## The Maharashtra Drugs (Control) Rules, 1963

MAHARASHTRA India

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# Rule THE-MAHARASHTRA-DRUGS-CONTROL-RULES-1963 of 1963

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The Maharashtra Drugs (Control) Rules, 1963Published vide Notification No. G. N., H. D., No. BDC. 1063-2, dated 14th August, 1963 (M. G., Part 4B, p. 1257)In exercise of the powers conferred by clauses (a), (b), (c), (f), (g), (h), (j), (k), (l), (m) and (o) of sub-section (2) of section 40 of the Bombay Drugs (Control) Act, 1959 (Bombay XI of 1960) and of all other powers enabling it in this behalf and in 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 10, namely :-Preliminary

#### 1. Short title and commencement.

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

#### 2. Definitions.

- In these rules, unless the context otherwise, re-quires-(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)"licensee" 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.Wholesaler's Licence

1

#### 3. Applications for wholesaler's 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. - 1 to the Collector for a licence in that behalf.

#### 4. Grant of wholesaler's 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.

### 5. Maintenance of accounts by licensed wholesaler.

(1)A licensed wholesaler shall maintain in Form N. D. - 1, true and proper accounts of all 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 under his signature, the full name and address of the purchaser, the quantities of 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, or, as the case may be, to the District Inspector of Prohibition and Excise of the area, a monthly return in Form N. D. - 3, in respect of notified drugs possessed, obtained and sold by him in the previous month.Retailer's Licence

## 6. Application for retailer's 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 retailer's 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 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.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 retailer.

(1)A licensed retailer shall maintain in Form N.D. - 4, true and proper accounts of all notified drugs obtained, sold 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 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 and Excise, of the area, a monthly return in Form N.D. - 3, in respect of notified drugs possessed obtained and sold by him in the previous month.

#### 9. Grant of permission under section 12(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 bona fide 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 a permit in Form N.D.P., on payment of a fee of rupee one.Transport of Notified Drugs

## 12. Application for transport pass.

- Subject to the provisions of section 14, any person desiring to transport a notified drug shall apply in Form N.D.A. - 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 N.D.T., on payment of a 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.General

## 14. [\* \* \*] [Deleted by G. N. of 15.7.1968.] Duration of licence, permit and pass.

- No 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.[\*\*\*] [Deleted by G. N. of 17.1.1967.]

#### 15. Sale at more than one 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.

(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, ever) 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 dispensed or sold and the quantity thereof.

## 17. Inspection of stocks, accounts etc.

- Every dealer or 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.

(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 licence unless the Collector agrees on application 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 this behalf, by a written nokarnama, 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 until countersignature is refused. If for any reason 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.

(1)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 pass holder.(3)When a duplicate licence or permit or pass is issued under sub-rule (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 the Act, etc.

- 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.] [Added by G. N. of 7.11.1970.]

#### 22. 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 entered 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.Form N.D.A. - l(See rules 3 and 6)(Emblem)Application for a wholesaler's/retailer's licence under the Bombay Drugs (Control) Act, 1959ToThe Collector of -

### 1. Name and address of the applicant -

(a)In the case of firm - Names and addresses of all partners.(b)In the case of an incorporated company-Names and addresses of its Directors (including the Directors who have the management of the affairs of the company) and of its Manager, Secretary or Managing Agent(s).(c)In the case of a co-operative society-Names and addresses of the members of the Managing Committee.

## 2. Exact address of the place, where business of sale is to be carried on -

Building.	Street	Village/town
	District	

- 3. Exact address of the place or places where notified drugs will be stocked.
- 4. Sales Tax Registration No. and date of registration.
- 5. Whether the applicant holds any licence under the Drugs Act, 1940, and if so, its number and date.

