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THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT,
(CAP 219)

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REGULATIONS

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(Made under section 122(1)(d)(e))

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THE TANZANIA MEDICINES AND MEDICAL DEVICES (GOOD STORAGE AND DISTRIBUTION PRACTICES) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

PART XIV
OFFENCES AND PENALTIES

THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT,
(CAP 219)

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(Made under section 122(1)(d)(e))

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THE TANZANIA MEDICINES AND MEDICAL DEVICES (GOODS STORAGE AND DISTRIBUTION PRACTICES) REGULATIONS, 2021

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations shall be cited as the Tanzania Medicines and Medical Devices (Good Storage and Distribution Practices) Regulations, 2021.

Scope of application

2. These Regulations shall apply in all regulatory controls related to good storage and distribution practices for regulated products in Mainland Tanzania.

Interpretation
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3. In these Regulations, unless the context otherwise requires-

"Act" means the Tanzania Medicines and Medical Devices Act;

"agreement" means the arrangement undertaken by and legally binding on parties;

"Authority" means the Tanzania, Medicines and Medical Devices Authority or in its acronym "TMDA";

"batch" means quantity of products processed in a single process or series of processes so that it is expected to be homogeneous;

"batch or lot number" means a distinctive combination of numbers or letters which uniquely identifies a batch, including on the labels, its batch records and corresponding certificates of analysis or conformity;

*"*consignment" means the quantity of products supplied at one time in response to a particular request or order comprising one or more packages or containers and may include products belonging to more than one batch;

*"*container" means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, not being a capsule or other article in which the product is or is to be administered or eaten, and, where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

"contamination" means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or product during handling, production, sampling, packaging or repackaging, storage or transportation;

"contract" means the business agreement for the supply of products or performance of work at a specified price;

“corrective and preventative actions or its acronym “CAPA”” means a system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.;

“cross-contamination” means contamination of a starting material, intermediate product or finished product with another starting material or product, during production, storage and transportation;

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

“distributor” means a person who buys products from importers or local manufacturers and who sells in bulk or wholesale to retailers and includes importers;

“donated products” means medicines, medical devices and diagnostics supplied by donor agencies recognised by the Authority but excluding medicines, medical devices and diagnostics supplied through vertical programmes;

“expiry date” means the date given on the individual container usually on the label of a product up to and including the date on which the product is expected to remain within specifications, if stored correctly;

“falsified product” means product that has been deliberately or fraudulently misrepresented as to its identity, composition or source.

“first expiry first out or its acronym “FEFO”” means the distribution procedure that ensures the stock with the earliest expiry date is distributed or used before an identical stock item with a later expiry date is distributed or used;

“fraudulent misrepresentation” means any substitution, adulteration or reproduction of an authorized product, or the manufacture of a product that is not an authorized product;

“good distribution practices or its acronym “GDP”” means that part of quality assurance that ensures that the quality of a product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated or misbranded products;

“good manufacturing practices or its acronym “GMP”” means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization;

“good storage practices or its acronym “GSP”” means that part of quality assurance that ensures that the quality of products is maintained by means of adequate control throughout the storage thereof;

“herbal product” means any labelled preparation in pharmaceutical dosage form that contains as active ingredients one or more substances of natural origin that are derived from plants and excludes traditional medicines;

“importation” means the act of bringing or causing any product to be brought into a customs territory including national territory, excluding any free zone;

“labeling” means the process of identifying a product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer or the supplier;

"manufacture" includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labeling of products;

"manufacturer" means a person or a firm that is engaged in the manufacture of regulated products;

“marketing authorization” means a legal document issued by the Authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality;

“owner of premises” means a person authorised to deal in the business of storage, transport and distribution of regulated products;

“premises” means land, building, structure, basement and vessel and in relation to any building includes a part of a building and any cartilage, forecourt, yard, or place of storage used in connection with building or part of that building; and in relation to “vessel”, means ship, boat, air craft, and includes a carriage or receptacle of any kind, whether open or closed;

“product recall” means a process of withdrawing or removing a product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product or concerns that the product is or may be falsified and such recall may be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency;

“quality risk management” means a systematic process for the assessment, control, communication and review of risks to the quality of products in the supply chain;

