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PHIL. ARCHIPELAGO INTERNATIONAL TRADING CORP.

Amendment to the Emergency Use Authorization (EUA) for Gamaleya National Center of Epidemiology and Microbiology Sputnik V Gam-COVID-Vac COVID-19 Vaccine (Ampoule)

This applies to the request for amendment of the Emergency Use Authorization (EUA) for Gamaleya National Center of Epidemiology and Microbiology Sputnik V Gam-COVID-Vac COVID-19 Vaccine (“Gamaleya Sputnik V Vaccine”). The request seeks revision of the issued EUA to extend the vaccination interval between Component I and II, and reflect additional packaging in 2 dose (1 mL) ampoule for Components I and II.

After due consideration, the Food and Drug Administration (FDA) hereby revises the EUA granted to Gamaleya Sputnik V Vaccine to reflect requested changes.

The foregoing revisions are made pursuant to the discretionary power of the FDA under Section 6 of Executive Order (EO) No. 121, entitled “Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefore, and for Other Purposes,” to revisit any issued EUA as may be appropriate to protect the general public health and safety.

The details of the Gamaleya Sputnik V Vaccine are as follows:

**Product Name:** Sputnik V Gam-COVID-Vac COVID-19 Vaccine  
**Dosage Strength and Form:** 0.5 mL intramuscular injection  
**Pharmacologic category:** Vaccine  
**Storage:** Store in a dark place at a temperature not exceeding -18°C  
**Shelf Life:** 6 months  
**Packaging:** Component I: 0.5mL (1 dose) ampoule 1.0mL (2 dose) ampoule  
Component II: 0.5mL (1 dose) ampoule 1.0mL (2 dose) ampoule  
**Manufacturer:** Gamaleya National Center of Epidemiology and Microbiology
**Indication:**
For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older

After careful consideration of the application, with all its supporting documents and a review of local experts, the FDA has been satisfied that all the conditions for the issuance of an EUA exist as provided under Executive Order (EO) No. 121, s. 2020 entitled “Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefore, and for Other Purposes,” particularly:

1. Based on the totality of evidence available to date, including data from adequate and well-known controlled trials, it is reasonable to believe that the Gamaleya Sputnik V Vaccine may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the Gamaleya Sputnik V Vaccine, when used to diagnose, prevent, treat COVID-19, outweigh the known and potential risks of said Vaccine as of date; and
3. There is currently no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19.

In issuing this EUA, consideration has been given to the emergency use authorizations given by counterpart National Regulatory Authorities (NRAs) such as Russia, Turkey, Armenia, Argentina and Hungary. This was followed by a rigorous and thorough review of all submitted published and unpublished clinical trial data and product information.

This EUA is not a marketing authorization or a Certificate of Product Registration (CPR). Hence, this EUA cannot be used as an authorization to market the vaccine commercially.

While the evaluation process was facilitated, strict conditions on the authorization granted in this Letter shall be imposed as follows:

**I. Scope**

The scope of the EUA shall be limited as follows:

A. Phil. Archipelago International Trading Corp. (PAITC) shall supply Gamaleya Sputnik V Vaccine only to emergency response stakeholders consistent with the terms and conditions of this EUA.

“Emergency response stakeholders” shall refer to the Department of Health (DOH) or the National Task Force Against COVID-19 (NTF) or their designees authorized to procure or purchase Gamaleya Sputnik V Vaccine in line with the COVID-19 vaccination program. Designees may include hospitals (public and...
private), health facilities of other National Government Agencies, Local Government Units (LGUs) and other members of the Private Sector.

B. The Gamaleya Sputnik V Vaccine shall be administered only by vaccination providers, and used only to prevent COVID-19 in individuals aged 18 and older.

“Vaccination providers” shall refer to the facility, organization, or a healthcare provider, including non-physician healthcare providers such as nurses or pharmacists, authorized by the DOH or the NTF to administer the Gamaleya Sputnik V Vaccine in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

Gamaleya Sputnik V Vaccine should be supplied as a frozen solution in dense, hardened, whitish mass. One (1) ampoule of Component I may contain 0.5mL single dose or 1.0mL two dose ampoule. One (1) ampoule of Component II may contain 0.5mL single dose or 1.0mL two dose ampoule. A homogenous colorless or a yellowish slightly opalescent solution results after thawing. First dose is Component I, and the second dose is Component II. Both doses are injected intramuscularly. Component II may be given 21 days to 42 days after Component I is administered.

