU.

I. Sharing the Knowledge

1st Annual Lebanese Pharmacovigilance Conference

The Pharmacovigilance Conference was an exceptional event, bringing together experts and professionals in the field to share valuable insights and knowledge. The high-quality presentations and engaging discussions showcased the latest developments and best practices in pharmacovigilance. Overall, the positive feedback from attendees featured the conference's success in providing valuable insights and fostering meaningful connections within the pharmacovigilance community.

II. Stay Vigilant, Stay Safe

Pre-conference Courses

Course 1: Pharmacovigilance and the Marketing Authorization Holders: Introduction to the Lebanese Good Pharmacovigilance Practices Guidelines (LGVP Guidelines)

On the 29th of September 2023, the National Pharmacovigilance Program team at the Ministry of Public Health conducted an introductory pre-conference course for the Marketing Authorization Holders (MAHs) on the Lebanese Good Pharmacovigilance Practices (GVP) Guideline. A total of 45 participants attended the course representing different multinational and local pharmaceutical companies and drug distributors.

The primary objectives of this course were threefold. Firstly, to ensure that the attendees recognize the importance of the GVP Guideline to establish an effective pharmacovigilance system. Secondly, the course aimed to provide the attendees with the roles and responsibilities of MAHs and the requirements in establishing robust pharmacovigilance systems within their respective companies. Lastly, to equip the attendees with practical guidance on implementing a comprehensive pharmacovigilance system tailored to their specific organizational needs.

II. Stay Vigilant, Stay Safe

Pre-conference Courses

Course 1: Pharmacovigilance and the Marketing Authorization Holders: Introduction to the Lebanese Good Pharmacovigilance Practices Guidelines (LGVP Guidelines)

The course was divided into 3 sessions:

Session I introduced the Lebanese GVP Guideline along with an overview of the eight selected modules for the initial phase of GVP implementation. This session was presented by Pr. Rita Karam - Coordinator of the National Pharmacovigilance Program at the Ministry of Public Health. She was assessed by the National PV Officers Dr. Aya Ibrahim and Dr. Sarah Reda El Sayed. And finally, Dr. Myriam Watfa, PV Consultant shared her experience in helping different MAHs in implementing their GVP guideline.

Session II and III were presented by Dr. Hadir Rostom, WHO Pharmacovigilance Consultant. She gave practical tips for establishing a PV system within pharmaceutical companies providing examples of challenges encountered by the MAHs throughout the process of implementing GVP guideline.

II. Stay Vigilant, Stay Safe

Pre-conference Courses

Course 2: The Patient and Medication Safety System: Optimizing Healthcare Systems Safety Operation

On the 29th of September 2023, the National Pharmacovigilance Program team at the Ministry of Public Health conducted an introductory pre-conference course for the Pharmacovigilance Hospital Focal points on "The Patient and Medication Safety System: Optimizing Healthcare Systems Safety Operation".

A total of 17 participants attended the course representing different hospitals, multinational and local pharmaceutical companies, drug distributors, and pharmacy students.

The primary objectives of the course were to:

- Introduce the participants to the successful implementation of the Lebanese National Pharmacovigilance Program in Lebanon.
- Enhance healthcare professionals' knowledge and skills in optimizing safety operations within Hospitals.
- Emphasize the importance of the establishment of a medication event reporting system in hospitals.
- Provide the participants with the needed tools to create an environment that encourages "Just Culture".
- Share the importance of an effective safety communication design.

II. Stay Vigilant, Stay Safe

Pre-conference Courses

2. Course Title: The Patient and Medication Safety System: Optimizing Healthcare Systems Safety Operation

The course was divided into 3 sessions:

- Session I: Medical Event Reporting
- Session II: Just Culture and Second Victim
- Session III: Safety by Design

Dr. Abeer Zeitoun, the Clinical and Technical Manager at the LNPVP, initiated the session with a presentation titled "The Journey of the Lebanese National Pharmacovigilance Program".
This was followed by a presentation on "Establishing a Medication Event Reporting System in Healthcare Organization" that was provided by Dr. Rabih Dabliz, the Senior Manager for Quality and Medication Safety Services at Cleveland Clinic Abu Dhabi.
Finally, the last presentation of session I "Stories from the Field – A Lebanese Experience" was presented by Dr. Elsy Ramiah, Clinical Associate Professor at the Lebanese American University – School of Pharmacy. In sessions II and III, Dr. Dabliz introduced the audience to "Just Culture" and "Designing Effective Communication and Storytelling".

II. Stay Vigilant, Stay Safe

Hospital Pharmacovigilance Focal Point Capacity Building

In recognition of the vital significance of maintaining pharmaceutical product safety and efficacy within the healthcare sector, the Lebanese National Pharmacovigilance Program (LNPVP) conducted a comprehensive Hospital Pharmacovigilance Focal Point Capacity Building.

