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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Good Import Practice

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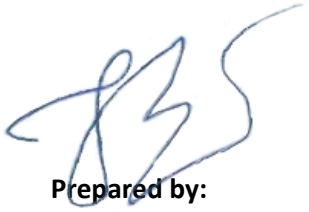

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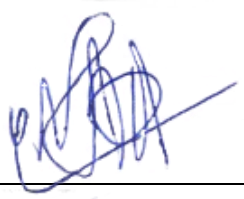
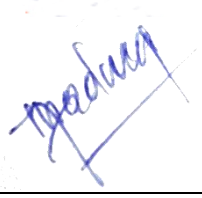
Verified by: **Ms. Aishath Mohamed** **Deputy Director General, Pharmaceuticals** **Medicine and Therapeutic Goods Division**		13.02.2020
Authorised by: **Ms. Thooma Adam** **Deputy Director General, Laboratory Services** **Maldives Food and Drug Authority**		13.02.2020

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Guideline on Good Import Practice

1 INTRODUCTION

This guide is based on the requirement for importers to ensure that imported pharmaceutical or medicinal products comply with the relevant statutes and regulations of the Maldives Food and Drug Authority, recognizing that the Maldives Food and Drug Authority has a responsibility of assuring the quality, safety and efficacy of medicinal products imported distributed and used nationally.

2 PURPOSE

The main objective of these guidelines is to provide importers of pharmaceuticals with the necessary information to enable them to comply with the law and regulations governing importation of pharmaceutical or medicinal products into The Maldives. This guideline applies to medicines and similar products intended for human use. It is recommended, however, that the same kind of attention be given to the importation of veterinary and alternative medicinal products.

3 SCOPE

Because of the wide variety of products and their production processes, the regulatory systems that apply to particular products and the range of product and importer relationships, it is difficult to develop a set of detailed recommendations that fits every product. All recommendations are not appropriate or feasible for every product, and for every importer, but it is recommended that importers identify and understand potential risks before deciding to import a particular product.

4 GUIDELINE CONTENTS

4.1 Principles

4.1.1 The safety, efficacy, and quality of pharmaceutical products can be highly affected by the lack of adequate control on importation. Both the regulator and the importer have the joint responsibility to ensure product quality, safety and efficacy of all products imported into the Maldives. In that regard,

4.1.1.1 Importers should have a good understanding of the products they are importing, the applicable regulatory requirements, and the compliance history of the products and the firms involved in the products' design, production and handling.

4.1.1.2 Importers should know the details of the imported product, such as its use, packaging, size, quantity, quality, composition, specifications, and safety concerns.

4.1.1.3 To ensure that the supply chain for imports receives appropriate administration, importers should establish a "Product Safety Management Program," including an organizational structure to facilitate implementation of the practices to ensure corporate responsibility. The organizational structure should include clearly-defined job functions and responsibilities; documented policies and procedures; adequate training; a process to analyze and evaluate risks during a product's life cycle (including conducting risk assessments), appropriate communication mechanisms; and a quality assurance program.

4.1.1.4 Importers should establish procedures for developing corrective action and preventive action plans, and for taking corrective and preventive actions. They should also put systems and business processes in place to ensure that all of their suppliers comply with applicable regulations and standards of MFDA. These should include;

- Identify and investigate the root cause of non-compliance with MFDA requirements
- Taking steps to remediate and prevent harm from present and future shipments and to
- Ensure non-compliance and safety problems do not recur; and

- Working with a non-compliant supplier to meet MFDA requirements (or ceasing to do business with that supplier).

4.2 Legal Requirements

4.2.1 All transactions concerning the importation of consignments of pharmaceutical products should be conducted through independent authorized pharmaceutical importers licensed by MFDA

4.2.2 Unless otherwise specified, only approved medicinal products will be permitted to be imported into Maldives.

4.2.3 The importation of all consignments of pharmaceutical products should be channeled exclusively through the designated ports of entry and will be cleared by customs after visual inspection by the MFDA pharmaceutical Port Control Unit.

