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)/ 577 Date: 23/ 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 COVID-19 Vaccine AstraZeneca, AZD1222 (ChAdOx1-S [recombinant]) via COVAX.

In response to your letter number: 45.00.0000.171.32.017.21.340, Dated: 19 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: COVID-19 Vaccine AstraZeneca, AZD1222 (ChAdOx1-S [recombinant]).
Trade Name: "Vaxzevira", "Korea AstraZeneca COVID-19 Vaccine".
Dosage form: Inj (1M), 0.5 ml/dose.
Presentation: 5 ml solution for injection, 10 doses/vial.
Method of Administration: Intramuscular (1M) injection only, preferably in the deltoid muscle.

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 4 to 12 weeks after 1st dose.

Address of Manufacturing plants: The plants are hereby authorized from where the AZD1222 are being procured/will be procured by COVAX as well as which are approved by WHO & NRAs worldwide for EUL/EUA. Such as-
1.CP Pharmaceuticals Ash Road North Wrexham LL13 9UF United Kingdom. 2. Catalent Anagni S.r.l Localita Fontana del Ceraso Snc S.P.12 Casilina 41 03012 Anagni Frosinone Italy. 3. Henogen S.A. site located in Seneffe, Belgium. 4. Halix facility located at Tinbergenweg 1, 2333 BB Leiden, The Netherlands. 5. Cobra Bio, Keele, UK. 6. Catalent Maryland, Inc. was formerly known as Paragon Bioservices, Inc, 7555 Harmans Road, Harmans, Maryland, 21077, USA 7. SK Bioscience Co Limited, Republic of Korea, 8. UNIVERSAL FARMA, S.L. ("Chemo"), C/ Del Tejido, 2, Azuqueca de Henares, Guadalajara, 19200, Spain. etc.

Marketing Authorization Holder: AstraZeneca AB SE-15185 Sodertalie, Sweden.

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: 6 months when stored at 2°C to 8°C. Once opened, multi-dose vials should be used as soon as possible and within 6 hours when kept between 2°C to 8°C.

Conditions on Emergency use Authorization of COVID-19 Vaccine AstraZeneca, AZD1222 (ChAdOx1-S [recombinant]):

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 AstraZeneca, AZD1222 (ChAdOx1-S [recombinant]).
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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