

**REGULATORY REQUIREMENTS FOR THE APPROVAL OF NARCOTIC DRUGS AS
PER CDSCO IN INDIA IN COMPARISON WITH CANADA****Dr. P. Ashok Kumar*, Deekshitha A., G. M. Jeevana, Lavanya A. M., Lavanya H. S., Madhushree B. M.**

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ABSTRACT

Narcotic drugs, derived largely from the opium poppy, have powerful pain-relieving effects but also carry a high risk of addiction. Therefore, most countries place strict controls on the manufacturing, trading, and use of these drugs. This report examines the regulatory frameworks governing narcotic drugs in India and Canada, alongside the international classification set out by the 1961 UN Single Convention. India relies on the NDPS Act, along with specialized bodies such as the CBN and NCB, working alongside the general regulator, CDSCO. Canada regulates narcotics mainly through Health Canada and the CDSA, using a single permit-based system under the Narcotic Control Regulations. The comparison highlights how each country licenses the manufacturing, import, export, and sale of narcotic drugs, and what these differences reveal about their regulatory approaches.

KEYWORDS: Narcotics, NDPS Act, CDSA, Regulatory framework, Drug licensing.**INTRODUCTION**

Thousands of years ago, the opium poppy was found to yield a powerful substance that, in small doses, produced a sedative and calming effect; in larger doses, it induced sleep; and in still larger doses, it rendered the user insensitive to pain. This substance, opium, became one of the principal medicines for relieving pain and is considered among humankind's earliest narcotics. Because their main therapeutic use has historically been pain relief, such drugs are often called narcotic analgesics. In 1803, the alkaloid compound in opium responsible for its painkilling effect was isolated and named morphine, after Morpheus, the Greek god of dreams — a discovery that laid the foundation for the modern understanding and medical use of narcotics.^[1]

Owing to their powerful pain-relieving effects and equally powerful potential for addiction, narcotics have become one of the most tightly regulated categories of drugs in the world, with most countries placing strict limits on their production, trade, and use.^[2] This report examines the pharmacology of narcotic drugs and

compares the regulatory frameworks governing their manufacture, import, export, and sale in India and Canada.

DEFINITION

Narcotics are drugs that produce analgesia, narcosis, and addiction, and sometimes euphoria, a feeling of great elation. The best-known narcotics are the opiates — compounds found in or derived from opium — with morphine being primarily responsible for opium's narcotic properties. Synthetic drugs with effects similar to morphine are called opioids, and the terms opiate, opioid, and narcotic are often used interchangeably.^[2]

MECHANISM OF ACTION OF NARCOTIC DRUGS**Receptors and Binding**

Narcotic drugs exert their pharmacological effects by binding to specific opioid receptors, which are members of the G protein-coupled receptor (GPCR) family. These receptors are classified into three major subtypes: μ (μ), δ (δ), and κ (κ) opioid receptors. Upon

binding, narcotic drugs act as agonists, initiating signal transduction pathways that modulate pain perception and transmission.^[3]

Cellular Signalling and Inhibition

Activation of opioid receptors inhibits adenylate cyclase, decreasing intracellular cyclic adenosine monophosphate (cAMP). This is accompanied by inhibition of voltage-gated calcium channels and activation of inward-rectifying potassium channels. Together, these cellular changes hyperpolarize neurons and inhibit neurotransmitter release, thereby suppressing the transmission of pain signals in the nervous system.^[3]

UN SCHEDULE CLASSIFICATION OF NARCOTIC DRUGS

The 1961 Single Convention on Narcotic Drugs, the principal international treaty governing narcotic drugs, classifies controlled substances into four schedules based on their potential for abuse relative to their medical utility, as follows: Schedule I covers substances that are highly liable to abuse and offer limited offsetting therapeutic value, such as opium, heroin, morphine, and methadone. Schedule II covers substances with a comparatively lower potential for abuse, such as codeine. Schedule III is reserved for preparations of scheduled substances that pose a negligible risk of abuse, such as codeine. Schedule IV, the most restrictive category, comprises Schedule I substances that are particularly liable to abuse and produce serious ill effects without commensurate therapeutic benefits. This tiered structure ensures that the strictest controls are reserved for the most dangerous narcotics.^[4]

REGULATORY FRAMEWORK FOR NARCOTIC DRUGS IN INDIA

CENTRAL DRUGS STANDARD CONTROL ORGANISATION (CDSCO)