4.2.4 The Pharmaceutical Import License shall be subject to renewal upon expiry.

4.2.5 No importation of pharmaceutical products shall be done by post.

4.3 Prohibition on Import of medicinal products

4.3.1 The following is prohibited for import for all importers:

a. Any drug which is not approved in the ADL

b. Any misbranded, spurious or adulterated drug

c. Drugs NOT labeled in a readable language (Dhivehi/English)

d. Drugs after the date of expiry as mentioned in label

e. If short expiry shall not be less than six months' shelf life

f. Drugs for which the market exclusivity is given to other importer (s)

g. Controlled drugs except for the authorized parties (STO & ADK)

4.4 Documentation

4.4.1 The authorized importer shall be required to submit the following documents to MFDA port control units 48hrs prior to clearance of a shipment. Submission of invoice should be carried out during the office hours (08:00 to 15:00hrs). Invoice submission via mails shall be accepted on reasonable cases only.

4.4.2 Multiple invoices attached as single set shall not be accepted. The set of documents shall include only one invoice with the packing list and Bill of Landing:

a. A true copy of the invoice
b. Detailed packing list
c. Bill of lading / Airway bill
d. Batch certificates or batch analysis for cold storage products
e. Original of the preauthorization letter issued from MFDA for medicines which require a preauthorization before import
f. Original of preauthorization for registration samples
g. Import certificate for all control drugs (from MFDA)
h. Export certificate for internationally control drugs (from Narcotic control bureau of the exporting country)
i. Copy of National Identity Card/Work visa/Passport for medicines imported for prescription (personal use)

***Note: The invoice should not be written in less than 12p font size.**

4.4.3 The invoice shall contain the following information:

a. Name and address of consignee
b. Name and address of consigner
c. Commercial invoice reference number
d. Buyers purchase order number with date ordered.
e. Invoiced date
f. Port of entry
g. Brand name of the drug
h. Generic name of the drug

i. Formulation of the drug
j. Dosage form of the drug
k. Strength of the drug
l. Manufacture of the drug
m. Country of origin
n. Manufactured date
o. Expiry date
p. Batch number / Lot number
q. Quantity to be imported for each batch or lot number
r. Total price for each quantity (Currency shall be in U.S. dollars only)
s. Signature of the authorized person (Exporter)
t. Authorized stamp (Exporter)

4.5 Shipment Containers and Container Labelling

4.5.1 Pharmaceutical products should be stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

4.5.2 Pharmaceutical products require controlled storage and transit conditions in order to ensure that their quality is not compromised

4.5.3 Shipping containers should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times. The shipment container should enable identification of the container's contents and source.

4.5.4 The need for any special transport and/or storage conditions should be stated on the shipment container label.

4.5.5 Normally, internationally and/or nationally accepted abbreviations, names or codes should be used in the labeling of shipment containers.

4.5.6 Special care should be taken when using dry ice in shipment containers. In addition to safety issues it must be ensured that the pharmaceutical product does not come into contact with the dry ice, as it may have an adverse effect on the quality of the product

4.6 Special Medicine Categories

4.6.1 Vaccine storage and handling are key components in maintaining the efficacy of immunization programs. Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and with administration of the vaccine.

4.6.2 The optimum temperature for refrigerated vaccines is between 2°C and 8°C. For frozen vaccines the optimum temperature is –15°C. In addition, protection from light is a necessary condition for some vaccines. Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range.

4.6.3 Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.

4.6.4 While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0° C [32° F] or colder) will destroy some. Liquid vaccines that contain an aluminum adjuvant can permanently lose potency when exposed to freezing temperatures.

4.6.5 The main reason for maintaining the potency of a vaccines is, failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine preventable disease.

