



JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)

An International Scholarly Open Access, Peer-reviewed, Refereed Journal

A STUDY ON REGULATORY REQUIREMENTS FOR CONTROLLED DELIVERY DRUGS

PUTTA PAVITHRA*, DAVID BLESSING RANI.J

Department of pharmaceutical regulatory affairs, Emmanuel college of pharmacy, Visakhapatnam, Andhra Pradesh, 531162.

ABSTRACT:

This research will be helpful to find out the loopholes and also its solution to make it strong for the benefit of general public. It will be helpful to make opinion or view for the legislature for proper amendment in the Act. Controlled Drugs play a decisive role in healthcare provision. The core rationale behind the development of controlled drug delivery systems is to adjust the pharmacokinetic and pharmacodynamic of therapeutic active molecules. In recent years, the international controlled drug industry has grown quickly which depended on a large number of persistently ill patients, upsurge in universal occurrences of malignancy, growing geriatric population and sturdy existence of channel drugs used for habitually ill circumstances. The principle is to safeguard the efficacy and safety of drugs. CDDS is still regarded as an emerging class of DDS, due to the issues related to the regulatory guidelines as followed by various pharma in major countries. It is also expected the study a new dimension of the issue may be disclosed which give new ground for further research. The study will give new solution to make an equilibrium between the government work and the right to know the public. This article discusses about the regulatory guidelines of CDDS in the south india, north india, west india and east india.

Key words: controlled drug delivery, regulatory guidelines, controlled drug delivery market- South india, north india, east india and west india.

INTRODUCTION

Controlled Drug is a common legal term referring specifically to substances controlled by Federal or State Laws. It is a drug or chemical the manufacture, possession, or usage of which was regulated by the government. The manufacture, custody, import, and supply of these drugs are stringently controlled or forbidden, although many might be dispensed by prescription only. Some precursors used for the production of illegal drugs are also termed as controlled substances in some countries, even though they are devoid of the pharmacological effects of the drugs themselves. Controlled Drugs are prescription drugs and include both Narcotic Drugs and Psychotropic substances (NDPS). Opioid pain-relieving drugs like morphine, oxycodone, heroin, fentanyl, methadone, etc.

Some examples

(1) National Institute of Health states that ‘Narcotic drugs effects by binding to opioid receptors in the brain and spinal cord and subsequently impede pain indicators.’ These drugs are prescribed to treat severe pain which is not responding to other forms of pain relievers like cancer pain or other severe diseases and post-surgical pain. Whereas Psychotropic drugs act by distressing the cognizance, feelings, and behaviour.

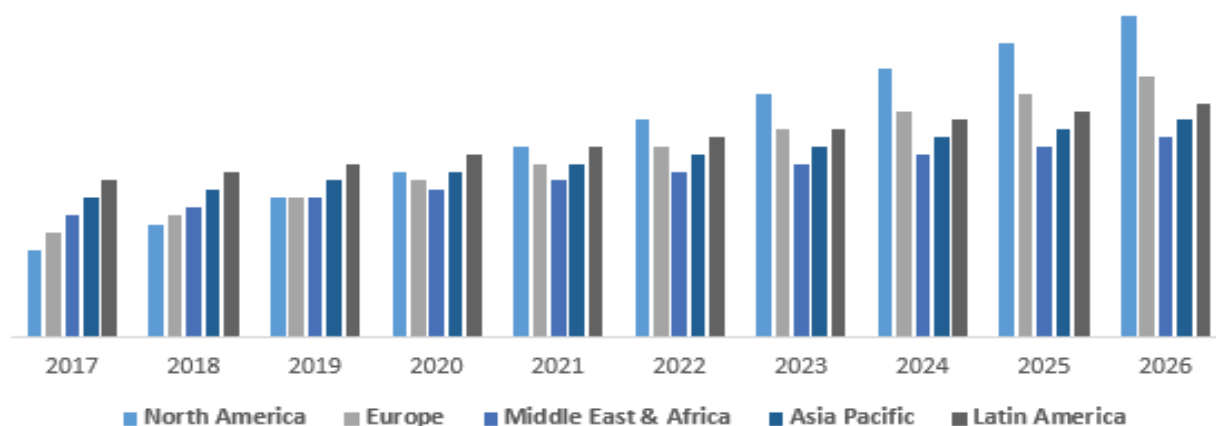
(2) Legally drugs that induce sleep are also called Narcotic drugs. Examples: Opiates, Cannabis or cocaine, etc. while those that are having the ability to alter the mind of individuals are psychotropic substances like LSD, Amphetamines and MDMA.

(3) Regulatory Requirements comprise of all authorizations, processes, obligatory principles, situations, manufacturing ethics, strategies, commands and determinations which may set out according to regulatory laws that apply to the production, sale, wrapping, labelling and/or marketing of drugs imposed by the government.

(4) The requirements can be statutory or regulatory requirements. Statutory means laws approved by a state or central government, while ‘regulatory’ denotes a regulation dispensed by a regulatory body appointed by the state or central government.

