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### MAHARASHTRA DRUGS (CONTROL) RULES, 1963

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# MAHARASHTRA DRUGS (CONTROL) RULES, 1963

In exercise of the powers conferred by clauses (a), (b), (c), (f), (g), (h), (j), (k), (1), (m) and (o) of sub-section (2) of section 40 of the Bombay Drugs (Control) Act, 1959 (Bom.XI of1960) and of all other powers enabling it in this behalf an din supersession of the Bombay Drugs (Control) Rules, 1958, published under the Government of Bombay Notification, Revenue Department, No, BDC.1058-(a), dated the 20th June, 1958, and the rules and orders issued in this behalf, under the Central Provinces and Berar Drugs (Control) Act, 1949, the Government of Maharashtra, hereby

makes the following rules, the same having been previously published as required by sub-section (3) of the said section 40, namely

#### 1. Short title and commencement :-

- (1) These rules may be called the Maharashtra Drugs (Control) Rules, 1963.
- (2) They still come into force on the 1st day of October, 1963.

#### 2. Definitions :-

In these rules, unless the context otherwise, requires

- (a) "Act" means the Bombay Drugs (Control) Act, 1959;
- (b) "Form" means a form appended to these rules;
- (c) "licence" means a licence granted under these rules;
- (d) "licencee" means a person who has been granted a licence under these rules;
- (e) "pass" means a pass granted under these rules;
- (f) "permit" means a permit granted under these rules;
- (g) words and expressions not defined in these rules shall have the meaning, respectively, assigned to them in the Act.

## 3. Applications for wholesalers licence :-

Any person desiring to carry on the business of a wholesaler in notified drugs and to possess such drugs for the purpose of his business shall apply in Form N D A-I to the Collector for the licence in that behalf.

#### 4. Grant of a wholesalers licence :-

On receipt of an application under rule 3, the Collector may, after making such enquiries as he deems necessary to verify or ascertain the truth of any statements made in the application and after satisfying himself that there is no objection to the grant of the licence applied for, grant the applicant a licence in Form N D W L. on payment of a fee of

- (a) Rs.60, in Greater Bombay, the City of Poona, the City of Nagpur and the Sholapur Municipal Borough, or
- (b) Rs.40, elsewhere.

# <u>5.</u> Maintenance of accounts by licensed wholesaler. Form N.D.1. Form N.D.2:-

- (1) A licenced wholesaler shall maintain in Form N.D.I , true and accounts of the notified drugs obtained, sold and possessed by him.
- (2) He shall also maintain a register of sale of notified drugs in Form N.D. 2, wherein he shall enter in under his signature, the full name and address of the purchaser, the quantities of the notified drug sold to him, the date of sale, the purpose for which they are sold and the number and date of the licence of the purchaser and of the transport pass or the order (if any), under section 14, held by him.
- (3) He shall, before the seventh day of every month furnish to the Superintendent of Prohibition and Excise of the area, as monthly return in Form N.D.-3, in respect of notified drugs possessed, obtained and sold by him in the previous month.

### 6. Applications for retailers licence :-

Any person desiring to carry on the business of a retailer in notified drugs, and to possess such drugs for the purpose of his business shall apply in Form N.D.A.1 to the Collector for a licence in that behalf.

#### 7. Grant of retailers licence :-

On receipt of an application under rule 6, the Collector may, after making such enquiries as he deems necessary to verify or ascertain the truth of any statement made in the application and after satisfying himself that there is no objection to the grant of the licence applied for, grant the applicant a licence in Form N.D.R.L. on payment of a fee of

- (i) Rs.30, in Greater Bombay, the City of Poona, the City of Nagpur and the Sholapur Municipal Borough, or
- (ii) Rs.20, elsewhere

## 8. Maintenance of Accounts by Licensed retailed retailer :-

- (1) A licenced retailer shall maintain in Form N.D-4., true and proper accounts of all notified drugs obtained; and possessed by him.
- (2) He shall also maintain a register of sale of notified drugs in Form N.D.5, wherein he shall enter under his signature, full name

and address of the purchaser, the quantities of the notified drugs sold to him, the date of sale, the purpose for which they are sold, and number and date of the order, where applicable, under section 14, held by him.

(3) He shall, before the seventh day of every month, furnish to the Superintendent of Prohibition and excise, or, as the case may be, to the District Inspector of Prohibition of Excise of the area, a monthly return in Form N.D.3, in respect of notified drugs possessed obtained apd sold by in the previous month.

## 9. Grant of permission under section 12(1):-

- (1)Any medical practitioner desiring to possess at any one time a notified drug in excess of the quantity determined by the State Government, under section 12 of the Act, shall apply, in writing, to the Collector, for permission in that behalf. Every such application shall state,
- (i) the name and address of the applicant,
- (ii) the quantity and description of notified drug or drugs required by the applicant,
- (iii) the place at which notified drug or drugs shall be kept, and
- (iv) the purpose for which notified drug or drugs is or are required.
- (2) On receipt of an application under sub-rule (1), the Collector may, after making such enquiries as he deems necessary to verify or ascertain the truth of any statements made in the application and after satisfying himself that there is no objection to giving the permission, grant the permission applied for in writing.

# 10. Application for permit :-

Any person not being a dealer or medical practitioner, desiring to possess any notified drug in excess of such quantities has been at any one time dispensed or sold on prescription for a bonafide medical use to him or to a member of his household, shall apply to the Collector in Form N.D.A.-2 for a permit in that behalf.

# 11. Grant of permit :-

On receipt of an application under Rule 10, the Officer duly empowered in this behalf, by the State Government, under clause (b) of sub- section (1) of Section 12 may, after making such enquiries as he deems necessary to verify or ascertain the truth of

any statements made in the application and after satisfying himself that there is no objection to the grant of the permit applied for, grant the applicant's permit in Form NDP, on payment of a fee of rupee one.

