**Maldives Food and Drug Authority**

Ministry of Health

Male', Maldives

# Guideline for Health Clearance of Pharmaceuticals at Entry Ports

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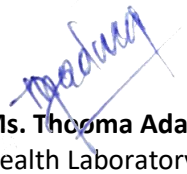

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**It is the property of:**
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## SUMMARY OF CHANGES

| Version No. | Issued Date | Section/Clause | Summary of Change | Changes Made by |
|---|---|---|---|---|
| 1 | 22.09.2024 | - | Creation of the document | Rafeea Afeef |

## Contents

## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| **POE** | Port of Entry |
| **AWB** | Airway Bill |
| **BL OR BOL** | Bill of Landing |
| **INN** | International Nonproprietary Names |
| **API** | Active Pharmaceutical Ingredient |
| **USP** | United States Pharmacopeia |
| **BP** | British Pharmacopeia |
| **IP** | Indian Pharmacopeia |
| **DEG** | Diethylene Glycol |
| **EG** | Ethylene Glycol |
| **DPT** | Diphtheria, Pertussis, and Tetanus (Vaccine) |
| **DT** | Diphtheria-Tetanus (Vaccine) |
| **HEP B** | Hepatitis B (Vaccine) |
| **TT** | Tetanus Toxoid (Vaccine) |
| **BCG** | Bacille Calmette-Guérin (TB Vaccine) |
| **MOU** | Memorandum of Understanding |
| **MFDA** | Maldives Food and Drug Authority |
| **COA** | Certificate of Analysis |
| **RBI** | Risk-Based Inspection |
| **ADL** | Approved Drug List |
| **MCH** | Male Commercial Harbor |
| **MACL** | Male Airports Company Limited |
| **MPL** | Maldives Ports Limited |

## DEFINITIONS

| | |
|---|---|
| **Port of Entry (POE)** | Means It is the primary point of entry that customs use to regulate and enforce the import of goods into their country in compliance with relevant laws and regulations. |
| **Manufactured date** | (MFG) refers to the date that the product was produced or manufactured |
| **Expiration or Expiry date** | Refers to the last day that a product such as a medicine will be at its full potency and safety, according to the manufacturer |
| **Shelf life** | Refers to the time that elapses between when the drug is made and the expiration date assigned by the manufacturer. The shelf life generally relates to a drug's quality over a specified period |
| **MOU** | Refers to a memorandum of understanding is an agreement between two or more parties outlined in a formal document |
| **Requirements** | Refers to the criteria pertinent to the pharmaceutical trade, including public health protection, purchaser protection, and equitable trade conditions |
| **Specification** | Refers to the key quality standard that sets out the set of factors that a drug substance or drug product must meet to be considered safe for its intended use |
| **Pre-authorization** | Refers to a pre-approval issued by MFDA before the importation of unregistered pharmaceutical products that require it |
| **Import certificate** | Refers to an authorization or permit issued from MFDA to import controlled drugs into the Maldives |
| **Export Certificate** | Means an authorization or permit issued from the regulatory authority to an eligible exporter of the exporting country to export the controlled drugs that the MFDA has authorized in the import certificate or permit |
| **Consignment** | Means several goods that are sent to a person or place to be sold |
| **Authorization** | Means import and export licenses, permits, certificates, and other types of approval issued by the Authority |
| **Exporter** | Means a person, country, or organization that sends goods or services to another Country |
| **Importer** | Means a person or organization that brings goods or services into a country from abroad. |

