Ethiopian Food and Drug Authority

Guidelines for Good Storage and Distribution Practice of medical devices

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Acronyms

CAPA	Corrective and Preventive actions
EFDA	Ethiopian Food and Drug Authority
GDP	Good Distribution Practice
GSP	Good Storage Practice
GMP	Good Manufacturing Practice
HPRA	Healthcare Products Regulatory Agency
HVAC	Heating Ventilation and Air Conditioning
IVD	In vitro diagnostic
QMS	Quality management system
MA	Marketing Authorization
WHO	World Health Organization

1. Introduction

Distribution and storage are important activities in the supply-chain of medical devices. Lack of adequate control over the activities that are carried out during storage and distribution process can adversely affect the quality of medical devices. Various entities are generally engaged in the product sourcing, procurement, transportation, delivery, storage, device tracking, installation, commissioning, use and after sale services.

As the safety and performance of medical devices directly affects the safety and health of patients; these activities need to be appropriately managed and controlled to ensure the safety and performance of medical devices at the point of use. Medical devices may be used for extremely vulnerable groups such as neonates and infants, the elderly, disabled and other patients who are particularly susceptible to diseases. They may also be used in high-risk surgical procedures and intensive care settings, where improper storage along the supply chain, amongst other aspects, may lead to undesirable, and in some cases extremely serious, consequences. Hence, storage and distribution are important activities in the supply chain management of medical devices. Various acters are responsible for the appropriate handling of medical products at different stages; for instance, during purchasing, storage, repackaging, relabelling, transportation and distribution. Implementation of good storage practices and good distribution practices may also minimize the risks of infiltration of substandard and falsified medical products into the supply chain.

This guideline is developed as per the provisions in the article 26(1) of the food and medicines administration proclamation1112/2019 which states that "the medicine or medical device institution or another appropriate person shall ensure that every product under its possession is stored, transported, and sold in accordance with good storage and distribution practices and in such a way that its quality, safety, and efficacy or effectiveness is maintained." Therefore, the guideline is intended to be applicable to all entities involved in any aspect of the storage and distribution of medical products throughout the distribution channel from the premises of the manufacturer of the medical product to the points of use i.e. importer and distributor warehouses; or the person dispensing or providing medical products directly to a patient. This includes all entities involved in different stages of the supply chain of medical products, manufacturers and wholesalers as well as, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees. This document sets out steps to assist in fulfilling the responsibilities involved in the different stages within the supply chain and to avoid the introduction of substandard and falsified medical devices into the market.

2. Scope

This guideline is applicable to all parties involved in the supply chain of medical devices including manufactures, importers, wholesalers or retail outlets of medical devices in Ethiopia. This guideline lays down requirements for the storage and distribution of medical devices; however, it does not replace GMP aspects of finished medical devices in bulk, distribution of labels or packaging, and starting materials.

3. Objectives

3.1 General objective

The objective of this guideline is to set requirements for medical device good storage and distribution to ensure their quality, safety and performance.

3.2 Specific objectives

- To set requirement for storage and handling of medical devices during installation, commissioning, servicing and maintenance. Calibration, etc.
- To set requirements for good distribution of medical device during transportation and delivery,
- to ensure the quality, safety and performance of medical device during all aspects of medical device supply chain, which include, but not limited to, product sourcing and procurement; transportation and delivery; storage; installation, commissioning, service and maintenance, calibration and after sales service; tracking, documentation, record-keeping practices and integrity of the supply chain.

4. Definitions

Commissioning is the process of ensuring that all systems and components of a medical device are designed, installed, tested, and operated according to the operational requirements and is ready to operate.

After-sales service is any support provided to a customer after the medical device has already been purchased. Examples of after-sales service include training, or repair for a medical device.

Calibration A procedure used to determine device's accuracy using test equipment whose own accuracy is appropriate and has been verified; and then, as needed, adjusting that device to meet the manufacturer's specification.

Maintenance is the activities performed to maintain the functional status of a medical device before (preventive maintenance) or after (corrective maintenance) its failure.

Installation is the process performed to assemble or adjust a medical equipment and its components to put it in service.

Storage is the storing of medical devices up to the point of use

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

5. General principles

All parties engaged in the supply chain of medical devices have the responsibility to ensure that the safety and performance of devices are maintained throughout the distribution process including storage and handling from the site of the manufacturer to end users.