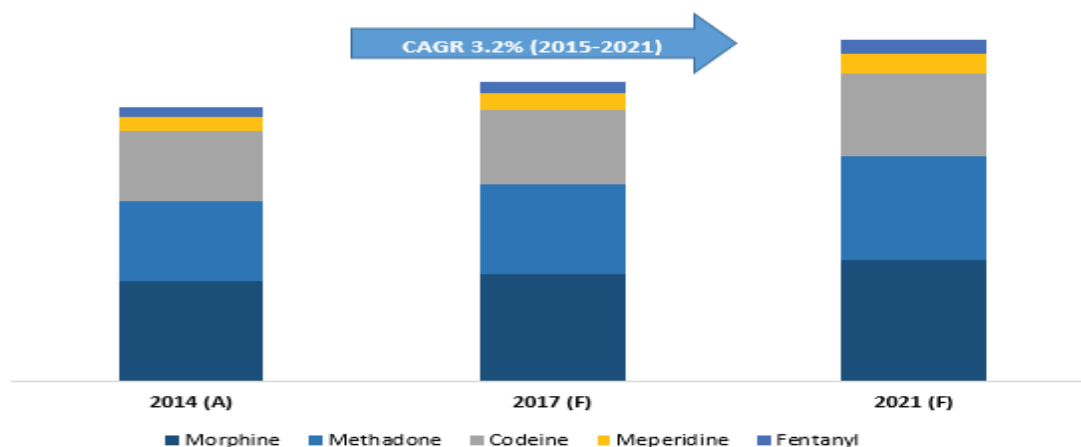
Global Opioid Drug Market

Global Opioids Drugs Market, by Region



Global Opioid Market Revenue 2014-2021

Global Opioid Market, Revenue By Products, US\$ Million, 2014, 2017 and 2021



Source: PMR, 2015

Historic Landmarks

Year Landmark

- 3400B.C Cultivation of Opium Poppy in Mesopotamia
- 1620-70 Introduction of Use of opium to Indian Soldiers by Mughals
- 1793 Monopoly of Opium Trade in India established by British East India Company
- 1821 Publishing of autobiography of Thomas De Quincey related to opium addiction: Confessions of an English Opium-eater
- 1827 Manufactured morphine commercially by E Merck
- & Company of Germany
- 1878 “Opium Act” to diminish opium ingestion and” Sea Customs Act “developed.
- 1905 Opium prohibition Us Congress
- 1910 Indo-China Opium Trade was dismantled
- 1925 Black market of opium use flourished in USA
- 1930 Dangerous Drugs Act
- 1985 “Narcotic Drugs and Psychotropic Substances Act” to counter the wave of ‘narco–terrorism’ and growing drug related ISSUES
- 1988 The Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act”
- 2001 Major amendments
- 2014 Major amendments
- 2017 NDPS Bill

Classification

Controlled Drugs are classified into specific Categories /Classes/Schedules in different countries based on potency, addiction liability, acceptable medical use and restrictions on how and when the prescription of NDPS can be filled or refilled. (19,20)

According to the 1961 UN Single Convention on Narcotic Drugs, as amended in 1972 Narcotic drugs are classified as follows

UN Classification of Narcotic drugs

Schedule s	Harmfulness	Degree of Control	Examples
I	Addictive- substances with serious risk of Abuse	Very Harsh	Cannabis and its derivatives, Cocaine, Heroin, Morphine, Opium
II	Substance for medical purposes with lowest risk of Abuse	Less stern	Codeine, Dihydrocodeine
III	Preparations of schedule II substances and	Lenient; no hazard of abuse	Preparations of Codeine and Dihydrocodeine

	Cocaine		
IV	Most dangerous	Very strict	Cannabis and its resin, Heroin

International Narcotic Control Bureau (INCB) listed the Psychotropic substances into five categories or schedules (Table 2) according to their characteristics, such as dangerousness, medical usage and addictive properties. The Schedules are denoted as I – V, with Schedule I being the most dangerous and the peak probability for abuse and Schedule V being the least dangerous and lowest potential for abuse.

INCB Classification of Psychotropic Substances

Schedule	Description	Grade of Control	Examples
I	<ul style="list-style-type: none"> Substances with high risk of abuse posing a predominantly grave danger to communal health very little or no therapeutic value 	Very strict use is prohibited except for scientific or limited medical purposes	LSD, MDMA, Mescaline, Psilocybin Tetrahydrocannabinol
II	<ul style="list-style-type: none"> Substances having a risk of abuse, posing a serious threat to public health low or moderate therapeutic value 	Less strict	Amphetamines Amphetamine-type stimulants
III	<ul style="list-style-type: none"> Substances showing a risk of abuse posing a serious threat to public health moderate or high therapeutic value 	These substances are available for medical purposes	Barbiturates like amobarbital Buprenorphine
IV	<ul style="list-style-type: none"> Substances presenting a risk of abuse posing a minor threat to public health 	These substances are available for medical purposes	Diazepam Phenobarbital Temazepam

