



# **THE NATIONAL PHARMACOVIGILANCE PROGRAM**

## **NEWSLETTER**

**LEBANON**

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# I. SHARING THE KNOWLEDGE

## EMPOWERING PATIENT ADVOCACY GROUPS (PAGS) IN PHARMACOVIGILANCE

The Lebanese National Pharmacovigilance Program (LNPVP) participated in a workshop entitled “Empowering Patient Advocacy Groups (PAGs) in Pharmacovigilance” in collaboration with the Lebanese Pharma Group (LPG) and SciencePro Academy.

This collaborative event focused on:

- ✓ Enhance the role of the PAGs in pharmacovigilance
- ✓ Encourage PAGs to report Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs), and all drug-related problems

The workshop featured a series of sessions led by a team of experts:

**The LNPVP Team**, Dr. Rita Karam, Dr. Abeer Zeitoun, and Dr. Aya Ibrahim, covered the program's journey from its launch in 2018 to its integration into the WHO Program for International Drug Monitoring (WHO PIDM) in 2021. They outlined the program's partners, stakeholders, and activities while explaining protocols for managing Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs). Additionally, they addressed the risks of counterfeit medications, focusing on identifying and managing substandard or falsified products. The role of educational materials in promoting medication safety and patient advocacy was highlighted. Finally, an interactive session introduced digital tools, the VigiMobile e-Form and e-reporting e-Form, providing participants with practical skills to support pharmacovigilance and report ADRs and AEFIs.

**LPG Representatives** Mrs. Badiaa Masri, shared her perception of safety from a Marketing Authorization Holder (MAH). As for Mrs. Miswa Mansour, she highlighted the importance of product quality for patient safety, addressing pharmaceutical industry measures taken to reduce the risks of counterfeit and falsified medications, and how to report product quality complaints.

**The President of CHANCE Association; Pediatric Oncologist**, Dr. Roula Farah, provided an overview of cancer treatment approaches and their associated side effects.

# I. SHARING THE KNOWLEDGE

## EMPOWERING PATIENT ADVOCACY GROUPS (PAGS) IN PHARMACOVIGILANCE

The event was moderated by Dr. Amani Ghadban and Dr. Ali Murad, from the LPG, ensuring smooth transitions between sessions and facilitating insightful discussions.

In conclusion, the workshop highlighted the importance of collaboration between different stakeholders in promoting patient safety. By equipping PAGs with the knowledge and tools to actively participate in pharmacovigilance, the LNPVP is encouraging a more transparent and patient-centered healthcare system as promoted by the LPG. Together, we are taking meaningful steps toward ensuring safer medicines and vaccines for all.



# II. A NEW MILESTONE

## RECENT PUBLICATION OF THE NATIONAL PV TEAM






ORIGINAL RESEARCH article

Front. Public Health, 20 November 2024

Sec. Infectious Diseases: Epidemiology and Prevention

Volume 12 - 2024 | <https://doi.org/10.3389/fpubh.2024.1480744>

### Descriptive analysis of adverse events following immunization with oral cholera vaccine in Lebanon

 Abeer Zeitoun<sup>1</sup>  Aya Ibrahim<sup>1</sup>  Sarah Reda El Sayed<sup>1</sup>  Eva Hobeika<sup>2</sup>  Rita Karam<sup>1,3,4\*</sup>

A newly published study, “Descriptive Analysis of Adverse Events Following Immunization with Oral Cholera Vaccine in Lebanon”, highlights the safety and effectiveness of the Oral Cholera Vaccine (OCV) during Lebanon's cholera outbreak response. The campaign, which used the Euvichol-Plus<sup>®</sup> vaccine, took place between November 2022 and February 2023 in response to Lebanon's first cholera outbreak in 30 years, recorded in October 2022.

The study aimed to assess the safety of the OCV by analyzing reports of Adverse Events Following Immunization (AEFIs) gathered through the Lebanese National Pharmacovigilance Program's (LNPVP) passive surveillance system. Researchers extracted case reports from the LNPVP's database. Key factors examined included the age, gender, and adverse events experienced by individuals who received the vaccine.



## II. A NEW MILESTONE

### RECENT PUBLICATION OF THE NATIONAL PV TEAM

#### Key Findings:

- **Total Reports:** A total of 115 adverse events following immunization (AEFIs) were reported, corresponding to 46 individual case reports.
- **Common Adverse Events:** The top three AEFIs were fever (39.13%), diarrhea (30.43%), and vomiting (30.43%).
- **Seriousness:** Notably, 82.6% of the reported adverse events were classified as non-serious, underscoring the vaccine's favorable safety profile.
- **Demographics:**
  - **Gender:** Females accounted for 56.5% of the case reports, indicating a higher representation among female recipients.
  - **Age:** The largest age group affected was children between 2 and 11 years old, representing 41.3% of the cases. The overall age range of reporters spanned from 1 to 74 years old.

