# MONITORING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES

## EXECUTIVE SUMMARY OF REPORT N°5


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*Period covered: February 14, 2021 to September 19, 2021*

This executive summary provides an overview of Adverse Events Following Immunization (AEFIs) that were temporally associated (i.e., occurred after administration of the vaccine) with the COVID-19 vaccines available in Lebanon during the mass campaign immunization between February 14th, 2021 and September 19th, 2021. 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 (64.8%), 1214 Hotline Call Center (23.7%), Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting" or direct contact with the PV program (10.5%), and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education and other departments at the MoPH (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 3,241,932. As a result, 39% of the total registered people on the national platform are fully immunized.

A total of 2,802,835 doses of COVID-19 vaccines have been administered, out of which 1,538,064 persons received the 1st dose (54.88%) and 1,263,048 persons received both doses (45.06%). As per the doses received, 2,215,246 doses of Pfizer-BioNTech (79.04%), 446,729 doses of AstraZeneca (15.94%), 117,115 doses of Sputnik V (4.18%) and 14,502 doses of Sinopharm (0.52%) were administered. A total of 5,256 case reports corresponding to 19,702 AEFIs were received following the administration of 2,802,835 doses of all four COVID-19 vaccines available in Lebanon between February 14th and September 19th, 2021. This is equivalent to a reporting rate 1.9 case reports and 7.0 AEFIs per 1,000 doses administered.

The consumers/non-healthcare professionals were the main reporters (86.4%). The age group of vaccine recipients who mostly reported AEFIs was between 18 to 44 years old (52%), with females reporting more AEFIs than males (62.4% vs. 37.6%). The 5 most frequently reported AEFIs, with the four vaccines were: Injection site pain (46%), general pain which may correspond to body pain or joint pain (46%), fatigue (44.4%), headache (38.7%), and pyrexia (32.9%).

Out of the 5,256 case reports, 4,929 case reports were non-serious (93.8%), and 327 case reports were classified as serious cases as per the WHO definition (6.2%).

In the period of time covered by this report, there were 102 case reports classified as serious per the WHO-UMC definition, representing 1.94% of all case reports and a serious AEFI reporting rate of 0.036 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.