The principles of good storage practice (GSP) and good distribution practices (GDP) are also applicable to medical devices those are conveyed back anywhere in the supply chain including from the point of use to manufacturers site for the purpose of corrective measures or destruction. The same principles of GSP & GDP should be applied to donated medical devices. The product owner should create awareness for all relevant parties who are directly or indirectly involved in the storage and distribution processes so that they practice in due diligence manner in accordance with procedures relating to traceability and in recognition of products safety risks.

The establishment and implementation of good storage practices and good distribution practices by an organization is dependent on the types; categories and classification of medical device; size and structure of the establishment; the processes it deals with as well as the nature and the range of the medical device and supply-chain activities. If any requirement of this guideline is not applicable due to any of these reasons, the organization should provide justification for exclusion from fulfilment of that requirement.

The establishment and implementation of good storage practices and good distribution practices by an organization is dependent on the types, categories and classification of medical device, size and structure of the establishment, the processes it deals with as well as the nature and the range of the medical device and supply-chain activities. If any requirement of this

guideline is not applicable due to any of these reasons, the organization should provide justification for exclusion from fulfilment of that requirement.

6. Quality Management System

6.1 General

All parties engaged in the storage and distribution of medical devices should establish, document, implement and maintain a quality management system applicable to the type of activities involved and maintain its effectiveness that is adequately robust to meet the requirements set out in this guideline and other EFDA published documents.

Where an organization chooses to outsource any activity that may affect the quality of medical devices during storage and distribution, it must ensure control over such processes.

6.2 Organization

The organization should:

a) define its organization`s structure demonstrated by an organizational chart and indicate the responsibility, authority and interrelationship of all key personnel who have roles in the handling, storage and distribution activities.

b) define the duties and responsibilities of its personnel with written job descriptions for every level of organization

c) ensure managerial and technical personnel have the authority and resources needed to carry out their duties; and

d) set up and maintain a GSP & GDP that complies with the regulatory requirements

e) establish a system for identifying and correcting deviations from the established system

6.3 Documentation requirements

a. General

The firm should identify the structure and level of detail required for its documentation system that would be adequate to serve the intended purpose based on its organization need; volume & types of devices handled, stored and distributed; the skills and qualifications of personnel involved in the activities. If necessary, the procedures or instructions may be presented in a form of text, graphic or audio-visual.

The documentation should include:'

- Quality manual
- Documented procedures required by the GSP & GDP guideline
- Documents needed by the organization to ensure the effective planning operation and control of its processes
- Records required by the GSP and GDP
- Any other documentation specified by the authority

All documented requirements, procedures and activities should also be implemented and maintained.

b. Quality manual

The organization should document a quality manual that outlines the structure of the documentation used in the QMS and that encompasses:

a) the scope of its quality management system

b) the documented procedures for the QMS, or reference to them

c) a description of the interaction between the processes of the QMS

c. Control of documents

Documents required by GSP and GDP should be controlled. Documented procedure should be established for the control of documents.

The organization should identify documents required by the QMS and should establish & maintain a suitable control procedure to ensure their accuracy, availability, legibility and traceability. All requirements and documented procedures should be implemented and maintained. The firm's procedure should:

a) ensure that documents reviewed for adequacy and approved prior to issue
b) ensure that changes to documents are reviewed, updated as necessary and re-approved prior to use
c) define ways to identify the current revision status and changes made to documents
d) Ensure availability of relevant versions at points of use
e) Ensure that documents remain legible and readily identifiable
f) Define how documents of external origin, that are necessary for the QMS, are identified and controlled
g) Define how to prevent deterioration or loss of documents

h) Define how to identify obsolete documents and prevent their unintended use

i) Define for how long (at least a copy of) obsolete documents should be retained.

