

**Zambia Medicines Regulatory Authority****GUIDELINES FOR GOOD COLD CHAIN MANAGEMENT PRACTICES**

Contact details:

Head Office, Plot No 2350/M, Off Kenneth Kaunda International Airport Road

P.O. Box 31890, Lusaka, ZAMBIA

Tel: +260 211 220429,

E-mail: pharmacy@zamra.co.zm;Website: www.zamra.co.zm

	Name	Designation	Signature	Date
Prepared by	Mr. Matthews Mwale	Director Licensing, Surveillance Enforcement		29/09/26
Reviewer	Mr. Makomani Siyanga	Director General		29/09/2026
Approver	Hon. Prof. Roma Chilengi, MP	Minster of Health		06.10.26





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1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) regulates medicines and allied substances in accordance with the provisions of the Medicines and Allied Substances Act No. 3 of 2013, (hereinafter referred to as “the Act”) and the relevant Regulations made thereunder.

These guidelines for Good Cold Chain Management Practices are issued by the Authority pursuant to section 68 of the Act. The Authority may from time to time amend any part of these guidelines.

To maintain product quality, safety and efficacy during distribution, Good Distribution and Storage Practices specify that temperature-sensitive products are to be stored, handled and distributed carefully throughout the distribution chain. Cold chain management begins when a time- and temperature-sensitive pharmaceutical product (TTSP) such as vaccines and other biological products are manufactured, stored and move through the distribution chain until they get to the end user at the time of administration. It is required that the product be held and distributed in a controlled environment throughout the supply chain to prevent degradation, contamination or loss of potency thereby safeguarding public and animal health

Therefore, it is considered critical to have adequate control of all steps and procedures involved both in manufacturing and quality control, storage and distribution, to ensure that product quality is maintained.

Anyone handling TTSPs is responsible for their potency, at each step in the transport and storage. These products are delicate biological substances that can become less effective or destroyed if they are frozen, exposed to heat, exposed to direct sunlight or fluorescent light and the loss of effectiveness of vaccines and other biological products is cumulative and cannot be reversed.

2. OBJECTIVE

These guidelines are intended to provide guidance to importers, exporters, wholesalers, distributors, retailers, hospitals / healthcare institutions, animal health facilities and transporters for storage and distribution of time- and temperature -sensitive pharmaceutical and biological products to ensure that their quality and efficacy will not be compromised.

3. SCOPE

These guidelines apply to all entities involved in the importation, exportation, storage, handling, transportation, and distribution of time- and temperature-sensitive pharmaceutical and biological



products across the supply chain. This includes, but is not limited to, importers, exporters, wholesalers, distributors, retailers, hospitals and healthcare institutions, animal health facilities, and transport service providers.

4. DEFINITION

In these guidelines, unless the context otherwise requires -

“Act” Means the Medicines and Allied Substances Act (No. 3) of 2013.

“Authority” Means the Zambia Medicines Regulatory Authority.

“Biological product” means vaccine, immune sera, anti-toxin, anti-venom, toxoid, blood and blood components, allergy products used in the prevention, treatment or cure of disease or condition in human beings and animals synthesized from living organisms or other products.

“Consignment” means the quantity of medical 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.

“Cross-contamination” means contamination of a starting material, intermediate product or finished pharmaceutical product or medical product with another starting material or product, during production, storage and transportation.

“Cold Chain” means the system used for storing and transporting temperature-sensitive products within the recommended temperature range from the point of manufacture to the point of use.

“Distribution” means the procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of medical products, with the exception of dispensing or providing medical products directly to a patient or his or her agent.

“Good Storage Distribution Practices (GSDP)” means that part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities that occur during the storage, trade and distribution process, as well as providing a tool to secure the distribution system from unapproved, illegally imported, stolen, substandard, falsified and/ or misbranded medical products.



“Heating, ventilation and air conditioning systems” means heating, ventilation and air conditioning, also referred to as environmental control systems.

“Importation” means the act of bringing or causing any goods to be brought into the Republic.

“Standard operating procedure (SOP)” A written set of step-by-step instructions that explains how to carry out a specific task or process consistently and correctly.

