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)/ 501 Date: 07 / 01 /2021

To
The Managing Director
Beximco Pharmaceuticals Limited
17, Dhanmandi R/A, Road No.02
Dhaka-1205.

Subject: Emergency use Authorization of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) ("COVISHIELD"; also known as SARS-CoV-2 AZD 1222, Oxford/AstraZeneca Vaccine).

In response to your letter number-BPL/Vaccine/210104, Dated: 04-01-2021 and letter number-BPL/Vaccine/210107, Dated: 07-01-2021 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, 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: ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) ("COVISHIELD"; also known as SARS-CoV-2 AZD 1222, Oxford/AstraZeneca Vaccine).
Dosage Form: Solution for Injection
Presentation: Multi-dose Glass vial (10 dose-5 ml)
Route of Administration: Intramuscular.
Composition: Each dose of 0.5 ml of vaccine contains:

Active Ingredients	**Quantity**
Replication-deficient chimpanzee adeno virus particles encoding SARS-CoV-2 spike (S) Glycoprotein*	$5X10^{10}$ virus particles
Inactive Ingredients	**Quantity**
L-Histidine and L-Histidine Hydrochloride	10mM
Sodium Chloride	35mM
Magnesium Chloride	1mM
Polysorbate 80	0.1%(w/v)
Sucrose	7.5%(w/v)
Ethanol	0.5%(w/v)
EDTA Disodium Salt	0.1mM
Water for Injection	q.s. to 0.5ml
* Produced in genetically human embryonic kidney (HEK) 293 cells.	

Name and Address of manufacturer (full name and address with telephone and e-mail address of manufacturer):
M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road Hadapsar Pune, Maharashtra (India)-411028. Tel. No: +91-20-26993900, 26992113 Fax No: +91-20-26993921, Email: ssj@seruminstitute.com
Name and Address of manufacturer Site (full name and address with telephone and e-mail address of manufacturer Site):
M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar Pune, Maharashtra (India)-411028
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 dose should be administered between 4 to 12 weeks after the first dose.
Name and Address of importer/local agent:
Beximco Pharmaceuticals Limited, 17, Dhanmandi R/A, Road No.02, Dhaka-1205.

Shelf life with storage condition:
6 months when stored at 2 to 8^0 C. once opened, multi-dose vials should be used as soon as possible and within 6 hours when kept between 2 to 8^0 C.

Conditions on Emergency use Authorization of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) ("COVISHIELD"; also known as SARS-CoV-2 AZD 1222, Oxford/AstraZeneca 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 factsheet for recipients and prescribing information/Package insert (PI).
3. The manufacturer should provide the updated Package insert, Summary of Product Characteristics (SmPC) & Factsheet for ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) ("COVISHIELD"; also known as SARS-CoV-2 AZD 1222, Oxford/AstraZeneca 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.

Major General Md Mahbubur Rahman
Directorate General 07 JAN 2021
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