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)/ 583 Date: 27/ 06 /2021

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

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

Subject: Emergency use Authorization of MODERNA mRNA-1273 COVID-19 VACCINE

In response to your letter number: 45.00.0000.171.32.017.21.356, Dated: 26 June, 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: MODERNA mRNA-1273 COVID-19 VACCINE

Dosage forms and strengths: Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.
Dose Preparation: The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration. Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.
Strength: 0.20 mg/mL
Target Fill Volume/Vial: 6.3 mL
Number of Doses/Vial: 10 Doses
Dosing and Schedule: For Active immunization of Individuals of ≥ 18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses (0.5 mL each) schedule. The second doses should be administered after 4 weeks.
Shelf life with storage condition: Shelf Life: 7 months (storage at -15°C to -25°C) that can include 30 days of storage at 2° to 8°C and 12 hours at 8° to 25°C. Vaccine is stable when hold for 6 hours after first puncture in the dosing vial followed by 8 hours in the dosing syringe, at either ambient temperature or at 2° to 8°C.
Storage Condition: The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C. Store in the original carton to protect from light.
Vials may be stored refrigerated between 2° to 8°C for up to 30 days prior to first use. Thawed vials can be handled in room light conditions. Do not refreeze once thawed.
Marketing Authorization Holder: Moderna TX. Inc.
Manufacturer: Moderna TX. Inc.
Manufacturing Sites: All sites approved by USFDA, EMA, and WHO.
Name and Address of legal organization in the country: Public Health-2, Health Services Division, Ministry of Health and Family Welfare, Bangladesh.

Conditions on Emergency use Authorization of MODERNA mRNA-1273 COVID-19 VACCINE:

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 MODERNA mRNA-1273 COVID-19 VACCINE.
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 center 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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