**PROCEDURE / RULES FOR SALE OF DRUGS**

14. **Licenses under the rules**.– The licensing authority may issue a license of a pharmacy or a license of a medical store.

15. **Application and fee for license**.–

(1) A person may apply to the licensing authority for the grant or renewal of a license referred to in rule 14 in
Form 8(A) or Form 8(B).

(2) The applicant shall deposit the fee for a license in the Head of Account No. 1252-Health-Other Receipt, at the following rates:

(a) three thousand rupees for a license of a pharmacy and two thousand rupees for a license of a medical store; and

(b) two thousand rupees for renewal of a license of a pharmacy and one thousand rupees for renewal of a license of a medical store.

(3) The licensing authority shall issue or renew a license subject to the conditions prescribed in the Act and the rules.

(4) The applicant shall pay 50% of the fee for change of the qualified person or the duplicate copy of the license.

16. **Forms of licenses to sell drugs**.– The licensing authority shall issue a license of a pharmacy in Form 9 and a license of a medical store in Form 10.

17. **Sale at more than one place**.– (1) If a person desires to sell, store, exhibit for sale or distribute drugs at more than one place, he shall apply for a separate license in respect of each place.

(2) Provision of sub-rule (1) shall not apply in case the drugs are properly stored in a godown, used only for storage of drugs and which meets the storage conditions and is enlisted along with its complete address on the license.

18. **Duration of licenses**.– (1) A license issued or renewed under these rules shall unless suspended or cancelled earlier, remain in force for two years from the date of issue.

(2) If a person fails to apply for the renewal of a license within thirty days after the expiry of the license, his license shall stand cancelled.

(3) If a person applies for the renewal of a license within thirty days after the expiry of the license, his license shall remain enforce until an order on the application is passed by the licensing authority.

(4) The licensing authority shall issue a receipt of an application of a license or renewal of a license.

(5) The licensing authority shall dispose of an application for a license or renewal of a license within 45 days of the receipt of the application.

(6) If the licensing authority fails to dispose of the application within the specified time, it shall record reasons for its failure.

(7) If in the opinion of the licensing authority, it is not expedient in public interest to grant a license, it may refuse the application.

(8) The licensing authority shall not renew a license without an inspection report of the Inspector.

19. **Conditions for issuance of licenses**.–

(1) The licensing authority shall not issue a license in Form 9 (pharmacy) and Form 10 (medical store) unless-

(a) The premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility;

(b) The premises is clean, hygienic and in tidy condition;

(c) In the case of a license of a pharmacy in which preparation or compounding of a drug is undertaken, the premises has fulfilled the requirements contained in the Schedule F;

(d) 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;

(e) the applicant is not a convict who has been sentenced for imprisonment for a period of one year or more or sentenced to pay fine of thirty thousand rupees or more for manufacturing or selling spurious drugs; and

(f) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) has agreed to personally supervise the sale of drugs for license in Form 9 (pharmacy) and a person who is registered under section 24(1)(a) & (b) of the said Act has agreed to supervise sale of drugs for license in Form 10 (medical store). Provided that provision of this rule for the licenses already issued shall come into force after ten years from the notification of these rules**.**

(2) The licensing authority shall not issue a license without inspection report by a committee comprising of Secretary of the District Board or the Area Drugs Inspector**.**

20. **Conditions of licenses**.–

(1) The licensing authority shall issue a license in Form 9 or Form 10 subject to the conditions stated in the license and to the following general conditions:

(a) in the case of a pharmacy, the person shall display the word “Pharmacy” outside wall of the pharmacy in white writing on a green colored signboard having minimum length of 5 feet and width of 2.5 feet and in the case of a medical store, the person shall display the words “Medical Store” in white writing on a blue colored signboard with the same minimum dimensions as required for a pharmacy;

(b) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs under license in Form 9 (pharmacy) and a person who is registered under section 24(1) of the said Act shall personally supervise sale of drugs under license in Form 10 (medical store);

(c) the supply of a drug shall be recorded suitably and the records, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale;

(d) a drug specified in the Schedules B and D and a preparation containing such drug shall not be sold except on and in accordance with the prescription (original to be retained by the pharmacy or the medical store) of a registered medical practitioner; a prescription may be dispensed with in case of an emergency (recorded in writing in the register); and no such prescription shall be required for sale of the drug to a registered medical practitioner, a hospital dispensary or any other institution;

