



# **THE NATIONAL PHARMACOVIGILANCE PROGRAM**

## **NEWSLETTER**

**LEBANON**

**ISSUE 7**

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at the Ministry of Public Health

# OUTLINE

**I.** Sharing the Knowledge: Counterfeit vs. Falsified/Substandard medications, is there a difference?

**II.** Stay Vigilant, Stay Safe: Get the Latest Pharmacovigilance News

**III.** Safeguarding Your Well-being: Your Gateway to Medication Safety and Monitoring - The Med Safety App

**IV.** Knowledge Corner: Discover Essential Pharmacovigilance Terms in Each Edition!"

# I. Sharing the Knowledge: Counterfeit vs. Falsified/Substandard medications, is there a difference?

## A. What Do We Know

### Counterfeit Medicinal Products

Counterfeit drugs are produced by a manufacturer other than the original, who manufactured the product by replicating an original product without permission or authorization with the goal to deceive or defraud, and then marketed the product as the original

01

### Falsified Medicinal Products

These pharmaceutical products might include the correct active ingredient but in lower or higher quantities than what is stated on the label, the wrong active ingredient, or no active ingredient at all

02

### Substandard Medicinal Products

Also called "out of specification", are products that are licensed and approved but lack the quality standards or requirements. This is mainly the result of inappropriate storage or manufacturing, or even expired authentic products. These may or may not be counterfeit or falsified

03

“ **An estimated 1 in 10 medical products circulating in low- and middle-income countries is either Substandard or Falsified** ”

### Consequences of Consuming Such Products

1. Lead to serious adverse reactions
2. Have no therapeutic response
3. Prolong illness
4. Lead to death
5. Create distrust about the effectiveness of medicines and vaccines
6. Create a lack of confidence in the Health Care System
7. Waste money of the public and the Health Care Systems
8. Provide income to criminal networks

# I. Sharing the Knowledge: Counterfeit vs. Falsified/Substandard medications, is there a difference?

## B. How To Prevent

1

### Education and Awareness



- Educate patients about counterfeit, falsified, and substandard products
- Emphasize the potential risks and dangers associated with using such products

2

### Comprehensive Legal Framework



- A comprehensive legal framework for counterfeit, falsified, and substandard drugs involves a range of laws, and regulations, aimed at preventing the production, distribution, and sale of counterfeit pharmaceutical products

3

### Check the Packaging for



- Storage conditions
- Spelling mistakes or grammatical errors
- Manufacture and expiry dates
- If the details on the outer packaging match those on the inner packaging

4

### Make sure the Medication



- Looks correct
- Not discolored/ degraded
- Doesn't have an unusual smell

**Do not forget to report Counterfeit Falsified, and Substandard medications**

4

# I. Sharing the Knowledge: Counterfeit vs. Falsified/Substandard medications, is there a difference?



## C. World Health Organization Alert



On December 27, 2022, subsequent to the occurrence of adverse events in oncology pediatric patients who were administered METHOTREXTM 50mg, health authorities in Yemen and Lebanon conducted microbiological analysis on the remaining, intact vials. The findings from both countries yielded positive results for *Pseudomonas aeruginosa*, thereby indicating the presence of product contamination. In response, the Lebanese Ministry of Public Health (MoPH) has initiated a recall of the implicated batch of METHOTREXTM 50mg to address the concern. The Lebanese National Pharmacovigilance Program (LNPVP) conducted a thorough investigation.

Following this, the World Health Organization (WHO) issued a notification regarding a specific batch of METHOTREXTM (methotrexate) 50mg, a cancer medication, which has been found to be substandard and contaminated with *Pseudomonas aeruginosa*

The screenshot shows the WHO website interface. At the top left is the WHO logo and name. A navigation bar contains links for Health Topics, Countries, Newsroom, Emergencies, Data, and About WHO. Below the navigation bar is a breadcrumb trail: Home / News / Medical Product Alert N°8/2022: Substandard (contaminated) METHOTREX 50mg. The main heading reads "Medical Product Alert N°8/2022: Substandard (contaminated) METHOTREX 50mg" with a small Arabic language icon to its right. Below the heading is a sub-heading: "Substandard (contaminated) METHOTREX 50mg identified in the WHO Eastern Mediterranean region". At the bottom left of the alert content, it says "27 December 2022 | Medical product alert | Geneva | Reading time: 2 min (534 words)". At the bottom right, there is a "Related" link.

