Republic of Kenya

Ministry of Health

PHARMACY AND POISONS BOARD

GUIDELINES FOR GOOD DISTRIBUTION PRACTICES FOR MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES IN KENYA

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PPB/INSP/GDP/GUD/019	GUIDELINES FOR GOOD DISTRIBUTION PRACTICES FOR MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES IN KENYA		Review Date:

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Date.....9/7/19.....

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ABBREVIATIONS AND ACRONYMS

PPB-	Pharmacy and Poisons Board
GUD-	Guidelines
GDP-	Good Distribution Practice
INSP-	Inspectorate
ICRC-	International Committee of the Red Cross
GSP-	Good Storage Practices
SOP-	Standard Operating Procedure
QMS-	Quality Management System
QSE-	Quality Safety and Efficacy
WHO-	World Health Organization
OPV-	Oral Polio Vaccine
POM-	Prescription only Medicines
SSFFP's-	Suspected Spurious Falsified and Falsely Labelled Products
FEFO-	First Expired First Out
FIFI-	First in First out
CAPA-	Corrective Action and Preventive Action

Acknowledgements

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The PPB gratefully acknowledges the contributions of the following persons who contributed to and reviewed the guideline.

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FOREWORD

The Pharmacy and Poisons Board is committed ensuring the availability of medical products and health technologies in Kenya which satisfy the needs of all citizens for the prevention, diagnosis and treatment of diseases using safe, efficacious, high quality and cost-effective pharmaceutical products

Pursuant to this mission, it is imperative that pharmaceuticals are distributed by highly qualified personnel through outlets that are duly licensed and professionally run. Pharmaceuticals require specialized handling to ensure their quality is maintained throughout the distribution chain and the risk of exposing the public to unsafe medicines should be avoided at all cost.

This new GDP guideline, which replaces the 2006 guideline, defines a number of new provisions. They have been prepared to provide persons involved or wishing to be involved in distribution Medical products and health technologies with a method of assessing eligibility and the process of lawfully operating distribution outlets. It further provides specific requirements on distribution that are practices currently acceptable.

The success of this initiative will ultimately depend on the active contribution and cooperation of every stakeholder. I trust that all will strive to uphold the standards of practice in pharmaceutical distribution.

The pharmacy and poisons board strongly encourages the widespread implementation of these guidelines and is ready to assist users in implementing them.

Dr. F.M Siyoi
CHIEF EXECUTIVE OFFICER

LEGAL FRAMEWORK

The pharmacy and poisons ACT CAP 244 laws of Kenya mandate the PPB to regulate the trade in medical products and health technologies.

Distribution is an important activity in the integrated supply chain management of medical products and health technologies. All parties involved in the distribution of medical products and health technologies have a responsibility to ensure that the quality of the products and the integrity of the distribution chain are maintained throughout the distribution process from the site of manufacture to the entity responsible for dispensing the product to the end user.

Article 43 (1) (a) of the constitution of Kenya 2010 provides that every person has the right to the highest attainable standard of health. Highest standards of health are only attainable if the quality of medical products and health technologies in the market are of the right quality.

DEFINITION OF KEY TERMS

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.

Authorised personnel: means a registered pharmacist, enrolled pharmaceutical technologist or any other person approved by the Pharmacy and Poisons Board.

Batch: A defined quantity of medical products and health technologies processed in a single process or series of processes so that it is expected to be homogeneous.

Calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring, recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established. Including the maximum permissible error or uncertainty of measurement;

Cold chain: All of the materials, equipment, processes and procedures used to maintain all products (which require cold chain conditions) within the required temperature range of 2 °C to 8 °C from the time of manufacture until the products are administered to individuals. However, Storage conditions should align with the manufacturer's label specifications.

Corrective action: Any action taken when the results of monitoring at the critical control point indicates a loss of control; and the action taken in response to audit findings;

Consignment: The quantity of medical products and health technologies 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 medical products and health technologies 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.

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

Dangerous goods: materials or items with hazardous properties which, if not properly controlled, present a potential hazard to human health and safety, infrastructure and/ or their means of transport. These are available as updated on: www.incb.org

Deviation: the failure to fulfil a specified requirement in terms of processes, standards and regulations prescribed.

Distribution: The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of medical products and health technologies, with the exception of the dispensing or providing medical products and health technologies 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.

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 medical products and health technologies.

Good Storage Practices (GSP): That part of quality assurance that ensures that the quality of medical products and health technologies is maintained by means of adequate control throughout the storage thereof.

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

Labelling: Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s)

Lagged containers: An insulated container which meets the requirements of transporting medical products and health technologies at the required temperatures for the necessary duration of time

Pharmacy student: an individual who has been approved by the Pharmacy and poisons board for training under the direct personal supervision of a registered pharmacist or enrolled Pharmaceutical technologist

Pest: Refers to any objectionable animals or insects including, but not limited to, bird, rodents, flies and larvae.

Preventive action: an action to eliminate the cause of a potential non-conformity or another undesirable potential situation.

Medical Product:

Product recall: the removal of specific batch/batches of a pharmaceutical product from the market for reasons relating to deficiencies in quality, safety or efficacy

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 medical products and health technologies isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

Repackaging & relabelling: Any operations in which the original labelling and or packaging materials more so, the primary and secondary packaging are subsequently changed or replaced, leading to loss of product traceability

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 batch.

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 medical products and health technologies up to the point of use.

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

Thermolabile: A substance that is subject to destruction, decomposition, or change in response to temperature.

Transit: The period during which medical products and health technologies 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 medical products and health technologies

Validation: Action of proving, in accordance with Good Distribution Practices, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification);

Withdrawal: The total removal of a pharmaceutical product from the market.

