MONITORING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES

EXECUTIVE SUMMARY OF REPORT N°3

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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) to the COVID-19 vaccines available in Lebanon during the mass campaign immunization between February 14, 2021 and May 30, 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 post-immunization can report through one of the following means: 1214 Hotline call center, Impact Platform, Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting", Preventive Medicine department, or Epidemiology Surveillance Program at the MoPH.

837,817 doses of COVID-19 vaccines have been administered, out of which 553,740 persons received the first dose of COVID-19 vaccine (66%) and 284,077 persons received both doses of COVID-19 vaccine (34%). As a result, 25.9% of the total registered people on the national platform are fully immunized. As per the doses received, 649,259 doses of Pfizer-BioNTech (77.5%), 117,493 doses of AstraZeneca (14.03%), 64,532 doses of Sputnik V Vaccine (7.7 %), 6,533 doses of Sinopharm Vaccine (0.77 %) were administered.

A total of 2,856 case reports/ 9,461 AEFIs were received following the administration of 837,817 doses of COVID-19 vaccines (Pfizer BioNTech, AstraZeneca, Sputnik V and Sinopharm) in Lebanon between the 14th of February and the 30th of May 2021. This is equivalent to a reporting rate of 3.4 case reports/11.3 AEFIs per 1,000 doses administered.

The Impact platform was the main mean of reporting. The vaccine recipients were the main reporters. The age group of vaccine recipients who mostly reported AEFIs was 18 to 44 years old (43.0%), with females reporting more AEFIs than males (63.4% vs. 36.5%).

Out of the 2,856 case reports, 2,713 case reports were non-serious (95% of total case reports), 94 case reports were follow-up cases (3.3% of total case reports), of which 9 case reports were important medical events (0.3 % of total case reports), and 49 case reports were serious (1.7% of total case reports).

The 5 most frequently reported AEFIs with the four vaccines were: General pain (45.8% of total reported AEFIs). Injection site pain (40.1 %), Fatigue (38.8 %), Chills (34.8 %), and Headache (34.2 %). General pain, reflecting body or joint pain, was the most frequently reported adverse event for the Pfizer-BioNTech Vaccine (42.0 %) while fatigue was the most common adverse event following all other vaccines: (58.6 %) of the total reported AEFIs related to AstraZeneca Vaccine, (63.6 %) related to Sputnik V, and (40.0 %) related to Sinopharm Vaccine. Most non-serious AEFIs reported on national basis are compatible with those reported on the international database.

Among the follow-up AEFIs, the most reported AEFIs that required close monitoring were: Hypertension (23 case reports), Tachycardia (13 case reports), Dyspnea (9 case report), Hypotension (6 case reports), Contusion/Echymosis (3 case reports) for Pfizer BionNTech Vaccine. Headache (13 case reports), Hypertension (7 case reports), Tachycardia (6 case reports), Contusion (4 case reports), Dyspnea (2 case reports), and Axillary Vein Thrombosis (1 case report) for AstraZeneca Vaccine. Dyspnea and Hypotension (2 case reports each) for Sputnik V Vaccine. Chest pain and Paresthesia (one case report) for Sinopharm Vaccine

Among the follow-up AEFIs, the most reported important medical events as per the EMA list were: Atypical pneumonia, facial paralysis, and Angioedema (1 case report each) for Pfizer BioNTech Vaccine. Bell's Palsy (one case report) for Pfizer BioNTech Vaccine and (1 case report) for AstraZeneca vaccine. Syncope (1 case report) for Sputnik V Vaccine and (1 case report) for AstraZeneca Vaccine. All follow-up cases were resolved, therefore not reclassified as serious.

In the period of time covered by this report, there were 49 case reports classified as serious, representing 1.7% of all case reports and a serious AEFI reporting rate of 0.058 per 1,000 doses of vaccines. Of the 49 cases, there were 5 reports who were missing essential information and their investigation is still pending. As for the remaining 44 case reports, there was 11 reports that were followed up by the phone only without the need for further investigation. The remaining 33 cases all required close follow up with investigation and causality assessment, out of these cases, 12 cases have been already assessed by the Serious AEFI Special Committee at Ministry of Public Health and a final decision confirmed a coincidental relationship with the vaccine. As for the remaining 21 case reports, they are still under assessment.

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 monthly reporting.