



MEDICINES CONTROL AGENCY

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GUIDELINE FOR STORAGE AND DISTRIBUTION OF MEDICINES AND RELATED PRODUCTS

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1 INTRODUCTION

1.1 LEGAL BASIS

- 1.1.1. The regulation of medicines in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 (“Act”), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.
- 1.1.2. Part II Section 4 (b) of the Act requires that the Agency regulates the storage and distribution of medicines and related products.
- 1.1.3. The Medicines and Related Products Regulations, 2019 (“Regulations”) details the legal requirements.
- 1.1.4. This guideline supports the implementation of the Pharmacy Council Act, 2014 and National Medicines Policy (2007).

1.2 INTERPRETATION AND ABBREVIATIONS

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: www.mca.gm

1.3 PURPOSE AND SCOPE

- 1.3.1. In pursuance of the law this document provides guidance to all persons involved in the supply chain management which includes storage, transportation and distribution of medicines and related products in both the public and private health sector.
- 1.3.2. The regulation of storage and distribution contributes to maintain the safety, quality and efficacy of medicines and related products at the time it reaches the user.
- 1.3.3. This guideline applies to medicines and related products as defined in the Act and the Regulations.

2 QUALITY MANAGEMENT

- 2.1. The quality system should include an appropriate description of the roles and responsibilities, procedures, processes and resources, as well as systematic actions necessary to ensure that requirements for quality are met. The totality of these actions is described as the quality system.
- 2.2. A designated person should be appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained.
- 2.3. The quality system should include provisions to ensure that the holder of the marketing or import authorization, entity identified on the label (if different from the manufacturer) and the MCA would be informed immediately in a case of confirmed or suspected substandard or falsified medicinal or related product. Such products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale.

- 2.4. Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies are recommended. Such certification should not, however, be seen as a substitute for compliance with this guideline and the applicable good practices guidelines relating to medicines and related products.
- 2.5. Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of medicines and related products. The quality system should be developed and implemented to address any potential risks identified. The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment.

3 PERSONNEL

- 3.1. There should be an adequate number of competent personnel involved in all stages of the storage and distribution of medicines and related products in order to ensure that the quality of the products is maintained.
 - 3.1.1. At the Central Medical Stores (CMS), personnel shall include
 - Supervising Pharmacist
 - Storekeeper
 - Logistics/clearing officer
 - Store hands
 - 3.1.2. At the Wholesales/ Regional Medical Stores (RMS)/Hospital, personnel shall include
 - Pharmacist
 - Storekeeper
 - Store hands
 - 3.1.3. At the Major Health Centres/ Drug Stores, personnel shall include
 - Pharmacy Technician
 - Store hand
 - 3.1.4. At the Minor Health Centres personnel shall include
 - Dispensing Assistant/ Nurse in- charge
- 3.2. All personnel should be adequately trained in:
 - Quality Assurance
 - Safety at work place
 - Good Storage and Distribution Practices
 - Regulatory requirements
 - Logistic Management Information System (LMIS)

- 3.3. Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality system, as well as to identify and correct deviations from the established quality system.
- 3.4. Personnel should receive initial and continuing training relevant to their tasks.
- 3.5. Personnel dealing with hazardous products (such as radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous products, as well as products presenting special risks of abuse, fire or explosion) should be given specific training.
- 3.6. Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.
- 3.7. Personnel employed in storage areas should wear suitable protective or working garments appropriate for the activities they perform.
- 3.8. Codes of practice and punitive procedures should be in place to prevent and address situations where persons involved in the distribution of medicines and related products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product.