### 12. Application for transport pass :-

Subject to the provisions of Section 14, any person desiring to transport a notified drug, shall apply in Form NDA-3, to the Officer duly empowered by the State Government in this behalf.

### 13. Grant of Transport Pass :-

- (1) On receipt of an application under Rule 12, the said officer may, after making such inquiries as he may deem necessary to verify or ascertain the truth of any statement made in the application and after satisfying himself that there is no objection to the grant of pass applied for, grant the applicant a pass in Form NDT, on payment of fee of rupee one.
- (2) Every holder of a transport pass shall get the details of the purchases of notified drugs made by him, entered in his transport pass by the dealer from whom he obtains such drugs.

## 14. Duration of licence permit and pass :-

 $^{1}$ N o licence, permit or pass granted under these rules shall be granted for a period beyond the 31st day of December next following the date of its commencement.  $^{1}$  [xxxx]

1. Deleted by G.N. of 17-I-1967

# 15. Sale at more than one place separate licence for each sale place :-

If notified drugs are intended to be sold by a dealer at more than one place, a separate licence shall be necessary in respect of each such place.

# 16. Preservation of records Register of accounts of notified drugs and register of sale lining :-

(1) Every dealer shall preserve a register of accounts of notified drugs and register of sale thereof, for not less than one year from the date of the last entry in the account book or, as the case may be, in the register of sale. He shall also preserve the delivery memoranda, invoices and sale memoranda relating to the sale or purchase of notified drugs or to the stock thereof, for a period of one year after the expiry of the year to which they relate.

(2) Every medical practitioner and licensed retailer shall preserve for a period of one year after the expiry of the year in which a notified drug is supplied, every prescription under which a notified drug was supplied, or a copy thereof, if the prescription is returned to the person presenting it. Where copies of the prescriptions are kept, the original shall, before being returned to the person presenting it be endorsed, as to the drug dispenses or sold and the quantity thereof.

### 17. Inspection of stocks, accounts, etc :-

Every dealer of medical practitioner shall produce all books of accounts and documents relating to notified drugs together with the licence and the stocks of notified drugs for inspection on demand by the Director or Collector, or any officer duly authorised under Section 31 and shall allow him to inspect and to take such copies or extracts as he thinks, fit, of all such books of accounts and documents relating to notified drugs which belong to or are under the control of such dealer or medical practitioner.

# 18. Regulation of business of licensee Licence in the name of partners:

- (1) No person shall be recognised as partner of the licensee for the purpose of his licence, unless the partnership has been declared to the Collector, before the licence is granted and the names of the partners have been entered jointly in the licence, or if the partnership is entered into after the granting of the license unless the Collector agrees on made to him to alter the licence and to add the name or names of the partner or partners in the licence.
- (2) The licensee shall carry on his business under the licence either personally or by an agent or servant duly authorised by him in his behalf by a written nokamama, signed by himself and countersigned by a Prohibition and Excise Officer not lower in rank than a Sub-Inspector:

Provided that any such nokarnama signed by the licensee, shall be valid under countersignature is refused, If for any the Collector shall order the withdrawal of any nokarnama, issued by the licensee the nokarnama shall be forthwith withdrawn. No nokarnama shall be issued to any person who is a minor and no such nokarnama, if issued, shall be valid.

# 19. Issue of duplicate licence or permit or pass :-

When the licence is lost, destroyed, torn or defaced, inti - mation to

be given to the Collector If at any time a licence, permit or pass is lost or is destroyed or is so torn or defaced, in any way, as to cease it to be reasonably legible, the licensee, the permit holder or, as the case may be, the pass-holder shall forthwith intimate the fact in writing to the Collector .

- (2) Upon receipt of such intimation the Collector may, after verifying the truth of the statements made in the intimation, issue a duplicate licence or permit or pass to the licensee, a permit holder or a pass holder.
- (3) When a duplicate licence or permit or pass is issued under subrule (2), it shall be clearly stamped "Duplicate" in red and shall be marked with the date of its issue.
- (4) In the case of a licence, or permit or pass which is torn or defaced, the duplicate shall not be issued unless the licence, or permit or pass is returned by the holder thereof, to the Collector.
- (5) The fee for a duplicate licence, or permit or pass shall be rupee one.

### 20. Licensee etc., to abide by the provisions of this act :-

The licensee, the permit, or pass holder shall abide by the conditions of the licence or permit, or as the case may be, the pass, the provisions of the Bombay Drugs (Control) Act, 1959, and the rules, and orders made thereunder and shall give an undertaking to that effect.

# 21. Maximum quantity of notified drugs to be possessed for purpose of sample :-

The quantity of any notified drugs that may be possessed by any person for the purposes of sample under Section 16 shall not exceed 116 millilitres [or 40 tablets or 80 capsules, as the case may be.]

# 22. Form of memorandum.Particular on the form of memorandum:-

The sale memorandum which a dealer is required to give under Section 17 shall include the following particulars:-

- (1) Number and date
- (2) Name of the licensee
- (3) Address of the licensee

- (4) Kind and number of licence held
- (5) Name of the purchaser and his address
- (6) Name of the notified drugs sold
- (7) Quantity of the notified drugs sold
- (8) Price charged
- (9) Signature of the purchaser or his authorised agent
- (10) Signature of the licensee or his authorised agent or servant

# 23. Details of sale of notified drugs to be enetered in transport pass:-

Every dealer shall enter in the transport pass presented by a purchaser, the details of the notified drugs sold or supplied by him.

#### 24. Transfer of licence from one name to another :-

No licence granted under Rules 4 and 7 shall be transferred from one name to another except with the previous sanction of the Collector.