The aim was to enhance the expertise and capabilities of the nominated Pharmacovigilance Focal Points in pharmacovigilance operations in order to improve the process of Adverse Events (AEs) reporting.

A total of 81 pharmacovigilance focal points attended the sessions. They were divided into 3 groups, each group attended two sessions.

The first session (Session I), titled "Introduction to Pharmacovigilance Operations", aimed to acquaint the participants with the fundamental concepts of pharmacovigilance, including the workflow and the process of reporting.
The subsequent session (Session II), titled "Mastering the Basics of Reporting", was a hands-on training session designed to equip the participants with the necessary skills to effectively utilize reporting tools and facilitate the preparation of comprehensive case reports.

III. Guiding Safety

Launching of the Lebanese Good Pharmacovigilance Practices Guideline

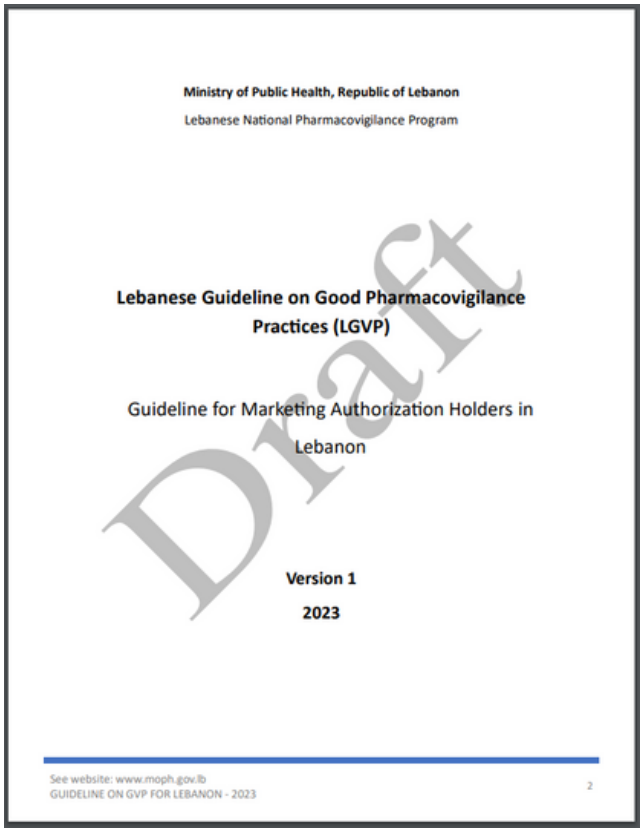
On the 30th of September 2023, the Lebanese National Pharmacovigilance Program at the Ministry of Public Health launched the Lebanese Good Pharmacovigilance Practices Guideline under the patronage of His Excellency Dr. Firass Al Abiad.

In his speech, Dr. Firass Al Abiad stated that strengthening pharmacovigilance and safety measures stands as a fundamental and inseparable component of the Ministry's goals, aimed at ensuring patient safety while alleviating financial burdens on healthcare systems and patients alike. Consequently, the pharmacovigilance program holds a distinctive position among the initiatives undertaken by the Ministry of Public Health.

He then officially announced the launching of the Lebanese Pharmacovigilance Practices Guideline which was followed by cutting a cake celebrating this momentum.

III. Guiding Safety

Launching of the Lebanese Good Pharmacovigilance Practices Guideline



The guideline was based on:

- The European Good Pharmacovigilance Practices (EU GVP) adheres to the International Council for Harmonization (ICH) PV guidelines.
- The Food and Drugs Administration (FDA) guidelines. Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.
- The Guidelines on Good PV Practices for Arab Countries prepared by the League of Arab Countries.
- Different PV guidelines were published by each of the regional Arabic countries including Iraq, Oman, UAE, Egypt, and Saudi Arabia.

III. Guiding Safety

Launching of the Lebanese Good Pharmacovigilance Practices Guideline

Eight selected modules from the GVP Guideline are to be implemented in the phases. The modules include:

MODULE I: Pharmacovigilance Systems and their Quality Systems
MODULE II: Pharmacovigilance System Master File
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
MODULE VIII: Post-Authorization Safety Studies
MODULE XV: Safety Communication
MODULE XVI: Risk minimization measures: selection of tool and effectiveness indicators

The modules will be released in a sequential matter in 3 phases starting October 16th, 2023 for public consultation.

Phase I (October 16, 2023 till January 16, 2024) includes:

- 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 (November 16, 2023 till February 16, 2024) includes:

- 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 (December 16, 2023 till March 16, 2024) includes:

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

The end of the public consultation is set to be March 16th, 2024.

For further details, refer to the ministry's website:
https://rb.gy/ksa1s

PV Team Members at The MoPH

Dr. Rita Karam - Dr. Abeer Zeitoun
Dr. Aya Ibrahim - Dr. Sarah Reda El Sayed
Dr. Myriam Watfa