

GOVERNMENT OF TAMIL NADU

ABSTRACT

Act and Rules - Tamil Nadu Narcotic Drugs Rules, 1985 - Making easy availability of "Morphine" drugs to needy cancer patients in Tamil Nadu – Simplification of procedure and making availability of medicines through Recognised Medical Institutions - Suggestions of Government of India and Representations of Indian Association of Palliative Care and Cancer Institute, Adyar accepted - Procedures prescribed – Amendments to Tamil Nadu Narcotic Drug Rules, 1985 - Orders issued.

PROHIBITION AND EXCISE (XV) DEPARTMENT

G.O. Ms.No.243

Dated: 26.12.2000

Read:

- 1 G.O. Ms.No.1215, Prohibition and Excise Dept,
Dated 14.11.1985

Read also :

- 1 From the Government of India, Ministry of Finance, (Department of Revenue), New Delhi, Letter F.No.664/63/97-NC, dated 8.5.1998.
- 2 From the Director of Drug control, Chennai,
D.O.Lr.No.3567/D2/2/98, dated 24.6.98 & 3.3.2000.
- 3 From the Director of Medical and Rural Health Services, Chennai,
Letter Ref.No.55435/CP1/1/98, dated 5.5.1999.
- 4 From the Additional Secretary to Government of India, Ministry of Finance, New Delhi, D.O.Lr.F.No.664/22/99-NC1, dated 21.6.1999.
- 5 From the Commissioner of Prohibition and Excise, Chennai-5,
Letter No.C1/28149/99, dated 17.12.99 & 24.4.2000.
- 6 From the President, Indian Association of Palliative Care, Cochin,
Letter No.Nil, dated 16.12.1999.
- 7 From the Deputy Director (Clinical), Cancer Institute, Chennai-20.
Letter Ref.No.C1/DDC/014/2000-1, dated 19.4.2000.
- 8 From the Commissioner of Prohibition and Excise, Chennai-5.
Letter No.C1/28149/99, dated 4.5.2000 & 21.7.2000.

ORDER:

The Government of India, Ministry of Finance has stated that there was a Public Interest Litigation in the Delhi High Court recently on the issue of scarce availability of morphine to the needy cancer patients and the Honourable Court was assured that the complex procedure existing in various States which often denied morphine to terminally ill cancer patients would be reviewed by the

Government and procedure simplified. It was also stated that consequent on the above Public Interest Litigation, a number of States have suitably modified their Narcotic Drugs and Psychotropic Substances Rules. The Government of India has therefore requested this State Government to simplify the procedure and to identify the Recognised Medical Institutions through which medicines are being supplied to ensure easy availability of morphine drugs to cancer patients by making necessary amendments in the State Narcotic Drugs Rules suitably. Representations have also been received from Indian Association of Palliative Care and Cancer Institute, Adyar, Chennai about the difficulties experienced by them in procuring morphine tablets to cancer patients.

2. The problem of scarce availability of morphine drugs to needy cancer patients and the related issues were elaborately discussed in a highlevel meeting held on 28.4.2000 with the Commissioner of Prohibition and Excise, Superintendent of Police, Narcotic Intelligence Bureau, Director of Drugs Control, Director of Medical and Rural Health Services, Joint Director of Public Health and Preventive Medicines, the representatives of Indian Association of Palliative Care and the Representative of Cancer Institute, Adyar.

3. In pursuance of the decisions taken in the meeting, the Commissioner of Prohibition and Excise has sent necessary proposals to amend the Tamil Nadu Narcotic Drugs Rules, 1985 for prescribing the procedure to identify the Recognised Medical Institutions for being permitted by the Director of Drugs Control for possession and supply of 'Morphine' drugs to the needy cancer patients on the line of the suggestion of Government of India in this regard.

4. The Government after careful consideration of the proposals of the Commissioner of Prohibition and Excise have decided to accept the proposal to make necessary provisions in the Tamil Nadu Narcotic Drugs Rules, 1985 in this regard. It has also been decided to accept the comprehensive draft amendments suggested by the Commissioner of Prohibition and Excise with suitable modifications for making special provisions in the Tamil Nadu Narcotic Drugs Rules, 1985 for identifying and declaring the recognised Medical Institutions by the Director of Drugs Control for possession and use of morphine drugs for being supplied to the terminally ill cancer patients in Tamil Nadu and to issue necessary amendments, to the Rules in this regard. Accordingly the following amendments are issued to the Tamil Nadu Narcotic Drugs Rules, 1985.