“Storage” means the storing of medical products up to the point of use.

“Time- and temperature-sensitive pharmaceutical product (TTSP)” means any medicine or allied substance which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.

“Temperature excursion” means an event in which a TTSP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different as they are determined by the product manufacturer, based on stability data.

“Vehicles” means trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means that are used to convey medical products.

5. ABBREVIATIONS

ZAMRA - Zambia Medicines Regulatory Authority

WHO-World Health Organisation

TTSP – Time and Temperature Sensitive Pharmaceutical Products

SOP – Standard Operating Procedure

RH – Relative Humidity

VVM – Vaccine Vial Monitor

GSDP – Good Storage Distribution Practice

GCCMP – Good Cold Chain Management Practice



6. GENERAL

These guidelines apply to individuals intending to engage in importation and distribution of TTSPPs in Zambia. They prescribe the minimum GSDP requirements for the facilities for storage and distribution of TTSPPs to ensure quality, safety and efficacy.

7. IMPORTATION

All importers and transporters importing TTSPPs into Zambia should ensure that the products are transported according to manufacturer's specifications and be accompanied by temperature loggers.

7.1 Port handling and customs clearance

7.1.1 Port of entry

- a. Importers of TTSPPs should ensure that they use a port of entry that is fully equipped to handle such products to minimize risk of damage. The importer should ensure that the cold chain is not broken throughout the supply chain of the product.
- b. In some situations, where the port of entry is not equipped with suitable cold storage facilities arrangements can be made for formal clearance to take place away from the port of entry, this can reduce the risk of temperature excursions.
- c. Importers should conduct risk assessment for import routes taking into account transit time and availability of cold chain infrastructure

7.1.2 Offloading

As soon as possible after arrival of the consignment, remove TTSPP shipments from the airport apron to a safe and suitable temperature-controlled storage location to avoid exposure to adverse ambient conditions.

7.1.3 Temporary storage at port of entry

- a. TTSPP shipments should be stored in a secure warehouse maintained under the conditions recommended by the product manufacturer or product specifications, with the product clearly labelled as "cold chain products" until the shipment has been authorized for removal by customs to avoid risk of theft or damage during temporary storage.
- b. TTSPPs should only be imported through those ports of entry where facilities are suitable for cold storage to avoid the increased risk of temperature excursions. If, any such excursion happen it should be properly documented and investigated.



8. REQUIREMENTS FOR A COLD CHAIN STORAGE FACILITY

8.1 General considerations

8.1.1 Location and Surroundings

The cold storage facility should be located away from open sewage, drain, public lavatories or similar unhygienic surroundings.

8.1.2 Building/facility

The building(s), used for the storage and maintenance of TTSPPs should be constructed in such a manner as to permit the operation of its activity under hygienic conditions and should avoid the entry of insects, rodents and flies. The facility should be well lit, ventilated and screened (mesh), wherever necessary. The facility should have an area of reasonable size for its operations. The walls and floors of the rooms, where storage equipment is kept, should be smooth, washable and capable of being kept clean.

8.2 Design and layout

Ensure that the storage buildings are well laid out and contain all the necessary storage areas, goods assembly, receiving and dispatch bays and office accommodation needed for efficient operation of the TTSPPs store.

8.2.1 Dispatch bays

Ensure that receiving and dispatch bays are designed to avoid conflict between incoming and outgoing products and are protected from direct sunlight, dust, dirt, rain, and from extremes of heat, cold and solar radiation that could damage TTSPPs, and measures are taken to minimize pest activity in these areas to ensure protection against damage and maintenance of product quality.

8.2.2 Receiving Bays

Provide receiving areas with suitable equipment to clean reusable transport containers after their contents have been unloaded, and before the containers are stored for re-use to protect against contamination of outgoing TTSPPs.

8.2.3 Goods assembly areas

Provide sufficient space to receive, assemble and pack TTSPPs for dispatch under temperature-modified conditions. Preferably, these areas should be physically close to the temperature-controlled storage area for protection of TTSPPs during arrival, order assembly and dispatch.