Note: Documents related to manufacturing and testing of medical devices should be available for at least the lifetime of the medical device.

d. Control of records

Every firm engaged in the distribution and storage of medical devices should have a system that enables it to maintain all records required to illustrate their compliance to the article 69(1) of proclamation 1112/2019. Where an electronic records system is used in place of a paper-based system, the system utilised should have built-in checks and balances to ensure the integrity of the records and to protect against unauthorised entries. The system should also incorporate audit trails for tracking changes. The firms should have documented procedures for control of records that defines:

- the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records
- how to make records be legible, readily identifiable and retrievable
- how to make changes to a record remain identifiable

Firms should retain the records for

- at least the lifetime of the medical device as defined by the manufacturer, or
- as specified by relevant EFDA legislative documents,
- not less than two years from the medical device release by the manufacturer.

Whichever is the longest.

7. Quality risk management

Firms should establish a system to assess, control, communicate and review risks identified at all stages in the supply chain of medical devices during under their control. The identification and evaluation of risk should be based on scientific knowledge and experience and ultimately be linked to the protection of the patient. Appropriate mitigation controls should be developed and implemented to address all risks. The effectiveness of the implemented controls should be evaluated at periodic intervals.

8. Self-audit

Firms should conduct internal audits at planned intervals (at least bi-annually) to monitor the implementation of and compliance with the requirements of GSP & GDPs.

It should ensure that its internal audit procedure defines the responsibility and requirements for planning and conducting internal audits and reporting results and maintaining the audits records.

Actions to eliminate detected nonconformities and their causes should be taken without undue delay. Verification of the actions taken, and the reporting of verification results should be recorded.

9. Management review

Firms should have procedure and a plan to conduct periodic management review (at least once per annum). The review should be led by the senior management of the firm and agenda should include at least:

a) Follow-up on recommendations from previous management review meetings. This should address major recommendations, implementation statuses as per recommendation, any pending action items.
b) review of the suitability & effectiveness of quality policy and quality objectives. This can measure by quality metrics and key performance indicators.
c) Reports from internal and external audits
d) reports from regulatory noncompliance
e) customer feedback, complaints, evaluation of compliance, corrective actions etc and
f) opportunities for continual improvement

The records of minutes and related documentation from management review meeting should be retained.

10. Complaints

The Firm should retain documented procedure for the handling of complaints. The procedure should specify:

a) How distinction between complaints about a medical product or its packaging and those relating to distribution should be made

b) Informing cases of a complaint about the quality of a medical product or its packaging to relevant entities such as the original manufacturer, marketing authorization holder, regulatory bodies
c) about timely investigation and identification of the root cause
d) how to prepare, implement and evaluating effectiveness of CAPAs
e) how to differentiate medical product quality problems and suspected cases of substandard or falsified products and how to handle such cases and sharing information with manufacturer and appropriate national and/or regional regulators

The firm should retain records of all complaints and where required, share the information with the authority.

11. Returned goods

A medical device should be considered as a 'returned good' once it has left the premises of the supplying establishment and subsequently returned to that premises. This may include the following:

a) where an establishment supplies a customer with the incorrect medical device which is subsequently returned
b) where a customer returns a medical device to an establishment which they ordered in error
c) where a product is received back to the premises of an establishment having never been received by the customer

The firms should retain documented procedure for receiving, storage, and disposition of returned medical devices. The procedures should ensure that medical devices returned to the firm are identified and distinguished from conforming product. All returned medical devices should be:

a) placed in quarantine upon receipt with clear status of the goods
b) stored in a manner that prevents access and distribution until a decision has been taken
c) stored as per the manufacturer recommended storage conditions applicable to the specific medical device
d) destroyed unless it is certain that their quality is satisfactory, after they have been critically assessed and necessary corrections are made in accordance with a written and authorized procedure.

When firms receive a returned goods, they should dedicate separate storage area to avoid risk of mixing the returned goods to saleable stock prior to assessment. This separate area should be clearly segregated from saleable stock (by physical means or by a validated computerised system).

When handling returned goods, firms should follow a risk-based process when deciding on the fate of the returned goods. They should be extremely cautious in their assessment of the suitability of the returned medical device to be placed back into saleable stock or reissued to the customer. They should provide, where possible, additional unique identifiers for such products before placing back into saleable stock to distinguish between the returned product and the remainder of the stock. The recipients of the returned goods must be extremely confident that the quality of the product has not been affected in any way whilst the product has been out of their care. It should ensure that the correct storage conditions have been maintained during the period the product was outside of their control. Recipients and its relevant staff members should be aware of the potential for falsified medical devices to enter the supply chain through the returns process. Seller entity should verify the safety features (the unique identifier or anti-tampering) for all returned medical devices. If the verification of the safety features results in suspicion over the authenticity of a product, it should be immediately quarantined, and the authority or relevant regional regulatory body should be notified and an investigation into the issue conducted. Attentions should be given to the time period elapsed since the product was dispatched and initiation of the return request. Vendors should have a predefined time period for accepting products returned from their customers in cases where an incorrect order has occurred or in the instance of an incorrect or failed deliver.

