



**REGULATION GOVERNING GOOD STORAGE AND
DISTRIBUTION PRACTICES OF MEDICAL PRODUCTS**

(Rwanda FDA law N° 003/2018 of 09/02/2018, Article 8)

RWANDA FDA
Rwanda Food and Drugs Authority

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY RWANDA FDA	9 th September 2021
STAKEHOLDERS CONSULTATION	28 th September 2021
ADOPTION OF STAKEHOLDERS' COMMENTS	15 th October 2021
DATE FOR COMING INTO EFFECT	29 th November 2021



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ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulation N° CBD/TRG/027 Rev. N° 0 Governing the Good Storage and Good Distribution Practices for Medical Products, made this 29th day of November, 2021.

E. Bienvenu
28/11/2021

Dr. Emile BIENVENU
Director General



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ABBREVIATIONS AND ACRONYMS

CAPA	: Corrective Actions and Preventive Actions
GDP	: Good Distribution Practices
FEFO	: First Expiry, First Out
LIFO	: Last- in first-out
GMP	: Good Manufacturing Practices
GDP	: Good Distribution Practices
GPP	: Good Pharmacy Practice
GSP	: Good Storage Practices
SOP	: Standard Operating Procedures
HIV/AIDS	: Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome



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CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

These regulations govern Good Distribution Practices of Medical Products.

Article 2: Citation

These regulations may be cited as the “*Regulation CBD/TRG/027 Rev. N° 0, Governing Good Storage and Good Distribution Practices of Medical Products*”.

Article 3: Application

These regulations shall apply in all regulatory controls related to good storage and distribution practices for medical products and shall apply to all persons and companies involved in any aspect of the distribution of medical products from the manufacturing site to the point of use.

These include but are not limited to governments at all levels, public and private health and storage facilities, manufacturers of medical products, importers, exporters, distributors, wholesalers, suppliers, retailers, freighters, forwarding agents, transporters, public and private customs bonded warehouse.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

“**Agreement**” means Arrangement undertaken by and legally binding on parties.

“**Auditing**” means an independent and objective activity designed to add value and improve an organization’s operations by helping the organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes.

“**Authority**” means Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under Law N° 003/2018 of 09/02/2018;

“**Batch (or lot)**” means a defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous;

“**Batch number or (lot number)**” means a distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, 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 the material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and tertiary containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary packaging encloses the primary packaging and tertiary packaging material means outer carton in which multiples of saleable units are packed. Secondary and tertiary containers are not intended to be in direct contact with the product.

“**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;

“**Counterfeit medical product**” A medical product that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit medical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging.

“**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 or organization who receives, stores, warehouses, handles, holds, offers, markets or displays pharmaceutical products. A distributor shall be an entity that is appropriately authorized by the competent authority to perform the intended function as prescribed in these regulations, and which can be held accountable for its activities. These include but not limited to governments at all levels, public and private health and storage facilities, manufacturers of finished products, importers, exporters, distributors, wholesalers, suppliers, retailers.

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

“Due diligence” This is a term used for a number of concepts, involving either an investigation of a distributors or persons prior to signing a contract, or an act with a certain standard of care.

“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 a distribution procedure that ensures the stock with the earliest expiry date is distributed and/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;

“**Labelling**” 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 medical 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;

“**Medical product**” includes medicines, vaccines, diagnostics, and medical devices.

“**Owner of premises**” means a person authorized to deal in the business of storage, transport and distribution of medical 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;

“Pharmaceutical products” means any substance or combination of substances presented or administered to human beings or animals for treating or preventing disease with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions in human beings or in animals. These include but not limited to medicines, vaccines, biologicals, herbal medicines, medical devices, disinfectants and diagnostics.

“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;

“Production” means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and re-labelling, to completion of the finished product.

“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;

“Quality assurance” means the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production.

“Quarantine” means the status of products isolated physically or by other effective means while a decision is waited 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 authorized to supervise and or dispense medical products under the Law 003/2018.

“Regulatory action” means Includes but not limited to product hold, recall, forfeiture, or destruction; sealing of distribution facility; withdrawal of registration certificate etc.

“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 medical products from one point to another within the supply chain;

“Validation” means action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.

“**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 recognized by the Authority.

In these Regulations, the following verbal forms are used:

“**Shall**” indicates a requirement;

“**Should**” indicates a recommendation;

“**May**” indicates a permission; and

“**Can**” indicates a possibility or a capability.



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CHAPTER II: GENERAL REQUIREMENTS

Article 5: Requirements for application for GDP inspections

- i. Duly filled application form for GDP inspection
- ii. Original authorization of the establishment issued by Rwanda FDA
- iii. Evidence of payment of prescribed fees to Rwanda FDA Accounts.
- iv. Notarized copy of Degree and equivalence if applicable of Responsible Pharmacist,
- v. Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council.
- vi. Curriculum vitae of the responsible pharmacist.
- vii. Copy of the identity card or passport of both the Managing Director and the responsible Pharmacist.
- viii. Copy of valid contract between responsible pharmacist and Managing Director of the pharmacy.

Article 6: Donations of Medical Products

The principles of GDP should also be adhered to in the case of medical products, which are donated. Distributors shall;

- 1^o Maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.
- 2^o Have sufficient competent personnel to carry out all the tasks for which the distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.
- 3^o Have suitable and adequate premises, installations and equipment, so as to ensure proper storage conditions and distribution of medical products.
- 4^o Have written documentation to prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medical products.
- 5^o Have all actions taken by distributors captured in a tracking system to ensure that the safety, quality and efficacy of the medical product are not lost and that the distribution of medical products is performed according to the information on the outer packaging.
- 6^o Have records of all complaints, returns, suspected falsified medical products and recalls according to written procedures. Records should be made available to the competent

authorities. An assessment of returned medical products should be performed before any approval for resale.

- 7^o Ensure that any activity covered by the GDP Regulations that is outsourced is correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party.
- 8^o Be responsible of ensuring that the quality of the medical products is maintained from the manufacturer to the stores and then to the final consumer, the retailer or/and client. It is the responsibility of the supplying distributor to protect medical products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport.
- 9^o Conduct Self-inspection in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures; Self-inspections shall be recorded;

Article 7: Distribution of Medical Products within and outside Rwanda

The distributor or the organization to which it belongs is accountable for the activities that it performs which relate to the distribution of medical products.

- 1^o Distributors or their agents shall only distribute a medical product within or to a country or territory if a marketing authorization or similar authorization has been granted, which allows the use of that medical product in that country or territory.
- 2^o Holders of an authorization to distribute medical products shall obtain their supplies of medical products only from persons or entities, which are in possession of the applicable authorization to sell or supply such products to a distributor.
- 3^o Distributors or their agents shall supply medical products only to persons or entities, which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a client.
- 4^o When duties and responsibilities of a distributor is delegated or contracted out. It shall be to suitably designated persons or entities as authorized and as necessary. Duties and responsibilities should be specified in a written agreement and periodic audits of such activities shall be done.

- 5^o In an event a distributor or his/ her agent subcontracts an activity to another entity, the person or entity to whom the activity is subcontracted shall be appropriately authorized to perform the subcontracted activity and should uphold the same standards as the distributor.
- 6^o The owner of premises shall ensure that storage and distribution of regulated medical products including automated storage and retrieval systems are carried out in accordance with these Regulations.
- 7^o 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

Article 8: Organization and management

- 1^o There should be an adequate organizational structure for each entity defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated.
- 2^o Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions. At every level of the supply chain, employees should be fully informed and trained in their duties and responsibilities.
- 3^o 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. The person should be appropriately qualified.
- 4^o 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.
- 5^o The responsibilities placed on any one individual should not be so extensive as to present any risk to product quality.
- 6^o There should be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of medical products.
- 7^o Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place.

Article 9: Personnel

- 1^o All personnel involved in distribution activities shall be competent on basis of education background, training, skills and experience in the requirements of good distribution and good storage. The distributors shall provide the needed training to achieve competency.
- 2^o Key personnel involved in the distribution of medical products should have the ability and experience appropriate to their responsibility for ensuring that medical products are distributed properly.
- 3^o There should be an adequate number of competent personnel involved in all stages of the distribution of medical products in order to ensure that the quality of the product is maintained.
- 4^o Personnel dealing with hazardous medical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous medical products, as well as products presenting special risks of abuse, fire or explosion) should be given specific training.
- 5^o Personnel dealing with hazardous medical products, including products containing materials that are highly active, toxic, infectious or sensitizing, should be provided with protective garments as necessary and material safety data sheet (MSDS) shall be in place for proper handling.
- 6^o 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.
- 7^o Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access medical products must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.
- 8^o Codes of practice and punitive procedures should be in place to prevent and address situations where persons involved in the distribution of medical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product.

Article 10: Quality assurance system

1^o There should be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality, as formally expressed and authorized by management within an organization.

2^o The quality system should include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality.

3^o The quality system shall include provisions to ensure that the holder of the marketing authorization, entity identified on the label (if different from the manufacturer), the Rwanda FDA and/or international regulatory bodies, as well as other relevant competent authorities, are informed immediately in a case of confirmed or suspected counterfeiting of a medical product.

4^o Where electronic commerce (e-commerce) is used; defined procedures and adequate systems should be in place to ensure traceability and reliance in the quality of the medical products concerned. Electronic transactions, relating to the distribution of medical products, should be performed only by authorized persons or entities.

5^o Authorized procurement and release procedures for all administrative and technical operations performed should be in place to ensure that appropriate medical products are sourced only from approved suppliers and distributed by approved entities.

6^o 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 is recommended. Such certification should not, however, be seen as a substitute for compliance with these GDP Regulations and the applicable principles of GMP relating to medical products.

7^o If measures to ensure the integrity of the medical products in transit are in place, they should be managed properly. Written procedures should be in place for use in situations where medical products are suspected of being or are found to be counterfeit.

8^o Distributors shall from time-to-time conduct risk assessments to assess potential risks to the quality and integrity of medical products. The quality system shall be developed and implemented to address any potential risks identified. The quality system shall be reviewed and revised periodically to address new risks identified during a risk assessment.

- 9^o Records shall be made at the time a transaction takes place and such that all significant activities and events are traceable. Records should be clear and readily available. Records must be kept for a minimum of ten years from the date of distribution.
- 10^o Records for each purchase or sale shall include date of purchase or supply, name of medical product, quantity supplied or received, batch number, expiry date, name and address of supplier or consignee.
- 11^o A suitable product coding, identification system should be in place and developed in collaboration with the various parties involved in the supply chain.
- 12^o 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:
- i. Appropriate organizational structure with defined responsibilities of the personnel recorded as job descriptions;
 - ii. Competent personnel;
 - iii. Suitable and sufficient premises, equipment and facilities; and
 - iv. Written and approved procedures for all activities.
- 13^o The quality assurance system should ensure that:
- i. Medical products are procured, held, supplied, imported or exported in a way that is compliant with the requirements of GDP;
 - ii. Management responsibilities are clearly specified;
 - iii. Products are delivered to the right recipients within a satisfactory time period
 - iv. Records are made on time and easily retrievable
 - v. Deviations from established procedures are documented and investigated;
 - vi. Appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.
- 14^o The quality assurance system shall extend to the control and review of any outsourced activities related to the procurement, holding, supply, import or export of medical products
- 15^o The quality assurance system shall assess the suitability and competence of the contract acceptor to carry out the activity, preserving the integrity and security of the medical

products, and requesting, preserving documentation, and checking authorization or marketing status, if required;

16° The quality assurance system shall define the responsibilities and communication processes for the quality-related activities of the parties involved;

17° The quality assurance system shall monitor and review of the performance of the contract acceptor, and the identification and implementation of any required improvements on a regular basis.

Article 11: Quality Risk Management

The owner of premises shall have a system to assess, control, communicate and review risks identified at all stages in the supply chain:

1° Distributors shall annually conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products. The quality system shall be developed and implemented to address any potential risks identified. The quality system shall be reviewed and revised annually to address new risks identified during a risk assessment

Article 12: Management review

1° The owner of premises shall establish a system for periodic management review which shall include the following;

- i. review of the quality system and its effectiveness by using quality metrics and key performance indicators;
- ii. identification of opportunities for continual improvement; and
- iii. follow up on recommendations from previous management review meetings.
- iv. The status of actions from previous management review meetings;
- v. Changes in external and internal issues that are relevant to the quality management system;
- vi. Information on the performance and effectiveness of the quality management system including trends in:
 - Customer satisfaction and feedback from relevant interested parties
 - Non conformities and corrective actions
 - Warehouse performance and conformity of products and services
 - Audit results
 - The performance of external providers
- vii. The adequacy of resources;

- viii. The effectiveness of actions taken to address risks and opportunities;
- ix. Opportunities for improvement

2° Minutes and related documentation from management review meetings shall be made available on request by the Authority.

Article 13: Premises, Warehousing and Storage

1° Categories of premises:

- i. manufacturing facilities;
- ii. importing wholesalers;
- iii. warehouses;
- iv. wholesalers;
- v. Retailers;
- vi. Hospital pharmacies;
- vii. District pharmacies
- viii. Central Medical stores;
- ix. Veterinary practice facilities;
- x. Transportation and medical products in transit (Vehicles, Vessels, Aircrafts, shipment containers etc.)
- xi. Public and private bonded warehouses
- xii. Medical laboratory facilities; and
- xiii. Any other premises as the Authority may designate.

2° Good storage practices (GSP) shall be applicable in all circumstances where medical products are stored and throughout the distribution process.

3° The personnel involved in storage activities shall always respect the storage conditions that include but not limited to:

- i. Clean and disinfect storeroom regularly
- ii. Store supplies in a dry, well-lit, well-ventilated storeroom out of direct sunlight
- iii. Secure storeroom from water penetration
- iv. Ensure that fire safety equipment is available and accessible and personnel are trained to use it
- v. Store condoms and other latex products away from electric motors and fluorescent lights.
- vi. Maintain cold storage, including a cold chain, for commodities that require it.
- vii. Keep narcotics and other controlled substances in a locked place.
- viii. Store flammable products separately from other products. Take appropriate safety precautions.

- ix. Stack cartons at least 10 cm (4 in) off the floor, 30 cm (1 ft) away from the walls and other stacks, and not more than 2.5 m (8 ft) high.
 - x. Store medical products away from insecticides, chemicals, old files, office supplies, and other materials.
 - xi. Arrange cartons so that arrows point up. Ensure that identification labels, expiry dates, and manufacturing dates are clearly visible.
 - xii. Store supplies in a manner accessible for FEFO, counting, and general management.
 - xiii. Separate and dispose of damaged or expired products immediately.
- 4^o Storage areas should be clean and free from litter, dust and pests. Distributors must ensure that premises and storage areas are cleaned regularly. There should also be written procedures for pest control. The pest control agents used should be safe and there should be no risk of contamination of medical products. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.
- 5^o If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas.
- 6^o Receiving and dispatch bays should protect medical products from the non-conductive environmental conditions. Receiving areas should be designed and equipped to allow incoming containers of medical products to be cleaned, if necessary, before storage.
- 7^o Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security.
- 8^o Physical or other equivalent validated segregation should be provided for the storage of rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned should be appropriately identified.
- 9^o Unless there is an appropriate alternative system to prevent the unintentional or unauthorized use of quarantined, rejected, returned, recalled or suspected counterfeit medical products, separate storage areas should be assigned for their temporary storage until further action taken.
- 10^o Radioactive materials, narcotics and other hazardous, sensitive and/ or dangerous medical products, as well as products presenting special risks of abuse, fire or explosion should be

stored in dedicated area(s) that is subject to appropriate additional safety and security measures.

- 11^o Medical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination. A system should be in place to ensure stock rotation first expiry/ first out (FEFO)) with frequent and regular controls that the system is working correctly.
- 12^o Broken or damaged items should be withdrawn from usable stock and stored separately.
- 13^o Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely.
- 14^o Medical products shall be stored separate from other goods and under the conditions specified by the manufacturer in order to avoid deterioration by light, moisture or temperature.
- 15^o Storage conditions for medical products shall comply with the recommendations of the manufacturer.
- 16^o Facilities should be available for the storage of all medical products under appropriate conditions Records should be maintained of these conditions if they are critical for the maintenance of the characteristics of the medical product stored.
- 17^o Records of temperature monitoring data shall be available for review.
- 18^o Equipment used for monitoring of storage conditions shall be calibrated at defined intervals.
- 19^o Periodic stock reconciliation shall be performed by comparing the actual and recorded stocks. This should be done at defined intervals.
- 20^o Stock discrepancies shall be 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 medical products. Documentation relating to the investigation should be kept for a predetermined period.
- 21^o Reception area must be separate from the storage area. Deliveries shall be examined on receipt in order to check that containers are not damaged and that the consignment corresponds to the order.

22° Upon receipt, medical products stored at specific requirements shall be immediately identified and stored according to specified storage conditions.

23° Distributors should conduct visual checks of the products that they receive

Article 14: Design of Premise

The owner of premises shall design and maintain storage areas to ensure GSP as provided for in these Regulations. The storage areas shall:

- i. Be suitably secure, structurally sound and of sufficient capacity to allow for the orderly handling and safe storage of medical products;
- ii. Be provided with adequate lighting to enable all operations to be carried out accurately and safely;
- iii. Be designed to prevent unauthorized persons from entering;
- iv. 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;
- v. Be designed or adapted to ensure appropriate and good storage conditions and shall be clean, dry and maintained within acceptable temperature limits;
- vi. Receiving areas shall be designed and equipped to allow incoming containers of products to be cleaned and appropriately stored

Article 15: Receiving Areas

1° A person receiving a consignment of medical products shall ensure that:

- i. Each incoming delivery is checked against the relevant documentation, to ensure that the correct medical product is delivered from the correct supplier which may include, the purchase order, containers, label description, batch or lot number, expiry date, medical product, quantity, certificate of analysis or certificate of conformity, where applicable;
- ii. 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 comprises of more than one batch:
- iii. Provided that, where the consignment has more than one batch, each batch shall be dealt with separately;
- iv. 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;

- v. Receiving areas are of sufficient size to allow for the cleaning of incoming medical products;
 - vi. When required, samples of medical 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;
 - vii. Following sampling, the medical products are subject to quarantine and batch segregation maintained during quarantine and all subsequent storage, where applicable;
 - viii. 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:
 - ix. Provided that, cold-chain materials and medical products received, are handled according to the approved conditions by the Authority, or as recommended by the manufacturer, as appropriate;
- 2° Products are not transferred to saleable stock until an authorized release is obtained.
- 3° Rejected products shall be segregated and securely stored while awaiting destruction or return to the supplier.

Article 16: Storage and Principles

The owner of premises shall observe the following during storage of medical products in premises:

- 1° 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;
- 2° Pallets shall be kept in a good state of cleanliness, repair and condition;
- 3° Premises and storage areas shall be kept clean;
- 4° There shall be a written programme for pest control and the pest control agents used shall be safe without risk of contamination of products;
- 5° 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;
- 6° Receiving and dispatch bays shall protect products from direct sunlight and rain;

- 7^o Handling and storage of products shall be in such a manner as to prevent contamination, mix-ups and cross-contamination;
- 8^o 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;
- 9^o Arrangement shall be made to withdraw broken or damaged items from usable stock and stored separately;
- 10^o Narcotic and psychotropic substances shall be stored in a secure area.
- 11^o 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.

Article 17: Storage conditions

- 1^o The owner of premises shall ensure that, storage conditions for medical products are in compliance with their labelling and information provided by the manufacturer.
- 2^o The owner of premises shall ensure that:
 - i. heating, ventilation and air conditioning systems are appropriately designed, installed, qualified and maintained to ensure that the required storage conditions are upheld;
 - ii. mapping studies for temperature, and relative humidity where appropriate, is done in storage areas, refrigerators and freezers;
 - iii. temperature and relative humidity, as appropriate, is controlled and monitored at regular intervals;
 - iv. the equipment used for monitoring temperature and relative humidity are calibrated and be suitable for its intended use; and
 - v. the records collected are reviewed and all records pertaining to mapping and monitoring shall be kept for a period of two years.

Article 18: Traceability of products

- 1^o The owner of premises shall put in place procedures for:

- i. Safe, transparent and secure distribution which includes product traceability throughout the supply chain;
 - ii. Document traceability of products received and distributed, to facilitate product recall;
 - iii. Identification of all parties involved in the supply chain depending on type of product;
- 2° 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 documentation enabling traceability of records including expiry dates and batch or lot numbers as part of a secure distribution.

CHAPTER III : PERSONNEL

Article 19: Competent personnel

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 medical products.

Article 20: Responsible person

- 1° The owner of premises shall appoint a person as responsible person whom shall meet the qualifications:
- 2° The responsible person shall have appropriate knowledge and experience in good storage and distribution practices;
- 3° 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

Article 21: Other personnel

- 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.

Article 22: Training of personnel

- 1° The responsible person shall ensure that personnel receive initial and continued training in accordance with a written training programme.
- 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.
- 3° The responsible person shall keep records of all training, attendance and assessments and the effectiveness of training shall be periodically assessed and documented.

Article 23: Personnel hygiene

- 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.

Article 24: Procedures and conditions of employment

- 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^o 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.

CHAPTER IV: TRANSPORTATION AND DISTRIBUTION

Article 25: Layout and design

- 1^o 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^o During transportation and distribution, the owner of premises or transporter shall ensure that:
- i. the risk to the quality of the product is eliminated or minimized to an acceptable level;
 - ii. product, batch or lot and container identity are maintained at all times;
 - iii. all labels remain legible;
 - iv. distribution records are sufficiently detailed to allow for a recall when required;
 - v. drivers of vehicles are identified and present appropriate documentation to demonstrate that they are authorized to transport products;
 - vi. vehicles are suitable for their purpose, with sufficient space and appropriately equipped to protect products;
 - vii. 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;
 - viii. 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;
 - ix. 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:
 - x. defective vehicles and equipment are not used and are either labelled as such or removed from service;
 - xi. procedures are in place for the operation and maintenance of all vehicles and equipment;

- xii. equipment and materials used for the cleaning of vehicles are not sources of contamination or have an adverse effect on product quality;
- xiii. 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;
- xiv. appropriate environmental conditions are maintained, monitored and recorded and such records kept for a period of not less than one year;
- xv. instruments used for monitoring conditions to include temperature and humidity, within vehicles and containers are calibrated at regular intervals;
- xvi. rejected, recalled, returned or suspected falsified products are securely packaged, clearly labelled and accompanied by the appropriate supporting documentation;
- xvii. measures are in place to prevent unauthorized persons from entering or tampering with vehicles or equipment to prevent the theft or misappropriation thereof;
- xviii. shipment containers have no adverse effect on the quality of the products and shall offer adequate protection to materials and products;
- xix. containers are labelled indicating handling and storage conditions, precautions, contents and source, and safety symbols, as appropriate;
- xx. 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
- xxi. 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.

Article 26: Dispatch

- 1^o 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^o The products shall have obtained prior marketing authorization issued by the Authority.
- 3^o Records for the dispatch of products under this regulation, shall be prepared and include the following information:
 - i. date of dispatch;
 - ii. complete business name and address;
 - iii. type of entity responsible for the transportation;
 - iv. telephone or mobile number;
 - v. names of contact persons;
 - vi. type of business of recipient;

- vii. a description of the products, including name, dosage form and strength, if applicable;
 - viii. quantity of the products including number of containers and quantity per
 - ix. container, if applicable;
 - x. applicable transport and storage conditions;
 - xi. a unique number to allow identification of the delivery order; and
 - xii. assigned batch or lot number and expiry date.
- 4^o 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.
- 5^o 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.
- 6^o The owner of premises shall ensure that:
- i. vehicles and containers are loaded carefully and systematically on a LIFO basis, to save time when unloading, to prevent physical damage and to reduce security risks;
 - ii. products and shipment containers are secure in order to prevent or to provide evidence of unauthorized access;
 - iii. vehicles and operators are provided with additional security where necessary, to prevent theft and other misappropriation of products during transportation;
 - iv. products are stored and transported in accordance with procedures such that:
 - a. the identity of the product is not lost;
 - b. the product does not contaminate and is not contaminated by other products;
 - c. adequate precautions are taken against spillage, breakage,
 - d. misappropriation and theft; and appropriate environmental conditions are maintained which includes using cold-chain for thermolabile products;
- 7^o 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; transportation of products containing hazardous substances or narcotics and other

dependence-producing substances, is done in safe, suitably designed, secure containers and vehicles;

- 8° Spillages are cleaned up as soon as possible, in order to prevent possible contamination, cross-contamination and hazards in accordance with written procedures;
- 9° Damage to containers and any other event or problem that occurs during transit is recorded, investigated and reported to the Authority, where necessary; and
- 10° Products in transit are accompanied by the appropriate documentation.

Article 27: Re-packaging and Re-labelling

- 1° A person shall not repack or relabel any product or material for the purpose of distribution to any premises.
- 2° where the owner of premises intends to repack or relabel any product or material, S/he shall seek an authorization from the Authority.
- 3° the owner of premises shall repack or relabel products or materials in accordance with good manufacturing practices requirements.
- 4° where the products have been repacked or re-labeled, 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 of within 3 months after its expiration.
- 6° Any extension of time for disposal of any expired product shall be sought from the Authority.
- 7° the Authority shall issue a disposal certificate as prescribed in the disposal regulations in force.

Article 28: Outsourced activities

The owner of premises or contract giver shall ensure that:

- 1° 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;

2° 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
- v. the contract giver; and
- vi. periodic audits.

3° the contract acceptor is assessed before entering into the contract through on-site audits, documentation and or licensing status review; and

4° the contract acceptor is provided with all relevant information relating to the material and products.

- i. The contract acceptor shall have adequate resources to include premises, equipment, personnel, knowledge, experience and vehicles, as appropriate to carry out the delegated functions.
- ii. the contract acceptor shall refrain from performing any act that may adversely affect the quality of materials or products handled.

CHAPTER V: SUBSTANDARD AND FALSIFIED PRODUCTS

Article 29: Handling of substandard and falsified products

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° where substandard and or falsified products are suspected or identified:

- i. the marketing authorization holder, manufacturer, supplier and the Authority shall be informed;
- ii. 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
- iii. records shall be maintained reflecting the investigations and action taken to include disposal of the product.

- 3° the owner of premises shall ensure that, sub-standard and falsified products do not re-enter the market.
- 4° 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

CHAPTER VI: COMPLAINTS HANDLING

Article 30: Good documentation practice

- 1° The owner of premises shall establish written procedures for the handling of complaints.
- 2° 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 these regulations, 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 these regulations, 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° 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 these regulations.

CHAPTER VII: RETURNS AND RECALLS OF PRODUCTS

Article 31: Returns

- 1° The owner of premises shall:
 - i. handle returned products in accordance with written procedures;
 - ii. place all returned products in quarantine upon receipt;
 - iii. take precautions to prevent access and distribution until a decision has been taken with regard to their disposition;
 - iv. maintain storage conditions applicable to the products until their disposition;

- v. ensure returned products are destroyed unless it is certain that their quality is satisfactory.
- 2^o The owner of premises shall, when handling returned products, take into consideration the following:
 - i. 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;
 - ii. the terms and conditions of the contract between the parties; and
 - iii. examining returned products, with decisions taken by suitably qualified, experienced and authorized persons.
- 3^o The owner of premises shall follow written procedures, including safe transport, where products are rejected.
- 4^o The owner of premises shall destroy returned products, where applicable in accordance with disposal regulations in force.
- 5^o The owner of premises shall keep records of all returned, rejected and destroyed products for a period of not less than one year.

Article 32: Recalls

- 1^o The owner of premises shall follow written procedures for recall of products.
- 2^o the Authority, original manufacturer, marketing authorization holder, customers or other relevant contract party, shall be informed in the event of a recall.
- 3^o The owner of premises shall ensure that, all recalled products are secure, segregated, transported and stored under appropriate conditions.
- 4^o recalled products shall be clearly labelled and storage conditions applicable to the product maintained, where possible.
- 5^o 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^o 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^o Without prejudice to the generality of these regulations, the owner of premises shall follow other recall procedures as provided for in the recall Regulations in force. For reference standards, the label or accompanying document shall indicate concentration, date of manufacture, expiry date, date the closure is first opened, and storage conditions where appropriate.

CHAPTER VIII: INSPECTION AND ENFORCEMENT

Article 33: Self-inspections

- 1^o The owner of premises shall ensure that, the quality system includes self-inspections.
- 2^o 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^o the team conducting the inspection shall be free from bias and individual members shall have appropriate knowledge and experience.
- 4^o 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^o necessary CAPA shall be taken and its effectiveness reviewed within a defined timeframe.

Article 34: Inspection by Authority

- 1^o 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^o 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^o 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 Rwanda at which storage and distribution of products is carried out.

4^o The Authority may, subject to the provisions of the Law 003/2018 of 09/02/2018 in Article 44, paragraph 3, 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.

Article 35: Types of inspections

1^o There shall be four types of good distribution practice inspections which shall be divided into the following categories:

- i. routine inspection;
- ii. enforcement inspection
- iii. follow-up inspection;
- iv. special inspection; and
- v. any other types as the Authority may designate.

The inspection should be conducted as follows:

2^o the routine inspection is a full inspection of all applicable components of GDP and licensing provisions. It may be indicated when the distributor:

- i. Newly established
- ii. Requests for renewal of a GDP Certificate
- iii. Has a history on non-compliance with GDP;
- iv. Modification to the storage and distribution methods
- v. Has not been inspected during in the last 3 to 5 years.

3^o Enforcement GDP inspections are the evaluation of limited aspects relating to GDP compliance within a facility. The distributor with a consistent record of compliance with GDP through previous routine inspections are eligible for enforcement inspections. The focus of an enforcement inspection is on a limited number of GDP requirements selected as indicators of overall GDP performance, plus the identification of any significant changes that could have been introduced since the last inspection. Evidence of unsatisfactory GDP performance observed during a concise inspection should trigger a more comprehensive inspection.

4^o Follow-up GDP inspections (reassessment or re-inspection) are made to monitor the result of corrective measures. They are normally carried out from 6 weeks to 6 months after the initial inspection, depending on the nature of the defects and the work to be undertaken. They are limited to specific GDP requirements that have not been observed or that have been inadequately implemented.

- 5^o Special GDP inspections may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports of adverse drug reactions. Such inspections may be focused on one product, a group of related products, or specific operations such as mixing, sterilization, or labeling. Special visits may be also made to establish how a specific product is manufactured as a prerequisite for marketing approval or issuance of an export certificate.

Article 36: Power of Inspectors

For the purposes of enforcing compliance for conducting inspections, an inspector appointed in accordance with these regulations shall, upon production of evidence that S/he is so authorized, have the right:

- 1^o At any reasonable time to enter any premises, other than premises used only as a private dwelling house, which he has reason to believe it is necessary for him to visit, including any premises of any person who carries out any of the activities referred to in these Regulations;
- 2^o To carry out at those premises during that visit inspections, examinations, tests and analyses as he considers necessary;
- 3^o To require the production of, and inspect any article or substance at, the premises;
- 4^o To require the production of inspect and take copies of, or extracts from, any book, document, data or record in whatever form it is held at, or in the case of computer data or records accessible at the premises;
- 5^o To take possession of any samples for examination and analysis and any other article, substance, book, document, data, record in whatever form they are held at, or in the case of computer data or records accessible at, the premises;
- 6^o To question any person whom, he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;
- 7^o To require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities; and
- 8^o To require, as he considers necessary, any person to afford him such facilities as he may

reasonably require that person to afford him; but nothing in this paragraph shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for disclosure in an action in the court or, as the case may be, on an order for production of documents in an action in the court.

- 9^o An inspector will enter the premise that are closed or unoccupied, the inspector is required to collaborate with the local administration and a representative of the public investigation body of the area.
- 10^o Together they shall provide written proof of the premises to be inspected before inspection. The written proof stated under this paragraph shall be signed and where necessary photos of the premises must be added to prove the premises were closed or unoccupied prior to physical inspection. The written proof shall be part of the report that must be submitted to the Authority.
- 11^o Upon exiting any premises which an inspector is authorised to enter by a warrant under paragraph 2 of this Article, he or she shall, if the premises are unoccupied, or the occupier is temporarily absent, leave the premises as effectively secured against trespassers as he or she found them.
- 12^o Where, pursuant to provisions of paragraph 5, an inspector takes possession of any article, substance, book, document, data or record, he or she shall leave at the premises with a responsible person, or if there is no such person present on the premises, leave in the premises in a prominent position, a statement giving particulars of the article, substance, book, document, data or record sufficient to identify and acknowledging that he or she has taken possession of the document.
- 13^o Where, pursuant to Paragraph 5 of this Article, an inspector takes a sample for analysis, the Director General may make such arrangements for analysis of that sample as he considers appropriate.

CHAPTER IX: DOCUMENTATION AND RECORDS KEEPING

Article 37: Documentations

- 1^o The owner of premises shall ensure that:

- i. documentation including all procedures, records and data, whether in paper or electronic form are appropriately designed, completed, reviewed, authorized, distributed and kept as required;
- ii. documents are readily available for inspection by the Authority;
- iii. written procedures are followed for the preparation, review, approval, use of and control of all documents;
- iv. documents are laid out in an orderly fashion and made easy to complete, review and check;
- v. all documents are completed, signed and dated as required by authorized personnel and shall not be changed without the necessary authorization;
- vi. records are accurate, legible, traceable, attributable, unambiguous and maintained for the back-up including restoration of data;
- vii. where applicable, electronic data is backed-up in accordance with written procedures;
- viii. procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation are followed;
- ix. 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;
- x. 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;
- xi. records are readily retrievable; and
- xii. comprehensive records are maintained for all receipts, storage, issues and distribution and shall include:
 - a. date of receipt or dispatch as appropriate;
 - b. name and description of the product;
 - c. quantity received, or supplied;
 - d. name and address of the supplier and customer;
 - e. batch, lot or serial number, where applicable;
 - f. expiry date, where applicable;
 - g. suitability of the supplier;
 - h. qualification of suppliers; and customer qualification.

Article 38: Records to be kept by Authority

- 1^o 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:
- i. all authorizations under these Regulations;
 - ii. notification of matters relating to substandard and falsified products;
 - iii. inspections or requests for information; and
 - iv. any other records as the Authority may deem appropriate.

Article 39: Measurement, analysis and improvement

- 1^o The warehouse shall determine:
- i. What needs to be monitored and measured;
 - ii. The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
 - iii. When the monitoring and measuring shall be performed;
 - iv. When the results from monitoring and measurement shall be analyzed and evaluated.
- 2^o The warehouse shall evaluate the performance and the effectiveness of the quality management system and shall retain appropriate documented information as evidence of the results.
- 3^o The warehouse shall apply suitable methods for monitoring and where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the operations to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Article 40: Environmental management

- 1^o The warehouse shall adopt a systematic approach to environmental management by implementing environmental practices such as adopting the 3Rs practice, for Re-use, Reduce and Recycle. The warehouse shall also keep up with environmental news and green trends to identify areas of improvement.
- 2^o The warehouse shall ensure that persons doing work under the warehouse's control are aware of its environmental approaches in order to ensure the proper implementation of environmental practices and promote a cultural shift.

- 3^o The warehouse shall institute an energy saving, waste management and recycling program and shall promote awareness among its employees to ensure proper implementation.

CHAPTER X: REFUSAL VALIDITY OF A CERTIFICATE

Article 41: Refusal to grant a certificate

A GDP certificate shall not be granted where the Authority finds the applicant not complying with the requirements prescribed in these regulations and relevant regulatory documents.

Article 42: Validity of a certificate

- 1^o A GDP certificate shall be valid for five (5) years renewable from the date of issuance, but may be suspended or withdrawn if any of the conditions under which it was granted, is violated.
- 2^o A GDP certificate issued to an applicant and shall not be transferred to another applicant or premise without prior written approval of the Authority.
- 3^o Any change(s) to the information contained on the certificate shall be notified to the Authority within a period of five (5) working days.

CHAPTER XI: CATEGORIZATION OF INSPECTION FINDINGS

Article 43: Issuance of a report

Following inspection, a report is issued to the inspected site where deficiencies are classified into three categories; critical, major and other. A summary for the criteria for judging deficiencies as critical, major or other are detailed below.

1^o Critical Deficiency:

Any departure from Regulations on Good Distribution Practice resulting in a medicinal product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medicines reaching the patients. A combination of a number of major deficiencies that indicates a serious systems failure. An example of a critical deficiency could be:

- i. purchase from or supply of medicinal products to a non-authorised person
- ii. storage of products requiring refrigeration at ambient temperatures
- iii. rejected or recalled products found in sellable stock.

2° Major Deficiency:

A non-critical deficiency:

- i. which indicates a major deviation from Good Distribution Practice;
- ii. or which has caused or may cause a medicinal product not to comply with its marketing authorisation in particular its storage and transport conditions;
- iii. or which indicates a major deviation from the terms and provisions of the wholesale distribution authorisation;
- iv. or a combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency.

3° Other Deficiency:

A deficiency which cannot be classified as either critical or major, but which indicates a departure from Regulations on Good Distribution Practice.

Inspected sites are requested to reply to the deficiencies stating proposed /completed corrective action(s) relating to the individual deficiency and date(s) for completion of the corrective action(s). It is expected that any critical or major findings are addressed immediately.

CHAPTER XII: ADMINISTRATIVE SANCTIONS

Article 44: Warning, Suspension, revocation of a certificate and/or monetary fines

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 Law.

- 1° A warning letter may be issued to the applicant or the certificate may be suspended or revoked where the Authority finds the applicant not complying with any of the requirements or conditions in these Regulations; or has ceased to be fit to carry on the business.
- 2° The notice of suspension or revocation shall be issued by the Authority in the standard format
 - i. Doc. No. DIS/FMT/024-*Notification for Suspension of Authorization; and*
 - ii. Doc. No. DIS/FMT/025-*Notification for Withdrawal/Revocation of Authorization.*
- 3° Monetary fines are provided in the Regulations No CBD/TRG/004 Rev_2 Related to regulatory service tariff/fees and fines.

REFERENCES

1. WHO good distribution practices for pharmaceutical products (WHO technical report series, No. 957, 2010)
2. WHO guide to good storage practices for pharmaceuticals (WHO technical report series, No. 908, 2003)
3. Commission guidelines on good distribution practices of medicinal products for human use, European commission, 2011
4. ISO 9001:2015, quality management systems requirements
5. OHSAS 18001:2007, occupational health and safety management systems requirements
6. ISO 14001:2015, environmental management systems requirements

End of Document