4 PREMISES AND EQUIPMENT

4.1 GENERAL REQUIREMENTS

- 4.1.1. Distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicines and related products.
- 4.1.2. Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of medicines and related products including products in quarantine and released, rejected, returned or recalled products.
- 4.1.3. Storage areas should be maintained in a clean, dry state and maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, checked, monitored and recorded.
- 4.1.4. Medicines and related products should be stored off the floor and suitably spaced to permit cleaning and inspection.
- 4.1.5. Pallets should be kept in a good state of cleanliness and repair.
- 4.1.6. The manufacturer or shipper's directions should be followed when stacking and for storage conditions.
- 4.1.7. All products should be stored in a secure place (see Section 6.9).

- 4.1.8. Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place (see Section 6.9).
- 4.1.9. As additional protection against theft, items that are fast moving, in short supply, in high demand by customers, expensive, lifesaving, and easy to hide or disguise should be monitored regularly.

4.2 ARRANGEMENT OF STOREROOM

- 4.2.1. The storerooms and shelves should be arranged as follows:

If pallets are used, stack cartons on pallets:

- at least 10 cm off the floor;
- at least 30 cm away from the walls and other stacks; and
- no more than 2.5 m high (general rule).

- 4.2.2. Liquid products should be placed on the lower shelves.
- 4.2.3. Cartons should be arranged so that arrows point up and identification labels, expiry dates, and manufacturing dates are visible.
- 4.2.4. Products that require cold storage should be stored in appropriate temperature controlled areas (see below).
- 4.2.5. Damaged or expired products should be separated from the usable stock without delay and documented. This should be communicated with Directorate of National Pharmaceutical Services (DNPS) for further action that needs to be taken, and for the private sector, the MCA should be contacted.

4.3 ORDERLY ARRANGEMENT OF PRODUCTS

- 4.4.1. Medical stores must have a system for classifying or organizing medicines and related products, and must ensure that all employees know the system being used.
- 4.4.2. Some common systems for arranging medicines include:
 - ***Alphabetical order by generic name:*** Often seen in both large and small facilities.
 - ***Therapeutic or pharmacologic category:*** Most useful in small storerooms or dispensaries.
 - ***Dosage form:*** Medicines come in different forms, such as tablets, syrups, injectables, and external use products such as ointments and creams. In this system, medicines are categorized according to their dosage form. Within the area for each form, a fixed, fluid, or semi-fluid system is used to store items.
Any of the other methods of categorizing can be used to organize the items more precisely.

4.4 HUMIDITY AND TEMPERATURE CONTROL

Humidity

- 4.4.1. When product labels state “protect from moisture,” the product should be stored in a space with no more than 65% relative humidity.
- 4.4.2. To reduce the effects of humidity the following should be considered:
 - Ventilation:
 - Open the windows or air vents of the storeroom to allow air circulation given that all windows have screens to keep out insects and birds, and either have bars or are not open wide enough for anyone to climb in.
 - Place boxes on pallets and ensure there is space between pallets and the walls of the storeroom.
 - Packaging:
 - Secure all lids;
 - Do not open a new container unless necessary.
 - Circulation:
 - Use a fan to circulate fresh (outside) air, preferably a ceiling fan. Standing fans may be useful in smaller storerooms.
 - Use air conditioners, if possible, especially in the CMS, RMS and wholesales/hospital stores.

Temperature and Light

- 4.4.3. Some medicines or related products are photosensitive and will be damaged if exposed to light. These include but are not limited to; multiple vitamins, furosemide, chlorpheniramine maleate, hydrocortisone, latex products (e.g. condoms), x-ray films, etc.
- 4.4.4. To protect products from sunlight the following should be considered:
 - Keep direct sunlight out of the storeroom by shading the windows or using curtains.
 - Keep products in cartons.
- 4.4.5. Heat affects many products. It melts ointments, creams and suppositories, and causes other products to become less effective. The points listed above for protecting products from humidity and sunlight will also help protect products from heat.
- 4.4.6. The points listed above for protecting products from humidity and sunlight will also help protect products from heat.

