

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 a particular year.
4. Each consignment of morphine shall be accompanied by this consignment note in quintuplicate (i.e. five)
5. Each consignment note 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 authorised officers whenever called upon during the course of their inspection.

Explanatory Note

(This does not form part of the notification, but is intended to indicate its general purport.)

The All Indian Lawyers Forum for Civil Liberties have filed a public Interest litigation before the Honourable High Court of Delhi seeking the Court's intervention to issue appropriate directions to the concerned Authorities for making availability of morphine easier for cancer patients. In the light of the above the Government of India have taken up the matter with the State Government to issue necessary rules. The State Government have examined the matter in detail and is of the view that the rule on the subject has to be liberalised in order to alleviate the difficulties now being experienced by cancer patients.

The above notification is intended to achieve this object.

Government of Kerala
EkrL s{6a{
1999



Reg. No. KL/TV(N)/12
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GOVERNMENT OF KERALA

Taxes (G) Department

NOTIFICATION

G.O. (Ms.) No. 165/99/TD.

Dated, Thiruvananthapuram, 26th Nov 1999.

S.R.O.No. 972/99 – In exercise of the powers conferred by sections 10 and 78 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (Central Act 61 of 1985), the Government of Kerala hereby make the following rules further to amend the Kerala Narcotic Drugs and Psychotropic Substances Rules, 1985 issued under Notification No. G.O. (Ms.) No. 135/85/TD. dated 7th November, 1985 and published as S.R.O. No. 1514/85 in the Kerala Gazette Extraordinary No. 966 dated 8th November 1985, namely: -

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33/5377/99MC.

RULES

1. *Short title and commencement.* – (1) These rules may be called Kerala Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 1999.
(2) These rules shall come into force at once
2. *Amendment of the Rules.* – In the Kerala Narcotic Drugs and Psychotropic Substances Rules, 1985. –
 - (1) In rule 2, after ‘q’ the following clauses shall be added, namely : –
 - (r) “morphine” means any preparation containing morphine;
 - (s) “recognised medical institution” means an Hospital or Medical Institution recognised by the Drugs Controller for the purposes for chapter IV A,”
 - (2) [In corporation of new part: (1)] after the existing part IV, the following part shall be inserted, namely : –

PART IV A

Special provision regarding morphine:

- 57 A. *Recognition of medical Institutions.* – (1) Every medical institution which intends to be recognised for the purpose under this chapter shall apply in the format at Annexure I to the Drugs Controller appointed by the State Government who shall convey his decision within three months of the receipt of the application.

(2) If it comes to the notice of the Drugs Controller that morphine obtained by recognised institution was supplied for non-medical use or that any of the Rules under this Chapter is not complied with, for reasons to be recorded in writing and after hearing the party, the Drugs controller may revoke the recognition accorded under these rules.
- 57 B. *Duties of the recognised Medical Institution.* – Every recognised medical institution shall, –
 - (1) designate one or more qualified medical practitioner who may prescribe morphine for medical purposes. When more than one qualified medical practitioner have been designated so, one of them shall be designated as over –all in charge.

ANNEXURE – V

(See rule 57 F)

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 consignor i.e
Recognised 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 vehicle, RR., if the transport is by railways etc).

Signature of the Consignor with date (Name and designation)

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)

33/5377/99/MC.

ANNEXURE – IV

(See rule 57 F)

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 of purchase).
5. Details of other orders for purchase made during the year.

<i>Sl No.</i>	<i>Quantity</i>	<i>To whom order was placed</i>
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Station: _____ Signature of the person authorised to
Date: _____ place order with name and designation

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.

- (2) The designated medical practitioner or the over-all in charge, as the case may be 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 the format enclosed as Annexure II, and;
 - (d) ensure that estimates, and other relevant information required to be sent by the recognised medical institution under this chapter are sent to authorities concerned in time.

57 C. *Sending of estimates of requirement of morphine by the recognised medical institution.* – Every recognised medical institution shall send their annual requirement of morphine in the format at Annexure III by 30th November of the preceding year along with the name and address of the supplier from whom they intend to buy it, to the Drugs Controller.

