بسم الله الرحمن الرحيم

# STANDARD FOR TRANSPORT, HANDLING AND STORAGE OF PHARMACEUTICALS.

**Maldives Food and Drug Authority**

Ministry of Health and Gender

Male', Republic of Maldives

## INTRODUCTION

This standard refers to the transport, handling and storage of pharmaceuticals at all levels.

Transport refers to the International transport and handling conditions of shipments from the port of dispatch, to the designated final port of entry including all transit and trans-shipment points. This includes transport and handling within the Maldives from the ports to the storage facility, pharmaceutical outlet or institution and transport during distribution from wholesalers to retailing outlets, health facilities and institutions

Storage refers to storage condition of medicines at all stages which includes but is not limited to:

- Pharmaceuticals kept at the ports for inspection and temporarily held items
- Storage conditions of the pharmaceuticals at the warehouses, whole sale go downs
- The storage conditions of the pharmaceuticals at the health facilities, pharmacy outlets until the point of use/dispensing.

## 1. SCOPE

The purpose of this standard is to establish standard practices when;

1. Procuring, distributing and sale of pharmaceutical by importers/related personnel,
2. Receiving of pharmaceuticals at the ports of entry,
3. Storage of pharmaceutical during transport from manufacturer until arrival at the ports of entry
4. Storage of pharmaceutical at various pharmaceutical storage facilities,
5. Handling of pharmaceuticals from the storage facilities, health facilities and pharmacy outlets

Thus, to lay down a minimum standard guideline at all these levels to ensure quality of the pharmaceuticals are maintained throughout this chain.

This standard also allows for the identification of counterfeits, substandard drugs entering the chain of distribution to further prevent such events and for withdrawal of such items.

The respective section of this standard is applicable for the concerned government authorities, regulatory bodies, health facilities, donor agencies and health care workers involved in any aspect of trade, handling, storing and distribution of pharmaceuticals.

## 2. RESPONSIBILITIES

All importers and parties involved in import and distribution of pharmaceutical are obligated to ensure quality and integrity of pharmaceuticals throughout the chain from manufacture to the point of use or dispensing. All persons involved in the process shall be responsible and accountable for their role in this process.

Companies and organizations engaged in pharmaceutical Import and sales, shall ensure responsibility and commitment of staff through updated organizational chart, designated and documented job responsibilities. All such records shall be made available for regulatory inspections by MFDA.

Collaboration between relevant stakeholders including the Customs Services, regulatory authorities, manufacturer, distributor, individuals responsible in procuring, supplying of pharmaceuticals shall be pursued to minimize or prevent counterfeits and substandard products entering the market.

## 3. REGULATION OF IMPORT, STORAGE AND DISTRIBUTION OF PHARMACEUTICALS

a) In accordance to the medicine regulation medicines shall be imported, distributed, stored and dispensed by authorized parties.
b) Finished and pre-labeled pharmaceuticals, as published on the most updated approved drug list (ADL) shall be imported.
c) No pharmaceuticals shall be imported via internet or mail order by any unauthorized party
d) International and national Regulations on Narcotics and psychotropic shall be followed for the import, distribution and sale of Narcotics and psychotropics.
e) International and national guidelines on pharmaceutical donations shall be followed. Currently Maldives follows the WHO guideline on donations of pharmaceuticals.
f) *Good Manufacturing procedures (GMP)* shall be followed by all manufactures and import shall be from such manufacturers only.

   If medicines are acquired through third party the procurement procedures shall be documented and well maintained. The importer shall ensure the product integrity, safety and quality and efficacy throughout the process via the supplier. This would avoid counterfeits, substandard medicines being imported.

*Good Storing Procedures (GSP)* shall be followed for storing of pharmaceuticals. This would include any special storing requirements by the manufacturer.

*Good Distribution Procedures (GDP)* as per manufacturer requirements shall be fulfilled for distribution. All relevant documents shall accompany pharmaceuticals during any transport.

All pharmaceuticals shall be imported, stored, distributed and sold as per the manufacturers specified storage conditions.

## 4.1. Giving clearance to Pharmaceuticals at Ports of entry

a) As all pharmaceuticals are solely imported from other countries it shall meet a minimum quality requirement as follows:
   i) Labels shall be in place to identify the contents of any container (container number, consignment details, packing list, and invoice).All labels shall be in English or local language which can be read easily as per the national labeling criteria.
   ii) Shall be packed in the manner specified by the manufacturer for transport.
   iii) Shall be stored at the required storage temperature. These requirements shall also be labeled on the container. This would include other special (i.e. Sunlight, humidity etc.) transport and storage conditions as per manufacturer requirement. Any deviation from storing conditions as required shall be informed upon arrival and proper actions taken immediately. These deviations, if any, shall be justified by the importing party, with evidence, that it does not hinder the quality, safety and efficacy of the product.
   iv) Shall be packed, stored and handled to maintain the integrity of the pharmaceutical product.
b) Consignments shall not be in a mixed container during transport with other items that might contaminate the pharmaceuticals. (e.g. Fertilizers and chemicals which may alter the efficacy of the product)
c) Pallets on which pharmaceuticals are kept and moved shall be clean and free from contaminations
d) Receiving port area or dispatch area shall be able to accommodate the movement load.

