



THE NATIONAL PHARMACOVIGILANCE PROGRAM NEWSLETTER

LEBANON

Issue 4

October 2022

Prepared by
Pharmacovigilance Team
at the Ministry of Public Health

OUTLINE

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I.

The Lebanese National Pharmacovigilance System: Officially Launched

Under the patronage and presence of his excellency the Minister of Public Health Dr. Firass Al-Abiad, the National Pharmacovigilance (PV) System in Lebanon was launched in an event held at the Mövenpick Hotel in Beirut, on September 14th, 2022.

The event was attended by key officials from the Ministry of Public Health (MoPH), the Lebanese University (LU), World Health Organization (WHO), World Bank (WB), École Supérieure des Affaires (ESA), Agence Française de Développement (AFD), and various representatives of the Lebanese pharmaceutical companies (LPG) and academic community.



Upon the arrival of the attendees, an agenda with the detailed schedule of the event, along with educational materials that introduced them to PV and its role as well as the newly launched Med Safety App were distributed. Speech topics and allotted speaking times were detailed for every speaker which ensured a smooth progression of the event. Each one of the nine speakers was introduced by the event moderator Mrs. Riwa Al Atrash who provided the audience with a brief overview on the topic to be presented.

Suspected adverse effect?

List of known adverse effects

Report to

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MINISTRY OF PUBLIC HEALTH**

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**REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH**

National Pharmacovigilance System Launching in Lebanon

Agenda

Duration	Topic	Speaker
12:00	Welcome Address	Mrs. Riwa Al Atrash
12:05	Overview of the National Pharmacovigilance System	Pr. Rita Karam National Pharmacovigilance System Coordinator
12:10	Promotional Video On the National Pharmacovigilance System	
12:15	Overview of the National Pharmacovigilance Reporting System: Med Safety Application and E- reporting	Dr. Abeer Zeitoun Clinical and Technical Manager of Pharmacovigilance Program
12:25	Med Safety Application Introductory Video (Arabic Language)	
12:30	Guest Speech	Pr. Bassam Badran President of the Lebanese University
12:35	Guest Speech	Dr. Abdinasir Abubakar WHO Representative - Lebanon
12:40	Guest Speech	Dr. Ronald Eduardo Gomez - Suarez Senior Health Economist World Bank representative - Beirut Office
12:45	Guest Speech	Dr. Houda Langar WHO – EMRO - Regional Advisor - Egypt
12:50	Guest Speech	Dr. Phil Treguno Medicines and Healthcare products Regulatory Agency - UK
12:55	Guest Speech	Dr. Shanthi Pal Narayan WHO Head Quarter Representative - Switzerland
1:05	Key Note Speech	Dr. Firass Al-Abiad Minister of Public Health - Lebanon
1:15	Closing and Cutting Cake	Mrs. Riwa Al Atrash

Cocktail and Networking

PROGRAPHI | *Simple BETTER*

Lebanon Pharma Group

The event was initiated and welcome remarks delivered by the Director of the Quality Assurance of Pharmaceutical Products Program (QAPPP) and the National Pharmacovigilance System Coordinator **Pr. Rita Karam**, who first used a promotional video to introduce the Lebanese National Pharmacovigilance Program (LNPVP). She further outlined the roadmap to the system's success and acquainted the audience with the achievements of the program despite the unfortunate work conditions that the country has been facing. The program's first milestone dates back to 2021, where the LNPVP succeeded in qualifying as a full member in the World Health Organization Program for International Drug Monitoring (WHO-PIDM), after relentless efforts to secure the sufficient human and material resources, and to ensure compliance with the relevant national and international legal requirements. This work culminated in a series of achievements that Pr. Karam proudly enumerated: issuing a number of regulations related to the means of reporting of drug or vaccine-related Adverse Events (AEs), in addition to decisions to form specialized committees to evaluate and follow up on these AEs, transitioning from paper to electronic reporting means including the newly-launched Med Safety App in collaboration with the Uppsala

**REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH**

National Pharmacovigilance System Launching in Lebanon

WHAT IS PATIENT SAFETY?

According to the WHO, patient safety is a health care discipline that emerged with the evolving complexity in health care systems and the resulting rise of patient harm in health care facilities.

It aims to prevent and reduce risks, errors and harm that occur to patients during provision of health care.

