MONITORING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES

INFORMATIVE EXECUTIVE SUMMARY OF REPORT N°1

Prepared by the Pharmacovigilance Team
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This executive summary provides an overview of Adverse Events Following Immunization (AEFIs) that were temporally associated (i.e., occurred after administration of the vaccine) to the Pfizer BioNtech COVID-19 Vaccine, the only available vaccine in Lebanon during the mass campaign immunization between February 14, 2021 and March 31, 2021.

Within the scope of the AEFI surveillance related to the available COVID-19 Vaccines in Lebanon, the PharmacoVigilance (PV) Program established a procedure for the management of reported AEFIs. Vaccine recipients experiencing any AEFI post-immunization can report through one of the following means: 1214 Hotline call center, Impact Platform, or vaccination sites. All case reports are screened and validated for data completion. Incomplete or inconsistent case reports are followed-up directly with the initial reporter. The case reports are classified as serious, follow-up or non-serious cases. The non-serious case reports are entered directly into the national web-based report management system, VigiFlow. Follow-up cases are reviewed and based on the type of AEFI reported and its outcome, they are classified either as serious or non-serious cases. The surveillance aims to establish a rigorous safety profile in regards to the COVID-19 Vaccines administered in Lebanon. A total of 705 case reports/ 1,344 AEFIs were received following the administration of 203,866 doses of Pfizer BioNTech COVID-19 vaccine in Lebanon between 14 February and 31 March 2021.The reporting rate is 3.5 case reports/6.6 AEFIs per 1,000 doses administered.

Out of the 705 case reports, 94% of total case reports were non-serious, 4.4% of total case reports were follow-up cases, of which 0.6% of total case reports were important medical events and 1.6% of total case reports were serious. The 5 most frequently reported AEFIs were general pain (31.7% of total reported AEFIs), chills (21.9% of total reported AEFIs), injection site pain (17.1% of total reported AEFIs), headache (16.6% of total reported AEFIs) and pyrexia (14.6% of total reported AEFIs).
The IMPACT platform was the main mean of reporting. The vaccine recipients were the main reporters. The age group of vaccine recipients who mostly reported AEFIs was 18 to 44 years old, with females reporting more AEFIs than males. Most AEFIs reported on national basis are compatible with those reported on the international database. To date, no safety signal nor clusters have been detected yet.

The PV Program continues to conduct continuous monitoring of the safety of COVID-19 vaccines in collaboration with its partners, including individual case review, daily analysis of surveillance data for vaccine safety signals and monthly reporting.

N.B. The full report is available upon request by email to: pv@moph.gov.lb