INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

Regulatory Requirements, Clinical Trials, and Licensing Aspects of Fentanyl in India

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ARTICLE INFO

Published: 22 Jun 2026
Keywords:
Fentanyl, NDPS Act, CDSCO, Clinical Trials, Opioid Regulation, Narcotic Drugs, India
DOI:
10.5281/zenodo.20806345

ABSTRACT

Fentanyl is a highly potent synthetic opioid used for severe pain management, anesthesia, and palliative care. Due to its high abuse potential and risk of addiction, strict regulations are implemented in India under the NDPS Act, Drugs and Cosmetics Act, and New Drugs and Clinical Trials Rules, 2019. Regulatory authorities such as CDSCO and DCGI monitor clinical trials, licensing, manufacturing, storage, and distribution of fentanyl. This review highlights the regulatory framework, clinical trial approval process, licensing system, and challenges associated with fentanyl regulation in India.

INTRODUCTION

Fentanyl is a synthetic opioid belonging to the phenylpiperidine class of narcotic analgesics. It is considered one of the most potent opioid drugs used in clinical practice and is estimated to be nearly 50–100 times more powerful than morphine. Because of its rapid onset of action and strong analgesic properties, fentanyl is extensively utilized in severe pain management, cancer therapy, surgical anesthesia, and palliative care. (10,11)

The drug is available in several dosage forms such as injections, transdermal patches, buccal tablets, and lozenges. Although fentanyl has major therapeutic benefits, its high potency significantly increases the risk of respiratory depression, dependence, overdose, and abuse. Therefore, strict monitoring and legal control are essential for its safe medical use. (10)

In recent years, concerns regarding opioid misuse and illegal trafficking have increased globally. India has implemented a comprehensive dual regulatory framework to control fentanyl through narcotic laws and pharmaceutical regulations. The NDPS Act mainly focuses on prevention of abuse, illegal possession, and trafficking, while the Drugs

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

and Cosmetics Act ensures quality, safety, efficacy, and manufacturing standards. This combination helps maintain a balance between medical accessibility and prevention of misuse. (1,2,4)

2. SEARCH METHODOLOGY

The information included in this review article was collected from various authentic scientific, regulatory, and academic sources related to fentanyl regulation and narcotic drug control in India. Major information for this review was obtained from Indian narcotic drug laws, pharmaceutical regulatory policies, clinical trial regulations, official drug control guidelines, healthcare organization reports, academic references, and scientific publications related to fentanyl regulation and opioid safety.

Relevant literature was searched using keywords such as "Fentanyl regulation in India," "NDPS Act," "Opioid regulation," "Clinical trial approval process," "Fentanyl licensing," "CDSCO guidelines," and "Narcotic drug control." Scientific articles, government notifications, and regulatory documents published between 2010 and 2025 were carefully reviewed and analyzed.

3. LITERATURE REVIEW

Several national and international studies have highlighted the medical importance as well as the regulatory concerns associated with fentanyl use. Fentanyl is widely recognized for its strong analgesic activity and rapid onset of action, particularly in severe pain management, cancer therapy, anesthesia, and palliative care.

The World Health Organization (WHO) has recommended balanced opioid policies to ensure availability of pain-relieving medicines while preventing misuse, addiction, and illegal trafficking. WHO guidelines also stress the importance of rational prescribing practices, pharmacovigilance monitoring, and patient safety during opioid therapy.

Several studies have reported that fentanyl misuse and overdose cases have increased globally because of illegal diversion and uncontrolled opioid distribution. These observations have led many countries to implement stricter control measures, improve surveillance systems, and strengthen regulations related to narcotic drugs and opioid monitoring.

In India, the NDPS Act, 1985 and Drugs and Cosmetics Act, 1940 form the primary legal framework for fentanyl regulation. Previous regulatory studies have shown that the introduction of Essential Narcotic Drugs (END) provisions has improved medical accessibility of opioids for cancer patients and palliative care centers while maintaining strict monitoring systems.

4. REGULATORY FRAMEWORK GOVERNING FENTANYL IN INDIA

The regulation of fentanyl in India is governed through multiple legal systems to ensure proper medical use and public safety.

