



Pharmacy Regulatory Division

GUIDELINES FOR COMMUNITY PHARMACY PRACTICE

NATIONAL MEDICINE REGULATORY AUTHORITY

No.120, Norris Canal Rd, Colombo 01000, Sri Lanka



Pharmacy Regulatory
Division

Effective Date: 15/02/2022

Issue No: GL 033

Issue Date: 07/02/2022

Revision No: 01

Revision Date: 9/12/2021

	TITLE	SIGNATURE	DATE
Prepared by			
Reviewed by			
Authorized by			



Pharmacy Regulatory
Division

Effective Date:	15/02/2022
Issue No:	GL 033
Issue Date:	07/02/2022
Revision No:	01
Revision Date:	9/12/2021

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GL-033-Guide Lines for Community Pharmacy Practice.

Version and Revision Number/ Code: V 1.0/ Rev No: 01



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1. Introduction

These guidelines serve as a set of standards that needs to be complied with setting up a community pharmacy, auditing and complementing the licensing requirement.

2. Purpose

Purpose of these guidelines is to ensure the quality of the community-pharmacy practice for the benefit of consumers/patients. For the purpose of these guidelines, community pharmacy is defined as premises holding a license issued by the National Medicines Regulatory Authority (NMRA) of Sri Lanka for the sale of medicines by retail.

3. Scope

The objective of the standards included in these guidelines is to create and maintain a suitable environment for the safe and effective practice of pharmacy.

These guidelines provide minimum standards and requirements for the establishment of new pharmacies and should be fulfilled by all new pharmacies. The existing pharmacies are also expected to comply with these minimum standards and requirements during renewal of the license issued by the NMRA.

4. Premises

4.1 Location

The premises should be located in a hygienic environment, and required to comply with the Local Authority laws. Pharmacy services must be provided in an environment that is appropriate for the provision of healthcare.

4.2 Criteria to establish a new pharmacy

4.2.1 Community (standalone) pharmacies:

First Criteria

Distance:

- Urban: The minimum distance from the nearest pharmacy in the shortest legal travel route should not be less than 250 meters.

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- **Non-Urban:** The minimum distance from the nearest pharmacy in the shortest legal travel route should not be less than 750 meters.

Already established pharmacy on criteria 4.2.3 will be exempted from considering distance to proposed community pharmacy location.

If the above criteria are not met, the second criteria can be considered, where applicable.

Second Criteria

Number of pharmacies permitted to be available within 01 kilometer radius of a government hospital, based on hospital category published by Ministry of Health:

Category of the Hospital	Number of pharmacies permitted
National Hospitals	06
Teaching Hospitals	06
Provincial General Hospitals	05
District General Hospitals	04
Base Hospitals – Type A	04
Base Hospitals – Type B	03
Divisional Hospitals – Type A	02
Divisional Hospitals – Type B	02
Divisional Hospitals – Type C	01
Primary Medical Care Units	01

4.2.2 Hospital pharmacies and pharmacies inside channeling centers.

First Criteria

Distance:

- **Urban:** The minimum distance from the nearest pharmacy in the shortest legal travel route should not be less than 250 meters.



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- **Non-Urban:** The minimum distance from the nearest pharmacy in the shortest legal travel route should not be less than 750 meters.

If the above criteria are not met, the second criteria can be considered, where applicable.

Second Criteria

Number of prescriptions generated should not be less than 500 per day.

4.2.3 Pharmacies inside supermarkets:

First Criteria

Distance:

- **Urban:** The minimum distance from the nearest pharmacy in the shortest legal travel route should not be less than 250 meters.
- **Non-Urban:** The minimum distance from the nearest pharmacy in the shortest legal travel route should not be less than 750 meters.

If the above criteria are not met, the second criteria can be considered, where applicable.

Second Criteria

- Minimum gross leasable floor area of at least 12000 sq.ft is necessary to establish a pharmacy and
- Only one pharmacy is allowed to establish in a shopping complex/mall and
- Two supermarkets belong to the same chain are not allowed to establish two separate pharmacies within 1 Km distance.