“quality system” means an appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product will satisfy given requirements for quality;

“quarantine” means the status of products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing;

“regulated products” means human medicines, veterinary medicines, biologicals including vaccines, biocidals including antiseptics and disinfectants, herbal medicines, medical devices, diagnostics, medical laboratory equipment and investigational products;

“re-test date” means the date when a material shall be re-examined to ensure that it is still suitable for use;

“responsible person” means superintendent or any other person authorised to supervise and or dispense regulated products under the Act, Pharmacy Act, Veterinary Act, Private Health Laboratories (Regulation) Act or any other written law;

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"sampling" means operations designed to obtain a representative portion of a product, based on an appropriate statistical approach for a defined purpose to include acceptance of consignments or batch release;

"self-inspection" means an internal process to evaluate the premises compliance with GSP and GDP in all areas of activities, designed to detect any shortcomings and to recommend and implement necessary corrective actions;

"shelf-life" means the period of time during which a product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product and it is used to establish the expiry date of each batch;

"standard operating procedure or its acronym "SOP"" means an authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature to include equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection;

"storage" means the storing of products up to the point of use;

"substandard products" means products authorized by the Authority but fail to meet specifications;

"supplier" means a person or entity engaged in the activity of providing products or services;

"transit" means the period during which products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination;

"transporter" means a person who transports regulated products from one point to another within the supply chain;

"vehicles" means trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey products; and

"vertical programmes" means national disease control programme for malaria, HIV/AIDS, tuberculosis and leprosy, immunization, neglected tropical diseases and any other programme for diseases of public health importance recognised by the Authority.

PART II
GENERAL PRINCIPLES

Principles

4.-(1) The owner of premises shall be required to ensure that storage and distribution of regulated products including automated storage and retrieval systems are carried out in accordance with these Regulations.

(2) Any person dealing with storage and distribution of regulated products shall ensure that the quality of products and the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his agent.

(3) Notwithstanding sub-regulation (2), the backward movement of products including donated products, in the distribution chain as a result of return or recall is

also applicable.

(4) Without prejudice to sub-regulation (2), all government agencies including Customs, Law enforcement agencies, Pharmacy Council, Veterinary Council, Private Health Laboratories Board and the Authority shall collaborate to prevent the exposure of patients to sub-standard and falsified products.

(5) Regulated products shall be sourced from or supplied to authorized entities.

PART III
TYPES OF PREMISES

Categories of premises

5.-(1) The premises under these Regulations shall be classified in the following categories-

(a) manufacturing facilities;
(b) importing wholesalers;
(c) warehouses;
(d) wholesalers;
(e) retailers;
(f) institutional pharmacies;
(g) veterinary practice facilities;
(h) vehicles;
(i) medical laboratory facilities; and
(j) any other premises as the Authority may designate.

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(2) Subject to sub-regulation (1), all owners of premises shall ensure that, storage, transportation and distribution of regulated products is done in registered premises in accordance with the Act, Pharmacy Act, Veterinary Act, Private Health Laboratories (Regulation) Act or any other applicable law.

PART IV
QUALITY MANAGEMENT

Quality System

6.-(1) The owner of premises shall have a comprehensively designed, documented and correctly implemented quality system that incorporates the principles of quality management as defined in these Regulations.

(2) The owner of premises shall have a documented quality policy describing the overall intentions and requirements regarding quality, authorized by the management and shall include the following-

(a) appropriate organizational structure with defined responsibilities of the personnel recorded as job descriptions;
(b) competent personnel;
(c) suitable and sufficient premises, equipment and facilities; and
(d) written and approved procedures for all activities.

Quality Risk Management

7.-(1) The owner of premises shall have a system to assess, control, communicate and review risks identified at all stages in the supply chain.

(2) Subject to sub-regulation (1), the evaluation of the risk shall be based on

scientific knowledge and experience and ultimately be linked to the protection of the patient, animal or consumer.

(3) Without prejudice to sub-regulations (1) and (2), appropriate controls shall be developed and implemented to address all risks including periodic reviews of the effectiveness of the controls.

Management review

8.-(1) The owner of premises shall establish a system for periodic management review which shall include the following-

(a) review of the quality system and its effectiveness by using quality metrics and key performance indicators;

(b) identification of opportunities for continual improvement; and

(c) follow up on recommendations from previous management review meetings.

