Summary Report of Preliminary Inspection Findings

Open Joint-Stock Company Pharmstandard - Ufa Vitamin Plant Ufa, Republic of Bashkortostan, Russia

Following an application for Emergency Use Listing (EUL) of the Gamaleya COVID-Vac vaccine, inspections were conducted by WHO at the four manufacturing sites named in the application. Draft inspection reports have been shared by WHO with the respective manufacturers and WHO expects to receive technical comments in due course.

It is emphasized that the preliminary inspection findings detailed below concern the operations of, and Gam-COVID-Vac batches that were manufactured by, **Open Joint-Stock Company Pharmstandard – Ufa Vitamin Plant** and are not applicable to any other manufacturers of Gam-COVID-Vac or any batches of this product manufactured at any other manufacturing sites.

The present report is published in line with paragraph 5.2.3 of the EUL Procedure and will be followed up with a report of the final inspection findings.

Following the inspection of **Open Joint-Stock Company Pharmstandard - Ufa Vitamin Plant, (28 Khudayberdina str, Ufa, Republic of Bashkortostan, 450077, Russia)** (hereinafter, the "manufacturer"), during the period from 31 May to 4 June 2021, WHO's PQT Inspection Team (WHO/PQT/INS) reported the following preliminary findings:

1. Identified concerns with the integrity of data and test results of microbiological and environmental monitoring during the manufacturing and quality control activities of Gam-COVID-Vac.

2. Identified concerns with the implementation of an appropriate Environmental Monitoring Program to monitor and control the aseptic operation and filling of Gam-COVID-Vac.

3. Identified concerns with the full traceability, identification and the history of the Gam-COVID-Vac batches and the Drug Substances of Component I and Component II manufactured at the inspection site, through the SAP system used.

4. Identified concerns with the implementation of adequate measures to mitigate the risks of cross contamination.

5. Identified concerns with adequate filling lines and gowning of aseptic operators to ensure the required sterility assurance level of aseptically filled Gam-COVID-Vac be supported.

6. Identified concerns with appropriate sterile filtration validation of Gam-COVID-Vac.

Communications have been initiated with the relevant manufacturer, the applicant and the respective national regulatory authority with the view that the preliminary findings outlined in this report are investigated and addressed as quickly as possible.

For further information please visit the WHO Prequalification Unit (PQT) website at https://extranet.who.int/prequal or contact PQT directly at prequal@who.int or Inspection Services of Prequalification Unit at prequalinspection@who.int

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