4.5 SPECIFIC STORAGE REQUIREMENTS

- 4.5.1. Items labeled to be stored at “Room or Ambient temperature” require:
 - Storage at 15° – 30°C
- 4.5.2. Items labeled “Keep cool” require:

- Storage between 8°–15°C (e.g. oxytocin, heparin injection, etc).
- 4.5.3. Items labeled “Store at 2°–8°C” require:
 - Storage in a refrigerator/cold room at 2°–8°C (see Section 6.6)
- 4.5.4. Some products are very heat sensitive but must not be frozen. Items labeled “Store at 2°–8°C, do not freeze”:
 - Storage usually in the first and second part of the refrigerator at 2°–8°C (never the freezer) (see Section 6.6)
- 4.5.5. Some products, such as certain vaccines, need to be transported within a cold chain and stored in a freezer. Frozen storage is normally for longer-term storage at EPI stores. Items labeled “Store frozen” require:
 - Storage at –20°C.

4.6 REFRIGERATORS AND FREEZERS

- 4.6.1. Refrigerators/Freezers that open on the top should be used, especially in the CMS, RMS and wholesales/hospital stores, because they are more efficient than vertical ones, since hot air rises while cold air falls.
- 4.6.2. The following arrangements should be observed:
 - Place products that are sensitive to freezing or very low temperatures on the upper shelves of vertical refrigerators as the coldest part is at the bottom.
 - There should always be enough frozen icepacks to transport items requiring cold storage in cold boxes and/or vaccine carriers. Use only icepacks filled with water. Icepacks prefilled with other liquids, which are usually blue or green, should not be used.
 - If there is enough space, place a few plastic bottles of water in the refrigerator. This helps to maintain the temperature for a longer period of time, if the power is cut off.
 - Place refrigerators and freezers with space between them and about an arm’s length away from the wall. This will increase the air circulation.
 - Under ideal conditions, rooms with multiple refrigerators and/or freezers should have air conditioning. Refrigerators and freezers generate large amounts of heat, which can damage the equipment over time.
 - If it is not possible to have air conditioning, install fans around the equipment to increase air flow. If installing fans, they should be placed so that the air also flows in the spaces behind the refrigerators.
 - Ideally, larger facilities should have a cold room rather than numerous refrigerators.

4.7 MONITORING TEMPERATURE AND HUMIDITY

- 4.7.1. Storage conditions for medicines and related products should be in compliance with the recommendations of the manufacturer.
- 4.7.2. Monitor the temperature and humidity, as applicable, of the different areas within the storeroom at least twice during working days. Place thermometers and hygrometers, if applicable, in various parts of the

storeroom to monitor temperature and humidity. For cold-chain products monitor the temperature at least twice every day.

- 4.7.3. The results of such checks should be recorded and retained. Records of temperature monitoring data should be available for review. All monitoring records should be kept for at least the shelf-life of the stored products plus one year.
- 4.7.4. Equipment used for monitoring should also be calibrated at defined intervals.
- 4.7.5. A system should be in place to ensure that in case of deviations from the storage requirements corrective and, if necessary, preventive actions will be performed.

4.8 PRODUCTS REQUIRING SPECIAL SECURITY

- 4.8.1. If products need increased security, an access-controlled storage should be established. This will probably include storing the products in a separate locked room, cabinet, or safe, or a locked wire cage within the storage facility.
- 4.8.2. Entry to the location of the access -controlled products must be limited to the most senior storekeeper or pharmacist and one other staff member.
- 4.8.3. The number of keys made for the controlled location should be limited and a list of people who have keys should be kept.
- 4.8.4. **Narcotics and other Controlled Medicines** are regulated according to international convention. These medicines need greater security ("lock and key"). There are specific procedures in place for the procurement, reception, storage, dispensing, and administration of controlled substances.
- 4.8.5. These products, that have a potential for abuse and addiction, need storage in an access-controlled, lockable area.
- 4.8.6. Typical examples are
 - Narcotics: morphine, opium preparations, pethidine, and tramadol.
 - Other opioid and strong analgesics: pentazocine, codeine, dihydrocodeine, dextropropoxyphene, dextromoramide, and buprenorphine.
 - Psychotropic drugs: e.g. benzodiazepines such as diazepam, temazepam, nitrazepam, flunitrazepam, oxazepam, and clonazepam, or barbiturates such as phenobarbital, thiopentone, pentobarbital, etc.
- 4.8.7. Other medicines, that are scarce and expensive including antiretroviral used to treat HIV/AIDS, may also need storage in a controlled facility.
- 4.8.8. Organizations **donating medicines** may require that those medicines be stored in a controlled environment. These may be products donated for a specific condition that can also be used for other conditions. For further details refer to the *Donation Guidelines for Medicines, Medical Supplies and Health Care Equipment in The Gambia*.