I/We hereby declare that I/We have been carrying on business in drugs continuously from......19........and request that 'wholesaler's/retailer's licence under the Bombay Drugs (Control) Act. 1959, may be granted to me/us.I/We have read the provisions of the Bombay Drugs (Control) Act. 1959 and the Maharashtra Drugs (Control) Rules, 1963.I/We agree to abide by the

provisions of the said Act, the rules and orders mad	e thereunder and the conditions of the licence
applied for by me/ us.(Signed)	Date :Place :Signature and designation of
the applicant* Strike off what is inapplicable.Form	N.D.W.L.(See rule 4)(Emblem)Licence No.
Licence for carrying on the business	of selling notified drugs, as wholesaler under
the Bombay Drugs (Control) Act, 1959Licence is her	eby granted under and subject to the provisions
of the Bombay Drugs (Control) Act, 1950, and the re	ıles and orders made thereunder
toof (hereinafter referred t	o as "the licensee") on payment of a licence fee
of Rs. [] [To be inserted in te	erms of rule 4,]authorising him to carry on the
business of selling notified drugs as a wholesaler an	d to possess them for the purpose of such
business at his premises situated atin the to	wn/village ofin the district of
(hereinafter referred to as ("the licen	sed premises") during the period commencing
onand ending on	on the following conditions, namely:-Conditions

1. The licensee shall not carry on the business of selling notified drugs as a wholesaler or possess any notified drugs for the purpose of such business at any place other than the licensed premises:

[Provided that, he may possess notified drugs for the purpose of such business at his warehouse situated at......] [This proviso should be struck off where not required.]

- 2. Subject to the provisions of section 14, the licensee shall not possess at any one time any notified drug in excess of the maximum quantity fixed in respect thereof under section 12.
- 3. The licensee shall not sell or supply notified drugs to any person in the State who is not a dealer or medical practitioner or a person authorised by the Collector under section 14.

4.

(1)The notified drugs shall not be delivered to any person who is not entitled under section 12 to have them in his possession. The licensee shall not deliver to any person unless such person has authority in writing to purchase the notified drugs, signed by the person duly licensed or authorised to purchase them. The licensee shall take every precaution and reasonable care and satisfy himself that the authority given and produced is genuine. (2) Where for the removal of the notified drug, a transport pass is necessary the licensee shall subject to the provisions of section 14 before permitting the removal of the notified drug from his shop by the purchaser, satisfy himself that the purchaser has obtained the necessary pass from the officer duly empowered in this behalf.

- 5. The licensee shall not, in any one transaction sell or supply to any person in the State, any notified drug exceeding the quantity determined by the State Government in this behalf under section 10.
- 6. The licensee shall keep affixed at the licensed premises a signboard showing the name of the shop or place of business.
- 7. The licensee shall display the licence at a conspicuous place on the licensed premises.
- 8. The licensee shall abide by the conditions of this licence and the provisions of the Bombay Drugs (Control) Act, 1959 and the rules and orders made thereunder.
- 9. The licensee shall comply promptly with all lawful orders and directions issued to him, from time to time, by the Director of Prohibition and Excise, Collector, Superintendent of Prohibition and Excise, or District Inspector of Prohibition and Excise.
- 10. The licensee, his heirs, legal representatives or assignees shall have no claim whatsoever to the continuance or renewal of this licence, after the expiry of the period for which it is granted. It shall be entirely within the discretion of the Collector to permit or not the assignee of the licensee, in case of sale or transfer, or the heir or legal representative of the licensee in case of death, to have the benefit of the licence for the unexpired portion of the term for which it was granted.
- 11. This licence may be suspended or cancelled in accordance with the provisions of section 18 of the Bombay Drugs (Control) Act, 1959.