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|---|---|
| **Import License** | Means an authorization/permit issued to the importer by the MFDA authorizing him/her to import pharmaceutical products or their respective raw materials into the country after complying with the importation requirements. |
| **Inspection** | Means the act of inspecting or viewing, especially carefully or critically |
| **Manufacturer** | Means a person, corporation, or other entity engaged in the business of manufacturing pharmaceutical products |
| **Prescription** | Means a lawful written direction by a doctor for the preparation and dispensation of a drug by a pharmacist |
| **Detained pharmaceutical product** | Means those that were deemed unfit for distribution, sale, or use in the country because they may be fake, adulterated, or contaminated |
| | |
| **Pharmaceutical product** | Means any medicine intended for human use for the prevention and treatment of a disease, presented in its finished dosage form |
| **Label** | Means any plate, mark, sign**, i**mage**,** or other description written, printed, stenciled, marked, embossed, or engraved on or attached to a container of a medicinal product |
| **Withholding a product** | Means to refrain from granting, giving, or allowing |
| **Temporarily detained product** | Means a product that is held for further verification |
| **Permanently detained product** | Means a product that is withheld for disposal |
| **Releasing a held product** | Means to allow or grant to take held products |
| **Discard** | Means get rid of |
| **Disposed of** | Means to get rid of |
| **Donation** | Means an act or instance of presenting medical products, processed foods, and other products regulated to recipients in an emergency or as a part of development aid in non-emergency situations |
| **NDMA report** | Refers to the report issued by the manufacturer for the level of N-nitroso dimethylamine (NDMA) in Ranitidine Hydrochloride |
| **DEG** | Refers to an extremely toxic chemical **Diethylene Glycol** |
| **EG** | Refers to an extremely toxic **Ethylene Glycol** |
| **Misbrand** | Means to brand (as a food item or drug) falsely or in a misleading way or to label in violation of statutory requirements |

| | |
|---|---|
| **Commercial invoice** | Refers to a document used in the international trade and shipping industry. |
| **Packing list** | Is a detailed document included in a package, allowing the recipient to verify its contents. It typically includes descriptions, quantities, batch numbers, and weights of each item. |
| **Bill of Landing** | Refers to an export document for international trade that accompanies a commercial invoice through the customs process |
| **Air waybill** | Refers to a consignment note, dispatch note, or waybill, which is a contract between the shipper and the carrier |
| **Indelible** | Refers to making marks that cannot be removed |
| **Engraved** | Cut or carved (a text or design) on the surface of a hard object |
| **Emboss** | Refers to carving with a design |
| **Primary container** | Refers to the packaging or container in direct contact with the product itself |
| **Secondary container** | Refers to the packaging or container outside of primary packaging |
| **Guideline** | Refers to a statement used to determine an action's course. The purpose of a guideline is to streamline specific processes according to a predetermined routine or sound practice |

## 1 INTRODUCTION

The Maldives completely depends on imported drugs because it lacks the manufacturing capacity to produce its products. Therefore, it is essential to ensure the safety, quality, and effectiveness of the medications imported because they have a direct impact on the health of the general public. Standards and criteria have been set up for this purpose.

The main objective of this guideline is to provide importers with the necessary information and to enable them to comply with the laws and regulations governing the control of the importation of medicinal products.

Clearance, as conducted by the Maldives Food and Drugs Authority (MFDA), typically entails document verification, visual inspection of pharmaceutical products, and approving the release of the consignment as required by the most relevant regulation related to medicinal products. This guideline will be reviewed regularly as the need arises.

The Maldives Food and Drugs Authority (MFDA) conducts clearance procedures, which involve verifying documents, visually inspecting pharmaceutical products, and approving the release of consignments by the relevant regulations for medicinal products. This guideline will be regularly reviewed as the need arises.

## 2 PURPOSE

These safety measures aim to ensure that patients receive high-quality medications and avoid introducing substandard or possibly counterfeit drugs into the supply system. This guideline has been developed to strengthen the control of the importation of pharmaceuticals and to assist those in the field to adhere to regulations when carrying out importation operations.

## 3 SCOPE

This guideline is directed to all parties importing pharmaceutical products in the Maldives, including Maldives Ports Limited (MPL) and Maldives Airports Company Limited (MACL) and importers. This guideline applies to any pharmaceutical, nutraceutical, alternative & veterinary products that are being imported and are destined for use within the Maldives and are intended to be adopted into prevailing national procedures and legal requirements.

