



**PHARMACY, MEDICINES & POISONS BOARD**

**MINIMUM  
REQUIREMENTS FOR A  
RETAIL PHARMACY  
BUSINESS**

Draft September 2015

## **1. SUBMISSION**

1. A completed retail pharmacy application form (PMPB/INS-FORM/ 03)
2. A copy of registration certificate of the pharmacist from PMPB
3. A valid practicing certificate of the pharmacist from PMPB or evidence of retention on the register of pharmacists
4. A declaration letter for continuous personal supervision of the premises from the pharmacist;
5. A sketch/plan of the premises;
6. A copy of certificate of business registration from the Registrar of businesses
7. A copy of payment receipt from PMPB

## **2. PREMISES**

1. The premises of a retail pharmacy shall be used exclusively for pharmaceutical services
2. The premises shall be well built, dry, well lit, air conditioned and of sufficient dimensions to allow the goods in stock, especially medicines to be kept in a logical appropriate manner.
3. Minimum area for retail pharmacy should be 20 square meters. The area of the section to be used as dispensary shall not be less than 6 square meters.
4. The floor of the pharmacy should be free from cracks and made of impervious material for easy cleaning.
5. The walls shall be plastered and painted with washable paint or tiled so as to maintain smooth and washable surfaces devoid of holes, cracks and crevices.
6. A suitable door shall separate the dispensing area from the other areas. The door shall be lockable to render the dispensary inaccessible in the absence of a pharmacist.
7. The dispensary shelves should be designed such that they discourage members of the public from reading the labels of prescription drugs.
8. A sink with adequate supply running water shall be provided within the dispensing area for washing hands, apparatus, etc. (some detergent and a means of drying hands, except cloths, should be provided)
9. A pharmacist shall be provided with an office. Its dimensions shall be at least four square meters and be able to accommodate two chairs and a table. It should be made of solid material and adjacent to the dispensing area
10. Well ventilated toilets shall be provided and shall not open directly to the pharmacy.
11. A min/max thermometer should be in the dispensary and anywhere where medicines are stored.

### **3. PERSONNEL**

1. The pharmacy shall be operated under the supervision of a full time registered practicing pharmacist.
2. A training plan for the staff should be in place and be implemented

### **4. FURNITURE AND APPARATUS**

1. The furniture and apparatus of a pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment.
2. A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with smooth washable and impervious material like stainless steel, laminated material, plastic, melamine, Formica etc.
3. A pharmacy shall be provided with a lockable steel cabinet fixed on the wall or floor for the dangerous drugs. The pharmacist shall be responsible for the key or lock combination and the register for these medicines shall be kept.
4. A pharmacy shall be provided with the following minimum apparatus and equipment.
  - i. A suitable number of tablets and capsules counters and spatulas to minimise contamination of medicines when dispensing
  - ii. A refrigerator unit capable of storing products within a selected temperature range e.g. 2-8°C. The efficiency of this refrigerator should be daily checked with a Min /Max thermometer and a record book of such in place.
  - iii. A suitable range of labels that shall bear the details of the pharmacy, batch number and the expiry date

### **5. REFERENCE MATERIAL**

A pharmacy should have access to the following minimum reference books:

1. The latest edition of Martindale (The Extra Pharmacopoeia) up to 4 years old;
2. The latest addition of Malawi Standard Treatment Guidelines
3. Copies of PMPB Act and Regulations
4. List of registered medicines in Malawi

### **6. SECURITY AND FIRE PROTECTION**

The pharmacy shall be equipped with an effective and appropriate security system and a suitable fire protection system which shall be regularly serviced.

## **7. PERATION REQUIREMENTS FOR RETAIL PHARMACY PRACTICE**

(After having been granted approval to start the business)

1. Original copies of the license of the premises and approval shall be displayed at all times in the premises.
2. The original registration and practicing certificates for the full time pharmacist shall be displayed at all times in the dispensary.
3. The name of the pharmacist in-charge shall be printed on a name plaque and shall be displayed conspicuously in the pharmacy at the dispensary on a place where it could be easily seen.
4. The pharmacy shall be operated under the continuous personal supervision of the pharmacist-in-charge. When it is compulsory that the pharmacist be absent from the pharmacy e.g. when sick then the following options may be adopted:
  - i. The services of a duly registered locum pharmacist may be engaged
  - ii. The pharmacy shall be closed until the services of a full time registered pharmacist are obtained.
5. PMPB should be informed immediately in writing of any change, engagement of locum pharmacist, resignation or dismissal of the pharmacist-in-charge or additional employment of other pharmacists in the pharmacy.
6. Good personal hygiene instructions and procedures shall be written and displayed in the pharmacy.
7. The Pharmacist should wear formal clothes and a white coat over his/her clothes and a badge.
8. All other staff should be provided with uniform
9. Smoking, eating and chewing should not be allowed in the Pharmacy.
10. "No Smoking", and "No Eating" signs shall be conspicuously displayed in the pharmacy.
11. The pharmacist shall engage in a suitable continuous education programme offered by any recognized institution. Records of such training shall be kept.
12. Cleaning procedures and schedules for cleaning of floors, shelves, toilets should be drawn up and displayed.
13. Drugs shall be segregated from all other materials.

14. A refrigerator for storage of thermo-labile materials shall be installed in the pharmacy, and shall not be used for foodstuff. A Min/ Max daily record shall be kept
15. All controlled drugs shall be kept under lock and key and all registers and records of ordering and dispensing of these shall be maintained and be made available for inspection.
16. A prescription record book or electronic records shall be kept for all prescription drugs. Copies of prescriptions and invoices/receipts shall be kept in the pharmacy for a minimum period of 2 years.
17. There shall be a written and displayed procedure for handling expired medicines. Records of expired medicines shall be kept for a period of 2 years
18. All expired drugs shall be segregated from other stocks and kept in a place labeled "Expired Medicines". The labels shall be printed on laminated or better material.
19. All different sections of the pharmacy shall be clearly labelled using laminated paper or better material.
20. Prescriptions should be dispensed in suitable containers that have been appropriately labelled
21. Only registered medicines shall be kept in the pharmacy.  
**NOTE:** No medicines shall be sold to any person below the age of sixteen
22. When the operation of a pharmacy is changed, the name and license change should be effected as soon as possible through application to PMPB