

Regulatory Procedure For Obtaining License of Medical Store in Punjab



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1. Legal Services, SMEDA-Punjab

The Legal Services (LS) is a part of Punjab office of the Small Medium Enterprises Development Authority (SMEDA) and plays a key role in providing an overall facilitation and support to the small and medium businesses. Information dissemination among the SMEs on the existing legal & regulatory environment and business to business and business to client contracting is of paramount importance and plays a pivotal role in their sustainable development.

2. Need for Registration Procedure for Obtaining License of Medical Store

While opening of Medical Store often, people don't know from where to start this business which deals with sensitive issue of human health. Keeping in view this element, the subject document is prepared in simplified form to facilitate the SME sector. This document is a demonstrative guide for business community who are interested in getting license of medical store in Punjab.

After the 8th amendment every province has its own health care rules and regulations. This document provide the licensing requirements of medical store in Punjab.

3. Disclaimer

The information contained in this template is meant to facilitate the businesses in documenting transactions. However, SMEDA, accepts no responsibility and expressively disclaim any and all liabilities for any and all losses/shortfalls caused by or motivated by recommendations from the information contained within this document. Although SMEDA's ambition is to provide accurate and reliable information; yet, the document is not an alternative to expert legal advice and should ideally be used in conjunction with the same. Any person using this document and or benefiting from the information contained herein shall do so at his/her own risk and costs and be deemed to have accepted this disclaimer.

All information contained in this document may be freely used provided that relevant acknowledgement is accurately quoted with each usage.

4. Words and Phrases¹

Serial #	Words and Phrases	Definition
1	Licensing Authority	Secretary to the Government, Health Department an officer of the Government duly authorized by the secretary
2	Medical store	Premises where drugs are stored, sold or offered for sale
3	Pharmacy	Premises where drugs are stored, sold, compounded, dispensed or prepared on prescription or distributed in case of authorized agent of manufacturer, indenter or importer
4	Provincial Board	Provincial Quality Control Board
5	Registered Medical Practitioner	Medical practitioner registered under the Pakistan Medical and Dental Council Ordinance 1962 (XXXII of 1962);

¹ PUNJAB DRUGS RULES, 2007

5. Relevant Law

The Pakistani laws that deals with License of medical store are as following:

- Punjab Drugs Act, 1976 (XXXI of 1976)
- Punjab Drug Rules 1988
- Punjab Drugs Rules 2007

6. Relevant Authority for Application For License of Medical Store

Under **Rule 2(g)** Punjab Drug Rules 2007, The Secretary to the Government of the Punjab, Health Department is the Licensing Authority or any officer of the government duly authorized by the secretary Health. However, he has delegated his powers to Executive District Officer (Health) at District level for public convenience, speedy and timely disposal of Licenses.

7. Background

Procedure for starting a medical store depends in which province the medical store is going to be opened because as per the 18th amendment of the Constitution of Pakistan 1973 health is a provincial matter and every province have its own Drug Regulatory Body and stipulates the law and rules for obtaining license for medical store.

In the subject document we are providing legal requirements and procedure for obtaining a license for medical store in the province of Punjab.

8. Relevant Offices in Punjab for the Submission of Application for Drug Sale License

Application for medical store or drug sale may be submitted physically or online but in both the cases applicant need to visit the following relevant office:

Serial #	District	Authority / Office Online	Authority / Office Manual
1	Lahore	Chief Drug Controller Office	Executive District Officer (Health)
2	Bahawalpur	Drug Testing Laborites	Executive District Officer (Health)
3	Multan	Drug Testing Laborites	Executive District Officer (Health)
4	Faisalabad	Drug Testing Laborites	Executive District Officer (Health)
5	Rawalpindi	Drug Testing Laborites	Executive District Officer (Health)
6	Rest of Districts of Punjab	Relevant Secretary District Quality Control Board Office	Executive District Officer (Health)

9. Eligibility Criteria

Doctor of Pharmacy, Five years degree holder is required for registration as a Pharmacist for opening of a medical store, however, any person can apply for license but he/she has to show hiring or appointment of a pharmacist or a qualified person (Dispenser) to run the medical store.

Note: It is important to verify the registration of the qualified person from the office of Punjab Pharmacy Council before applying the license of medical store from the office of Executive District Officer (EDO) Health – Punjab.

Any medical organization that desires to recruit any pharmacist/pharmacy assistant/pharmacy technician may verify his registration and related status from the office of Punjab Pharmacy Council to know the genuineness.

Fee for any kind of verification shall be submitted in the form of Bank Draft for PKR 500 in the name of Secretary, Punjab Pharmacy Council.

10. Address of Punjab Pharmacy Council

“Block # 7, LDA Flats,
Huma Block, Allama Iqbal Town Lahore,
Ph: 042: 99260298”.

11. Types of License for Sale of Drugs

The licenses are of four types

•License No.9. For retail sale.
•License No.10. For wholesale.
•License No.11. For sale of narcotics, and other controlled drugs.
•License No 12. For establishment of Pharmacy. (Only issued to Graduate Pharmacist registered in Category-A).