(2) Subject to sub-regulation (1), minutes and related documentation from management review meetings shall be made available on request by the Authority.

PART V
PREMISES, WAREHOUSING AND STORAGE

Design of premises

9.-(1) The owner of premises shall design and maintain storage areas to ensure GSP as provided for in these Regulations.

(2) Subject to sub-regulation (1) the storage areas shall-

(a) be suitably secure, structurally sound and of sufficient capacity to allow for the orderly handling and safe storage of regulated products;

(b) be provided with adequate lighting to enable all operations to be carried out accurately and safely;

(c) be designed to prevent unauthorized persons from entering;

(d) have segregated areas designated for storage of products in quarantine and for storage of released, rejected, returned or recalled products as well as those suspected to be sub-standard or falsified;

(e) be designed or adapted to ensure appropriate and good storage conditions and shall be clean, dry and maintained within acceptable temperature limits;

(f) receiving areas shall be designed and equipped to allow incoming containers of products to be cleaned, if necessary, before storage; and

(g) have dedicated areas with appropriate additional safety and security measures and shall be provided for storage of radioactive materials, narcotics and other hazardous, sensitive and or dangerous products, as well as products presenting special risks of abuse, fire or explosion to include combustible or flammable liquids, solids and pressurized gases.

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(3) Without prejudice to the provisions of this regulation, other requirements for storage areas and conditions shall be as specified in the Act, Pharmacy Act, Veterinary Act and Private Health Laboratories (Regulation) Act.

Receiving area

10.-(1) A person receiving a consignment of products shall ensure that-

(a) each incoming delivery is checked against the relevant documentation, to ensure that the correct product is delivered from the correct supplier

which may include, the purchase order, containers, label description, batch or lot number, expiry date, product, quantity, certificate of analysis or certificate of conformity, where applicable;

(b) the consignment is examined for uniformity of the containers and, if necessary, is subdivided according to the supplier's batch or lot number; in case the delivery comprise more than one batch:

Provided that, where the consignment has more than one batch, each batch shall be dealt with separately;

(c) a representative number of containers in a consignment is sampled and checked according to a written procedure and any suspect containers or, if necessary, the entire delivery, quarantined for further investigation;

(d) receiving areas are of sufficient size to allow for the cleaning of incoming products;

(e) when required, samples of products are taken by appropriately trained and qualified personnel and in strict accordance with a written sampling procedure and sampling plans:

Provided that, where sampling has been done containers from which samples have been taken shall be labelled accordingly;

(f) following sampling, the products are subject to quarantine and batch segregation maintained during quarantine and all subsequent storage, where applicable;

(g) materials and products requiring transport and storage under controlled conditions of temperature and relative humidity, as applicable, are handled as a priority and the transportation temperature data, where appropriate, reviewed upon receipt, to ensure that the required conditions had been maintained:

Provided that, cold-chain materials and products received, are handled according to the approved conditions by the Authority, or as recommended by the manufacturer, as appropriate;

(h) products are not transferred to saleable stock until an authorized release is obtained; and

(i) measures are taken to ensure that rejected products cannot be used, are segregated and securely stored while awaiting destruction or return to the supplier.

Storage practices

11.-(1) The owner of premises shall observe the following during storage of regulated products in premises-

(a) products shall be stored off the floor away from walls and ceilings, protected from direct sunlight and suitably spaced, to permit ventilation, cleaning and inspection;

(b) pallets shall be kept in a good state of cleanliness, repair and condition;

(c) premises and storage areas shall be kept clean;

(d) there shall be a written programme for pest control and the pest control agents used shall be safe without risk of contamination of products;

(e) if sampling is performed in the storage area, it shall be conducted in such

a way as to prevent contamination or cross-contamination and adequate cleaning procedures shall be in place for the sampling areas;

(f) receiving and dispatch bays shall protect products from direct sunlight and rain;

(g) handling and storage of products shall be in such a manner as to prevent contamination, mix-ups and cross-contamination;

(h) there shall be a system in place to ensure that the products due to expire first are sold and or distributed first or its acronym FEFO and exceptions shall be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products;

(i) arrangement shall be made to withdraw broken or damaged items from usable stock and stored separately;

(j) narcotic and psychotropic substances shall be stored in compliance with international conventions and the controlled drugs Regulations in force; and

(k) maintaining acceptable and specified temperature limits and where the labels show special storage conditions are required including temperature and relative humidity, they shall be provided, controlled, monitored and recorded.