5. The following Notification will be published in the Tamil Nadu Government Gazette:-

NOTIFICATION

In exercise of the powers conferred by section 10 read with section 78 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (Central Act 61 of 1985), the Governor of Tamil Nadu hereby makes the following amendments to the Tamil Nadu Narcotic Drugs Rules, 1985:-

AMENDMENTS

In the Said Rules,-

(1) in rule 2,-

(i) after clause (iv), the following clause shall be inserted, namely:-

“(IV-A) “Drugs Controller” means the Director of Drugs control appointed by the Government to have control on drugs in the State”;

(ii) after clause (xii), the following clause shall be inserted, namely:-

“(xii-A) “Morphine” includes any preparation containing morphine”;

(iii) after clause (xiv), the following clause shall be inserted, namely:-

“(xivA) “Recognised medical institution” means a hospital or Medical Institution recognised for the purpose under Chapter IX to these rules”;

(2) after Chapter VIII, the following Chapter shall be added, namely:-

“CHAPTER –IX”

MORPHINE

47. Recognition of medical institutions:-

(1) Every medical institution which intends to be recognised for the purpose under this chapter shall apply in Form ND/M1 to the Drugs Controller appointed by the Government, who shall convey his decision within three months on the receipt of the application.

(2) If it comes to the notice of the Drugs Controller that morphine obtained by the recognised medical institution is supplied for non-medical use or that any of the rules in this Chapter is not complied with, for reasons to be recorded in writing, the Drugs controller may revoke the recognition accorded under these rules.

48. **Duties of recognised medical institution** - Every recognised medical institution shall, -

(i) designate one or more qualified medical practitioner, who may prescribe morphine for medical purposes. When more than one qualified medical practitioner have been designated, one of them shall be designated as over-all in charge;

(ii) the designated medical practitioner or the over-all in charge, as the case maybe, shall, -

- (a) endeavour to ensure that the stock of morphine is adequate for patient needs;
- (b) maintain adequate security over stock of morphine;
- (c) maintain a record of all receipts and disbursements of morphine in Form ND/M2 and
- (d) ensure that estimates, and other relevant information required to be sent by the recognised medical institution under this Chapter are sent to the authorities concerned.

49. **Sending of estimates of annual requirement of morphine by the recognised medical institution.--**

Every recognised medical institution shall send their estimate of annual requirement of morphine in Form ND/M3 by the 30th November of the preceding year alongwith the name and address of the supplier from whom they intend to buy it to the Drugs-Controller.

50. **Approval of estimates by the Drugs Controller. --** On receipt of the estimate of annual requirement from the recognised medical institution, the Drugs Controller shall consider the annual requirement of morphine and if required, call for necessary clarifications. A reply on the estimate of the annual requirement accepting or rejecting such estimate shall be sent before the 21st of December of the preceding year. A copy of the communication shall be sent each to the supplier whose name has been given in the estimate, if the supplier is located in another State, the Drug-Controller of that State, the Drugs Controller General of India and the Narcotics Commissioner of India.

51. **Supplementary estimates.--** If the requirement of the recognised medical institution exceeds the annual estimate approved by the Drugs Controller, the recognised medical institution may send a supplementary estimates at any time to the Drugs Controller, which shall be considered and dealt with by the Drugs Controller in the same manner as in the case of annual estimates.