The Central Drugs Standard Control Organisation (CDSCO), functioning under the Directorate General of Health Services, Ministry of Health and Family Welfare, is India's National Regulatory Authority for drugs and cosmetics. Headquartered at FDA Bhawan, Kotla Road, New Delhi, it operates through six zonal offices, four sub-zonal offices, 13 port offices, and seven laboratories across the country.^[5]

The Drugs and Cosmetics Act, 1940, and the Rules of 1945 entrust the CDSCO and state regulators with responsibility for the uniform enforcement of drug and cosmetic regulations, aimed at safeguarding the safety, rights, and well-being of patients. Under the Act, CDSCO approves new drugs, oversees clinical trials, sets drug standards, controls the quality of imported drugs, and coordinates the activities of State Drug Control Organizations.^[5]

Within this structure, the Drugs Controller General of India (DCGI) is the central licensing authority for new drugs, clinical trials, and medical devices. Zonal and sub-

zonal offices in cities such as Mumbai, Kolkata, Chennai, Hyderabad, Ahmedabad, and Ghaziabad handle inspections and post-marketing surveillance, while Central Drug Testing Laboratories (CDTLs) in Kolkata, Mumbai, Chandigarh, Guwahati, and Chennai test drug samples for quality. Specialized divisions cover biological products, medical devices, cosmetics, and clinical trials, ensuring coordination between central and state authorities.^[6]

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (NDPS) ACT, 1985

The NDPS Act, 1985, consolidates and amends the law relating to narcotic drugs, imposing stringent provisions for the control and regulation of activities involving narcotic drugs and psychotropic substances, and providing for the forfeiture of property derived from or used in illicit trafficking.^[7]

Under the Act, the Central Government is empowered to take all measures necessary to prevent and combat the abuse of, and illicit traffic in, narcotic drugs and psychotropic substances, including the coordination of actions among various officers, State Governments, and other authorities.^[7]

NARCOTICS CONTROL BUREAU (NCB)

Pursuant to this provision, the Government of India constituted the Narcotics Control Bureau (NCB) on March 17, 1986. Operating under the supervision of the Central Government, the Bureau is responsible for:

- Coordinating actions by various offices, state governments, and other authorities under the NDPS Act, the Customs Act, the Drugs and Cosmetics Act, and other applicable laws;
- Implementing India's obligations under international conventions and protocols concerning countermeasures against illicit drug traffic.
- Assisting foreign authorities and international organisations to facilitate coordinated action against illicit trafficking; and
- Coordinating the actions of other ministries, departments, and organizations on matters relating to drug abuse.^[8]

As the apex coordinating agency, the NCB also functions as an enforcement agency through its zones, located in Ahmedabad, Bengaluru, Chandigarh, Chennai, Delhi, Guwahati, Indore, Jammu, Jodhpur, Kolkata, Lucknow, Mumbai, and Patna, and its sub-zones. These units collect and analyze seizure data, study trafficking trends and modus operandi, gather and disseminate intelligence, and work closely with Customs, State Police, and other law enforcement agencies.^[8]

CENTRAL BUREAU OF NARCOTICS (CBN)

The Central Bureau of Narcotics (CBN) is India's National Opium Agency under the 1961 Convention and its competent national authority under the three principal UN drug conventions: the Single Convention on Narcotic

Drugs, 1961 (as amended by the 1972 Protocol); the Convention on Psychotropic Substances, 1971; and the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. It controls the manufacture of narcotic drugs, international trade in narcotic drugs and psychotropic substances, and precursor chemicals listed under Article 12 of the 1988 Convention.^[9]

The CBN's stated vision is to be the world's premier drug-control agency through a balance of enforcement and facilitation, with a mission to ensure the availability of narcotic drugs, psychotropic substances, and precursor chemicals for medical and scientific purposes while preventing their diversion into illicit channels.^[9] Its key responsibilities include the following:

- Regulating international trade in narcotic drugs, psychotropic substances, and precursor chemicals
- Issuing import certificates, export authorizations, and no-objection certificates for precursor chemicals.
- Liaising with the International Narcotics Control Board (INCB), UN Office on Drugs and Crime, and foreign competent authorities
- Allocating and monitoring INCB-approved quotas for narcotic drugs
- Licensing and controlling the manufacture of narcotic drugs, including synthetic drugs
- Inspecting manufacturers' stock and input material records
- Overseeing online return filing by manufacturers and dealers of narcotic drugs and psychotropic substances
- Administering and monitoring licit opium poppy cultivation and the production of opium gum and poppy straw
- Gathering intelligence and destroying illicit opium poppy and cannabis cultivation.
- Preventing illicit trafficking in narcotic drugs, psychotropic substances, precursor chemicals, and new psychoactive substances, and conducting search, seizure, and arrest operations under the NDPS Act; and
- Regulating international trade in poppy seeds.^[9]

