PHARMACOVIGILANCE IN THE CONTEXT OF COVID-19 VACCINES

Identifying and Reporting Adverse Events Following Immunization (AEFI)

BRIEFING - WEBINAR 1-3-8 November 2021

Organized by
National Pharmacovigilance Program
The Quality Assurance of Pharmaceutical Products
Ministry of Public Health - Lebanon

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Pharmacovigilance in the context of COVID-19 Vaccines
Identifying and Reporting Adverse Events Following Immunization - Briefing

The Ministry of Public Health (MoPH) hosted a capacity building that featured a discussion over the program of the pharmacovigilance in the context of COVID-19 vaccines. The webinar was organized by the National Pharmacovigilance Program and combined short presentations by specialists, with structured discussion on the identification and reporting of the Adverse Events Following Immunization (AEFI) post COVID-19 Vaccine.

The objective of this conference was twofold:
1. Share the Pharmacovigilance process in the context of COVID-19 from A to Z
2. Give insights about the importance of detection and reporting of AEFI's aiming to increase the reporting rate

The three-days conference comprised 6 speakers. Each speaker was given 20 minutes to present, followed by 5-10 minutes for questions. The panelists included: Dr. Rita Karam, Dr. Madonna Matar, Dr. Atika Bery, Dr.Katia Iskandar, Dr. Myriam Watfa, Dr. Abeer Zeitoun.

The capacity building occurred over three days, November 1st, 3rd and 8th. The first day was specific to the vaccination sites that offer the Pfizer-BioNTech vaccine for immunization. November 3rd targeted the vaccination centers that provide the AstraZeneca vaccine. The last day, November 8th, was specific to all healthcare providers.

Dr. Karam opened the webinar by providing an introduction and presentation of the speakers. The agenda included an overview of the mechanism of action and potential adverse events of available COVID-19 vaccines. A presentation on the mechanism of handling the COVID-19 vaccines process from the MoPH perspective was also elaborated. The process of implementation of a National Pharmacovigilance System and Reporting Process was included. The types of COVID-19 vaccines AEFIs were classified and the management and the handling of serious AEFIs was detailed. Investigation, causality, and decision making by the AEFI committee of serious adverse events were explained.

This capacity building was the second of a series of webinars. The targeted outcome was to tackle the most important step in the pharmacovigilance process which is REPORTING. It was made clear that serious and non-serious adverse events should be reported and that both the public, the health care professional and workers are able to report. The means of reporting were highlighted, the IMPACT platform and the Hotline 1214 are particular to the public, whereas the hospital facilities and vaccination center have a standardized reporting tool which is the "Kobo Toolbox: AEFI's Software for reporting". The panelists made sure to explain how the serious AEFIs undergo investigation and causality assessment followed by a thorough review by an Adverse Events Following Immunization (AEFI) special committee that includes a group of experts that help in the final decision of the causality assessments.

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Identifying and Reporting Adverse Events Following Immunization

INTERMEDIATE - CAPACITY - BUILDING - BRIEFING - SECOND OF A SERIES

OBJECTIVES

- Share the Phatmacovogilance process in the context of COVID-19 from A to Z
- Give insights about the importance of detection and reporting of AEFIs aiming to increase the reporting rate

DATES AND AUDIENCE

- 1 NOV 2021: Pfizer-BioNTech Vaccination Sites
- 3 NOV 2021: AstraZeneca Vaccination Sites
- 8 NOV 2021: All Healthcare Professionals

6 SPEAKERS

Dr. Rita Karam
Dr. Madonna Mata
Dr. Atika Berry
Dr. Katia Iskandar
Dr. Myriam Watfa
Dr. Abeer Zeitoun

7 TOPICS PRESENTED

- Overview of the Mechanism of Action and Potential Adverse Events of Available COVID-19 Vaccines
- Overview of the Mechanism of Handling The COVID-19 Vaccines Process: MOPH Perspective
- Overview of the National PharmacoVigilance (PV) System Implementation and Reporting Process: Focus on COVID-19 Vaccines AEFI Reporting Journey
- Types of COVID-19 Vaccines AEFIs: Classification and Categorization
- Management of Reported COVID-19 AEFI
- Handling of Serious COVID-19 Vaccines AEFIs: Investigation and Causality
- Decision Making and Communication of COVID-19 Vaccines AEFI

TAKE HOME MESSAGES

- Most important step in the PV process is REPORTING
- Serious and non-serious adverse events should be reported
- The public and the health care professionals/workers are able to report
- Reporting means for the public: IMPACT platform and Hotline 1214
- Reporting tool for hospital facilities/vaccination centers: "Kobo Toolbox: AEFI's Software for reporting" - https://ee.kobotoolbox.org/x/um9QwK2N
- Serious AEFIs undergo investigation and causality assessment
- A group of experts, the serious AEFI special committee, helps in the final decision of causality assessments

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