Storage conditions

12.-(1) The owner of premises shall ensure that, storage conditions for regulated products are in compliance with their labelling and information provided by the manufacturer.

(2) Subject to sub-regulation (1), the owner of premises shall ensure that-

(a) heating, ventilation and air conditioning systems are appropriately designed, installed, qualified and maintained to ensure that the required storage conditions are upheld;

(b) mapping studies for temperature, and relative humidity where appropriate, is done in storage areas, refrigerators and freezers;

(c) temperature and relative humidity, as appropriate, is controlled and monitored at regular intervals;

(d) the equipment used for monitoring temperature and relative humidity referred to under paragraph (c), are calibrated and be suitable for its intended use; and

(e) the records collected under paragraph (c), are reviewed and all records pertaining to mapping and monitoring shall be kept for a period of two years.

Stock control and stock rotations

13.-(1) The owner of premises shall control stock and stock rotations and ensure the following-

(a) records of stock levels for all regulated products in store are maintained, in either paper or electronic format and such records shall be updated after each operation including entries, issues, losses and adjustments;

(b) periodic stock reconciliation is performed at defined intervals by comparing the actual and recorded stock;

(c) the root cause for stock discrepancies is identified and appropriate corrective and preventive actions taken to prevent recurrence;
(d) when damaged containers are received, they shall be brought to the attention of the owner of premises and any action taken shall be documented and in case the quality of products has shown to be affected, the containers shall not be issued;
(e) all stock shall be checked at regular intervals, to identify items that are close to their retest or expiry dates and appropriate action taken, such as removal of these items from useable stock; and
(f) stock discrepancies are investigated in accordance with a specified procedure to check that there have been no inadvertent mix ups, incorrect issues and receipts, thefts and or misappropriations of products.

Traceability of products

14.-(1) The owner of premises shall put in place procedures for-

(a) safe, transparent and secure distribution which includes product traceability throughout the supply chain;
(b) document traceability of products received and distributed, to facilitate product recall;
(c) identification of all parties involved in the supply chain depending on type of product;
(d) ensuring products have documentation that can be used to permit traceability throughout distribution channels from the manufacturer or importer to the entity responsible for selling or supplying the product to the patient or his agent; and
(e) documentation enabling traceability of records including expiry dates and batch or lot numbers as part of a secure distribution.

PART VI
PERSONNEL

Competent personnel

15.-The owner of premises shall be required to have sufficient, qualified and competent personnel to carry out activities related to the storage and distribution of regulated products.

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16.- (1) The owner of premises shall appoint a person as responsible person whom shall meet the qualifications as specified in the Pharmacy Act, Veterinary Act, Health Laboratory Practitioners Act or any other relevant laws.

(2) Subject to sub-regulation (1), the responsible person shall have appropriate knowledge and experience in good storage and distribution practices;

(3) Subject to sub-regulation (1), the responsible person shall have the defined authority and responsibility for ensuring that a quality management system is implemented and maintained.

(4) The responsible personnel shall be independent from the person responsible for operations and shall ensure compliance with good storage and

distribution practices.

Other personnel

17.-(1) The owner of premises shall recruit other personnel and provide adequate 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.

(2) The owner of premises shall make arrangements to ensure that 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 products.

(3) The owner of premises shall put in place safety procedures to protect personnel, property, environment and products.

Training of personnel

18.-(1) The responsible person shall ensure that personnel receive initial and continued training in accordance with a written training programme.

(2) Subject to sub-regulation (1), the training may cover the requirements of good storage and distribution practices as provided for in these Regulations.

(3) Notwithstanding sub-regulation (2), specific training shall be given to personnel dealing with hazardous products to include highly active materials, radioactive materials, narcotics and other hazardous, environmentally sensitive and or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion.

(4) The responsible person shall keep records of all training, attendance and assessments and the effectiveness of training shall be periodically assessed and documented.