## II. Stay Vigilant, Stay Safe: Get the Latest Pharmacovigilance News

### A. The First Annual Lebanese Pharmacovigilance Conference

#### **“Exploring Pharmacovigilance in the MENA Region and Shaping the Good Pharmacovigilance Practices - Launching of the Lebanese Good Pharmacovigilance Practices Guidelines”**

Under the patronage and presence of His Excellency the Minister of Public Health and in collaboration with the Lebanese American University – School of Pharmacy, the first annual Lebanese Pharmacovigilance Conference will be held on the 29th and 30th of September 2023 in alignment with the World Patient Safety Day, at the Lebanese American University, Byblos Campus.



This annual meeting will include two pre-conference educational courses held on the first day – Friday, September 29th, 2023:

- Pharmacovigilance and the Marketing Authorization Holders (MAHs): Introduction to the Lebanese Good Pharmacovigilance Practices Guidelines (LGVP Guidelines)
- The Patient and Medication Safety System: Optimizing Health Care Institution Safety Operations.

The courses will be followed by one conference day, on Saturday 30th, 2023, highlighting the global Pharmacovigilance approach, and the Pharmacovigilance Moroccan, Iraqi, and Jordanian experiences, while emphasizing on the national Pharmacovigilance system.

This event will introduce attendees to Pharmacovigilance-related operations in the MENA region and announce the launching of the Lebanese Good Pharmacovigilance Practices Guidelines, which will be deliberately discussed in the afternoon sessions.

Please register in advance to attend this meeting using the below link:  
<https://sciencepro.me/first-annual-lebanese-pharmacovigilance-conference.html>

## II. Stay Vigilant, Stay Safe: Get the Latest Pharmacovigilance News

### B. Nomination of Pharmacovigilance Focal Points in Hospitals

With the aim of ensuring public safety, the Lebanese National Pharmacovigilance Program released an official letter on June 6, 2023, requesting hospitals to nominate a Pharmacovigilance Focal Point. The nominated focal person will be responsible for reporting Adverse Events (AEs) on behalf of his/her health facility.

A series of training sessions focused on Pharmacovigilance, what to report, how to report, and when to report will be conducted to enhance the reporting process of Adverse Events.

<https://moph.gov.lb/en/Media/view/69878/1/letter-related-to-the-nomination-of-hospital-pharmacovigilance-focal-points>

الجمهورية اللبنانية  
وزارة الصحة العامة  
الوزير

REF: 120/05-23/GH/FA  
بيروت في ٢٠٢٣/٦/٦

٤٨٨٦٩٩٥  
١٤٤٤٠٦٢٢

الموضوع: تعيين ضابط اتصال (Focal point) في المستشفيات مسؤول عن البقطة الدوائية

حضرة المدراء المحترمين،

يسر وزارة الصحة العامة اعلان إنضمام لبنان إلى البرنامج الدولي لمراقبة الأدوية (PIDM) من خلال برنامج ضمان جودة المستحضرات الصيدلانية في الوزارة ، وذلك بالتعاون مع منظمة الصحة العالمية في بيروت الداعم الأساسي لمشروع البقطة الدوائية في لبنان.

و في هذا الإطار، نرجو من حضرتكم تسمية ضابط اتصال من المستشفى بهدف التواصل مع وزارة الصحة حول هذا الموضوع وسوف تتم دعوة ضابط الاتصال للمشاركة في دورات تدريبية حول موضوع البقطة الدوائية (Pharmacovigilance) بهدف تشجيع الإبلاغ عن الأحداث الجانبية للأدوية والتفاعلات والمشاكل المتعلقة باستخدامها، وللأطلاع على وسائل التبليغ الورقية والإلكترونية، كما وعلى تقنيات الاستقصاء و تقديمها وتحليل السببية.

وسوف تتضمن الدورات التدريبية عدداً من الندوات والمحاضرات العملية كما وسيتم تقسيم المشركين إلى مجموعات وسيلعب جميع المعنيين بمواعيد التدريب في الوقت المناسب (التاريخ، الوقت، وطريقة تنظيم الدورات).

نرجو تعبئة المعلومات عن ضابط الاتصال على الشكل التالي:

المستشفى	الإسم	رقم الهاتف	البريد الإلكتروني

وإرسالها عبر البريد الإلكتروني [pv@moph.gov.lb](mailto:pv@moph.gov.lb) و [pv.moph@gmail.com](mailto:pv.moph@gmail.com) إلى برنامج ضمان جودة المستحضرات الصيدلانية وذلك في مدة أقصاها ٢٠٢٣/٠٦/٣٠.

