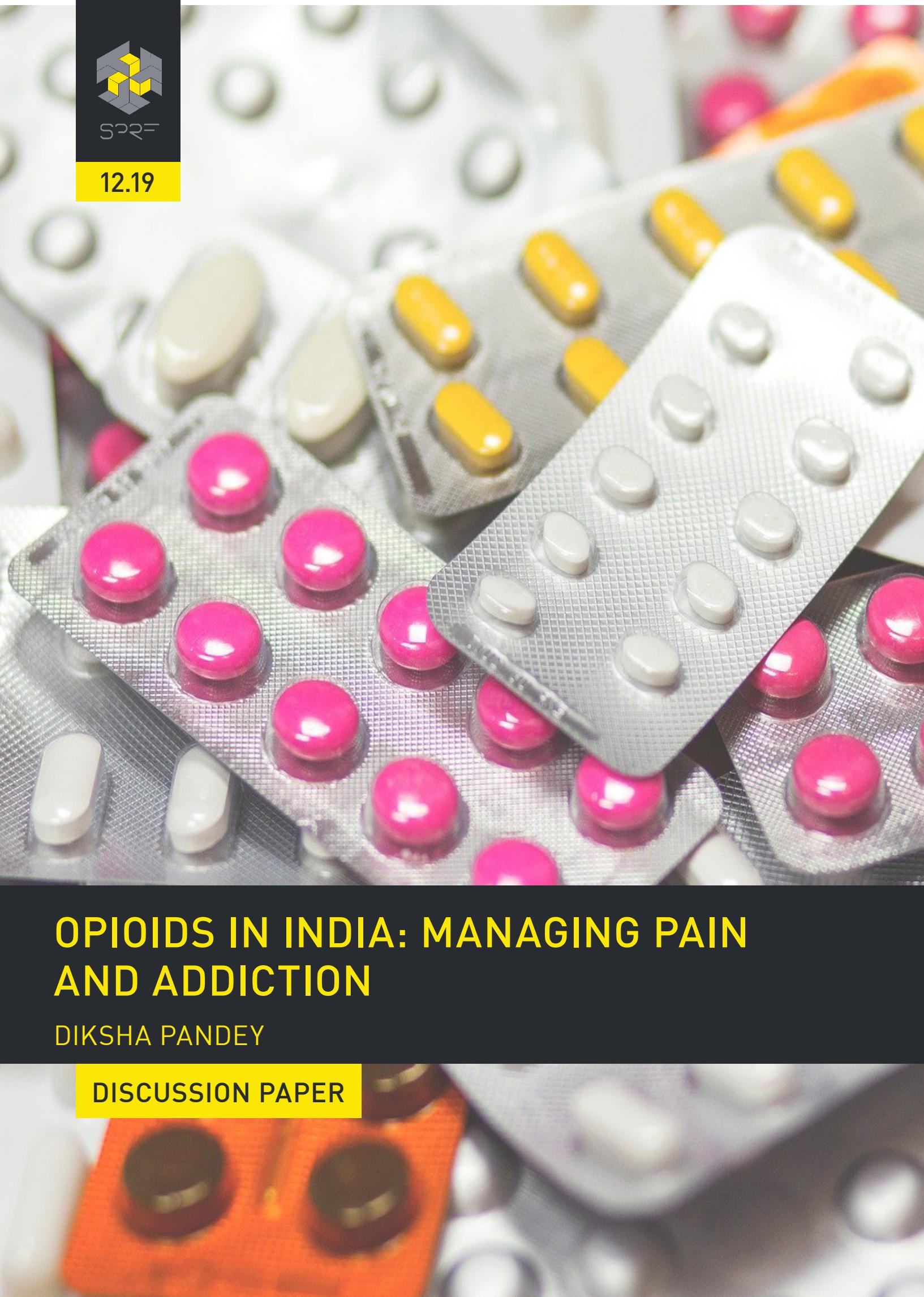




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OPIOIDS IN INDIA: MANAGING PAIN AND ADDICTION

DIKSHA PANDEY

DISCUSSION PAPER

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ABSTRACT

Over the years, India has emerged as a major producer and exporter of opium. However, only a small percentage of the total domestic cultivation of opium is utilized to meet the medical needs of patients in India, an issue which lies at the core of the opioid paradox facing the country. This paper explores the delicate balance between ensuring availability of and access to opioids for medical usage, primarily for pain relief, and regulating their diversion for illicit trade, consumption and abuse.

