

**Amendment of NDPS Act 2014 - Frequently asked questions**

**1. What is the NDPS Act about?**

This is the Narcotics and Psychotropic Substances Act made in 1985, that governs control and availability of groups of drugs called “narcotics” like Morphine and “psychotropics” like Amphetamine which have medical value. The scope of the Act did not adequately address the accessibility and availability issues of these drugs for medical treatment of patients in pain.

**2. What exactly are “opioids” and “narcotics”?**

Opioids are derivatives of opium like morphine and similar synthetic substances like Fentanyl. They are most helpful in treating severe pain conditions. When used correctly, they relieve pain so that the person can get back to normal activities. The term “narcotic” is used to mean “opioid” in our NDPS act.

**3. Why was the earlier Act of 1985 inadequate?**

Patients with severe pain in India are not able to get opioid medicines for pain relief because the state NDPS Rules make it difficult for hospitals to store and dispense opioids. Hospitals have to obtain licences for stocking, import, export, transport etc, each license requiring concurrence from different departments [Excise, Drugs Control, Health administration]. These licenses need to be valid at the same time, though often the validity period of a license is as short as a month. By the time the institution gets a second licence, often the first would have expired validity.

Most institutions solve this problem by not stocking these medicines at all to avoid legal hassles. This includes even medical colleges, and hence generations of doctors pass out, who do not have any experience of using this medicine.

The overall impact is denial of pain relief to millions of people in India.

**4. Was any action taken in the past to solve this problem?**

Joint action taken by palliative care activists in collaboration with Mr David Joranson of Pain and Policy Studies Group (PPSG) resulted in an instruction by the Department of

Revenue of Government of India to simplify state rules in 1998. Persistent work with state governments resulted in simplification of rules in 16 states over 15 years.

A Public interest litigation was filed in 2007 by The Indian Association of Palliative Care<sup>1</sup> [IAPC] along with Ms Poonam Bagai<sup>2</sup> and Dr Ravi Ghooi<sup>3</sup> pleading for adequate access to pain relief for cancer patients in the country. This case is presently with the Supreme Court awaiting final hearing.

The opioid availability committee of IAPC and Pallium India<sup>4</sup>, in collaboration with Lawyer's collective<sup>5</sup> filed representations with the Department of Revenue, Ministry of Finance and the Standing Committee on Finance [June 2012] with regard to necessary amendments required. This has been scrutinized, analysed and incorporated in the NDPS (Amendment) Bill 2011, which was finally passed by Lok Sabha on 20th and by Rajya Sabha on the 21st of February 2014.

The amendment is aimed at ensuring availability of Essential opioid medicines for medical use for needy patients.

#### **5. What are the important provisions of the amendment?**

There will be a uniform national policy on these few selected medicines and the power to amend the rules will be vested with the Government of India.

- a. Currently, each state has its own regulations which vary from state to state. The amendment will make them uniform for all states and union territories.
- b. The power to amend the rules of Essential Narcotic Drugs (Morphine, Fentanyl and Methadone) will be vested with Central Government, ensuring uniformity.
- c. Each institution will require only a single order approving them as a Recognized Medical Institution (RMI) instead of the current system of 4-5 different licenses.

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<sup>1</sup> The national association for Palliative Care.

<sup>2</sup> A cancer survivor, vice-chair of Pallium India and chairperson of Cankids..Kidscan.

<sup>3</sup> A pharmacologist who had got a favorable verdict earlier from the High Court of Delhi asking for morphine for his mother with cancer.

<sup>4</sup> A charitable trust working to increase access to pain relief and palliative care all over India.

<sup>5</sup> An NGO working in this area.

- d. In each state, instead of multiple agencies being involved in the process of licensing, there will be only one – the drugs controller, thus eliminating the interdepartmental red tape.
- e. The overall expected impact would be improved availability of pain medications for use within hospitals from where patients with severe pain can access them.

**6. With the amendment, will the process of narcotics control get transferred from the States to the Central Government?**

No. The licensing and monitoring will continue to be done by the State Drugs Controller.

**7. Will the amendment increase the chance of diversion of the opioid medicines to illicit channels thus increasing addiction among our population?**

Emphatically, **No**. Enough control measures have been put in the amendment of the Act to prevent such a consequence. The amendment brings in the principle of balance, that is, while preventing diversion and abuse, availability of opioids for pain relief is permitted.

**10. So, can we expect immediate access to pain relief for all who need it?**

Unfortunately, no. The amendment will come into force when the President of India signs the document, but for it to cause change there are several additional requirements.

a. Standard operating procedures (which have already been drawn up) will have to be sent by Department of Revenue to state governments.

b. We shall have to work at the state level to ensure implementation of the amended Act with no cumbersome procedures brought in.

c. We shall have to work through Medical and Nursing Colleges to ensure that assessment and management of pain is taught to them and that in-service training is given to professionals.

d. We shall need to work with state National Health Mission and Health authorities for integration of palliative care in health care as envisaged in the National Program for Palliative Care<sup>i</sup> and to ensure submission of "program implementation plan (PIP) to Ministry of Health of Government of India."<sup>ii</sup>

<sup>i</sup> [http://palliumindia.org/cms/wp-content/uploads/2014/01/National-Palliative-Care-Strategy-Nov\\_2012.pdf](http://palliumindia.org/cms/wp-content/uploads/2014/01/National-Palliative-Care-Strategy-Nov_2012.pdf)

<sup>ii</sup> <http://palliumindia.org/cms/wp-content/uploads/2014/01/Model-PIP-under-NPPC-MOH-Delhi.pdf>