Maldives Food and Drug Authority

Ministry of Health
Male'
Republic of Maldives

1st revision on the Approval to use COVISHIELD (ChAdOx1nCoV-19 CORONA VIRUS Vaccine, recombinant, of AstraZeneca, UK) imported from India, manufactured by Serum Institute of India PVT LTD.

Maldives food and Drug Authority (MFDA)hereby, under the chapter VII, Section 63, Sub section B and Section 65 Sub section C, of the Health Services Act 29/2015, and under the Medicine's Regulation 2014/R-46, with the technical advice from National Pharmaceutical Board, and with the submitted dossier information by the Serum institute of India PVT LTD , give authorization for COVISHIELD (ChAdOx1 AstraZeneca Covid 19) vaccine to be used in Maldives given that the following conditions are met:

1. This approval is exclusively issued for restricted use in emergency situation for COVID 19 pandemic, subjected to various regulatory provisions.
2. The emergency as mentioned above in point 1 shall be defined by the Health protection Agency under the power vested to Director General, Public Health by the Public Health Protection Act 7/2012, (chapter 7). During this emergency situation the Director General of Public Health may determine the need for vaccination in the Maldives.
3. Vaccines shall be used only under the context of Government use.
4. Vaccines shall be supplied to the immunization program and vaccination shall be carried out only in designated immunization centers equipped to handle anaphylactic reactions. Following the administration of the vaccine, the recipient must be monitored for any immediate reactions. For this purpose, all immunization centers must monitor individuals for **at least 15 to 30 minutes** for any reactions following the administration of these vaccines. Individuals must be well informed to report any adverse events even afterward through the Adverse Events Following Immunization (AEFI) reporting mechanism established for immunization program.
5. A contact point from the immunization center shall be provided to the patient after vaccine administration for reporting any AEF, side effects or any other reactions regarding post-vaccination.
6. The staffs at the immunization centers shall be well-trained in administration of the vaccine and in identifying the side effects as well as probable adverse reactions associated with the vaccine. Trained medical staffs must be present at all times to handle any serious adverse events.
7. Vaccines shall be administered to individuals who meet the set requirement as mentioned in point 8 and point 9 of this document.
8. All the information on COVISHIELD vaccine with the side effects of the vaccine and probable adverse effects of it must be provided to the patient and consent of individuals must be obtained before to administration of the vaccine.
9. The vaccine shall only be administered to individuals above 18 years of age.
10. Sufficient stock must be secured to be utilized for the 2nd dose in consideration, that the vaccine is administrated in 2 doses, with a duration of 4 to 6 weeks between the first and second dose.
11. AEFI reporting mechanisms shall be vigilant in identifying adverse events and proper treatment protocols (Emergency medications, consumables and equipments) shall be readily available at the vaccine administration centers.

Maldives Food and Drug Authority ★ Male' Republic ★

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12. COVID-19 Vaccines: Safety Surveillance Manual Module: Responding to adverse events following COVID-19 immunization (AEFIs) by WHO is an important document to follow for reporting and managing AEFI (attached in annex 1).

13. It is important to check the current AEFI forms in use, in the country, to ensure that the required information for signal detection and causality assessment is sufficient. In the case of Covid-19 immunization in addition to standard information, it is important to record the brand name, the manufacturer, as well as the batch numbers (because vaccines are likely to be manufactured on different platforms, with different antigen targets, adjuvants, and dosage forms). Therefore, we recommend to following the Vaccine-specific Vigiflow tool. Also, it is recommended to ensure that technical expert committee inclusive of clinical experts, to evaluate the adverse reactions and causality assessment is established. MFDA shall provide all the support in further enhancing the AEFI reporting and management system.

14. In case of recall MFDA shall take all necessary actions to recall the vaccines from all points and shall have a procedure in place with plan of action.

15. The COVISHIELD vaccine must be stored at 2 to 8 degrees Celsius and must have a mechanism to ensure that the cold chain is maintained throughout the process till the vaccine is administered to patients.

16. This approval will be reviewed and is subjected to change, based on the further information (including but not limited to the following) furnished by Serum Institute of India PVT LTD or any other reliable source:

    16.1. Consideration on the recommendation of the Maldives Technical Advisory Group for immunizations (MTAGI), the WHO prequalification approval for COVISHIELD

    OR

    The approval to be listed in WHO emergency use listing (EUL) of vaccines.

    OR

    Regulatory approval for the use of COVISHIELD vaccines from any of the stringent Regulatory authorities

    OR

    Regulatory approval from category 1 country's regulatory authorities and defined by MFDA