Note: (Persons convicted for the sentence one year or more or sentenced to pay fine Rs. 30,000/- or more under section 27(1) of the Drug Act 1976 are not eligible for the grant of License.

12. Procedure for Application

As per rule 15 Punjab Drug Rules 2007, a person may apply for the grant or renewal of a license for sale of drugs to the licensing authority in the prescribed form 8 (A) and 8 (B)*1.

13. FEE of License

Srl.	Category	Fee (Rs.)
I.	License of Pharmacy	3,000/-
II.	License of Medical Store	2,000/-
III.	Renewal of License of Pharmacy	2,000/-
IV.	Renewal of License of Medical Store	1,000/-

14. Head of Account for Submission of Challan

Head of Account No.1252-Health

15. Sale at More than One Place

As per rule 17 of Punjab Drugs Rules 2007, separate License for each place is required for opening of more than one medical store or pharmacy. However, for storage purpose separate license is not required.

16. Duration of License

Duration of License is almost two year unless suspended or cancelled earlier. License expires on every 31st day of December of calendar year. Renewal application may be submitted within 60 days from the expiry date.

17. Documents need to be attached with the Application for License

- i. Original receipt of fee deposited in the head account
- ii. Original certificate of pharmacist or dispenser with Punjab Pharmacy Council
- iii. Attested copy of CNIC of the applicant

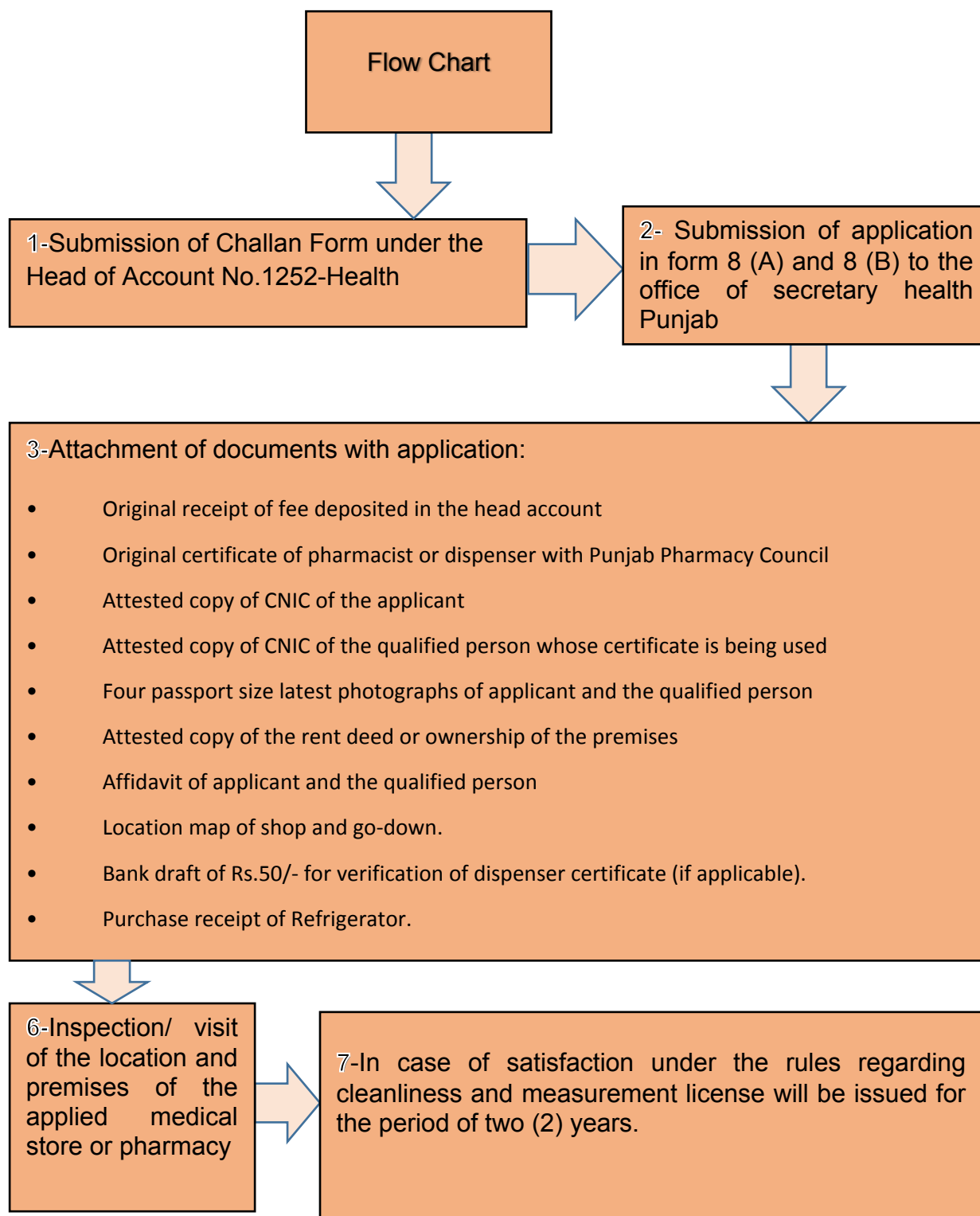
- iv. Attested copy of CNIC of the qualified person who's certificate is being used
- v. Four passport size latest photographs of applicant and the qualified person
- vi. Attested copy of the rent deed or ownership of the premises
- vii. Affidavit of applicant and the qualified person
- viii. Location map of shop and go-down.
- ix. Bank draft of Rs.50/- for verification of dispenser certificate (if applicable).
- x. Purchase receipt of Refrigerator.

