



REPUBLIC OF KENYA
PHARMACY AND POISONS
BOARD

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GUIDELINES
FOR GOOD DISTRIBUTION
PRACTICES
FOR PHARMACEUTICALS

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Guidelines for Good Distribution Practices for Pharmaceuticals

This document has been prepared to serve as a guide to licensees regarding the distribution of pharmaceuticals (both retail and wholesale). These guidelines are based on the provisions of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya and reflect the Pharmacy and Poisons Board's current thinking on the safety, quality and efficacy of medicines. The Board reserves the right to request for compliance with any additional requirements or make amendments in keeping with the knowledge which is current at the time.

FOREWORD

The Pharmacy and Poisons Board is committed to its mission to ensure the availability of pharmaceutical services in Kenya which satisfy the needs of all 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.

These guidelines have been prepared to provide persons involved or wishing to be involved in pharmaceutical distribution with a method of assessing eligibility and the process of lawfully operating drug 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.

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REGISTRAR.

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PART ONE:

**GUIDELINES FOR GOOD WHOLESALING
PRACTICE FOR PHARMACEUTICALS**

GUIDELINES FOR GOOD WHOLESALING PRACTICE FOR PHARMACEUTICALS

1. INTRODUCTION

Wholesale distribution and retail forms part of the supply chain of manufactured therapeutic goods. Wholesalers are responsible for effective, efficient and safe handling, storage and distribution of such products. On the other hand retailers are the final/contact personnel with the clients/patients. As such, these guidelines set out appropriate steps for meeting these responsibilities.

Current Good Distribution Practices for pharmaceutical products incorporates and provide for minimum requirements on aspects of the following:

- 1.1 Building and grounds
- 1.2 Facilities
- 1.3 Personnel
- 1.4 Stock handling and Stock control
- 1.5 Transport
- 1.6 Complaints
- 1.7 Documentation and records
- 1.8 Counterfeit products
- 1.9 Sale of unregistered medicines

2. BUILDING AND GROUNDS

- 2.1 Warehousing of pharmaceuticals should be carried out in buildings or parts of buildings that have been built for, or adapted to, this purpose.
- 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.

- 2.3 Buildings should be kept free of rodents, vermin, birds, pets and pests.
- 2.4 Buildings should provide protection for the pharmaceuticals from contamination and deterioration, including protection from excessive local heating or undue exposure to direct sunlight. The pharmaceuticals received or dispatched at receiving areas or dispatch bays/ platforms should also be protected from dust, dirt and rain.
- 2.5 Buildings should have sufficient security to help prevent pilferage of the pharmaceuticals.
- 2.6 Sufficient space should be provided for the orderly receipt, warehousing and dispatch of pharmaceuticals and, in particular, a quarantine area for isolation when necessary, including isolation of faulty packs and recalled goods.
- 2.7 Buildings and fixtures should be kept clean and well maintained. Cleaning equipment should be stored in hygienic conditions.
- 2.8 Sufficient lighting should be provided to enable all operations to be carried out accurately and safely.

3. FACILITIES

- 3.1 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.

- 3.2 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.
- 3.3 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.
- 3.4 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.
- 3.5 Instruments or equipment used for monitoring temperature should be calibrated on a regular basis to ensure their accuracy.
- 3.6 Special storage facilities should be provided for poisons, drugs and addiction, “Dangerous Drugs” or other categories of goods as required by applicable legislation.
- 3.7 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.

4. PERSONNEL

- 4.1 Pharmacists or Pharmaceutical technologists 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.

- 4.2 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.
- 4.3 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.
- 4.4 During operating hours, the business must at all times be conducted under the continuous personal supervision of a pharmacist or pharmaceutical technologists.

5. STOCK HANDLING AND STOCK CONTROL

- 5.1 Handling and storage of pharmaceuticals 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 pharmaceuticals. Attention should be paid to any special instructions from the manufacturer relating to handling or storage of the pharmaceuticals.
- 5.2 Importers should take all reasonable measures to ensure that pharmaceuticals are not mishandled or exposed to adverse storage conditions at ports of entry e.g. airports.

