

PHARMACY COUNCIL



PROCEDURES FOR APPROVING LOCATION OF NEW PHARMACY PREMISES AS APPROVED ON THE 41ST COUNCIL MEETING

(Made under Section 34 (3-C) of the Pharmacy Act, Cap 311)

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INTRODUCTION

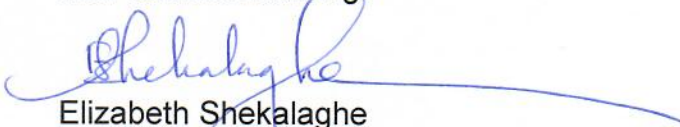
The Pharmacy Council is committed to its mission to ensure high quality pharmacy practice and services that will be continuously available, accessible, affordable and transparent to all, through providing opportunities for training, guaranteed law enforcement and regulation of professional conduct and Code of Ethics.

Approval of location of premises for dealing in pharmaceutical businesses is a prerequisite requirement, which ensures quality pharmacy practice prior to commencing of such businesses. This requirement is stipulated under Section 34 (3-c) of the Pharmacy Act, Cap 311. The legislation also prohibits the use of any premises for dispense, sale, sell, supply or storage of pharmaceuticals unless the premises has been registered by the Pharmacy Council for that purpose. Furthermore to this, Section 36 of the Act requires all dealers in such business to apply to the Council for permits and obtain such permits before starting operation.

Approval of location of premises and licensing of pharmaceutical businesses shall not be considered as the sole means of controlling operations of these premises. However, there are other valuable means of aid in enforcing relevant legislation, such as adherence to good pharmacy practices that ensure day-to-day operations of these premises are in line with the laws and regulations.

This order has stipulated criteria for approval of location for establishment of pharmacies based on the facts such as distance, population and other situations. The requirements intend to ensure even distribution of pharmacies, to limit the number of pharmacies in metropolitan areas and hence improve access of quality pharmaceutical services especially to underserved areas.

These orders shall also serve as a tool of reference by inspectors to create uniformity in their decision-making.


Elizabeth Shekalaghe
REGISTRAR

1. CRITERIA FOR APPROVAL OF LOCATION

During inspection of a location, Inspectors shall use several criteria to approve the location. The Criteria are:

1.1. DISTANCE BETWEEN PREMISES

- 1.1.1. Approval of location for retail pharmacy shall be granted if it is at least 150 meters radius away from existing retail pharmacies.

1.2. POPULATION OF THE AREA

- 1.2.1. The Council may on good cause approve location for establishment of premises for retail business in areas where there is high population and places that are highly visited such as market places and bus stands.
- 1.2.2. In such conditions in (1.2.1) above, the distance between the retail pharmacies shall not be less than 100 meters from existing retail pharmacies.
- 1.2.3. For wholesale business and warehouses, distance between existing wholesale and retail pharmacies shall not apply.

1.3. DISTANCE BETWEEN DRUG PREMISES AND PUBLIC HEALTH FACILITIES

- 1.3.1. Approval to establish a pharmacy in any case shall not be granted in areas near Public Health Facilities (Tertiary Health Facilities, Secondary Health Facilities and Primary Health Facilities) and shall comply with the following:
- 1.3.2. The premises near Tertiary Health Facilities (Zonal Referral and National Hospitals) must be located not less than 500 meters from the facility boundary in radius.
- 1.3.3. The Premises near Secondary Health Facilities, that is Regional Referral Hospitals and District Hospitals must be located not less than 400 meters and 300 meters respectively from the facility boundary in either side
- 1.3.4. The premises near the Primary Health Facilities that is Health Centres and Dispensaries must be located not less than 200 meters from the facility boundary in either side.

1.4. PRIVATE HEALTH FACILITY

- 1.4.1. Approval for establishment of stand-alone pharmacy owned by a health facility outside their premises shall be granted without consideration of distance criterion from other existing retail pharmacies and vice-versa

1.5. UNSUITABLE LOCATION

- 1.5.1. The premises shall be located 100 meters away from sites or activities which emit obnoxious materials and wastes like fuel fumes, contaminants, noises, open sewage or any other places as the council may deem unfit for the business of a pharmacist to be carried out.
- 1.5.2. The premises should be 50 meters away from stand alone medical laboratories where the business is housed

1.6. UPGRADING OF ACCREDITED DRUGS DISPENSING OUTLETS (ADDOS)

- 1.6.1. Approval of upgrading premises that were valid registered shops such as Duka la Dawa Baridi (DLDB) or Accredited Drug Dispensing Outlets (ADDO); upgrading such outlets to pharmacy, the distance criterion shall not apply.

1.7. PREMISES THAT WAS PREVIOUSLY REGISTERED AS PHARMACY

- 1.7.1. In event where the premises was previously registered as a pharmacy of which the owner eventually surrendered the pharmacy business, the approval shall not consider distance from nearby existing pharmacies provided that no other new application of pharmacy has been granted on that locality.

1.8. PRESENCE OF TWO OR MORE TARMAC ROADS

- 1.8.1. In event where the existing retail pharmacy is separated from new application by a double tarmac road, the new application will be granted regardless of the distance across the double roads.

1.9. FORCE MAJEURE OR NATURAL CALAMITIES

- 1.9.1. In the event of change of registered premise with the same locality due to force majeure, that is, building demolition due to Government Development plans, natural calamities fire and others, such application will be granted to reallocate the premises within the same locality without consideration of distance issues from other applications or registered premises.

1.10. BUILDING COMPLEXES

- 1.10.1. Application within shopping centres such as malls, supermarkets and building complexes, shall be confined within those premises and distance criteria from one application or pharmacy to another on the different floor and from outside existing pharmacies shall not apply.

1.11. VALIDITY OF APPLICATION

- 1.11.1. Approval granted by the Council shall be valid for six(6) months from the date of first inspection. The Council reserves the rights to consider other applicants for the same area after a period of six months has elapsed since approval.
- 1.11.2. Approval of an application does not constitute authorisation to commence business until all conditions and requirements for the issuance of registration and business permit are fulfilled.

1.12. POWER TO APPROVE LOCATION

- 1.12.1. The Registrar may approve an application regardless of distance criteria; the approval may be specified for a certain period of time.

1.13. FINANCIAL COMMITMENT

- 1.13.1. The Council shall not be under any obligation to approve an application because of financial commitments or any commitments made prior by an applicant before approval.