PRODUCTION AND CONSUMPTION OF OPIOIDS IN INDIA

Being one of the few countries in the world where the cultivation of opium poppy for medicinal and scientific purposes is legal, India is a top producer of opium for the legal medical market globally.¹ In 2017, India accounted for 98.4% of the total opium production in the world. In the same year, India was also the only licit exporter of raw opium, with 91.4% of all global exports coming from India (International Narcotics Control Board 2018: 24).

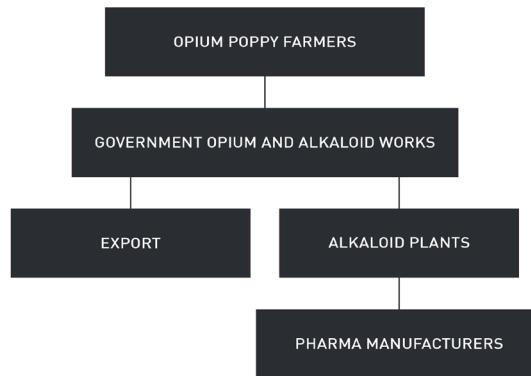
Within India, licensed opium cultivation is seen in the states of Madhya Pradesh, Rajasthan and Uttar Pradesh, albeit under strict governmental supervision² (Department of Revenue n.d.). Poppy farmers working on notified tracts in these states are required to tender their entire produce to the Central Bureau of Narcotics, which transfers it to Government Opium and Alkaloid Works (GOAWs) situated at Neemuch, Madhya Pradesh and Ghazipur, Uttar Pradesh. The opium factories under these GOAWs dry the opium for export and for use in alkaloid³ plants, which further sell them to pharmaceutical manufacturers.

1. As per information collated from multiple sources, eleven countries apart from India, which are, Australia, Austria, France, China, Hungary, the Netherlands, Poland, Slovenia, Spain, Turkey and Czech Republic, cultivate opium poppy legally (Department of Commerce 2000; Narcotics Control Bureau 2011: 12). Illicit production, however, is seen in over 50 countries (United Nations Office on Drugs and Crime 2016: 26).

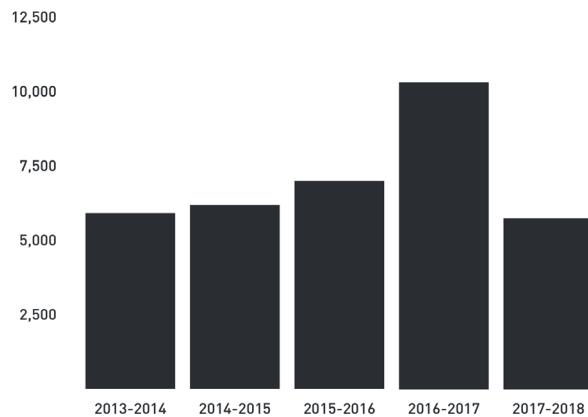
2. However, during 2017, illicit cultivation of opium poppy was found in the states of West Bengal, Arunachal Pradesh, Manipur, Uttarakhand, Jharkhand, Bihar, Jammu & Kashmir, Maharashtra and Himachal Pradesh (Narcotics Control Bureau 2017: 26).

3. Alkaloids are naturally occurring bases. The pharmacologically active principles of opium reside in its alkaloids. Well-known alkaloids include morphine and nicotine.