57 D. *Approval of estimates by the Drugs Controller.* – The Drugs Controller of the State, who receive the annual requirement, shall consider it. A reply on approved estimates or rejection of the estimate shall be sent before 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 and to the Drugs Controller of the State/

57 E. *Supplementary estimates.* – If the requirements of the recognised medical institution exceeds the annual estimate approved by the Drugs Controller of the State the recognised medical institution may send a supplementary estimates at any time to the Drugs Controller which shall be considered and dealt with by him in the same manner as the annual estimates.

57 F. *Possession, transport purchase etc.* – 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, transport, purchase, sale, import inter-state, export inter-state or use of morphine in respect of a recognised medical institution, possession, transport, purchase, sale, import inter-state, export inter-state or use of morphine in respect of a recognised medical institution shall be in accordance with the following provisions:

(See rule 57 C)

ESTIMATE OF ANNUAL REQUIREMENT

1. Name and address of the recognised medical institution
2. Period for which the estimate is submitted
3. Quantity 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

<i>Sl. No.</i>	<i>Name and address of the supplier</i>	<i>Quantity</i>
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6. If there is a supplementary requirement, give details of annual requirements sent earlier and the reasons for giving a supplementary requirement.

Station :
Date

(Signature of the authorised medical practitioner / in-charge with name)

(a) The recognized medical institution shall place orders for purchase to a manufacturer/supplier in the format at Annexure IV along with a photocopy of the communication of the Drugs Controller vide which the institution was recognised for the purposes for the purposes of this chapter and a copy of the communication of the Drugs Controller vide which the approved estimates were conveyed. A copy of the order for purchase shall be sent to the Drugs Controller and the Narcotics Communication of India.

(b) Any manufacturer/Supplier shall send morphine to the recognised medical institution under this chapter only on the basis of an order for purchase received in the format at Annexure IV along with copies of recognition granted by the Drugs Controller and the approved estimates communicated by the drugs Controller. The manufacturer/supplier shall dispatch the morphine consignment along with a consignment note in quadruplicate in the format given in Annexure V. Copies of the consignment note shall be sent by the manufacturer/supplier is located, the Drugs Controller of the State in which the recognised medical institution is located and the Narcotics Commissioner of India. He shall also keep a copy of the consignment note.

(c) On receipt of the consignment, the recognised medical institution shall enter the quantity received with date in all the copies of the consignment note, retain the original consignment note, sent the duplicate to the supplier, triplicate to the Drugs Controller, the quadruplicate to the to the drugs Controller of State (in cases in which the consignment originated outside the State) in which the supplier is located and the quadruplicate to the Narcotic Commissioner of India.

57G. *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 State Government under Section 41 and 42 of the Narcotic Drugs and Psychotropic Substances Act, 1985.

57H. *Inspection of Stocks of morphine* – The stocks of morphine under the custody of a recognized medical institution shall be open for inspection by the Drugs controller or any other Officer subordinate by his.

57I. *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, Department of Health, Government secretariat, Thiruvananthapuram within ninety days from the date of communication of such decision or order.

ANNEXURE – I

(See rule 57 a)

1. Name of the Institution and Address :
2. Name of the Head/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. Out patient :
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. Out patient :
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) :

Station :
Date

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

ANNEXURE –II
(See rule 57 B)
RECORD OF RECEIPT DISBURSEMENT AND BALANCE OF MORPHINE

Date	Quantity in hand at the beginning of the day.		Details of Quantity received			Details of quantity disbursed			Quantity in hand at the close of the day
	Sl. No.	Quantity	From whom received	Consignment Note/Bill of Entry No.	Name of the persons and address to whom disbursed	Sl. No.	Quantity	Name of the Medical practitioner who 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 authorised medical practitioner/in-charge or any person authorised by them shall initial after entry of each day with date. The pages of the register shall contain necessary numbers.
2. This record shall be retained for two years from the date of last entry.
3. This record shall be produced to the authorised officers whenever called upon during the course of their inspection.