Hence, at least the following should be considered before deciding on the fate of returned medical devices:

a) the nature of the product, storage conditions, condition of the product history, time-lapse since distribution and the manner and condition of transport while being returned.
b) the terms and conditions of the agreement between the establishment and customer
c) examination of the returned goods and decisions to be taken by a competent and authorized person.
d) Personnel involved in the returns process have received appropriate training and have sufficient experience in relation to the handling of such products and have ability to identify falsified medicinal products.

After decision has been taken, the products to be rejected should be placed into a reject area and disposition of products should be done in accordance with waste management and disposal directive of EFDA, international, national and other local requirements regarding disposal or decommissioning of such medical devices, and with due consideration to the protection of the environment.

The firms should retain records of all stages of the return process of all returned, rejected and destroyed medical devices and keep it for a period equivalent to the expected life of the device, but in no case less than 2 years from the date of making final decision. This documentation should allow all stages of the returns process to be traced including the person conducting each activity. Firms should present information and supporting documentation relating to returned goods to EFDA inspector in a concise and consolidated manner. There should be a register or log of returns in place which should include all product details and reasons for return. The assessment performed on returned product should be documented and should include the final disposition. the release of returned medical device to saleable stock should formally approved by an authorized person.

12. Recalls

12.1 General

EFDA has the authority to order recall of any regulated product and cease distributions in cases of in contravention of applicable laws and, when the use or exposure to the product will have adverse health consequences. Firms engaged in the storage and distribution of medical devices should retain a written recall procedure in place in accordance with relevant efda`s pharmaceutical recall directive No. 30/2010 and guideline for medical devices recall. It should ensure that the procedure allows the immediate and effective recall from the marketplace of defective and/or potentially harmful medical devices.

12.2 The recall procedure

The recall procedure should include, at a minimum, the following:

- designated responsible person and his/her clear role
- other designated responsibilities for coordination of the recall action
- contact numbers for the company and the authority
- requirement to discuss with relevant parties

- requirement to notify and agree any action with the authority before recall action is carried out
- the various classifications of a recall based on risk
- description of the traceability system and method of identification of product
- recipients within the distribution chain
- method of handling recalled medical device
- arrangements to ensure segregation of recalled medical devices from saleable product
- arrangements for return of recalled medicinal product to the MA holder or for destruction
- investigation and reconciliation report to be sent to the MA holder
- details of steps to be followed in the event of a quality defect being discovered on-site

The effectiveness of the recall procedure should be regularly challenged (at least once per year) to ensure that the process is effective and capable of tracing all customers and products in the event of a recall in a timely manner and updated as necessary. This challenge should take account of the complexity of wholesaler operations and should be carried out on a risk-basis. A challenge to the recall system need not be carried out where the company has participated in an actual recall during the previous year which has utilised the same traceability system. The effectiveness of all recalls (including recalls to challenge the system and actual recalls) should be evaluated after the recall has concluded. Where the review of effectiveness identifies gaps in the process, those gaps should be appropriately addressed in a timely manner and the recall procedure revised accordingly.

There should be an efficient and effective method for identifying customers supplied with a product subject to a recall along with templates of forms and letters for the execution of a recall.

12.3 Handling recalled product

All recalled medical devices should be kept secure, segregated, transported and stored under appropriate conditions applicable to the specific device and clearly labelled as “recalled products”.

Recipients of recalled products should identify a batch of a product and reconcile quantities received with those in stock and distributed to customers.

12.4 Information sharing & records

The Authority and/or regional regulatory authority, original manufacturer and/or marketing authorization holder, or other relevant contract party should be informed in the event of a recall. The authority may promptly inform competent authorities of other countries to which a given medical product may have been distributed based on the risk of the recalled product.

