Government of the People's Republic of Bangladesh

Directorate General of Drug Administration
Aushad Bhaban, Mohakhali, Dhaka-1212
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Replace with same memo and date

Memo No-DGDA/15-05/19(674)/8211 Date: 29/04/2021

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 COVID-19 Vaccine (Vero Cell), Inactivated.

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: COVID-19 Vaccine (Vero Cell), Inactivated.
Trade Name: Zhong Al Ke Wei/COVILO.
Main Ingredient: Inactivated SARS-CoV-2 virus (19nCoV-CDC-Tan-HB02 strain)
Dosage Form: Injection.

Strength:
(1) 0.5 ml/syringe (Each pre-filled syringe contains 0.5 ml of product for each administration, each dose contains 6.5 U of inactivated SARS-CoV-2 antigen).
(2) 0.5 ml/vial (Each vial contains 0.5 ml of product for each administration, each dose contains 6.5 U of inactivated SARS-CoV-2 antigen).
(3) 1 ml/vial (Each vial contains 1 ml of product for two dose administration, each dose contains 6.5 U of inactivated SARS-CoV-2 antigen).

Presentation:
(1) Each non-auto disable syringe/vial contains 0.5 ml of product for each administration, each dose contains 3.9-10.4 units of inactivated SARS-CoV-2 antigen and 0.3-0.6 mg/ml aluminium hydroxide adjuvant.
(2) For vial contains 1.0 ml of product for two administrations, each administration requires 0.5 ml as one dose, each dose contains 3.9-10.4 units of inactivated SARS-CoV-2 antigen and 0.3-0.6 mg/ml aluminium hydroxide adjuvant.

Marketing Authorization Holder:
Name: Beijing Institute of Biological Products Co, Ltd.
Address: Room 205, Second Floor, Building 4, No 9 Boxing 2nd Road, Economic- Technological Development Area, Beijing, P.R, China.

Manufacturer: Beijing Institute of Biological Products Co, Ltd.
Address: No. 6 & 9 Boxing 2nd Road, Economic-Technological Development Area, Beijing, P.R, China.

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 28 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:
Shelf Life 24 months (tentative)
Storage Condition: 2 to 8^0 C.

Conditions on Emergency use Authorization of COVID-19 Vaccine (Vero Cell), Inactivated:

1. This Emergency Use Authorization (EUA) will be valid up to the COVID-19 Pandemic Situation.
2. 1000 personnel will be administered by the vaccine and closely observe 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 COVID-19 Vaccine (Vero Cell), Inactivated.
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.

28.06.2021

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