وتفضلوا بقبول الإحترام،

مدير الصحة العامة  
فراس الأبيض

بيانات:  
المديرة العامة للصحة  
مسلمة الصبيح و الوثائق التابعة لها  
برنامج ضمان جودة المستحضرات الصيدلانية  
منظمة الصحة العالمية  
تفئة المستشفيات الخاصة  
تفئة الصيدلة في لبنان  
تفاني الأطباء في لبنان  
السلطة الإلكترونية لوزارة الصحة في لبنان

### III. Safeguarding Your Well-being: Your Gateway to Medication Safety and Monitoring The Med Safety App

#### About the App

The Med Safety Application is the latest tool provided by the Lebanese National Pharmacovigilance Program (LNPVP) to improve patient safety by identifying potential Adverse Events associated with the use of medications. It is a software platform designed to help consumers and healthcare professionals report Adverse Drug Reactions (ADRs), Adverse Events Following Immunization (AEFIs), and other medication errors

#### How to Get the App

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



For more information, you can visit the website for an introductory video on the Med Safety App <https://moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon#/en/view/64327/introductory-video-on-the-med-safety-app>

### III. Safeguarding Your Well-being: Your Gateway to Medication Safety and Monitoring

## The Med Safety App

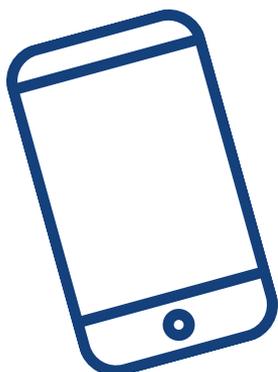
#### How to Use the App

1. Once logged in or as a guest, the user is presented with different tabs at the bottom that includes: News, Products, Watch List, and Report
2. When creating a "new report", the user is asked to enter the patient details such as gender, date of birth, and initials
3. The user is then required to enter details about the suspect medicine
4. Next, the user is required to enter details about the suspect reaction. The user can select from free text or select from a list
5. The user can add details of any relevant medical history
6. Upon submission, a message from the app and an email acknowledgment of the submission are sent to the user



#### Benefits of the App

1. Reports can also be created and saved offline
2. The user can save the report and complete it at a later time
3. Users can add products of interest to their watch list to better track their safety information



## IV. Knowledge Corner: Discover Essential Pharmacovigilance Terms in Each Edition!"

### A. Expand Your Vocabulary

#### Adverse Event (AE)

Any untoward medical occurrence in a patient to whom a medicinal product is administered, and which does not necessarily have a causal relationship with this treatment. Unfavorable and unexpected sign, symptom, and disease

#### Adverse Drug Reaction (ADR)

A response to a drug which is noxious and unintended and which occurs at doses normally used for prophylaxis, diagnosis, therapy of disease, or for the modification of physiologic function

#### Medication Error

A misuse of a medication that occurs during prescribing, transcribing, dispensing, administering, or adherence to a drug



**The annual expenditure related to medical errors is approximately \$20 billion In the United States**

## IV. Knowledge Corner: Discover Essential Pharmacovigilance Terms in Each Edition!"

### B. How to Avoid Medication Errors at the Hospitals



**Eliminate distractions at working place**

**FYI**

**Avoid the use of unapproved "Abbreviations"**



**Always state the indication of the drug**



**Use an understandable Hand Writing**



**Always perform an independent double-check before giving the medication**

**Always make sure to follow the 5 Rights**



**Right Patient**



**Right Drug**



**Right Dose**



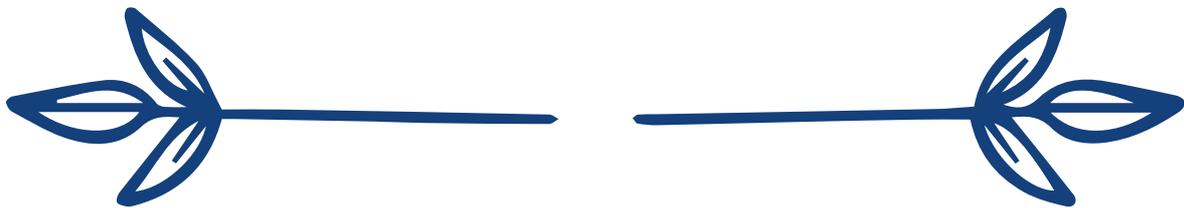
**Right Route**



**Right Time**

**And Don't forget to report medication errors!**

## **PV Team Members at The MoPH**



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