WHAT CAN BE DONE?

Information to Patients

Increase health literacy by:

- Providing accessible information
- Using patient-friendly language
- Developing dialogue between healthcare professionals and patients

Patient Involvement

Healthcare professionals and decision-makers need to:

- Listen to patients
- Take their drug safety concern seriously
- Accept them as equal partners

CREATE A PATIENT SAFETY CULTURE THROUGH

- Blame-free Environment
- Open Communication
- Team Work

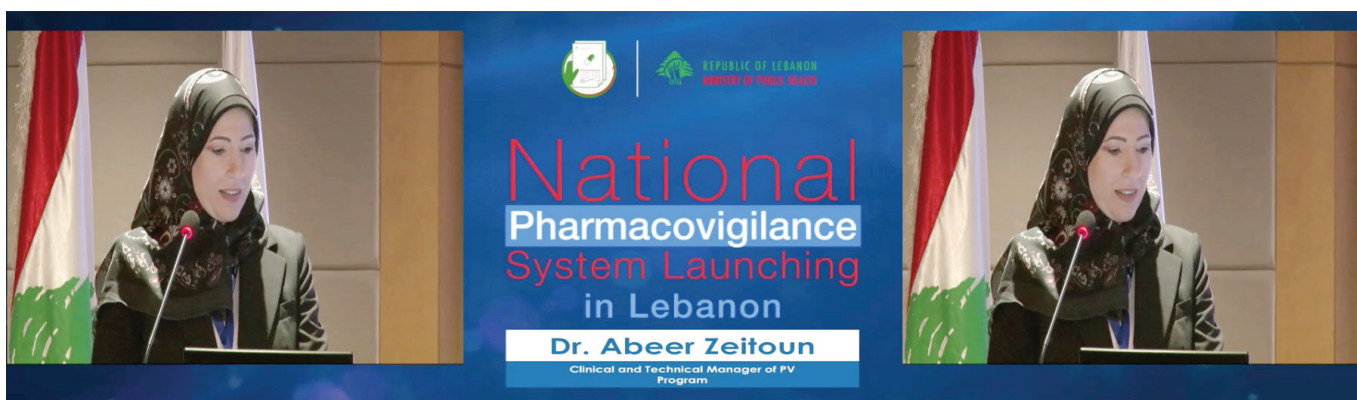
Monitoring Centre (UMC) and the Medicines and Healthcare products Regulatory Agency (MHRA), preparing and publishing periodic reports detailing the Adverse Events Following Immunization (AEFIs) associated with the COVID-19 vaccines, and conducting numerous educational initiatives including workshops, capacity buildings, distributing promotional material, and vaccination site visits, all in the objective of raising awareness on the importance of AEs reporting using the available reporting tools.



In line with the program’s vision to becoming a national and regional reference in PV, **Pr. Karam** shared the educational impact that the LNPVP has marked on the scientific community through multiple publications, both accepted and under peer review, the latest of which depicting the Lebanese success story in implementing a PV system in the context of COVID-19 in a resource-limited setting (<https://lnkd.in/eECF4z23>).