Personnel hygiene

19.-(1) The responsible person shall ensure that, personnel are trained in, and observe high levels of personal hygiene and sanitation.

(2) Personnel handling products shall be required to wear garments suitable for the activities that they perform.

(3) The responsible person shall ensure that, personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, infectious or sensitizing, are provided with protective garments as necessary.

(4) The responsible person shall ensure that, appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out to include health and clothing of personnel, are established and observed.

Procedures and conditions of employment

20.-(1) The owner of premises shall ensure that, procedures and conditions of employment, including contract and temporary staff, and other personnel having access to products, are designed and implemented to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

(2) The owner of premises shall ensure that, codes of practice and procedures are in place to prevent and address situations where persons involved in

the storage and distribution of products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or falsification of any product.

PART VII
EQUIPMENT, QUALIFICATION AND VALIDATION

Equipment

21.-(1) The owner of premises shall ensure that, equipment, including computerized systems, are appropriately designed, located, installed, qualified and maintained for the intended use.

(2) Computerized systems referred to in sub-regulation (1), shall be capable of achieving the desired output and results.

(3) Subject to sub-regulation (2), where electronic commerce or its acronym "e-commerce" is used, defined procedures and adequate systems shall be in place to ensure traceability and confidence in the supply chain and products concerned.

(4) Notwithstanding sub-regulation (2), electronic transactions including transactions conducted via the internet, relating to the distribution of products shall be performed only by authorized persons, according to defined and authorized access and privileges.

Qualification and validation

22.-(1) The owner of premises shall determine the scope and extent of qualification and validation of premises, utilities, equipment and instruments, processes and procedures where appropriate, using documented risk management principles.

(2) Subject to sub-regulation (1), qualification and validation shall be done following written procedures and protocols and results including outcomes recorded in reports.

(3) Subject to sub-regulation (2), deviations shall be investigated and the completion of the qualification and validation concluded and approved.

PART VIII
TRANSPORTATION AND DISTRIBUTION

Transportation and distribution

23.-(1) The owner of premises or transporter shall ensure that, products are transported in accordance with the conditions stated on the labels and described by the manufacturer.

(2) Subject to sub-regulation (1), during transportation and distribution, the owner of premises or transporter shall ensure that-

(a) the risk to the quality of the product is eliminated or minimized to an acceptable level;

(b) product, batch or lot and container identity are maintained at all times;

(c) all labels remain legible;

(d) distribution records are sufficiently detailed to allow for a recall when required;

(e) drivers of vehicles are identified and present appropriate documentation to demonstrate that they are authorized to transport products;

(f) vehicles are suitable for their purpose, with sufficient space and appropriately equipped to protect products;
(g) the design and use of vehicles and equipment aiming 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;
(h) where feasible, consideration is given to adding technology, to include electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security and traceability of vehicles with products;
(i) where possible, dedicated vehicles and equipment are used for products and where non-dedicated vehicles and equipment are used, procedures shall be in place to ensure that the quality of the products will not be compromised:

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Provided that dedicated vehicles used are registered under the Act, Pharmacy Act, Veterinary Act or any other applicable law;
(j) defective vehicles and equipment are not used and are either labelled as such or removed from service;
(k) procedures are in place for the operation and maintenance of all vehicles and equipment;
(l) equipment and materials used for the cleaning of vehicles are not sources of contamination or have an adverse effect on product quality;
(m) vehicles used for transportation of products are qualified, where applicable, to demonstrate their capability to maintain the required transport conditions and a maintenance programme for the cooling or heating is in place;
(n) appropriate environmental conditions are maintained, monitored and recorded and such records kept for a period of not less than one year;
(o) instruments used for monitoring conditions to include temperature and humidity, within vehicles and containers are calibrated at regular intervals;
(p) rejected, recalled, returned or suspected falsified products are securely packaged, clearly labelled and accompanied by the appropriate supporting documentation;
(q) measures are in place to prevent unauthorized persons from entering or tampering with vehicles or equipment to prevent the theft or misappropriation thereof;
(r) shipment containers have no adverse effect on the quality of the products and shall offer adequate protection to materials and products;
(s) containers are labelled indicating handling and storage conditions, precautions, contents and source, and safety symbols, as appropriate;
(t) special care is taken when using dry ice and liquid nitrogen in shipment containers, owing to safety issues and possible adverse effects on the quality of products; and
(u) written procedures are available for the handling of damaged or broken shipment containers and particular attention shall be paid to those

containing potentially toxic and hazardous products.