4.9 SECURITY AND SAFETY MEASURES

4.9.1. Prevention of physical damage:

- Crushing products stored in bulk should be avoided. Products should be stacked no more than 2.5m.
- Heavier or fragile items (such as those packaged in glass) should be placed in smaller stacks.
- Sharp edges or corners in the store should be bound with tape. Most important, it should be ensured that nothing in the store can fall and injure members of the staff.

4.9.2. Prevention and protection from fire:

- Smoking or open flames such as candles must be strictly prohibited in the store.
- Fire extinguishers should be available.
- Fire extinguishers should be inspected every 2–3 months to ensure that pressures are maintained and the extinguisher is ready for use.
- Fire extinguishers should be serviced at most every 12 months.
- Smoke detectors should be placed throughout the storage facility and checked every 2–3 months to ensure that they are working properly.
- The use of sand to extinguish fires may be considered where there are no fire extinguishers.
- Fire training should be conducted for every new staff and for all personnel every 12 months. This should include how to use fire extinguishers, where they are available.
- Emergency exits should be clearly marked and checked regularly to be sure they are not blocked or inaccessible.
- Fire precaution signs should be displayed in appropriate places in the storage facility and especially in locations where flammables are stored.

4.9.3. For protection against pests the following should be observed:

Inside the storage facility

- Design or modify the storeroom to facilitate cleaning and prevent moisture.
- Maintain the environment clean to prevent conditions that favour pests.
- Do not store or leave food in the storage facility.
- Keep the interior of the building as dry as possible.
- Keep all windows of the storage facility screened off from the outside.
- Paint or varnish wood, as needed.
- Make sure that there are no holes in the walls, floor, or ceiling.
- Seal all open spaces to prevent pests from entering the facility.
- Inspect the storage facility regularly for evidence of pests.
- Packaging and shipping cartons can be treated to prevent pest infestation.

- Facilities like CMS and RMS should regularly undergo professional pest control measures.

Outside the storage facility:

- Inspect regularly the premises to ensure they are clean and free of pests, especially areas where garbage is stored.
 - Check for any rodent burrows, and it should be ensured that garbage and other waste are stored in covered containers.
 - Check for still or stagnant pools of water in and around the premises, and ensure that there are no buckets, old tires, or other items holding water.
- 4.9.4. The environmental health unit or the vector control unit should be contacted for regular disinfestation.
- 4.9.5. For protection against pilferage during transportation of products the following should be observed:
- Use covered vehicle
 - Verify documents.
 - Ensure packing seals are used.
 - Use strong boxes/containers.
 - Provide reliable/well-maintained vehicles.
 - Ensure drivers and escorts are accountable.
 - Ensure rapid clearance at air and sea ports and through on-land borders.
- 4.9.6. For protection against pilferage at storage facilities the following should be observed:
- Limit access to only authorized staff.
 - Limit the number of keys made for the facility.
 - Keep a list of people who have keys and instruct them to keep keys secure.
 - Secure all locks and doors.
 - Make unannounced spot checks.
 - Provide independent stock count/inventory control.
 - Ensuring all windows either have bars or are not open wide enough for anyone to climb in.
- 4.9.7. For protection against pilferage at health facilities the following should be observed:
- Lock the storeroom/cupboards.
 - Provide keys only to the storekeeper and duplicates to officer in charge, and instruct them to keep keys secure.
 - Have inventory control cards for each product.
 - Ensure dispensers record individual prescriptions on daily consumption form and keep all dispensed prescriptions in a safe place.

