Government of the People's Republic of Bangladesh

Directorate General of Drug Administration
Aushad Bhaban, Mohakhali, Dhaka-1212
www.dgda.gov.bd

Memo No-DGDA/15-05/19(674)/ 8118 Date: 27 / 04 /2021

To
Secretary
Health Services Division,
Ministry of Health and Family Welfare.

Attention: Additional Secretary, Public Health-2, HSD, Ministry of Health and Family Welfare.

Subject: Emergency use Authorization of Sputnik V (Gam-COVID-Vac).

In response to your letter number: 45.00.0000.171.32.017.32.017.21/206, Dated: 25 April, 2021 as per directives of Section-4.2 (Kha) of Drug Policy-2016 and the notification published in the additional number of the Bangladesh Gazette dated May 17, 2020 in page no. 3825-3826 which bears the notification no. 45.00.0000.182.99.017.08-110, Dated: 13 May, 2020 of Health Services Division, MOHFW and the memo no: 45.00.0000.182.89001.21.93, dated: 24 April, 2021 of Health Services Division, MOHFW, Directorate General of Drug Administration (DGDA) issues an Emergency Use Authorization (EUA) for importing the following vaccine into Bangladesh as described below.

Name of Product: Sputnik V (Gam-COVID-Vac).

Dosage Form: Solution for intramuscular Injection/Lyophilized powder for solution.
Presentation: Multi-dose Glass vial (5 dose-3 ml)
Route of Administration: Intramuscular.

Composition: Each dose of 0.5 ml of vaccine contains:

Component I Contains:	
Active Ingredients	**Quantity**
Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene in the amount of $(1.0\pm0.5)\times10^{11}$ particles per dose.	$(1.0\pm0.5)\times10^{11}$ particles per dose.
Inactive Ingredients	**Quantity**
Tris (hydroxymethyl) aminomethane	1.21 mg
Sodium chloride	2.19 mg
Sucrose	25.0 mg
Magnesium chloride hexahydrate	102.0 µg
EDTA disodium salt dihydrate	19.0 µg
polysorbate	80-250 µg
Ethanol 95%	2.5 mcL
Water for injection	Up to 0.5 ml

Component II Contains:	
Active Ingredients	**Quantity**
Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 protein S gene in the amount of $(1.0\pm0.5)\times10^{11}$ particles per dose.	$(1.0\pm0.5)\times10^{11}$ particles per dose.
Inactive Ingredients	**Quantity**
Tris (hydroxymethyl) aminomethane	1.21 mg
Sodium chloride	2.19 mg
Sucrose	25.0 mg
Magnesium chloride hexahydrate	102.0 µg
EDTA disodium salt dihydrate	19.0 µg
polysorbate	80-250 µg
Ethanol 95%	2.5 mcL
Water for injection	Up to 0.5 ml

Name and Address of manufacturer (full name and address with telephone and e-mail address of manufacturer):
GENERIUM Joint-Stock Company (GENERIUM JSC), located at 273 Zavodskaya Street, Volginsky, Petushinsky District, Vladimir Region, 601125.
Tel.
Vaccine Developed & MA Holder: FSBI N.F. Gamaleya RCEM of the Ministry of Health of Russia

Contact Address:
The Russian Direct Investment Fund (RDIF), Capital City, South Tower,
7th, 8th floor, 8 bld. 1 Presnenskaya nab.
Moscow, Russia 123112
T: +7 495 644 3414
F: +7 495 644 3413
Email: sputnikvaccine@rdif.ru

Indication:
For Active immunization of Individuals of ≥ 18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second doses should be administered after 21 days from the first dose.

Name and Address of legal organization in the country:
Public Health-2, Health Services Division, Ministry of Health and Family Welfare, Bangladesh.

Shelf life with storage condition:
6 months when stored at -20 ±2^0 C for Solution for intramuscular Injection and 2-8^0 C for Lyophilized powder for solution. (Once opened, multi-dose vials should be used as soon as possible. It can be used for 6 hrs when kept between temp 2 to 8^0 C).

Conditions on Emergency use Authorization of Sputnik V (Gam-COVID-Vac):

1. This Emergency Use Authorization (EUA) will be valid up to the COVID-19 Pandemic Situation.
2. 100 personnel will be administered the vaccine and closely observed for 7 days and having satisfactory observations the mass vaccination could be continued.
3. The Vaccine should be supplied along with fact sheet for recipients and prescribing information/Package insert (PI).
4. The manufacturer should provide the updated Package insert, Summary of Product Characteristics (SmPC) & Fact sheet for Sputnik V (Gam-COVID-Vac).
5. The importer should submit safety data including the data on AEFI and SAE, with due analysis every 15 days for the first two months & monthly thereafter.
6. The manufacturer and the importer should implement Risk Management Plan.
7. The manufacturer should submit ongoing stability (real time and accelerated) of drug substance & drug product.
8. Each batch/lot of the vaccine shall be released from National Control Laboratory (NCL), DGDA.

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&
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