e) Receiving port area/dispatch shall be have restricted access. Unauthorized access shall be monitored. Movement of pharmaceuticals shall be further more monitored.
f) The area shall be free of dust, waste, pests and contamination or any other source that may hinder the efficacy of the pharmaceutical products stored.

g) All pharmaceuticals shall be stored above the ground and not touching any walls and suitably spaced.

h) Any spillage shall be cleaned properly and procedures for cleaning and dealing with spillage adapted.

i) Inspection area shall not be such that pharmaceuticals are exposed to direct sunlight/rain or temperatures exceeding the manufacturer requirement.

j) Radioactive materials, hazardous items, items at risk of fire or explosive in nature (combustible/flammable solids/liquids/pressurized gases) and items at risk of abuse (especially controlled drugs) shall be stored at dedicated area with adequate safety measures in place. All personnel accessing the area shall be trained on safe handling of such items.

### 4.1.1. Documents for inspection and clearance of pharmaceuticals.

a) Importer is obligated to ensure all documents submitted are authentic original documents and include brand name, generic name, strength, dosage form, manufacturer, manufactured date, expiry date, quantity and price of all pharmaceuticals.

b) Prescriptions for personal use items

c) Packing lists

d) Batch certificates for any vaccines or biological

e) Import authorization from MFDA for psychotropic and narcotics

f) Export authorization from the regulatory authority of exporting country, for internationally controlled drugs.

**During inspection:**

1. Any special requirement by the manufacturer on transport and distribution shall be informed to the inspectors at the port of entry.
2. No package or containers shall have hampered seals prior to inspections.
3. No pharmaceutical shall be kept in conditions exceeding the requirement of the manufacturer.
4. All items shall be of good physical conditions (shall comply with the manufacturer's requirement)
5. Only approved products shall be imported. (Refer to current Approved Drug list.)It is an offence to import substandard, mislabeled, counterfeit products.

6. Pharmaceuticals that need further information and/or clarification of documents or Quarantined pharmaceuticals shall be temporarily held for 3 days.
7. All pharmaceuticals that do NOT meet the regulations and rules and do not conform to standards shall be held by port inspectors and destroyed as applicable.

## 4.2. Storing Facility for Quarantined pharmaceuticals

a) Quarantined pharmaceutical shall be stored in a dedicated space separate from other items with restricted access and 24 hour surveillance.
b) Records of permanently held products shall be sent to the MFDA official designated for disposal.
c) Confiscated or Permanently held items shall be destroyed under supervision as per disposing procedures of a predetermined frequency, which does not exceed 3 months.
d) A decision on the status of temporarily held products shall be made within a minimum of 3 working days. After this period the product would then be either transferred to the permanently held zone and subsequently destroyed or released to the importer.

### 4.2.1. Storage for Quarantined and/or Temporarily held medicine

a) Any pharmaceutical that requires to be held temporarily shall be considered as item that can enter the market. And therefore all necessary storing requirements required must be met.
b) Temporarily held items shall be made tamper proof, marked as “temporary held” with identification label and kept at the designated temperature for the product, in an access controlled storage facility.

c) The area shall be free of dust, waste, pests and contamination or any other source that may contaminate the products and hinder the efficacy.

d) All pharmaceuticals shall be stored above the ground and not touching any walls and suitably spaced.
e) Any spillage shall be cleaned properly and procedures for cleaning and dealing with spillage adapted.

## 4.3. Transport of Pharmaceuticals

a. Pharmaceuticals shall be transported to appropriate storage facilities as soon as the clearance procedures are completed to ensure maximum safety of pharmaceuticals.
b. All transport of pharmaceuticals shall be carried out in an effective and less time consuming manner. And all the conditions required for transport including temperature, special packing shall be adapted. Vehicles and transport containers shall be loaded carefully.
c. Importers or their agents are responsible to ensure the products are protected from adverse effects and transport to correct storage conditions with minimum time.

