



**MINISTRY OF HEALTH**

**PHARMACY AND POISONS BOARD**

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

**November 2023**

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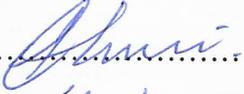
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## **Abbreviations and Acronyms**

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
SSFFPs-	Suspected Spurious Falsified and Falsely Labelled Products
FEFO-	First Expired First Out
FIFI-	First in First out
SF -	Substandard and Falsified Medical Products
CAPA-	Corrective Action and Preventive Action

## **Glossary of 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.

**Authorized personnel:** A registered pharmacist, enrolled pharmaceutical technologist, or any other person approved by the Pharmacy and Poisons Board.

**Batch:** A defined quantity of health products and 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 indicate a loss of control; and the action taken in response to audit findings;

**Consignment:** The quantity of health products and 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 health products and 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](http://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 health products and technologies, with the exception of the dispensing or providing health products and 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 health products and technologies.

**Good Storage Practices (GSP):** That part of quality assurance that ensures that the quality of health products and 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 health products and 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, birds, 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 health products and 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 labeling 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 health products and 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 health products and 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 health products and 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.

## **Acknowledgments**

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## **Foreword**

The Pharmacy and Poisons Board is committed to ensuring the availability of health products and 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 GDP guideline, which replaces the 2019 guideline, defines a number of new provisions. They have been prepared to provide persons involved or wishing to be involved in distribution Health products and 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**

## **1.0 INTRODUCTION**

### **1.1 Legal framework**

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

Distribution is an important activity in the integrated supply chain management of health products and technologies. All parties involved in the distribution of health products and 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 health products and technologies in the market are of the right quality.

## **2.0 GENERAL CONSIDERATIONS**

### **2.1 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:

1. 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.
2. 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.

3. Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality management system, as well as to identify and correct deviations from the established quality management system.
4. The responsibilities placed on any one individual should not be so extensive as to present any risks to the health products and 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.
5. 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
6. Any person who wishes to start the business of a pharmacy may first consult the concerned Pharmacy and Poisons Board regional office for guidance on suitability of proposed location prior to making financial commitments.

## **2.2 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:

1. Communicating the importance of adhering to customer, regulatory (Good distribution Practices) and legal requirements, including environmental, health and safety aspects;
2. Establishing functional quality objectives;
3. Ensuring regular reviews of quality management systems;
4. Applying risk assessments;
5. Maintaining appropriate conditions throughout the organization for processes and systems
6. Ensuring the availability of resources to support quality management system
7. Ensuring the integration of quality management system into their operations and processes.
8. Supporting other relevant management roles to demonstrate leadership as it applies to their areas of responsibilities.
9. Ensuring that customer satisfaction is enhanced and maintained.
10. Establish a system for handling customer compliments and complaints

Every entity shall establish and maintain documented information on:

1. Standard Operating Procedures (SOPs) for all activities affecting the quality, safety, and efficacy of health products and technologies;
2. Work Instructions and Process Maps;
3. 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 health products and 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.

### **2.3 Personnel**

1. Authorized personnel shall bear the responsibility of ensuring that health products and 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 health products and 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 health products and technologies should be supplied with appropriate

personal protective equipment suitable for the activities that they perform. Personnel dealing with hazardous health products and 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.

## **2.4 Premises, Warehousing and Storage**

### **2.4.1 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 health products and 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 health products and 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 health products and technologies.
5. Warehousing of health products and technologies should be carried out in permanent buildings or parts of the

permanent building that have been built for, or adapted to warehouse health products and 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 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 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 health products and technologies.
13. Sufficient space should be provided for the orderly receipt, warehousing and dispatch of health products and 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 health products and 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 health products and technologies are handled by wholesale.