52. The provisions of these rules in other Chapters in respect of possession, transport, purchase, sale, import inter-state, export inter-state or use of manufactured drugs shall not apply to possession, Import or use of morphine in respect of a recognised medical institution. Import, possession or use of morphine in respect of a recognised medical institution shall be in accordance with the following provisions, namely.-

- (1) The recognized medical institution shall place orders for purchase to a manufacturer or supplier in Form ND/M4 alongwith a photocopy of the communication of the Drugs Controller in which the institution was recognised for the purposes of this Chapter and a copy of the communication of the Drugs Controller in which the approved estimates were conveyed. A copy of the order for purchase shall be sent to the Drugs Controller and the Narcotics Commissioner of India.
- (2) Any manufacturer or supplier shall send morphine to the recognized medical institution under this Chapter only on the basis of an order for purchase, received in Form ND/MS alongwith copies of recognition granted by the Drug Controller and the approved estimates communicated by the Drugs Controller. The manufacturer or supplier shall despatch the morphine consignment along with a consignment note in quintuplicate in ND/M5. Copies of the consignment note shall be sent by the manufacturer or supplier to the Drugs Controller of the State in which the manufacturer or supplier is located, the Drugs Controller of the State in which the recognized medical institution is located and the Narcotics Commissioner of India. He shall also keep a copy of the consignment note.
- (3) On receipt of the consignment, the recongnised medical institution shall enter the quantity received with date in all the copies of the consignment note, retain the original consignment note, send the duplicate to the supplier, triplicate to the Drugs Controller, the quadruplicate to the Drugs Controller of the State (in cases in which the consignment originated outside the State) in which the supplied is located and the quintuplicate to the Narcotics Commissioner of India.-

53. Maintenance of records.- All records generated under this Chapter shall be kept for a period of two years from the date of transaction which shall be open for inspection by the officers empowered by the Government under section 41 and 42 of the Act.

54. Inspection of stocks or morphine.- The stocks of morphine under the custody of a recognised medical institution shall be kept open for inspection by the Drugs Controller or any other officer subordinate to him or the officers of other Departments of the Government empowered under section 41 and 42 of the Act.

55. Appeals.- Any institution aggrieved by any decision or order passed by the Drugs Controller relating to recognition, revocation of recognition of any institution or estimates may, appeal to the Secretary to Government, Health and Family Welfare Department within ninety days from the date of receipt of the communication of such decision or order.

(3) in the Appendix, after Form ND/AC, the following shall be added, namely:-

FORM ND/M1

(see rule 47)

Application for grant of Recognition to Medical Institution

To
The Director of Drugs Control,
Chennai – 600 006.

- 1 Name of the Institution
and address
- 2 Name of the Head or
In-charge of the Institution
- 3 No. of persons employed:
 - (i) Doctors
 - (ii) Nursing Staff
 - (iii) Others
- 4 No. of patients treated during
the previous calendar year
 - (i) Inpatient
 - (ii) Outpatient
- 5 Whether the hospital has facilities
to treat cancer patients Yes/No
- 6 No. of cancer patients treated
During previous calendar year.

- (i) inpatient
 - (ii) outpatient
- 7 Name of the qualified medical Practitioner who would prescribe Morphine (If there are more than one qualified medical practitioner who would prescribe morphine, indicate the name of the medical practitioner who would be overall In-charge)
- 8 Whether the institution's recognition for the purpose was withdrawn earlier (if the recognition was withdrawn earlier the details are to be given) Yes/No

Station:
Date:

Signature of the Head/in-charge
of the institution with name

FORM ND/M2

(See rule -48)

Record of receipt, disbursement and balance of Morphine:

Date:

Quantity in hand at the beginning of the day	<u>Details of quantity received</u>				<u>Details of quantity disbursed</u>				Quantity in hand at the close of the day
	S.No	Quantity	From	consignment	S.No	Quantity	Name of	Name	
			Whom	note/bill			the person	of the	
			Received	of entry No.			and	Medical	
							address to	practitioner	
						whom	was who		
						disbursed	Prescribed		

Signature

Note:

1. This record is to be maintained on day to day basis and entries shall be made for each day the institution functions. Entries shall be completed for each day before the close of the day. The authorized Medical practitioner/in-charge or any person authorized by them shall initial after entry of each day with date. The pages of the register shall contain necessary number.
2. This record shall be retained for two years from the date of last entry.
3. This record shall be produced to the authorized officers whenever called upon during the course of their inspection.

(FORM ND/M3)

(see rule-49)

Estimate of annual requirement of Morphine

- (1) Name and address of the recognised medical institution
- (2) Period for which the estimate is submitted
- (3) Quantity estimated to be disbursed during the previous year.
- (4) Quantity estimated to be disbursed during the year for which estimate is submitted
- (5) Supplier who would supply the quantity

Sl.No.	Name and address of the supplier	Quantity
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- (6) If this is supplementary requirement, give details of annual requirement sent earlier and the reasons for giving a supplementary requirement.