# 4 CATEGORIES OF PHARMACEUTICAL IMPORTERS

## 4.1 Registered importers

4.1.1 Health Protection Agency (Medicines imported for the use of national programs)

4.1.2 Ministry of Health (as Recipient of donations), can import medicines in health emergencies

4.1.3 Import of over-the-counter medicine (OTC) for personal use

4.1.4 Import of pharmaceutical products for personal use that require a prescription

# 5 GENERAL REQUIREMENTS FOR MEDICINE IMPORT

5.1.1 All medicinal products (for commercial purpose) must be registered or granted special approval prior to import.

5.1.2 Importers must hold a valid import license issued by MFDA

5.1.3 To ensure compliance, all products require pre-approval must be accompanied by valid pre-approvals from MFDA.

5.1.4 The importation of all consignments of pharmaceutical products should be channeled exclusively through a designated port of entry (POE).

5.1.5 No importation of pharmaceuticals or related consignment shall be done by post or brought in by hand.

5.1.6 All documents required for the pharmaceutical consignment shall be submitted a minimum of 10 Calander days before the clearance.

5.1.7 The submitted documents must be legible and not written in a font size smaller than 12

5.1.8 All imported consignments of pharmaceutical products shall be subjected to physical inspection at the port of entry before being released to ensure that they comply with the claimed specifications.

5.1.9 All imported pharmaceuticals or medicinal product must have a half-shelf.

5.1.10 For government agencies or authorities that import medicines for noncommercial use, the concerned agency should submit an approval from MFDA, before the arrival of the consignment.

5.1.11 In the case of donations, the consignment should have an approval from MTG/MFDA

5.1.12 In the case of prescription medicines, include a clear, valid prescription and a copy of the patient's National ID card or Work Permit.

5.1.13 Pharmaceutical or related consignments should be accorded the highest priority.

5.1.14 In the case of controlled drugs (narcotics, psychotropics), a commercial invoice will 2be accompanied by an import certificate from the Maldives Food and Drug Authority (MFDA) and an export certificate from the exporting country.

5.1.15 In addition to the specific importation requirements, the MFDA reserves the right, when deemed necessary and for justifiable reasons, to request any other document or information from the importer for further analysis.

**Note:** The documents for pharmaceutical consignments that fail to meet any of the import standards will be rejected within three working days. The port control unit will notify the applicant and provide a written explanation for the rejection.

### 5.2 Important notice for port operators:

5.2.1 Pharmaceutical or related consignments should be accorded the highest priority.

5.2.2 All pharmaceuticals and related consignment should be store stored in accordance with the manufacturer's recommendations, which are listed on the product label.

## 6 LABELING REQUIREMENTS FOR MEDICINE IMPORT

a. The information printed on labels must be indelible, engraved, or embossed on a primary and secondary container
b. The immediate outer packaging of the pharmaceutical products should be clearly labeled in English or Dhivehi language
c. The trade or brand name shall be stated
d. Generic name
e. Quantities of active ingredients in the given formulation/API
f. Strength
g. Dosage form

h. Volume of the medicine
i. Date of manufacture and expiry
j. Batch or Lot number
k. Special storage conditions and handling requirements where applicable
l. Name and full address of the manufacturer with the country of origin
m. Enclosed and accompanying patient leaflets must be in English or Dhivehi

**Note:** Apart from the above labeling if the product is registered or got a pre-Approval art work and the label should meet the registered or pre-approved pack and the art work**.**

## 7 DESIGNATED PORT OF ENTRY (POE)

7.1.1 Male Commercial Harbor (MCH) and the international airport at Hulhule are two designated ports of entry (POE) for pharmaceutical, nutraceutical, alternative or herbal, and veterinary products. Using any other port for the importation of these products is prohibited. MFDA will not be responsible for losing the goods imported by any non-designated port.

7.1.2 The Seaport Port Pharmaceutical Unit will handle the consignments of goods received by sea. Therefore, the documents related to the sea consignments should be submitted to the Seaport Pharmaceutical Unit.

7.1.3 The Airport Port Pharmaceutical Unit will handle the consignments of goods received by air. Therefore, the documents related to the air consignments should be submitted to the Airport Pharmaceutical Unit.

