ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES IN LEBANON

EXECUTIVE SUMMARY OF REPORT N°12

Prepared by:
The Pharmacovigilance Team
Ministry of Public Health and Lebanese University
Beirut, Lebanon

Team Lead:
Karam Rita, Pharm D, PhD

Senior Technical and Clinical Manager:
Zeitoun Abeer, Pharm D, MS

Period covered: February 14, 2021 to December 14, 2022

This executive summary provides an overview of Adverse Events Following Immunization (AEFIs) that were temporally associated with the administration of COVID-19 vaccines available in Lebanon during the mass campaign immunization between February 14th, 2021, and December 14th, 2022. 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 can report through the following means: IMPACT Platform, which was the main mean of reporting (53.8%), 1214 Hotline Call Center (29.7%), Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or direct contact with the PV program (13.3%). Other sources included Marketing Authorization Holder (MAH) (2.2%), Preventive Medicine department, Epidemiology Surveillance Program, Health Education Department, and other departments at the Ministry of Public Health (1.0%).

During the time period covered by this report, the total number of registered persons on the national platform for the mass immunization with COVID-19 vaccines was 6,420,891.

A total of 5,602,239 doses of COVID-19 vaccines have been administered, out of which 2,601,912 persons received the 1st dose (46.44%), 2,292,534 persons received the 2nd dose (40.92%), 661,974 persons received their 3rd dose (11.82%), and 45,819 persons received their 4th dose (0.82%). As per the doses received, 4,672,331 doses of Pfizer-BioNTech (83.40%), 721,018 doses of AstraZeneca (12.87%), 123,740 doses of Sputnik V (2.21%), 49,879 doses of Moderna (0.89%), and 21,724 doses of Sinopharm (0.38%) were administered. A total of 7,188 case reports corresponding to 25,841 AEFIs were received following the administration of 5,602,239 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Moderna, and Sinopharm) in Lebanon between February 14th, 2021, and December 14th, 2022. This is equivalent to a reporting rate of 1.28 case reports and 4.61 AEFIs per 1,000 doses administered.

The vaccine recipients were the main reporters (83.0%). The 7,188 case reports were received from 8 governorates in Lebanon (Mount Lebanon, Beirut, North Lebanon, Bekaa, South Lebanon, Nabatiyeh, Akkar, and Baalbeck-Hermel). Case reports were mainly received from Mount Lebanon governorate (40.45%). The age group of vaccine recipients who mostly reported AEFIs was between 18 and 44 years old (54.5%), with females reporting more AEFIs than males (61.0% vs. 39.0%). The 5 most frequently reported AEFIs, with the four vaccines were: Injection site pain (39.2%), fatigue (38.2%), general pain which may correspond to body pain or joint pain (37.3%), headache (34.6%), and pyrexia (31.0%).

Out of the 7,188 case reports, 6,654 case reports were non-serious (92.6%), and 534 case reports were classified as serious cases as per the WHO definition (7.4%).

In the period of time covered by this report, there were 143 case reports classified as serious per the WHO-UMC definition which resulted in either hospitalization or death, representing 1.98% of all case reports and a serious AEFI reporting rate of 0.026 per 1,000 doses of vaccines. These cases are assessed by the PV program and shared with the Serious AEFI Special Committee for a final decision. Details of all serious cases are available in the full report.

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 regular reporting.