### 4.3.1. Vehicles for Transport of Pharmaceuticals.

**Vehicle standards**

a) The vehicles for transport shall be clean, free from pests and free of contamination.
b) The integrity of the pharmaceutical products shall be maintained during transport.
c) During transport a designated trusted person shall be responsible for the safe transport of the pharmaceuticals and unauthorized access to the products shall be monitored. Any breach of such procedure shall be investigated and reports sent to the relevant authorities.
d) Appropriate packaging such as water proof packaging and other means to protect the pharmaceutical shall be used to ensure integrity and safety of pharmaceutical during sea transport, within Maldives. Transport via sea shall be monitored well to avoid damage to the pharmaceuticals.
e) Once the destination of storage has been reached, assigned staff shall be responsible in receiving the pharmaceuticals and careful verification of the items received shall be done.
f) Any missing or damage shall be reported and handled according to the procedures laid down by the individual company/party

## 4.4. Standard for pharmaceutical Storage Rooms.

### 4.4.1. Stock Control

Pharmaceutical supplies shall be moved to the storage room as soon as they arrive and be unpacked and moved to their respective shelf/place of store as soon as possible.

### 4.4.2. Quality standards in pharmaceutical storage rooms:

a) Pharmaceuticals shall not be kept on the floor and shall not touch wall surface during storage.
b) Rotate stock so that the stock closest to expiry date is kept in front (FEFO: First Expiry First Out)
c) When new stock arrives write the expiry date clearly on the box or container and place it behind stock with an earlier expiry date
d) Temperature of the room and fridges shall be maintained at all times and carefully monitored and recorded.
e) Records of temperature monitoring shall be kept until the shelf-life of the product.
f) Equipment to monitor storage conditions shall be calibrated regularly.
g) The storage area shall be free of dust, waste, pests and contamination or any other source that may hinder the efficacy and safety and quality of the pharmaceutical products.
h) All documents of the pharmaceuticals in the store shall be kept in the store until the end of their shelf- life or until the item is removed or dispatched from the store.
i) The store shall have and shall maintain all the detail records of the products in the store (E.g. procurement records, distribution and sales etc) and it shall be easily available for regulatory inspections by MFDA
j) Any stock discrepancies shall be investigated and dealt with according to the in- house procedures of the facility. Reports shall be kept available for regulatory inspections by MFDA.

k) All Store Staff must ensure that:

    i) The drug storage room is kept locked when not in use and access controlled. Only authorized staff shall be allowed to enter the storage room.
    ii) All Pharmaceuticals and medicine containers must be labeled at a minimum, with the name, strength, batch number and expiry date.
    iii) Expired drugs or other pharmaceutical products shall not be kept on the shelves. It shall be segregated from non-expired medicines in a manner that prevents accidental use or issue, and discard as soon as possible.
    iv) Refrigerators designated for pharmaceuticals shall contain only pharmaceutical products.
    v) The storage room shall be reserved for pharmacy related functions only.

vi) Floors, walls, sinks, benches, shelves and containers are clean and free of anything likely to contaminate drugs

vii) Store room, benches and surrounds are free from clutter and items not required for packaging of medicines

viii) Floors and aisles are free of stock or other obstructions.

l) **General Requirements for Storage Rooms/Ware houses.**

i) Keypad locks or, a lockable room with secure Doors and emergency exits

ii) Store room shall have adequate space accommodate all the pharmaceuticals in an orderly manner without overcrowding and facilities to store at their required conditions

iii) Adequate lighting in all areas of the room in order to see the products and read labels clearly.

iv) A mechanism such as air-conditioning to maintain a temperature of 25°c or below, with cooling units that operate 24 hours per day without interruption.

v) Temperature controlled equipment including air conditioners must be connected to an emergency power supply.

vi) A dedicated refrigerator for storage of vaccines, if vaccines are being stored.

vii) A refrigerator for cold storage of pharmaceutical products requiring refrigeration, in addition to the vaccine refrigerator

viii) Lockable cupboard or mechanism to keep all controlled drugs locked and accessible to an identified responsible officer.

ix) Adequate shelving labeled for appropriate storage of the different categories of medicines stored in the facility, to avoid mix up.

x) Mechanism to segregate broken and damaged items from usable stock and packed in containers for damaged and expired products labeled " For Destruction"

xi) Work space or bench for handling medicines and documentation.

xii) Hand washing facilities such as sink, preferably with elbow taps, soap dispensers and paper towels with holders

xiii) A portable, a sturdy ladder, if shelving is above normal height. Height of ladder shall be adequate for the person standing on it, to see the back of top shelves.

xiv) Fire extinguishers and smoke detectors shall be in place in all pharmaceutical storage facility. And emergency exits shall be accessible and clearly seen.

xv) A mechanism shall be in place for the stock maintenance to monitor the existing stock, sales, arrival of new stock and any damaged and expired pharmaceuticals. (e.g. Computer software)

### 4.4.3. Drug Storage Layout

A standard categorization of pharmacy items in the following categories:

- Refrigerated
- Drug safe /Controlled drugs
- Oral
- Injectable
- Topical
- Infusion
- Inhalational
- Non Drug ( shall be separated from pharmaceuticals)

**Refrigerated**

- Medicines are to be stored in dedicated refrigerators or cold rooms. FOOD and beverages or eatables shall not be stored in these refrigerators, but in a separate small locked fridge/freezer.
- Total Parenteral Nutrition shall be stored between 2 and 8 degrees.
- A list of items in the fridge including their expiry shall be labeled on door of the fridge
- Medicines intended for storage in a fridge (2 – 8 degrees) shall NEVER be place in the freezer compartment.
- Temperature shall be monitored 24 hourly and noted on the temperature monitoring sheet *of* the respective refrigerator. If any variations are noticed this has to are notified and corrective measures taken.