CHAPTER ONE

1.1 VISION

To be a centre of excellence in regulation of Pharmacy profession, medical products and health technologies.

1.2 MISSION

To protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of medical products and health technologies.

1.3 CORE VALUES

The values and principles that underpin the operations of the Board and provide operational guidelines for service delivery are:

- Commitment to public health
- Professionalism
- Integrity
- Timeliness
- Teamwork

1.4 CORE FUNCTIONS

1. To ensure the quality, safety and efficacy of medical products and health technologies
2. Regulation of training and practice of pharmacy
3. Advising the government on any matter relating to the regulation of medical products, health technologies and pharmaceutical services

CHAPTER TWO:

2.1 GENERAL CONSIDERATIONS

2.1.1 ORGANIZATION STRUCTURE AND MANAGEMENT

The distributor must be an entity that is appropriately authorized to perform the intended function in terms of the applicable legislation, and which can be held accountable for its activities by ensuring that:

i. There should be an adequate organizational structure defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated. This must be duly dated, be current, valid and authorized.
ii. A designated qualified person (Pharmacist/ pharmaceutical technologist) shall be appointed at each distribution outlet that has the defined authority and responsibility for ensuring that a quality management system is implemented and maintained.
iii. Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality management system, as well as to identify and correct deviations from the established quality management system.
iv. The responsibilities placed on any one individual should not be so extensive as to present any risks to the medical products and health technologies' quality or process. Individual 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 legislation.
v. Duties may be delegated or contracted out to suitably designated persons or entities as necessary and documented. There should, however, be no gaps or unexplained overlaps with regard to the application of Good Distribution Practices. These activities should be

documented in quality agreements or contracts. There should be periodic audits of such activities concerning the application of Good Distribution Practices

2.1.1.1 QUALITY MANAGEMENT SYSTEM

Every distribution entity shall have a quality management system that assures quality of medicinal products and health technologies. Senior management should demonstrate its commitment to the development and implementation of the Quality Management System (QMS) and continual improvement of its effectiveness and performance by:

i. Communicating the importance of adhering to customer, regulatory (Good distribution Practices) and legal requirements, including environmental, health and safety aspects;
ii. Establishing functional quality objectives;
iii. Ensuring regular reviews of quality management systems;
iv. Applying risk assessments;
v. Maintaining appropriate conditions throughout the organization for processes and systems
vi. Ensuring the availability of resources to support quality management system
vii. Ensuring the integration of quality management system into their operations and processes.
viii. Supporting other relevant management roles to demonstrate leadership as it applies to their areas of responsibilities.
ix. Ensuring that customer satisfaction is enhanced and maintained.
x. Establish a system for handling customer compliments and complaints

Every entity shall establish and maintain documented information on:

i. Standard Operating Procedures (SOPs) for all activities affecting quality, safety and efficacy of medical products and health technologies;
ii. Work Instructions and Process Maps;

iii. Forms and Records.

Entities shall have in place effective measures for Risk Management to ensure risks are controlled to such an extent unwanted outcome can be mitigated adequately.

Additionally, wholesalers should annually conduct risk assessments to assess potential risks to the quality and integrity of medical products and health technologies. The quality system should be developed and implemented to address any potential risks identified. The quality system should be reviewed and revised annually to address new risks identified during a risk assessment.

2.1.1.2 PERSONNEL

1. Authorized personnel shall bear the responsibility of ensuring that medical
   products and health technologies are correctly handled, stored and distributed. Such personnel should have the relevant education, training, experience and/ or combination of these elements that will allow them to effectively discharge this responsibility.
2. A pharmacy student may provide or perform all the services or acts pertaining to the scope of practice as per the PPB Training guidelines under the direct personal supervision of a registered pharmacist or an enrolled pharmaceutical technologist.
3. Operating personnel should be trained to perform assigned duties and functions at an acceptable level. Records of any training relevant to their functions should be kept.
4. Procedures and job descriptions for employees and other persons having access to the products must be designed and administered to minimize the possibility of drugs coming into unauthorized possession.

5. During operating hours, the business must at all times be conducted under the continuous personal supervision of a registered pharmacist or an enrolled pharmaceutical technologist.
6. There must be an adequate number of competent personnel involved in all stages of the distribution of medical products and health technologies in order to ensure that the quality of these products is maintained. Dispensing and medication use counselling is the responsibility of authorized personnel only. Regulations by the relevant authorities with regard to qualification and training of personnel should be complied with.
7. Personnel involved in the wholesaling or distribution of medical products and health technologies should be supplied with appropriate personal protective equipment suitable for the activities that they perform. Personnel dealing with hazardous medical products and health technologies, including products containing materials that are highly active, toxic and infectious or sensitizing, should be provided with specialized protective garments as necessary.
8. Appropriate procedures relating to personnel personal hygiene and sanitation relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.

2.2 PREMISES, WAREHOUSING AND STORAGE

2.2.1.1 GENERAL REQUIREMENTS

1. Premises should provide protection for the goods from contamination and deterioration, including protection from excessive local heating, humidity/ moisture or undue exposure to direct sunlight.