PRODUCTION OF OPIOIDS IN INDIA

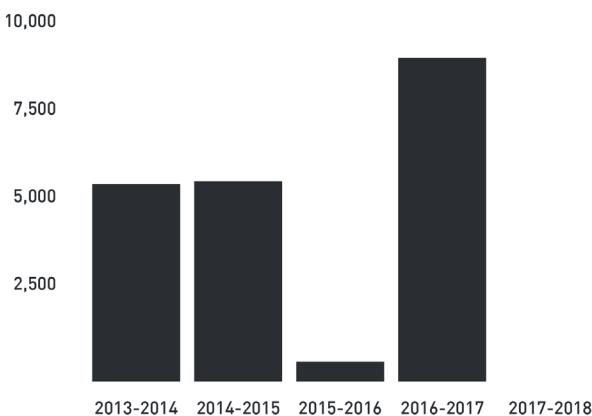


AREA LICENSED FOR OPIUM POPPY CULTIVATION
(FIGURES IN HECTARES)



SOURCE: CENTRAL NARCOTICS BUREAU

AREA HARVESTED FOR OPIUM POPPY CULTIVATION
(FIGURES IN HECTARES)



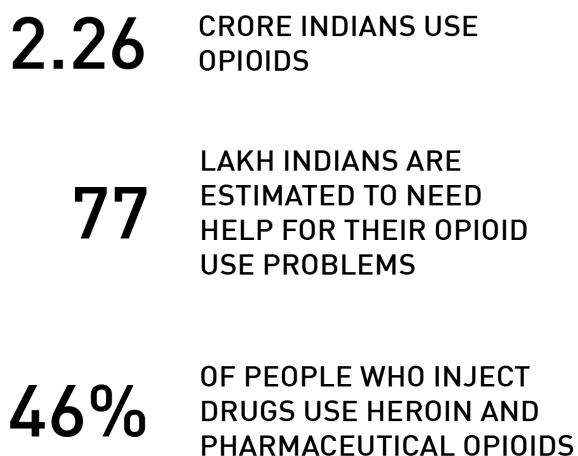
SOURCE: CENTRAL NARCOTICS BUREAU
DATA FOR 2017-2018 NA

India is also the only country authorised by the United Nations Single Convention on Narcotic Drugs of 1961 to legally produce opium gum, an extract containing several indispensable, naturally-occurring alkaloids such as morphine and codeine¹ (Department of Revenue n.d.). Opium farmers are required to turn over a fixed amount of this extract (known as Minimum Qualifying Yield) to the Government works at Ghazipur, Uttar Pradesh, and Neemuch, Madhya Pradesh, failing which the renewal of their licenses is denied.

It has been reported that farmers are paid INR 1,800 per kilogram of harvested opium gum by the government (Bera 2017). The price for the same, if sold illegally in a ‘black/grey market’, ranges between INR 60,000 and INR 1,20,000 (*Ibid.*). This stark discrepancy in prices is a major factor driving heirloom poppy license holders to divert their produce towards illegal trade and consumption.

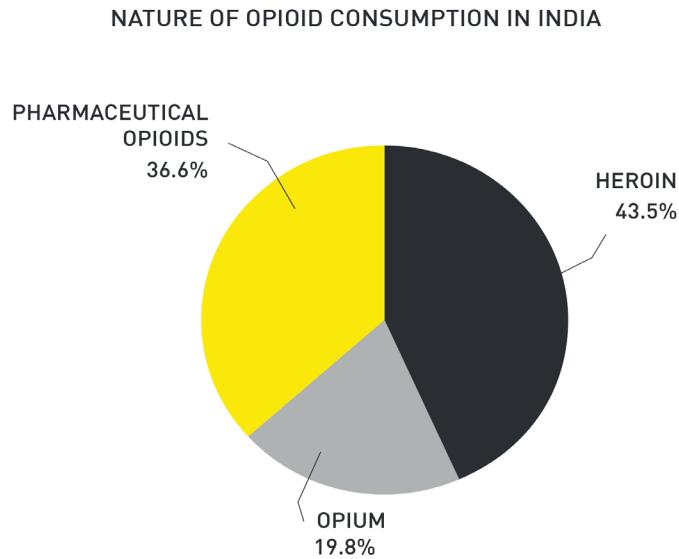
Illicit use of pharmaceutical drugs is widespread in India, with cases of abuse reported in all the states (Narcotics Bureau of India 2017: 39). India has thrice the global average prevalence of illicit opiate consumption (Ministry of Social Justice and Empowerment 2019: 4). After alcohol and cannabis, opioids, including opium and its variants (such as poppy husk, also known as doda or phukki²), heroin (including its impure form called smack or brown sugar) and pharmaceutical opioids are the most commonly used substances in India (Ministry of Social Justice and Empowerment 2019: 2).