(e) subject to rule 1, a licensee of a medical store shall not sell or store a drug mentioned in the Schedule G; and

(f) the sale of a drug specified in the Schedules B and D shall be recorded at the time of supply in a register specially maintained for the purpose and the serial number

of the entry in the register shall be entered in the prescription, and the following particulars shall be entered in the register:

| | | |
|---|---|---|
| (i) S. No., | (ii) Date of Sale; | (iii) Name of the prescriber; |
| (iv) Name of the patient; | (v) Name of the drug; | (vi) Name of the manufacturer; |
| (vii) Quantity sold; | (viii) Batch No; | (ix) Signature of the qualified person; and |

(x) Quantity purchased and balance.

**Explanation**.– If the drug specified in the Schedule D is sold on a prescription on which the drug has been sold on a previous occasion, it shall be sufficient if the entry in the register includes Sr. No., the date of sale; the quantity sold; and a sufficient reference to an entry in the register recording the sale of the drug on the previous occasion.

(2) For the purpose of this rule, a prescription shall-

(i) be in writing and be signed by the person giving it with his usual signature and be dated by him;

(ii) specify the name and address of the person for whose treatment it is given; and

(iii) indicate the total quantity of the drug to be supplied and dose to be taken.

(3) An invoice or a bill for the purchase of a drug shall be preserved for a period of at least three years.

(4) A manufacturer, importer or the seller of a drug shall sell the drug only to a holder of a valid drug sale license or to a registered medical practitioner and shall issue an invoice and warranty at the time of sale of the drug.

(5) In case of sale of a drug to a registered medical practitioner, the manufacturer, importer or seller of a drug shall send a copy of the invoice and warranty to the Inspector.

(6) A registered medical practitioner or a doctor of veterinary medicine is exempted from the requirement of a drug sale license, if:

(a) the drug is for his patients; and

(b) the record of a drug specified in the Schedules B and D is maintained as prescribed under this rule. Provided that no pharmacy or medical store shall be allowed except and in accordance with the provisions of these rules.

(7) The invoice and warranty shall bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and shall be dated.

(8) The manufacturer, importer or seller of a drug shall maintain record of purchase or sale of a drug and shall preserve the record for a at least three years containing the following particulars:

(a) the date of purchase or sale;

(b) the name and address of the concern from which the drug is purchased or the concern to whom the drug is sold;

(c) the name of the drug, its batch number, the date of its expiry and the quantity of the drug;

(d) the name of the manufacturer.

(9) Except as otherwise provided in these rules, a record required to be maintained under these rules shall be preserved for a period of not less than three years from the date of the last entry.

(10) The licensee shall produce for inspection by an Inspector on demand a register or record maintained under these rules, and shall supply to the Inspector such information as the Inspector may require.

(11) A substance specified in the Schedule E and that fall under the list of poisons and the drug specified in the Schedule B shall be stored in:

(a) in a part of the promises to which customers do not have access; or

(b) in a locked almirah, cupboard or drawer, reserved solely for the storage of the substance or the drug.

(12) A substance that falls under the list of poisons in the Schedule E shall be stored in a container, impervious to the poison, and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.

(13) A substance that fall in the list of poisons under the Schedule E when compounded and dispensed shall be labeled with the word “Poison”.

21. **Cancellation or suspension of licenses.**– The licensing authority may, on the report of an Inspector or the Provincial and the District Board, after giving the licensee an opportunity to show cause and by an order in writing stating the reasons, cancel a license issued under these rules or suspend it for such period as it deems fit, if in its opinion the licensee has failed to comply with any of the conditions of the license or with any of the provisions of the Act or these rules.

22. **Provincial Appellate Authority**.–

(1) A person aggrieved by an order of the licensing authority may prefer an appeal to the Provincial Appellate Authority within thirty days of the date of the order.

(2) The Additional Chief Secretary of the Government shall be the Provincial Appellate Authority for the purpose of hearing appeals against an order of the licensing authority.

(3) The Provincial Appellate Authority may direct an officer or an official of the Government to assist the Authority.

(4) The Provincial Appellate Authority shall, after giving the appellant an opportunity of hearing, pass such order as it deems fit and the order of the Authority shall be final and cannot be called in question before any forum.