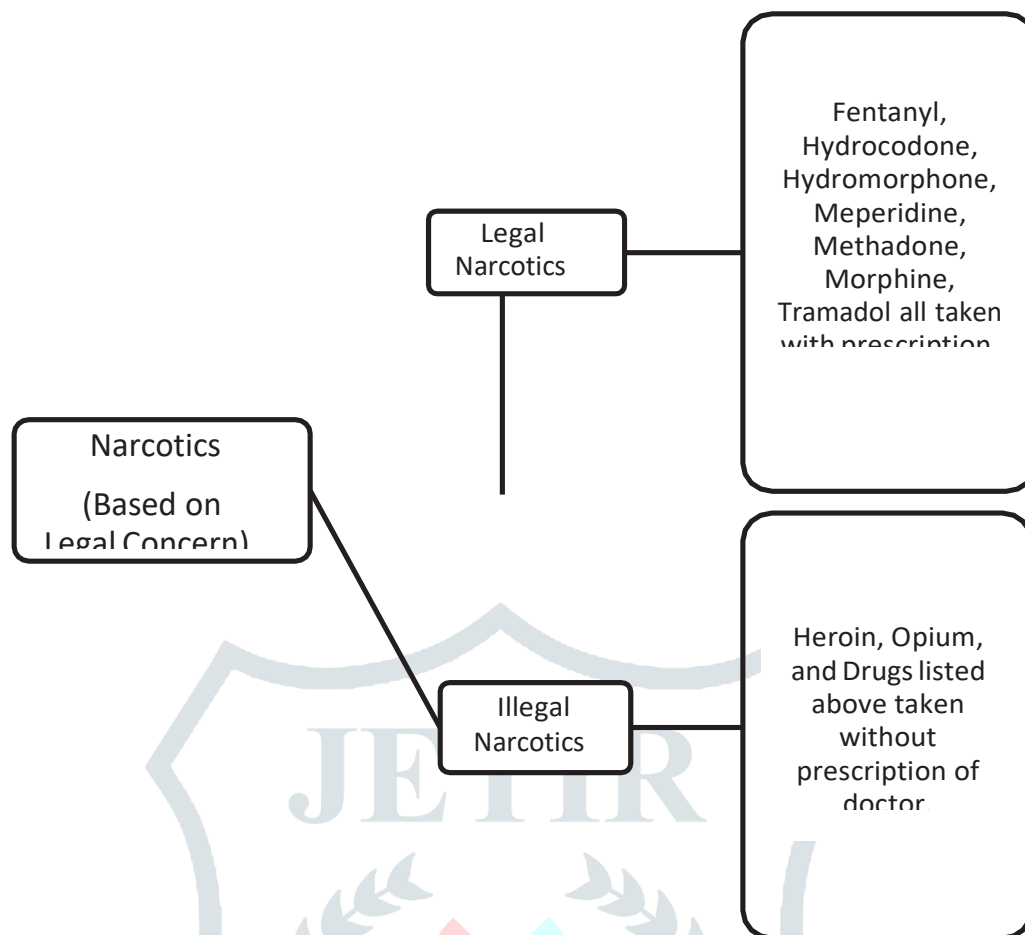
In US the Department of Justice and Drug Enforcement Agency (DEA) enforces Controlled Substance law. DEA segregate Controlled Substances as I - V Schedules (Table 3) as per abuse potential, therapeutic price and the threat of stern physical effects to the user.

Even though the above referred are the basic schedules, different countries contribute different drugs under NDPS and thus there is slight variation in the classification/categorization.

Schedule of Controlled Substances by DEA

Schedule	Description	Examples
I	<ul style="list-style-type: none"> – High potential for abuse and no accepted medical use in treatment in the U.S. – Lacks accepted safety for use under medical supervision – Investigational drugs for actives not currently approved for use in the U.S. 	Dronabinol Marijuana Heroin Crystal methamphetamine
II	<ul style="list-style-type: none"> – High potential for abuse – Currently accepted medical use in treatment in the U.S. or accepted with severe restrictions – Abuse may lead to severe psychological or physical dependence 	Fentanyl Hydrocodone Hydromorphone Methamphetamine Methylphenidate Morphine Tapentadol
III	<ul style="list-style-type: none"> – Abuse potential less than Schedules I and II – Currently accepted medical use in treatment in the U.S. – Abuse may lead to moderate or low physical dependence or high psychological dependence 	Buprenorphine Ketamine Testosterone
IV	<ul style="list-style-type: none"> – Low potential for abuse relative to Schedule III – Accepted medical use in treatment in the U.S. – Abuse may lead to limited physical or psychological dependence relative to Schedule III 	Diazepam Clonazepam Midazolam Carisoprodol
V	<ul style="list-style-type: none"> – Low potential for abuse – Accepted medical use in treatment in the U.S. – Abuse may lead to limited physical or physiological dependence 	Codeine-containing cough medications Diphenoxylate

Based on legal concern the narcotics can be of following types:



Types of Narcotic drugs based on legal concern

Based on source of origin these drugs are classified as follows

Types of Controlled drugs based on source of origin

Type	Natural	Opium, Ganja, Hashish, Hashish oil, Coca leaves and Coca paste
Drugs	Opium poppy (Papaver somniferous)	Plant produces beautiful red and white flowers which mature into bolls. Incisions are made on the bolls through a process called lancing and latex oozes out and sticks to the surface of the boll. On exposure to atmosphere, the latex turns brownish to black, gummy and resinous and this substance is called the opium or opium gum
	Cannabis	Cannabis plant grows wild and is also illegally cultivated. The flowering tops of cannabis are called Ganja. The resin produced by crushing the plant is called Hashish or Charas. Hashish oil is also produced through distillation