- Limit unauthorized access to the stores.
- 4.9.8. For prevention of uncleanness the following should be observed:
- Ensure the storeroom has access to a water outlet for cleaning; the drums should be refilled regularly.
 - Sweep and mop or scrub the floors of the storeroom regularly.
 - Wipe down the shelves and products to remove dust and dirt.
 - Dispose of garbage and other waste daily, in a manner that avoids attracting pests.
 - Store garbage in covered receptacles outside the storage facilities.
 - Use appropriate detergents or other cleaning agents for cleaning.
 - Keep the outside of the facility clean
 - Gather the garden rubbish and empty cartons at the collection points for the health labourer to collect for disposal.

5 DOCUMENTATION

5.1 GENERAL REQUIREMENTS

- 5.1.1. Written instructions and records which document all activities relating to the storage and distribution of medicines and related products, including all applicable receipts and issues (invoices) should be available.
- 5.1.2. Documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of medicines and related products, should be designed, completed, reviewed and distributed with care.
- 5.1.3. All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.
- 5.1.4. Permanent records, written or electronic, should exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates. Pharmacopoeial requirements for medicines and the current MCA *Guidelines for Registration of Medicines in The Gambia* concerning labels and containers should be followed at all times.

5.2 STOCK RECORDS

- 5.2.1. Each medical store should maintain a standard list of stock items that includes all medicines and related products they handle, with their specifications, including form, strength, and quantity per package. The list should be regularly updated and distributed to all officers handling supplies.
- 5.2.2. A logistics information system has three different types of records: stock keeping records, transaction records, and consumptions records.
- 5.2.3. The minimal information that should be collected on stock keeping records for medicines and related products includes

- Product name/description (including the dosage form [e.g. capsule, tablet, liquid suspension, etc.] and strength for medicines)
- Stock on hand/opening stock balance
- Receipts
- Issues
- Losses/adjustments
- Closing/ending balance
- Expiry date and Batch number
- Transaction reference (e.g., issue voucher number or name of supplier or recipient).
- Unit prices
- Minimum stock level / Maximum stock level.

5.2.4. Stock keeping records should also include certain calculated data items:

- Consumption data, such as average monthly consumption
- Lead times for ordering/requisition

5.2.5. Inventory records should be maintained for all products.

5.2.6. Standard documents used for inventory control include:

- Inventory control cards (Tally cards)
- Combined Receipt and Issue Voucher (CRIV)
- Receipt vouchers
- Physical inventory forms
- Goods return/transfer forms
- Daily consumption form
- Monthly return forms

5.2.7. Inventory Control Software may also be used as electronic stock records.

5.3 TRACEABILITY OF PRODUCTS

5.3.1. There should be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.

5.3.2. All parties involved in the supply chain should be identifiable.

5.3.3. Measures should be in place to ensure that medicines and related products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/importer to the entity responsible for selling or supplying the product to the patient or his or her agent. Records including expiry dates and batch numbers may be part of a secure distribution documentation enabling traceability.

5.3.4. Ideally there should be a procedure in place for the creation and maintenance of a pedigree for medicines and related products. Provision should be made for a visual and/or analytical identification of potential substandard or falsified products.

