ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES IN LEBANON

EXECUTIVE SUMMARY OF REPORT N°7

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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 November 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 (60.2%), 1214 Hotline Call Center (27.0%), Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or direct contact with the PV program (11.8%), 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 4,083,747.

A total of 3,627,736 doses of COVID-19 vaccines have been administered, out of which 1,874,756 persons received the 1st dose (51.7%), 1,667,808 persons received the 2nd dose (46%), and 84,282 persons received their 3rd dose (2.3%). As per the doses received, 2,864,056 doses of Pfizer-BioNTech (79.0%), 616,110 doses of AstraZeneca (17.0%), 120,627 doses of Sputnik V (3.3%) and 16,191 doses of Sinopharm (0.4%) were administered. A total of 6,038 case reports corresponding to 22,439 AEFIs were received following the administration of 3,627,736 doses of all four COVID-19 vaccines available in Lebanon between February 14th and November 19th, 2021. This is equivalent to a reporting rate of 1.7 case reports and 6.1 AEFIs per 1,000 doses administered.
The vaccine recipients were the main reporters (85.5%). The age group of vaccine recipients who mostly reported AEFIs was between 18 to 44 years old (54.0%), with females reporting more AEFIs

than males (61.68% vs. 38.32%). The 5 most frequently reported AEFIs, with the four vaccines were: Injection site pain (44.3%), fatigue (43.1%), general pain which may correspond to body pain or joint pain (42.7%), headache (38.0%), and pyrexia (33.5%).

Out of the 6,038 case reports, 5,635 case reports were non-serious (93.3%), and 403 case reports were classified as serious cases as per the WHO definition (6.7%).

In the period of time covered by this report, there were 112 case reports classified as serious per the WHO UMC definition which resulted in either hospitalization or death, representing 1.85% of all case reports and a serious AEFI reporting rate of 0.03 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.