	Coca	The leaves of coca plant and the coca paste made from these leaves are stimulating drugs.
Type	Semi-synthetic	Natural drug is treated chemically to either isolate its active ingredient or modify it, to produce semi-synthetic drugs
Drugs	Morphine	
	Codeine	3-methylmorphine (derivate of morphine, alkaloid contained in opium & poppy straw)
	Heroin	Diacetylmorphine (derivative of morphine)

	Cocaine	Methyl ester of benzoylecgonine (an alkaloid found in coca leaves or prepared by synthesis from ecgonine)
Type	Synthetic drugs	Produced purely through chemical processes
Drugs	Amphetamines (Stimulants), ecstasy, diazepam, methaqualone	

Classification of Controlled Drugs in Various Countries

Country	Classification
INDIA	Multiple
US	Schedule I-V
JAPAN	Varies with 5 Laws
EU	Varies with nation
BRAZIL	A1, A2, A3, B1, B2, C1
CHINA	As per Controlled Drugs Act
RUSSIA	List I-IV
SOUTH AFRICA	Schedule I-V
AFGANISTAN	Afghan national classification of controlled drugs - 4 types
PAKISTAN	Class A and B
BANGLADESH	A, B, C, D
NEPAL	Natural, Synthetic
BHUTAN	Schedule I-IV
MALDIVES	Prohibited Psychotropics used as medications
SRILANKA	Narcotic Drugs Psychotropic Substances Precursor chemicals

It shows the classification of controlled drugs in all selected countries, which implies that there is non-uniform classification exist worldwide.

NATIONAL POLICY ON NARCOTIC DRUGS AND PSYCHOTROIC SUBSTANCES

- Article 47 of the Constitution of India which mandates that the 'State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health'.
- The Governments' policy has thus been to promote their use for medical and scientific purposes while preventing their diversion from licit sources, and prohibiting illicit traffic and abuse.
- The NDPS Act It is also possible for the central and State Governments to notify any new class of officers of any department to enforce.
- Controlled delivery is an investigative tool that helps to accomplish this objective, particularly in cases where illicit products trafficking is identified or intercepted in source or transit and then delivered under surveillance in order to identify the intended recipients. It is also used to monitor and gather evidence on subsequent distribution within an organized criminal group or in the illegal supply chain. In some cases, it is possible to substitute the illicit consignments with licit or fake material in order to prevent the risk of losing the illicit consignments during the course of delivery

NEED OF POLICY

As discussed above, several departments and organisations of the Central and State Government are involved in various activities relating to narcotic drugs and psychotropic substances. Some of these are listed below:

S.No.	Action	Government/ Department/Organisation
1.	Drug law enforcement	Central Government <ol style="list-style-type: none"> 1. Narcotics Control Bureau 2. Central Bureau of Narcotics 3. Directorate General of Revenue Intelligence 4. Commissionerates of Customs 5. Commissionerates of Central Excise 6. Coast Guard State Governments Vary from State to State, usually: <ol style="list-style-type: none"> 1. State Police 2. State Excise Officers
2.	Identification and destruction of illicit opium and cannabis crops	Satellite survey of suspected areas Central Economic Intelligence Bureau (CEIB) coordinates the survey and shares the information with NCB and CBN. Central Government <ol style="list-style-type: none"> 1. Narcotics Control Bureau, MHA, GOI 2. Central Bureau of Narcotics, Gwalior, DoR, GOI State Governments Vary from State to State, usually: <ol style="list-style-type: none"> 1. State Police State Excise Officers