6 OPERATIONS

6.1 RECEIVING AND ARRANGEMENT OF PRODUCTS

- 6.1.1. When receiving medicines and related products they should be put under quarantine until they are authorised for release.
- 6.1.2. Each incoming delivery should be checked against the relevant purchase order or delivery notes/Combined Requisition and Issue Voucher (CRIV), and each container should be verified physically, e.g. by the label description, batch number, type of medicines or related product and quantity.
- 6.1.3. When receiving medicines and related products:
 - It should be ensured the products are registered.
 - It should be ensured that there is sufficient and appropriate storage space.
 - The areas used for receiving and storing the incoming products should be prepared and cleaned.
 - Packages should be inspected for damaged or expired products
- 6.1.4. If damage or expiry is discovered, the products should not be accepted. The problem(s) should be noted on the delivery note and communicated with the supplier.
- 6.1.5. At reception, the following should be recorded on the Tally card:
 - date and quantity received
 - the CRIV number
 - item description
 - batch number and expiry date
- 6.1.6. It should be ensured that the expiry date is visibly marked on every package or unit.
- 6.1.7. The products in the storage area should be arranged to facilitate the First Expiry First Out (FEFO) procedure (See section on stock rotation).

6.2 PHYSICAL INVENTORY / STOCKTAKING

- 6.2.1. Physical inventory is the process of counting the number of each type of product in the store at any given time. A physical inventory helps ensure that the stock on hand balances recorded on stock keeping records match the quantities of products actually in the store.
- 6.2.2. When conducting a physical inventory, each product needs to be counted individually by generic name, unit of issue, dosage form, and strength, where applicable.
- 6.2.3. There are two types of physical inventory/ stocktaking:
 - **Complete physical inventory/** stocktaking: All products are counted at the same time and checked against the stock keeping records. A complete

inventory should be taken at least once a year. More frequent inventory (quarterly or monthly) is recommended. For large warehouses, this may require closing the storage facility for a day or longer.

- **Cyclic or random physical inventory/stocktaking:** Selected products are counted and checked against the stock keeping records on a rotating or regular basis throughout the year. This process is also called cycle counting.

Products for Cyclic physical inventory/stocktaking are selected based on value, risks, fast moving and vitality in facilities that manage large quantities of products.

6.2.4. In the public sector (CMS, RMS and Health Centres) an annual inventory is conducted with the following stakeholders: Board of Surveyors (Representatives of the Attorney General Chamber, Office of Accountant General, National Audit Office, Drug Revolving Fund Office and Directorate of Pharmaceutical Services)

6.2.5. The following steps should be conducted in a physical inventory/stocktaking:

- Planning for taking inventory
 - For a complete physical inventory, schedule the day(s) and time
 - For a cyclic or random physical inventory, identify which products will be counted and the corresponding time period for those products
 - Assign staff.
- Taking inventory
 - Make sure open cartons and boxes are visible
 - Count the usable products.

6.2.6. The stock keeping records should be updated by writing the date of the physical inventory and the words "Physical Inventory"/ Stocktaking on the respective forms.

6.2.7. The following steps should be conducted:

- Using a different colour ink, write the quantity of the product that you counted during stocktaking on the Tally card.
- Take action based on the results of the physical inventory.
- If the results of the physical inventory differ from the balance on the Tally card, update the balance by adding or subtracting the excess or missing quantities.
- Separate damaged or expired products found during the physical inventory from the usable stock.
- For either of the above, identify, document, and correct the cause of the problem.
- Take corrective and preventive actions, if required.

6.2.8. Medicines likely to be stolen or misused (e.g., antibiotics, narcotics, psychotropic, antiretroviral) should be selected for more closely monitoring as follows:

- Check periodically inventory records for stock on hand. Then, conduct a physical inventory (physically count the quantities on hand) and compare the results.
- Check the inventory records to determine the consumption during a specified period. Then, check prescription pads and count the number of treatment courses during the same period. Convert treatment courses into dose units and compare this figure with the stock issued from the storage area.

6.3 STOCK ROTATION

6.3.1. FEFO minimizes wastage from product expiry. The following steps should be observed:

- Always issue products first that will expire first.
- Ensure they are not too close to or past their expiry date.
- Ensure Shelf life remaining is sufficient for the product to be used before the expiry date.
- Facilitate FEFO, by placing products that will expire first in front of those with a later expiry date.
- Write and monitor expiry dates on the tally card, so stocks can be sent to facilities at least 6 months before they expire.