Collector of	•••••					
Form N. D 1[S	See rule 5(1)	](Emblem)Registo	er of accounts of no	otified drugs	possesse	d and sold
during the mon	th of		Name of the licens	sed wholesa	ler	
	•••••	Address	Licence	No	Na	me of the
notified drug	•••••					
Date Opening	Quantity	Name and	Total quantity	Quantity	Closing	Signature of
balance	obtained	address of the	possessed	sold	balance	the licensee

Date:

				person fro obtained	om (c	columns 2 )	and		
(1)	(2)	(3)		(4)	(5		(6)	(7)	(8)
licens	sed wh	olesaler	Name of	f the license	d wholesa	ler	otified drugs to		d by a Licenc
No					Name o	of the notif	ied drug		•••••
Date	person whom	ss of the n to eddrug	licence number ofthe of section	r and date rder under 14 of the the case	Quantity sold	Purpose for which sold	Number and of the transportant pass held by thepurchaser whether applicable	ort Remarks	Signature s of the licensee
(1)	(2)		(3)		(4)	(5)	(6)	(7)	(8)
sold o Nam Addro Nam	during e of the ess e of otified	the mone e license  Openin balance	g e on the		wholes Total o	alerretaile  quantity sed nns 2 and	eturn of the no		Signature of the
(1)		(2)		(3)	(4)		(5)	(6)	(7)
sellin grant and o on pa him t purpo of from.	g notif ed und orders i syment o carry ose of s	ied drug ler and s made the of a lice on the such bus (h	s as a resubject the ereunder fee business at ereinaft	etailer under to the proviser to	r the Bombions of the control of the	bay Drugs e Bombay ] [Here in ugs as a re at licensed p ug condition	icence for carry (Control) Act, Drugs (Control) (hereinafter resert fee in terms etailer and to possible to the control of the	1959Licence i l) Act, 1959, and ferred to as "t as of rule 7.] au assess them for any illage of in any the period	s hereby  nd the rules  he licensee")  thorising  or the  the district

retailer or possess any notified drug for the purpose of such business at any

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place other than the licensed premises :

- 2. The licensee shall not obtain any notified drug for the purpose of his business except from a person who is a licensed wholesaler.
- 3. The licensee shall not, in any one transaction, sell to any person in the State any notified drug exceeding the quantity determined under section 10 of the Act.

#### 4.

- (1)The licensee shall not sell or supply any notified drug to any person in the State who is not a medical practitioner or a person authorised under section 14, or a person holding a prescription for that drug in his favour issued by a medical practitioner or a permit in Form N.D.P.(2)The notified drugs shall not be delivered to any person who is not entitled under section 12 to have them in his possession. The licensee shall not deliver to any person unless such person has authority in writing to purchase the notified drugs, signed by the person duly licensed or authorised to purchase them. The licensee shall take every precaution and reasonable care and satisfy himself that the authority so given and produced is genuine.(3)Where for the removal of the notified drug, a transport pass is necessary, the licensee shall, before permitting the removal of the notified drug from his shop by the purchaser, satisfy that the purchaser has obtained the necessary pass from the officer duly empowered in this behalf.(4)In the case of sale to a person holding a prescription, the licensee shall retain the original prescription or a true copy thereof, endorse thereon the quantity of the notified drug sold to such person and the date of sale.
- 5. The licensee shall keep affixed at the licensed premises a signboard showing the name of the licensed premises.
- 6. The licensee shall display the licence at a conspicuous place on the licensed premises.
- 7. The licensee shall abide by (he conditions of this licence and the provisions of the Act and the rules and orders made thereunder.
- 8. The licensee shall comply promptly with all lawful orders and directions issued to him, from time (o time, by the Director or Prohibition and Excise, Collector, Superintendent of Prohibition and Excise and District Inspector of Prohibition and Excise.

- 9. The licensee, his heirs, legal representatives or assignees shall have no claim whatsoever, to the continuance or renewal of this licence after the expiry of the period for which it is granted. It shall be entirely within the discretion of the Collector to permit or not, the assignee of the licensee in case of sale or transfer, or the heir or legal representative of the licensee in case of death, to have the benefit of the licence for the unexpired portion of the term for which it was granted.
- 10. This licence may be suspended or cancelled in accordance with the provisions of section 18 of the Bombay Drugs (Control) Act, 1959.