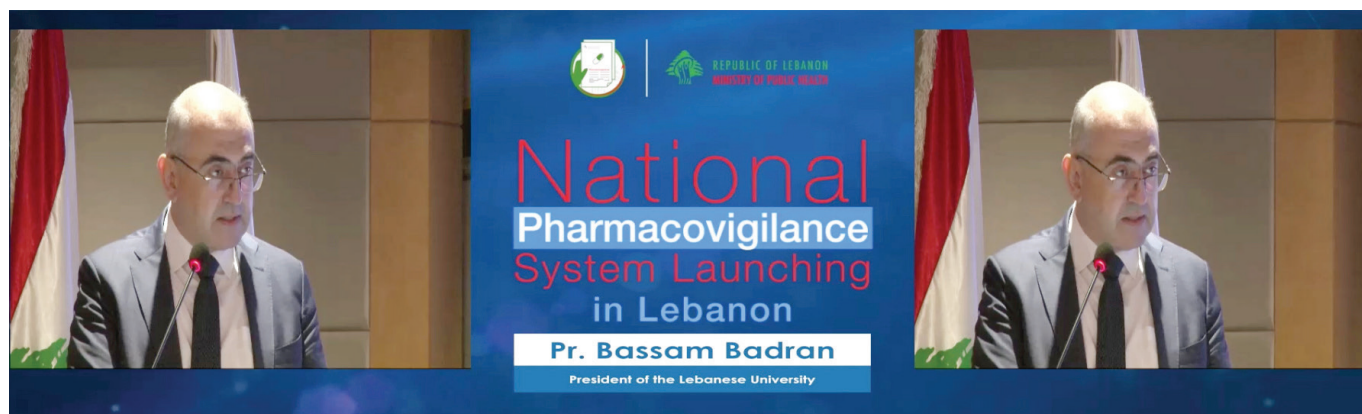
“Today we have an operating National PV Program that day by day secures better procedures and identifies, evaluates and reports Adverse Drug Reactions (ADRs)”, said Pr. Karam. “Over a very short period of time, we reported over 21,000 ADRs and 7,000 AEFIs, both numbers being record-breaking figures in the Middle East region”. The program’s future aspirations were finally presented to keep the audience updated on the country’s PV planned agenda: cross-functional collaborations are encouraged between the MoPH and the Lebanese academic community in order to incorporate the science of PV in the curricula taught in medical professions, more educational activities targeting all PV stakeholders are fostered, and Good PV Guidelines are being drafted in order to build an effective PV community across Lebanon.

The LNPVP’s Senior Clinical and Technical Manager **Dr. Abeer Zeitoun** then took the floor to highlight the reporting tools that are put in place to ensure the safe and effective use of medicines. She began her speech by reminding the audience that the objectives of the LNPVP are three-fold: promoting the rational use of medications, establishing a proactive strategy to identify medication problems by defining their risk-benefit ratio, and promoting a PV notification culture through reporting, evaluating and comprehending ADRs. To this end, the LNPVP has circulated a list of tools to enhance the reporting culture that is at the core of all PV activities. Since the peak of the LNPVP’s activity coincided with the COVID-19 pandemic, Dr. Zeitoun began by listing the tools that were implemented to support the reporting of AEFIs with the COVID-19 vaccines. She proceeded to introduce each tool starting with the 1214 Hotline call center which is available for the general public to call and provide all details about the encountered AEFIs. On the other hand, upon registration for the vaccine, the IMPACT platform provides the patient with a link that can be accessed to report any AEs. Finally, the KoBotoolbox: AEFIs Software for Reporting is a tool that was developed by the LNPVP specifically for Healthcare Professionals (HCPs) to report through. She then elaborated on the other ADR reporting tools that are available. These include two telephone numbers (01- 830 254, 01- 830 255), the PV office email (pv@moph.gov.lb), an ADR paper reporting form, an e-reporting form, and the new Med Safety App. The latter was finally presented with a promotional video detailing its mode of use to report ADRs/AEFIs (<https://youtu.be/kRFaiDVzDz4>).



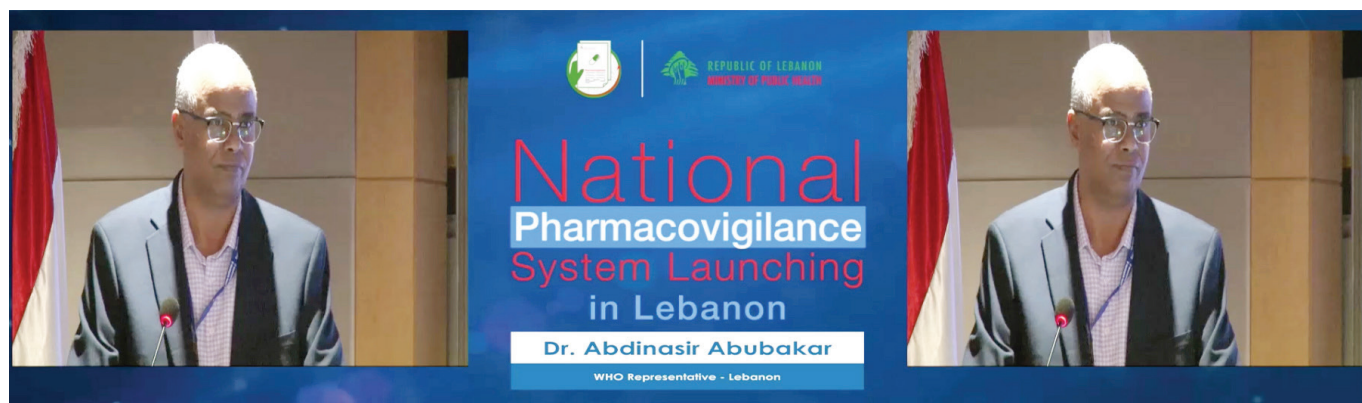
These AEs received through all channels are processed by the PV team and fed into the available UMC web-based tool. VigiFlow, being a web-based PV management system compatible with the International Council for Harmonization (ICH) E2B guidelines for Individual Case Safety Report (ICSR) reporting, eases data entry options for ADR and AEFI reports. It uses integrated standardized medical terminologies such as the Medical Dictionary for Regulatory Activities (MedDRA), supports the use of different causality assessment methods, and provides access to VigiBase, the WHO global database.

