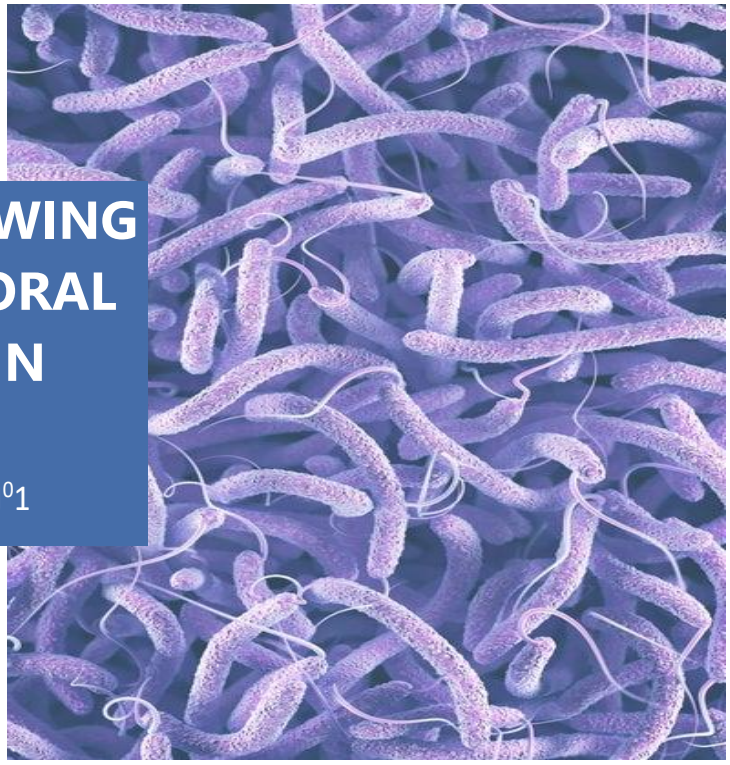
ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH ORAL CHOLERA VACCINES IN LEBANON

EXECUTIVE SUMMARY OF REPORT N^{0}1



Phase I: November 12, 2022, to December 7, 2022

Prepared by:

The Pharmacovigilance Team
Ministry of Public Health, Beirut, Lebanon
Team Lead:
Karam Rita, Pharm D, PhD
Senior Technical and Clinical Manager:
Zeitoun Abeer, Pharm D, MS

On October 6th 2022, Lebanon recorded its first confirmed case of cholera since 1993. The outbreak spread across eight governorates and 19 out of the 26 districts in Lebanon. The number of the suspected cases gradually increased across all affected areas to reach 4,966 cases and 23 deaths by the end of the period covered by this report.

This executive summary provides an overview of the Adverse Events Following Immunization (AEFIs) that were temporally associated to the Oral Cholera Vaccines (OCV) available in Lebanon during phase 1 of the national immunization campaign, in the period between November 12th, 2022, and December 7th, 2022. Within the scope of the multi-sectorial response to contain the cholera outbreak, the Lebanese National Pharmacovigilance Program (LNPVP) was the main entity concerned with monitoring and evaluating AEFIs with OCVs during the campaign, with the aim of ensuring patient and medication safety.

The objective of this report is to describe serious and non-serious AEFIs reported to the LNPVP following the administration of the OCV deployed during phase 1: Euvichol-Plus®.

A total of 22 case reports corresponding to 50 AEFIs were received following the administration of 479,679 doses of Euvichol-Plus® in Lebanon between November 12th, 2022, and December 7th, 2022. This is equivalent to a reporting rate of 0.046 case reports and 0.104 AEFIs per 1,000 doses administered.
The majority of case reports were reported through the 1787 hotline (50.0%), followed by the landline, (40.9%), then the KoboToolbox: AEFIs Software for Reporting (9.1%).

The age group of vaccine recipients who mostly reported AEFIs was between 2 and 11 years old (40.91%), with females reporting more than males (54.55% vs.45.45%).

Most of the reported AEFIs, 17 AEFIs (77.3% of the total AEFIs), belonged to the "Gastrointestinal Disorders" System Organ Class with abdominal pain (10 AEFIs, 45.5%) being the most reported AEFI, followed by vomiting (7 AEFIs, 31.8%), and finally diarrhea (5 AEFIs, 22.7%). The second most reported System Organ Class was "General Disorders and Administration Site Conditions" with a total of 7 AEFIs (31.8%) reported. In this class the most report AEFIs were Fatigue (4 AEFIs, 18.2%) followed by Fever (4 AEFIs, 18.2%)

Only 5 case reports were classified as serious as per the WHO seriousness classification criteria. These cases were assessed by the PV program and shared with the Serious AEFI Special Committee for a final decision. An example of serious case handling is provided in the annex of the full report.

The LNPVP at the Ministry of Public Health is the reference entity of reporting concerned with AEFIs associated with OCVs. In collaboration with its partners, the PV team continues to conduct constant monitoring for the safety of the vaccines. Reporting of any encountered AEFI is highly encouraged to contain the outbreak and to reduce the strain on the health system.