All records, including distribution records, should be readily accessible to the designated person(s) responsible for recalls. These records should contain enough information on products supplied to customers

The progress of a recall process should be recorded, and a final report issued, which includes a reconciliation between delivered and recovered quantities of medical devices.

13. Premises

13.1 General

a) Firms engaged in the storage and distribution of medical devices should have a premise that is suitably located, designed, constructed and maintained, to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of medical devices.
b) Storage areas should have adequate space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness.
c) Enough security should be provided, and access should be controlled.
d) Appropriate controls and segregation should be provided for products
e) requiring specific handling or storage conditions, such as radiation emitting medical devices, products containing hazardous substances and products to be stored under controlled temperature and relative humidity conditions.
f) Receiving and dispatch bays should be provided to protect products from weather conditions.
g) Activities relating to receiving and dispatch should be done in accordance
h) with written procedures and the areas should be suitably equipped for such
i) operations.
j) Premises should be kept clean and the cleaning equipment and cleaning agents should not become possible sources of contamination.
k) A rodent and pest control programme should be in place and the premises should be protected from the entry of birds, rodents, insects and other animals.

l) Toilets, washing, rest and canteen facilities should be separate from areas where products are handled. Eating, drinking and smoking should be prohibited in all areas where medical products are stored or handled.

13.2 Receiving area

a) The firm should retain documented procedure accompanied by a checklist for verifying all incoming delivery against the relevant documentation, to ensure that the correct product is delivered from the correct supplier. This may include, but not limited to:

- the purchase order,
- containers,
- packing list,
- accessories,
- label description,
- batch number,
- expiry date,
- quantity

b) Receiving area should be provided with receiving bay

c) Receiving areas should be of adequate space to allow inspection and cleaning of incoming medical devices

d) The consignment should be inspected for any visible damage, possible contamination, tampering, uniformity of the containers, quantity, supplier's batch number; transportation temperature data (example cold-chain materials), and other relevant information and records should be maintained.

e) There should be separate space for quarantining any defective product or suspect containers, or the entire delivery while waiting for investigation and decisions are taken.

f) The firm should dedicate adequate and appropriately clean space and tools for sampling of medical devices. If the firm take samples of medical products; it should ensure that

- a representative number of containers in a consignment are sampled and checked,
- sampling is undertaken by appropriately trained and qualified personnel
- containers from which samples have been taken are labelled
- all activities are undertaken in accordance with a written sampling procedure and sampling plans.

g) Following sampling, the goods should be subject to quarantine. Batch segregation should be maintained during quarantine and all subsequent storage.

h) Proper care should be taken to ensure materials and products requiring controlled conditions of temperature and relative humidity during transport and storage, as applicable, are handled as a priority item during receiving.

i) Firm should have a mechanism for release control and authorizing medical products transfer to saleable stock

j) Proper space should be provided for segregating and securely storage of devices awaiting destruction or return to the supplier and care should be taken to ensure that such medical products cannot be used.

13.3 Storage areas

a) The firm should design, construct, maintain or adapt appropriate storage area for the medical devices to be handled. The storage areas should be of sufficient capacity to allow orderly storage of the various categories of medical device, maintained clean and there should be sufficient space and lighting.

b) There should be a mechanism in place for preventing unauthorized persons entrance to the storage areas. List of names of authorized people to enter storage areas should be provided.

c) Storage areas should be maintained within acceptable and specified temperature limits. Where the labels show special storage, conditions are required (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded.

d) Medical devices should be stored off the floor (unless supplied with stands or wheels by design), away from walls and ceilings, protected from direct sunlight and suitably spaced, to permit ventilation, cleaning and inspection. Suitable pallets should be used; as appropriate and kept in a good state of cleanliness and repair.

e) The firm should maintain documented procedure for storage area management including cleaning (the frequency of cleaning and the methods to be used) as well as afire control (prevention of fire, fire detection and fire drills), and all relevant records should be retained as necessary.

f) Any system (e.g. computerized systems) replacing physical separation and labelling, or demarcation should be validated to demonstrate security of access.

g) When sampling is necessary, it should be done under controlled conditions and conducted in such a way that there is no risk of contamination or cross-contamination. Adequate cleaning procedures should be followed after sampling.

h) Firms should store all devices in conditions that assure that their quality is maintained, and stock should be appropriately rotated.

i) The firm should provide area for storage of broken or damaged items which should be withdrawn from usable stock and stored separated.

j) The firm should provide adequate fire-detection and firefighting equipment as appropriate (based on the type of devices and store are) and the equipment should be serviced regularly.