- 5.3 Storage, supply, distribution and recording of drugs of addiction (narcotic drugs and psychotropic substances) must be in accordance with applicable legislation. They should be kept in segregated areas under lock and key and all measures taken to restrict access to authorized persons only.
- 5.4 Storage areas should be adequate and organised to permit segregation and identification of the various materials and products stored and should enable stored goods to be easily maintained in a clean, dry and orderly condition. Particular care should be taken to avoid mould growth in refrigerated rooms or cabinets.
- 5.5 There should be a system to ensure stock rotation, with frequent regular checks that the system is operating correctly. Products beyond their expiry date or shelf-life should be removed from usable stock and it must be ensured that they are neither sold nor supplied.
- 5.6 Spilled substances should be cleaned up promptly and rendered safe as quickly as practicable and under the supervision of a responsible person. A written procedure for dealing with spillage of items of special hazard, such as catatonic drugs, should be available.
- 5.7 Measures should be taken to demonstrate that restricted goods are not pilfered.
- 5.8 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.
- 5.9 Where, inevitably, stocks held happen to expire or are very close to their expiry, such goods must be

withdrawn from sale and quarantined pending disposal in accordance with agreements between the wholesaler and the supplier. The Pharmacy and Poisons Board must be informed of the same and arrangements made for disposal under supervision.

6.10 INWARDS GOODS – FROM SUPPLIERS

- 6.10.1 Stock should be received and examined for correctness against order, for expiry date and for absence of damage.
- 6.10.2 There should be a system for the recognition and prompt handling of drugs of addiction, of those products requiring specific temperature storage, of products that have a short shelf life and of any other products that require special care.
- 6.10.3 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.

6.11 OUTWARDS GOODS – TO RETAIL PHARMACIES

- 6.11.1 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.
- 6.11.2 It is unlawful to sell products to unlicensed pharmaceutical outlets or to unauthorized persons
- 6.11.3 Where necessary the wholesaler may be asked to provide details of the distribution list of a product

6.11.4 Under certain circumstances it may be necessary to have a distributor/ wholesaler recall a product from the market (see recall guidelines). Each wholesaler should put in place mechanisms to execute a recall as may be necessary.

6.12 **DAMAGED GOODS FROM STOCK**

6.12.1 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.

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

6.13 **RETURNED GOODS FROM CUSTOMER**

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

- (a) they are in their original unopened containers, in good conditions and bear a valid expiry date;
- (b) it is not evident that they have been subject to adverse conditions;
- (c) they are packed separately from other goods and accompanied by a separate Returns Note; and
- (d) 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

require. If necessary, advice should be sought from the person responsible for the quality assurance of the manufactured product.

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

6.14 RETURNED GOODS – FROM RECALL

- 6.14.1 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. Their procedure should be consistent with the “Recall Procedure for Pharmaceutical Goods” issued by the Authority. 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.

7. TRANSPORT

- 7.1 Containers for delivery of goods should be clean and be able to provide adequate protection for the goods delivered.
- 7.2 Goods labelled as requiring refrigerated storage should, where appropriate, be transported in insulating containers with ice or other cooling agent. The agent should not cause freezing of goods marked ‘Refrigerate – do not freeze’. Goods

labelled as requiring frozen storage should be transported in such a way that they remain frozen. Where appropriate, the transport packaging should be fitted with devices to detect exposure to conditions outside specific limits.

- 7.3 Delivery of other goods requiring controlled temperatures should be carried out by the fastest practical means. These goods may, in suitable circumstances, remain temporarily outside the specified temperature range while on delivery in any particular case, due account should be taken of the time required for delivery, prevailing or likely weather conditions and the nature of goods and their labelled storage requirements. Special procedures should be established for goods likely to be exposed to unfavourable environments over holiday periods.

8. COMPLAINTS

- 8.1 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.