OPIOIDS IN INDIA



SOURCE: AIIMS 2019

1. Manufacture of the alkaloid diacetylmorphine (commonly known as heroin), however, is completely prohibited.
 2. Until 2015, poppy farmers were also allowed to sell poppy husk or doda chura, which is known to be mildly narcotic. However, a ban was imposed on its sale following reports of consumption of husk worsening the addiction problem in Punjab. Farmers are now required to burn the husk. Alternatively, the Government in some instances has also bought all the husk directly from farmers to prevent its misuse. (Datta 2018)



SOURCE: AIIMS 2019

DISTRIBUTION AND ACCESS TO OPIOIDS: DRUG LAWS IN INDIA

Such an over-consumption of opioids, leading to addiction, is made possible, in part, due to their unencumbered sales as over-the-counter (OTC) drugs¹. India is yet to notify under the law a clear definition of OTC drugs, as well as compile a list of notified OTC drugs. Furthermore, there is an absence of a strict policy framework overlooking distribution, marketing and consumption of OTC drugs. For example, the Drugs & Cosmetics Act lists all drugs available to an Indian consumer under different Schedules to determine their regulatory status. Drugs under Schedule H, H1 and X cannot be sold without a doctor's prescription. Despite this, H1 Scheduled opioids such as Tramadol² are sold as an OTC drug across the country. In fact, India is the biggest supplier of Tramadol globally. Tramadol has been a major source of opioid addiction in the United States, the Middle East, and Africa, to the extent that Tramadol deaths have outnumbered heroin deaths (Tecimer 2018).

Last year, the Government of India acknowledged that Tramadol addiction in particular is rising among the Indian population (Tecimer 2018). Reports of abuse in Punjab and illicit Indian Tramadol traced in regions of Nigeria controlled by Boko Haram militants further compelled the authorities³ to declare it a psychotropic substance, with its sales being monitored by the Narcotics Control Bureau (NCB).

While Tramadol can now only be obtained by prescription, freely operating black markets continue to complicate the situation.

1. Over-the-counter (OTC) drugs are medications that can be purchased without a prescription from a healthcare provider. These drugs have been deemed safe and effective for use when taken in specified doses for relief from allergies, common cold, cough and flu such as paracetamol and ibuprofen. In contrast, prescription drugs are dispensed by pharmacists only at the request of a physician's prescription. Both prescription and OTC drugs are misused.

2. Tramadol is an opioid pain medication used to treat moderate to moderately severe pain.

3. The notification was issued by the Department of Revenue, Ministry of Finance.

The opioid problem facing the country, as is evident from above, is deeply rooted in the legal framework that governs the supply and distribution of drugs and narcotics in India. While cultivation and use of opium has been known to be prevalent in India since the 10th century, it was only under the British Empire that its cultivation turned into an organized, commercial enterprise. Nationalist leaders and provincial governments during India's independence movement were critical of the Empire's drug policy and wanted to strengthen control over drugs derived from poppy by heavily regulating its cultivation and processing. This prohibitionist sentiment continued post-independence.