4.1 Narcotic Drugs and Psychotropic Substances Act, 1985

The NDPS Act is the principal legislation controlling narcotic drugs and psychotropic substances in India. Since fentanyl is categorized as a narcotic opioid drug, all activities related to its manufacture, possession, sale, transport, storage, and distribution require authorization under this Act. (1)

The Act prohibits unauthorized handling of fentanyl and imposes strict penalties for illegal

possession, trafficking, or misuse. Important sections such as Section 8, Section 9, and Section 21 provide legal control over narcotic activities and prescribe punishments depending on the quantity involved. (1,6)

The NDPS Act also introduced the concept of Essential Narcotic Drugs (END), under which fentanyl is included. This classification allows easier medical accessibility for hospitals and palliative care centers while maintaining strict monitoring systems. (1,4)

4.2 Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act regulates the pharmaceutical quality and safety of fentanyl products. Under this Act, fentanyl formulations must meet approved pharmacopoeial standards and Good Manufacturing Practices (GMP). (2,4)

The Act ensures:

1. Drug quality and purity
2. Manufacturing control
3. Safety and efficacy evaluation
4. Licensing for sale and distribution

Fentanyl is generally regulated under Schedule H and Schedule X drugs, which means it can only be sold on prescription by a registered medical practitioner. Strict record maintenance and secure storage are compulsory for pharmacies and hospitals handling the drug. (2)

4.3 New Drugs and Clinical Trials Rules, 2019

The New Drugs and Clinical Trials Rules (NDCTR), 2019 regulate clinical research and approval of new fentanyl formulations in India. These rules ensure ethical conduct of research, participant protection, and scientific validity of clinical trials. (3)

Before initiation of any clinical study involving fentanyl, approval from CDSCO and the Ethics Committee is mandatory. Applications are submitted through the SUGAM portal using prescribed forms such as CT-04 and approval is granted through CT-06 after regulatory review. (3,4,5)

Table 1: Major Regulatory Frameworks Governing Fentanyl in India

Sr. No.	Regulatory Authority/Act	Major Function
1	NDPS Act, 1985	Control of narcotic drugs and prevention of misuse
2	Drugs and Cosmetics Act, 1940	Regulation of drug quality, safety, and manufacturing
3	NDCTR Rules, 2019	Regulation of clinical trials and new drug approval
4	CDSCO	Approval and monitoring of clinical studies
5	DCGI	Final authorization for drug approval
6	Narcotics Control Bureau	Monitoring illegal trafficking and narcotic control

5. CLINICAL TRIAL APPROVAL PROCESS FOR FENTANYL

Clinical trials involving fentanyl follow a structured regulatory pathway to ensure patient safety and scientific accuracy.

Application Submission through SUGAM Portal
↓
Review by CDSCO
↓
Ethics Committee Approval
↓
Subject Expert Committee (SEC) Review

↓

Final Approval by DCGI

↓

Pharmacovigilance and Safety Monitoring

Flowchart: Clinical Trial Approval Process for Fentanyl in India

Application Submission

The sponsor or pharmaceutical company submits the clinical trial application through the SUGAM portal along with:

1. Clinical trial protocol
2. Investigator brochure
3. Preclinical data
4. Informed consent documents
5. Investigator and site details. (3,4)

Review by CDSCO

CDSCO evaluates the submitted data for:

1. Scientific validity
2. Safety profile
3. Dose justification
4. Risk-benefit assessment

Special attention is given to fentanyl because of its high risk of respiratory depression and overdose. (4,10)

Ethics Committee Approval

An Ethics Committee registered with CDSCO reviews the trial to ensure:

1. Participant safety
2. Ethical compliance
3. Proper informed consent
4. Confidentiality protection. (3,4)

Subject Expert Committee (SEC)

The SEC reviews the safety, efficacy, and therapeutic importance of the study and provides recommendations to DCGI. (4,5)

Final Approval by DCGI

After satisfactory evaluation, the Drugs Controller General of India grants final approval for the clinical trial. Adverse event reporting and pharmacovigilance monitoring remain mandatory throughout the study period. (3,5)

6. LICENSING SYSTEM FOR FENTANYL

Due to its narcotic nature, fentanyl requires multiple licenses under Indian law. (1,2)

Manufacturing License

Manufacturers must obtain:

1. Manufacturing license under Drugs and Cosmetics Act
2. NDPS authorization for narcotic handling

Compliance with GMP and secure storage conditions is mandatory. (1,2)

Sale License

Retail and wholesale licenses are compulsory for pharmacies and distributors. Sale is permitted only on valid prescription. (2)

Possession License

Hospitals and research institutions require possession authorization specifying approved quantities and usage purposes. (1)

Transport License

Movement of fentanyl requires transport authorization containing:

1. Quantity details
2. Route information
3. Authorized personnel information

The licensing procedure includes document verification, inspection by Drug Inspectors, NDPS compliance checks, and periodic renewals. (1,2)

7. SPECIAL REGULATORY CONTROLS FOR FENTANYL

Due to the significant risk of misuse, dependence, and illegal diversion associated with fentanyl, strict regulatory and safety measures have been established in India to control its handling and medical use. (1,10)

Storage Control

1. Double-lock storage systems
2. Restricted access
3. Regular stock verification

Prescription Control

1. Prescription only by registered medical practitioners
2. Complete patient and dosage details mandatory
3. No over-the-counter sale allowed

Transport Control

Transportation requires legal documentation and monitoring to prevent diversion and trafficking. (1)

Record Maintenance

Hospitals and pharmacies must maintain:

1. Stock registers
2. Prescription logs
3. Usage records
4. Purchase and sale documentation

These records are regularly inspected by narcotics and drug control authorities. (1,2)

8. CHALLENGES IN FENTANYL REGULATION

Despite strict regulations, India faces several challenges in fentanyl control.