REGULATORY FRAMEWORK FOR THE NARCOTIC DRUGS IN CANADA

HEALTH CANADA

Health Canada is the federal department responsible for helping Canadians maintain and improve their health, to make Canada one of the countries with the healthiest people in the world, as measured by longevity, lifestyle, and effective use of the public healthcare system. It acts as a regulator, service provider, and funder, relying on high-quality scientific research as the basis for its work and communicating information on disease prevention to protect Canadians from avoidable risks. This role includes ongoing consultation with Canadians on their long-term healthcare needs.^[10]

CONTROLLED DRUGS AND SUBSTANCES ACT (CDSA)

The Controlled Drugs and Substances Act (CDSA) establishes that, except as authorized under the regulations, no person may possess a substance included in Schedules I, II, or III. To keep the law adaptable to new substances, the Governor in Council may amend Schedules I to VI by adding or removing items, allowing the government to maintain strict control over possession and classification.^[11]

Under the associated Food and Drug Regulations, a “controlled drug” is one listed in the schedule to the relevant part of the Regulations. Handling these drugs requires authorisation: the Minister may license a person to produce, make, assemble, import, export, sell, provide, transport, send, or deliver a controlled drug, ensuring that only authorised parties undertake such activity under government oversight.^[12]

REGULATORY REQUIREMENTS FOR THE MANUFACTURING, IMPORT, EXPORT, AND SALE OF NARCOTIC DRUGS IN INDIA

MANUFACTURING

Manufacturing narcotic drugs in India begins upstream, with the cultivation of the opium poppy, and proceeds through a chain of licences before a finished drug can be legally produced. The NDPS Act empowers the Central Government to permit and regulate poppy cultivation for medical and scientific purposes; the government notifies, through annual “Opium Policies,” the tracts where cultivation may be licensed — currently limited to notified areas in Madhya Pradesh, Rajasthan, and Uttar Pradesh. Cultivators must meet a minimum qualifying yield to remain eligible for a licence the following year. The Central Bureau of Narcotics, Gwalior, under the Narcotics Commissioner, issues cultivation licences and individually measures each licensed field to prevent excess cultivation.^[14]

Actual manufacturing requires separate approval. Narcotic drugs not manufactured directly by the Central Government may only be manufactured after obtaining a licence from the Narcotics Commissioner, who grants it only once the applicant holds a manufacturing licence under the Drugs and Cosmetics Act/Rules from the State Drugs Controller and the requisite licences under the State NDPS Rules for possession, use, and sale.^[13] In effect, a company must clear three layers of approval:

1. State Drugs Controller — manufacturing licence under the Drugs and Cosmetics Act/Rules
2. State Government — licence for possession, use, and sale under the State NDPS Rules; and
3. Narcotics Commissioner (Central Government) — final manufacturing licence, granted once the above conditions are met.^[13]

IMPORT

Import of narcotic drugs into India is permitted only subject to Rule 53 of the NDPS Rules, 1985, while

import of drugs listed in Schedule I to the Rules is prohibited outright.^[13] Raw and semi-processed substances — opium, concentrate of poppy straw, morphine, codeine, thebaine, and their salts — may be imported only by the Government Opium Factory, under Rule 54 of the NDPS Rules.^[14]

A narrow exception exists for manufacturers requiring these substances for export, and for importers of samples not exceeding 1 kilogram per year for analytical purposes; such imports require Central Government notification and an import certificate in Form No. 4A, issued under Rule 55.^{[13][14]} In all permitted cases, the importer must obtain an import certificate from the Narcotics Commissioner for each consignment.^[13]

EXPORT

The export of narcotic drugs is similarly restricted: the export of substances listed in Schedule I of the NDPS Rules is prohibited, and each export shipment requires an individual export authorization from the Narcotics Commissioner.^[13] Authorizations are governed by an estimate system, ensuring that the annual estimated requirement of a drug — as published by the International Narcotics Control Board — does not exceed the importing country's estimated requirement.^[14]