9. DOCUMENTATION AND RECORDS

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.

- 1.1 Invoices or packaging slips should be issued for each delivery and accompany the goods.
- 1.2 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).
- 1.3 An updated list of all premises allowed to store, dispense or sell drugs should be available at all premises to ensure medicines are only sold to these persons or premises.
- 1.4 Keep records of each sale or purchase, showing date of purchase (supply) name of medicinal product, quality 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-order that they can be identified.

10. COUNTERFEIT MEDICINAL PRODUCTS

Products which are suspected to be counterfeit 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.

11. UNREGISTERED MEDICINES

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:

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

PART TWO:

**GUIDELINES FOR GOOD RETAIL
PRACTICE FOR PHARMACEUTICALS**

GUIDELINES FOR GOOD RETAIL PRACTICE FOR PHARMACEUTICALS

12. NATURE AND SET UP OF PREMISES

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

- 12.1 The construction must be of a permanent nature
- 12.2 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.
- 12.3 The premises should be well lit, ventilated and secure
- 12.4 The premises should be protected against adverse weather conditions, ground water seepage, vermin and pest infestation.
- 12.5 The premises should have sufficient space for the carrying out of the necessary operations.
- 12.6 There should be no overcrowding of customers and staff thus promoting efficient flow of work, effective communication and supervision.
- 12.7 The minimum recommended size for the dispensary shall be 8 feet by 10 feet. For the general shop area the minimum acceptable will be 10 feet by 10 feet.
- 12.8 The premises must be used exclusively for the business of a pharmacy.
- 12.9 Premises should have running potable water, toilet facilities, waste disposal system and space dedicated for the storage of cleaning equipment

- 12.10 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
- 12.11 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.
- 12.12 Pharmacy only drugs must be separated from over the counter drugs and narcotic and psychotropic drugs shall be kept in a secure fixed and lockable storage place.
- 12.13 There should be a separate office or administrative office for the pharmacist, 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.

13. **EQUIPMENT**

There should be some basic equipment:

- (i) A refrigerator
- (ii) Weighing balance
- (iii) Measuring cylinders with a capacity to accurately measure volumes between 0 and 100 ml
- (iv) Pestle and mortar
- (v) Spatula and Slab

14. **REFERENCE BOOKS**

The following **reference books** should be available and they should be the latest or next to latest editions

- (i) British National Formulary
- (ii) Martindale, the extra pharmacopoeia

- (iii) Chapter 244, Laws of Kenya
- (iv) Code of Ethics
- (v) Kenya Standard Treatment Guidelines
- (vi) Kenya National Drug Policy
- (vii) Lists of drugs that are registered in Kenya
- (viii) Mims
- (ix) East African Pharmaceutical Loci or other text that gives trade names of drugs on the market.

15. LICENCE TO OPERATE A RETAIL PHARMACY

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 holder of a certificate of Registration or Enrolment from the Pharmacy and Poisons Board
- b) Is not a holder of another such licence for a different premises
- c) Is not engaged as a pharmacist/pharmaceutical technologist in any other enterprise
- d) Holds a satisfactory inspection report from the Board's Pharmaceutical Inspectorate
- e) Has not been previously convicted of an offence involving wrongful or illegal dealing in, supply and/or possession of drugs
- f) Pays the prescribed fee.

16. OPERATIONS

- 16.1 The dispensing of prescriptions and sale of pharmacy only medicine shall be under the supervision of a named pharmacist or pharmaceutical technologist

- 16.2 The Pharmacy shall not dispense any prescription or sell any Pharmacy only medicine when the pharmacist is not present.
- 16.3 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.
- 16.4 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.
- 16.5 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.
- 16.6 Records of all stocks received their source, batch number, expiry date and quantity received shall be maintained.
- 16.7 All records will be retained for a minimum of five years for narcotic drugs and two years for other drugs.
- 16.8 All records should be available for inspection by the pharmaceutical inspectorate at all reasonable times
- 16.9 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.