Illegal Diversion and Black Market Supply

Leakage from legal supply chains and improper record maintenance may contribute to illegal distribution and abuse. (1,6)

Complex Licensing Procedures

Multiple laws and authorities create lengthy approval and licensing procedures for institutions handling fentanyl. (1,2,4)

Limited Accessibility for Patients

Strict regulations sometimes reduce opioid availability in rural areas and create fear among healthcare professionals regarding legal complications. (2,7)

Public Health Concerns

Fentanyl misuse can result in:

1. Addiction
2. Overdose deaths
3. Respiratory depression
4. Substance abuse problems

Therefore, India continues to face the challenge of balancing patient access with prevention of misuse and illegal trafficking.

9. CASE STUDY: FENTANYL MISUSE AND REGULATORY CHALLENGES

A major concern associated with fentanyl regulation is the risk of illegal diversion and misuse. In several reported cases globally, unauthorized distribution of fentanyl resulted in overdose deaths and serious public health emergencies. Due to its extremely high potency, even small quantities of fentanyl may cause severe respiratory depression and fatal toxicity. In India, regulatory authorities strengthened monitoring systems, prescription control, secure storage requirements, and transportation authorization to reduce illegal trafficking and misuse. This case highlights the importance of balancing medical accessibility of fentanyl with strict narcotic control measures for patient safety and public health protection.

10. DISCUSSION

Fentanyl regulation in India represents a balance between ensuring patient access to effective pain management and preventing misuse, addiction, and illegal trafficking. Due to its extremely high potency and abuse potential, fentanyl requires stricter regulatory supervision compared to many other pharmaceutical drugs.

India has established a dual regulatory system through the NDPS Act, Drugs and Cosmetics Act, and New Drugs and Clinical Trials Rules to ensure proper control over manufacturing, distribution, prescription, transport, and clinical use of fentanyl. The involvement of regulatory authorities such as CDSCO, DCGI, and Narcotics Control Bureau has strengthened monitoring and approval processes associated with fentanyl use.

Despite these regulatory advancements, challenges such as illegal diversion, online trafficking, limited opioid accessibility, and fear of legal complications among healthcare professionals continue to affect implementation of fentanyl control systems in India. Therefore, continuous regulatory improvements, digital monitoring systems, pharmacovigilance activities, and healthcare education are essential for effective opioid management and patient safety.

11. CONCLUSION

Fentanyl is an important opioid analgesic used in pain management and palliative care, but its high abuse potential requires strict regulatory control. Indian regulatory authorities including CDSCO, DCGI, and NDPS authorities ensure proper monitoring of clinical trials, licensing, storage, and distribution of fentanyl. Continuous improvements in regulatory systems and pharmacovigilance are essential to maintain patient safety and prevent misuse of narcotic drugs.

AUTHOR CONTRIBUTIONS

Urvashi P. Gaidhane, Vedshri S. Gadewar, Achal R. Chavhan, and Prajakta D. Gawande equally contributed to literature review, data collection, analysis of information, and preparation of the manuscript. Mrs. Sneha K. Salve and Dr. Manisha D. Kitukale guided and supervised the overall

work, provided academic support, and critically reviewed the manuscript prior to submission.

ACKNOWLEDGEMENT

The authors sincerely acknowledge P. Wadhwani College of Pharmacy for providing academic guidance, institutional support, and the necessary resources for successful completion of this review study. The authors are especially grateful to Mrs. Sneha K. Salve and Dr. Manisha D. Kitukale for valuable guidance, encouragement, and continuous support during preparation of the manuscript.

FUNDING STATEMENT: The authors declare that no financial support or funding was received for preparation of this review article.

CONFLICT OF INTEREST: The authors declare that there is no conflict of interest regarding publication of this review article.

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HOW TO CITE: Urvashi Gaidhane, Vedshri Gadewar, Achal Chavhan, Prajakta Gawande, Sneha Salve, Dr. Manisha Kitukale, Regulatory Requirements, Clinical Trials, and Licensing Aspects of Fentanyl in India, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 6, 5821-5827. https://doi.org/10.5281/zenodo.20806345