Export authorizations cannot be amended or extended; the full shipment must be made within the validity of the authorization, and exporters must report export details immediately after shipment. Applications must include the prescribed form, the original import certificate from the importing country, a licence fee of Rs. 1,000 by demand draft, a valid drug manufacturing or sale/distribution licence, a copy of the foreign buyer's purchase order, and a transport permit from the State Excise Authority.^[14]

SALE

Sale of narcotic drugs in India is licensed separately from manufacturing and falls under Schedule X of the Drugs and Cosmetics Rules, 1945, which subjects narcotic and psychotropic substances to stricter controls than ordinary drugs, including locked storage, special licence forms, and detailed inventory records.^[16] Retail sale requires Form 20F and wholesale requires Form 21G — distinct from the standard forms used for ordinary medicines — both granted by the state Drug Controllers.^[15]

Schedule X medicines must be stored in a secure, access-restricted facility, with meticulous records of quantities received, used, and sold, batch numbers, and buyer/seller details.^[16] Unauthorized sale is a serious offence: under the NDPS Act, penalties can include heavy fines, imprisonment ranging from a few months to twenty years, licence cancellation, and seizure of goods and premises — consequences that can follow even from unintentional lapses such as poor record-keeping or exceeding permitted quantities.^[15]

REGULATORY REQUIREMENTS FOR THE MANUFACTURING, IMPORT, EXPORT, AND SALE OF NARCOTIC DRUGS IN CANADA

MANUFACTURING

Under the CDSA, “produce” is defined to include manufacturing — obtaining a substance by any method or process, including manufacturing, synthesising, or otherwise altering its chemical or physical properties — and, except as authorised by regulation, no person may produce a substance listed in Schedule I, II, III, IV, or V.^[11]

The Narcotic Control Regulations (NCR) provide the licensing framework for authorized manufacturing; the Minister may, on application, issue a dealer's licence to a person meeting residency or corporate requirements, and a licensed dealer may then produce, make, assemble, import, export, sell, provide, transport, send, or deliver a narcotic in accordance with the terms of that licence — ensuring that manufacturing occurs under rigorous federal supervision to prevent illegal diversion.^[17]

IMPORT

Importing narcotic drugs into Canada requires a separate permit for each shipment obtained by a licensed dealer beforehand. The application must state the dealer's licence number, details of the narcotic (name, quantity, and purity if a raw material), the exporter's information, and the intended customs office and transport route, signed and attested by a qualified person in charge. The Minister then issues a permit valid for up to 180 days, or until the dealer's licence expires, whichever comes first, subject to any conditions needed to protect public health or meet international obligations.^[17]

A permit must be refused if the dealer lacks proper authorization, required security measures are absent, or the import would breach an international obligation or foreign law; a permit also becomes invalid if the dealer's licence or the corresponding foreign export permit is suspended or revoked. After importation, the dealer must submit a declaration to the Minister within 15 days, confirming the identity, quantity, and release from customs.^[17]

EXPORT

Exporting narcotic drugs from Canada likewise requires a separate permit for each shipment. The application must include the dealer's licence number, details of the narcotic, the importer's name and address in the destination country, the intended customs office and transport route, and a copy of the destination country's import permit — signed and attested by the qualified person in charge, confirming compliance with the destination (and any transit) country's laws and the accuracy of all information submitted. The Minister may request additional information before finalizing the review, which the dealer must provide by the specified deadline.^[17]

SALE

The sale of narcotic drugs by pharmacists in Canada is tightly restricted. A pharmacist may sell or provide a narcotic only to a person exempted under the CDSA, or upon a written order or prescription signed by a practitioner, with the signature verified if not already

known. Methadone carries an added allowance, permitting sale to a licensed dealer, another pharmacist, a hospital employee, or a practitioner. Pharmacists are also barred from selling or providing narcotics to another pharmacist or practitioner named in an active Ministerial notice restricting their access.^[17]

Tableno 1: Comparison of Narcotic drug Regulatory Frameworks: India Vs Canada.

