



**PHARMACY, MEDICINES & POISONS BOARD**

# **GUIDELINES FOR DISPENSING PREMISES**

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## **1. INTRODUCTION**

The last step in the process of maintaining high quality medicines to patients requires rational prescribing practices, good dispensing procedures and patient adherence. These guidelines provide guidance on preserving and monitoring the quality of medicines to the dispensers. It identifies specific actions they can take to ensure that the appropriate medicines of good quality are properly dispensed and used. Inappropriate dispensing practices can jeopardize the quality of patient care and negatively affect treatment. In this guideline, dispensing premises refers to hospitals and clinics.

## **2. Role and responsibilities of dispensers**

Dispensing is often considered to be simple and routine with little room to error. However the significant investment made in ensuring product quality up to the point of dispensing may be lost if the correct medicine in the right form is not delivered to the right patient ,in the prescribed dosage and quality, with clear instructions and in an appropriate package that preserves the quality of the medicines. The traditional role and responsibility of a dispenser focuses on six major activities:

1. Maintain a proper dispensing environment
2. Receiving and checking medicine/supply orders
3. Receiving, confirming and understanding prescriptions
4. Preparing medications for dispensing
5. Recording the actions taken
6. Issuing medications to clients with clear instructions and advice

## **3. Dispensing Premises**

In this guide, dispensing premises refer to the following:

### **A. Hospitals:**

Private hospitals

Public hospitals (Government and CHAM)

**B. Clinics:**

Admission clinic

Non admission

Maternity clinic

**3.1 Minimum Requirements for hospitals:**

**3.1.1 Submission**

1. Premise license from Medical Council of Malawi
2. Practicing license of the applicable medical personnel for the premises from medical council (Doctor/Clinical Officer for hospitals)
3. PMPB filled application form no. PMPB/Ins/Form/05
4. Details of qualified pharmacy personnel
5. Proof of payment for registration from PMPB

**3.1.2 Pharmacy premises**

1. Premises shall be constructed and maintained so as to be protected against weather, ground seepage and the entrance and harboring of vermin, pest and pets.
2. Premises should be maintained in a good state of repair. The condition of the buildings should be reviewed regularly and repairs effected where necessary. Special care should be exercised to ensure that buildings and repair or maintenance operations do not hazard products.
3. Premises should provide sufficient space to suit the operations to be carried out, allow an efficient flow of work and permit effective communication and supervision.
4. Toilet should be well ventilated and should not open directly to storage areas.
5. Floor should be made of impervious materials, laid to an open surface and should be free from cracks and open joints. If not carpeted floors should have tiles to facilitate easy cleaning. Walls should be sound and finished with a smooth, impervious and washable surface. Ceilings should be so constructed and finished that they can be maintained in a clean condition.

6. Buildings should be effectively lit and properly ventilated with air control facilities
7. All premises including stores, passage ways and external surroundings should be maintained in a clean and tidy condition
8. Premises in which medicinal products are stored should be made secure with access restricted to authorized personnel
9. Waste material should not be allowed to accumulate but it should be collected in suitable receptacles for removal to collection points outside the building and disposed of at regular and frequent intervals.
10. The dispensary should be separate and independent from other operations and should be locked when the pharmacist is not present. The dispensary should have running water(cold or warm) and adequate working and cleaning benches with Formica tops and adequate shelving
11. **Scheduled cleaning:** dust and dirt can contaminate medicines. Floor, shelving, storage and work surfaces should be cleaned daily
12. **Dispensing equipment:** Having adequate equipment available, such as tablet counters, measuring cylinders, stirring rod, and balances; ensures accuracy when medicines are prepared for dispensing. A pharmacy shall where relevant have other equipment as follows: fridge, a fixed lockable DDA cupboard.
13. **Scheduled equipment cleaning:** dispensing equipment must be cleaned after each use and at the end of the day to avoid possible cross-contamination of medicines.
14. **Staff hygiene:** Dispensing personnel must practice good personal hygiene according to standard operating procedures(SOP) to avoid contamination
15. **Organized workplace:** medicines should be organized logically and be stored in accurately labeled containers to minimize the risk of choosing the wrong medicine. Shelves should be organized according to dosage forms in tablets, capsules, syrups and mixture and arranged in alphabetical order, pharmacologically or by schedules for easy access.
16. **Inventory rotation system:** Use inventory rotation system such as FEFO or FIFO to avoid product loss from expiry and to ensure that medicines are monitored regularly and that quality is maintained at all times.

