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)/ 9439 Date: 09/06/2022

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 COMIRNATY (Tozinameran - COVID-19 mRNA vaccine (nucleoside modified).

In response to your letter number: 45.00.0000.171.32.017.32.017.21/206, Dated: 25 April, 2021, e-mail on 20 April, 2022 and letter from EPI No: স্বা. অধি/ ইপিআই/সার্ভিল্যান্স/কোভিড-১৯/২০২২/৯১০, date: 07/06/2022 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: Tozinameran-COVID-19 mRNA vaccine (nucleoside modified)
Trade Name: COMIRNATY
Main Ingredient: Based on the SARS-CoV-2 spike glycoprotein (S) antigen encoded by mRNA Formulated in lipid nanoparticles (LNP).

Dosage Form: Intramuscular Injection.

Number of Doses per container: (1) 6, Each dose 0.3 ml after dilution and (2) 6, Each dose 0.3 ml without dilution.

Strength: 1) Vial (0.45 mL/vial), Diluent 1.8 ml 0.9% NaCl

2) 2.25 mL/vial, No Dilution, drug product containing TRIS/SUCROSE.

3) 1.3 mL/vial, Diluent 1.3 ml 0.9% NaCl

Presentation: (1) Vial (0.45 mL/vial) (vial cap color- Purple) (6 doses per vial (after dilution)

(2) Vial (2.25 mL/vial) (vial cap color- Grey) (6 doses per vial) and

(3) Vial (1.3 mL/vial) (vial cap color- Orange) (10 doses per vial (after dilution).

Marketing Authorization Holder:
Name and Address: BioNTec Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany.

Manufacturer Name and Address: Pfizer Manufacturing Belgium NV, PGS Puus, Rijkweg 12, 2870 Puurs, Belgium. Also all plants approved by NRAs & WHO.

Indication:
For Active immunization of Individuals of (Vial (0.45 mL/vial), Diluent 1.8 ml 0.9% NaCl) and (2.25 mL/vial, No Dilution) for ≥12 years old and (1.3 mL/vial, Diluent 1.3 ml 0.9% NaCl) for 5 to 11 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second doses should be administered after 3-4 weeks 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: 9 months

Storage Condition:
(1) Freezer storage time (-90°C to -60°C) 9 month shelf life; once removed from the freezer, the unopened vaccine vial can be stored for up to 1 month at 2°C to 8°C and up to 2 hours at the temperature up to 30°C, prior to use. After First Punch (2°C to 30°C) discard after 6 hours. The vaccine should not be re-frozen.
(2) and (3) Freezer storage time (-90°C to -60°C) 9 month shelf life. Do not store in -25°C to -15°C. The unopened vaccine vial can be stored for up to 10 weeks at 2°C to 8°C and up to 12 hours at the temperature up to 30°C, prior to use. After First Punch (2°C to 30°C) discard after 12 hours. The vaccine should not be re-frozen.

Conditions on Emergency use Authorization of mRNA based COVID-19 Vaccine:

1. This Emergency Use Authorization (EUA) will be valid up to the COVID-19 Pandemic Situation.
2. Initially the vaccine will be administered 200 persons and will be observed for 7 days and having satisfactory observations the mass vaccination programme will be started.
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 COMIRNATY (Tozinameran - COVID-19 mRNA vaccine (nucleoside modified).
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. Each vaccination centre should be equipped with necessary arrangement for management and resuscitation of Serious AEFI cases specially Anaphylaxis.
10. A minimum period of 15-minute of observation after vaccination, given the risk of potentially life-threatening anaphylactic/anaphylactoid reactions.

With this approval previous approval of memo no: DGDA/15-05/19(674)/7316, date: 21/04/2022 has been cancelled.

09 JUN 2022

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