## 8 DOCUMENTS REQUIRED FOR MEDICINE CONSIGNMENT

a. Invoice and a detailed packing list
b. Bill of Landing (BL or BOL) or Airway Bill (AWB)
c. A statement or email from the importer confirming that the submitted invoice and the packing list are authentic copies of the original and are identical to the original invoice and packing list submitted to customs.
d. Batch certificates or certificates of analysis for IV fluids, vaccines, and other products that require them (As per ADL requirement)
e. Import certificate for both nationally and internationally controlled drugs (from MFDA)
f. export certificate for internationally controlled drugs from the exporting country

g. A valid copy of the preauthorization, for the products that require it (From MFDA)
h. Sample authorization for the products imported for registration (From MFDA)
i. NDMA report for the products that require it
j. DEG and EG test reports for the products that require them
k. COA for the finished products that require a COA before import
l. Other supportive documents if required

**Note:** The required documents may vary depending on the situation.

## 9 REQUIREMENTS FOR DOCUMENTATION

### 9.1 The commercial invoices shall state the following:

a. Invoice number and date
b. Name and address of the supplier
c. Product number or P number (The number given for each product in the ADL)
d. The International Non-Proprietary name (generic name) of the drug.
e. Trade (brand name) or proprietary name.
f. Name of the manufacturer, manufacturing site & Country of origin
g. Strength of the drug
h. If the product containing more than one active ingredient the name, and strength of each shall be stated
i. The pharmacopeia specification of the ingredient such as BP, USP & IP
j. The quantity to be imported for each batch separately
k. The unit price, total price in dollars (Each batch quantity separately)
l. The batch number(s) for each product
m. Manufactured date
n. Manufactured date
o. Special storage conditions and handling requirements where applicable

### 9.2 The packing list shall state the following;

a. Invoice number and date
b. Name and address of the supplier
c. Box number
d. The packing list must clearly state the following information for each specific box:
    - Brand name
    - Dosage form

- Batch number of the product
- Batch quantity of the product

## 10 IMPORTATION OF MEDICINES FOR PERSONAL USE

### 10.1 OTC AND POM PRODUCTS

10.1.1 Each product in the approved drug list (ADL) is assigned to a specific category. Any product categorized as an OTC (over-the-counter) drug can be imported with or without a prescription for personal. However, POM products (prescription-only medicines) require a valid prescription.

10.1.2 The import of medications for personal use will be restricted to a 90-day supply, and supplies exceeding 90 days will necessitate the submission of additional documents about the patient's medical history. With the submission of additional documentation, he or she may import pharmaceuticals for six months.

10.1.3 Prior to import a medicine for a prescription, the importer needs to submit the soft copy of the prescription information sheet

10.1.4 The importation of medications for personal use must be accompanied by a valid prescription (not older than three months from the date of the prescription).

10.1.5 Over-the-counter drugs imported for personal use, up to a three-month supply, will be allowed for release. However, the amount of medicine allowed will be determined by the port staffs based on the intended use. Importers who repeatedly bring in over-the-counter medications for personal use without a prescription will face consequences.

### 10.2 PRESCRIPTION SHALL BEAR:

a. Full name of the patient with NID number
b. Address of the patient
c. Prescribed date
d. Indication /diagnosis
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

## 11 IMPORT OF CONTROLLED DRUGS FOR PERSONAL USE

11.1.1 The importation of controlled drugs for personal use requires a valid prescription (Not more than three months from the date of the prescription.) and a copy of the patient's identity card or passport. This applies to both local and international prescriptions; however, if prescription is issued from a local health facility or institute, the original blue prescription must be submitted.

### 11.2 REQUIREMENTS FOR CONTROLLED DRUG PRESCRIPTIONS ISSUED BY LOCAL HEALTH FACILITIES

a. Serial number and date
b. Name, age, and sex of the patient
c. Registration number of the hospital, the health center, or the clinic
d. Indication of the drug or diagnosis of the patient
e. Generic name/brand name of the prescribed drug
f. Strength and dosage form of the drug
g. To discourage alterations to written prescription orders, the total quantity of prescribed medications must be stated in words and figures.
h. Dose: only official abbreviations should be used.
i. Dosage (the interval between the dose or the frequency of administrations)
j. Duration of the treatment
k. Name of the doctor, registration number, signature, and the official seal of the institution

**Note:** Upon receiving the blue prescription MTG port control unit shall perform a thorough evaluation of the prescription including the serial number tracing.

