ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES

EXECUTIVE SUMMARY OF REPORT N°6

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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 October 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 (62.9%), 1214 Hotline Call Center (25.5%), Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or direct contact with the PV program (10.6%), 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 3,625,963.

A total of 3,190,574 doses of COVID-19 vaccines have been administered, out of which 1,723,389 persons received the 1st dose (54%), 1,463,757 persons received the 2nd dose (45.9%), and 2,837 persons received their third dose (0.1%). As per the doses received, 2,522,577 doses of Pfizer-BioNTech (79.06%), 523,809 doses of AstraZeneca (16.42%), 118,903 doses of Sputnik V (3.73%) and 15,253 doses of Sinopharm (0.5%) were administered. A total of 5,627 case reports corresponding to 21,183 AEFIs were received following the administration of 3,190,574 doses of all four COVID-19 vaccines available in Lebanon between February 14th and October 19th, 2021. This is equivalent to a reporting rate of 1.8 case reports and 6.6 AEFIs per 1,000 doses administered.

The vaccine recipients were the main reporters (86.4%). The age group of vaccine recipients who mostly reported AEFIs was between 18 to 44 years old (53.13%), with females reporting more AEFIs than males (62.2% vs. 37.8%). The 5 most frequently reported AEFIs, with the four vaccines were: Injection site pain (45.6%), fatigue (44.3%), general pain which may correspond to body pain or joint pain (43.9%), headache (38.6%), and pyrexia (33.4%).

Out of the 5,627 case reports, 5,251 case reports were non-serious (93.3%), and 376 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 110 case reports classified as serious per the WHO-UMC definition which resulted in either hospitalization or death, representing 1.95% of all case reports and a serious AEFI reporting rate of 0.034 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.