

Period covered: February 14, 2021 to January 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 January 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 (57.5%), 1214 Hotline Call Center (28.64%), Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or direct contact with the PV program (12.86%), and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education, and other departments at the MoPH (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 5,658,190.

A total of 4,765,458 doses of COVID-19 vaccines have been administered, out of which 2,404,201 persons received the 1st dose (50.5%), 1,959,448 persons received the 2nd dose (41.1%), and 400,209 persons received their 3<sup>rd</sup> dose (8.4%). As per the doses received, 3,903,866 doses of Pfizer-BioNTech (81.92%), 711,566 doses of AstraZeneca (14.93%), 123,340 doses of Sputnik V (2.5%) and 17,281 doses of Sinopharm (0.36%) were administered. A total of 6,578 case reports corresponding to 24,237 AEFIs were received following the administration of 4,765,458 doses of all four COVID-19 vaccines available in Lebanon between February 14th, 2021, and January 19th, 2022. This is equivalent to a reporting rate of 1.38 case reports and 5.08 AEFIs per 1,000 doses administered.

The vaccine recipients were the main reporters (84.6%). The age group of vaccine recipients who mostly reported AEFIs was between 18 and 44 years old (54.6%), with females reporting more AEFIs than males (60.9% vs. 39.1%). The 5 most frequently reported AEFIs, with the four vaccines were: Injection site pain (43.2%), fatigue (41.8%), general pain which may correspond to body pain or joint pain (41.4%), headache (37.3%), and pyrexia (33.2%).

Out of the 6,578 case reports, 6,146 case reports were non-serious (93.43%), and 432 case reports were classified as serious cases as per the WHO definition (6.57%).

In the period of time covered by this report, there were 121 case reports classified as serious per the WHO-UMC definition which resulted in either hospitalization or death, representing 1.84% 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.