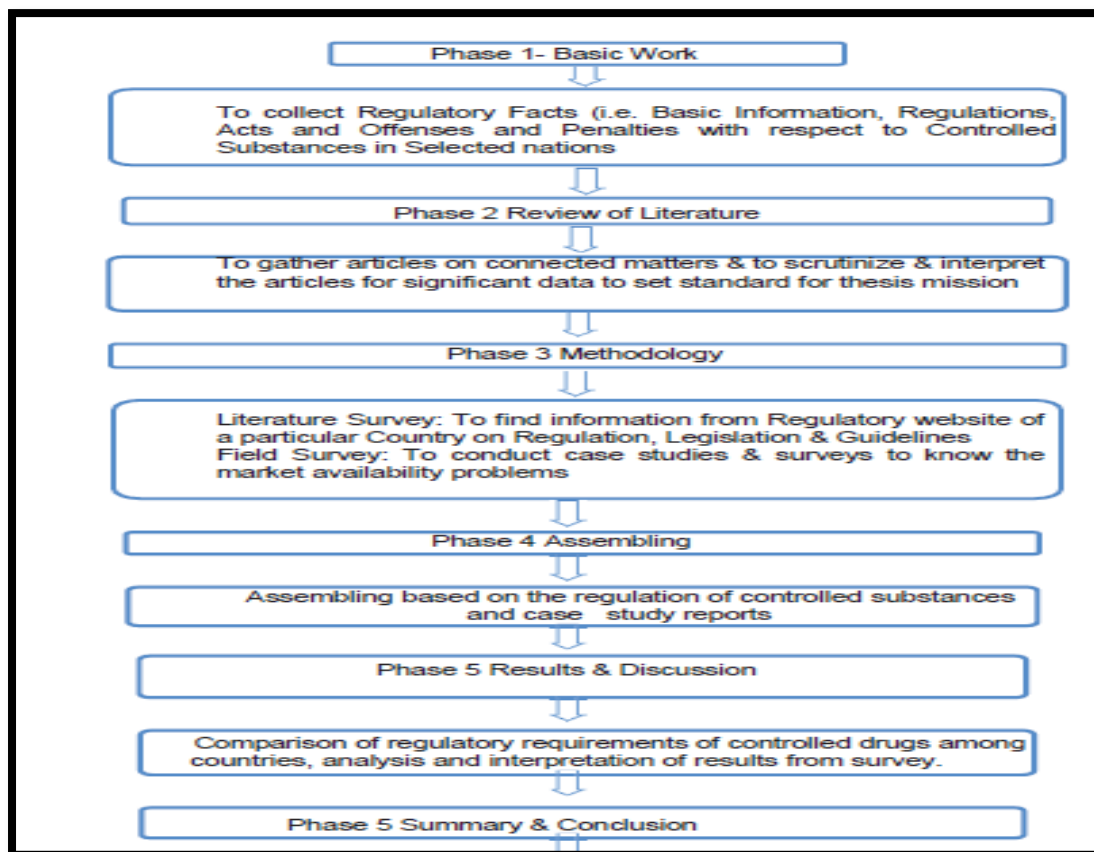
S.No.	Action	Government/ Department/ Organisation
3.	Framing rules to regulate various activities indicated in Section 9 of the NDPS Act, 1985	Department of Revenue, Ministry of Finance, Government of India
4.	Framing rules to regulate various activities indicated in Section 10 of the NDPS Act, 1985	State Governments
5.	Licensing and supervision of cultivation of opium poppy	Central Bureau of Narcotics, Gwalior
6.	Licensing of manufacture of narcotic drugs	Central Bureau of Narcotics, Gwalior
7.	Drying and export of opium	Chief Controller of Factories, New Delhi
8.	Extraction of alkaloids from opium	Chief Controller of Factories, New Delhi
9.	Import of alkaloids of opium	Chief Controller of Factories, New Delhi
10.	Allocation of INCB approved estimates of narcotic drugs as quotas and subsequent monitoring	Central Bureau of Narcotics, Gwalior
11.	Supply of samples of narcotic drugs to testing labs, training institutions, etc.	Chief Controller of Factories, New Delhi
12.	Control on sale, use, consumption, movement, etc. of narcotic drugs	State Governments usually through their State Excise Departments
13.	Control on import and export of narcotic drugs and psychotropic substances and precursors	Central Bureau of Narcotics, Gwalior
14.	Registration of import contracts for poppy seeds	Central Bureau of Narcotics, Gwalior
15.	Regulation of manufacture, trade, etc. of psychotropic	State Drugs Controllers under the NDPS Rules read with Drugs and
S.No.	Action	Government/ Department/ Organisation

	substances	Cosmetics Act and Rules. Narcotics Commissioner for import & export
16.	Receipt and monitoring of returns regarding controlled substances under the NDPS (Regulation of Controlled Substances) Order, 1993	Narcotics Control Bureau, MHA, GOI
17.	Controlled delivery operations	Director General, Narcotics Control Bureau
18.	Seizure, freezing and forfeiture of properties of drug traffickers, their relatives and associates	Competent Authority appointed under the NDPS Act (Delhi, Chennai, Mumbai & Kolkata, presently)
19.	Management of properties seized or forfeited	Administrator appointed under the NDPS Act (Delhi, Chennai, Mumbai & Kolkata, presently)
20.	Supply of opium to addicts	State Governments, usually through the State Excise Departments
21.	Regulation of poppy straw	State Governments subject to guidelines dated 30th November 2009 of the Department of Revenue, Government of India.
22.	Drug demand reduction through NGOs engaged in drug de-addiction and rehabilitation of addicts	Ministry of Social Justice and Empowerment, Govt. of India
23.	Training personnel of NGOs in drug demand reduction	National Institute of Social Defence under the MSJ&E
24.	Preventive education	Ministry of Social Justice and Empowerment
25.	Treatment of drug addicts through Government hospitals	Ministry of Health and Family Welfare, GOI
26.	Training doctors in drug demand reduction	National Drug Dependence Treatment Training Centre, AIIMS, New Delhi
27.	Drug demand reduction activities at the State level	Social Welfare Departments of the States

28.	Treatment of addicts through State Government hospitals	Health Departments of the States
29.	Testing of samples of seized drugs	<ol style="list-style-type: none"> 1. Central Revenue Control Laboratory 2. Laboratories of Government Opium and Alkaloids Works (GOAW) 3. Central Forensic Science Laboratories 4. State Forensic Science Laboratories of different States
30.	Training of personnel in drug law enforcement	<ol style="list-style-type: none"> 1. National Academy of Customs, Excise and Narcotics (NACEN) 2. National Police Academy 3. State Police Training Schools 4. National Institute of Criminology and Forensic Sciences 5. CRCL 6. Narcotics Control Bureau (NCB)
31.	Filing of returns to the International Narcotics Control Board and the Commission on Narcotic Drugs	Narcotics Control Bureau, MHA, GOI
32.	Compilation of seizure statistics from different agencies	Narcotics Control Bureau, MHA, GOI
33.	Exchange of live information on import and export of drugs and precursors with the competent authorities of other countries and with the INCB	Central Bureau of Narcotics, Gwalior
34.	Access to morphine / opioids for cancer/pain relief and palliative care	Ministry of Health & F. W., Government of India, Health Department of States, State Drug Controllers, and Chief Controller

		of Factories
--	--	-----------------

Each of the organisations indicated above has a large complement of staff with some of these such as the State Police having several thousands of personnel.