17. **Proper record maintenance:** Accurate and up –to- date records must be retained for all products issued in compliance with PMPB regulations. For hospital dispensers, a list of available medicines should be updated at each location so that prescribers know which medicines can be used. Follow SOP for inventory. Prescriptions should be kept for a minimum period of two years and should be numbered and filed chronologically. Records of receipts with expiry dates and Lot. No. should be kept for a minimum of two years. Availability of Inspection report register and complaints handling book
18. **Expired drugs book:** All expired drugs should be properly recorded and accounted for.
19. **Reference books:** The following reference books should be kept by a hospital pharmacy: British National Formulary(BNF), Malawi Standard Treatment Guidelines(MSTG), Malawi National Formulary(MNF) and PMP Act NO 15 (1988).
20. **Personnel:** A hospital pharmacy should be under the direct supervision of a full-time registered pharmacy personnel assisted by appropriately trained personnel approved by the Board.
21. **Proper staff scheduling:** work should be scheduled to ensure that there is adequate staff coverage during peak demand hours.
22. **Proper storage conditions:** Products should be stored as much as possible according to the storage conditions recommended by the manufacturer-temperature range, light exposure restrictions, closed containers etc- to maintain product quality.

### **3.1.3 Maintain a proper dispensing environment**

Keeping a clean, organized environment can reduce the chance of making dispensing errors, protecting both the dispenser and the public from hazardous. To maintain the high standards possible during the preparation process, the work setting should exhibit the following characteristics:

1. **Building layout:** The building housing the medicines outlet should be a spacious, permanent structure, with an efficient working area that allows staff to move freely.

### **3.1.4 Receive and check medicine orders**

When medicines arrive at the dispensary, the staff should make sure that the product conforms to what they ordered and that it is in good condition. The product label and packaging information should be visually inspected to verify the product name, dosage form, strength, batch number, lot number, date of manufacture, expiry date, manufacturers name and address. The product quantity should be confirmed as correct. The package should be visually inspected for damage and proper sealing. The product should be visually inspected for discoloration, deterioration and physical degradation. If damage is discovered, the staff should record and report the information to the responsible personnel (purchasing personnel) who will resolve the issue with the supplier. Damaged and defective products should be returned to the supplier as stated in the agreement: If return is not feasible, arrangements should be made for disposal according to disposal guidelines.

### **3.1.5 Requirements in basic dispensing functions**

#### **3.1.5.1 Receiving, confirming and understanding prescriptions**

A prescription should contain the following information:

1. Name of the patient
2. Name of the medicine, its strength and quantity dispensed
3. Directions for use
4. Signature, date and address of the prescriber

A prescription should be checked and endorsed after dispensing.

When a prescription is received, dispensing staff should take the following actions to ensure the patient receives appropriate medication in the correct quantity:

1. Read the prescription to confirm the name of the medicine prescribed and the patients name, age and address.

2. Interpret any abbreviations written by the prescriber and contact the prescriber with questions
3. Confirm that the prescribed dosage is within the acceptable range for the patient(considering the patients age and gender)
4. Calculate and confirm the dosage and quantity of medication and issue the required quantity.
5. Determine whether the potential for drug-drug interactions exist and notify the patient of any questionable possibilities

### **3.1.6 Preparing medicines for dispensing**

Proper medicine preparation practices must be followed when dispensing medicines. Following a regular routine when dispensing helps make sure that medicines are handled correctly and reduces the possibility of medication errors or other mistakes. Develop a written policy and standard operating procedures to provide clear directions to pharmacy staff as to what is expected. The following are the standard practices for preparation of medicines:

1. **Select product storage container:** The container label should be read and the medicine name, dosage strength cross checked against the prescription.
2. **Measure and count products:** counting products to confirm quantity should always be done on a clean, dust free surface. Triangular tablet counters, a sheet of paper ,a knife or pan weighing scales may be used for this purpose .A dispensers hands should never directly contact the product to avoid product contamination. Liquids must be measured in clean well labeled containers with tight fitting covers and should be poured from the stock bottle with the label kept upwards to avoid damaging the label with spilled liquid.
3. **Reseal the storage container:** once the product has been measured or counted the storage container should be closed, because exposure to air gradually diminishes medicine quality. After closing the container, the label should be rechecked for the medicines name and strength.
4. **Pack the product:** A suitable container will provide the quality of the product until a patient uses the medicine. Tablets and capsules should be

packed in clean, dry containers such as bottles or plastic envelopes. Liquid preparations should be dispensed in pharmaceutical bottles to distinguish them from non-pharmaceutical preparations such as food and drinks.

5. **Label the product:** The label should include information about the brand and generic international nonproprietary names, strength, dose, quantity dispensed, frequency and duration of use, dispensing and expiry dates, patient name, supplier name, directions for use, date of dispensing, name of pharmacy/dispensing unit and address and child safety and other warnings.
6. **Double-check the preparation against prescription and storage conditions:** A second dispensing staff member should double-check the preparation against both the prescription and its storage container before releasing it to the patient.
7. **Recording the actions taken:** In order to track inventory records must be maintained of all products dispensed. This allows contact with the patient should a problem with the medication arise. Key information to record include the patients name, age and contact details, name and strength of the medicine dispensed, total amount dispensed, date dispensed and the names of both the prescriber and dispenser
8. **Issuing medicines with clear instructions and advice:** To enable patients to comply with the instructions on the prescription package, they must be clearly written. The container should list what the medicine is used for, what the dosage is, when to take the medicine and for how long, how to take the medicine and how to store and care for the medicine (ie use -by date or end of treatment).The medicine dispenser should always strive to confirm that the patient clearly understands the instructions.

