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Republic of Kenya

Ministry of Health

PHARMACY AND POISONS BOARD

GUIDELINES FOR TRANSPORTATION OF PHARMACEUTICALS IN KENYA

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Legal framework

Pharmacy and Poisons Board is empowered by section 44(1, f) of the Pharmacy and Poisons Act, Chapter 244 Laws of Kenya to regulate transportation of Pharmaceuticals in Kenya. Indeed, Rule 15 under the said section specifies some poisons that cannot be transported without appropriate labeling and segregation from food items and food containers

LIST OF ABBREVIATIONS AND ACCRYNORMS

APIs	Active Pharmaceutical Ingredients
FPPS	Finished Pharmaceutical Products
HVAC	Heating, Ventilation and Air-Conditioning
KEBS	Kenya Bureau of Standards
NB	Note Below
POE	Port Of Entry
PPB	Pharmacy and Poisons Board
SOPS	Standard Operating Procedures
UPS	Uninterruptible Power Supply
WHO	World Health Organization
IATA	International Air Transport Association

Definition of Key Terms

Active Pharmaceutical Ingredient: Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.

Batch: A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous.

Cold chain: all of the materials, equipment, processes and procedures used to maintain all products (which require cold chain conditions) within the required temperature range of 2 °C to 8 °C from the time of manufacture until the products are administered to individuals;

Consignment: The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

Container: The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

Finished Pharmaceutical Products: The medicinal product that has undergone all stages of production, including packaging in its final container. The specifications for release of the finished product must comply with the PPB regulations.

Lagged containers: an insulated container which meets the requirements of transporting pharmaceutical products at the required

temperatures for the necessary duration of time

Product recall: the removal of specific batch/batches of a pharmaceutical product from the market for reasons relating to deficiencies in quality, safety or efficacy

Importation: The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

Standard operating procedure (SOP): An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

Storage: The storing of pharmaceutical products up to the point of use.

Supplier: A person or entity engaged in the activity of providing products and/or services.

Transit: The period during which pharmaceutical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

Vehicles: Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products

Withdrawal: the total removal of a pharmaceutical product from the market

1. Introduction

Pharmaceutical products and starting materials used in the manufacture of pharmaceuticals should be stored and transported under conditions which ensure that their quality is maintained. Transportation should be regarded as an extension of the storage activities and each journey should be treated as unique, with the length and complexity, as well as any seasonal variations being considered when choosing the packing method and mode of transport. There is little point in storing products appropriately if they are compromised by inappropriate transportation

This draft guideline sets out the requirements for transportation of pharmaceuticals to guarantee product quality through the distribution channel from manufacture to consumption/ disposal. The document takes into consideration existing global best practices and attempts have been made to tailor it to the Kenyan scenario. The target audience includes regulators, logisticians and pharmaceutical professionals in industry, government and the international agencies.

The transport risk assessment should be considered in view of following conditions:

a. Temperature impact
b. Humidity
c. Vibration/ Shock impact
d. Handling delays during transportation
e. Failure of data-loggers
f. Topping up liquid Nitrogen (inert coverage to product) e.g. Environmental conditions monitoring throughout the transport.

This document considers reference from the 'WHO *Model guidance for the*

storage and transport of time- and temperature–sensitive pharmaceutical products' and *https://www.researchgate.net/publication/308594913_Pharmaceutical_Good_Transportation_Practices_GTP_-An_Innovative_Concept_In_GXP_Acronym*[accessed Dec 26 2018]

2. Ports of Entry

2.1 Importation/Exportation

Air Transport

All Pharma & Healthcare Products Handling whether import or export by Air should meet the IATA requirements. The vessel of transport in this category is primarily aircrafts.

Transporting healthcare products by air demands a rigorous logistical approach. If mishandled, the intactness or integrity of these products can be compromised by temperature changes during transportation.

With the pharmaceutical industry moving over one trillion dollars worth of cargo every year, upholding a shipment's quality requires specific equipment, storage facilities, harmonized handling procedures and, above all, strong cooperation among the cold chain partners.

