



MINIMUM REQUIREMENTS FOR DISPENSING FACILITIES

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. A copy of business registration from registrar of businesses
5. A copy of valid premises certificate for clinic or hospital issued by the Medical Council or Nurse's Council
6. A valid registration and practicing licence of the full time practitioner issued by Medical Council and Nurse's
7. Valid registration certificate with PMRA in the case of a pharmacy personnel
8. A letter from medical or nurse's council authorizing the applicant to operate a clinic.
9. A copy of payment receipt from PMRA

B. PREMISES:

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
2. 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.
3. 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.
4. 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.
5. Toilet should be well ventilated and should not open directly to storage areas.

6. 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.
7. Walls should be sound and finished with a smooth, impervious and washable surface.
8. Ceilings should be so constructed and finished that they can be maintained in a clean condition.
9. Buildings should be effectively lit and properly ventilated with air control facilities
10. Temperature control mechanism should be provided at the medicine storage area.
11. All premises including stores, passage ways and external surroundings should be maintained in a clean and tidy condition
12. Premises in which medicinal products are stored should be made secure with access restricted to authorized personnel
13. 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 off at regular and frequent intervals.
14. The dispensary should be separate and independent from other operations and should be locked when the 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
15. The dispensary and consultation room should be elevated overlooking pharmacy and medicine counter.
16. **Scheduled cleaning:** dust and dirt can contaminate medicines. Floor, shelving, storage and work surfaces should be cleaned daily
17. **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: ridge, a fixed lockable DDA cupboard.
18. **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.

19. **Staff hygiene:** Dispensing personnel must practice good personal hygiene according to standard operating procedures(SOP) to avoid contamination
20. **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.
21. **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.
22. **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. Patient profile cards should be kept where possible. 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
23. **Expired drugs book:** All expired drugs should be properly recorded and accounted for.
24. **Proper staff scheduling:** work should be scheduled to ensure that there is adequate staff coverage during peak demand hours.
25. **Personnel:** A clinic drug store and dispensary should be under direct supervision of a full-time pharmacy personnel/nurse approved by the Authority.
26. **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.
27. **Reference books:** The following reference books should be available British National Formulary(BNF), Malawi Standard Treatment Guidelines(MSTG), and Malawi National Formulary(MNF)