(3) Any person found in unlawful possession of government's owned products commits an offence and upon conviction, shall be liable to a fine of not less than five million shillings or to imprisonment for a period of not less than seven years or to both.

Dispatch

24.- (1) The owner of premises or distributor shall sell or distribute products to persons or entities that are authorized to acquire such products in accordance with these Regulations.

(2) The products referred to under sub-regulation (1), shall have obtained prior marketing authorisation issued by the Authority.

(3) The owner of premises shall not dispatch and transport products until after receiving a valid order.

(4) Records for the dispatch of products under this regulation, shall be prepared and include the following information:

(a) date of dispatch;
(b) complete business name and address;
(c) type of entity responsible for the transportation;
(d) telephone or mobile number;
(e) names of contact persons;
(f) type of business of recipient;
(g) a description of the products, including name, dosage form and strength, if applicable;
(h) quantity of the products including number of containers and quantity per container, if applicable;
(i) applicable transport and storage conditions;
(j) a unique number to allow identification of the delivery order; and
(k) assigned batch or lot number and expiry date.

(5) The owner of premises shall ensure that, records of dispatch contain sufficient information to enable traceability and facilitate the recall of a batch of a product, if necessary as well as the investigation of sub-standard and falsified products.

(6) The owner of premises shall not supply or receive products after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the patient, animal or consumer.

(7) The owner of premises shall ensure that-

(a) vehicles and containers are loaded carefully and systematically on a last-in first-out or its acronym "LIFO" basis, to save time when unloading, to prevent physical damage and to reduce security risks;
(b) products and shipment containers are secure in order to prevent or to provide evidence of unauthorized access;
(c) vehicles and operators are provided with additional security where necessary, to prevent theft and other misappropriation of products during transportation;
(d) products are stored and transported in accordance with procedures such

that-

(i) the identity of the product is not lost;

(ii) the product does not contaminate and is not contaminated by other products;

(iii) adequate precautions are taken against spillage, breakage, misappropriation and theft; and

(iv) appropriate environmental conditions are maintained which includes using cold-chain for thermolabile products;

(e) written procedures are in place for investigating and dealing with any failure to comply with storage requirements to include temperature deviations and in case-

(i) a deviation has been noticed during transportation, by the person or entity responsible for transportation, it shall be reported to the supplier, distributor and recipient; and

(ii) where the recipient notices the deviation, it shall be reported to the distributor;

(f) transportation of products containing hazardous substances or narcotics and other dependence-producing substances, is done in safe, suitably designed, secure containers and vehicles;

(g) spillages are cleaned up as soon as possible, in order to prevent possible contamination, cross-contamination and hazards in accordance with written procedures;

(h) damage to containers and any other event or problem that occurs during transit is recorded, investigated and reported to the Authority, where necessary; and

(i) products in transit are accompanied by the appropriate documentation.

Repackaging and relabeling

25.-(1) A person shall not repack or relabel any product or material for the purpose of distribution to any premises.

(2) Without prejudice to sub-regulation (1), where the owner of premises intends to repack or relabel any product or material, he shall seek an authorisation from the Authority.

(3) Subject to sub-regulation (2), the owner of premises shall repack or relabel products or materials in accordance with good manufacturing practices requirements.

(4) Subject to sub-regulation (2), where the products have been repacked or relabed, the owner of premises shall dispose original packaging to prevent re-use thereof in accordance with disposal procedures in place.

(5) Without prejudice to the generality of this regulation, any expired product shall be declared to the Authority and disposed off within 3 months after its expiration.

(6) Subject to sub-regulation (5), any extension of time for disposal of any expired product shall be sought from the Authority.

(7) Subject to sub-regulation (5), the Authority shall issue a disposal certificate as prescribed in the disposal regulations in force.