RESULTS & DISCUSSION

Factsheets of Indian country was prepared under the major headings like Geographical distribution, Economic status, Pharmaceutical market, Regulation, Regulatory authority, Offense and penalties, major seizures etc. The fact sheets provide an insight to the regulation of controlled drug.

Factsheet for Controlled Drug Regulation in India

Country	India	Drug Type	Narcotic Drug & Psychotropic substances
Regulating Ministry	Ministry of Home Affairs	Regulatory Authority	NCB, CBN, DRI, Excise, Drugs Control
Act/Law	NDPS Act		

Pharmaceutical Market

India is the only country authorised by the United Nations Single Convention on Narcotic Drugs (1961) to produce gum opium. The pharmaceutical sector was valued at US\$ 33 billion in 2017. The country's pharmaceutical industry is expected to expand at a CAGR of 22.4 per cent over 2015–20 to reach US\$ 55 billion. The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture.

Classification

- Natural opium derivatives – narcotic drugs that are derived from the poppy plant are classified as natural narcotics. These include morphine and codeine.
- Partially synthetic – this classification is narcotic drugs that are derived from morphine. They include heroine, oxycodone and hydromorphone and oxycodone.

Synthetic compounds — drugs in this category are formulated similarly in structure to morphine

Drug Laws

NDPS Act

- Chapter I-Definition, Classification
- Chapter II-Authorities and Officers
- Chapter III-Prohibition, Control and Regulation

Chapter IV-Offenses and Penalties

Regulation

The regulation of narcotic drugs and psychotropic substances is governed by the NDPS Act. The Narcotics Control Bureau (NCB) is India's primary national drug control agency, established to prevent and combat the abuse of narcotic drugs and psychotropic substances under Ministry of Home Affairs. The Directorate of Revenue Intelligence (DRI) and the Indian Customs Service are also authorized to pursue narcotics investigations. The Central Bureau of Narcotics (CBN) is India's supervising agency over the licit cultivation of opium poppy in India. CBN is responsible for abuse prevention and enforcement functions, including investigations of violations of the NDPS Act, the issuance of licenses for the manufacture of synthetic narcotic drugs, and export/import authorizations for narcotic drugs and psychotropic substances

In states Excise Department, Drugs Control Department, Police Department etc., are involved in regulation of Narcotic drugs and Psychotropic substances. Among States licensing is non-uniform. NDPS Rules available in each state. Moreover, the latest NDPS Act amendment implementation is not proper in all the states.

New Amendment -New Delhi, the 13th March, 2019

G.S.R. 215(E). -In exercise of the powers conferred by section 9, read with section 76 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules further to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985, namely:

(1) These rules may be called the **Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 2019**.

(2) They shall come into force on the date of their publication in the Official Gazette. In the Narcotic Drugs and Psychotropic Substances Rules, 1985, in Schedule I, under the heading "**Psychotropic substances**", for serial number 27 and the entries relating thereto shall be substituted with new molecules.

OFFENCES AND PENALTIES OF NDPS ACT

S. No	Offences	Penalty	Sections of the Act
1	Cultivation of opium, cannabis or coca plants without license	Rigorous imprisonment-up to 10 years + fine up to Rs.1 lakh	Opium - 18(c) Cannabis - 20 Coca-16
2	Embezzlement of opium by licensed farmer	Rigorous imprisonment -10 to 20 years + fine Rs. 1 to 2 lakhs (regardless of the quantity)	19
3	Production, manufacture, possession, sale, purchase, transport, import inter-state, export inter-state or use of narcotic drugs and psychotropic substances	Small quantity - Rigorous imprisonment up to 6 months or fine up to Rs. 10,000 or both. More than small quantity but less than commercial quantity - Rigorous imprisonment up to 10 years + fine up to Rs. 1 Lakhs. Commercial quantity - Rigorous imprisonment 10 to 20 years + fine Rs. 1 to 2 Lakhs	Prepared opium-17 Opium — 18 Cannabis - 20 Manufactured drugs or their preparations-21 Psychotropic substances -22
4	Import, export or transshipment of narcotic drugs and psychotropic substances	Same as above	23
5	External dealings in NDPS-i.e. engaging in or controlling trade whereby drugs are obtained from outside India and supplied to a person outside India	Rigorous imprisonment 10 to 20 years + fine of Rs. 1 to 2 lakhs (Regardless of the quantity)	24

