بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Import, Distribution and Sale of Vaccines and Biologicals in the Maldives

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Guideline on Import, Distribution and Sale of Vaccines and Biologicals in the Maldives

is released under the authority of

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Guideline on Import, Distribution and Sale of Vaccines and Biologicals in the Maldives

1 INTRODUCTION

Vaccines are imported to the Maldives under the National Immunization Program, pandemic and epidemic related imports, and vaccines that are not included in the National Immunization Program. Vaccines may be imported as donations from other countries and international agencies, national procurement, or private procurement by medicine importers.

The Maldives Food and Drug Authority (MFDA) regulates and monitors the vaccines imported to the Maldives to ensure the safety, quality and efficacy of the products.

2 PURPOSE

This Guideline outlines the procedure for approve vaccines in the Maldives. Vaccines are regulated to ensure the safety, quality, and efficacy of vaccines provided to the public, and ensure the products imported to the Maldives are approved by MFDA.

3 SCOPE

This guideline has been developed to guide the interested parties on the process of vaccine approvals.

4 RESPONSIBILITY

- National Pharmaceutical Board shall be responsible for the approval and rejection of the vaccines applied for registration.
- Director General shall be responsible for authorizing the addition or modification or deletion of vaccines from the ADL.
- Deputy Director General (DDG), Pharmaceuticals shall be responsible for verifying

documents submitted to the National Pharmaceutical Board; approving addition or modification, and deletion of vaccines from the ADL; authorising Pre-Authorisation Permit for Importing vaccines.

- Director, Pharmaceuticals of Regulation section shall be responsible for verification of Product Evaluation Summary and check all documents; Presenting the Product Evaluation Summary to the National Pharmaceutical Board; Checking and verifying approvals for addition or modification, and deletion of vaccines from the ADL; approving the processing of Pre-Authorization approvals; and verifying Pre-Authorization Permits.
- Pharmaceutical Officers of MTG involved in marketing authorization process shall be responsible for following the procedure outlined in this SOP

5 GUIDELINE CONTENTS

5.1 Vaccines in the National Vaccines Program

5.1.1 Health Protection Agency is responsible to share the updated list of vaccines used in the National Immunization Program (NIP) once in every year with the consolation of National Immunization Program (NIP) run by Health Protection Agency (HPA),

5.1.2 The list of vaccine used in the the National Immunization Program (NIP), from the Approved Drug List (ADL) shall be updated annually and published.

5.1.3 To import the vaccines categorized for National Immunization Program (NIP), a Pre-Authorization (PA) Shall be taken prior to import as per the Guideline on Pre-Authorization Approval of Medicines (MTG/RE-PA/GLN-TE010).

5.1.4 The pre-authorisation approval for vaccines shall be expedited on the same day based on the urgency and need.

5.1.5 The pre-authorisation approval shall be given only for WHO pre-qualified vaccines.

5.2 Vaccines imported for a pandemic or epidemic

5.2.1 Vaccines imported for pandemic or epidemic shall be in the Approved Drug List and can be

imported by the government only.

5.2.2 Prior to import of such vaccines, a Pre-Authorization shall be obtained for each shipment.

5.2.3 The pre-authorisation approval for vaccines shall be expedited and given as soon as possible, even on the same day the application is received.

5.2.4 The pre-authorisation approval shall be given for WHO pre-qualified vaccines or for Emergency Use Listed Vaccines (EUL).

5.2.5 The documents for the approval of the WHO EUL vaccines are limited to the documents as indicated in the "Regulatory Requirements for product registration and approval of vaccines in emergency situation" (Annex I)

5.2.6 In case of vaccines which is not WHO prequalified or WHO EUL, individual case by case evaluation of the vaccines will be done bases on the situation and submitted documents. The documents submitted shall be as indicated in the "Documents required for evaluation and approval of COVID 19 vaccine which are not WHO EUL" (refer to annex 2).

5.2.7 Any vaccines which are not in the Approved Drug List and required to import for a pandemic or epidemic situation, the below documents are required to be submitted.

5.2.8 Company Profile

5.2.8.1 The company profile documents should include the detail of the following.

5.2.8.2 Brief history of company with its detailed address including phone and fax number.

5.2.8.3 Brief description of the Organization.

5.2.8.4 Organization chart

5.2.8.5 List of the product category manufactured

5.2.9 Product Profile:

5.2.9.1 The product profile should provide the following information on the finished product;

5.2.9.2 Generic or INN name

5.2.9.3 Brand name /Product Name

5.2.9.4 Dosage Form

5.2.9.5 Strength of the finished product

5.2.9.6 Reference of the official standards of the finished product (eg: compendia pharmacopeias or manufacturer's in-house specification).

5.2.9.7 6.2.10 GMP certificate (Valid WHO type GMP certificate).

5.2.9.8 6.2.11 Batch release of lot release certificate of the vaccine

5.2.9.9 6.2.12 Information of all ADR reports and reported death during the clinical trial

5.2.9.10 6.2.13 List of all the ingredients in the dosage form and their amount on a per unit basis, as per the label claim and batch quantities.

