

Government of the People's Republic of Bangladesh

Directorate General of Drug Administration

Aushad Bhaban, Mohakhali, Dhaka-1212

Memo No-DGDA/15-05/19(674)/ 10418

Date: 03/06/2021

To

Vice Chairman

Incepta Vaccine Ltd.

40 Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208.

Subject: Emergency use Authorization of CoronaVac® (COVID-19 Vaccine (Vero Cell), Inactivated).

In response to your letter number: IVL/Vaccine/01/2021, Dated: 11 May, 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: CoronaVac® (COVID-19 Vaccine (Vero Cell), Inactivated)

Presentation:

Each vial (syringe) contains 0.5 mL with 600SU of inactivated SARS-CoV-2 virus as antigen and Each vial contains 1 mL with 1200SU of inactivated SARS-CoV-2 virus as antigen.

Composition: Each ml contains: 1200SU of inactivated SARS-CoV-2 virus as antigen.

Adjuvant: Aluminum hydroxide

Excipients: Disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride.

Package:

Vial or pre-filled syringe. One vial or syringe per box. 40 vials or 10 syringes per box.

Name and Address of manufacturer (full name and address with telephone and e-mail address of manufacturer):

Sinovac life Sciences Co., Ltd.

Address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China.

Vaccine MA Holder: Sinovac life Sciences Co., Ltd.

Address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science, Park, Daxing District, 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 14-28 days from the first dose.

Name and Address of legal organization in the country:

Incepta Vaccine Ltd, 40 Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1208.

Shelf life with storage condition:

Tentatively 24 months, and then the final shelf life will be defined according to the stability study data.

Storage Condition: Store and transport between +2-8°C, and protect from light.

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

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 CoronaVac® (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.


Major General Md Mahbubur Rahman

Director General 03 JUN 2021

Directorate General of Drug Administration

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Licensing Authority of Drugs

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