Next **Pr. Bassam Badran**, the President of the Lebanese University (LU), took the stage. Pr. Badran expressed the LU's commitment to advance medical education through its continuous cooperation with the MoPH in the context of patient safety. He further highlighted the urgent need to consolidate the foundations of cooperation between all drug regulators. Being committed to the highest educational and ethical standards, the LU places the health and safety of citizens at the forefront of its priorities. All concerned parties were therefore urged to participate in the AEs reporting cycle with the aim of enabling the PV officers in the Ministry to take appropriate measures as a regulatory body in the provision of effective and safe drugs. "Today, while I cannot but commend the tireless work of the LNPVP under the supervision of Pr. Rita Karam who undertook the responsibility of coordinating between all stakeholders, we affirm our pride in laying the appropriate foundation for such a program at the Lebanese University's Faculty of Pharmacy", concluded Pr. Badran.



A series of interventions from Country Directors and representatives of various MoPH partners of international backgrounds then proceeded with their interventions. While each and every speaker tackled the event's subject in the context of their own area of specialty, all speeches remarkably converged back to highlight the major achievements of the program in Lebanon. All commended and congratulated the PV team as well as all PV stakeholders for this great milestone.

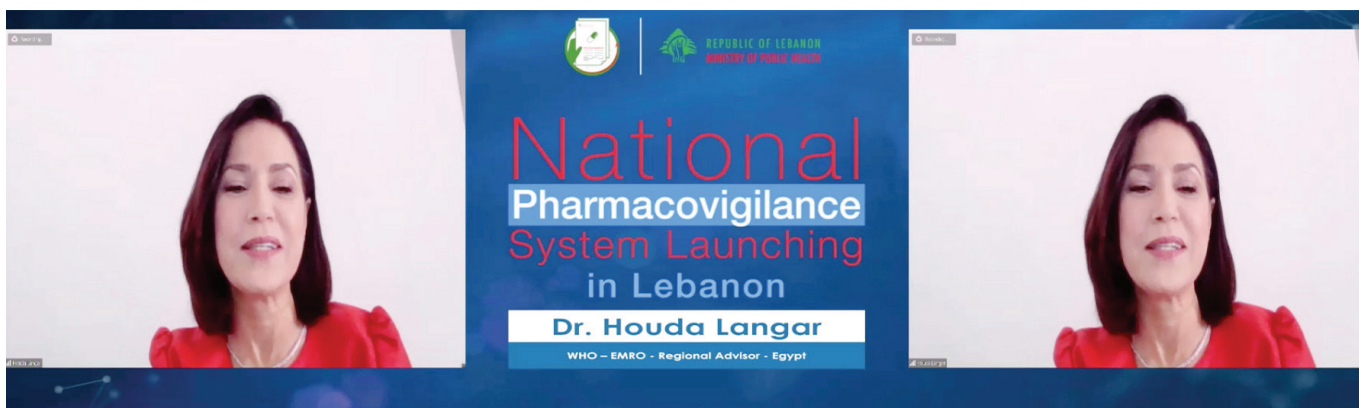
First, the WHO Representative in Lebanon, **Dr. Abdinasir Abubakar**, expressed his pleasure to have collaborated with the LNPVP in the regulation of the COVID-19 response. "After witnessing the quality of the work submitted by the Lebanese PV team, we aimed to extrapolate those efforts and replicate them in neighboring countries", he explained. "In Lebanon, the establishment of the National PV System is a landmark in the pharmaceutical and public health systems". And in accordance to the WHO motto: no countries left behind for safer medications and safer patients, Dr. Abubakar pledged on behalf of the WHO to continue their support of all PV activities in Lebanon.