At the peak of the United States' worldwide campaign against drugs in the 1980s, India passed the Narcotic Drugs and Psychotropic Substances Act of 1985, followed by the Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act in 1988⁴. In the face of increasing instances of trafficking and abuse of opioid analgesics, both the laws prescribed stringent measures, including a 10-year mandatory minimum prison term for violations involving narcotic drugs. As a consequence of this tough legal attitude towards consumption of opium, India exported much of its opioid production in the form of controlled and prescription drugs (International Narcotics Control Board 2018: 24).

However, another unintended consequence of the same has been the negative impact on the general availability of pain medications across the country. Opioids are the most common drugs of choice for relieving acute pain in terms of both diminishing the perception of pain as well as increasing tolerance of pain.

In the period following the introduction of these laws, use of morphine for medical purposes in India dropped by a staggering 97 per cent, meeting only 4% of the domestic demand (Cleary et al. 2013). To put this in perspective, while India has only 43 milligrams of morphine available per patient in need, Canada, in contrast, has 68,194 milligrams available per patient, over 3000% of what is the demand (Knaul et al. 2017). Similarly, despite being the biggest producer of legal opium in the world, as mentioned previously, India imports the alkaloid codeine, used in cough syrups, to cater to the total domestic requirement (Rajagopal 2019; Department of Revenue n.d.).

Even after the 2014 amendment, 70 per cent of the country's population is still not getting opioids for their pain management (Gorman 2019). No more than 2 per cent of Indians have access to palliative care (Shelar 2018). Experts have often commented that the nature of the regulatory framework is such that it has been easier to obtain heroin, for example, for recreational purposes, when compared to accessing a prescribed opioid medicine (Gorman 2019). The repercussions on the delivery of patient care services as well as the impact on the quality of life of patients across the country have been drastic.

4. These domestic legislations also gave effect to the three United Nations drug conventions – the 1961 Single Convention on Narcotic Drugs (1961 Convention), the 1971 Convention on Psychotropic Substances (1971 Convention) and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention).

PROFITING FROM PAIN: A LOOK AT THE PAIN MANAGEMENT INDUSTRY IN INDIA

Since then, following the work of lobbyists and palliative care¹ specialists, the NDPS Act has been amended three times, in 1988, 2001, in 2014. Following the 2014 amendment, the government released a list of six ‘essential narcotic drugs’ including codeine, fentanyl, hydrocodone, methadone, morphine, and oxycodone. With the creation of this new class of narcotics, the government acknowledged, for the first time, not just the medical usage of opioids, but also its responsibility to make these opioids available to the general public.

India’s post-colonial journey towards modernity is rooted in the broadening of public delivery of welfare services. In a country where, traditionally, pain remained untreated, this change in the socio-cultural perception of pain points towards the rise of India’s middle class as well as their aspirations for a better quality of life. As pain is increasingly being seen as a disease and not merely a symptom, opioids are also being seen as a necessity and not merely an indulgence (Varney 2019).

As prescription opioid laws are being loosened, not only are opium-derived painkillers starting to populate pharmacies, pain management using opioid pharmaceuticals has come forth as a steadily growing cash-intensive industry. All major hospitals and healthcare centers across the country have set up dedicated pain management sections with pain specialists, and standalone for-profit pain clinics have come up in both Tier-1 and Tier-2 cities. As per the latest information available, India is estimated to have about 30 to 40 pain clinics already, making over 200 crores in business every year (Jayakumar 2014).

However, further profusion of this industry needs to happen under proper oversight. Pain medicine is a young specialty and as a result, is fairly unorganized. Despite an increasing demand for pain treatment, there is a dearth of trained pain specialists. Only about 30 pain physicians in India are certified by the World Institute of Pain (Jayakumar 2014). While in the United States, a two-year postdoctoral study and a certification by the American Board for Pain Management is a prerequisite to practise pain management, there are no government certified courses in India for aspiring pain specialists (Jayakumar 2014).