The following issues should be considered before air transport of

pharmaceuticals and healthcare products is initiated:

i) Protecting lives

The logistics provider, agents representing importers/exporters or consignee's should consider the key value of these products which is protecting lives of patients and other users. Therefore air transporters should always refer to IATA Manual which provides for the requirements and standards for the transportation and handling of pharmaceutical products, including the compulsory use of the Time and Temperature Sensitive Label. This manual contains parameters identified by the Pharmaceutical industry most importantly **Temperature Control Regulations (TCR)**

ii) Time & Temperature Sensitive Label

Mandatory from July 2012, the IATA Time and Temperature Sensitive Label is a shipment label specific for the healthcare industry. It must be affixed to all shipments booked as time and temperature sensitive cargo and indicate the external transportation temperature range of the shipment.

It is the responsibility of the shipper (or designated shipper's agent by service agreement) to ensure that the label is applied properly for time and temperature sensitive healthcare cargo shipments booked as such.

iii) Acceptance Checklist for time and temperature sensitive shipments

The purpose of the IATA Standard Acceptance Checklist is to inform airlines and ground-handling agents of the minimum checks to execute in temperature sensitive healthcare shipments. This ensures that the process meets all the requirements established by the TCR.

Since July 2013, this Acceptance Checklist is a requisite for the transportation of time and temperature sensitive healthcare shipments.

Sea Transport

The vessels of transport here are boats and ship(s).

All imported pharmaceuticals by the sea must be transported in

REEFER system (refrigerated container for transporting temperature sensitive cargo), considering the manufacturer's storage specifications.

Import of pharmaceuticals (APIs /FPPS) must be through a gazetted Port (s) of Entry (POE) that is adequately equipped to handle these products. This equipment includes but is not limited to temperature and relative humidity-controlled rooms/ storage.

Upon arrival at the POE, remove the API/FPP from the transporting vessel (Ship, Aircraft, Vehicle, etc.) as soon as possible and move them to a safe and suitable temperature-controlled storage location.

This is to minimize the risk of temperature/ humidity related damage and theft.

The importer shall receive and forward records of storage conditions during transportation to the verifying officer (PPB inspector) at the POE. This shall be checked to ensure compliant storage on transit. Any excursions shall be reported to the owner of the consignment and adequately addressed.

For export consignments, the exporter shall ensure that the same conditions above apply.

c) Road Transport

Pharmaceutical Transportation vessels including trucks, vans, cars, trailers, railway carriages are a few prominent means for transportation by road. As per principles of Good Distribution Practice of Medicinal Products for Human Use (GDP Guideline), transportation should be executed in accordance with the storage conditions defined in the marketing authorization and/or technical agreement depending upon product stability study data

(PDF) Pharmaceutical " Good Transportation Practices (GTP) " -An Innovative Concept In " GXP " Acronym. Available from: https://www.researchgate.net/publication/308594913_Pharmaceutical

_Good_Transportation_Practices_GTP_-
An_Innovative_Concept_In_GXP_Acronym

Various quality issues are cropped up during transportation and distribution operations of pharmaceutical products, which may result into a gross business loss and damage to goodwill of organizations. Such quality issues include:

a. Product mix-up during transportation
b. Deterioration of product quality
c. Discoloration of formulation
d. Microbial contaminations
e. Label mutilation
f. Loss of product integrity
g. Arrival to wrong destination
h. Abnormal delay

All the above issues should be considered by transporters before execution of transport.

from: https://www.researchgate.net/publication/308594913_Pharmaceutical_Good_Transportation_Practices_GTP_-
An_Innovative_Concept_In_GXP_Acronym

2.2 Loading and receiving bays

Receiving and dispatch areas must have sufficient facilities and space allowance to ensure pharmaceuticals are protected from adverse environmental conditions.

Ensure, where possible, that areas where pharmaceuticals are

temporarily held during arrival or dispatch are:

- Maintained within the temperature range specified for the goods being handled.
- Maintained within the humidity range specified for goods being handled.
- Protected from undue exposure to environment (Direct sunlight, dust, rain, etc.)
- Adequately ventilated and lit

Parameters such as temperature and humidity must be monitored at all times, and evidence of the monitoring documented in temperature logs, humidity logs, etc. which are retrievable for reference.