#### 2.4.2 **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 health products and 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. Health products and 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 health products and 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 health products and 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:
  - a) Health products and technologies that await release by the Holder of the Certificate of Registration;
  - b) Suspected and confirmed substandard and falsified health products and technologies
  - c) Returned, damaged or expired health products and technologies for disposal;
  - d) Health products and technologies that have been recalled or withdrawn from the market;

- e) Health products and technologies that are being investigated after a cold-chain failure;
  - f) 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 health products and 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. Health products and 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:
  - a) Restricted entry and exit points to the warehouse being used
  - b) Vehicles (other than delivery vehicles) not being allowed near the warehouse;
  - c) All goods leaving the store being carefully checked against the relevant documentation;
  - d) Security checks of all vehicles entering or leaving the warehouse area taking place;
  - e) High-risk goods being well protected, ideally in a separate area that is sealed off from the rest of the warehouse with access control;
  - f) Implementing good housekeeping;
  - g) Ensuring that workers are not able to leave the warehouse area during working hours without going through security;
  - h) Preventing theft by using appropriate security systems;
  - i) Avoiding fires in the warehouse by removing combustible waste materials several times a day. No-Smoking policies and notice boards should be in place.
  - j) Firefighting equipment should be frequently serviced and maintained.
  - k) 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.

### 2.4.3 Storage conditions

1. Storage conditions for health products and technologies as described by the product storage requirements should follow 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 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 the 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.

#### 2.4.4 **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 health products and technologies plus one year.

#### 2.4.5 **Good cold chain management Storage**

1. All thermolabile products must be stored in a refrigerator/cold room/freezer exclusively dedicated to 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. The 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. The refrigerator, freezer, or cold room must be connected to a standby generator or other emergency power system to ensure an 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 health products and technologies should at a 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.

## **2.5 Good Retail Practice for Pharmaceuticals**

### **2.5.1 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 distance of not less than 200 metres shall exist between registered premises per cadre of superintendent (pharmacist to pharmacist and pharmaceutical technologist to pharmaceutical technologist).

***For clarity, it is the Cadre of the superintendent under consideration and not the cadre of the owner.***

In addition, consideration shall be made as to the level of urbanization, population status among other factors (streets, malls and metropolitan cities).

The issue of distance between registered pharmacies does not apply to registered hospital pharmacies.

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. The crosses should be conspicuous and located before and at the end of the premises name. In addition, branding to reflect practice level is a requirement at pre-registration inspection. For clarity, the colour of the crosses shall be determined by the cadre of the superintendent and not the cadre of the owner.



Above: Green cross branding for a retail pharmacy where the superintendent is a pharmacist.

In the middle is the name of the pharmacy as the case may be



Above: Blue cross branding for a retail pharmacy where the superintendent is a pharmaceutical technologist.

In the middle is the name of the pharmacy as the case may be

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. There should be a lockable door separating the dispensary from the over the counter area.
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.
16. The number of registered pharmacists or enrolled pharmaceutical technologists) per premises shall be determined by the workload at the premises.

#### 2.5.2 **Equipment**

There should be some basic equipment:

- a) A tablet counter
- b) A refrigerator
- c) Appropriate litter bins
- d) Drinking water dispenser
- e) Weighing balance
- f) Measuring cylinders with a capacity to accurately measure volumes between 0 and 100 ml
- g) Pestle and mortar
- h) Spatula and Slab

#### 2.5.3 **Reference materials**

The following reference books and materials should be available and they should be the latest editions

1. Guidelines
  - a. GDP guidelines
  - b. Safe management of Pharmaceutical waste
  - c. Product recall and withdrawal
  - d. Transportation of pharmaceuticals
2. CAP 244 laws of Kenya
3. Professional code of ethics
4. 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
5. Any other text that gives trade names of drugs on the market.
6. Online reference materials

#### 2.5.4 **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 premise has been certified for suitability by the Pharmacy and Poisons Board's inspectorate department.
- f. Pays the prescribed fee.

#### 2.5.5 **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 qualified pharmacist or pharmaceutical technologist. Warehousing may be contracted out e.g. for scientific offices, but only to Pharmacy and Poisons Board registered warehouses. This should be documented in written contracts and quality agreements
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 pharmaceutical inspectors at all reasonable times.
9. Adequate personal hygiene and clothing should be maintained throughout 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.

#### **2.5.6 Good Wholesale Practice for Pharmaceuticals**

Wholesale distribution forms part of the supply chain of manufactured health products and 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.

#### **2.5.7 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<sup>2</sup>.
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.

#### 2.5.8 **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 analysed 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.