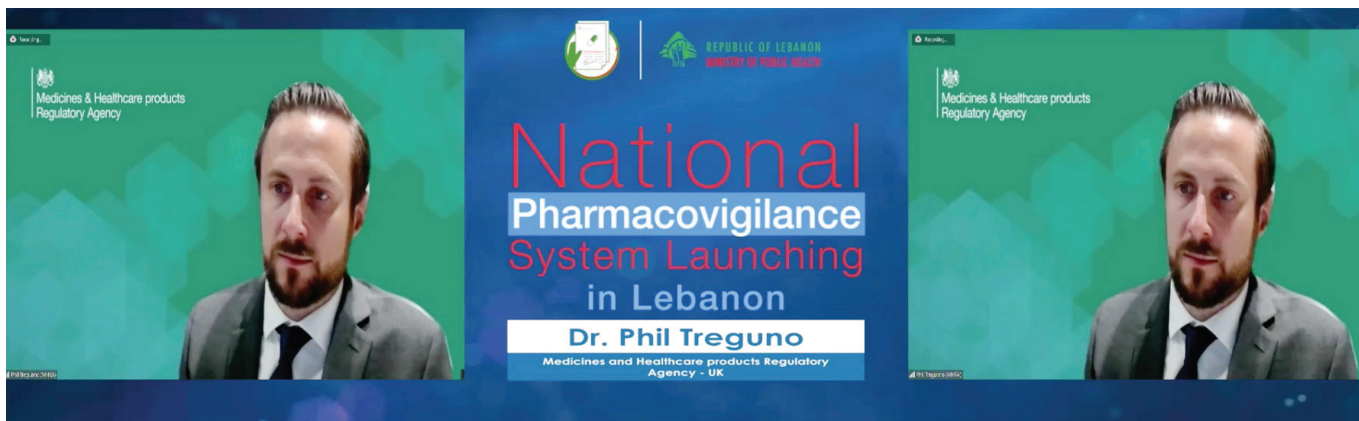
The Senior Health Economist World Bank representative of the Beirut office, **Dr. Ronald Eduardo Gomez – Suarez**, first acknowledged the dedication of the PV team to national patient safety despite the volatile economic and political situation of the country. He invited the audience to recognize the numerous challenges that could have impeded the establishment of the LNPVP from the lack of awareness of PV, the lack of funds, to the underreporting of AEs.



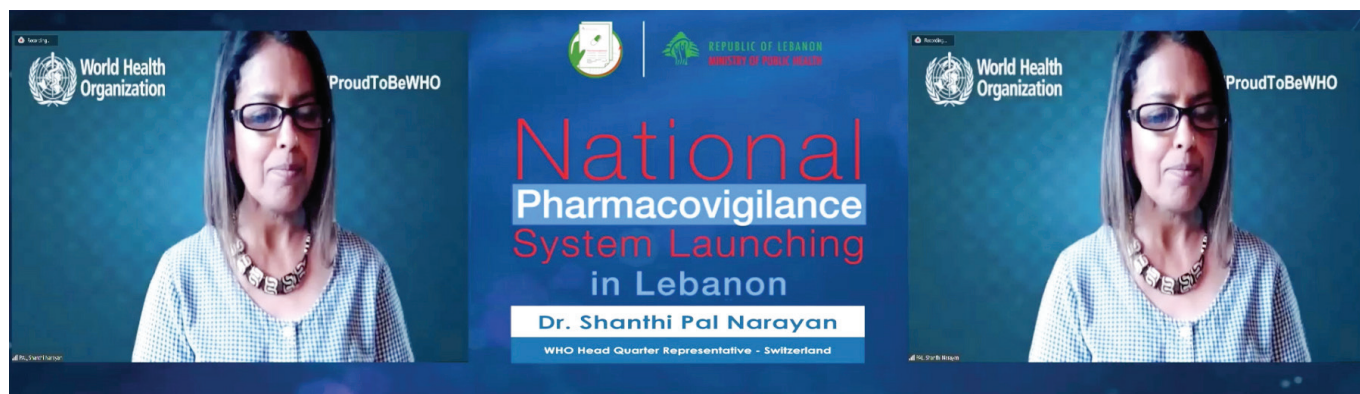
Next, **Dr. Houda Langar**, the WHO Regional Office for the Eastern Mediterranean (WHO-EMRO) Regional Advisor in Egypt congratulated Lebanon on this important achievement. She further admired how the LNPVP used the COVID-19 pandemic as an opportunity to strengthen the PV system.



