



ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES IN LEBANON

EXECUTIVE SUMMARY OF REPORT N°11

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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 June 30th, 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 (54.7%), 1214 Hotline Call Center (29.7%), Vaccination Sites/Hospital Sites through “Kobo toolbox: AEFIs Software for reporting” or direct contact with the PV program (13.5%), the Marketing Authorization Holder (MAH) (1.1%) and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education, and other departments at the Ministry of Public Health (1.1%).

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 6,243,469.

A total of 5,427,072 doses of COVID-19 vaccines have been administered, out of which 2,561,338 persons received the 1st dose (47.2%), 2,253,619 persons received the 2nd dose (41.52%), and 601,949 persons received their 3rd dose (11.1%). As per the doses received, 4,500,089 doses of Pfizer-BioNTech (82.92%), 720,793 doses of AstraZeneca (13.28%), 123,740 doses of Sputnik V (2.28%), 49,817 doses of Moderna (0.91%), and 19,228 doses of Sinopharm (0.35%) were administered. A total of 7,029 case reports corresponding to 25,484 AEFIs were received following the administration of 5,427,072 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Moderna, and Sinopharm) in Lebanon between February 14th, 2021, and June 30th, 2022. This is equivalent to a reporting rate of 1.30 case reports and 4.70 AEFIs per 1,000 doses administered.

The vaccine recipients were the main reporters (83.4%). The 7,029 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 (41.12%). The age group of vaccine recipients who mostly reported AEFIs was between 18 and 44 years old (54.8%), with females reporting more AEFIs than males (60.8% vs. 39.2%). The 5 most frequently reported AEFIs, with the four vaccines were: Injection site pain (42.1%), fatigue (40.6%), general pain which may correspond to body pain or joint pain (40.0%), headache (36.4%), and pyrexia (32.6%).

Out of the 7,029 case reports, 6,515 case reports were non-serious (92.69%), and 514 case reports were classified as serious cases as per the WHO definition (7.31%).

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 2.03% 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.