### 11.2. MINIMUM REQUIREMENTS FOR CONTROLLED DRUG PRESCRIPTIONS ISSUED FROM ABROAD

a. The institution which issued the prescription
b. Patient's name and age
c. Doctor's name and signature
d. Name of the drug
e. Dosage form
f. The strength of the drug
g. Directions and duration of the drug

## 12 IMPORT OF MEDICINE SAMPLES FOR REGISTRATION

12.1.1 Importers who intend to import medicines for registration purposes should obtain authorization from MFDA before the arrival of registration samples

a. The samples should meet the authorization given by MFDA

b. The invoices for samples should be accompanied by the authorization issued from MFDA for the specific products

## 13 IMPORT OF PHARMACEUTICAL PRODUCTS FOR MOU LIST

13.1.1 MFDA port shall stick on the specific MOU list .and shall only accommodate the items included or authorized under the MOU list only.

13.1.2 Prior to import a medicine for MOU, the importer needs to submit the soft copy of the MOU medicine information sheet:

13.1.2.1 Except for the brand name and manufacturer information, all other details of imported pharmaceuticals must conform to the MoU list

13.1.2.2 The importer should provide the product photo and the accurate URL to verify the brand name and the manufacturing site

13.1.2.3 Medicines authorized under the MoU shall only be imported solely for that specific hospital use and shall not be sold to another hospital or health facility or any other outside party unless otherwise requested by MFDA in writing

13.1.2.4 Medicines authorized under the MoU may only be imported for the specific hospital's use and may not be sold to any other hospital, health facility, or outside party, unless the MFDA requests in writing otherwise

13.1.2.5 Medicines imported under the MoU list shall be used for that specific hospital's inpatients only

13.1.2.6 Medicines that are registered by other parties and are specified as "can be imported by a specific party". Such products will be held permanently and disposed of within 14 working days

13.1.2.7 The Ministry of Health holds the right to cancel or terminate the agreement at any time if the conditions mentioned in the agreement are not followed as per the given timeline.

## 14 INSPECTION OF IMPORTED CONSIGNMENTS AT PORTS OF ENTRY

14.1.1 An inspection is a thorough visual examination of the items in a pharmaceutical consignment. The pharmaceutical port control unit conducts risk-based inspections.

14.1.2 Risk-Based Inspection (RBI) is a systematic approach to establish an accurate and well-targeted inspection strategy based on risk. Inspection strategies are developed to address the specific failure factors identified.

14.1.3 Each consignment of pharmaceutical items must be inspected at the port of entry by pharmaceutical officers to ensure that it conforms with the approved requirements and applicable regulations.

14.1.4 The list of documents stated under "Documents required for a pharmaceutical consignment" must accompany the consignment.

14.1.5 In instances where a significant volume of products is discovered or the entire consignment, requires inspection, inspectors will proceed with the examination until the port closes. The owner of the goods will then reschedule the inspection for the following day or as soon as possible. This measure ensures that the medicines are not exposed to direct sunlight during the inspection, which takes place in extreme heat at the seaport, and prevents any probable damage.

14.1.6 To avoid demurrage charges, the importer should provide documents that are clear, readable, and legitimate, a minimum of 5 working days before customs clearance. Additionally, all goods must be arranged in an orderly manner, allowing for easy accessibility throughout the inspection process. Failure to comply with these requirements may result in significant delays and demurrage fees that the importer will be responsible for.

14.1.7 All shipments of controlled medications must pass a thorough 100% visual inspection. This 100% inspection's goal is to make sure the amount imported matches the approved amount and doesn't deviate in any way.

## 15 RELEASE OF CONSIGNMENTS AFTER INSPECTION

15.1.1 At the port of entry, the inspector shall release the consignment if it meets the quality, documentary, and physical verification requirements for the importation of pharmaceutical products, by stamping the supporting documents or giving approval to release the consignment.