5.2.10 The approvals for these will be a conditional approval and the final decision of the approval will be given as per the technical advice of the National Pharmaceutical Board

5.2.11 If approved the products will be added to the Approved Drug List.

5.3 Vaccines other than NIP or pandemics or epidemics

5.3.1 The vaccines imported for purposes other than National Immunization Program or pandemics and epidemics require a full dossier.

5.3.2 Follow the Procedure for Registration of Medicine with Full Dossier Submission outlined in the Guidelines on Product Registration and Approval of Medicines (MTG/RE-PP/GLN-TE001).

5.4 Storage of Vaccines

5.4.1 The Storage of vaccines Vaccine effectiveness cannot be guaranteed unless the vaccine has been stored correctly.

5.4.2 Vaccines should be stored in the original packaging, retaining batch numbers and expiry dates.

5.4.3 Vaccines should be stored according to the manufacturer's summary of product characteristics (SPC) – usually at +2˚C to +8˚C and protected from light.

5.4.4 Prolonged exposure to ultraviolet light will cause loss of potency. Within the refrigerator, sufficient space around the vaccine packages should be left for air to circulate.

5.4.5 Vaccines should be kept away from the side and back walls of the refrigerator; otherwise, the vaccines may freeze rendering them inactive and unusable.

5.5 Health clearance of vaccines at ports of entry

5.5.1 For Health clearance of vaccines, the importer shall submit a valid batch certificate for all vaccines imported to National Immunization Program, pandemics and epidemics and other vaccines as well.

5.5.2 Health Clearance for vaccines shall be expedited and given as soon as possible, even on the same day the request for clearance is received.

5.6 Distribution of Vaccines

5.6.1 For distribution of vaccines, validated cool boxes and cool packs from a recognized medical supply company should be used in conjunction with validated maximum – minimum thermometers.

5.6.2 Cool packs should be stored in accordance with the manufacturer's instructions given by the manufactures. usually at +2˚C to +8˚C (not a freezer compartment) to ensure they maintain the cold chain at the right temperature.

5.6.3 In general, ice packs and frozen cool packs should not be used as there is a danger of these freezing some vaccine doses during transit. The exception to this is when the cool box manufacturer's instructions specifically state that ice packs should be used. Individual manufacturer's instructions should be strictly adhered to.

5.6.4 Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool box with cool packs as per the manufacturer's instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage.

5.6.5 When transporting vaccines, the named individuals are responsible for ensuring that only the amounts of vaccines necessary for each session are removed from the vaccine refrigerator. These should be placed quickly into the validated cool boxes and opening must be kept to a minimum.

5.6.6 If there are any unused vaccines left over at the end of a vaccination session, providing there is evidence from the temperature monitoring that the cold chain has been maintained, the vaccines can be returned to the vaccine refrigerator.

5.7 Dispensing Vaccines

5.7.1 Vaccines categorized as a "Prescription Only Medicine" (POM), can be stored, and sold in the pharmacies.

5.7.2 Other category medicines cannot be stored or sold in the pharmacy.

5.8 Post-market surveillance

5.8.1 Post-market surveillance of vaccines shall be conducted as per the post-market surveillance plan and Standard Operating Procedure for Post-Market Surveillance.

5.8.2 Random sterility testing of vaccines imported to the Maldives shall be conducted regularly as per the plan.

6 Annex

- Annex I - Regulatory Requirements for Product Registration and Approval of Vaccines in Emergency Situations

7 Reference

- Medicine Regulation 2014/R-46
- Guideline on Product Registration and Approval of Medicines (MTG/RE-RP/GLN-TE 001)
- Guideline on Pre-Authorization Approval of Medicines (MTG/RE-PA/GLN-TE010).

ANNEX I

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Ministry of Health

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Regulatory Requirements for Product Registration and Approval of Vaccines in Emergency Situations

Normal Condition For Approving Vaccine Products	Emergency Situation
1. Company Profile The company profile documents should include the detail of the following. a. Brief history of company with its detailed address including phone and fax number. b. Brief description of the Organization. c. Organization chart d. List of the product category manufactured	Required in emergency situation

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Authorized by: Director General, MFDA		
Doc. No: MTG/RE-VA/STD-TE 003	Rec. Name: Regulatory Requirements for Product Registration and Approval of Vaccines in Emergency Situations			
Issue No: 01	Issue Date: 01.12.2020	Prepared by: Director Pharmaceuticals, Enforcement Section	Approved by: Deputy Director General, Pharmaceuticals	Copy Letter:
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG		Page No: Page 1 of 2

2. Product Profile: The product profile should provide the following information on the finished product; a. Generic or INN name b. Brand name /Product Name c. Dosage Form d. Strength of the finished product e. Reference of the official standards of the finished product (eg: compendia pharmacopeias or manufacturer's in-house specification). f. List of all the ingredients in the dosage form and their amount on a per unit basis, as per the label claim and batch quantities.	Required in emergency situation
GMP certificate (Valid WHO type GMP certificate).	Required in emergency situation
Batch release of lot release certificate of the vaccine	Required in emergency situation
Information of all ADR reports and reported death during the clinical trial	Required in emergency situation

Approved on: 1st December 2020

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