8.2.4 Quarantine area

Provide a quarantine area for the isolation of returned, faulty, recalled and otherwise withdrawn products pending a decision on disposal or re-stocking by the Authority. Materials within quarantine areas must be clearly identified with their status:

- a) with temperature control, for items returned for re-stocking;
- b) with temperature control, for items recalled for testing; and
- c) without temperature control, for items awaiting disposal.

The quarantine area may be a physically separated zone. Items for re-stocking, testing and disposal should be kept separate to avoid the risk of inappropriate use.

8.3 Environmental control of ancillary areas

Ensure, where possible, that ancillary areas where TTSPs are temporarily held during arrival, order assembly or dispatch are:

- a) maintained within the temperature range specified for the goods being handled.
- b) maintained within the humidity range specified for goods that are adversely affected by high relative humidity and are not sufficiently protected by their packaging.

Note: Active environmental control of ancillary areas may not be needed if all TTSPs are kept in temperature-controlled packaging and/or humidity- protective packaging when passing through these areas, protected from undue exposure to direct sunlight, protected from the weather, protected against dust, dirt and waste accumulation as well as adequately ventilated.

8.4 Building security

Ensure that buildings used to store TTSPs have access control to prevent misappropriation of products and to protect against vandalism, theft and other illegal incursions.

9 FIRE PROTECTION

9.1 Fire protection equipment

Provide suitable fire detection and fire-fighting equipment, including fire hydrants where applicable. In all TTSPs storage areas, ensure that systems and equipment are appropriate for the class of occupancy and product storage arrangements and are approved by the local fire authority. Ensure equipment is regularly serviced in accordance with the equipment manufacturers' recommendations.

**9.2 Fire prevention, detection and control procedures**

Develop and implement standard operating procedures (SOPs) for fire prevention, detection and control.

10 BUILDING CLEANLINESS**10.1 Cleaning program**

Implement a cleaning program for all areas to ensure protection against damage and contamination of TTSPPs and to minimize the risk of pest infestation:

- a. Do not allow the accumulation of dust, dirt and waste, including packaging waste.
- b. Take precautions against spillage or breakage, and cross-contamination.
- c. Collect waste in designated closed containers and arrange for safe disposal at frequent intervals.
- d. Do not permit consumption of food or beverages other than in designated areas.
- e. Maintain cleaning records to demonstrate compliance.

10.2 Pest control

Implement a program to keep all areas free of pests. This should include enclosed receiving and loading bays to protect against damage and contamination of TTSPPs. Maintain records to demonstrate compliance with a robust pest control program

11 POWER SUPPLY**11.1 Uninterrupted power supply**

Ensure that all temperature-controlling equipment for TTSPPs storage are connected to a backup power supply system.

11.2 Power failure contingency plan

Develop and maintain a contingency plan to protect TTSPPs in the event of power failure which places products at risk. Alternative emergency cooling systems (e.g. liquid nitrogen or dry ice) are acceptable.

**12 PERSONNEL****12.1 Training**

Provide regular and systematic training for all relevant personnel responsible for storage, loading and unloading areas used for non-hazardous TTSPPs to ensure that all relevant personnel are competent to carry out their duties, covering the following:

- a. applicable pharmaceutical legislation and regulations;
- b. SOPs;
- c. safety issues; and
- d. Response to emergencies.

Ensure that each employee understands his or her specific responsibilities. Provide similar training for drivers who are responsible for transporting these substances. Maintain individual training records to demonstrate compliance and regularly evaluate the effectiveness of training program.

12.2 Health and sanitation, and protective clothing

The personnel should be free from contagious or infectious diseases. They should be provided with clean adequate protective clothing. There should be adequate, clean and convenient hand washing and toilet facilities.

13 TEMPERATURE-CONTROLLED STORAGE**13.1 Storage capacity of temperature-controlled stores**

The net storage capacity of the temperature-controlled stores should be of sufficient size to accommodate peak TTSPPs stock levels and their associated transit temperature protection components (i.e. freezer blocks, flexible ice blankets, refrigerated gel packs, phase change materials and insulated packaging, if retained), under correct temperature conditions and in a manner which enables efficient and correct stock management operations to take place.