**Controlled Drug Cupboards**

- Cupboards reserved solely for the storage of Controlled Drugs must be secured to the wall and have strong locks. The lock must not be common to any other lock facility
- Controlled drugs that need refrigeration must be kept separate from other medicines in locked refrigerators.

- All controlled medicines need to be clearly balanced in a separate log book and all sales need to be well documented

**Non-Controlled Drug Medicines**

Separate storage arrangements must be made for internal medicines (simple linctus), external medicines (aqueous cream), inhalations and disinfectants for use by clinical staff (eg.chlorhexidine) and labeled clearly.

## 5. Management Responsibilities

a) Ensure all staff are aware of their designated responsibilities
b) Coordinate the management of the drug storage room and respective staff
c) Endorse all the documents for procurement and distribution of pharmaceuticals
d) Nominate staff members who are given access to the store
e) Report any changes to the drug storage room access to the staff in-charge/storekeeper
f) Ensure safe working environment and that all personnel abide to the safety procedures
g) Responsible for the safekeeping of all pharmaceuticals in the store
h) Maintain the stocks and all relevant documents
i) Maintain all temperature monitoring records
j) Supervise the movement of pharmaceuticals in and out of the facility
k) Report to the manager if any maintenance services are required
l) Prepare procurement documents for pharmaceuticals and obtain endorsement from manager
m) Check items received as per order
n) Check condition of received items
o) Responsible for the safekeeping of all pharmaceuticals in the store
p) Report any breach of security to the manager

### 5.1. Store auditor

a) Conduct regular audits of drug storage facilities and report to the manager
b) Maintain audit reports for MFDA inspector's visits

## 6. Documentation

a) Standard procedures on documentation shall be available in each facility or organization which is involved in transport, handling and distribution of pharmaceuticals. This would include the documents for procuring, transport, receiving, all relevant receipts and invoices.

b) All distributors shall keep records of the pharmaceuticals they have received and distributed until the shelf of the individual drug ends. This would include brand name, generic name, strength, dosage form, manufacture & expiry date, quantity received/dispatched, date received/dispatched and detailed address of the supplier. These records shall be detailed such that in case of recall or otherwise individual batches of products shall be traceable.

c) All parties/organizations/ person involved in the supply shall be identifiable. Any agreement made with a third party or organization regarding the import/transport, handling and distribution shall be kept. Such documents shall be available on request by MFDA, to identify sources of counterfeits entering the chain of distribution.

d) All procedure with regard to maintaining the quality of pharmaceutical shall be kept. This would include calibration procedures followed and special requirements of the manufacturer regarding storage, handling and distribution.

e) Invoices and related documents for individual items shall be filed such that in the event of a recall event the whole chain of acquiring the drug can be identified.

f) A responsible senior staff shall validate all the documents regularly before filing.

g) Documents on handling damaged, expired drugs shall be maintained. A standard procedure shall be in place to identify products near expire, methods of segregating such products for disposal.

h) Any breach of security, stock discrepancies or other matters investigated, shall be documented and readily available for regulatory visits.

i) All documents shall be easily accessible, readily available upon request for the relevant authorities and backup systems shall be in place.

j) All documentation procedures shall be reviewed and updated.

## 7. Recalls

a) An updated, written procedure shall be in place for recall of pharmaceuticals in case of international/national regulatory alerts, suspected counterfeit or substandard products. This procedure shall include how such a recall decision shall be taken, how to convey the

information to the stakeholders and also identify the designated contact personnel and their level of commitment.

b) All recall information shall be shared with the relevant authorities, organizations, businesses/companies or person handling/prescribing/dispensing. Public announcements shall also be made to make the community aware of the issue.

c) All recalled pharmaceuticals shall be segregated, labeled, dated and further importation prohibited. Disposal shall be done in an organized manner such the facility to store the recall items does not get over loaded.

d) The progress of recall and recovered quantities, disposed quantities and other legal action taken to date shall be recorded and all documents regarding the recall collected, and a final report on the event compiled. This data shall be accessible to the relevant authorized organizations in the time of need.

***Annex1: Model Temperature monitoring sheet***

## TEMPERATURE MONITORING FORM

Fridge no:

Month:

| Date | Time | Temperature | Name of staff | Signature |
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