बी. एन. शर्मा
P. N. SHARMA, IAS
अपर सचिव एवं मु. स. अ.
ADDITIONAL SECRETARY & C. V. O

सत्यमेव जयते

D.O. No. N.11011/1/2014-NC-II
भारत सरकार
वित्त मंत्रालय
राजस्व विभाग
नॉर्थ ब्लाक, नई दिल्ली–११०००१
GOVERNMENT OF INDIA
MINISTRY OF FINANCE
DEPARTMENT OF REVENUE
NORTH BLOCK, NEW DELHI-110001

22nd July, 2016

Dear Sir,

As you are aware, 'opioids' like Morphine, is considered the best analgesic and is recommended by the World Health Organization (WHO) in cases of excruciating pain such as one suffered by terminally ill cancer patients. At least two-third of estimated 2.5 million cancer patient in the country would require opioids for pain relief.

2. However, the issue of adequate access to opioids for medical use has been a subject matter of concern in India. After reaching a peak of 573 kilograms in 1985, morphine use began to decrease. Between 1985 and 1997, morphine consumption decreased by 97%, reaching a low of 18 kilograms in 1997. In 1997, India's per capita consumption of morphine ranked among the lowest in the world (113th of 131 countries). During the same period, global consumption of morphine increased by 437%. Needless to say that in the present scenario aggressive action was required to address the issue.

3. The Central Government, vide notifications dated 05.05.2015, has notified six narcotic drugs as 'Essential Narcotic Drugs' - (i) Codeine, (ii) Dihydrocodeinone (commonly known as Hydrocodone), (iii) Dihydroxy Codeinone (commonly known as 'Oxy-codone and Dihydroxycodeinone), (iv) Fentanyl, (v) Methadone, and (vi) Morphine – and amended the Narcotic Drugs and Psychotropic Substances Rules, 1985 (NDPS Rules) wherein regulatory provisons relating to sale, purchase, possession, consumption, use, etc. of essential narcotic drugs have been simplified. For your ready reference, a summary of the major provisions is annexed herewith.

4. These new simplified provisions maintain a fine balance between the easy availability of the essential narcotic drugs for medical use and the required control to prevent their diversion for abuse. The concept of 'Recognized Medical Institution' has been introduced for stocking and dispensing essential narcotic drugs. **Such Recognized Medical Institutions will not require any additional approval or licence to stock essential narcotic drugs hitherto required under the rules made by the State Government. All hospitals, dispensaries, etc. run by Government, Municipal Corporation, Municipal Council, Zila Parishad shall be deemed Recognized Medical Institutions without seeking any additional approval.** Further, medical institutions in private sector can get themselves recognized by the State Government recognized medical institutions.

5. In the light of the above, I would request you to take following action urgently:-

a. aforesaid regulatory provisions may be brought to the knowledge of all enforcement agencies for being followed up scrupulously through appropriate directives, including amendment of State NDPS Rules, if required;

b. hospitals and dispensaries in the Government sector may be advised to keep adequate stock of essential narcotic drugs for their medical use;

c. hospitals and dispensaries in the private sector may be encouraged to get themselves recognized for stocking and dispensing essential narcotic drugs for medical use.

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6. You will no doubt agree with me that the above action will go a long way in augmenting the availability of essential narcotic drugs for mitigating the sufferings of the patients and treatment of opioid dependence.

Regards,

Yours sincerely,

Encl: As above.

(B.N. Sharma)

Chief Secretary / Administrator of all State Governments / Union Territories

Salient features of the regulations pertaining to Essential Narcotic Drugs (END) **Annexure**

The following are the essential features of the amendment relating to the Essential Narcotic Drug (END) –

(i) Requirement of multiple licences, such as possession licence, transport licence, etc. have been dispensed with in respect of ENDs.

(ii) For manufacture of essential narcotic drugs a license will be required from the Narcotics Commissioner. This is presently also true for all 'manufactured drugs' under the NDPS Act, 1985. However, for manufacture of preparations containing essential narcotic drugs (for example Morphine Tablets) it would be the state licensing authorities that would license such manufacture and not the Narcotics Commissioner. This is in keeping with the distribution of regulatory powers under Sections 9 and 10 of the NDPS Act.

(iii) The Rules provide for possession of essential narcotic drugs by different categories of persons. Thus a patient can possess ENDs in the quantities sold or dispensed to him in accordance with these rules. A registered medical practitioner may possess ENDs for use in his practices, but not for sale or distribution the quantities specified hereunder:

S.No.	Essential narcotic drug	Quantity
1.	Morphine	500 Milligram
2.	Codeine	2000 Milligram
3.	Oxycodone	250 Milligram
4.	Hydrocodone	320 Milligram
5.	Fentanyl	Two transdermal patches one each of 12.5 mcg/hr and 25 mcg/hr

The Controller of Drugs has powers to authorize a practitioner to possess ENDs in quantities larger than as specified in the above table.

(iv) As regards 'licensed chemist' and 'licensed dealer' any dealer or chemist who intends to stock or sell essential narcotic drugs will have to obtain a license from the appropriate agency in the State Government on exactly the lines of the other 'manufactured drugs'. Essentially therefore, the position which is in vogue for other 'manufactured drugs' so far as chemists and dealers are concerned will continue to apply in respect of ENDs also. The details of such provisions may please be seen in Rule 52 B.

(v) For transport of essential narcotic drugs there is provision of a consignment note, with suitable exceptions. There is also provision for transmission by posts, courier, rail or road.

(vi) The Rules have a complete chapter in respect of the special provisions pertaining to 'Recognized Medical Institutions'. Essentially these are such institutions that would be

recognized by the State Drug Controllers on the lines of the existing position in certain states who have adopted the model regulations which DOR had circulated in 1998. Such RMIs are required to designate one or more trained medical practitioner for prescribing and dispensing ENDs. The RMIs would also need to indicate to the state drug controller their yearly estimates of requirement of ENDs. They will also be required to keep records of ENDs and their dispersal. Other than these requirements, the RMI would not be required to follow any State Government licensing or regulatory provisions in respect of drugs.

(vii) The Rules also provide that all hospitals, dispensaries etc. run by Government, Municipal Corporation, Municipal Council, Zila parishad would be deemed to be recognized medical institutions and would therefore not be required to obtain separate recognition from the drug controller of the state provided they have at least one medical practitioner with the required training and follow all other provisions like maintenance of stock etc. as has been provided for private hospitals who are required to seek recognition from the drug controller.

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