2. Premises should be kept free of rodents, vermin, birds, pets and pests. Storage of food products should be separated from medical products and health technologies.
3. Premises should have dedicated and demarcated areas available for the receipt of stock, general storage area, goods in quarantine, goods rejected, cold-chain storage, goods returned, dispatch and storage of medical products and health technologies. The goods received or dispatched at receiving or dispatch bays, docks, platforms or areas should be protected from dust, dirt and rain in line with GDP
4. The storage areas at a wholesaler should be of sufficient capacity to allow the orderly storage of the various categories of medical products and health technologies.
5. Warehousing of medical products and health technologies should be carried out in permanent buildings or parts of permanent building that have been built for, or adapted to warehouse medical products and health technologies.
6. The layout of a pharmaceutical warehouse shall consist of Receiving area, ordering /sales, dispatch, quarantine, and storage area.
7. The grounds should be established and maintained so as to minimize ingress into the buildings of dust, soil or other contaminants and should be maintained in an orderly condition. They should be free of the accumulated waste, dirt and debris. Waste should be collected in designated closed containers and disposed of at frequent intervals.
8. Premise must have a permanent address and be located at a site approved by the local authority and/or other related Acts or Regulations which must be adhered to by the licensee.
9. Where premises are not directly operated by the company, a written contract should be in place. The contracted premises should have a separate authorisation for distribution.
10. Where one has more than one storage or warehousing facility separate from the main registered premise, a separate authorization for the premise shall be sought.
11. Wholesale and retail practices shall be carried out separately in distinct different premises.

12. Buildings should have sufficient security to help prevent pilferage of the medical products and health technologies.
13. Sufficient space should be provided for the orderly receipt, warehousing and dispatch of medical products and health technologies and, in particular, a quarantine area for isolation when necessary, including isolation of faulty packs and recalled goods.
14. Buildings and fixtures should be kept clean and well maintained. Cleaning equipment should be stored in hygienic conditions.
15. Sufficient lighting should be provided to enable all operations to be carried out accurately and safely.
16. Storage facilities should protect goods from deterioration. The conditions of storage for goods should be compatible with the storage conditions specified on their labels. All medical products and health technologies should be stored off the floor.
17. Controlled storage environments, e.g. deep freeze, refrigeration, should be monitored using suitable temperature recording devices and the records reviewed and filed. Refrigerated and freezing storage environments should be fitted with signals to indicate that refrigeration has failed. The signal should permit resetting only by the authorized person.
18. Temperatures and humidity conditions in other areas where goods requiring specific storage conditions are held should be monitored and the results tabulated and analysed so as to demonstrate the suitability of these areas for their purposes.
19. If any temperature and or humidity records are found to have deviated outside the relevant recommended conditions for an extended time, the products shall be quarantined and the report sent to the Quality Safety and Efficacy (QSE) committee of the PPB for further direction.
20. Instruments or equipment used for monitoring temperature and humidity should be calibrated by a Kenya Bureau of Standards (KEBS) recognized agency on a regular basis to ensure their accuracy. The reference used should be traceable to International and or National Standards

21. Special storage facilities should be provided for Narcotic drugs, psychotropic substances, precursors , Dangerous Goods ,or other categories of goods as required by applicable legislation.
22. Incompatible activities such as manufacture (including repackaging) or the handling of toxic chemicals should be avoided in areas in which medical products and health technologies are handled by wholesale.

2.2.1.2 General Storage Areas

1. Precautions must be taken to prevent unauthorized persons from entering storage areas.
2. Storage areas should have sufficient capacity to allow the orderly storage of the various categories of medical products and health technologies namely usable products, products in quarantine, released, rejected, returned or recalled products.
3. Storage areas should be designed or adapted to ensure good storage conditions. In particular they should be clean and dry and maintained within specified temperature and humidity limits. Medical products and health technologies 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.
4. Secure measures should be taken to ensure that rejected products cannot be used and they should be stored separately from other products while awaiting destruction or return to the supplier. The measures adopted should possess adequate safeguards to prevent uncontrolled or unsatisfactory medical products and health technologies from being used or released.
5. Written procedures and a sanitation program should be available, indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.
6. A cleaning log must be in place, completed, signed and checked by the appropriate designated person.
7. There should be a written procedure and a programme available for pest control. The pest control agents used should be safe, and there

should be no risk of contamination of medical products and health technologies. A site flow plan, indicating where the bait stations are situated, must be available.

8. There should be appropriate written procedures available for the clean-up of any spillage to ensure complete removal of any risk of contamination.
9. There should be appropriate written procedures available for the removal of spilled hazardous products and cytotoxic substances and products to ensure any risk of contamination or health hazard is controlled.
10. If sampling is performed in the storage area, it should be conducted in accordance with a written procedure and in such a way as to prevent contamination or cross-contamination.
11. Written procedures should be available for the isolation and control of goods. Goods should be moved to a controlled area in the event of:
    i. Medical products and health technologies that await release by the Holder of the Certificate of Registration;
    ii. Suspected substandard, spurious, falsified and falsely labelled medical products and health technologies
    iii. Returned, damaged or expired medical products and health technologies for disposal;
    iv. Medical products and health technologies that have been recalled or withdrawn from the market;
    v. Medical products and health technologies that are being investigated after a cold-chain failure;
    vi. Instructions issued by the regulatory authority or the Holder of the Certificate of Registration
12. Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorised personnel. Any system replacing physical quarantine should provide equivalent security. For example, computerised systems can be used, provided that they are validated to demonstrate security of access.

13. Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned products. The products and areas concerned should be appropriately identified.
14. Radioactive materials, narcotics and other hazardous, sensitive and/ or dangerous medical products and health technologies, as well as products presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurised gases) should be stored in dedicated areas that are subject to appropriate additional safety and security measures that include but not limited to lock and key, security cameras, restricted rights of access and frisking of persons accessing the dedicated storage areas.
15. Medical products and health technologies should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
16. Broken or damaged items should be withdrawn from usable stock and stored separately.
17. Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.
18. Sufficient warehouse security should be maintained to prevent misappropriation of the goods by preventing unauthorised possession of, or access to the product and to allow for appropriate stock control.
19. Stock losses should be minimised by taking the following appropriate measures:
    i. Restricted entry and exit points to the warehouse being used
    ii. Vehicles (other than delivery vehicles) not being allowed near the warehouse;
    iii. All goods leaving the store being carefully checked against the relevant documentation;
    iv. Security checks of all vehicles entering or leaving the warehouse area taking place;
    v. High-risk goods being well protected, ideally in a separate area that is sealed off from the rest of the warehouse with access control;

vi. Implementing good housekeeping;
vii. Ensuring that workers are not able to leave the warehouse area during working hours without going through security;
viii. Preventing theft by using appropriate security systems;
ix. Avoiding fires in the warehouse by removing combustible waste materials several times a day. No-Smoking policies and notice boards should be in place.
x. Fire fighting equipment should be frequently serviced and maintained.
xi. Implementing and adhering to The Occupational Health and Safety code. Details of the code should be displayed in the work environment for all staff to see.

2.2.1.3 Storage conditions

1. Storage conditions for medical products and health technologies as described by the product storage requirements should be in compliance with the instructions on the label and package insert, which are based on the results of stability testing. When specified on the label, controls for temperature, humidity, light etc. should be in place.
2. The warehouse should be maintained at a temperature not exceeding 30 °C, and a relative humidity not exceeding 75% Relative humidity (WHO zone IVb requirements) at all times.
3. All warehouses should be temperature and humidity mapped over a period of at least one year to determine the temperature distribution under seasonal extremes.
4. Temperature mapping should be repeated every two to three years and after every significant modification to the premises, stock layout or ventilation system
5. Temperature monitoring should be done at strategic locations (hot and cold spots identified from the temperature mapping process) covering the stock containment areas and data recorded at least twice daily (morning and afternoon) and records maintained. Temperature

monitoring should be in accordance with Storage requirements to specifically reflect manufacturer's label specifications, such as Oral polio Vaccine (OPV), etc.

6. Continuous temperature monitoring devices or systems should be validated.
7. Written procedures should be available describing the action to be taken in the event of temperature deviating outside of the set standards and conditions must be appropriately investigated. The fate of the goods outside of the set standards must be decided by the Responsible Pharmacist in consultation with the Holder of Certificate of Registration.

2.2.1.4 Monitoring of storage conditions

At all times, Temperature and humidity should be controlled and monitored using calibrated monitoring devices based on temperature mapping.

Recorded temperature monitoring data should be available for review. The equipment used for monitoring should be checked at suitable intervals and the results of such checks should be recorded.

Monitoring equipment should be calibrated once a year by a KEBS approved agent and all monitoring records be kept for at least the shelf-life of the stored medical products and health technologies plus one year.

2.2.1.5 Storage for thermolabile products

1. All thermolabile products must be stored in a refrigerator/cold room/freezer exclusively dedicated for medical products.
2. All thermolabile products must be stored in a refrigerator/cold room in a temperature regulated environment between 2 °C and 8 °C or as

per the information on the product label; and the cold chain must be maintained at all times, and records of the same kept for review when necessary.

3. Thermolabile products that are required to be frozen must be maintained at temperatures in accordance with manufacturers storage requirements.

4. The temperature of the freezers for all products including coolants must be temperature monitored.
5. Refrigerator, freezer or cold room must be connected to an alarm system - in the event of a power failure or if the temperature limits are not met.
6. Refrigerator, freezer or cold room must be connected to a standby generator or other emergency power system to ensure uninterrupted power supply in the event of a power failure.
7. There must be a written procedure in place in the event of a power failure.
8. Refrigerators, cold rooms and freezers used to store thermolabile medical products and health technologies should at minimum:
    a. Be well maintained;
    b. Be equipped with temperature and humidity monitoring devices;
    c. Be free from frost build-up;
    d. Allow for adequate air distribution and orderly storage within the chamber. Good storage practices and loading configurations should not lead to the obstruction of air distribution.
    e. Have sensors for continuous temperature and humidity monitoring and alarms located at the points representing the temperature extremes.
9. The refrigerator, freezer or cold room must be mapped in terms of temperature.
10. Products should not be stored in areas shown by temperature mapping to present a risk (e.g. in the airflow from the refrigeration unit).

11. Sufficient space should be maintained to permit adequate air circulation especially between shelving. If the refrigerator is filled to capacity, the effect on temperature distribution should be investigated.
12. Ensure that no condensation from chillers collects or drips onto product or collects inside the facility.
13. On receipt of a shipment of thermolabile stock, all cold chain items should be moved to the refrigerator within the shortest possible time from offloading the truck.
14. When a lagged container used for transportation of the product is opened, all cold chain products must immediately be removed and stored in the refrigerator, in order to maintain the cold chain. Checks should be done to ensure that the cold chain has been maintained during transportation.

2.3 GUIDELINES FOR GOOD RETAIL PRACTICE FOR PHARMACEUTICALS

2.3.1 Nature and setup of premises

These guidelines will serve as the minimum acceptable requirements for premises, which will be licensed as retail pharmacies.

1. The premises must be fixed. For the purpose of this guideline, a fixed premise does not include a vehicle, trailer, caravan or any other thing which may be transported on, in or attached to a vehicle. It does not include unroofed and/or temporary structures. The premise should meet all the relevant local bylaws and planning regulations.
2. A reasonable distance shall exist between registered premises, preferably, 200 meters with consideration of urbanization, population status among other factors (consider streets, malls and metropolitan cities).