durin	g the mon	th of		](Emblem)Registe Nam ldress	e of the licensed re	etailer		and sold
No		•••••	•••••	Nam	e of the notified			
Date	Opening balance	Quant obtair		Name and address of the person from whom obtained	Total quantity possessed (columns 2 and 3)	Quantity sold or supplied	Closing balance	Signature of the licensee
(1)	(2)	(3)		(4)	(5)	(6)	(7)	(8)
Form	N. D 5[S	See rul		)](Emblem)Regist	ers of Sale of Noti	_		
Form Licen	N. D 5[S	See rule	Nan	)](Emblem)Regist ne of the licensed i Licer	ers of Sale of Noti retailer nce No.		Address	
Form Licen	N. D 5[3 sed Retails Name and address of	See rule er	Nan Numl under perm presc	)](Emblem)Regist ne of the licensed i Licer	ers of Sale of Notiretailernce NoName of the order Act, or e iththe name Quartner by	the notified Purpos	Address drug se	Signature

Collector of.....(1)Name and address of the applicant(2)Quantity and description of

Dated:

- 1. The permit-holder shall not possess under the permit any notified drugs other than those specified in column (1) of the Appendix and in quantities exceeding those specified against each of them in column 2.
- 2. The permit-holder shall not keep the notified drugs except at the premises mentioned above.
- 3. The permit-holder shall not use notified drugs except for the purpose of......
- 4. This permit is non-transferable.
- 5. The permit-holder shall comply with all lawful orders issued to him by the Collector or the Superintendent of Prohibition and Excise or District Inspector of Prohibition and Excise of his district.
- 6. The permit-holder shall abide by the conditions of this permit and the provisions of the Bombay Drugs (Control) Act, 1959, and the rules and orders made thereunder.
- 7. The permit may be suspended or cancelled in accordance with the provisions of section 18 of the Bombay Drugs (Control) Act, 1959.
- 8. In case the permit is suspended or cancelled, the stock of notified drugs in the possession of the permit-holder on the date of such suspension or cancellation, shall forthwith be surrendered by him to the Collector.

#### **Appendix**

Description of notified drugs	Quantity of notified drugs
(1)	
(2)	
Granted this day of	
Signature and designation of theaut	hority granting the permit
Form N.D.A 3(See rule 12)(Emblem	)Application for a Pass for Transport of Notified Drugs within
the StateTo The	

- 1. Name and address of the applicant.
- 2. Kind of licence/permit held by the applicant. and its number and date and by whom granted.
- 3. Quantity(ies) and description of notified drug(s) to be transported.
- 4. The purpose for which notified drug(s) is/are to be transported.
- 5. The place from which notified drug(s) is/are to be transported.
- 6. The place to which notified drug(s) is/ are to be transported.
- 7. The name of the person to be authorised to transport.
- 8. Route.
- 9. The period for which the pass is required.

I request that a transport pass for the transport of the abovementioned quantity(ies) of notified drug(s) may be issued to me.I hereby undertake to abide by the conditions of the transport pass and the provisions of the Bombay Drugs (Control) Act, 1959, and the rules and orders made thereunder.Signature of the ApplicantForm N.D.T.(See rule 13)(Emblem)Pass for the Transport of Notified DrugsNo.......Dated 19

- 1. Name and address of the transporter.
- 2. Kind of licence/permit held by the transporter and its number and date.

- 3. Place from which notified drugs are to be transported.
- 4. Place to which notified drugs are lo be transported.
- 5. Purpose for which notified drugs are to be transported.
- 6. Date up to which the pass shall be valid.

This pass is granted under and subject to the provisions of the Bombay Drugs (Control) Act, 1959 (Bombay XI of 1960) and the rules and orders made thereunder, authorising the transport of the notified drugs mentioned on the reverse thereof, subject to the condition that the whole quantity of notified drugs obtained a I a time shall be transported in one consignment only and its bulk shall not be broken in transit.

Signature of the Officer, issuing the pass and his Designation Reverse of Form N.D.T.Details of Notified Drugs to be transported

Date	Name of e notified drug	Quantity of notified drug	Name of the licensee and his licence number fromwhom the quantity of notified drug mentioned in column 3 ispurchased and the signature of the licensee or his authorisedagent	Remarks
(1)	(2)	(3)	(4)	(5)