THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

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at the Ministry of Public Health

OUTLINE

I SHARING THE KNOWLEDGE

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I. Sharing the Knowledge

A. 30th Annual Congress & 23rd French Symposium in Anesthesia, Critical Care & Pain Management

On the 11th of November 2023, the 30th Annual Congress & 23rd French Symposium in Anesthesia, Critical Care & Pain Management hybrid conference was convened at Metropolitan Hilton Hotel, Beirut, Lebanon.
Dr. Abeer Zeitoun, the Clinical and Technical Manager of the Lebanese Pharmacovigilance Program (LNPVP), contributed with a presentation titled “Medication Safety in Anesthesia Practice”.
Dr. Zeitoun tackled the broad subject of patient safety and medication safety, before exploring the field of anesthesia medications safety. An overview of the common sources of anesthesia medication errors was presented supported by recommended prevention strategies. Special emphasis was placed on “Just Culture” as an approach to encourage Adverse Drug Reactions (ADRs) reporting by fostering an environment where individuals in hospital settings feel comfortable to report ADRs.

I. Sharing the Knowledge

B. 24th Annual Conference: Vaccines and Vaccination - Lebanese Epidemiological Association Day (LEAD 24)

On the 24th of November 2023, the 24th Annual Conference: Vaccines and Vaccination - Lebanese Epidemiological Association Day (LEAD 24) was hosted at Gefinor Rotana Hotel, Beirut, Lebanon

Pr. Rita Karam, Director of the Lebanese Pharmacovigilance Program, participated in the conference as a speaker with a presentation titled ”A One-Year Analysis of Adverse Events Following COVID-19 Vaccination in Lebanon”.

The presentation reminisced the conference theme of vaccines and vaccination while targeting experts in epidemiology, public health, the primary healthcare sector, and health-sciences students. The objective of the presentation was reached by acquainting the audience with the Lebanese National Pharmacovigilance Program’s (LNPVP) vaccine Adverse Events Following Immunization (AEFIs) management system which was implemented during the COVID-19 pandemic in 2021. AEFIs associated with the deployed COVID-19 vaccines in Lebanon and reported to the LNPVP between February 2021 and February 2022 were presented. A descriptive and distribution analysis of the results was performed, correlating the AEFIs to age, gender, dose number, and seriousness.

II. Stay Vigilant, Stay Safe

Med Safety Week

During the annual Med Safety Week in November 2023, Uppsala Monitoring Centre (UMC) teamed up with medicines regulatory authorities and national pharmacovigilance centers worldwide. Around 86 countries, including Lebanon, participated in this campaign to raise awareness of adverse drug reactions on social media.

For one week each year, medicines regulators across the globe simultaneously share campaign materials on their social media channels, with the hashtag #MedSafetyWeek.

The 2023 campaign took place from 6 to 12 November, focusing on 'Who can report?': how patients, doctors, pharmacists, and other health professionals can contribute to pharmacovigilance.

The Lebanese National Pharmacovigilance Program participated among other countries in this activity.

II. Stay Vigilant, Stay Safe

Med Safety Week

The event was a collaborative effort with UMC, where proposed awareness posts were disseminated across all Ministry of Public Health (MoPH) social media platforms in accordance with UMC guidelines. These posts may 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://twitter.com/mophleb

Each day during the Med Safety Week (November 6th till 12th) featured tailored posts, videos, and poll questions, strategically shared both in the morning and afternoon.

The primary objective of these posts was to acquaint the public with the concept of reporting Adverse Events (AEs), introducing them to the what to report and detailing the available reporting means at the Lebanese National Pharmacovigilance Program (LNPVP).

Each post was accompanied by a clear and easily understandable caption for the benefit of the general public.

II. Stay Vigilant, Stay Safe

Med Safety Week

The poll questions were designed to enhance the public's knowledge regarding what and how to report Adverse Events (AEs). The questions were as follows:

1. **Have you ever had a side effect after taking a medicine?**
2. **Have you ever reported a side effect from a medicine using the Med Safety mobile application or the e-reporting form?**
3. **Do you know where to report side effects of medicines?**
4. **In your opinion, which types of side effects should be reported?**
5. **Do healthcare professionals have a duty to report side effects?**

Interestingly, the survey results showed that:

59% of respondents had experienced a side effect from medication.

76.5% had never reported these incidents.

93.3% of respondents being unaware of where to report AEs.

87% of the respondents recognized that all types of AEs should be reported.

88% acknowledged that it is the responsibility of healthcare professionals to report such events.

In terms of engagement, the social media interactions were noticeable, with the public actively participating and responding to the content. The overall outcome of Med Safety Week was deemed a success, as it effectively achieved its goal of raising awareness about pharmacovigilance, encouraging reporting of AEs, and giving a meaningful engagement with the public.

III. Knowledge Corner

A. Expanding your vocabulary

How to differentiate between the below terms

Definition

Based on the European Medicines Agency (EMA) - Guideline on good pharmacovigilance practices (GVP)* the following are defined as:

Off-Label Use

This relates to situations where the medicinal product is intentionally used for a medical purpose not in accordance with the terms of the marketing authorization.