3. The floors and walls will be made of washable and impervious materials, and the ceiling covered with a non-flaking finish that allows for easy cleaning.
4. The premises should be well lit, ventilated and secure. Measures on security concerns including metallic grills and panels shouldn't undermine Good Pharmacy Practices including patient service.
5. The premises should be protected against adverse weather conditions, ground water seepage, vermin and pest infestation.
6. The premises should have sufficient space for the carrying out of the necessary operations.
7. There should be no overcrowding of customers and staff thus promoting efficient flow of work, effective communication and supervision.
8. Premises should be well designed with sufficient spaces. This includes an overall surface area not less than 4meters by 6meters, divided into at least a dispensary (4meters by 2meters) and the general area (4meters by 4meters).
9. Premises shall reflect the practice level, painted as white with a green cross for pharmacists, and white with a blue cross for pharmaceutical technologists.
10. Licensed premises should be used for the practice of pharmacy. However, any other additional business activity beyond the practice of pharmacy should be notified to PPB for approval.
11. Premises should have running potable water, toilet facilities, waste disposal system and space dedicated for the storage of cleaning equipment.
12. Premises should be maintained in a good state of repair and decoration. When these processes are being carried out, they will not cause or tend to cause any contamination of ingredients or products.
13. All products should be protected from light, heat and moisture and there must be temperature-controlled storage facilities for ingredients and drugs, which are sensitive.
14. Prescription only medicines (POM) must be separated from over the counter drugs and narcotic and psychotropic drugs shall be kept in a

secure fixed and lockable storage place. Records of these products must be maintained at all times, reflecting true stock balances.

15. There should be a separate office or administrative office for the pharmacist or pharmaceutical technologist, where prescription, purchase records and other administrative records may be maintained and it should be located so as to have a full view of the dispensary.

2.3.2 Equipment

There should be some basic equipment:

i. A tablet counter
ii. A refrigerator
iii. Appropriate litter bins
iv. Drinking water dispenser
v. Weighing balance
vi. Measuring cylinders with a capacity to accurately measure volumes between 0 and 100 ml
vii. Pestle and mortar
viii. Spatula and Slab

2.3.3 Reference materials

The following reference books and materials should be available and they should be the up to date editions

i. Guidelines
    a. GDP guidelines
    b. Safe management of Pharmaceutical waste
    c. Product recall and withdrawal
    d. Transportation of pharmaceuticals
ii. CAP 244 laws of kenya
iii. Professional code of ethics
iv. Reference books
    a. British National Formulary

b. Martindale, the extra pharmacopoeia
c. Kenya Standard Treatment Guidelines
d. Kenya National Drug Policy
e. Lists of drugs that are registered in Kenya
f. East African Pharmaceutical Loci or

v. Any other text that gives trade names of drugs on the market.
vi. Online reference materials

2.3.4 Retail pharmacy licence

No person will be issued with a licence to operate a retail pharmacy, unless the person complies with the requirements stipulated in the guidelines for registration of premises including, but not limited to, the following:

a. Is a registered pharmacist with the Pharmacy and Poisons Board.
b. Is an enrolled Pharmaceutical technologist with the Pharmacy and Poisons Board, with three years post enrolment experience
c. Is not a holder of another such licence for a different premise.
d. Is not engaged as a pharmacist/pharmaceutical technologist in any other enterprise
e. The premises has been certified for suitability by the Pharmacy and Poisons Board's inspectorate department.
f. Pays the prescribed fee.

2.3.5 Operations

Operations in the retail outlet shall ensure that:

1. The dispensing of prescriptions and sale of pharmacy only medicine shall be under the supervision of a named pharmacist or pharmaceutical technologist.
2. The Pharmacy shall not dispense any prescription or sell any Pharmacy only medicine when the registered pharmacist/ enrolled pharmaceutical technologist is not present.

3. No prescription only medicine is to be dispensed except in compliance with a valid prescription written by a registered Medical Practitioner, Dental Surgeon or Veterinary Surgeon.
4. Every retail pharmacy should keep and use suitable dispensing containers and labels. The container shall be capable of keeping dispensed medicines in a safe and usable condition.
5. A suitable and adequate prescription/patient recording system shall be maintained which shall consist of a prescription record ledger well indexed and up to date. This may be supplemented by patient profile cards, a computerized system or any other approved recording system.
6. Records of all stocks received their source, batch number, expiry date and quantity received shall be maintained.
7. All records will be retained for a minimum of five years for narcotic drugs and two years for other drugs.
8. All records should be available for inspection by the pharmaceutical inspectors at all reasonable times.
9. Adequate personal hygiene and clothing should be maintained throughout the working hours. Professionals shall wear white dust coats with name tags clearly displayed. Non – technical staff will use grey dust coats.
10. The retail pharmacy shall comply with these and any other requirement as may be specified by the Pharmacy and Poisons Board from time to time.

2.4 GUIDELINES FOR GOOD WHOLESALE PRACTICE FOR PHARMACEUTICALS

Wholesale distribution forms part of the supply chain of manufactured medical products and health technologies. Wholesalers are responsible for effective, efficient and safe handling, storage and distribution of such products. As such, these guidelines set out appropriate steps for meeting these responsibilities.