The MHRA’s support and congratulations were then delivered by its representative **Dr. Phil Treguno**, who also took the time to elaborate on the importance of the Med Safety App as an easily-accessible reporting tool that engages both patients and HCPs.



On a similar note, the WHO Head Quarter Representative in Switzerland, **Dr. Shanthi Pal Narayan**, extended her praise of the LNPVP resilience through the obstacles that had placed strain on every healthcare care aspect.



The keynote speech was finally delivered by the Minister of Public health, **Dr. Firass Al-Abiad**, who reminded the audience that the LNPVP launching event conveniently coincided with the WHO World Patient Safety Day. “The launching of this program is a milestone in the Lebanese drug policy, as it lays the foundations that will lift the Lebanese health system to international levels”, confirmed Dr. AL-Abiad. He then called out the crucial role that HCPs play in reporting and flagging patient safety issues, including reporting through the Lebanese PV program.

And in this context, he took the time to encourage the implementation of the Med Safety App as an exciting new platform that will transform our ability to collect more detailed information for assessment, faster than ever before with unprecedented ability to engage with patients and HCPs.



As an appreciation of all the effort invested in the development and establishment of the LNPVP, his excellency Dr. Firass Al- Abiad granted three awards to Pr. Rita Karam, Dr. Aber Zeitoun, and Dr. Myriam Watfa.



Finally, as the speeches wrapped up, the officials from the PV team were invited on stage for the cake cutting ceremony to celebrate the present milestone.



In a final note, Pr. Karam expressed her deep appreciation for the PV team's invaluable work to the LNPVP. She then proceeded to thank all supporting entities, both global and local, that helped bringing the program to life.





This launching event came as the fruit of labor, dedication and commitment of the PV team to the sacred mission of patient safety. And from this platform, the LNPVP pledges to spare no effort in safeguarding the health of the Lebanese population. We therefore invite you to stay tuned to the many more successful milestones we will share in the future.




II.

Sharing The Knowledge


1. Capacity Building: Overview of Pharmacovigilance National Program: Activities Developed During the COVID-19 Pandemic

 Date	<ul style="list-style-type: none">• September 21 & 23, 2022• 2:30 p.m. - 4:00 p.m.
 Objectives	<ul style="list-style-type: none">• Introducing the Lebanese National Pharmacovigilance Program (LNPVP)• Sharing the LNPVP's objectives, implementation steps and role in the context of COVID-19 vaccines
 Target Audience	<ul style="list-style-type: none">• Pharmacists and patient safety advocates from the Lebanese healthcare community• 82 participants
 Speakers	<ul style="list-style-type: none">• Pr. Rita Karam• Dr. Abeer Zeitoun• Dr. Carla Allam

Topics Presented

- 
1. Overview of Pharmacovigilance: Establishment and Operations
 2. Pharmacovigilance General Operations with Emphasis on Adverse Events Following Immunization Reporting Means
 3. Overview of the Safety Profile of COVID-19 Vaccines: February 14th, 2021 – August 30th, 2022
 4. Evaluation of the COVID-19 Vaccination Process in Lebanon: A National Descriptive Study

Take Home Messages

- 
1. Involvement of patients, healthcare professionals, and pharmaceutical companies in the pharmacovigilance process is fundamental
 2. The LNPVP's regular report on the COVID-19 safety profile presents data related to means of reporting, received dose numbers, geographical location, and seriousness criteria
 3. Patients are encouraged to report AEFIs through the Med Safety App
 4. Regular assessment of the Lebanese vaccination centers should be conducted to ensure compliance with national and international standards

2. WORLD PATIENT SAFETY DAY



Topics

«IMPACT and dissemination of vaccines in times of crisis»

«Management of Adverse Reactions of COVID Vaccines in Lebanon»



On the occasion of World Patient Safety Day 2022, the Francophone Community of practice established within the International Society for Quality in Health Care (ISQua), organized two virtual webinars.