Misuse

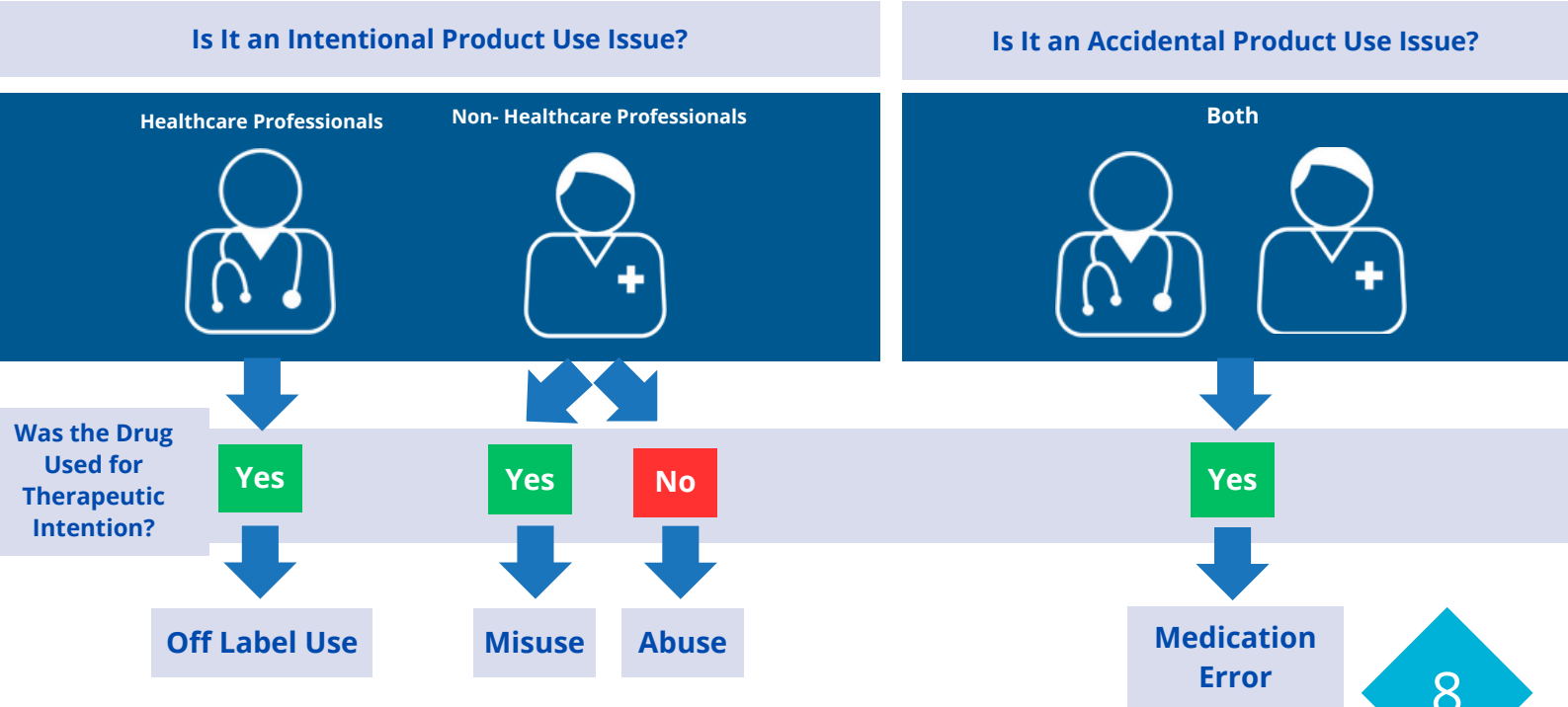
This refers to situations where the medicinal product is intentionally and inappropriately used not in accordance with the terms of the marketing authorization.

Abuse

This corresponds to the persistent or sporadic, intentional excessive use of a medicinal product, which is accompanied by harmful physical or psychological effects.

Medication Error

This is an unintended failure in the drug treatment process that leads to, or has the potential to lead to harm to the patient.



*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-and-submission-reports-suspected-adverse-reactions-medicinal-products-rev-2_en.pdf

III. Knowledge Corner

B. Empower Your Safety: What and How to Report

1. What to Report

Unsolicited and solicited case reports are to be reported whether they are serious or non-serious.

What are unsolicited and solicited case reports?

Unsolicited reports

- Spontaneous reports
- Literature reports
- Reports from non-medical sources
- Information on suspected adverse reactions from the internet or digital media

Solicited reports

Case reports derived from organized data collection systems, which include:

- Clinical trials
- Non-interventional studies
- Registries
- Other patient support and disease management programs
- Surveys of patients or healthcare professionals
- Compassionate use or named patient use
- Information gathered on efficacy or patient compliance

III. Knowledge Corner

B. Empower Your Safety: What and How to Report

1. **What to Report**

What are serious case reports?

According to the WHO seriousness criteria*, a serious case report is considered serious if it contains at least one serious reaction.
A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- Results in death
- Is Life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Resulted in a congenital anomaly/birth defect

*"Safety Of Medicines A Guide To Detecting And Reporting Adverse Drug Reactionswho_Edm_Qsm_2002.2.Pdf." Accessed: Jan. 26, 2023. [Online]. Available: Https://Apps.Who.Int/Iris/Bitstream/Handle/10665/67378/Who_Edm_Qsm_2002.2.Pdf;Jsessionid=56803222adb4b4da5d188c5668970a37?Sequence=1

III. Knowledge Corner

B. Empower Your Safety: What and How to Report

2. How to Report

For Healthcare Professionals and Public

1. Med Safety Mobile Application

1. Search App Store or Google Play for Med Safety App
2. Install the App to your device
3. Select Lebanon as a region
4. Select the language

2. Electronic Reporting

By clicking the link below, you will be directed to the main reporting page.

https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=LB

3. Direct Contact with the Lebanese National Pharmacovigilance Program

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For Marketing Authorization Holder

Based on the Ministerial Resolution MR #181 issued in 2021, MAHs should adhere to the internationally agreed ICH guidelines and standards and send the reports in XML format as specified in ICH E2B (R2 or R3) guidelines.

(https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/Karar%20181-2021.pdf).

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