



Maldives Food and Drug Authority

Ministry of Health
Male
Republic of Maldives

Emergency use authorization to use Sinopharm vaccine (SARS-CoV-2 vaccine (Vero cell) inactivated), 6.5U/0.5ml/vial, 6.5U/0.5ml/pre-filled syringes, imported from China, manufactured by Beijing Institute of Biological Products Co.,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 technical advice from National Pharmaceutical Board, upon evaluation of the information submitted by Sinopharm, give emergency use authorization for SARS-CoV-2 vaccine (Vero cell) inactivated, to be used in Maldives given that the following conditions are met:

1. This approval is exclusively issued for restricted use in public health emergency situation for COVID 19 pandemic, subjected to regulatory provisions. In the event that the public health emergency has been lifted, the authorization shall only be valid for 60 days. Further use of the vaccine requires registration of the vaccine in compliance with the Medicines Regulation 2014-R/46.
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 for active immunization against Covid-19 to be administered to individuals 18 to 60 years of age ONLY.
4. The SARS-CoV-2 vaccine (Vero cell) inactivated 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 until vaccine administration.
5. All the information on SARS-CoV-2 vaccine (Vero cell) inactivated, with its official translation, 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.
6. Official translation of the vaccine pack, vial and pre filled injections shall be available in the immunization centers at all times and vaccinators and staff working in the centers shall be thorough with the translation and shall be in a position to accurately convey the information to the patient.
7. 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.
8. 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 at least 15 to 30 minutes. Individuals must be well informed to report any adverse events even afterwards through the Adverse Events Following Immunization (AEFI) reporting mechanism established for immunization program.

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9. AEFI reporting mechanisms shall be vigilant in identifying adverse events and proper treatment protocols (Emergency medications, consumables and equipment) shall be readily available at the vaccine administration centers.
10. 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).
11. 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 addition to standard information for Covid-19 immunization, it is important to record the brand name, the manufacturer, as well as the batch numbers. Therefore, it is recommended following the Vaccine-specific Vigiflow tool.
12. 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.
13. Sufficient stock must be secured to be utilized for the 2nd dose in consideration, that the vaccine is administrated in 2 doses, with duration of 2 to 4 weeks between the first and second dose.
14. All vaccinators or immunization facilities shall report any products suspected of quality defect or product issues to Maldives Food and Drug Authority. Such products must NOT be administered to any individuals. The product(s) must be separated, properly labeled and stored in at 2 to 8 degrees Celsius to be handed over to MFDA officials for further evaluation.
15. In case of recall MFDA shall take all necessary actions to recall the vaccines from all points and shall follow the procedures in place for the recall.
16. Sinopharm shall submit any new safety concerns or findings or changes to product information sheet as it becomes available.
17. This approval will be reviewed and is subjected to change, based on the further information (including but not limited to the following) furnished by Sinopharm or any other reliable source:

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

OR

Regulatory approval for the use of SARS-CoV-2 vaccine (Vero cell) inactivated from any of the stringent Regulatory authorities

OR

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

18. MFDA has the right to revoke this authorization based safety assessments and technical advice from Pharmaceutical board.

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