18. Conditions for Issuance of License

Form 9 or Form 10 (License) will only be issued if the following requirements are fulfilled:

- i. The premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility;
- ii. The premises is clean, hygienic and in tidy condition;
- iii. The covered area of the premises of a pharmacy is not be less than 140 square feet with minimum breadth of 8 feet in the front and height of 8 feet and in case of a medical store, 96 square feet with minimum breadth of 8 feet and height of 8 feet.

19. Flow Chart of Stepwise Procedure



20. Annexure: A**FORM NO. 8(A)****{See rule 15 (1)}****Application for the license to sell, store and exhibit for sale & distribute drugs by way of pharmacy.**

1. I / We _____ .of M/S

_____ hereby apply for

License of Pharmacy;2. The sale of drugs will be under the personal supervision of;
(Name, registration No, NIC No & address with qualification).

1. _____

2. _____

3. I / We am / are submitting herewith the following documents;

A) Testimonials of the person (s), registered under section 24(1) (a) of the Pharmacy Act 1967, who has agreed to personally supervise the sale of drugs for License in Form 9 (pharmacy) and the proprietor (s)

i) Three attested copies of registration certificate issued by a pharmacy Council.

ii) Four attested copies of National Identity Card & passport size

Photographs of the proprietor (s) and person (s) in charge who has agreed to personally supervise the sale of the drugs.

iii) Affidavit of the person who will supervise the sale of drugs and the proprietor, duly verified, to the effect that they:-

a) Shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

b) Have not been convicted of any offence from any Court of law.

[See rule 19 (1) (e)];

c) Shall inform the Licensing Authority for any change in supervisory staff etc.

d) Are not working in any government / semi government /autonomous organization.

e) Shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force.

B) Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of go-down (if any).

C) Treasury receipt / Challan No & dated _____ amounting to Rs. _____ in the Head of Account 1252-Health & Other receipts.

Dated: _____

Signature: ----- Signature: -----

Name, address and Permanent Home Name, address and Permanent Home

Address of the person (s) who will address of the proprietor (s)

Personally supervise the sale of drugs.

=====

21. Annexure: B**FORM NO. 8(B)**

{See rule 15 (1)}

**Application for the license to sell, store, exhibit for sale & to distribute drugs
Excluding the drugs specified in Schedule "G" by way of Medical
Store**

1. I / We. of M/S
..... hereby apply for

License of Medical Store;

2. The sale of drugs will be under the personal supervision of;
(Name, registration No, NIC No & address with qualification).

1.

2.

3. I / We am / are submitting herewith the following documents;

A) Testimonials of the person (s), registered under section 24(1) (a) or (b) of the Pharmacy Act 1967, who will supervise the sale of drugs for license in Form 10 (medical store) and the proprietor (s); and

Testimonials of the person (s), registered under section 24(1) of the Pharmacy Act 1967, who will personally supervise the sale of drugs for license in Form 10 (medical store) and the proprietor (s).

i) Three attested copies of registration certificate issued by a pharmacy council.

ii) Four attested copies of National Identity Card & passport size photographs of the proprietor (s) and person (s) in charge who has agreed to personally supervise the sale of the drugs.

iii) Affidavit of the person who will supervise the sale of drugs and the proprietor, duly verified, to the effect that they:-

f) Shall comply with the provision of the Drugs Act, 1976 and rules framed there under;

g) Have not been convicted of any offence from any Court of law.

[See rule 19 (1) (e)];

h) Shall inform the Licensing Authority for any change in supervisory staff etc.

i) Are not working in any government / semi government / autonomous organization.

j) Shall not sell / stock any expired, spurious, substandard, unregistered misbranded, counterfeit or any drugs in violation to the drugs laws in force.

B) Plan indicating the exact location and specification of the premises including covered area, dimensions, signboard, air conditioning and refrigeration facilities and addresses of godown (if any).

C) Treasury receipt /Challan No & dated _____ amounting to Rs. _____ in the Head of Account 1252-Health & other receipts.

Dated: _____

Signature: ----- Signature: -----

(i) Name, address and Permanent Home Name, address and Permanent Home

Address of the person (s) who will address of the proprietor (s) personally supervise the sale of drugs.

(ii) Name, address and Permanent Home Address of the person (s) who will supervise the sale of drugs (if different from (i) above.