The movement for deregulation of opioids with the aim of ensuring access and availability of opioids for medical and scientific use has been co-opted by the pharmaceutical industry to further their profit-making motives. Similar to their role in the opioid epidemic in the United States, multinational pharmaceutical companies are aggressively marketing opioids in India, without cautioning the consumers, having discovered a new market for pain of 1.3 billion people. For instance, when in 2018 the Government placed stricter restrictions on Tramadol, as discussed earlier in this paper, pharmaceutical companies began funding research, to be circulated in all leading national medical journals, speaking to the negative impact of regulating Tramadol on pain care services in India (Varney 2019).

1. Palliative care is focused on pain relief and does not address the medical conditions causing the pain.

As a result, local markets in India are flooded with synthetic opioids, some almost 50 times more potent than heroin, in forms of injections and patches as well as oral (Varney 2019; Centers for Disease Control and Prevention n.d.).

Alongside the problem of regulating pharmaceutical retail, proper dispensing of opioids-based medicines is also an area of concern. Physicians have become relatively comfortable with the idea of treating their patients' pain with previously controlled substances, with the threat of prosecution no longer hanging over their heads. However, unsupervised over-prescription of opioids directly heightens the risk of addiction or over-prescription. The phenomenon of over-prescription of opioids is rooted in the structure of our healthcare system. Doctors in private practice who can benefit financially by increasing the volume of patients they see by ensuring patient satisfaction have a clear incentive to over-prescribe pain medication. The lack of proper training for pain specialists, as mentioned before, exacerbates the problem.

Further, owing to doctor-patient confidentiality and lack of coordination between state health departments and between the health and narcotics department, consumers have the scope to stock numerous opioid prescriptions in excess and sell it in the black markets with a decent profit margin.

However, many doctors justify their decision of agreeing to the demands of patients for recurring prescriptions on moral grounds, citing their responsibility of providing relief to a person in pain. The problem is further compounded by the fact that pain can't be objectively quantified or measured, making it difficult to ascertain if a patient is fraudulently seeking opioids or is in fact in real need. It is also impossible to fix the necessary dosage to treat pain from a specific injury or illness, making it difficult to deny patients more pain medication when they ask for it. The only pragmatic way to intervene then is to regulate the profit-driven practices of opioid manufacturers.

WAY FORWARD

Opioid misuse and the epidemic of overdoses can quickly become a hard to manage public health crisis, as seen in the United States. The most immediate challenge facing India is to fight the widespread perception that opioids can only be addictive when their usage is recreational in nature, implying that their usage for treating pain can have no harmful effects. Simultaneously, India also needs to fight 'opiophobia', based on exaggerated claims of opioid risks, acting as a barrier to palliative care.

While it is generally believed that the Indian Government has been successful in regulating the production of opium, the need to increasingly privatize the process is emergent. The only two government opioid works, mentioned earlier in this paper, are often shut down temporarily, failing to secure environmental clearances (Singh 2017). Not only does this drive up the prices of otherwise cheap palliative care drugs, poor infrastructural status of these century-old factories also limit the scope for India to dominate the global legal narcotics trade. It is due to these considerations that recently, the government has allowed private manufacturers to obtain licenses for production of alkaloids from home grown opium (Datta 2018). India occupies a vulnerable geographical position, sandwiched between the 'Golden Crescent' and the 'Golden Triangle', major opium producing regions of South West and South East Asia respectively. Several trafficking routes pass through India, compounding not only the problem of illicit consumption of opium derivatives due to diversion, but also diversion of licit opium produce to illicit international drug markets.

However, no legal interventions can curtail the economic motives that drive in illegal trade in narcotics and drug markets.

Hence, the focus within the legal system should be to achieve the delicate balance between ensuring availability of opioids for medical use and preventing their misuse. The first step towards this will be to accurately estimate the medical requirement of opioids in India and also measure the levels of consumption.

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