13.2 Temperature-controlled storage

The TTSPPs should be stored in temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers which comply with the following requirements;

- a. Be preferably equipped with an auto-defrost circuit which has a minimal effect on temperature within the unit during the defrost cycle and maintains temperature within specification for this period;



- b. Ensure there is an alternative source of power;
- c. Be equipped with a calibrated continuous temperature monitoring system with sensors located at points representing greatest temperature variability and temperature extremes;
- d. Be preferably equipped with continuous humidity monitoring devices with sensors located at points representing humidity extremes;
- e. Be equipped with alarms to indicate temperature excursions and/or refrigeration failure;
- f. Be fitted with lockable doors, or an access control system, as necessary; locks must have a safety device so that doors can be freely opened from the inside;
- g. Be capable of maintaining the temperature range specified by the TTSPPs manufacturer over the full annual ambient temperature range experienced at the storage site; and
- h. Be equipped with calibrated temperature monitoring devices appropriate to the level of risk but preferably capable of continuous recording and with sensor(s) located at a point or points within the cabinet which most accurately represents the temperature profile of the equipment during normal operation.

Note: Refrigerators without freezers and stand-alone freezers usually perform better at maintaining the precise temperatures required for vaccine storage. Vaccines should be stored centrally in the refrigerator or freezer, not in the door or on the bottom of the storage unit, and sufficiently away from walls to allow air to circulate.

14 TEMPERATURE AND HUMIDITY CONTROL AND MONITORING IN STORAGE

14.1 Temperature monitoring

Provide air temperature monitoring systems and devices for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers, used to store TTSPPs. Comply with the following minimum requirements:

- a. Monitoring sensors accurate to $\pm 0.5^{\circ}\text{C}$ or better for electronic devices and $\pm 1^{\circ}\text{C}$ or better for alcohol, bi-metal gas or vapor pressure thermometers;
- b. Monitoring sensors calibrated as described above;
- c. Monitoring sensors located in areas where greatest variability in temperature is expected to occur within the qualified and/or tested storage volume as defined above;
- d. Monitoring sensors positioned so as to be minimally affected by transient events such as door opening;



- e. Temperature monitoring devices, temperature traces or electronic temperature records manually shall be checked at least twice a day, in the morning and evening, seven days a week, including public holidays; and
- f. Temperature monitoring records should be maintained.

14.2 Humidity monitoring

Provide humidity monitoring systems and devices in temperature-controlled rooms that are used to store TTSPPs which require a humidity-controlled environment. Comply with the following minimum requirements:

- a. sensors accurate to $\pm 5\%$ RH;
- b. sensors calibrated as above;
- c. sensors located to monitor worst-case humidity levels within the qualified storage volume;
- d. sensors positioned to be minimally affected by transient events such as door opening;
- e. humidity monitoring records should be maintained; and
- f. continues to operate independently in the event of a power failure.

Reason: To maintain labelled TTSPP humidity conditions during long-term storage ensure that there is a contingency plan to move products stored in non-functioning equipment to a safe location before damage to the product occurs if equipment cannot be repaired in a timely manner.

15 EQUIPMENT

Equipment used in the storage, release and distribution of vaccines and other biologicals products should be maintained, located and operated in accordance to the manufacturers' instructions.

The equipment should be regularly observed and calibrated in accordance with an approved SOP and should operate in the manner for which it was designed. Equipment should be calibrated relatively frequently in order to establish accuracy, i.e. their meteorological stability or the change in their measuring ability between calibrations.

15.1 Refrigerator/Chillers

Combination refrigerator/freezer units sold for home use are not adequate for vaccines and other biological products storage as domestic refrigerators do not have good temperature control. However, if the refrigerator and freezer compartments each have a separate door, vaccines and other biologicals products should not be stored near the cold air outlet from the freezer to the



refrigerator. It should be ensured that the door to the refrigerator closes properly, the rubber seals are not broken and the hinges adjusted if necessary.