Aspect	India	Canada
Main law	NDPS Act, 1985 (+ Drugs & Cosmetics Act, 1940 and Rules, 1945)	Controlled Drugs and Substances Act (CDSA), 1996 (+ Food and Drug Regulations, Narcotic Control Regulations)
National regulator	CDSCO (general drug regulator, under Ministry of Health)	Health Canada
Drug-specific control agency	Central Bureau of Narcotics (CBN) - India's National Opium Agency; Narcotics Control Bureau (NCB) - enforcement/coordination	No single dedicated narcotics bureau - Health Canada and provincial authorities administer the CDSA/NCR
Regulatory structure	Two-tier: CDSCO (general regulator) plus dedicated narcotics agencies (CBN, NCB)	Single-tier: Health Canada regulates both general drugs and narcotics under one roof
Field infrastructure	CDSCO: 6 zonal + 4 sub-zonal + 13 port offices + 7 labs; NCB: enforcement zones in 13 cities (Delhi, Mumbai, Bengaluru, etc.)	No equivalent zonal/field network described - regulation runs centrally through Health Canada and the Minister
Classification system	Schedule X (Drugs & Cosmetics Rules) for sale controls; separate NDPS Schedule for banned/controlled substances	Schedules I-VI under the CDSA, amendable by the Governor in Council
Cultivation	Licensed poppy cultivation only in notified tracts of Madhya Pradesh, Rajasthan, Uttar Pradesh, under annual Opium Policy	Not a feature of the framework - focus is on manufacture/handling, not poppy cultivation
Poppy straw / poppy seeds	CBN administers licit cultivation, poppy gum/poppy straw production, and regulates international poppy seed trade	Not covered - no poppy cultivation dimension
Precursor chemicals	CBN issues no-objection certificates and monitors precursor chemicals under Article 12 of the 1988 UN Convention	Not separately detailed - CDSA covers controlled substances broadly rather than a named precursor-chemical track
Manufacturing licence	Three-layer approval: State Drugs Controller, then State NDPS Rules license, then Narcotics Commissioner (Central)	Single dealer's licence issued by the Minister under the Narcotic Control Regulations
Import	Mostly prohibited (Schedule I substances); raw materials only via Government Opium Factory; import certificate (Form 4A) for exceptions	Per-shipment import permit, valid up to 180 days or until dealer's licence expires, whichever is sooner
Post-import compliance	Not specifically detailed for imports	Dealer must file a declaration with the Minister within 15 days confirming identity, quantity, and customs release
Sample imports	Special exception: samples up to 1 kg/year allowed for analytical use, with Central Government notification	No equivalent sample-import exception mentioned
Export	Export authorization required per shipment from the Narcotics Commissioner; tied to INCB-approved annual estimates	Per-shipment export permit; requires the destination country's import permit to be attached
Quota/estimate system	Exports capped by INCB-approved annual	No estimate/quota system

	estimates so they cannot exceed the importing country's stated requirement	mentioned - control is permit-based per shipment instead
License fee example	Export license fee: Rs. 1,000 by demand draft, plus supporting documents	No license fee specified - permits are approval-based rather than fee-based as described
Sale (retail/wholesale)	Form 20F (retail) and Form 21G (wholesale) under Schedule X; locked storage and strict inventory records required	Pharmacist may sell only against a prescription or to an exempted person
Methadone handling	Not separately called out	Additional allowance: methadone may also be sold to a licensed dealer, another pharmacist, a hospital employee, or a practitioner
Penalties	NDPS Act: fines, imprisonment up to 20 years, licence cancellation, and seizure - even for unintentional lapses like poor record-keeping	Framed around license/permit suspension or revocation rather than criminal-style penalties for paperwork lapses
International liaison role	CBN explicitly liaises with the INCB and UNODC and allocates INCB-approved quotas	Compliance is built into the permit process itself (e.g., needing the destination country's import permit) rather than a standalone liaison body

Most differences trace back to one structural choice: India built separate specialized bodies (CBN for control and international liaison, NCB for enforcement) on top of its general regulator (CDSCO), while Canada folded the same functions into Health Canada and the Minister's permit powers.

CONCLUSION

India and Canada regulate narcotic drugs differently, but with the same aim: keeping these drugs available for genuine medical use while preventing their diversion into illegal channels.

India follows a layered model. The NDPS Act provides the legal basis, CDSCO handles general drug regulation, and specialized bodies — the CBN and NCB — manage narcotics specifically, from cultivation licensing to enforcement and international liaison with the INCB. Canada takes a more centralized approach, with Health Canada and the CDSA covering the entire process through a single dealer's licence and shipment-based permits, without a separate narcotics agency.

This comparison shows a clear trade-off: India's specialized institutions allow closer oversight of complex functions such as cultivation and international quotas, while Canada's centralized system achieves control with less institutional complexity.

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