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4.3 Pharmacy Area

- i. Should be at least 180 sq ft. (This area would be varied with the designated additional services provided). All pharmacies are expected to fulfill this criterion.
- ii. Should display the following in a conspicuous place of the of the pharmacy
 - a) The license issued by the NMRA and \
 - b) A photograph and the certificate of registration as a pharmacist issued by the Sri Lanka Medical Council (SLMC) of the Responsible Pharmacist and
 - c) A photograph of the on-duty pharmacist (Certificate of registration of the on-duty pharmacist should be made available for the inspection).
- iii. Should consists of:
 - a. A waiting area - minimum of 60 sq. ft with seating facilities for at least 3 people (not applicable for supermarkets) and
 - b. A Separate lockable area minimum 60 sq. ft for storage and dispensing of Schedule II and III medicines. This area should be kept closed when there is no pharmacist on duty. All pharmacies are expected to comply with this requirement since 2018 and
 - c. Separate area for Schedule I medicines and other medical supplies and
- iv. Other merchandise should be stored away from the medical supplies and
- v. Items available for sale should not interfere with the maintenance of hygienic environment of the pharmacy.
- vi. A pharmacy within a facility/supermarket/shopping complex/ business center/ multistory building should be at least 75 ft away from the storage areas of meat, fish, or any other animal based or targeted products, etc. So that exposure of such items would not affect the hygienic environment of the pharmacy.
- vii. Medicine Dispensing Area/ Prescription Counter



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- Medicines should be displayed in a neat and tidy manner projecting a professional image and
- Size and organization of this area should be adequate for the volume of work and
- Should enable safe and efficient workflow and
- Pharmacist should be able to maintain direct supervision of the pharmacy and the staff from this area and
- Should preferably without any barrier for effective communication with the patient, but should facilitate confidentiality where necessary. A separate window /counter should be provided for this purpose.

viii. A separate counseling area (Optional)

A minimum of 40 sq ft for counseling, which is properly designed for maintenance of confidentiality and comfortability. If it is a room, the door should be made of half glass.

4.4 Relocating a pharmacy

Moving an existing pharmacy to a new location will be considered as “relocating”. The distance from the existing pharmacy to the new location should be within a radius of 2 Km in the urban areas and 3 Km in the non-urban areas. The distance to the new location should not be less than 50 meters away from the existing pharmacy. Relocating of a pharmacy is allowed only after 3 years from the date of registration unless special permission from the NMRA is granted (such as in natural disasters, destruction of existing buildings under government policies, etc.).

4.5 Signboard & Advertisements

Pharmacy signboard must project the professional image of a pharmacy. The logo permitted by the NMRA should be displayed for easy identification. Neither medicinal nor other advertisements are permitted on any pharmacy signboard. This applies to signboards of both existing and new pharmacy businesses. Any posters or product advertisements displayed to public must be in accordance with the relevant regulations/guidelines of NMRA.

“No Smoking” sign must be displayed prominently to promote healthy lifestyle.

4.6 Infrastructure requirements - General

- a) Accessibility for wheelchairs
- b) Access to washing and toilet facilities
- c) Adequate lighting to reduce risk of medication errors
- d) Acceptable noise level -soft background music is allowable
- e) Medicine storage areas should be air-conditioned and regular maintenance of air-conditioner(s) is needed to ensure the stability maintenance of medicines and the comfort of staff and customers.

4.7 Facilities

(a) Refrigerator (preferably a medical refrigerator)

- Should be maintained at temperature between 2 – 8°C.
- Daily temperature reading must be recorded and certified.
- Temperature records must be properly maintained and available for inspection
- Appropriate action should be taken to rectify any problems identified
- The refrigerator used for the storage of medicines should not be used to store have any food or drink

(b) Medicines Preparation Area

- A separate washbasin with water supply should be available.

