Government of the People's Republic of Bangladesh

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

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To
Line Director
MNC&AH, Directorate General of Health Services
And Member Secretary, The Task Force to collect and management of COVID-19 Vaccine,
Directorate General of Health Services.

Subject: Emergency use Authorization of COVID-19 Vaccine Janssen (Ad26.COV2.S).

In response to your letter number: 45.00.0000.171.32.017.21 (part-4)-10, Dated: 09 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: Ad26.COV2.S
Trade Name: COVID-19 Vaccine Janssen
Composition: Recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein.
Dosage Form: Intramuscular Injection
Number of Doses per container: Single dose, one vial (2.5 mL) contains 5 doses of vaccine.
Strength: One vial (2.5 mL) contains 5 doses of vaccine (each dose 0.5 ml).
Marketing Authorization Holder: Janssen–Cilag International NV (Belgium)
Manufacturer: Janssen-Cilag International NV' Belgium' and all plants approved by WHO or approved by NRAs.
Indication:
Adults greater than or equal to 18 years of age for the prevention of corona virus disease (COVID-19) when administered in one dose schedule.

Name and Address of legal organization in the country:
Line Director, MNC&AH, Directorate General of Health Services and Member Secretary, The Task Force to collect and management of COVID-19 Vaccine, Directorate General of Health Services.

Shelf life with storage condition:
Shelf Life: 2 years (stored frozen at -25°C to -15°C)

Storage Condition: 2-8°C (once remove from the freezer- for a single period of up to 3 months)

Conditions on Emergency use Authorization of COVID-19 Vaccine Janssen (Ad26.COV2.S):

1. This Emergency Use Authorization (EUA) will be valid up to the COVID-19 Pandemic Situation.
2. The Vaccine should be supplied along with fact sheet for recipients and prescribing information/Package insert (PI).
3. The manufacturer should provide the updated Package insert, Summary of Product Characteristics (SmPC) & Fact sheet for COVID-19 Vaccine Janssen (Ad26.COV2.S).
4. 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.
5. The manufacturer and the importer should implement Risk Management Plan.
6. The manufacturer should submit ongoing stability (real time and accelerated) of drug substance & drug product.
7. Each batch/lot of the vaccine shall be released from National Control Laboratory (NCL), DGDA.
8. Each vaccination centre should be equipped with necessary arrangement for management and resuscitation of Serious AEFI cases specially Anaphylaxis.

9. A minimum period of 15-minute of observation after vaccination, given the risk of potentially life-threatening anaphylactic/anaphylactoid reactions.

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