राजस्थान सरकार
वित्त (आबकारी) विभाग

क्रमांक प.4(41)वित्त/आब/2001 जयपुर, दिनांकः जून, 2015

25 JUN 2015

आयुक्त,
आबकारी विभाग,
राजस्थान, उदयपुर

विषयः Amendments in the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985

महोदय,

उपरोक्त विषयान्तर्गत अपर सचिव एवं मु.स.अ, राजस्व विभाग, वित्त मन्त्रालय, भारत सरकार, नई दिल्ली द्वारा मुख्य सचिव महोदय, राजस्थान सरकार को प्रेषित अर्द्धशासकीय पत्र क्रमांक N.11011/1/2014-NC-II दिनांक 09.06.2015 की छायाप्रति पत्र के साथ संलग्न कर निर्देशानुसार आवश्यक कार्यवाही हेतु प्रेषित है।

संलग्नः उपरोक्तानुसार

भवदीय,

(हृदयेश कुमार जुनेजा)
संयुक्त शासन सचिव

प्रतिलिपि–

1. प्रमुख शासन सचिव, चिकित्सा एवं स्वास्थ्य विभाग को प्राप्त पत्र की प्रति संलग्न कर आवश्यक कार्यवाही हेतु प्रेषित है।
2. प्रमुख शासन सचिव, चिकित्सा शिक्षा विभाग प्राप्त पत्र की प्रति संलग्न कर आवश्यक कार्यवाही हेतु प्रेषित है।
3. निजी सचिव, मुख्य सचिव, राजस्थान, जयपुर को आपकी डायरी संख्या 814323/15/सीएस/ दिनांक 15.06.2015 के संदर्भ में सूचनार्थ प्रेषित है।

संयुक्त शासन सचिव

कमरा नं. 4120 व 5125 मुख्य भवन, शासन सचिवालय, जयपुर–302005
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रश्मि वर्मा
RASHMI VERMA, IAS
अपर सचिव एवं मु. स. अ.
ADDITIONAL SECRETARY & C. V. O.

सत्यमेव जयते

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

PSF

(C. S. Rajan)
Chief Secretary

मुख्य सचिव कार्यालय
राजस्थान, जयपुर
प्राप्ति संख्या 814323/15/(C) वित्त (आ...)
दिनांक 15-06-15

D.O. No. N.11011/1/2014-NC-II
Dated June, 2015

शासन सचिवालय, जयपुर
डायरी क्र. 4185
दिनांक 16 JUN 2015

Dear Shri Rajan,

As you are aware, certain amendments were effected in the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 in 2014, which were aimed at removing the regulatory barriers which are perceived as hindrances in adequate access to morphine and other opioids for genuine medical needs such as pain relief and palliative care. Essentially, the amendments provide for notification of certain narcotic drugs, used for medical purposes including that of pain relief, as 'essential narcotic drugs', by the Central Government, the complete powers of regulation in respect of which shall vest with the Central Government, thus paving the way for their uniform regulation throughout the country.

2. In exercise of these powers, the Central Government has issued the following notification on 5th May 2015:

(i) S.O. 1181(E) notifying 6 narcotic drugs namely, (i) Codeine, (ii) Dihydrocodeinone (commonly known as Hydrocodone), (iii) Dihydroxy Codeinone (commonly known as 'Oxycodone and Dihydroxycodeinone), (iv) Fentanyl, (v) Methadone, and (vi) Morphine as 'Essential Narcotic Drugs', and

(ii) G.S.R. 359 (E) further amending the Narcotic Drugs and Psychotropic Substances (NDPS) Rules, 1985 to incorporate two new chapters relating to sale, purchase, possession, consumption, use, etc. of essential narcotic drugs.

3. The aforesaid notifications are available on the website of the Department of Revenue http://dor.gov.in/. I would request that the provisions of both these notifications may be gone through in detail and may be circulated to the relevant authorities involved with drug control in your State including the State Licensing agencies, as it would be noted that the implementation of several provisions of the new regulations is to be done through such agencies of the State. Proper awareness and publicity of the new regulations therefore needs to be ensured.

4. For your ready reference, a summary of the major provisions is annexed herewith.

5. It is also intended to organize a National workshop for sensitization of the State Drug control agencies and other stakeholders such as manufacturers and the palliative care community shortly, the details of which will be provided to you in due course with the request for sending suitable representatives from the State.

With regards,

Yours sincerely,

(Rashmi Verma)
9.6.15

Encl: As above.

Shri C.S. Rajan,
Chief Secretary,
Government of Rajasthan,
Secretariat, Jaipur-302005.

वित्त विभाग प्राप्ति संख्या 5411
16 JUN 2015

Annexure

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

The following would be the essential features of the amendment relating to the Essential Narcotic Drugs (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) By definition the 'Registered medical practitioner' who can prescribe and possess essential narcotic drug is one who has undergone training in pain relief and palliative care or training on opioid substitution therapy depending on whether he shall be treating patents for pain or for drug dependence.

(v) 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.

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(vi) 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.

(vii) 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.

(viii) The Rules also provide that all hospitals, dispensaries etc. run by Government, Municipal Corporation, Municipal Council, Zila parishad would be deemed to be recognized medial institutes 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.

(ix) **A transition period of 180 days (six months) has been provided** for obtaining licence under the new rules to sell essential narcotic drugs by licenced chemist / licenced dealer and also to seek recognition as Recognized Medical Institution.

क्रमांक : डीसी/A-II/NDPS/2015/533 दिनांक :24/8/2015

प्रतिलिपिः– प्रभारी, सर्वर रूम, मुख्यालय को भेजकर लेख है कि कृपया पत्र को औषधि नियंत्रण संगठन के पोर्टल पर प्रदर्शित करें एवं समस्त सहायक औषधि नियंत्रक तथा समस्त औषधि नियंत्रण अधिकारियों को ई–मेल भी करें।

24/8/15

(अजय कुमार जैन)
औषधि नियंत्रक
राजस्थान, जयपुर