(c) Dry Compounding Area

- A designated area with a minimum area of 12 sq ft for counting tablets/capsules, filling and packing of medicines and for labeling the prepared medicines
- Should be away from food and drink
- Should provide suitable and hygienic means for counting tablets/capsules (e.g. counting tray)

(d) Wet Compounding Area

(For the purpose of extemporaneous preparations only)

- A designated area with sink and water supply
- Minimum of 30 sq ft floor area
- Should be away from food and drink

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- All working surfaces and shelves should have a smooth impervious surface and washable material finishing.
- Wet compounding area must be equipped with the following:
 - i. Weighing scale - regular calibration by a relevant authority/organization is required to ensure reliability and efficiency
 - ii. Mortar and pestle - must be maintained in good condition.
 - iii. Tile/glass slabs with spatula - must be maintained in good condition.
 - iv. Measuring appliances - must be maintained in good condition.
 - v. Other required equipment depending on the types of preparation

(e) Health Screening Area (optional)

- Should be equipped with appropriate equipment and devices appropriate for the services offered.
- Equipment and devices should be regularly calibrated and in reliable condition at all times.

(f) Storage and Disposal of Expired Medicines etc.

- Should adhere to NMRA regulations
- A segregated area or separate cupboard should be provided to store products which are expired, recalled, damaged or spoilt. These areas and cupboards should be kept under lock and key. A signboard or a notice should be provided indicating “Expired products, not for sale”.

The Responsible Pharmacists should take appropriate action to dispose expired medicines according to NMRA regulations.

***The annexure 1 give the typical layout plan of the pharmacy with required designated areas.**

4.8 Equipment

- (i) **Computerized system (where available) for managing store and retail inventory**
- (ii) **Refrigerator**

(iii) Temperature monitoring system

Temperature should be monitored and recorded at regular intervals. Monitoring system must indicate the temperature of the inside pharmacy and the refrigerator.

Furthermore, relative humidity should be monitored and recorded.

(iv) Printer (Optional)

- For the production of labels, leaflets or any printed materials

(v) Cabinets

- Adequate number of cabinets should be available for the storage of documents / records
- These should be kept clean and dust free

(vi) Labels

- Should be of appropriate sizes and shapes
- Preferably printed to prevent/ minimize errors due to illegible handwriting
- NMRA regulations should be followed for labeling of medicines

(vii) Other Requirements

- Pantry area for staff (optional)
- Adequate toilet facilities, should be clean and in good condition
- Arrangement must be made for the regular collection and safe disposal of pharmaceutical waste and other refuse.

4.9 Safety and Quality Improvement Activities

- Secure locks on main door and grille/gate.
- Secure locks on back doors and grille/gate if applicable.
- Entrance should be prohibited to the lockable area during non-working hours.
- Electronically controlled locks may be utilized.
- Additional safety control such as video cameras and alarm system are advisable.
- Policy for appropriate security should be arranged.
- To comply with relevant statutory requirements

4.10 Cleanliness

- There should be appropriate pest control measures in place
- Daily cleaning to maintain the pharmacy in a tidy and clean state
- Written cleaning procedures and schedules should be set out and made available.

4.11 Occupational and safety requirements:

The premises should be safe for the public and staff working in the pharmacy. Must comply with all statutory requirements where appropriate:

- Appropriate fire escape route
- Fire alarm
- Fire extinguisher
- Safety ladder

5. Practice

5.1 Services

5.1.1 Essential Services and Value Added Services

Essential Services

- Screening of prescription(s)
- Dispensing of medicines
- Compounding of medicines (patient specific)
- Counseling and advisory
- Pharmacy management in drug procurement
- Proper documentation

Value Added Services

- Tele pharmacy and home delivery
- Health Screening
- Health promotional activities

5.1.1.1 Extemporaneous Dispensing

- Ensure that the formula and intended method of preparation is correct.
- Required facilities and equipment for the preparation are available and maintained in good order.
- Ingredients must be sourced from reliable pharmaceutical supplier and be of a quality accepted for use in the preparation of the extemporaneous products.
- All calculations, ingredients and quantities should be checked by a second person who is a pharmacist.
- Pharmacists must pay particular attention to substances that may be hazardous and require special handling techniques.
- The product must be suitably labeled with the necessary information, including special requirements for the safe handling and storage of the product including an expiry date.
- All preparations should be documented and records should be maintained for at least 2 years. The records must include the formula, the ingredients and the quantities used, their source, batch number, expiry date, date of preparation and personnel involved in the preparation.
- All documentations should be certified and duly stamped by a registered pharmacist with his/her registration number indicated