2.4.1 Building and grounds

1. Warehousing of pharmaceuticals should be carried out in permanent buildings or parts of buildings, made of stone/ brick that have been built for, or adapted to this purpose. The minimum requirement in square meters for storage space in a wholesale set up is $100M^2$.
2. The grounds should be established and maintained so as to minimize ingress into the buildings of dust, soil or other contaminants and should be maintained in an orderly condition. They should be free of the accumulated waste, dirt and debris. Waste should be collected in designated closed containers and disposed of at frequent intervals, as per the guideline on disposal of pharmaceutical waste.
3. Buildings should have sufficient security to help prevent pilferage of the pharmaceuticals.
4. Buildings and fixtures should be kept clean and well maintained. Cleaning equipment should be stored in hygienic conditions.
5. Sufficient lighting should be provided to enable all operations to be carried out accurately and safely.

2.4.2 Facilities

1. Storage facilities should protect goods from deterioration. The conditions of storage for goods should be compatible with the storage conditions specified on their labels. All pharmaceuticals should be stored off the floor.
2. Controlled storage environments, e.g. deep freeze, refrigeration, should be monitored using suitable temperature recording devices and the records reviewed and filed. Refrigerated and freezing storage environments should be fitted with signals to indicate that refrigeration has failed. The signal should permit resetting only by the authorized person.
3. Temperatures in other areas where goods requiring specific storage conditions are held should be monitored and the results tabulated

and analyzed so as to demonstrate the suitability of these areas for their purposes.

4. If any temperature is found to have deviated outside the relevant recommended conditions for an extended time, the manufacturer of the goods should be consulted and the suitability of the product for use resolved.
5. Instruments or equipment used for monitoring temperature should be calibrated on a regular basis to ensure their accuracy.
6. Special storage facilities should be provided for poisons, drugs and addiction, "Dangerous Drugs" or other categories of goods as required by applicable legislation.
7. Incompatible activities such as manufacture (including repackaging) or the handling of toxic chemicals should be avoided in areas in which pharmaceuticals are handled by wholesale.

2.4.3 Personnel

1. Pharmacists bearing the responsibility for ensuring that products/materials are correctly handled, stored and distributed, should have the education, training experience or combination of these elements that will allow them to effectively discharge this responsibility.
2. Operating personnel should be trained to perform assigned duties and functions at an acceptable level. Records of any training relevant to their functions should be kept.
3. Procedures and job descriptions for employees and other persons having access to the products must be designed and administered to minimize the possibility of drugs coming into unauthorized possession.
4. During operating hours, the business must at all times be conducted under the continuous personal supervision of a pharmacist or pharmaceutical technologists.

2.4.4 Wholesale pharmacy licence

No person will be issued with a licence to operate a wholesale pharmacy, unless the person complies with the requirements stipulated in the guidelines for registration of premises including, but not limited to, the following:

a. Is a holder of a certificate of Registration as a pharmacist from the Pharmacy and Poisons Board
b. Is not a holder of another such licence for a different premise
c. Is not engaged as a pharmacist in any other enterprise
d. The premises has been certified for suitability by the Pharmacy and Poisons Board's inspectorate department.
e. Pays the prescribed fee

3.0 HANDLING AND CONTROL OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES AND HEALTH TECHNOLOGIES

Handling and storage of medical products and health technologies and health technologies should be in accordance with established procedures designed to prevent contamination or deterioration, damage to packs or confusion of products. Particular care should be given to maintaining the integrity of seals on packs of sterile products and thermo-labile products. Attention should be paid to any special instructions from the manufacturer relating to handling or storage of the products.

Importers should take all reasonable measures to ensure that medical products and health technologies are not mishandled or exposed to adverse storage conditions at ports of entry e.g. airports.

3.1 Inward Goods – From Suppliers

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

Stock should be received and examined for correctness against order, for expiry date and for absence of damage. Additionally, the registration/ retention status of these products MUST be verified with PPB.

The wholesaler will ensure that received goods comply with PPB approved labelling and packaging requirements.

There should be a system for the recognition and prompt handling of drugs of addiction, or those products requiring specific temperature storage, of products that have a short shelf life and of any other products that require special care.

Goods from suppliers rejected by the wholesaler because of error, breakage, leaking containers or other faults should be placed in quarantine until the matter is resolved with the supplier.

Goods bearing an expiry date must not be received or supplied after their expiry date or so close to their expiry date that they are likely to expire before they are used by the consumer.

3.2 Outward Goods – To Retail Pharmacies

Dispatch bays should protect products from the weather. Dispatch areas should be designed and equipped to allow out going containers of products to be inspected, if necessary, before dispatch.

Every wholesaler/ distributor must put in place a mechanism of tracing the products distributed by their batch numbers. It is very necessary to account for all the stock.

It is unlawful to sell products to unlicensed pharmaceutical outlets or to unauthorized persons. The wholesaler shall keep an up-to-date database of client's registration status with healthcare regulatory authorities.

The wholesaler shall at all times maintain a record of distribution of their products.

3.3 Port Handling and Customs clearance

Where an organization, imports or distributes medical products for more than one manufacturer, the importer shall identify the range of different requirements and accommodate them all within the same carrier.

In ensuring quality, efficacy and safety, medical products should be stored under conditions complying with instructions from the manufacturer, in particular concerning appropriate humidity, temperature and light requirements; this will ensure storage conditions will prevent damage, deterioration or other adverse effects to the medicinal products.

The use of actively powered systems using electricity or other fuel source to maintain a temperature controlled environment inside an insulated enclosure under thermostatic regulation especially for time and temperature sensitive medical products and health technologies are recommended for example refrigerated ocean and air containers, temperature controlled trucks, cold rooms etc.