6.3.2. The order in which products are received is not necessarily the order in which they will expire. Products that were received most recently may expire sooner than those received earlier. Therefore, it is extremely important to always check the expiry dates and to make sure the dates are visible while the products are in storage.

6.4 RETURNED GOODS

6.4.1. Returned goods (e.g. expired or near expired, damaged stock, excess stock, wrong supply, etc), should be handled in accordance with approved procedures and records should be maintained.

6.4.2. All returned goods should be placed in quarantine. They should only be returned to usable stock after this has been approved by an authorised person following a satisfactory quality re-evaluation.

6.4.3. Provision should be made for the appropriate and safe transport of returned products in accordance with the relevant storage and other requirements.

6.4.4. In case of recalled products they should be placed under quarantine until the MCA makes a final decision on the products (see *MCA Guideline for Recall of Medicines and Related Products*).

6.4.5. Any stock reissued should be identified as such and recorded in stock records. Medicines and related products returned **from patients** to the pharmacy should **NOT** be taken back as stock, but should be destroyed

according to MCA *Guideline for Safe Disposal of Medicines and Related Products*.

6.5 EXPIRED PRODUCTS

- 6.5.1. It is the responsibility of the person in-charge of the store, or his/her designates, to routinely check for expiry date of the products and, if expired, to take action, as follows:
- All expired medicines and related products should be removed from the shelves, packed in boxes, labelled 'Expired Products' and stored at a separate location within the warehouse.
 - The expired quantity shall be deducted from the Tally card.
 - For health centres, the Goods Return form should be filled with details and the products returned to the Regional Medical Stores.
 - For regional medical stores and hospitals, the Goods Return form should be filled and the products sent to the central medical store.
 - The central medical store should follow the MCA *Guidelines for Safe Disposal of Medicines and Related Products*.
 - For the private sector, the person in-charge should follow the MCA *Guidelines for Safe Disposal of Medicines and Related Products*.

6.6 DISPATCH AND TRANSPORT OF PRODUCTS

- 6.6.1. Dispatch and transport procedures should be established and documented, taking into account the nature of the products concerned and any special precautions that might be required.
- 6.6.2. The dispatch and transport of medicines and related products should be carried out only after receipt of a delivery note.
- 6.6.3. Records of dispatch should contain enough information to enable traceability of the medicines and related products and should state at least.
- the date of dispatch and time, where appropriate;
 - the complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons;
 - the complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic);
 - the product description, e.g. name, dosage form and strength, where applicable;
 - assigned batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability);
 - 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.

- 6.6.4. All records should be retained, readily accessible and available on request.
- 6.6.5. Medicines and related products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained.
- 6.6.6. Medicines and related products should be distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.
- 6.6.7. Shipping containers should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times. The shipment container should enable identification of the container's contents and source.
- 6.6.8. Special safety precautions should be exercised when using dry ice in cold chains. In addition to observing safety precautions, it must be ensured that the products do not come into direct contact with dry ice, as this may adversely affect the product quality, e.g. by freezing.
- 6.6.9. Where appropriate, the use of devices to monitor conditions such as temperature during transportation is recommended. Monitoring records should be available for review.
- 6.6.10. The outside container should offer adequate protection from all external influences and should be indelibly and clearly labeled.
- 6.6.11. Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

6.7 PRODUCT RECALL

The MCA *Guideline for Recall of Medicines and Related Products* shall be used. This will include removal of medicines and related products from shelves that are declared by the MCA for recall, packed in boxes, labelled 'Recalled Products' and stored at a separate location within the warehouse.