Outsourced activities

26.-(1) The owner of premises or contract giver shall ensure that-

(a) any activity relating to the storage and distribution of a product that is delegated to another person or entity is performed by the appropriately authorized parties, in accordance with these Regulations and the terms of a written contract;

(b) there is a written contract between the entities and such contract shall define the responsibilities of each entity and cover at least the following:

(i) compliance with these Regulations;

(ii) the responsibilities of all entities for measures to avoid the entry of substandard and falsified products into the distribution chain;

(iii) training of personnel;

(iv) conditions of subcontracting subject to the written approval of the contract giver; and

(v) periodic audits.

(c) the contract acceptor is assessed before entering into the contract through on-site audits, documentation and or licensing status review; and

(d) the contract acceptor is provided with all relevant information relating to the material and products.

(2) The contract acceptor shall have adequate resources to include premises, equipment, personnel, knowledge, experience and vehicles, as appropriate to carry out the delegated functions.

(3) Subject to sub-regulation (2), the contract acceptor shall refrain from performing any act that may adversely affect the quality of materials or products handled.

PART IX
SUBSTANDARD AND FALSIFIED PRODUCTS

Handling of substandard and falsified products

27.-(1) The owner of premises shall have a quality system which includes procedures to assist in preventing, identifying, responding or handling products that are suspected to be substandard and or falsified.

(2) Notwithstanding sub-regulation (1), where substandard and or falsified products are suspected or identified-

(a) the marketing authorization holder, manufacturer, supplier and the Authority shall be informed;

(b) the suspected or identified products shall be stored in a secure, access controlled, segregated area and clearly identified to prevent further distribution or sale; and

(c) records shall be maintained reflecting the investigations and action taken to include disposal of the product.

(3) Subject to sub-regulation (1), the owner of premises shall ensure that, sub-standard and falsified products do not re-enter the market.

(4) Notwithstanding the provisions of this regulation, the marketing

authorization holder shall be responsible for the quality, safety and efficacy of the product while on the market including recall of substandard products.

PART X
COMPLAINTS HANDLING

Complaints handling

28.-(1) The owner of premises shall establish written procedures for the handling of complaints.

(2) Subject to sub-regulation (1), in case of a complaint about the quality of a product or its packaging, the original manufacturer or marketing authorization holder shall be informed within seven days from the date of receiving a complaint.

(3) The complaints referred to under sub-regulation (1), shall be recorded and appropriately investigated including conducting the root cause analysis and the impact on the affected batches, lots or products.

(4) After completion of the procedure referred to under sub-regulation (3), the owner of premises shall take corrective and preventive actions, and when so required, such information shall be shared to the Authority with a view, where necessary, to initiate recalling.

(5) Subject to sub-regulation (2), a distinction shall be made between complaints about a product or its packaging and those relating to distribution.

(6) Where a product is suspected to be substandard or identified to be falsified, such product shall be handled according to regulation 27.

PART XI
RETURNS AND RECALLS

Returns

29.-(1) The owner of premises shall-

(a) handle returned products in accordance with written procedures;

(b) place all returned products in quarantine upon receipt;

(c) take precautions to prevent access and distribution until a decision has been taken with regard to their disposition;

(d) maintain storage conditions applicable to the products until their disposition;

(e) ensure returned products are destroyed unless it is certain that their quality is satisfactory.

(2) The owner of premises shall, when handling returned products, take into consideration the following-

(a) assessing risks when deciding on the fate of the returned products to include 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 contract between the parties; and

(c) examining returned products, with decisions taken by suitably qualified, experienced and authorized persons.

(3) The owner of premises shall follow written procedures, including safe transport, where products are rejected.

(4) The owner of premises shall destroy returned products, where applicable in accordance with disposal Regulations in force.

(5) The owner of premises shall keep records of all returned, rejected and destroyed products for a period of not less than one year.

Recalls

30.-(1) The owner of premises shall follow written procedures for recall of products.

(2) Subject to sub-regulation (1), the Authority, original manufacturer, marketing authorization holder, customers or other relevant contract party, shall be informed in the event of a recall.

(3) The owner of premises shall ensure that, all recalled products are secure, segregated, transported and stored under appropriate conditions.

(4) Subject to sub-regulation (3), recalled products shall be clearly labelled and storage conditions applicable to the product maintained, where possible.

(5) The owner of premises shall ensure that, all records, including distribution records, are readily accessible to the designated person(s) responsible for recalls and such records shall contain sufficient information on products supplied to customers including name, address, contact detail, batch or lot numbers, quantities and safety features.