6	Knowingly allowing one's premises to be used for committing an offence	Same as for the offence	25
7	Violations pertaining to controlled substances (precursors)	Rigorous imprisonment up to 10years + fine Rs. 1 to 2 lakhs	25A
8	Financing traffic and harbouring offenders	Rigorous imprisonment 10 to 20years + fine Rs. 1 to 2 lakhs	27A
9	Attempts, abetment and criminal conspiracy	Same as for the offence	Attempts-28 Abetment and criminal conspiracy— 29
10	Preparation to commit an offence	Half the punishment for the offence	30
11	Repeat offence	One and half times the punishment for the offence. Death penalty in some cases.	31 Death - 31A
12	Consumption of drugs	Cocaine, morphine, heroin - Rigorous imprisonment up to 1 year or fine up to Rs. 20,000 or both. Other drugs- Imprisonment up to 6 months or fine up to Rs. 10,000 or both. Addicts volunteering for treatment enjoy immunity from prosecution	27 Immunity - 64A
13	Punishment for violations not elsewhere specified	Imprisonment up to six months or fine or both	32

There were extreme confiscations of all narcotic drugs except hashish and cocaine over the last 5 years. NCB officials credited the maximum seizure of these drugs in the last few years. The quantity recovered from seizures in 2017 is the highest as per NCB officials. The following (Table 7) shows

the Seizure and case details of various controlled drugs during the period 2015-2019.

National Drug Enforcement Statistics as on 31/03/2019

		2015	2016	2017	2018	2019
SEIZURE OF DRUGS IN KG. WITH NO. OF CASES						
Opium	Seizure	1687	2251	2551	4324	3771
	Cases	860	933	1408	1177	86
Morphine	Seizure	61	28	449	21	0
	Cases	92	62	57	106	1
Heroin	Seizure	1476	1675	2146	1248	98
	Cases	3831	4565	7070	7590	565
Ganja	Seizure	94403	2934	35253	3149	3073
	Cases	8130	1440	21477	2135	1243
Hashish	Seizure	3349	2805	3218	3899	802
	Cases	2295	2567	2943	3079	250
Cocaine	Seizure	113	28	69	35	3
	Cases	100	81	132	102	12

Seizure of opium was increasing from 2015 to 2018 (Table 8) and there is a slight decline in 2019. Number of cases also augmented up to 2018 then decreased. This indicate the strict regulatory reform. Seizure of morphine is found to be zero and 1 case in 2019.

There is no need of illegal trafficking as oral morphine is made easily available to all palliative care centers as a part of implementation of 2015 NDPS Amendment. According to Annual report 2018-19-homeministry the number of cases registered with regard to various substance category are listed in table below

Narcotic drug cases registered (2015-2018)

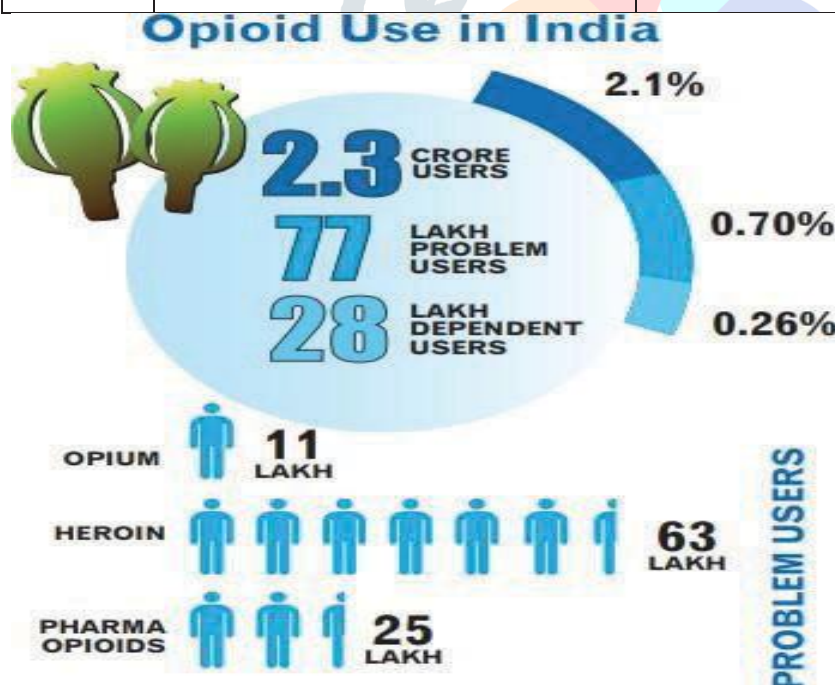
Substance Category	Number of cases registered		
	2015-16	2016-17	2017-18
OPIUM	15	30	22
OTHER OPIATES	6	17	24
CANNABIS	391	663	536
HEROIN	52	131	150
BROWN SUGAR	2	9	6
MULTIPLE DRUGS	20	41	34

OTHERS (POPPY HUSK, CHARAS, GANJA, TABLETS, CAPSULES)	150	165	187
GRAND TOTAL	2331	3417	3533

Reports shown that during 2018-19 itself 571 cases were registered, 761 individuals have been detained and Charas (30.8 Kg), Opium(53.7Kg), Ganja (3348.94Kg), Smack(328.69Kg), Poppy Head (1891.04 Kg) and Cocaine (1.030 Kg) were seized.