5.1.1.2 Health Screening (optional)

- All staff involved in providing the above service should be trained in the use of the monitoring devices and the procedures. They should also be aware of the limits of the tests provided.
- The pharmacy must have a suitable area with facilities to perform the tests and provide counseling.
- Ensure that the devices used are in good order.
- Keep up to date with the latest development and know when to refer patients to medical practitioners.
- Before conducting the test, procedure should be explained to the patient.
- Communicating test results to the patient in a manner in which he/she can understand and providing appropriate counseling is needed.

5.1.1.3 Health Promotion

- Health promotion is the process of enabling people to have increased control over, and to improve their health. Community pharmacists can play a very important role in promoting, maintaining and improving the health of communities that they serve

5.1.2 Awareness of original and counterfeit drugs, OTC and herbal supplements

- Pharmacist should only buy medicines from legitimate sources
- Pharmacies may use suitable device such as “Meditag reader” in order to ascertain if a product is genuine and registered with the NMRA.
- Pharmacists must educate customers on how to identify counterfeit medicines.
- Pharmacists must be able to check the registration of a product through the NMRA website.
- Pharmacists must be aware of the latest information on de-registered products, products found to contain adulterated ingredients, changes to product information approved by NMRA and safety issues.

5.2 Quality added services

The types of services offered should be displayed clearly inside the premises. Examples of such services are:

- Extemporaneous preparations
- Health screening e.g.-: blood Glucose Test, Electronic blood pressure monitoring
- Other service(s) such as home care, smoking cessation etc. may be displayed subject approval by NMRA

5.3 Record keeping and documentation

- Records and documentations should be kept and updated systematically as stipulated by the law.
- Documentation - Proper documentation should be maintained to fulfill legal and professional requirements
- Preferably, the pharmacy should maintain patient medication records:
 - To check the progress of the treatment and provide information on the medical history of the patient.
 - To be kept in pharmacy computer systems or in manual records.
 - Should be pertinent, accurate, up-to-date, stored securely and treated as confidential and used only for the purpose for which it is obtained.
 - Should be easily retrievable when necessary.

6. Personnel

6.1 Pharmacists

- Must be registered with the Sri Lanka Medical Council
- Comply with all the pharmacy legislations of Sri Lanka
- The photograph of the Responsible Pharmacist and on duty Pharmacist must be displayed
- Dress code
 - i. Pharmacist White Coat
 - ii. Must project the professionalism
 - iii. Name tag must have the word “Responsible Pharmacist” or “Pharmacist” as applicable

6.2 Pharmacy support staff

- Suitable number
- The role of the pharmacy support staff is to help in the preparation of medicines to be dispensed. They are not allowed to dispense Schedule II & III medicines.
- It is the responsibility of the Responsible Pharmacist to provide required training to Pharmacists and Pharmacy support staff

7. Storage of medicines

- All medicines must comply with labeling requirements and should be kept in the original packaging or properly labeled containers.
- Different categories of items should be systematically arranged.
- Separate storage should be provided for internal and external medicines.
- Medicines with similar names and packaging should be distinctively separated to prevent dispensing errors.
- Storage conditions must comply with manufacturer instructions and cold chain requirements where relevant
- Schedule II and III medicines
 - A separate, safe and locked cabinet should be used for storage of psychotropic substances and dangerous drugs away from other goods/medicines.
 - All keys of medicine cupboards must be kept by the Responsible Pharmacist/a Senior Pharmacist on duty.

7.1 Type of products

- 70% of the merchandise in a community pharmacy should consist of regulated pharmaceutical products, health and nutritional products, surgical and medical devices, personal care and rehabilitation aids.

Sale of goods and food which are harmful to health is strictly prohibited (E.g. cigarettes, liquor etc.).

8. Store Management

Computerized or manual operation for the followings should be available for the store management.