6.8 MONITORING PRODUCT QUALITY

- 6.8.1. Products of different types show damage in different ways. Some indicators can be used to detect damage. These indicators are:

All products

- broken or ripped packaging (vials, bottles, boxes, etc.)
- missing, incomplete, or unreadable label(s)
- change of colour or odours

Liquids

- discoloration
- cloudiness
- sediment
- broken seal on bottle
- cracks in ampoule, bottle, or vial

- dampness or moisture in the packaging sensitive products (such as x-ray film)
- torn or ripped packaging
- dry
- brittle
- cracked presence of odour
- caking or precipitation

Tablets

- discoloration
- crumbled tablets
- missing tablets (from blister pack)
- stickiness (especially coated tablets)
- unusual smell
- capping
- mottle appearance

Capsules

- discoloration
- stickiness
- crushed capsules
- leaking contents
- perforations or holes in the capsule

Suppositories, creams, ointments, lotions, liniments, etc

- leaking contents
- cracking
- colour change
- caking (lotions)

Injectables

- colour change
- presence of particles in ampoules/vials

Sterile products (e.g. IUDs)

- torn or ripped packaging
- missing parts
- broken or bent parts
- moisture inside the packaging
- stained packaging

Foil packs

- perforation(s) in packaging or container
- discoloration

- lack of or incomplete heat seal
- misplaced lids/tops/closures or crimp seals

Lubricated latex products

- sticky packaging
- discolored product or lubricant
- stained packaging
- leakage of the lubricant (moist or damp packaging)
- dryness
- brittleness

- 6.8.2. Damaged products or products that are suspected to be damaged should never be issued to facilities or dispensed to clients.
- 6.8.3. If there is uncertainty whether a product is damaged, the relevant person at the next level should be contacted.
- 6.8.4. Any defective product should be documented as appropriate.
- 6.8.5. Any defects should be reported, as appropriate, and the defective products should be sent back to the facility that issued them accompanied by the Goods Return form.

7 CONTRACT ACTIVITIES

- 7.1. Any activity relating to the distribution of a medicines or related product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.
- 7.2. The contract should define the responsibilities of each party including observance of the applicable regulations and guidelines and relevant warranty clauses. It should also include responsibilities of the contractor for measures to avoid the entry of substandard or falsified products into the distribution chain, such as by suitable training programmes.
- 7.3. All contract accepters should comply with the requirements in this guideline.
- 7.4. Subcontracting may be permissible, under certain conditions and subject to the written approval of the contract giver; however, the subcontractors should be authorized for the function.
- 7.5. Contract accepters should be audited periodically.

8 FINAL PROVISIONS

- 10.1. This Guideline is the second version published by the MCA and will be effective at 01 July 2020.
- 10.2. The guideline will be reviewed before 5 years after becoming effective.

9 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019
- Pharmacy Council Act, 2014
- The Gambia National Medicines Policy, 2007
- WHO Good Distribution Practices for Pharmaceutical Products, Annex 5, WHO Technical Report Series 957, 2010
- WHO Guide to Good Storage Practices for Pharmaceuticals Annex 9, WHO Technical Report Series, No. 908, 2003
- Joint FIP/WHO Guidelines on Good Pharmacy Practice
- MCA Guidelines for Registration of Medicines (MCA-GL-102)
- MCA Guidelines for Registration of Herbal Medicinal Products (MCA-GL-106)
- MCA Guideline for Repackaging and Labelling of Medicines (MCA-GL-101)
- MCA Guideline for Recall of Medicines and Related Products (MCA-GL-303)
- MCA Guideline for Safe Disposal of Medicines and Related Products (MCA-GL-304)
- MoHSW, Donation Guidelines for Medicines, Medical Supplies and Health Care Equipment in The Gambia, 2010

10 DOCUMENT HISTORY

Version #	Implementation Date	Reasons for Change:
1	25 July 2017	New document
2	01 July 2020	Editorial changes, harmonisation of format for MCA guidelines,

FLOW CHART ON DISTRIBUTION