13.4 Storage conditions

a) All medical devices should be stored in compliance with their labelling and information provided by the manufacturer.
b) The firm should establish a procedure for appropriate designing, installation, qualification and maintenance of, HVAC systems to ensure that the required storage conditions are upheld.
c) The firm should do for temperature, and relative humidity Mapping studies where appropriate, for example in storage areas, refrigerators and freezers
d) Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded, and the records should be reviewed. The equipment used for monitoring should be calibrated and be suitable for its intended use. All records pertaining to mapping and monitoring should be kept for a suitable period of time and as required by national legislation.

14. Stock control and rotation

The firms should maintain documented procedure for stock control and rotation. It should also retain up to dated records of stock levels for all medical devices in store after each operation (e.g. entries, issues, losses, adjustments). These records should include:

a) periodic stock reconciliation (performed at defined intervals)
b) root cause for stock discrepancies (if any)
c) CAPAs taken to prevent recurrence of discrepancies
d) damaged containers received (if any) and actions taken
e) List of Items identified as close to their retest or expiry date and or removed from useable stock (due to expiry).

15. Qualification and validation

The firm should establish and maintain documented procedure for qualification and validation; where appropriate, based on risk management principles. The procedure should define the scope and extent of qualification, and validation. Such activities should consider premises, utilities, equipment and instruments, processes and procedures.

Qualification and validation should be done following procedures and protocols. The results and outcome of the qualification and validation should be recorded in reports. Deviations should be investigated, and the completion of the qualification and validation should be concluded and approved.

16. Personnel

a) Firms should possess an adequate number of personnel with appropriate educational qualification, experience and training relative to the activities undertaken.
b) There should be a designated person within the organization, with appropriate qualification and training, who has the defined authority and responsibility for ensuring that a quality management system is implemented and maintained. This person should preferably be independent from the person responsible for operations and should ensure compliance with GSP and GDP.
c) Personnel should have the authority and resources needed to carry out their duties and to follow the quality systems, as well as to identify and correct deviations from the established procedures.
d) The firm should ensure that its management and personnel are not subjected to commercial, political, financial or other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of medical devices.
e) Safety procedures should be in place relating to all relevant personnel and property, environmental protection and product integrity.
f) Personnel should receive initial and continued training in accordance with a written training programme. The training should cover the requirements of GSP and GDP (as applicable), personal hygiene and sanitation as well as other on-the-job trainings such as product security, product identification and the detection of falsified products.
g) Personnel dealing with special types of medical devices (e.g. IVDs, radiation emitting devices) should be given specific training.
h) Records of all training, attendance and assessments should be kept.
i) Personnel handling medical devices should wear garments suitable for the devices they handle and the activities that they perform.
j) There should be a clear procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to medical devices

k) The firm should develop and implement codes of practice and procedures to prevent and address situations where persons involved in the storage and distribution of medical devices are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or falsification of any product. It should notify the authority and other relevant agencies if such unethical conducts are observed.

17. Activities and operations

All activities and operations should be conducted in accordance with the country`s relevant legislations, this guideline and other relevant guidelines as well as firm`s documented procedures.

Firms should assign authorized persons to ensure proper storage and distribution of medical products in accordance with written procedure.

17.1 Receipt

Firms should procure raw materials or finished medical devices only from appropriately authorized suppliers. It should examine deliveries for damage, seal intactness, signs of tampering, labelling, completeness of order and other related aspects (e.g. availability of a certificate of analysis, where applicable), at the time of receiving.

Containers and consignments that do not meet acceptance criteria at the time of receipt should be labelled, kept separate and investigated. This includes suspected substandard and falsified products.

17.2 Storage

Medical devices requiring specific storage conditions should be processed without delay and stored in accordance with their requirements.

Appropriate controls should be implemented to prevent contamination and/or mix-ups during storage.

Controls and procedures should be in place to prevent and handle spillage and breakage.