#### Conclusion:

This analysis highlights the generally mild nature of the adverse events associated with the OCV, reinforcing the vaccine's safety. The monitoring of AEFIs during the emergency campaign further supports the positive safety profile of the oral cholera vaccine, offering reassurance to public health officials and the public.

**Read More at:** <https://doi.org/10.3389/fpubh.2024.1480744>

# III. STAY VIGILANT, STAY SAFE

## MED SAFETY WEEK 2024



During the annual Med Safety Week in November 2024, the Uppsala Monitoring Centre (UMC) collaborated with medicines regulatory authorities and national pharmacovigilance centers worldwide to run a social media campaign aimed at raising awareness about adverse drug reactions. For one week each year, medicines regulators across the globe share campaign materials on their social media platforms using the hashtag #MedSafetyWeek.

In 2024, the Lebanese National Pharmacovigilance Program (LNPVP), in collaboration with the WHO and UMC, actively participated in Med Safety Week. The event took place from November 4th to 10th, 2024, under the theme "Preventing Side Effects."

The main goal of the campaign was to familiarize the public with the importance of reporting Adverse Events (AEs), explaining what to report, and detailing the reporting methods available through the LNPVP.



# III. STAY VIGILANT, STAY SAFE

## MED SAFETY WEEK 2024

Each day during Med Safety Week featured custom posts, videos, and poll questions, strategically shared in both the morning and afternoon. These posts were accompanied by clear and straightforward captions to ensure they were easily understood by the general public. The event was a collaborative effort with UMC, with the proposed awareness content shared across all Ministry of Public Health (MoPH) social media platforms, following UMC guidelines. The posts can be accessed through the following links:



<https://www.facebook.com/mophleb/>



<https://www.linkedin.com/company/mophleb/>

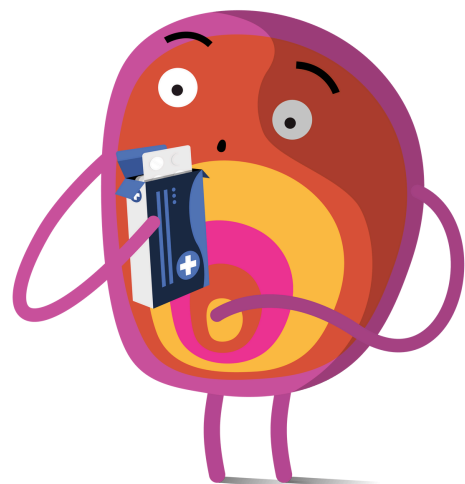


[https://www.instagram.com/ministry\\_of\\_public\\_health/](https://www.instagram.com/ministry_of_public_health/)



<https://twitter.com/mophleb>

In terms of public engagement, the campaign saw active participation and interaction with the content shared. Overall, the 2024 Med Safety Week was considered a success, as it effectively raised awareness about pharmacovigilance, encouraged the reporting of AEs, and fostered meaningful public engagement.





# IV. EMPOWER YOUR SAFETY

## VIGIMOBILE E-FORM AND E-REPORTING E-FROM

### VigiMobile e-Form live for Lebanon

In collaboration with WHO - UMC, the Lebanese National Pharmacovigilance Program (LNPVP) announces the release of a new reporting tools, the VigiMobile e-Form (for Adverse Events Following Immunization with Vaccines) and e-Reporting e-From (for Adverse Drug Reactions with Medications).

- Downloaded as an App
- Easy to use
- No sign-up procedure
- Offline Data Entry
- Digital reporting

## Report Now!



# IV. EMPOWER YOUR SAFETY

VIGIMOBILE E-FORM AND E-REPORTING E-FROM

SCAN QR CODE TO REPORT



**VACCINES**



**MEDICATIONS**

**DOWNLOAD NOW!**



**Vaccines – Adverse Events Following Immunization (AEFIs):**

<https://vigiflow-eforms.who-umc.org/lb/lnpvpv>



**Medications – Adverse Drug Reactions (ADRs):**

<https://vigiflow-eforms.who-umc.org/lb/lnpvpe>

# PV Team Members at The MoPH

Dr. Rita Karam

Dr. Abeer Zeitoun

Dr. Aya Ibrahim

Stay Vigilant  
Stay Safe  
Report



ابقَ يَظَنَّا  
ابقَ آمِنًا  
بِئَع