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, PAITC shall provide appropriate cold chain requirements for storage, transport and handling until it is delivered to the inoculation sites, and ensure that a contingency plan is in place.

PAITC shall have a system of monitoring to ensure traceability and that the vaccine is consistent with the storage requirements from the manufacture and transport to the inoculation sites.

PAITC shall observe strict compliance with the standards for Good Distribution Practices (GDP) and Good Storage Practices (GSP) adopted pursuant to Administrative Order No. 2013-0027 including supplements thereto (i.e. WHO Technical Report Series No. 961, 2011, Annex 9 and Technical Report Series No. 992, 2015, Annex 5). PAITC shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

PAITC shall have a comprehensive pharmacovigilance system for Gamaleya Sputnik V Vaccine following system or protocol for a registered drug and biologic product as stated in the FDA Circular No. 2020-003. Submission of serious and non-serious adverse reaction reports is mandatory.

As committed, PAITC shall update the Risk Management Plan (RMP), and shall immediately submit the same once available. Pending submission and approval of the
RMP, PAITC shall not ensure that the Gamaleya Sputnik V Vaccine is not administered by emergency response stakeholders.

PAITC shall ensure compliance with the RMP along with the Philippine-specific Annex. Additional pharmacovigilance activities such as interventional and non-interventional studies (ongoing or new studies, or additional activities) shall be implemented as stated in the RMP. The RMP must be updated whenever there is a significant change which may affect the benefit-risk profile of the vaccine or when an important milestone is reached.

PAITC shall submit six (6) monthly summary safety reports as planned and discussed in the RMP.

V. Responsibility of Emergency Response Stakeholders and Vaccination Providers

Under FDA Circular No. 2020-036 or the Guidelines for the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19, the pharmacovigilance obligations and post-authorization commitments imposed in the Letter shall be shared to the fullest extent possible and applicable by the national procurer and health program implementors, and their designees. Emergency response stakeholders and vaccination providers shall have the following responsibilities.

A. Emergency response stakeholders shall:

1. Identify inoculation sites to receive the Gamaleya Sputnik V Vaccine, and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with PAITC;
2. Ensure administration of the Gamaleya Sputnik V Vaccine is consistent with the terms of this Letter, latest product information and the COVID-19 Vaccination Program; and
3. Ensure that vaccination providers of the procured Gamaleya Sputnik V Vaccine are aware of this Letter of Authorization and the terms herein and any subsequent amendments thereof, instructed about the means which they are to obtain and administer the Gamaleya Sputnik V Vaccine, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the Gamaleya Sputnik V Vaccine, in accordance with this EUA, and participate and comply with the terms and training required by the DOH for the COVID-19 Vaccination Program;
2. Provide fact sheets to the recipients and caregivers, and provide necessary information for receiving their second dose;
3. Obtain written informed consent from the recipient of the Gamaleya Sputnik V Vaccine prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of Gamaleya Sputnik V Vaccine;
5. Monitor and comply with vaccine management requirements (e.g. obtaining, tracking and handling vaccine) of the DOH; and
6. Ensure that records associated with this EUA are maintained until notified by FDA. Such records shall be made available to DOH and FDA for inspection upon request.

Notwithstanding the foregoing, PAITC has the ultimate responsibility for monitoring the safety and quality of the Gamaleya Sputnik V Vaccine.

VI. Validity

Unless otherwise revoked, this EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, or upon issuance of a marketing authorization/Certificate of Product Registration.

In the event that the declared public health emergency is lifted, or when a COVID-19 drug or vaccine is registered with the FDA, this EUA shall have a provisional validity for a period of one (1) year from date of lifting of the declaration or registration of the drug or vaccine for the sole purpose of exhausting remaining products.

This EUA is subject to revocation, suspension or cancellation due to violations of pharmacovigilance obligations and post authorization commitments, as well as any violation of the EO No. 121, and RA 3720 as amended by RA No. 9711, FDA Circular No. 2020-036, and other rules and regulations issued thereunder.

For strict compliance.