The first webinar took place on the 13th of September tackling the integration of a qualified electronic prescriber in a university hospital in Quebec. The presentation covered the analysis of failure modes, their effects and criticality.

On the 20th of September, the second virtual webinar explored the COVID-19 experiences of Lebanon through two presentations.

The moderator, Dr. Denis Herbaux, opened the virtual webinar with the aim to raise awareness about patient safety.

Dr. Alsharabti started with the first presentation entitled “IMPACT and dissemination of vaccines in times of crisis”. She went over the process of digitalization of vaccination data, an innovative approach for data transparency that significantly enhanced public trust in the vaccination program.

La Gestion des Effets Indésirables des Vaccins COVID-19 au Liban

Dr. Rita Karam
Coordinatrice du Programme National de Pharmacovigilance

Ministère de la Santé Publique

Dr. Karam covered the topic of “Management of Adverse Reactions of COVID Vaccines in Lebanon”.

A definition of Adverse Events Following Immunizations (AEFIs) was given, the means of reporting were presented and finally the management and handling of serious AEFI was elaborated.

Few take home messages were highlighted such as the importance of reporting AEFIs as it is an essential component of vaccine safety monitoring systems.

Date

20 September 2022

Organized by

International Society for Quality in Health Care (ISQua)

Speakers

Dr. Carole Alsharabati
Professeure de Sciences Politiques, Université Libanaise de Beyrouth ; Liban

Dr. Rita Karam
Coordinatrice du Système National de Pharmacovigilance, Professeur à L'Université Libanaise de Beyrouth ; Liban



3. TV Interview: Raising Awareness on Pharmacovigilance

Pharmacovigilance (PV) is an important pillar in healthcare systems worldwide, as was successfully advocated by the National Pharmacovigilance Program launching event on September 14th. Recognizing the importance of such a program in promoting the safe and effective use of medicines namely on the occasion of the World Patient Safety Day, Al Manar TV dedicated a section of their morning program to promote the Lebanese National Pharmacovigilance Program (LNPVP).

On September 27th, 2022, the program's Senior Clinical and Technical Manager, Dr. Abeer Zeitoun, was invited to Al Manar's daily morning talk show "نهار جديد" to elaborate on the LNPVP's scope of work and to answer all queries.

“ Patients and healthcare professionals should remain vigilant about drug-related adverse events for the safe and effective use of medicines. ”

The interview was broadcast live at 9:00 a.m. and was initiated by a brief overview of the launching event. Quotes from the Minister of Public Health Dr. Firass Al-Abyad's speech were recalled to emphasize on patient safety through medication safety.

Dr. Zeitoun then used the infamous thalidomide tragedy of the 1960s to display that drugs can have a harmful effect under certain circumstances, and to highlight the turning point in medical history that awoke the need for a PV system in regulating patient safety.

Then at the request of the interviewer, she proceeded to explain the structure of the LNPVP. Like most countries, Lebanon operates a national PV system as part of its healthcare policies, with the goal of ensuring timely identification of suspected safety problems in medicinal products.



3. TV Interview: Raising Awareness on Pharmacovigilance

She then acknowledged the relentless efforts of the PV team under the management of Pr. Rita Karam, that qualified the LNPVP as full member in the World Health Organization Programme for International Drug Monitoring (WHO-PIDM).

The definition of PV was further elaborated by Dr. Zeitoun when asked about the specific steps involved in PV: from the detection, assessment, understanding and prevention of Adverse Events (AEs) or any other possible drug-related problems. In the ultimate goal of raising awareness among patients, viewers were also acquainted with the LNPVP's scope of work once those AEs are received, and how they are fed into VigiFlow (a national database) then Vigibase (WHO global database). She concluded by emphasizing on the urgent need for the PV system in the light of drug shortages, counterfeit medications, and increased self-medication among patients in Lebanon.

