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)/ 4340 Date: 22/02 /2022

To
Managing Director
Beximco Pharmaceuticals Limited
17 Dhanmondi R/A, Road No. 2, Dhaka 1205, Bangladesh.

Subject: Emergency use Authorization of COVOVAX (SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine)

In response to your letter number: BPL/Vaccine/220131, Dated: 31 January, 2022 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: COVOVAX

Presentation: COVOVAX is supplied as ready to use liquid in rubber-stoppered single and multidose vial.

Package: Glass vial (50 single dose vials, 300 single dose vials, 50 multidose vials, 300 multidose vials)

Composition: One dose (0.5 ml) contains 5 micrograms of SARS-CoV-2 recombinant spike protein antigen with 50 micrograms of Matrix-M1 adjuvant.

Adjuvant: 50 micrograms of Matrix-M1 adjuvant.

Excipients: Matrix –M1, Sodium phosphate dibasic heptahydrate, Sodium phosphate monohydrate monobasic, Sodium chloride, Polysorbate 80, Water for injections.

Strengths: 1 dose (0.5 ml), 2 dose (1 ml), 10 dose (5 ml)

Name and Address of manufacturer: Serum Institute of India Pvt. Ltd.
Address: **Site 1**: S. No. 105-110, Manjari BK, Tal – Haveli, Pune- 412 307, Maharashtra, India
Site 2: 212/2 Hadapsar, Pune- 411028, Maharashtra, India.

Vaccine MA Holder: Serum Institute of India Pvt. Ltd.
Address: Regd.off : 212/2, Hadapsar, Pune- 411028.
TEL: +91-20-26993900/04
Website: www.seruminstitute.com
E-mail: serumexports@seruminstitute.com

Name and Address of Legal Organization in the country: Beximco Pharmaceuticals Limited
Address: Operational Headquarter: 19 Dhanmondi R/A, Road No.7, Dhaka 1205, Bangladesh.
Corporate office: 17 Dhanmondi R/A, Road No. 2, Dhaka 1205, Bangladesh.

Dosage: The vaccination course for COVOVAX is a series of two doses of 0.5 ml each by intramuscular injection. The second dose is to be administered 3 to 4 weeks after the first dose.

Dosage form: Suspension for Injection

Indication: COVOVAX is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

Contraindication: Hypersensitivity to the active substance or to any of the excipients

Shelf life with storage condition: The expiry date of vaccine is indicated on the label and packaging. Once opened (first needle puncture), multi-dose vials should be used as soon as practically possible and within 6 hours when kept between +2° C and +25° C. All opened (punctured) multidose vials of COVOVAX should be discarded at the end of immunization session or six hours after the first needle puncture, whichever comes first.

Storage: Store in a refrigerator (+2°C to +8°C). Do not freeze. Keep vials in outer carton to protect from light. Discard if vaccine has been frozen.

Conditions on Emergency use Authorization of COVOVAX (SARS-CoV-2 rS Protein (COVID-19 recombinant spike protein Nanoparticle Vaccine) :

1. This Emergency Use Authorization (EUA) will be valid up to the COVID-19 Pandemic Situation.
2. The vaccine will be administered 1000 personnel 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 COVOVAX (SARS-CoV-2 rS Protein (COVID-19 recombinant spike protein Nanoparticle Vaccine).
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.
9. This Emergency Use Authorization (EUA) may be reconsidered if its safety and efficacy issues are not met in future review.

Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority of Drugs
Phone: 02222280803
E-mail: dgda.gov@gmail.com

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