### **3.1.7 Training of Staff**

Medicine dispensing should be performed by a trained and licensed pharmacist. Support dispensing staff should require training that is appropriate for the range and complexity of the medicines they dispense. Individuals other than licensed pharmacist (eg a pharmacy technician)who dispense medicines must have the following knowledge:

1. Common uses, side effects, drug-drug interactions and storage requirements for medicines being dispensed
2. Good calculation skills



3. Ability to assess the quality of preparations
4. Good hygiene
5. Ability to communicate effectively with patients

## **3.2. Minimum Requirements of Clinics**

### **3.2.1 Submission**

1. Premise license from Medical Council of Malawi
2. Practicing license of the applicable medical personnel for the premises from medical council
3. PMPB filled application form No. PMPB/Ins/Form/06
4. Details of a dispenser (Admission clinics and Clinics operated by Doctor – pharmacy personnel)
5. Proof of payment for registration from PMPB

### **3.2.2 Dispensing premises**

1. Premises shall be constructed and maintained so as to be protected against weather, ground seepage and the entrance and harboring of vermin, pest and pets.
2. Premises should be maintained in a good state of repair. The condition of the buildings should be reviewed regularly and repairs effected where necessary. Special care should be exercised to ensure that buildings and repair or maintenance operations do not hazard products.
3. Premises should provide sufficient space to suit the operations to be carried out, allow an efficient flow of work and permit effective communication and supervision.
4. Toilet should be well ventilated and should not open directly to storage areas.
5. Floor should be made of impervious materials, laid to an open surface and should be free from cracks and open joints. If not carpeted floors should have tiles to facilitate easy cleaning. Walls should be sound and finished

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9. Waste material should not be allowed to accumulate but it should be collected in suitable receptacles for removal to collection points outside the building and disposed of at regular and frequent intervals.
10. The dispensary should be separate and independent from other operations and should be locked when nurse/pharmacy personnel is not present. The dispensary should have running water(cold or warm) and adequate working and cleaning benches with Formica tops and adequate shelving
11. **Scheduled cleaning:** dust and dirt can contaminate medicines. Floor, shelving, storage and work surfaces should be cleaned daily
12. **Dispensing equipment:** Having adequate equipment available, such as tablet counters, measuring cylinders, stirring rod, and balances; ensures accuracy when medicines are prepared for dispensing. A pharmacy shall where relevant have other equipment as follows: fridge, a fixed lockable DDA cupboard.
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14. **Staff hygiene:** Dispensing personnel must practice good personal hygiene according to standard operating procedures(SOP) to avoid contamination
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18. **Expired drugs book:** All expired drugs should be properly recorded and accounted for.
19. **Reference books :** The following reference books should be kept by a clinic medicine store: British National Formulary(BNF), Malawi Standard Treatment Guidelines(MSTG), Malawi National Formulary(MNF) and PMP Act NO 15 (1988).
20. **Personnel:** A clinic drug store should be under direct supervision of a full-time pharmacy personnel/nurse approved by the Board.
21. **Proper staff scheduling:** work should be scheduled to ensure that there is adequate staff coverage during peak demand hours.
22. **Proper storage conditions:** Products should be stored as much as possible according to the storage conditions recommended by the manufacturer-temperature range, light exposure restrictions, closed containers etc- to maintain product quality.

### **3.2.3 Maintain a proper dispensing environment**

Keeping a clean, organized environment can reduce the chance of making dispensing errors, protecting both the dispenser and the public from hazardous. To maintain the high standards possible during the preparation process, the work setting should exhibit the following characteristics:

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gradually diminishes medicine quality. After closing the container, the label should be rechecked for the medicines name and strength.

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### **3.2.7 Training of Staff**

Medicine dispensing should be performed by trained pharmacy personnel. The dispenser participates in training that is appropriate for the range and complexity of the medicines they dispense. Individuals who dispense medicines must have the following knowledge:

1. Common uses, side effects, drug-drug interactions and storage requirements for medicines being dispensed
2. Good calculation skills
3. Ability to assess the quality of preparations
4. Good hygiene
5. Ability to communicate effectively with patients

## **Definitions**

**Dispensing premises:** these are referred to hospitals and clinics that are involved in dispensing of medicines to clients under trained personnel

## **References:**

1. **Good pharmacy practice in developing countries from international pharmaceutical federation**
2. **Management Sciences for health,**
3. **Ensuring the quality of medicines in resource limited countries, WHO**
4. **PMPB Regulations**