Maldives Food and Drug Authority

Ministry of Health
Male'
Republic of Maldives

3rd REVISION ON THE APPROVAL TO USE PFIZER-BIONTECH COVID-19 VACCINE

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 and give authorization for Pfizer-BioNTech COVID-19 vaccine to be used in Maldives given that the following conditions are met:

1. Pfizer-BioNTech COVID 19 Vaccine (BNT162b2/COMIRNATY Tozinameran (INN)) is to be used for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 to 11 years of age (10 mcg) and 12 years of age and older (30 mcg). The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles.
2. This approval is exclusively issued for restricted use in emergency situation for COVID 19 pandemic, subjected to various 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.
3. The emergency as mentioned above in point 2 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.
4. Vaccines shall be used only under the context of Government use. The vaccines shall be supplied to the immunization program and shall be used as per the guidelines and standards of Health Protection Agency (HPA).
5. During import of the vaccine, each batch of the vaccine imported, shall be accompanied by the batch certificate or batch analysis report.
6. Storing and handling of the vaccine must strictly follow the requirements of the manufacture.
7. All the information on Pfizer-BioNTech COVID-19 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 prior to administration of the vaccine
8. Administration of the vaccines 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. Individuals must be informed to report any adverse events even afterward through the Adverse Events Following Immunization (AEFI) reporting mechanism established for immunization program.
9. 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.
10. 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.

11. 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.
12. AEFI forms in use, in the country must be updated and should contain information for signal detection and causality assessment. 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).
13. Technical expert committee inclusive of clinical experts, shall evaluate the adverse reactions and causality assessment must be done. Findings must be shared to re-evaluate the safety and future use in the population. MFDA shall provide all the support in further enhancing the AEFI reporting and management system.
14. Sufficient stock must be secured to be utilized for the 2nd dose in consideration; all people for whom vaccination is indicated should receive 2 doses 21 days apart.
15. 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.
16. In case of recall, MFDA shall take all necessary actions to recall the vaccines from all points and shall follow procedure in place.
17. This approval will be reviewed and is subjected to change, based on the further information.
18. MFDA may revise or revoke this authorization based on safety concerns and new scientific findings to justify such change.
19. Those who are vaccinated under this condition shall be monitored for a longer period and routine check-ups shall be done every three months and recorded.

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