

Period covered: February 14, 2021 to February 19, 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 February 19th, 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 (56.3%), 1214 Hotline Call Center (29.0%), Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or direct contact with the PV program (13.6%), 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 6,017,418.

A total of 5,134,093 doses of COVID-19 vaccines have been administered, out of which 2,493,054 persons received the  $1^{st}$  dose (48.55%), 2,134,017 persons received the  $2^{nd}$  dose (41.60%), and 505,062 persons received their 3rd dose (9.85%). As per the doses received, 4,259,387 doses of Pfizer-BioNTech (82.96%), 717,370 doses of AstraZeneca (13.97%), 123,520 doses of Sputnik V (2.41%), 17,934 doses of Sinopharm (0.35%) and 2,189 doses of Moderna (0.04%) were administered. A total of 6,808 case reports corresponding to 24,837 AEFIs were received following the administration of 5,134,093 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm) in Lebanon between February 14th, 2021, and February 19th, 2022. This is equivalent to a reporting rate of 1.33 case reports and 4.84 AEFIs per 1,000 doses administered.

The vaccine recipients were the main reporters (83.9%). The 6,808 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 (41.80%). 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 four vaccines were: Injection site pain (42.6%), fatigue (41.1%), general pain which may correspond to body pain or joint pain (40.6%), headache (36.8%), and pyrexia (32.7%).

Out of the 6,808 case reports, 6,356 case reports were non-serious (93.4%), and 452 case reports were classified as serious cases as per the WHO definition (6.6%).

In the period of time covered by this report, there were 131 case reports classified as serious per the WHO-UMC definition which resulted in either hospitalization or death, representing 1.92% 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 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.