15.1.2 Importers should notify the customs of the requirement to clear consignments ahead of time.

## 16 WITHHOLDING OF PRODUCTS

16.1.1 At the port of entry, all consignments entering the Maldives will be physically inspected and validated. The importer must ensure that all consignments follow the norms and regulations of the MFDA, and failing to do so will result in the detention and disposal of the particular consignment.

### 16.2 WITHHOLDING A PRODUCT PERMANENTLY

16.2.1 If a product is detained permanently due to any of the following reasons the products will be kept in the temperature specified on the held form for 14 working days. Subsequently, the product will be disposed of. If the importer has any queries regarding the detained product, the importer shall send a mail detailing the queries within this time frame.

a. Products that do not comply with the ADL
b. Counterfeit, fake, and misbranded medicine or medicine with incomplete information
c. Products that shall be withheld due to any alerts
d. Products that are banned in the exporting country or the Maldives
e. Suspicious products
f. Sexual enhancement medicine or any product of this nature imported for personal use or sale without a doctor's prescription
g. Medicines that are specified as "can be imported by a specific party"
h. Batches in the Invoice/Packing List that do not correspond to the batches imported
i. Pre-authorization required products that are imported without a valid preauthorization
j. Any nationally controlled(s) drug imported without a valid import certificate issued by MFDA
k. Any internationally controlled(s) drug imported without a valid import certificate issued by MFDA and export certificate issued from the regulatory authority of the importing country
l. Any controlled drug(s) imported for personal use without a valid prescription
m. Samples of products imported without a valid permit and products that do not meet MFDA permits
n. Products that have less than half of their shelf life remaining, including imported personal, prescription, or commercial use.

### 16.3 The following are prohibited to import, for all importers (registered and non-registered);

16.3.1 Any drug which is not approved in the ADL

16.3.2 Any misbranded, spurious, or adulterated drug

16.3.3 Drugs NOT labelled in Dhivehi and English language

16.3.4 Drugs after the date of expiry as mentioned in the label

16.3.5 Importers are only allowed to import products according to the specific categories set by the ADL

### 16.4 WITHHOLDING A PRODUCT TEMPORARILY

16.4.1 If a product requires further verification, it will be temporarily withheld. Typically, a decision will be made within three working days, and the product will either be released or permanently held based on the MFDA's decision. While the product is being held, it will be stored at the temperature specified on the held form.

## 17 DISPOSAL OF WITHHELD PRODUCTS

17.1.1 The Maldives Food and Drug Authority (MFDA) is tasked with overseeing the disposal of medications in the country. To ensure proper disposal, the MFDA adheres to both the Medicine Regulation (Regulation Number: 2014/R-46) and the Health Service Act (Law Number: 29/2015).

17.1.2 After 14 days have passed, the pharmaceutical officers at the port control units will complete a disposal sheet (MTG/BC-HD/Re 0116/) and a disposal request note (MTG/BC-DR/Re 0117/) for any items that are being held. These documents will then be handed over to either MACL or MPL for verification. Once verified, MACL/MPL must send an email to mtg@health.gov.mv requesting the disposal of any medicines being held at entry ports. The email should include a comprehensive list of the items that require disposal.

17.1.3 The staff responsible for the disposal of medications will complete the Medicine Disposal Form (MTG/REDF/Fo 0007) based on the received list. If additional information is required, staff will inspect the medications to be discarded and visit the location. The port pharmaceutical unit will inspect and verify the products according to the Medicine Disposal Form. Once verified, the boxes will be sealed with the signature of the staff and the date of inspection.

17.1.4 The disposal of these medicines shall be coordinated with MFDA, MACL/MPL, Maldives Customs, and Waste Management Corporation (WAMCO).

17.1.5 After the disposal process is complete, the MFDA must receive the documentation as proof of disposal in writing within 5 working days.