- a. The refrigerator should be placed in an air-conditioned room, away from direct heat or sunlight, at least 20cm to 30cm from the wall and with at least 40cm of clear space above;
- b. The room should be well ventilated so that the heat from the refrigerators and chillers will not heat up the room. If several refrigerators or freezers are kept in one room, they should be properly spaced, at least 30cm from each other. The refrigerator/chillers should be properly labelled and identified; and
- c. At least 50% of the space in the refrigerator should be filled at all times to allow for adequate circulation of cold air, and to stabilize the refrigerator temperature.

The products should be maintained at the manufacturer's recommended temperature range.

Note: Food and drinks should not be stored in a refrigerator used for vaccine/biopharmaceutical storage. Frequent opening of the refrigerator to retrieve food items can affect the temperature of the unit and thus affect the efficacy of the products.

15.2 Freezers

Freezers used to condition ice packs used in the transportation of vaccines and other biopharmaceutical products should be maintained in like manner as the refrigerator and chillers.

15.3 Walk-in Refrigeration units

- a. A calibrated max/min thermometer should be placed inside the unit for quality assurance and to confirm the temperature indicated on the recorder;
- b. Products should not be stored next to the door and product sensitive to temperatures below 2°C should not be placed in the airflow from the refrigeration unit;
- c. Probes should be sited within an appropriate load simulator so that transient rises in temperature (such as might occur when a door is opened) do not trigger the alarm. The probes should be sensitive and efficient to detect temperature excursions;
- d. The walk-in chamber should have in-built alarm systems. The low temperature alarm must trigger before the temperature drops below +2°C and before excursion to 8°C;
- e. Temperature mapping should be repeated if significant changes take place, such as the repair or replacement of the refrigeration unit or changes to the internal storage layout; and



- f. There should be access control in place.

15.4 Water packs

Water packs are leak-proof plastic containers that can be filled with tap water. They are used to line the inside of the cold box to keep vaccines at the required temperature range inside cold boxes and carriers. It is important to use the correct number and size of water packs and to follow the instructions printed inside the lid of the container.

The appropriate temperature of the water pack will depend on the type(s) of products being transported, the ambient temperatures to which the cold box or carrier will be exposed, and the duration of transport.

15.5 Cold Boxes

These are insulated containers that can be lined with water packs to keep vaccines, diluents and other biologics in the required temperature range during transport or short-term storage. The duration for which the cold boxes can maintain the recommended storage temperature should be validated. Once packed, cold boxes should not be opened until the products are needed. The cold box to be used should be chosen based on the storage capacity needed for the supply period, temperature required and number of water packs compatible with the size of the cold box.

Note: It is important to use the correct number and size of water packs.

The following steps should be followed when packing a cold box:

- a. Remove fully frozen icepacks from the freezer and leave to thaw for a few minutes to allow the surface frost to melt. If there is frost, the temperature may be between -15°C and -25°C and susceptible products may be damaged if they come into direct contact with it;
- b. Line the bottom and sides of the cold box with fully frozen ice packs;
- c. Place the products and pre-cooled diluents into the cold box. Do not place products in direct contact with ice packs; and
- d. Cover the products and their diluents with the frozen icepacks (but ensuring that they do not come in direct contact with the products) and replace the lid. Secure the lid tightly. Keep the cold box in the shade.

**15.6 Temperature monitoring devices**

These are the instruments used to monitor and record the storage temperature of the products such as stem thermometers, in-built thermometers and temperature loggers.

The instruments should be calibrated within the required range of storage. Calibration should be documented and evidence of calibration should be readily available and should show the reference standards used.

16 PREVENTIVE MAINTENANCE

A preventive maintenance schedule should be developed and implemented for all equipment and the frequency should be increased as the equipment age increases. All Maintenance records should be documented and kept. Preventive maintenance activities should include but not limited to the following:

- a. Equipment breakdowns should be reported immediately;
- b. Regular checks of refrigerator seals to ensure cold air does not leak. If seals are brittle or torn, they should be replaced; and
- c. Area around the refrigerator should be kept clean and dust free.