17.3 Repackaging and Relabeling

The authority does not encourage repackaging and relabelling of medical devices. Where repackaging and relabelling must occur, these activities should only be performed by entities

appropriately authorized to do so and in compliance with the authority's relevant directive(s) for repacking and in accordance with cGMP requirements.

Procedures should be in place for the controlled disposal of original packaging, to prevent re-use thereof.

17.4 Distribution and transport

Medical devices should be transported in accordance with the conditions stated on the labels and described by the manufacturer. The risk to the quality of the medical device during transport and distribution should be eliminated or minimized to an acceptable level. Product, batch, and container identity should be always maintained, and all labels should remain legible. Distribution records should be sufficiently detailed to allow for a recall when required. The vehicles used for transportation should be identified and the drivers should present appropriate documentation to demonstrate that they are authorized to transport medical devices. Vehicles should be suitable for their purpose, with sufficient space and appropriately equipped to protect medical device. The design and use of vehicles must aim to minimize the risk of errors and permit effective cleaning and/or maintenance, to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the products. Where required and appropriate, the vehicles should be provided with shock absorbers when transporting fragile medical devices.

The firm should establish and implement standard procedures for the distribution and transporting of medical devices about selection of appropriate vehicles. Appropriate environmental conditions should be maintained, monitored, and recorded during transportation of sensitive devices. Instruments (data loggers) used for monitoring conditions, for example, temperature and humidity, within vehicles and containers should be calibrated at regular intervals. Such monitoring records and calibration certificates should be kept at least for two years and made available for inspection by the authority`s inspectors.

Rejected, recalled, and returned products, as well as those suspected as being falsified, should be securely packaged, clearly labelled, and accompanied by the appropriate supporting documentation.

Shipment containers should have no adverse effect on the quality of the medical devices and should offer adequate protection to the devices. Containers should be labelled indicating, for example, handling and storage conditions, precautions, source, and safety symbols, as appropriate.

Special cares should be taken when using dry ice and liquid nitrogen in shipment containers, owing to safety issues and possible adverse effects on the quality of medical products. Written procedures should be available for the handling of damaged and/or broken shipment containers or broken medical devices.

The firm should use lifting equipment for proper loading and unloading of medical devices without damage to the device.

17.5 Dispatch

There should be documented, detailed procedures for the dispatch of Medical devices.

Firms should ensure that medical devices are only sold and/or distributed to persons or entities that are authorized to acquire such products. They should retain copies of written proof of such authorization or special permit obtained prior to the distribution of products to such persons or entities.

Dispatch and transportation should be undertaken only after the receipt of a valid order, which should be documented. Records for the dispatch of products should be prepared and should

include information such as, but not limited to:

- date of dispatch.
- complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number, names of contact persons; status of the addressee (e.g. retail pharmacy, public hospital or community clinic, private health institution);
- a description of the products,
- quantity of the products, i.e. number of containers and quantity per container (if applicable);
- applicable transport and storage conditions.
- a unique number to allow identification of the delivery order; and
- assigned batch number and expiry date (as appropriate)

Records of dispatch should contain sufficient information to enable traceability of the devices. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of falsified or potentially falsified products. In addition, the assigned batch number and as appropriate the expiry date of medical devices should be recorded at the point of receipt, to ensure traceability.

Vehicles and containers should be loaded carefully and systematically on a last-in/first-out (LIFO) basis, to save time when unloading, to prevent physical damage and to reduce security risks. Extra care should be taken during loading and unloading of fragile medical devices to avoid breakage. Outdated technology medical devices and expired or so close to the expiry date should not be supplied or received.

Medical devices and shipment containers should be secured to prevent or to provide evidence of unauthorized access. Vehicles and operators should be provided with additional security where necessary, to prevent theft and other misappropriation of the devices during transportation.

Medical devices should be stored and transported in accordance with procedures such that:

- the identity of the devices is not lost.
- the device does not contaminate and is not contaminated by other products.
- adequate precautions are taken against spillage, breakage, misappropriation, and theft; and
- appropriate environmental conditions are maintained, for example, using cold chain for thermolabile reagents.

Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, for example, temperature deviations. If a deviation has been noticed during transportation, by the person or entity responsible for transportation, this should be reported to the supplier, distributor, and recipient. In cases where the recipient notices the deviation, it should be reported to the distributor and retain copies of such communications.