This is aimed at protecting the pharmaceuticals and assures quality during arrival, storage and dispatch from the POE.

Equipment/ appliances/gadgets used in temperature control (i.e. refrigerators, freezers, building, heating, ventilation and air-conditioning (HVAC) systems, alarms, must be connected to uninterruptible power supply (UPS) system/ power backup.

2.3 Transport and delivery

Pharmaceuticals shall be transported in a manner that meets the product specifications for storage. Any excursions from the manufacturer's labeled storage conditions should not adversely affect product quality.

It is the responsibility of the consignor to ensure product storage specifications are maintained during transportation.

Temperature/ humidity -controlled vessels shall be used for transportation of pharmaceuticals, and these shall be calibrated by an accredited standardization body to ensure they comply with temperature and humidity requirements. Additionally, these vessels shall be:

- Equipped with calibrated temperature monitoring devices with sensors located at points representing temperature extremes;
- Equipped with alarms to alert the operator in the event of temperature/ humidity excursions and/or refrigeration unit failure;
- fitted with doors with security seals and/or security locks that protect against unauthorized access during transit;

These vehicles/vessels shall be regularly calibrated and maintained and records demonstrating compliance kept

2.4 Security for pharmaceuticals during transportation

- All pharmaceuticals shall be transported in the following manner: Vehicles/vessels shall be equipped with lockable doors and an intruder alarm.
- Security-cleared delivery drivers are employed.
- All deliveries are documented and tracked.
- Signed dispatch and arrival records are kept.

Drivers are informed about the perishability of the product if any, and the maximum acceptable transport time. In addition to the above, pharmaceuticals with high illicit value should be transported in secured

vessels, escorted by armed personnel and the time of transportation to be between 7am-6pm

This is meant to prevent theft of the pharmaceuticals

2.5 Monitoring of storage conditions during transit

(A) Temperature

Vehicles/ vessels used in transportation of pharmaceuticals shall be fitted with temperature control systems which should comply with the following minimum requirements:

- system able to continuously maintain air temperatures within the set point limits
- Temperature monitoring device accuracy should be within ± 0.5 °C;

NB- Sensitivity of sensors to be researched and referenced here

At all times, temperature monitoring to be documented

(B) Humidity

Vessels used for transport of pharmaceuticals should have humidity monitoring systems and devices. These should comply with the following minimum requirements.

- Humidity measuring device should have an accuracy of ± 5% RH;
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- At all times, humidity monitoring to be documented

NB- Sensitivity of sensors to be researched and referenced here

2.6 Audit of transporters/ Qualification of temperature-controlled road vehicles

Where temperature-controlled vehicles/vessels are used, qualify each vehicle before it becomes operational, wherever possible. The qualification procedure should:

- Demonstrate that the air temperature and humidity is uniformly distributed in the temperature-controlled compartment of the vehicle. This is through installation of temperature probes.
- demonstrate the time taken for temperatures to exceed the designated maximum in the event that the temperature-controlling unit fails;
- And document the qualification exercise.

This is to ensure that pharmaceuticals are transported safely within the temperature indicated by each product and those specified by the Pharmacy and Poisons Board (PPB).

2.7 Calibration of transport vessels and Devices

All vessels used for transportation of pharmaceuticals must undergo routine calibration for temperature and humidity by the Kenya Bureau of Standards (KEBS) or any other certified authority to ensure compliance.

Calibration records must be maintained to demonstrate compliance.

2.8 Shipping containers

Select shipping containers that:

- Protect personnel and the general public from hazards arising from spillage and/ or leakage
- Protect the product being transported against mechanical damage and the anticipated temperature changes encountered in transit; and
- Can be closed in a manner that allows the recipient of the consignment to establish that the product has not been tampered with during transport.
- All containers used in transport of pharmaceuticals must be insulated.

This will guarantee product quality and safety.

