



ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES IN LEBANON

EXECUTIVE SUMMARY OF REPORT N°10

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Period covered: February 14, 2021 to April 15, 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 April 15th, 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 reported experienced AEFI through one of the following means: IMPACT Platform, which was the main mean of reporting (55.6%), 1214 Hotline Call Center (29.6%), Vaccination Sites/Hospital Sites through “Kobo toolbox: AEFIs Software for reporting” or direct contact with the PV program (13.6%), and other resources (1.2%).

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 6,207,837.

A total of 5,332,315 doses of COVID-19 vaccines have been administered, out of which 2,538,552 persons received the 1st dose (47.60%), 2,223,451 persons received the 2nd dose (41.70%), and 568,153 persons received their 3rd dose (10.70%). As per the doses received, 4,406,518 doses of Pfizer-BioNTech (82.63%), 720,077 doses of AstraZeneca (13.50%), 123,740 doses of Sputnik V (2.32%), 18,598 doses of Sinopharm (0.35%) and 16,667 doses of Moderna (0.31%) were administered. A total of 6,918 case reports corresponding to 25,108 AEFIs were received following the administration of 5,332,315 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm, and Moderna) in Lebanon between February 14th, 2021, and April 15th, 2022. This is equivalent to a reporting rate of 1.30 case reports and 4.71 AEFIs per 1,000 doses administered.

The vaccine recipients were the main reporters (83.9%). The 6,918 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 (41.60%). The age group of vaccine recipients who mostly reported AEFIs was between 18 and 44 years old (55.0%), with females reporting more AEFIs than males (60.7% vs. 39.3%). The 5 most frequently reported AEFIs, with the five vaccines were: Injection site pain (42.4%), fatigue (40.7%), general pain which may correspond to body pain or joint pain (40.4%), headache (36.6%), and pyrexia (32.7%).

Out of the 6,918 case reports, 6,447 case reports were non-serious (93.2%), and 471 case reports were classified as serious cases as per the WHO definition (6.8%).

In the period of time covered by this report, there were 137 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 0.025 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 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.