MONITORING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES

INFORMATIVE EXECUTIVE SUMMARY OF REPORT N°2

Prepared by the Pharmacovigilance Team
Ministry of Public Health and Lebanese University
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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 April 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 site, Preventative Medicine or Epidemiology Surveillance program (MoPH). All case reports are screened and validated for data completion. Incomplete or inconsistent case reports are followed-up directly with the initial reporter. The case reports are classified as serious, follow-up or non-serious cases. The non-serious case reports are entered directly into the national web-based report management system, VigiFlow. Follow-up cases are reviewed and based on the type of AEFI reported and its outcome, they are classified either as serious or non-serious cases. An investigation followed by a causality assessment are carried out for serious cases and findings are discussed with the Serious AEFI Special Committee at the MoPH sated by the Ministerial decision 603/1.

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 (47.1%), with females reporting more AEFIs than males (65% vs. 35%).

A total of 463,792 doses of COVID-19 vaccines have been administered during the period of time covered by the report. Out of 836,642 registered patients on the national platform, 278,635 patients received the first dose of COVID-19 vaccine (33.3%) and 185,157 patients received both doses of COVID-19 vaccine (22.1%). As per the doses received, 401,468 doses for Pfizer-BioNTech vaccine (86.6%), 38,897 doses for AstraZeneca vaccine (8.4%), 22,357 doses for Sputnik V vaccine (4.8%) and the remaining 1,070 doses for Sinopharm vaccine (0.2%) were administered. Related AEFIs were not collected in the period of time covered by the report.

A total of 1,801 case reports/4,896 AEFIs were received following the administration of 462,722 doses of COVID-19 vaccines (Pfizer BioNTech, AstraZeneca and Sputnik V) in Lebanon between 14 of February and 30th of April 2021. This is equivalent to a reporting rate of 3.9 case reports/10.6 AEFIs per 1,000 doses administered. Out of the 1,801 case reports, 1,708 case reports were non-serious (94.9% of total case reports), 62 case reports were follow-up cases (3.4% of total case reports) of which 3 case reports were important medical events (0.2% of total case reports) and 31 case reports were serious (1.7% of total case reports)

The most reported AEFIs for all COVID-19 vaccines per symptom were general pain (44.5%), injection site pain (32.6%), and chills (31.4%). The most reported AEFIs by System Organ Class SOC were general disorders and administration site conditions (83.2%), followed by nervous system disorders (32.2), and gastrointestinal disorders (17.1%). General pain, reflecting body or joint pain, was the most frequently reported adverse event for the Pfizer-BioNTech Vaccine (44.8%). Fatigue was the most common adverse event following both AstraZeneca Vaccine (59%) and Sputnik V Vaccine (59.8%). 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 symptoms that required close monitoring were Hypertension (18 case reports) associated with Pfizer BioNTech vaccine and 2 case reports of Hypertension for AstraZeneca Vaccine. One axillary vein thrombosis case report, 1 lymphadenopathy case report, and 1 contusion case report were also associated with AstraZeneca Vaccine.
Among the follow-up AEFIs, the most reported important medical events were atypical pneumonia and facial paralysis that were identified in two cases for Pfizer BioNTech Vaccine while Sputnik V had 1 case report of syncope. All follow-up cases were resolved, therefore not reclassified as serious.

There were 31 case reports classified as serious, representing 1.7% of all case reports and a serious AEFI reporting rate of 0.07 per 1,000 doses of vaccines. Twenty-four recipients were above 75 years old, 4 were between 45 and 64 years old and 3 were between 18 and 44 years old. The 31 vaccine recipients experienced AEFIs within 20 minutes to 33 days after being vaccinated. Out of the 31 vaccine recipients, 12 died and 19 were hospitalized. The death cases were reported to the Serious AEFI Special Committee at the MoPH to evaluate potential causal relationship with the vaccine.

Hypertension and CVAs following vaccination with Pfizer BioNTech Vaccine are potential signals. 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.