#### 2.5.9 **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. It shall be the responsibility of the superintendent pharmacist/pharmaceutical technologist to submit to the concerned Pharmacy and Poisons Board regional office reports on the consumption/distribution of Narcotics and Psychotropic medicines on a quarterly basis.

The superintendent should also provide an updated list of clients preferably biannually in January and in July of every year.

Any superintendent should always officially notify writing PPB/Regional office whenever they are away from their registered premises indicating the name and registration number of the professional holding brief for them.

The superintendent pharmacist/pharmaceutical technologist for active reporting of poor-quality

medicines and suspected adverse drug reactions by retail pharmacies and wholesale pharmacies.

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 pharmacist or pharmaceutical technologists.

#### **2.5.10 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 premise has been certified for suitability by the Pharmacy and Poisons Board's inspectorate department.
- e. Pays the prescribed fee.

## **2.6 Good Hospital Pharmacy Practice for Pharmaceuticals**

### **2.6.1 Nature and Setup of premises.**

1. The premises are to consist of one room, at least 4 meters by 3 meters in dimension, with lockable cabinets for controlled substances and quarantined products.
2. Premises to have a designated office area for the superintendent, where administrative activities will be done and records kept and maintained, with a full view of the pharmacy and where necessary a separate drug store.
3. The premises will be permanent in nature, made of materials providing ease of cleaning and suitable sanitary conditions. All products will be protected from light, heat, moisture and there must be temperature control facilities in the pharmacy area.
4. The premises will have suitable and adequate provisions for light and ventilation, with hand wash facilities with clean running water, waste disposal bin within the pharmacy with toilet facility and storage for cleaning equipment.
5. The pharmacy design will include provisions for privacy for the patients during service and sufficient space for carrying out operations.
6. The premises structure will be protected against adverse weather conditions, ground water slippage, vermin and pest infestation.
7. Pharmacy premises to reflect the level of practice, painted as white with a green cross for pharmacist, and white with a blue cross for pharmaceutical technologist.



**Above: Green cross branding for a hospital pharmacy where the superintendent is a pharmacist.**

**In the middle is the name of the hospital as the case may be and the word pharmacy**



**Above: Blue cross branding for a hospital pharmacy where the superintendent is a pharmaceutical technologist.**

**In the middle is the name of the hospital as the case may be and the word pharmacy**

8. There should be restricted entry to the pharmacy.
9. There should be no other unauthorized activities within the hospital pharmacy.

#### **2.6.2 Hospital Pharmacy licence.**

No person will be issued with a licence to operate a hospital pharmacy unless the person complies with the requirement stipulated in Guidelines for Registration of Premises including, but not limited to, the following:

1. Is a registered pharmacist with the Pharmacy and Poisons Board.
2. Is an enrolled pharmaceutical technologist with the Pharmacy and Poisons Board.
3. Is not a holder of retail, hospital, wholesale or such licence for a different premise.

4. Is not engaged as a pharmacist or pharmaceutical technologist in any other enterprise.
5. The premises have been certified for suitability by the Pharmacy and Poisons Board's Inspectorate Department.
6. Such a premise should have a valid license from the Kenya Medical Practitioners and Dentist Council.
7. Pays the prescribed fee.

### 2.6.3 **Staff establishment**

The Ministry of Health Human Resources for Health Norms and Standards Guidelines for the Health Sector, August 2014 will apply. The minimum requirement will be as follows;

1. Level 2 Hospitals. One pharmaceutical technologist
2. Level 3A Hospitals
  - One pharmacist
  - Three pharmaceutical technologists
3. Level 3B Hospitals
  - One pharmacist
  - Four pharmaceutical technologists
4. Level 4 Hospitals
  - Four pharmacists
  - Ten pharmaceutical technologists
5. Level 5 Hospitals
  - 6 pharmacists
  - 10 pharmaceutical technologists
  - At least one specialist pharmacist
6. Level 6 Hospitals
  - Depending on specialization and workload