For temperature sensitive products, the authorized importer should alert customs officials in advance of the anticipated arrival of consignments so that necessary arrangements are put in place to transfer to the designated storage facilities without breaking the cold chain

3.4 Special/ temporary storage facilities at Ports of Entry

The requirements described herewith apply to temporary storage of Medical Products and Health Technologies awaiting clearance and release from Ports of Entry in the Republic of Kenya.
These temporary storage facilities include but not limited to the following: Container Freight Stations (CFS's), Warehouses, Customs cage(s) and shades. These facilities store consignments as pre-clearance procedures are being worked on. Consignments arrive into the country through Air ports, Dry land ports, and Sea ports.

3.5 Handling during Importation of Medical Products and Health Technologies

All import/export consignments containing Medical Products and Health Technologies must be accompanied with import/export authorizations from the Pharmacy and Poisons Board.

The Port of Entry to be used must be declared in the import/export authorization permits by the consignee and shall be adhered to.

Importers/Exporters of medical products and health technologies and Health Technologies shall declare to Customs and Drug Regulatory Officials upon arrival or expected arrival of consignments of interest.

Pharmaceutical inspectors in collaboration with Customs officials and importers/exporters will carry out physical examination of all imported consignment of medicinal products and their documentation.

Where necessary, the pharmaceutical inspector will carry out random sampling of medical products and health technologies in accordance

with laid down guidelines on sampling of medicinal products imported into the country for drug analysis.

All products whose details cannot be verified or fall within the scope of SSFF should be forfeited and destroyed as per provisions in the legislation (Anti-counterfeit Act 2008).

Storage of all medical products should adhere to the following basic requirements: -

i. Clean, dry and dust free storage facility
ii. Suitable space to allow cleaning and inspection
iii. Surfaces and shelves in ware houses and shades should be made of covered/and impermeable materials to enable proper and safe cleaning in order to maintain product integrity.
iv. Storage areas should be adequately lit and ventilated in order for tasks to be performed in the appropriate and safe manner while ensuring product quality is maintained.
v. Adequate storage area for proper segregation and arrangement of products to prevent cross -contamination and mix-up.
vi. Temperature, moisture and humidity control tools and protocols
vii. Prevent Exposure to light
viii. Direction the package should face
ix. Maximum number of packages staked above each other.

If the manufacturer requires products to be stored or transported at certain conditions (e.g temperature and humidity) these conditions shall be monitored and periodically recorded. Such records shall be maintained and available for review.

If packaging labels do not include information about the required storage and transport conditions, such information should be obtained from the manufacturer.

Importers/Exporters of medical products and health technologies and Health Technologies shall declare to Customs and Drug Regulatory Officials upon arrival or expected arrival of consignments of interest

Pharmaceutical inspectors in collaboration with Customs officials and importers/exporters will carry out physical examination of imported consignments of medicinal products and their documentation as per risk assessment reports.

Where necessary, the pharmaceutical inspector will carry out random sampling of medical products and health technologies in accordance with laid down guidelines on sampling of medicinal products imported into the country for drug analysis.

All products whose details cannot be verified or fall within the scope of SSFFCP's should be forfeited and destroyed as per provisions in the legislation (Anti-counterfeit Act 2008)

3.6 Damaged Goods from Stock

Stock which has been damaged or withheld from sale and which is not immediately destroyed should be placed in quarantine until disposal so that it cannot be sold in error or, in the case of liquid leakage, cause contamination to other goods.

Stocks of products with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied.

3.7 Returned Goods

3.7.1 From customers

Goods which have left the care of the wholesaler should only be returned to saleable stock if:

i. they are in their original unopened containers, in good conditions and bear a valid expiry date;
ii. it is not evident that they have been subject to adverse conditions;

iii. they are packed separately from other goods and accompanied by a separate Returns Note; and

iv. they have been examined and assessed by a person authorized to do so. Such assessment should take into account the nature of goods, and any special storage conditions they may quire. If necessary, advice should be sought from the person responsible for the quality assurance of the manufactured product.

Reconditioning or repackaging (including re- labelling) of medical products and health technologies goods must not be carried out by wholesalers unless such activity is specifically exempted by the PPB from the requirement to hold a manufacturers license.

3.7.2 **From recall**

There should be a written procedure detailing the action to be taken in recalling goods on behalf of their manufacturer or sponsor, subject to any amendment necessary in specific circumstances.

The above procedure should be consistent with the "PPB Recall guidelines for Pharmaceutical and allied products". The Wholesaler should be able to facilitate a recall procedure relative to the area to which goods have been supplied. Recalls carried out should be documented and records of all recalled goods received into the warehouse should be kept. A person should be designated as responsible for execution and co-ordination of recalls.

3.7.3 Inventory Management

Written procedures should describe the different operations which may affect the quality of the products or of the distribution activity: receipt and checking of deliveries, storage, cleaning and maintenance of the premises, (including pest control), recording storage conditions, security of stocks and on site, consignments in transit, withdrawal from saleable stock records, including records of clients' orders,

returned products, recall plans, etc. These procedures should be approved, signed and dated by the person responsible for the quality system.

Invoices or packaging slips should be issued for each delivery and accompany the goods.

Clear and readily available records should be maintained showing the receipt and disposal of all products purchased and sold. Such records should be kept in an accessible form and place for the appropriate legislated period (currently five years).

Keep records of each sale or purchase, showing date of purchase (supply) name of medicinal product, quantity received (or supplied) name and address of suppliers or consignee. Records should ensure traceability of the origin and destination of products, e.g. by use of batch numbers in the order that they can be identified/ traced.

Periodic (at least annually) physical counts should be done, involve counting all items and comparing the counts with the records.