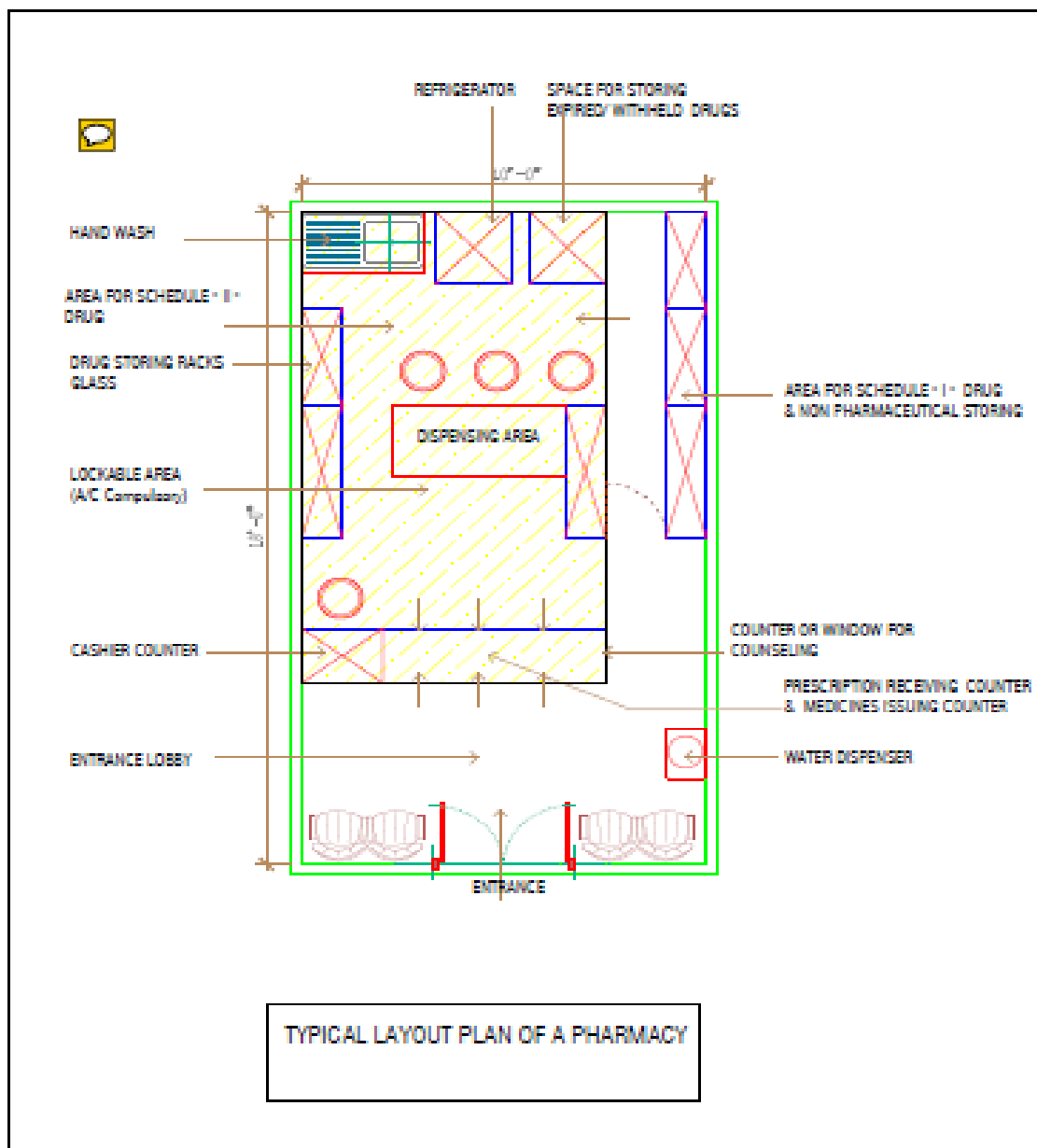
- Pharmacy Information Software
- Inventory/Stock keeping
- Printing of labels
- Printing of customer information leaflets
- Maintenance of patient medication records
- Itemized billing
- Appropriate drug naming system

9. References

The following references are recommended.

- British National Formulary (BNF edition should not be older than 5 years)
- All relevant pharmacy legislations and guidelines
- Optional: References for herbal medicines

Annexure





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