#### 2.6.4 **Operations**

1. Quality assured Health products and technologies will be procured through robust and appropriate process supervised by the superintendent pharmacist or pharmaceutical technologist.
2. Pharmaceutical expertise will be available with relevant, up to date, evidence-based information to healthcare professionals prescribing, administering and monitoring effect of drug at point of care.
3. Pharmaceutical staff will be integrated into clinical teams in the hospital and provide safe and appropriate pharmaceutical care directly to the patients.
4. The pharmaceutical staff will ensure that all aspects of medicinal use within the hospital are safe.
5. Medicine is to be prepared, labelled and dispensed by a registered pharmacist or an enrolled pharmaceutical technologist.
6. There will be systems of work established that are safe, productive, support quality improvement, are regularly audited, and comply with relevant regulations.
7. Patient care will be provided in a secure, appropriate, and suitable environment, ensuring the confidentiality and dignity of the patient.
8. Suitable, appropriate, and relevant records will be kept in an environment that is safe and in a secure form.
9. For extemporaneous preparations, necessary SOPs and Reference materials must be available.
10. Where manufacturing activities take place, necessary Good Manufacturing Practice (GMP) requirements apply.

#### 2.6.5 **Equipment (where necessary)**

- Hot plate

- Weighing machines
- Source of clean water
- Dispensing Cylinders of various sizes
- Beakers
- Motor and Pestles
- Trituration Slabs
- Spatula
- Refrigerator
- Tablet/capsule counters

### 2.6.6 **Reference materials**

#### 1. PPB Guidelines

- GDP guidelines
- Safe Management of Pharmaceutical Waste
- Product recall and withdrawal
- Transportation of Pharmaceuticals
- Safety and Vigilance of Health products and technologies.
- Guidelines for Implementation of Continuing Professional Development for Pharmacy Practitioners

#### 2. Cap 244 Laws of Kenya

#### 3. Professional Code of Ethics

#### 4. Reference books

- BNF – Latest Edition
- Standard Treatment Guidelines
- Kenya National Drugs Policy
- Hospital Formulary
- EA Pharmaceutical Loci
- Guidelines for Medicines and therapeutics Committee.

#### 5. Any other text that gives trade names of drugs on the market

## 2.7 Good E-Pharmacy Practice for Pharmaceuticals

1. E-pharmacy” means business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode.
2. Any person who intends to conduct the business of e-pharmacy shall apply for grant of the registration to the Pharmacy and Poisons Board through the prescribed portal.
3. The e-pharmacy registration holder shall inform the Boards Licensing Department in writing in the event of any change in the constitution of the firm operating under the registration.
4. The e-pharmacy registration holder shall make provision for a duly registered brick and mortar pharmacy outlets for supplies, customer support, redress of grievances among other supportive services, e.g., answering customer queries through a customer helpline.
5. The HPT requested/ordered through e-pharmacy shall be delivered to the patient by a registered pharmacist or enrolled pharmaceutical technologist within the period of validity of the prescription received from the patient.
6. For providers of e-pharmacy who link clients to existing Registered Pharmaceutical premises, such information must be shared with PPB.
7. Information received by the e-pharmacy registration holder from the customer by way of prescription or in any other manner shall not be disclosed by the e-pharmacy registration holder for any other purposes nor shall the same be disclosed to any other person.
8. Details of records /documents in regard to dispensing made against a cash or credit memo generated through the e-pharmacy portal shall be maintained by the e-pharmacy registration holder, e.g., patient details, serial number and

date of the cash/credit memo, etc, for a period of at least six years.

9. The e-pharmacy registration holder shall not carry out e-pharmacy business with respect to the drugs covered under the categories of
10. Narcotic and psychotropic as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985).
11. The e-pharmacy registration holder shall not advertise any drug unless the advertisement has been approved by the Pharmacy and Poisons Board.
12. The e-pharmacy registration holder shall maintain and update, from time to time, the information regarding the drug's availability, types of drugs offered for sale, supply channels or vendor lists, details of registered pharmacists, registered medical practitioner (if any), and any other requirements of the Pharmacy and Poisons Act and rules there under, to Pharmacy and Poisons Board.
13. The e-pharmacy registration holder shall demonstrate adequate backup for their online data.
14. All products supplied through e-pharmacy should have a valid market authorization from PPB.

### **3.0 HANDLING AND CONTROL OF HEALTH PRODUCTS AND TECHNOLOGIES**

Handling and storage of health products and 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 health products and 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.