The differences should be reconciled i.e. all significant stock discrepancies should be investigated to check that there have been no inadvertent mix-ups, incorrect issue and/or misappropriation of medical products and health technologies; and any stock discrepancy must be referred to the Responsible Pharmacist

A written procedure must be in place to ensure effective stock rotation. Medical products and health technologies due to expire first must be sold and/or distributed in accordance with the first expiry, first out (FEFO) principles. Where no expiry dates exist for the medical products and health technologies, the first in, first out (FIFO) principle should be applied.

All stock must be checked regularly for obsolete and short dated stock items. All due precaution should be observed to prevent the issuance of such short dated or expired stock.

Medical products and health technologies with broken seals, damaged packaging or suspected of possible tampering/ contamination must not be sold or supplied and must be segregated pending an investigation and decision.

3.7.4 Suspected Spurious Falsified and Falsely labelled products (SSFF) / Unregistered Products

Products which are suspected to be SSFF should be kept in a designated area apart from other medicinal products to avoid confusion. They should be clearly labelled as "NOT FOR SALE". The Pharmacy and Poisons Board and the holder of the products registration should immediately be informed.

Sale of unregistered medicines is not allowed, but should written permission under the appropriate provisions in the Pharmacy and Poisons Act be given by the Board, the following should be observed:

i. Records of sales should be kept. This may also include special conditions imposed by the Board on giving the permission; and
ii. The medicines should be stored separately from other registered medicines. The area should be clearly indicated as to its use to ensure adequate control of sales.

Handling, storage, distribution or trade in Substandard, Spurius, Falsified and falsely labelled (SSFF) products is highly prohibited. Any such product encountered/ detected should be quarantined and PPB be notified for necessary regulatory action.

3.7.5 Complaints

Complaints regarding the product or its packaging, as distinct from those relating solely to matters within the wholesalers' control, must be notified promptly to the manufacturer or sponsor of the goods. Complaints relating to the wholesalers' own activity should be evaluated and measures taken, where appropriate, to prevent their recurrence.

All complaints shall be comprehensively documented, as per inhouse procedure for handling complaints.

3.7.6 Self-Audit

The System of Quality Assurance of the distribution outlets should include self- audit. These inspections should be in line with the principles of Good Distribution Practices and if necessary, to trigger corrective and preventative measures.

The Authorized person should ensure that self-audit is performed and any deviations are followed up and concluded. Written procedures for self- audit should be established to provide minimum and uniform standards.

Self-audit should be conducted in an independent and detailed way by a designated and competent person, and should cover all aspects of Good Distribution Practices.

The frequency of self-audit should be at least twice a year.
Audit reports should include results, evaluation, conclusions, and recommended measures. These reports should be summarized and periodically submitted to Senior Management as an integral part of the management review process.

There should be an effective follow-up programme whereby company management must evaluate both the report and corrective measures.

The follow-up activities should verify the effectiveness of the corrective action taken.

3.7.7 Corrective Action and Preventive Actions (CAPA)

3.7.7.1 Corrective Action

Entities should have Corrective action procedures in place to eliminate causes of existing non-conformities or other undesirable situations.

Corrective action procedures must be implemented and the effectiveness of the results must be verified. It must be determined whether the non-conformity is an isolated or a repetitive problem, and any actions to be taken, if necessary.

3.7.7.2 Preventive Action

Entities should have Preventive action in place to prevent occurrence of existing non-conformities or other undesirable situations.

Preventive action should be considered if there are opportunities to improve the quality management system.

Corrective action is taken after nonconformities are identified. Preventive action is taken when a potential non-conformity is identified as a result of the analysis of records and other relevant sources of information, such as:

(a) Statistical process control documents;
(b) Customer complaints;
(c) Review product, process and quality system information;
(d) Risk analysis and risk assessment of products and processes.

Records relating to the product performance should be analyzed regularly, to detect trends and to identify areas of risk that may lead to non-conformities.

The analysis should also determine how to prevent any identified potential problems.
Information on preventive action taken must be part of the management review to maintain and improve the quality system.

3.8 Validation

Wholesalers should have a Validation Master Plan. The Validation Master Plan provides a summary of the company's philosophy, policy, intentions and approach to validation.
The following should be validated at minimum:

a. Warehouse premises: ambient and cold-chain storage conditions including temperature mapping
b. Lagged containers
c. Cold-chain processes
d. Computerized systems and
e. Transportation systems

Validation should be conducted in accordance with a validation protocol. A written Validation Report should be available after completion of the validation exercise

3.9 Calibration

All measuring equipment must be calibrated in accordance with an approved schedule that details which equipment requires calibration, as well as the frequency of calibration. The frequency will depend on the type of equipment used, as well as the purpose for which it is used.
It is the Authorized person's responsibility to approve the calibration schedule.

3.10 Electronic records

Data, especially, legal records, may be recorded by electronic data processing systems but detailed procedures relating to the system in use should be available and the accuracy of the records should be checked.

A written detailed description of the system should be produced (including diagrams as appropriate) and kept up to date. It should describe the principles, objectives, security measures and scope of the system and the main features of the way in which the computer is used and how it interacts with other systems and procedures.

Only authorized persons should be able to enter or modify data in the computer. Access should be restricted by passwords or other means. User should have a unique identifier (User ID) for their personal and sole use so that activities can subsequently be traced to the responsible individual

Written procedures should be in place for the validation of computerized systems in order to demonstrate security of access and data integrity.

There should be a record of changes and deletions. Any alteration to an entry of critical data (which must be defined by each organization) should be authorized and recorded with the reason for the change in accordance with the procedure. Consideration should be given to the system creating a complete record of all entries and amendments (an "audit trail").

Records electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper or other means, at regular intervals. Back-up data should be stored as long as possible at a separate and secure off-site location.

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