

PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

MINIMUM REQUIREMENTS FOR MEDICINE STORE

A. SUBMISSION REQUIREMENTS FOR A MEDICINE STORE

- 1. A completed, filled, signed and stamped application form for registration of premises
- 2. Premises layout and sketch
- 3. A copy of taxpayer identification number issued by MRA
- 4. Copy of certificate of registration of the pharmacy personnel with PMRA.
- 5. PMRA copy of valid practicing certificate of the pharmacy personnel (Pharmacist, Pharmacy technician or Pharmacy assistant)
- 6. Signed contract or commitment letter from the full time pharmacy personnel
- 7. A copy of business registration from Registrar of businesses
- 8. A copy of payment receipt from PMRA

B. PREMISES

- 1.1 The premises should be constructed and maintained so as to protect the medicines from weather, ground seepage and the entrance and harboring of vermin and pests.
- 1.2 The 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 the building; repair or maintenance operations do not hazard the products.
- 1.3 The premises should provide sufficient to suit the operations to be carried out, allow efficient flow of work and permit effective communication and supervision.
- 1.4 Floors and walls should be free from cracks and made of impervious

- materials for easy cleaning.
- 1.5 The building should be effectively lit and properly ventilated.
- 1.6 The building should be adequately secure with no access to unauthorized persons.
- 1.7 Space adequate to allow easy communication and supervision of operations, Note: Size not less than 15 square Meters with one side not less than 3 m and height about 2.5m.
- 1.8 Toilets should be well ventilated and should not open directly to the medicine store.
- 1.9 The store should have adequate shelving for medicines.
- 1.10 Medicines and other supplies should be arranged on shelves in an orderly manner.
- 1.11 The store should be provided with temperature control mechanisms like fans and or air conditioners.
- 1.12 Storeroom should be provided with firefighting equipment (fire extinguisher, steel bucket of sand).
- 1.13 Expired medicines should not be on the shelves.
- 1.14 No unregistered medicines should be kept in stock or dispensed.

C. Records

- 2.1 Records of sources of medicinal products, receipt of goods should be available on file.
- 2.2 Records of stock movement and balances available for each medicinal product e.g. tally cards or bin cards

D. Human Resources

3.1 A medicine store should be managed and supervised by a full time registered pharmacy personnel or a veterinary professional if it is for animals.

- 3.3 Other suitably qualified staff may also be employed to assist the supervisor.
- 3.4 Security watchmen should be deployed.

E. Equipment and reference books

- 4.1 Measuring cylinders for dispensing reconstituted powders must be made available.
- 4.2 Refrigerators in good working conditions (for medicines needing refrigeration) must be provided.
- 4.3 Medicines counting trays for tablets and capsules must be provided.
- 4.4 Dispensing packs/pill bags or containers must be available.
- 4.5 A disposal of waste should be provided.
- 4.6 Current editions of publications must be made available-
 - British National Formulary.
 - Malawi Standard Treatment Guidelines.
 - PMRA Act and PMRA Regulations