Transportation of products containing hazardous devices (e.g. radiation emitting devices), should be transported in safe, suitably designed, secured containers and vehicles in compliance with the requirements of applicable international agreements and relevant Ethiopian laws.

Spillages or broken parts should be cleaned up as soon as possible to prevent hazards and there should be a written procedure in place for the handling of such occurrences.

Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant agencies and/or the authority and investigated. The outcome of such investigation should be recorded and retained. Any medical device in transit must be always accompanied by the appropriate documentation.

18. Outsourced activities

Firms should have a documented procedure for outsourcing any activity relating to the storage and distribution of a medical devices. Such outsourcing activity should be performed by the appropriately authorized parties, in accordance with relevant Ethiopian legislation and the terms of a written contract.

There should be a written contract between the entities which defines the responsibilities of contract giver and contract acceptor. The contract should cover at least the following:

- compliance with this guideline and the principles of GSP and GDP;
- the responsibilities of all entities for measures to avoid the entry of substandard and falsified medical devices into the distribution chain.
- training of personnel
- conditions of subcontracting subject to the written approval of the contract giver; and
- periodic audits

The contract giver should assess the contract acceptor before entering into the contract, e.g. through on-site audits, documentation and licensing status review.

The contract giver should provide to the contract acceptor all relevant information relating to the medical devices to be stored or distributed.

The contract acceptor should have adequate resources (e.g. premises, equipment, personnel, knowledge, experience and vehicles, as appropriate) to carry out the work.

The contract acceptor should refrain from performing any activity that may adversely affect the medical devices to be handled.

19. Substandard and falsified medical devices

The quality system established and maintained by the firm should include procedures to assist in identifying and handling medical devices that are suspected to be substandard and/or falsified. Where such medical products are identified, the firm should immediately inform the holder of the marketing authorization, the manufacturer, and the authority, as well as other relevant national authorities.

Such medical devices should be stored in a secure, segregated access-controlled area and clearly identified to prevent further distribution or sale.

The firm should ensure that the falsified products will not re-enter the market and it should

retain records reflecting the investigations, findings and action taken, such as disposal of the product.

20. Medical device disposal

Disposal of medical devices should be controlled such that they cannot re-enter the supply chain. All medical devices that are rejected in-house, rejected when received as a return from a customer or recalled stock should, if instructed accordingly, be destroyed in an appropriate and timely manner and in accordance with waste legislation and any associated manufacturer instructions as provided in the product labelling and instructions for use. The firm should consult with the manufacturer and responsible local agencies such as radiation authority and/or environmental protection agency if required. The decision to dispose of medical devices should be documented and recorded.

There should be an inventory of medical devices placed into waste. Records and certificates of destruction should be maintained. When disposal service is provided by a third party, service level agreements should be in place with the third-party contractors.

21. Inspection of storage and distribution facilities

The firm should cooperate with and provide all required information during inspection of its storage and distribution facilities by inspectors of the authority. This may be done at determined, periodic intervals or as surprise visit. Inspections will be undertaken to assess compliance of the firm`s operations with national legislation, GSP, GDP and other related guidelines as appropriate. It will cover the premises, equipment, personnel, activities, quality system, qualification and validation and other related aspects, as contained in this guideline.

An inspection report prepared by the authority, containing observations categorized based on risk assessment, will be provided to the inspected entity within a defined period from the last day of the inspection.

The inspected firm should prepare CAPA for observations listed as non-compliances in the inspection report and submitted for review to the authority within the defined period, as requested by the inspectors but not exceeding one month period from the date of receipt of the report. Inspections should be closed with a conclusion after the review of the CAPAs.

References

1. WHO Good storage and distribution practices for medical Products, Annex 7, WHO Technical Report Series 1025, 2020.
2. Medical devices quality management systems requirements for regulatory purposes, ISO 13485:2016
3. Guidance notes on good distribution practice, Regulatory guidance, March, 2021, Health Science Authority, Singapore.
4. Good distribution practice for Medical devices(GDPMD), Regulatory requirements for medical device safety and performance, MDA/RR No. 1, Nov, 2015, 1st edition, Malaysia
5. Guide to Good distribution Practices for medicines products for human use, March, 2021, HPRA (Irish).