17 TRANSPORTATION AND HANDLING

Products should be handled and transported under conditions specified by the manufacturer to maintain the cold chain to prevent deterioration, spoilage and breakage to ensure that the product quality is maintained up to the time of delivery to the consumer. Products should be arranged inside cold chain equipment in a manner that helps ensure that they remain in good condition with minimum risk of exposure to damaging temperatures. The products should be arranged such that:

- a. Vaccines, its diluents and other biologicals are in a refrigerator that is reserved for this purpose only. If other heat sensitive supplies, such as ointments, sera and samples, have to be stored in the refrigerator, these should be labelled clearly and keep them completely separate;
- b. Air can circulate freely as this also makes it easier to handle the products;



- c. Products supplied in their original cartons should be at least two-centimeter space between stacks. The cartons should be marked clearly, and the markings should be visible when the door or lid is opened;
- d. For products that are supplied as individual containers (vials, ampoules or tubes), a plastic tray, plastic box or other arrangement should be used for storage in an orderly fashion and labelled accordingly for easy identification;
- e. If diluents are packaged with their products, the complete packaged product should be stored in the refrigerator;
- f. If diluents are supplied separately from their products, they should also be stored in the refrigerator;
- g. If there is a freezer compartment, it should not be used to store biologics and diluents unless stipulated by manufacturer;
- h. Expired biologics should not be kept in the refrigerators/chillers /walk-in units; and
- i. Vaccines should not be kept with VVMs that have reacted or are beyond their discard point. Discard all these items immediately according to the Authority's requirement for disposal.

18 TEMPERATURE-CONTROLLED TRANSPORT

18.1 Temperature-controlled vehicles

Ensure that temperature-controlled road vehicles used for the transport of TTSPPs are:

- a) capable of maintaining the temperature range defined by the system set points over the full annual ambient temperature range experienced over known distribution routes and when the vehicle is in motion or parked with the main engine stopped;
- b) Equipped with a low temperature protection circuit in cold climates where there is a risk of breaching the low temperature set point for TTSPPs that are damaged by exposure to low temperatures;
- c) Equipped with calibrated temperature monitoring devices with sensors located at points representing temperature extremes;
- d) Equipped with alarms to alert the driver in the event of temperature excursions and/or refrigeration unit failure; and
- e) Fitted with doors with security seals and/or security locks that protect against unauthorized access during transit.

**18.2 Product handling during packing and transport**

Handle TTSPPs correctly during packing and transport:

- a. Pack TTSPPs in an area set aside for the assembly and packaging of these products;
- b. Take precautions against spillage or breakage, contamination and cross-contamination.
- c. Deliver TTSPPs to outside recipients by the most suitable mode(s) of transport available to minimize delivery time; and
- d. Ensure that patients receiving TTSPP deliveries are given clear advice on correct storage of the product before use to maintain TTSPP quality during transport.

18.3 Cleaning Road vehicles and transport containers

Implement a cleaning and decontamination program for all road vehicles and reusable shipping containers used to transport TTSPPs:

- a. Ensure that all internal surfaces of load compartments are regularly cleaned;
- b. Do not allow the accumulation of dust, dirt and waste, including packaging waste in load compartments, or in reusable shipping containers;
- c. Take precautions against spillage or breakage, and cross-contamination;
- d. Do not allow accumulation of frost and ice in refrigerated vehicles, particularly ice contaminated by spillages;
- e. Collect waste in designated closed containers and arrange for safe disposal at frequent intervals; and
- f. Maintain cleaning records for vehicles and reusable shipping containers to demonstrate compliance.

19. DOCUMENTATION

Documents, and in particular instructions and procedures relating to any activity within the cold chain that could have an impact on the quality of pharmaceutical products, should be designed, completed, reviewed and distributed with care. They should be available at all times, reviewed regularly and should be retained for a period of not less than five (5) years.



20. REFERENCES

- a. GUIDE-0069: Guidelines for temperature control of drug products during storage and transportation. Ottawa, Ontario, Health Canada. Health Products and Food Branch Inspectorate, 2005.
- b. WHO, Annex 9, Model guidance for the storage and transport of time- and temperature– sensitive pharmaceutical products (WHO technical report series, No. 961, 2011)
- c. NAFDAC Good Cold Chain Management for vaccines & other biopharmaceutical products guidelines 2019
- d. WHO Technical Report Series, No. 908, 2003 Annex 9 Guide to good storage practices for pharmaceuticals¹