4.6.6 The invoice of vaccine/biological should be accompanied with batch or lot release certificate for each batch to be imported.

a. Consignments of vaccines /biological products shall be stored under suitable conditions for as short a time as possible, at the port of entry.

b. Cold storage products shall be imported in accordance with the storage conditions indicated on the packaging information and on the label.

c. Importers shall take all reasonable steps to ensure that vaccines/biological products are not mishandled or exposed to adverse storage conditions at wharves or airports.

d. Procedures shall be in place for quality assessment of imported vaccine/biological products.

e. Vaccine/biological products shall be stored and transported in accordance with procedures such that:

- The identity of the product is not lost.
- The product does not contaminate and is not contaminated by other products.

f. Adequate precautions are taken against spillage, breakage, misappropriation. Spillage during transport shall be handled as per type of vaccine (e.g. live, killed, etc.) according to the standard operating procedures of the manufacturer.

g. Appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

4.6.7 Cold chain equipment for transport of vaccine/biological:

4.6.7.1 Vaccines and biological should be stored in foam boxes with hard ice packs or ice gel packs. The temperature recommended by the manufacturer should be maintained throughout the transportation. A guide to specific vaccine storage temperatures and recommendations is given in Appendix I.

4.6.7.2 The individuals responsible for the transportation of Vaccines/biological products shall be informed about all relevant conditions for storage and transportation. These requirements shall be adhered to throughout transportation and at any intermediate storage stages.

4.7 Importation of medicines for personal use

4.7.1 Importation of medicines for personal use will be limited to 90 days' supply, for supplies more than 3 months (90 days) shall require additional relevant documents related to the history of patient's illness. With submission of additional documents, he/she is eligible to import medicines to be used in a duration of 6 months.

4.7.2 Importation of medicines for personal use should be accompanied by a valid prescription (not older than 3 months from the prescribed date) from a registered medical practitioner.

4.7.3 A prescription shall bear:

a. Full name of the patient

b. Address of the patient

c. Prescribed date

d. Indication

e. Name of the medicine (generic/brand)

f. Dosage form

g. Strength

h. Dosage (the amount of medicine that should be taken at one time)

i. Duration of treatment

j. Doctor's name, registration number, signature and official seal of the institution

4.8 Importation of controlled drugs

4.8.1 To ensure quality and safety, import of controlled drugs by various agents from undesignated sources is not permitted. All controlled drugs shall be imported only through the designated importers STO & the ADK pharmaceutical company. The MFDA shall issue a special authorization prior to importation of any controlled drug.

4.8.2 It is an offense to import any controlled drug into Maldives without obtaining the import certificate from MFDA.

4.8.3 Categories of controlled drugs:

a. Internationally controlled drug

b. Nationally controlled drug

4.8.4 Invoices for controlled drugs should be accompanied with:

a. Import certificate for the respective Narcotic consignment

b. Import certificate for the respective Psychotropic consignment (from MFDA)

c. Export certificate for the respective internationally controlled drugs consignment (from Narcotic control bureau of the exporting country).

4.8.5 Consignment for controlled drugs shall be cleared within the period given in the Import certificate. It is solely the importer's responsibility to make all the arrangements for the clearance of the controlled drug consignment before the expiry of the import certificate.

Note: No importation of controlled medicinal products shall be done by post.

4.9 Importation of Controlled drugs for prescription

4.9.1 Importation of controlled drug for prescription should be limited to 30 days' supply, for patients with chronic illness can be of maximum 90 days' supply. For controlled drugs more than three months' stock shall need the documents related to patient's illness history along with his/her valid prescription. A validity of a controlled drug prescription is 90 days from the prescribed date.

4.9.2 The physician has to make sure that the following principle requirements for prescriptions are fulfilled:

a. Prescriptions ordering controlled drugs are signed and dated by the prescriber, and the prescriber's address is specified.

b. The written prescription order is precise and distinctly legible to enhance effective communication between the physician and the pharmacist.

c. The prescription is stated in prescriber's own handwriting in ink, or so as is indelible.

4.9.3 A prescription ordering Controlled Drugs shall bear;

a. Serial number and date

b. Name, age, sex, hospital / health center / clinic registration number, address of the patient and diagnosis generic names of prescribed drugs (writing brand names in parenthesis is optional)

c. Dosage form and strength of the preparation

d. Total quantity of prescribed drug in words and figures in order to discourage alterations in written prescription orders

e. The dose, only official abbreviations should be used.

f. The interval between doses (frequency of administration)

g. Duration of treatment

h. Validity period of maximum one week from the date stated there on

i. Doctor's name, registration number, signature and official seal of the institution

4.10 Importation of Free Medical Samples

4.10.1 Importation of free medical samples shall meet the following criteria:

a. Samples should bear a label printed "Free sample – Not for sale"

b. The invoices of Free samples shall include unit price for each product

c. The samples of unregistered medications shall not be allowed to be imported for the purpose promotions

4.11 Medicines for registration purpose

4.11.1 Importers who are intending to import medicines for registration purpose should obtain an authorization from MFDA prior to the arrival of registration samples. The samples should meet the authorization given by MFDA.