The stock should be received and examined for correctness against the order, for expiry date and for the 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 and technologies 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 sources to maintain a temperature-controlled environment inside an insulated enclosure under thermostatic regulation, especially for the time and temperature-sensitive health products and 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 the temporary storage of Health products and 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 Health products and technologies**

All import/export consignments containing Health products and 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 health products and 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 health products and 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 health products and 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 health products and 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. If it is evident that they have not 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 consider the nature of goods, and any special storage conditions they may require. 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 health products and technologies goods must not be carried out by wholesalers unless such activity is specifically exempted by the PPB from the requirement to hold a manufacturer's 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 in the warehouse should be kept. A person should be designated as responsible for the 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 the date of purchase (supply) name of the 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, involving 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 issues, and/or misappropriation of health products and technologies; and any stock discrepancy must be referred to the Responsible Pharmacist

A written procedure must be in place to ensure effective stock rotation. Health products and 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 health products and 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 precautions should be observed to prevent the issuance of such short-dated or expired stock.

Health products and 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 **Substandard and Falsified Medicals products (SF) and Unregistered Products**

Products which are suspected or confirmed to be SF 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

Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their 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.

Sale of unregistered medicines is not allowed, but should have 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 SF 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 are taken, where appropriate, to prevent their recurrence.

All complaints shall be comprehensively documented, as per in-house 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 Action (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 non-conformities 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 product performance should be analysed 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 approaches 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.

### 3.11 **Good Distribution Practices Certification**

Based on an inspection report, the plan for corrective actions taken by the inspectee(s), and recommendation by PPB GDP inspectors,

the premises shall be deemed compliant/non-compliant with regulatory requirements and a Certificate of Compliance/Non-compliance with Good Distribution Practices will be issued.

In the event that an inspectee wishes to appeal the decision, the appeal should be submitted in writing to the Chief Executive Officer, Pharmacy and Poisons Board within 30 days from the date of the decision.

#### 4.0 REFERENCES

1. Constitution of Kenya 2010
2. Pharmacy and Poisons Act, Cap 244 laws of Kenya
3. PPB 2020-2025 Strategic Plan
4. Code of ethics for PPB Inspectors
5. WHO Technical Report Series No.957, annexe 5. WHO good distribution practices for pharmaceutical products.
6. European Medicine Agency. Good Distribution Practice.
7. Good Distribution Practice, TMDA, United Republic of Tanzania.

#### 5.0 REVISION HISTORY

Revision No:	Date	Reviewer	Section(s) revised	Description of change
Revision No.1	12/01/2022	Dr. Kariuki	Document numbering	To be in line with the new organogram
			2.5	Inclusion of guidelines for hospital pharmacy
			2.6	Inclusion of guidelines for e-pharmacy
Revision No.2	01/11/2023	Dr. Kariuki	Cover page	Inclusion of the new Court of arms

	01/11/2023	Dr. Kariuki	Table of contents	Correction of the table of contents for formatting errors.
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## 6.0 CONTRIBUTORS/REVIEWERS

<b>NO</b>	<b>NAME</b>	<b>POSITION</b>
1.	Dr. F.M. siyoi	Chief Executive Officer
2.	Dr. Ahmed Mohamed	Director, Health Products and Technologies
3.	Dr. Dominic Kariuki	Deputy Director, Inspectorate and Enforcement
4.	Dr. Tom Kauki	Regional Head, Central Region
5.	Mr. Julius Kaluai	Regional head, Nairobi Region
6.	Dr. Paddy Agoro	Regional Head, Coast Region
7.	Dr. Kibet Chebeo	Regional Head, North rift Region
8.	Dr. Sibalile Simiyu	Regional Head, South rift Region
9.	Dr. Onesmus Kilonzo	Regional Head, Western Region
10.	Dr. Washington Oyoo	Regional Head, Nyanza Region
11.	Dr. James Gathogo	Regional Head, Upper Eastern Region
12.	Dr. Benson Kanji	Regional Head, Lower Eastern Region
13.	Mr. Omar Sheikh	Regional Head, North Eastern Region
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15.	Mr. Denis Otieno	Head Drug Crime Investigation

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