2.9 Temperature monitoring in shipping containers

Use chemical or electronic freeze indicators, electronic loggers (with or without alarms) and/or other suitable indicators to monitor temperature and/or humidity exposure during transportation.
Monitor and document indicator status upon arrival.

This is meant to ensure that pharmaceuticals are safely transported within the transport temperature profile and safety and efficacy is assured.

2.10 Qualification of insulated containers (cool boxes, etc.)

For short-term (≤12 hours) transportation of s temperature sensitive pharmaceuticals, insulated containers with icepacks may be used. These containers shall be qualified to ensure the ice or gel packs, cool water packs or warm packs used maintain desired

temperature throughout the transport period.

For anticipated long transit time (12 -96 hours) in remote areas, war zones, etc., use of the up to 96 hours insulated containers (cooling units) is mandatory for transportation of cold chain pharmaceuticals.

Whenever these containers are used, the sender shall document the initial temperature during packing, and the same attached with the container. Upon delivery, the recipient shall immediately check the temperature of the contents and any excursions noted and documented.

It is the responsibility of the sender to ensure that the packaging system is capable of maintaining the pharmaceuticals within the temperature range needed to meet the product stability requirements as stated by the manufacturer.

2.11 Product handling during packing and transport

Handle pharmaceuticals correctly during packing and transport. Precaution should be taken against spillage or breakage, contamination and cross- contamination.

2.12 Transport of returned, recalled and withdrawn pharmaceuticals

Ensure that returned pharmaceuticals are transported under the same conditions as those used for the initial delivery, and necessary documentation maintained. The sender and recipient must work together so that that the product is maintained within the temperature range needed to meet the manufacturer's stated product stability profile.

Ensure that recalled or withdrawn pharmaceuticals are adequately marked as either "recalled" or "withdrawn".

3. Incoming goods

3.1 Product arrival checks

Check and record the following for all incoming pharmaceuticals:

- product name, item code if any, strength, and batch/lot number;
- quantity received against order;
- name and address of the supplying site;
- examine containers for tampering, damage or contamination;
- examine expiry dates — accept short-dated products only if prior agreement has been reached with the supplier; do not accept products that have expired or which are so close to their expiry date that this date is likely to occur before use by the consumer;
- delays encountered during transport;
- status of any attached temperature recording device(s) and/or time/ temperature indicators; and
- Verify that required storage and transport conditions have been maintained.

3.2 Actions following arrival checks

Upon receiving and verifying the consignment, the recipient shall:

- Enter product details, including product name/number, strength, batch numbers, quantities received, expiry dates and acceptance status into the stock recording system.
- Store checked goods under the correct temperature and security immediately upon receipt.
- Quarantine defective or potentially defective products,

- Communicate to the sender on the findings of the consignment and document the communication

3.3 Traceability or stock tracking

The sender and recipient of pharmaceuticals shall ensure that stock and transport/ distribution records are traceable for stock tracking of pharmaceuticals from the point of supply to the end-user or patient. Traceability shall include but not limited to records of the temperature and humidity exposure of the product during transport and storage.

3.4 Emergencies and contingency planning

Transport providers must have contingency arrangements for the safe storage of pharmaceuticals in cases of extended power outages, equipment failure, and vehicle breakdown during transport of pharmaceuticals.

4. Record-keeping

Maintain comprehensive records and ensure that they are laid out in an orderly fashion and are easy to check. These records shall be in paper and electronic formats.

Paper records must be:

- Stored and maintained so that they are accessible and easily retrievable;
- Labeled, dated and filed for easy identification;

- Protected against deterioration and loss due to fire, flood or other hazards;
- Kept secure and protected against unauthorized access; and
- Signed and dated by authorized persons and not changed without due authorization.

Electronic/computer records must be:

- Logically filed for easy identification and retrieval;
- Kept secure and protected against unauthorized access;
- Where feasible, manually signed, dated and scanned
- Regularly backed-up and archived

5. Standard operating procedures (SOPs)

The person responsible for dispatching, transporting and receiving pharmaceuticals shall develop, domesticate and maintain SOPs covering correct transport of pharmaceuticals. This is to ensure posterity and compliance.

END OF DOCUMENT

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