Med Safety App

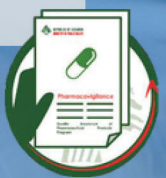


<https://youtu.be/kRFaiDVzDz4>

“ The LNPVP's role relies on passive reporting from both patients and healthcare professionals, which is essential for detecting signals. ”

In its final section, the interview touched base on the most important stakeholders in the PV cycle: the reporters. After highlighting the essential role of healthcare professionals in spreading awareness on the PV program and the reporting tools, Dr. Zeitoun provided the audience with a practical example on how to proceed when encountering any AEs. Since the implementation of the early PV activities coincided with the launch of the COVID-19 vaccination campaign, she gave the example of a patient experiencing an AE following a COVID-19 vaccine, and elaborated on the steps they should follow in order to ensure a proper PV cycle.

A promotional video describing the Med Safety App was finally displayed to further familiarize patients on the importance of reporting adverse events post both medications as well as COVID-19 vaccines to the LNPVP.



III. A New Milestone: Recent Publication

“Implementation of a Pharmacovigilance System in a Resources-Limited Country in the Context of COVID-19: Lebanon’s Success Story”

The article “Implementation of a Pharmacovigilance System in a Resources-Limited Country in the Context of COVID-19: Lebanon’s Success Story” was published in September 2022 in the Journal of Therapeutic Innovation and Regulatory Science.

This paper describes the implementation of an effective national Pharmacovigilance (PV) system in Lebanon in the context of COVID-19, within a limited resources setting and with the absence of a guaranteed funding.

Indeed, the Lebanese experience shows that it is not only possible, but also crucial to implement a PV system in low to middle-income countries in order to be able to promote patients’ safety.

The paper highlights the key elements that allowed the implementation of a PV system such as the system framework, the steps followed to facilitate the work functions, and the enhancement steps that were set in place to improve the system. Support from organizations like WHO and World Bank, skilled leadership, hard work and dedicated staff with efficient training, and finally mass awareness initiatives were all considered as key elements to implement a successful PV System. In the midst of a turbulent political, economic and health context, Lebanon has been able to develop one of the most active and rapidly evolving PV systems in the Middle East.

In summary, the Lebanese PV program managed to establish a rigorous safety profile despite the financial, political and technical difficulties, so much so that in a short period of time, a total of 7,000 case reports and 24,837 Adverse Events Following Immunization were received following the administration of 5,134,093 doses of COVID-19 vaccines for an estimated population of 6,825,000 people.

Use the following link to access the full article: <https://link.springer.com/article/10.1007/s43441-022-00460-7>

Therapeutic Innovation & Regulatory Science
<https://doi.org/10.1007/s43441-022-00460-7>

REVIEW

Implementation of a Pharmacovigilance System in a Resources-Limited Country in the Context of COVID-19: Lebanon’s Success Story

Hanine Abbas¹ · Abeer Zeitoun² · Myriam Watfa² · Rita Karam^{1,2}

Received: 23 April 2022 / Accepted: 1 September 2022
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Abstract
Implementation of Pharmacovigilance (PV) systems in resource-limited countries is a real challenge. The objective of this paper is to describe the implementation of an effective national PV system in Lebanon in the context of COVID-19, within a limited resources setting and with the absence of a guaranteed funding. In 2018, the PV center hosted at the Lebanese University, Faculty of Pharmacy under the supervision of the Quality Assurance of Pharmaceutical Products Program within the Lebanese Ministry of Public Health became an associate member of the World Health Organization (WHO) Program of International Drug Monitoring and recognized as Full member in 2021. This analysis highlights the requirements of the WHO that were met in Lebanon to create an effective PV system. The Lebanese experience shows that it is not only possible, but also crucial to implement a PV system in low to middle-income countries with limited resources and with the absence of a guaranteed funding in order to be able to promote patients’ safety. Support from organizations like WHO and World Bank, skilled leadership, hard work and dedicated staff with efficient training, and finally mass awareness initiatives were all considered as key elements to implement a successful PV System. In the midst of a turbulent political, economic and health context, Lebanon has been able to develop one of the most active and rapidly evolving PV systems in the Middle East.

Keywords Pharmacovigilance · Lebanon · Resources limited country · Ministry of Public Health · Adverse Events · COVID-19

PV Team Members at The Moph:

Dr. Rita Karam - Dr. Abeer Zeitoun
Dr. Sara Al Sayed - Dr. Carla Allam
Dr. Myriam Watfa - Dr. Katia Iskandar