MONITORING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES

EXECUTIVE SUMMARY OF REPORT N°4

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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 August 1st, 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 one of the following means: IMPACT Platform (70.94%), 1214 Hotline Call Center (22.13%), Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting" (6%), and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education and other departments from the MoPH (0.93%).

2,052,456 doses of COVID-19 vaccines have been administered, out of which 1,142,267 persons received the first dose of COVID-19 vaccine (55.7%) and 909,188 persons received both doses of COVID-19 vaccine (44.3%). 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 2,319,763. As a result, 39.2% of the total registered people on the national platform are fully immunized. As per the doses received, 1,648,032 doses of Pfizer-BioNTech (80.3%), 278,375 doses of AstraZeneca (13.5%), 107,775 doses of Sputnik V Vaccine (5.3%) and 12,362 doses of Sinopharm Vaccine (0.6%) were administered. 5,912 doses were identified by IMPACT Platform as missing (0.3%).

A total of 4,508 case reports corresponding to 16,709 AEFIs were received following the administration of 2,052,456 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V and Sinopharm) in Lebanon between the 14th of February and the 1st of August, 2021. This is equivalent to a reporting rate of 2.2 case reports and 8.14 AEFIs per 1,000 doses administered.

The IMPACT Platform was the main mean of reporting (70.94%). The vaccine recipients were the main reporters (85%). The age group of vaccine recipients who mostly reported AEFIs was between 18 to 44 years old (48.3%), with females reporting more AEFIs than males (62.9% vs. 37.1%).

Out of the 4,508 case reports, 4,242 case reports were non-serious (94.1% of total case reports), 266 case reports were classified as serious cases per WHO definition (5.9% of total case reports), out of which 177 case reports (3.92% of total case reports) were identified as Other Medically Important Events, which did not require hospitalization nor lead to death. 89 case reports were serious cases that were either admitted to the Hospital or resulted in Death (1.98% of total case reports).

The 5 most frequently reported AEFIs with the four vaccines were: Injection Site Pain (44.6% of total reported AEFIs), General Pain (44.0 %), Fatigue (43.1%), Headache (37.5 %), and Chills (32.8 %).

Among the Other Medically Important Events, the 5 most frequently reported AEFIs with the four vaccines that required close monitoring were Hypertension, Tachycardia, Angioedema Hypoesthesia and Contusion.

In the period of time covered by this report, there were 89 case reports classified as serious per the WHO-UMC definition, representing 2% of all case reports and a serious AEFI reporting rate of 0.044 per 1,000 doses of vaccines. Of the 89 cases, there were 37 reports that were followed up by phone only, without the need for further investigation. The remaining 52 cases required close follow up with investigation and causality assessment, out of which 30 cases were assessed by the Serious AEFI Special Committee at the MoPH, and a final decision was concluded with the agreement of all members. As for the remaining 22 serious case reports, they are still under the assessment by the PV team.

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.