## 18 VACCINE TRANSPORT CONTAINERS AND MATERIALS

### 18.1 For the secure transport of vaccines, proper supplies are required. These should at a minimum include:

a. Hard-sided insulated containers
b. Insulating materials (e.g., bubble wrap or corrugated cardboard): enough to form two layers per container
c. Digital Data Logger for each container
d. Do not use commercially available soft-sided coolers. Most are poorly insulated and likely to be negatively affected by ambient temperatures.
e. Never utilize frozen gel packs or coolant packs from vaccine consignment, even if they are in good physical condition and appear to be perspiring, they can cause vaccines to chill.

### 18.2 PROCEDURE FOR PLACING THE ICEPACKS IN THE COLD BOX OF VACCINE

18.2.1 Vaccines should be kept in a cold box with conditioned ice packs in the bottom and around the sides, and the vaccine containers should be made of solid plastic or Styrofoam. A cold box is an insulated container with a tight-fitting insulated lid. The temperature inside the box is maintained by ice packs.

a. The chilly compartment should be equipped with a thermometer.
b. Do not use frozen ice packs in the Cold Box.
c. Do not place DPT, DT, Hep B, and TT vials in direct contact with conditioned ice packs.
d. After placing the required quantity of vials, place two rows of ice packs above and securely close the lid

e. Do not remove the rubber seal of the Cold Box.

f. Do not place any weight or other cold boxes on the lid.

## 19 IMPORTANT THINGS TO KEEP IN MIND

**The vaccine must always be transported in insulated boxes with sufficient ice to ensure it remains between 0 and +8 o C. Never use un-insulated boxes, or forget the ice!**

- *All vaccines lose potency gradually, even stored correctly.*
- *Observe storage temperatures and expiration dates.*
- *All vaccines lose potency much more rapidly when exposed to temperatures above +8 degrees Celsius.*
- *Any loss of vaccine potency is irreversible*
- *The cumulative effect of multiple heat or light exposures is detrimental.*
- *Hepatitis B, DPT, DT, Td and TT are destroyed by freezing.*
- *BCG and measles vaccines are damaged by exposure to strong light as well as heat.*

## 20 Annex

1. Annex 1 – Sample commercial invoice
2. Annex 2- Vaccine Storage Temperature and Recommendations
3. Annex 3- Sample Invoice Certification Note Format

## 21 LEGAL BASIS AND REFERENCES

1. Medicine regulation R-46 (2014)
2. Medicine regulation amendment R-49 (2016)
3. Health service act (29/2015)
4. Standard Operating Procedure for Health Clearance of Pharmaceuticals/ Medicines from Entry Ports
5. Safe vaccine handling, cold chain, and immunizations by WHO
6. Guideline for the Rational Use of controlled drugs
7. Masthuvathakecha behey new gaanoonu (17/2011)

## Annex 1 – Sample commercial invoice

| Commercial Invoice | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Exporter: | | | | | | | Invoice No:<br>Invoiced date:<br>Buyer's Po Number & date : | | | Exporters Ref:<br>LC Details: | | | |
| Consignee: | | | | | | | | | | | | | |
| 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:Male Maldives | | | | | | | Final destination: | | | Terms of delivery and Payment: | | | |
| No | MFDA P Code | Brand Name | Generic Name / Formulation | Strength | Volume / Pack size | Dosage Form | Batch no | Manufacturer / Country of Origin | Manufacture date | Expiry date | Total Quantity per Batch | Unit Price | Total Price |
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| | | | | | | | | | | | | | |
| Amount Chargeable (In words) : | | | | | | | | | | FOB:<br>Insurance :<br>Fright : | | | #REF! |
| | | | | | | | | | | CIF Value | | | #REF! |
| Particulars | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| Authorized Stamp & Signature | | | | | | | | | | | | | |

**Annex 2- Vaccine Storage Temperature and Recommendations**

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

**Annex 3- Sample Invoice Certification Note Format**

Address.....

Date.....

Invoice Copy Certification

I hereby certify that the invoice and packing list that I have submitted are accurate, legitimate and are identical copies of the documents that were submitted to the customs.

Name:
Designation:
Sign:
Stamp: