Guidelines on Good Distribution Practice for Pharmaceutical Products

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1.0 BACKGROUND

National Drug Authority (NDA) was established by an Act of Parliament, the National Drug Policy and Authority Act, Cap 206 of the laws of Uganda. The Authority is mandated to ensure the availability at all times of essential, efficacious, and cost effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

NDA endeavours to achieve the objectives for which it was established in general and more specifically to ensure that drugs are handled in a manner that will protect the consumer. The authority has therefore laid down the following guidelines with regard to minimum standards for distribution of pharmaceutical products. The first guidelines for Good Distribution Practices (GDP) were published in 2013 as a way of enforcing and ensuring quality within the pharmaceutical distribution chain. These were adapted from the WHO and EU guidelines for good distribution practices.

A review of the guidelines was conducted, to reflect the changes in the pharmaceutical sector, resulting into the second edition of these guidelines.
Compliance with these guidelines will assist in ensuring that drugs are handled properly and reasonable control over the acquisition, storage, sale, supply or disposal of drugs is maintained as defined in the NDP/A Act Cap 206 of the Laws of Uganda.

2.0 INTRODUCTION

Distribution is an important activity in the integrated supply-chain management of pharmaceutical products. Various people and entities are generally responsible for the handling, storage and distribution of such products. In some cases, however, a person or entity is only involved in and responsible for certain elements of the distribution process. The objective of these guidelines is to assist in ensuring the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to, procurement, purchasing, storage, distribution, transportation, repackaging, relabeling, documentation and record-keeping practices.

The storage, sale and distribution of pharmaceutical products are often carried out by various companies, institutions and individuals. This document sets out appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of falsified medicines into the marketplace via the distribution chain. The relevant sections should be considered by

various participants as applicable to the particular role that they play in the distribution of pharmaceutical products.

The nature of the risks involved is likely to be similar to that for risks encountered in the manufacturing environment, e.g. mix-ups, adulteration, contamination and cross-contamination. When the distribution chain is interrupted by manufacturing steps such as repackaging and relabeling, the principles of good manufacturing practices (GMP) should be applied to these processes.

Counterfeit pharmaceutical products are a real threat to public health and safety. Consequently, it is essential to protect the pharmaceutical supply chain against the penetration of such products. Weak points in the distribution processes of pharmaceutical products provide an avenue for counterfeit as well as illegally imported, stolen and substandard medicines to enter the supply chain. This is a concern in both developed and developing countries. The methods by which such products enter the supply chain have become increasingly complex and have resulted in the development of thriving secondary and grey markets throughout the world. The involvement of unauthorized entities in the distribution and sale of pharmaceutical products is a particular concern. Only a joint approach including all parties involved in the supply chain can be successful in the fight against counterfeit pharmaceutical products and, therefore, all parties active in the market should take an active part in collaborative activities.

Different models for the distribution of pharmaceutical products are used in different countries and sometimes within the same sector. These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in trade and distribution of medicines including pharmaceutical manufacturers, pharmaceutical wholesalers as well as other parties such as brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees.

To maintain the original quality of pharmaceutical products, every party active in the distribution chain has to comply with the provisions of the NDP/A Act in regard to handling of medicines. Every activity in the distribution of pharmaceutical products should be carried out according to the principles of good storage practice (GSP) good distribution practice (GDP) and good pharmacy practice (GPP) as applicable.

2.1 Scope of this document

This document lays down guidelines for the distribution of pharmaceutical products. These guidelines shall apply equally to products for human and for veterinary use. The guidelines thus cover products for which a prescription is required by the patient, products which may be provided to a patient without a prescription, biologicals and vaccines. Although medical devices are not included in the definition of pharmaceutical products for the purposes of this document, the main principles established in this document may also be used where applicable for medical devices. The document does not specifically cover GMP aspects of finished products in bulk, distribution of labels or packaging, as these aspects are considered to be covered by other guidelines.

3. GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents.

Agreement
Arrangement undertaken by and legally binding on the parties concerned.

Auditing
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.

Batch
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
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.

Class C Drug Shop
An entity authorised to dispense or provide only Class C drugs directly to a patient or his or her agent. Class C drug shops are not authorised to supply any other class of medicines other than class C and only on retail basis.

Consignment
The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

Container
The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product

Contamination
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transportation.

Contract
Business agreement for the supply of goods or performance of work at a specified price.

Counterfeit pharmaceutical product
A pharmaceutical product which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical 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.

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

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

Expiry date
The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

First expiry/first out (FEFO)
A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

Forwarding agent
A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person and includes a consignment agent.

Good Distribution practices (GDP)
That part of quality assurance that ensures that the quality of a pharmaceutical 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 counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

Good manufacturing practices (GMP)
That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Good pharmacy practice (GPP)
The practice of pharmacy aimed at providing and promoting the best use of medicines and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.

Good storage practices (GSP)
That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.

Good trade and distribution practices (GTDP)
That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities which occur during the trade and the distribution process.

Importation
The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

Importer
An individual or entity that undertakes the act of importation

Intermediate product
Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product.

Labelling
Process of identifying a pharmaceutical 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 and/or the supplier.

Manufacture
All operations of purchase of materials and products, production, packaging, labelling, quality control, release, storage and distribution of pharmaceutical products, and the related controls.

Marketing authorization
A legal document issued by the competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic

names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Once a product has been given marketing authorization, it is included on a list of authorized products — the register — and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

Pedigree
A complete record that traces the ownership of and transactions relating to a pharmaceutical product as it is distributed through the supply chain.

Pharmaceutical product
Any product intended for human use, or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. It does not, however, include medical devices.

Product recall
A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product, unauthorised entry on to the market and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, Local Technical Representative (LTR) wholesaler, distributor or National Drug Authority.

Quality assurance
A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality system
An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

Quarantine
The status of pharmaceutical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

Retailer
An entity authorised to carry on the business of dispensing or providing pharmaceutical products directly to a patient or his or her agent only. Retailers are not authorised to supply pharmaceutical products to distributors or other retailers.

Sampling
Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.

Shelf-life
The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each product.

Standard operating procedure (SOP)
An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

Storage
The storing of pharmaceutical products up to the point of use.

Supplier
A person or entity engaged in the activity of providing products and/or services.

Transit
The period during which pharmaceutical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

Vehicles
Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products.

Wholesaler
An entity that is authorised to carry on the business of selling pharmaceutical products in large quantities to other authorised sellers with the exception of dispensing or providing pharmaceutical products directly to a patient or his or her agent.

4.0 GENERAL PRINCIPLES

4.1 The principles of GDP are applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing pharmaceutical products to the patient and to products which are moving backwards in the chain, for example, as a result of the return or recall thereof.

4.2 All entities involved in the distribution process should apply due diligence with adherence to the principles of GDP in procedures relating to traceability and in recognition of risks.

4.3 The principles of GDP should also be adhered to in the case of pharmaceutical products which are donated.

4.4 Good manufacturing procedures (GMP) ensure that products released for distribution are of appropriate quality. Good distribution practices (GDP) make sure that the quality is kept during distribution until the medical product reaches the end user. All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is 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 or her agent.

4.5 Wholesale distributors must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. All distribution activities should be clearly defined and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated. The quality system is the responsibility of the organisation's management and requires their leadership and active participation and should be supported by staff commitment.

4.6 The correct distribution of medicinal products relies upon people. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

4.7 Wholesale distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.

4.8 Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products.

4.9 All actions taken by wholesale distributors should ensure that the identity of the medicinal product is not lost and that the wholesale distribution of medicinal products is performed according to the information on the outer packaging. The wholesale distributor should use all means available to minimise the risk of falsified medicinal products entering the legal supply chain.

4.10 All complaints, returns, suspected falsified medicinal products and recalls must be recorded and handled carefully according to written procedures. Records should be made available to the competent authorities. An assessment of returned medicinal products should be performed before any approval for resale. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified medicinal products.

4.11 Any activity covered by the GDP Guide that is outsourced should be 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.

4.12 It is the responsibility of the wholesaler to ensure that the quality of the medicinal products is maintained from the manufacturer to his stores and then to the final consumer, the retailer or/and patient.

4.13 It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport. Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.

4.14 Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.

5.0 REGULATION OF THE DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

5.1 The distribution of pharmaceutical products is regulated by the NDP/A Act Cap 206 of the Laws of Uganda and the accompanying NDA Regulations.

5.2 The distributor or the organization to which the distributor belongs should be an entity that is appropriately authorized in terms of the NDP/A Act Cap 206 to perform the function(s) that it intends to perform. The distributor or the organization to which it belongs is accountable for the activities that it performs which relate to the distribution of pharmaceutical products.

5.3 Only persons or entities which are authorized to do so and/or which hold the appropriate licence should be entitled to import or export pharmaceutical products.

5.4 Distributors or their agents may only distribute a pharmaceutical product within or to a country or territory if a marketing authorization or similar authorization has been granted, which allows the use of that pharmaceutical product in that country or territory.

5.5 Holders of an authorization to distribute pharmaceutical products should obtain their supplies of pharmaceutical products only from persons or entities which are in

possession of the applicable authorization to sell or supply such products to a distributor.

5.6 Distributors or their agents should supply pharmaceutical 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 patient or to his or her agent.

5.7 Some duties and responsibilities may be delegated or contracted out to suitably designated persons or entities as authorized and as necessary. Duties and responsibilities may only be delegated to entities which are suitably authorized in line with the NDP/A Act Cap 206. Duties and responsibilities should be specified in a written agreement. There should be no gaps or unexplained overlaps with regard to the application of GDP. These delegated and contracted out activities should be documented in agreements or contracts. There should be a periodic audit of such activities with regard to application of GDP.

5.8 If a distributor or his or her agent subcontracts an activity to another entity, the person or entity to whom the activity is subcontracted must be appropriately authorized to perform the subcontracted activity and should uphold the same standards as the distributor.

5.9 The sale of pharmaceutical products via the Internet is limited to registered and authorized mail-order pharmacies or other authorized entities.

6.0 ORGANIZATION AND MANAGEMENT

6.1 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.

6.2 Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions. Certain activities may require special attention, such as the supervision of performance of activities, in accordance with the NDP/A Act Cap 206. At every level of the supply chain, employees should be fully informed and trained in their duties and responsibilities and the training sessions recorded.

6.3 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 with a degree in Pharmacy.

6.4 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 (see section 8).

6.5 The responsibilities placed on any one individual should not be so extensive as to present any risk to product quality.

6.6 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 pharmaceutical products.

6.7 Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place.

7.0 PERSONNEL

7.1 All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable. Training should be based on written standard operating procedures (SOPs). Personnel should receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training programme. In addition, training of the personnel should include the topic of product security, as well as aspects of product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. A record of all training, which includes details of subjects covered and participants trained, should be kept.

7.2 Key personnel involved in the distribution of pharmaceutical products should have the ability and experience appropriate to their responsibility for ensuring that pharmaceutical products are distributed properly.

7.3 There should be an adequate number of competent personnel involved in all stages of the distribution of pharmaceutical products in order to ensure that the quality of the product is maintained.

7.4 The NDP/A Act Cap 206 and regulations relating to the qualifications and experience of personnel should be adhered to.

7.5 Personnel dealing with hazardous pharmaceutical products (such as 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) should be given specific training.

7.6 Personnel involved in the distribution of pharmaceutical products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, infectious or sensitizing, should be provided with protective garments as necessary.

7.7 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.

7.8 Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to pharmaceutical products must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

7.9 Codes of practice and punitive procedures should be in place to prevent and address situations where persons involved in the distribution of pharmaceutical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product.

8.0 QUALITY SYSTEM

8.1 Within an organization, quality assurance serves as a management tool. 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.

8.2 The quality system should include an appropriate organizational structure, procedures, 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. The totality of these actions is described as the quality system.

8.3 The quality system should include provisions to ensure that the holder of a marketing authorization, entity identified on the label (if different from the manufacturer), the NDA and/or international regulatory bodies, as well as other relevant competent authorities, would be informed immediately in case of confirmed or suspected counterfeiting of a pharmaceutical product. The confirmed or suspected counterfeiting products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale.

8.4 Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the distribution steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of the pharmaceutical products concerned. Electronic transactions (including those conducted via the Internet), relating to the distribution of pharmaceutical products, should be performed only by authorized persons or entities.

8.5 Authorized procurement and release procedures for all administrative and technical operations performed should be in place to ensure that appropriate pharmaceutical products are sourced only from approved suppliers and distributed by approved entities. The approval should come from the competent authority of the individual country where the legal entity is registered.

8.6 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 guidelines and the applicable principles of GMP relating to pharmaceutical products.

8.7 If measures to ensure the integrity of the pharmaceutical products in transit are in place, they should be managed properly. For example, if seal control programmes for transit shipment are used, numbers should be issued in a tracked and sequential manner, the integrity of seals should be monitored and numbers verified during transit and upon receipt. Written procedures should be in place for use in situations where pharmaceutical products are suspected of being or are found to be counterfeit.

8.8 Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products. The quality system should be developed and implemented to address any potential risks identified. The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment.

Traceability of pharmaceutical products

8.9 Regulations should foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. This is a shared responsibility among the parties involved.

8.10 Records should 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 five years.

8.11 Records for each purchase or sale must include date of purchase or supply, name of medicinal product, quantity supplied or received, batch number, name and address of supplier or consignee.

8.12 All parties involved in the supply chain should be identifiable, depending on the type of product and the NDP/A Act Cap 206 and regulations.

8.13 Measures should be in place to ensure that pharmaceutical products have documentation that can be used to permit traceability of the products throughout distribution channels. For transactions between manufacturer/importer, wholesaler and the entity responsible for selling or supplying the product to the patient or his or her agent (see also 14.2), records must include expiry dates and batch numbers as part of a secure distribution documentation enabling traceability.

8.14 There should be a procedure in place for the creation and maintenance of a pedigree for pharmaceutical products. There needs to be a written procedure to be followed when a suspected product is identified. The procedure should include the method for visual and/or analytical identification of the potentially counterfeit product. Additionally, the procedure should include the course of action for notification, as appropriate, of the holder of the marketing authorization, National Drug Authority. National Drug Authority will then investigate the case and inform international

regulatory bodies when necessary (For more on counterfeit products, see section 19).

8.15 A suitable and, to the extent possible, internationally compatible product coding, identification system should be in place and developed in collaboration with the various parties involved in the supply chain. While it is understood that a differentiated approach may be necessary for different products and regions, pedigree and/or track-and-trace technologies provide possible options to ensure traceability.

9.0 PREMISES, WAREHOUSING AND STORAGE

9.1 Good storage practices (GSP) are applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process. For additional guidance relating to the general principles of storage of pharmaceutical products, refer to the WHO guide to good storage practices for pharmaceuticals (1).

Storage areas

9.2 Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment.

9.3 Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products, namely commercial and non-commercial products, products in quarantine, and released, rejected, returned or recalled products as well as those suspected to be counterfeits.

9.4 Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be dry and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.

9.5 Storage areas should be clean and free from litter, dust and pests. Organizations in charge of distribution must ensure that premises and storage areas are cleaned regularly. There should also be a written programme for pest control. The pest

control agents used should be safe and there should be no risk of contamination of pharmaceutical products. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

9.6 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.

9.7 Receiving and dispatch bays should protect pharmaceutical products from the weather. Receiving areas should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.

9.8 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. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.

9.9 Physical or other equivalent validated (e.g. electronic) 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.

9.10 Unless there is an appropriate alternative system to prevent the unintentional or unauthorized use of quarantined, rejected, returned, recalled or suspected counterfeit pharmaceutical products, separate storage areas should be assigned for their temporary storage until a decision as to their future has been made.

9.11 Radioactive materials, narcotics and other hazardous, sensitive and/ or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids and solids and pressurized gases) should be stored in dedicated area(s) that is subject to appropriate additional safety and security measures.

9.12 Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

9.13 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.

9.14 Broken or damaged items should be withdrawn from usable stock and stored separately.

9.15 Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

9.16 Pharmaceutical products should be stored separate from other goods and under the conditions specified by the manufacturer in order to avoid deterioration by light, moisture or temperature.

Storage conditions and stock control

9.17 Storage and handling conditions should comply with the NDP/A Act Cap 206 and the certificate of suitability of premises regulations, 2014 (Statutory Instrument. No. 36)

9.18 Storage conditions for pharmaceutical products should be in compliance with the recommendations of the manufacturer e.g. store at 15^0 - 25^0C.Facilities should be available for the storage of all pharmaceutical products under appropriate conditions (e.g. environmentally controlled when necessary). Records should be maintained of these conditions if they are critical for the maintenance of the characteristics of the pharmaceutical product stored.

9.19 Records of temperature monitoring data should be available for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year, or as required by national legislation. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in the hottest areas and those that are most likely to show fluctuations.

9.20 Equipment used for monitoring of storage conditions should also be calibrated at defined intervals.

9.21 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. This should be done at defined intervals.

9.22 Stock discrepancies should 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 pharmaceutical products. Documentation relating to the investigation should be kept for a predetermined period.

Receipt

9.23 The reception area must be separate from the storage area. Deliveries should be examined on receipt in order to check that containers are not damaged and that the consignment corresponds to the order.

9.24 Upon receipt, pharmaceutical products stored at specific conditions (e.g. narcotics or products requiring specific storage temperature) should be immediately identified and stored according to specified storage conditions.

9.25 At a minimum the wholesalers should conduct visual checks of the products that they receive. The visual check would compare a “master” of the package with the actual. The “master” is either a copy of the package “blue print” received from the manufacturer of the product, or a sample or photo of the package approved by NDA and available from the LTR

10.0 VEHICLES AND EQUIPMENT

10.1 Vehicles and equipment used to distribute, store or handle pharmaceutical products should be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind.

10.2 The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the pharmaceutical products being distributed.

10.3 Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security of pharmaceutical products while in the vehicle.

10.4 Dedicated vehicles and equipment should be used, where possible, when handling pharmaceutical products.

10.5 Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the pharmaceutical product will not be compromised. Appropriate cleaning should be performed, checked and recorded.

10.6 Procedures should be in place to ensure that the integrity of the products is not compromised during transportation.

10.7 Where third-party carriers are used, distributors should develop written agreements with carriers to ensure that appropriate measures are taken to safeguard pharmaceutical products, including maintaining appropriate documentation and records. Such agreements should be in line with national and regional regulatory requirements.

10.8 Defective vehicles and equipment should not be used and should either be labelled as such or removed from service.

10.9 There should be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

10.10 Vehicles, containers and equipment should be kept clean and dry and free from accumulated waste. Organizations in charge of distribution must ensure that vehicles used are cleaned regularly.

10.11 Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should be written programmes and records for such pest control. The cleaning and fumigation agents used should not have any adverse effect on product quality.

10.12 Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should be approved by management.

10.13 Special attention should be paid to the design, use, cleaning and maintenance of all equipment used for the handling of pharmaceutical products which are not in a protective shipping carton or case.

10.14 Where special storage conditions (e.g. temperature and/or relative humidity) are required during transportation, these should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf-life of the product distributed plus one year. Records of monitoring data should be made available for inspection by the NDA or other oversight body.

10.15 Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals.

10.16 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products during transportation.

10.17 Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products as well as those suspected of being counterfeits. Such goods should be securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

10.18 Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

11.0 SHIPMENT CONTAINERS AND CONTAINER LABELLING

11.1 Pharmaceutical products should be stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

11.2 Shipping containers should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly

handled and secure at all times. The shipment container should enable identification of the container's contents and source.

11.3 The need for any special transport and/or storage conditions should be stated on the shipment container label. If a pharmaceutical product is intended for transfer to areas outside the control of the manufacturer's products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements, including safety symbols, should also be included on the container label.

11.4 Normally, internationally and/or nationally accepted abbreviations, names or codes should be used in the labelling of shipment containers.

11.5 Special care should be taken when using dry ice in shipment containers. In addition to safety issues it must be ensured that the pharmaceutical product does not come into contact with the dry ice, as it may have an adverse effect on the quality of the product.

11.6 Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

12.0 DISPATCH AND RECEIPT

12.1 Pharmaceutical products should only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the NDA act and regulations. Written proof of such authority must be obtained prior to the distribution of products to such persons or entities.

12.2 Appropriate environmental conditions are maintained, e.g. using cold chain for thermo labile products.

3.0 STORAGE

13.1 The required storage conditions for pharmaceutical products should be maintained within acceptable limits during transportation. If a deviation has been noticed during transportation by the person or entity responsible for transportation, this should be reported to the distributor and recipient. In cases where the recipient notices the

deviation, it should be reported to the distributor. Where necessary, the manufacturer of the pharmaceutical product should be contacted for information about appropriate steps to be taken.

13.2 Where special conditions are required during transportation that are different from or limit the given environmental conditions (e.g. temperature and humidity) these should be provided by the manufacturer on the labels, monitored and recorded.

13.3 Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, e.g. temperature deviations.

13.4 Transportation and storage of pharmaceutical products containing hazardous substances, such as toxic, radioactive material, and other dangerous pharmaceutical products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas, and transported in safe, suitably designed, secured containers and vehicles. In addition, the requirements of applicable international agreements and NDA regulations should be met.

13.5 Products containing narcotics and other dependence-producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas.

13.6 In addition, applicable international agreements and the NDP/A Act and regulations should be complied with.

13.7 Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

13.8 Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned pharmaceutical products and suspected counterfeits. The products should be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

13.9 The interiors of vehicles and containers should remain clean and dry while pharmaceutical products are in transit.

13.10 Packaging materials and shipment containers should be of suitable design to prevent damage of pharmaceutical products during transport. Seal control programmes should be in place and managed properly.

13.11 Drivers of vehicles should identify themselves and present appropriate documentation to demonstrate that they are authorized to transport the load.

13.12 Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority, and investigated.

13.13 Pharmaceutical products in transit must be accompanied by the appropriate documentation.

14. DOCUMENTATION

14.1 Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) should be available. Records should be kept for a minimum of five years.

14.2 Distributors should keep records of all pharmaceutical products purchased or supplied. Records should contain at least the following information:

1) date of purchase or supply;
2) name of the pharmaceutical product; batch number, quantity received, or supplied; and 3) name and address of the supplier or consignee.

14.3 Procedures should be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process. Procedures must be in place for both internally generated documents and those from external sources.

14.4 Documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of pharmaceutical products, should be designed, completed, reviewed and distributed with care. These procedures include but are not limited to;

1) receipt and checking of deliveries
2) storage
3) cleaning and maintenance of the premises including pest control
4) recording of the storage conditions
5) security of stocks on site and of consignments in transit
6) withdrawal from saleable stock
7) records
8) returned products
9) recall plan.

14.5 The title, nature and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous. Documents should be laid out in an orderly fashion and be easy to check.

14.6 All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization.

14.7 The nature, content and retention of documentation relating to the distribution of pharmaceutical products and any investigations conducted and action taken, should comply with national legislative requirements. Where such requirements are not in place, the documents should be retained for at least one year after the expiry date of the product concerned.

14.8 The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

14.9 All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

14.10 Documents should be reviewed regularly and kept up to date. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version.

14.11 Mechanisms should exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to the NDA as required.

14.12 Records relating to storage of pharmaceutical products should be kept and be readily available upon request in accordance with the WHO guidelines on good storage practice for pharmaceuticals (1).

14.13 Permanent records, written or electronic, should exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates. Pharmacopoeial requirements and current NDA regulations concerning labels and containers should be respected at all times.

14.14 Procedures should be in place for temperature mapping, security services to prevent theft or tampering with goods at the storage facilities, destruction of unsalable or unusable stocks and on retention of the records.

14.15 Where the records are generated and kept in electronic form, backups should be maintained to prevent any accidental data loss.

15.0 REPACKAGING AND RELABELING

15.1 Repackaging and relabeling of pharmaceutical products should be limited, as these practices may represent a risk to the safety and security of the supply chain.

15.2 Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the NDA GMP guidelines.

15.3 In the event of repackaging by companies other than the original manufacturer, these operations should result in at least equivalent means of identification and authentication of the products.

15.4 Procedures should be in place for the secure disposal of original packaging.

16.0 COMPLAINTS

16.1 There should be a written procedure in place for the handling of complaints. A distinction should be made between complaints about a product or its packaging and

those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/ or marketing authorization holder should be informed as soon as possible.

16.2 All complaints and other information concerning potentially defective and potentially counterfeit pharmaceutical products should be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.

16.3 Any complaint concerning a material defect should be recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g. repackaging procedure or original manufacturing process).

16.4 If a defect relating to a pharmaceutical product is discovered or suspected, consideration should be given to whether other batches of the product should also be checked.

16.5 Where necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint. There should be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.

16.6 Product quality problems or suspected cases of counterfeit products should be documented and the information shared with the National Drug Authority.

17.0 RECALLS

17.1 There should be a system, which includes a written procedure, to effectively and promptly recall pharmaceutical products known or suspected to be defective or counterfeit, with a designated person(s) responsible for recalls. The system should comply with the guidance issued by the national or regional regulatory authority. This procedure should be checked regularly and updated as necessary.

17.2 The original manufacturer and/or marketing authorization holder should be informed in the event of a recall. Where a recall is instituted by an entity other than the original manufacturer and/or marketing authorization holder, consultation with the original manufacturer and/or marketing authorization holder should, where possible, take place before the recall is instituted. Information on a recall should be shared with

the NDA. If a recall of the original product is necessary because of a counterfeited product which is not easily distinguishable from the original product, the manufacturer of the original product and the relevant health authority should be informed.

17.3 The effectiveness of the arrangements for recalls should be evaluated at regular intervals. All recalled pharmaceutical products should be stored in a secure, segregated area pending appropriate action.

17.4 Recalled pharmaceutical products should be segregated during transit and clearly labelled as recalled products. Where segregation in transit is not possible, such goods must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

17.5 The particular storage conditions applicable to a pharmaceutical product which is subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

17.6 All customers and competent authorities of all countries to which a given pharmaceutical product may have been distributed should be informed promptly of any intention to recall the product because it is, or is suspected to be, defective or counterfeit.

17.7 All records should be readily available to the designated person(s) responsible for recalls. These records should contain sufficient information on pharmaceutical products supplied to customers (including exported products).

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

17.9 When necessary emergency recall procedures should be implemented.

17.10 To ensure the efficacy of the emergency plan, the system of deliveries should enable all destinations of a medical product to be immediately identified and contacted. Wholesalers may decide to inform all customers or those that has received the batch to be recalled.

17.11 The recall message (approved by the holder of marketing authorisation and competent authorities) should indicate whether the recall should be carried out also at retail level. The message should request that the products be removed immediately from saleable stock and stored separately in a secure area until they are sent back according to instructions in the holder of the marketing authorisation.

17.12 The same system should apply to all countries where the product has been authorised for sale.

18.0 RETURNED PRODUCTS

18.1 A distributor should receive pharmaceutical product returns or exchanges pursuant to the terms and conditions of the agreement between the distributor and the recipient. Both distributors and recipients should be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of counterfeit products.

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

18.3 Rejected pharmaceutical products and those returned to a distributor should be appropriately identified and handled in accordance with a procedure which involves at least:

1) the physical segregation of such pharmaceutical products in quarantine in a dedicated area; or
2) Other equivalent (e.g. electronic) segregation.

This is to avoid confusion and prevent distribution until a decision has been taken with regard to their disposition. The particular storage conditions applicable to a pharmaceutical product which is rejected or returned should be maintained during storage and transit until such time as a decision has been made regarding the product in question.

18.4 Provision should be made for the appropriate and safe transport of rejected pharmaceutical products prior to their disposal.

18.5 Products which have left the wholesaler can only be returned to saleable stock if:

1) the goods are in their original unopened containers and in good condition

2) the remaining shelf life period is acceptable.
3) it is known that the goods have been stored and handled under proper conditions
4) they have been examined and assessed by a person authorised to do so.

18.6 The responsible person should formally release the goods to be returned to stock in case of non-defective medicinal products. Products should be placed such that the first expiry first out system operates effectively.

18.7 Destruction of pharmaceutical products should be done in accordance with NDA guidelines regarding disposal of such products, and with due consideration to protection of the environment.

18.8 Records of all returned stock should be filled at the time it is carried out and should be available to authorities. Rejected and/or destroyed pharmaceutical products should be kept until a formal decision has been made on the disposal of the products and the decision should be documented and recorded. The person responsible for the quality system of the wholesaler and, where relevant, the holder of marketing authorisation should be involved in the decision making process.

19. COUNTERFEIT PHARMACEUTICAL PRODUCTS

19.1 Counterfeit pharmaceutical products found in the distribution chain should be kept apart from other pharmaceutical products to avoid any confusion. They should be clearly labelled as not for sale and national regulatory authorities and the holder of the marketing authorization for the original product should be informed immediately.

19.2 The sale and distribution of a suspected counterfeit pharmaceutical product should be suspended and the national regulatory authority notified without delay.

19.3 Upon confirmation of the product being counterfeit a formal decision should be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded.

20.0 IMPORTATION

20.1 Consideration should be given to the National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations 2014 (S.I. No. 34) as well as the WHO

guidelines on import procedures for pharmaceutical products (6). The following aspects should be given particular attention.

20.2 NDA has designated the ports of entry for the handling of imports of pharmaceutical products.

20.3 The imported drugs shall be accompanied by the certificate of analysis of the drug issued by the country or manufacture and the certificate of conformity or the test report, relating to the specific batch or lot imported. There should also be accompanied by a Pro-forma invoice verified by NDA, an invoice and a packing list.

20.4 The Importers have responsibility for the quality of the products imported into the country. At a minimum the, products should be checked for compliance with physical parameters, tested for active ingredient and the secondary packing should be checked against an approved secondary master.

20.5 At the port of entry, consignments of pharmaceutical products should be stored under suitable conditions for as short a time as possible.

20.6 All reasonable steps should be taken by importers to ensure that products are not mishandled or exposed to adverse storage conditions at wharves or airports.

20.7 Where necessary, persons with pharmaceutical training should be involved with the customs procedures or should be readily contactable.

20.8 The WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce should be used to provide data regarding quality assessment of imported pharmaceutical products.

20.9 Customs, enforcement agencies and NDA should establish means for cooperation and information exchange in order to prevent importation of counterfeit pharmaceutical products.

21. CONTRACT ACTIVITIES

21.1 Any activity relating to the distribution of a pharmaceutical product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.

21.2 The contract should define the responsibilities of each party including observance of the principles of GDP and relevant warranty clauses. It should also include responsibilities of the contractor for measures to avoid the entry of counterfeit medicines into the distribution chain, such as by suitable training programmes.

21.3 All contract accepters should comply with the requirements in these guidelines.

21.4 Subcontracting may be permissible, under certain conditions and subject to the written approval of the contract giver; however, the subcontractors should be authorized for the function.

21.5 Contract accepters should be audited periodically.

22. SELF-INSPECTION

22.1 The quality system should include self-inspections. These should be conducted to monitor implementation of and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

22.2 Self-inspections should be conducted in an independent and detailed way by a designated, competent person.

22.3 The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report and the records of any corrective actions taken.

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Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
15th/02/2013	0	INS/GDL/001	Kate Kikule	This is the first issue of this document
20/03/2018	1	INS/GDL/001	Onen Solomon Amos Atumanya	1) Editorial changes 2) National Legislation was replaced with NDPA Act Cap 206 of the Laws of Uganda and the accompanying NDA Regulations. 3) Background of the GDP guideline was changed to reflect the progress of the guideline since the first version. 4) Editing of the principles of GDP. 5) Inclusion of quality checks by wholesalers under 9.25 6) Storage period for quality documents changed from 7 years to 5 years under 14.1. 7) Editing the section on importation under section 20 to include requirements for importers.

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