Station:
Date :

(Signature of the Authorised
medical practitioner/ In-charge
with name)

(FORM ND/M4)

(see rule-52)

Orders for purchase

To

(Name and address of the supplier)

- 1 Name and address of the recognised medical Institution which places the order
- 2 Description of the quantity for which order is placed
- 3 Whether the institution has been recognised by the Drugs Controller
(A photocopy of the recognition is to accompany each order for purchase)
- 4 Whether this order is covered by the estimate approved by the Drugs Controller (A photocopy of the approved estimate is to accompany each order for purchase)
- 5 Details of other orders for purchase made during the year

Sl.No. Quantity
 To whom order was placed

Station:

Date :

(Signature of the person authorised
to place order with name and
Designation, if any.)

Note:-

1. A copy of this order shall be kept by the recognised medical Institution which places the order.
2. This shall be retained for two years from the date of transaction.

(FORM ND/M9)

(see rule-52)

CONSIGNMENT NOTE

To accompany a consignment of morphine

Date and time of dispatch
of the consignment.....

1. Name and address of consignor
2. Name and address of the consignee (recognized medical institution)
3. Description and quantity of the consignment:

No. of Packages Quantity
Gross Net

4. Mode of transport (Particulars of the transporter, Registration Number of the vehicles, RR, if the transport is by railways etc.)

Signature of the Consignor with date
(Name and designation, if any)

To be filled by consignee:-

5. Date and time of receipt by the consignee and his remarks
6. Quantity received by the consignee.

No. of Packages Quantity
Gross Net

Signature of the Consignor with date
(Name and designation, if any)

Note:-

1. This consignment note shall be serially numbered on annual basis.
2. The consignor should record a certificate on the cover page of each Book containing consignment notes indicating the number of pages contained in the consignment note-book.
3. The consignor should maintain a Register showing the details of the books of consignment note brought in use during the particular year.
4. Each consignment of morphine shall be accompanied by the consignment note in quintuplicate.

5. The consignment not shall be retained for a period of two years from the date of transaction.
6. The records referred to at items 2 to 5 above in this note shall be produced to the authorized officers whenever called upon during the course of their inspection.

(BY ORDER OF THE GOVERNOR)

SANTHA SHEELA NAIR
SECRETARY TO GOVERNMENT

To

The Works Manager,

Government Central Press, Chennai -79.

(for publication of the Notification in the next issue of the Tamil Nadu

Government Gazette and send 100 copies of the Notification to

Government)

The Secretary to Government of India,

Ministry of Finance, Department of Revenue, North Block, New Delhi-110 001.

The Commissioner of Prohibition and Excise, Chennai -5.

The Director of Drugs Control, No.259-261, Anna Salai, Chennai-6 (2 copies)

The Director General of Police, Chennai 4

The Inspector General of Police (Enforcement),

Swami Sivananda Salai, Chennai-5.

The Inspector General of Police, Crime (Special Investigation Team), Chennai-2.

The Superintendent of Police, NIB., CID., Chennai-2.

The Director of Medical Education, Chennai – 10.

The Director of Medicals & Rural Health Services,

Teynampet, Chennai-6.

The Director of Public Health and Preventive Medicine, Chennai-6.

The Director of Indian Medicine & Homeopathy, Chennai 106.

The Director, Tamil Nadu Forensic Science Lab., Chennai-4.

The Registrar, High Court, Chennai -104.

All Collectors.

All Superintendents of Police / Commissioners of Police, Chennai/

Madurai/Coimbatore/Salem/Trichirapalli and Tirunelveli.

Copy to:

The Law / Finance & Health and Family Welfare Departments, Chennai-9.

All Sections in Prohibition and Excise Department, Chennai-9.

The President,

Indian Association of Palliative Care Society, Medical College P.O.,

Calicut, Kerala, P.C.673008.

The Director,

Cancer Institute (WIA), Adyar, Chennai-20.

The Secretary to Chief Minister, Chief Minister's Office, Chennai-9

Sf/Sc

/Forwarded / By Order/

Section Officer