4.11.2 The invoices for samples should be accompanied with the authorization issued from MFDA for the specific products.

4.12 Clearing of consignments

4.12.1 The importation of all consignments of medicines should be done through the designated ports of entry, which are:

- XYZ Airport
- ABC Border Post

Note: No importations through ordinary or registered post shall be sanctioned.

4.12.2 Importers should give prior notification of the need to clear consignments.

4.12.3 All consignments entering the Maldives will be physically inspected and verified at the port of entry. Importers should be aware and accept that unsatisfactory consignments will not be cleared and will be immediately quarantined. Inappropriate medicines will be destroyed in accordance with national guidelines and procedures.

4.13 Other importations

4.13.1 The following categories of items shall be imported only with a valid authorization from MFDA:

a. Pharmaceutical products for emergences e.g. outbreaks, natural disasters

b. Medicines imported for National Programs only

c. Medicines for donations (shall be imported according to the drug donation guideline)

4.13.2 The concerned agency should request MFDA in writing for the authorization and, it should be obtained prior to the arrival of the consignment.

5 Annex

- Annex I - Commercial Invoice Example
- Annex 2 - Vaccine Storage Temperatures and Recommendations

Annex I: Commercial Invoice Example

Commercial Invoice

Exporter:	Invoice No:	Exporters Ref:
	Invoiced date:	
	Buyer's Po Number & date :	LC Details:
Consignee:	Buyer:	

Pre-carriage by:	Place of Receipt by pre-carrier:	BL/Air way bill No:
Vessel/flight No:	Port of loading :	Mode of transport:
Port of discharge:	Final destination:	Terms of delivery and Payment:

No	Brand Name	Generic Name (with Formulation)	Dosage Form	Batch no	Manufacturer	Country of origin	Manufactured date	Expiry date	Total Quantity per Batch	Unit Price	Total Price
Amount Chargeable (In words)								FOB:			
								Insurance :			
								Fright :			
Particulars											

Authorized Stamp & Signature

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Appendix II: Vaccine storage temperatures and recommendations

Vaccine storage temperatures and recommendations			
Vaccine(s)	Temperature storage recommended	Diluent storage temperature	Comments
Diptherea,Tetanus,Pertussis-containing vaccines (DTaP,DT,Tdap,Td)	35°F-46-°F(2°-8°C) Do not freeze	No diluent	Irreversible loss of potency occurs with exposure to freezing temperatures.
Hepatitis A	35°F-46-°F(2°-8°C) Do not freeze	No diluent	Irreversible loss of potency occurs with exposure to freezing temperatures.
Hepatitis B	35°F-46-°F(2°-8°C) Do not freeze	No diluent	Irreversible loss of potency occurs with exposure to freezing temperatures.
Hib (ActHIB)	35°F-46-°F(2°-8°C)	35°F-46-°F(2°-8°C) Do not freeze	The lyophilized pellet may be stored at freezer temperature. The reconstituted vaccine should be stored at refrigerator
Hib(PedvaxHIB)	35°F-46-°F(2°-8°C)	No diluent	
HPV	35°F-46-°F(2°-8°C)	No diluent	Irreversible loss of potency occurs with exposure to freezing temperatures. Protect from light
Influenza(LAIV)	35°F-46-°F(2°-8°C)	No diluent	Do not expose to temperatures above the recommended range
Influenza(TIV)	35°F-46-°F(2°-8°C)	No diluent	Protect from light
Meningococcal (MCV4-Menactra)	35°F-46-°F(2°-8°C)	No diluent	Protect from light
Meningococcal (MCV4-Menveo)	35°F-46-°F(2°-8°C)	35°F-46-°F(2°-8°C)	Protect from light