



MINIMUM REQUIREMENTS FOR PRESCRIPTION WHOLESALE PHARMCY

A. DOCUMENTS TO BE SUBMITTED

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 (Pharmacist, Pharmacy technician, Pharmacy assistant) with PMRA.
5. PMRA copy of valid practicing certificate of the pharmacy personnel
6. Signed contract or commitment letter from the full time personnel
7. A copy of business registration from Registrar of businesses
8. A copy of payment receipt from PMRA
9. A copy of payment receipt from PMRA

B. PREMISES

1. The premises should be constructed and maintained so as to protect the medicines from weather, ground seepage and the entrance and harbouring of vermin and pests.
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.
3. The premises should provide sufficient space to suit the operations to be carried out, allow efficient flow of work and permit effective communication and supervision.
4. Floors and walls should be free from cracks and made of impervious materials for easy cleaning.
5. The building should be effectively lit and properly ventilated.
6. The building should be adequately secure with no access to unauthorized persons.

7. Minimum total floor space of 60 square meters with one side not less than 5 meters and minimum height of 2.5 meters from floor to the ceiling
8. Minimum continuous floor space of 30 square meters for the sales and administrative area. Within the 30 square meters, there shall be a pharmacist office or administrative office with a full view of the sales area for the responsible pharmacist and records shall be maintained in this office or area.
9. Toilets should be well ventilated and should not open directly to the wholesale pharmacy.
10. The store should have adequate shelving for medicines.
11. Medicines and other supplies should be arranged on shelves in an orderly manner off the floor.
12. The store should be provided with temperature control mechanisms like fans and or air conditioners.
13. Storeroom should be provided with fire fighting equipment (fire extinguisher, steel bucket of sand).
14. Segregated storage should be provided for rejected, expired and unusable returns.
15. No unregistered medicines should be kept in stock or sold.
16. Van selling should be restricted to items on general sales list

C. EQUIPMENT AND REFERENCE BOOKS

1. Pallets and elevators where necessary, can be provided for easy storage of bulky medical supplies.
2. Current editions of publications must be made available-
 - 2.1 British National Formulary.
 - 2.2 Malawi Standard Treatment Guidelines.
 - 2.3 PMRA Act No. 9 of 2019.
 - 2.4 PMRA Regulations
 - 2.5 Good Distribution Practise guidelines

D. RECORDS

1. Records of sources of allied substances, receipt of goods should be available on file
2. Records of stock movement and balances available for each allied substances e.g. tally cards or bin cards

E. HUMAN RESOURCES

1. Prescription wholesale pharmacy operations shall be carried out under the direct full time supervisor of a pharmacist who shall be responsible for the funding, procurement, clearing, receipting, storage, distribution and documentation relating to medicinal products.
2. The services of a locum pharmacist may be used for a period not exceeding 3 months and upon approval granted by the Authority

F. STORAGE AND SECURITY

The storage areas for pharmaceutical products and allied substances shall be well covered and off the floor in an area:

- a) that are secured and with adequate space
- b) that is laid out to allow clear separation of different materials and products to minimize risks of mix up
- c) with access to materials and goods restricted to authorised personnel
- d) that temperature sensitive products shall be kept in a temperature controlled facility
- e) with separate areas for recalled, expired or rejected and shall be kept under lock and key.
- f) with special and segregated areas for storage of flammable and explosive substances, highly toxic substances.
- g) with space for storage of cleaning materials
- h) Burglar bars installed