(6) The owner of premises shall record the progress of a recall process and a final report issued, to include reconciliation between delivered and recovered quantities of products.

(7) Without prejudice to the generality of this regulation, the owner of premises shall follow other recall procedures as provided for in the recall Regulations in force.

PART XII
INSPECTION AND ENFORCEMENT

Self-inspections

31.-(1) The owner of premises shall ensure that, the quality system includes self-inspections.

(2) Subject to sub-regulation (1), the owner of premises shall ensure that self-inspections are conducted on annual basis to monitor the implementation, compliance with and effectiveness of standard operating procedures, as well as compliance with these Regulations.

(3) Subject to sub-regulation (2), the team conducting the inspection shall be free from bias and individual members shall have appropriate knowledge and experience.

(4) Subject to sub-regulation (2), the results of all self-inspections shall be recorded and reports shall contain all observations made during the inspection and presented to the relevant personnel and management.

(5) Notwithstanding sub-regulation (4), necessary CAPA shall be taken and its effectiveness reviewed within a defined timeframe.

Inspection by Authority

32.-(1) The Authority may at any time conduct inspection of premises

storing or distributing products for the purpose of identifying non-conformances and ensuring that all premises comply with the requirements of these Regulations.

(2) The Authority may serve a notice to the owner of premises requiring such person to furnish with such information concerning its compliance with these Regulations within such period as shall be specified in the notice.

(3) Any reference to an inspection of the premises which the Authority is required or empowered to conduct by virtue of this regulation, shall be construed so as to include an inspection of such premises within Mainland Tanzania at which storage and distribution of products is carried out.

(4) The Authority may, subject to the provisions of the Act, appoint inspectors necessary for the proper discharge of its functions under these Regulations and provide such terms and conditions for appointment as it shall be deemed appropriate.

Powers of inspectors

33.-(1) For the purposes of ensuring compliance or conducting inspections under these Regulations, the powers of inspectors shall be as prescribed under the Act.

PART XIII
DOCUMENTATION AND RECORDS KEEPING

Documentation

34.-(1) The owner of premises shall ensure that-

(a) documentation including all procedures, records and data, whether in paper or electronic form are appropriately designed, completed, reviewed, authorized, distributed and kept as required;
(b) documents are readily available for inspection by the Authority;
(c) written procedures are followed for the preparation, review, approval, use of and control of all documents;
(d) documents are laid out in an orderly fashion and made easy to complete, review and check;
(e) all documents are completed, signed and dated as required by authorized personnel and shall not be changed without the necessary authorization;
(f) records are accurate, legible, traceable, attributable, unambiguous and maintained for the back-up including restoration of data;
(g) where applicable, electronic data is backed-up in accordance with written procedures;
(h) procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation are followed;
(i) documents are reviewed regularly and kept up-to-date and when a document has been revised, a system shall exist to prevent inadvertent use of the superseded version;
(j) all records are stored and retained using facilities that prevent unauthorized access, modification, damage, deterioration or loss of documentation during the entire life-cycle of the record;

(k) records are readily retrievable; and

(l) comprehensive records are maintained for all receipts, storage, issues and distribution and shall include-

(i) date of receipt or dispatch as appropriate;

(ii) name and description of the product;

(iii) quantity received, or supplied;

(iv) name and address of the supplier and customer;

(v) batch, lot or serial number, where applicable;

(vi) expiry date, where applicable;

(vii) suitability of the supplier;

(viii) qualification of suppliers; and

(ix) customer qualification.

Records to be kept by Authority

35. The Authority may keep such records of information which it receives from, or relating to, storage and distribution of products as it considers appropriate and may, in particular, keep records relating to-

(a) all authorizations under these Regulations;

(b) notification of matters relating to substandard and falsified products;

(c) inspections or requests for information; and

(d) any other records as the Authority may deem appropriate.

PART XIV
OFFENCES AND PENALTIES

Offences and penalties

36. Any person who contravenes or fails to comply with these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations, commits an offence and shall upon conviction, be liable to the penalty prescribed under the Act.

Dodoma,

……. ……., 2021

Minister for Health, Community Development, Gender, Elderly and Children