Seizures of controlled drugs by NCB and other departments during 2018-2019 (01.04.2018 to 31.03.2019)

Name of Drug	Drug seized in India by all agencies (Kg)	Drug seized by NCB alone (kg)
Heroin	1150	255.844
Opium	8023	375.45
Morphine	14	2660
Ganja	364068	35106134
Hashish	3745	950.015
cocaine	39	22471



Opioid use in India based on Survey by MoSJE

Narcotic Drug Regulation in Indian States- South Zone

NDPS regulation in South India

States	Regulatory Authority	Lice	NDPS Rule
--------	----------------------	------	-----------

		nces	
Kerala	Excise Department Police Department Drugs Control Department	Excise Department issues the licences under Rule 63 of NDPS Act. ND1, ND2, ND3, ND14, ND15, ND-16 and ND20 Drugs Control Department issue RMI Certificate along with allotment of END as per 2015NDPSAmendment	Kerala NDPS Rule,1985
Karnataka	Excise Department Police Department Drugs Control Department	Excise Department Drugs Control Department	Narcotic Drugs and Psychotropic Substances (Karnataka) Rules, 1985
Tamilnadu	Narcotic Intelligence Bureau (NIB) of Police Department Drug Control Department	Excise department. Drugs Control Department issues certificate to palliative centres	The Tamil Nadu Narcotic Drugs Rules, 1985
Andhra Pradesh	Excise Department Police Department Drugs Control Department	Drugs Control -Grant of licenses (NDPS-1 & NDPS-2)	Andhra Pradesh & Narcotic Drugs and Psychotropic Substances Rules, 1986

NDPS regulation in North India

States	Regulatory Authority	Licences	NDPS Rule
Jammu andKashmir	Excise Department Drugs Control Department Police Department	Issued by Excise Department	The Jammu and Kashmir Narcotic Drugs Rules, 1986
HimachalPradesh	Excise Department Drugs Control Department Police Department	Excise commissioner - Licensing of Narcotic drugs Drugs Controller - Psychotropic substances	The Himachal Pradesh Narcotic Drugs and Psychotropic Substances Rules, 1989
Uttarakhand	Excise Department Police Department	Excise Department issues licence for Hemp cultivation	-

Haryana	Excise Department	NDPS controlled by By Excise Department	Haryana Narcotic Drugs and Psychotropic Substances Rules, 1985
Punjab	Excise Department Police Department Drugs Control Department	Anti-Narcotic Task Force of Police Department	Punjab Narcotic Drugs and Psychotropic Substances Rules, 2012
Uttar Pradesh	Excise Department Collector	Collector issues licence	Uttar Pradesh Narcotic Drugs Rules, 1986

NDPS regulation in East India

States	Regulatory Authority	Licenses	NDPS Rule
Bihar	Excise Department Police Department Drugs Control Department	Collector along with Excise-grant license. ND1, ND2	Bihar Narcotic Drugs and Psychotropic Substances Rules, 1985
Orissa	Excise Department Police Department Drugs Control Department	Drugs Control - NDPS-1, NDPS-2 All other licenses by Excise	Orissa Narcotic Drugs and Psychotropic Substances Rules, 1989
West Bengal	Excise Department Police Department Drugs Control Department	Excise Department	West Bengal Narcotic Drugs and Psychotropic Substances Rule, 1985
Mizoram	Excise Department Police Department Drugs Control Department	Excise Department	Mizoram Narcotic Drugs and Psychotropic Substances Rules, 2004
Meghalaya	Excise Department Police Department Drugs Control Department	Drugs Control Department- RMI Certificate	Meghalaya Narcotic Drugs and Psychotropic Substances Rules, 1986 Amendment in 2012

Sikkim	Excise (Abkari) Department	Excise	Sikkim Narcotic Drug and Psychotropic Substance Rules
Arunachal Pradesh	Excise Department Police Department Drugs Control Department	Excise Department	Arunachal Pradesh Narcotic Drugs and Psychotropic Substances Rules 2000
Assam	Excise Department Police Department Drugs Control Department	Excise Department	Assam Opium Rules 1945 Assam NDPS Rules 1988 Assam Opium Prohibition Rules.1948 The Assam Opium Prohibition (Amendment) Rules,
Chhattisgarh	Excise Department	Excise Department Issues licenses.	Union Territory Chandigarh Narcotic Drugs and Psychotropic Substances Rules, 2005
Tripura	Police Department Revenue Intelligence Department	RI & Police	Tripura Narcotic Drugs Rules, 1986
Manipur	Excise Department	Excise Department	The Manipur Narcotic Drugs Rules, 1986

NDPS regulation in West India

States	Regulatory Authority	Licences	NDPS Rule
Maharashtra	Food, Drugs Control Department Maharashtra Excise	Maharashtra Excise issues licences	Maharashtra Narcotic Drugs and Psychotropic Substances Rules, 1985
Madhya Pradesh	Collector Excise Department CBN Drugs Control Department	Collector issues licence- O.P. 1 and 2	Narcotic Drugs and Psychotropic Substances (Madhya Pradesh) Rules 1985
Rajasthan	Excise Department Police Department Drugs Control Department	Additional Commissioner, Excise-N.D.P.S.L-2, N.D.P.S. L-4, N.D.P.S.L-6	Rajasthan Narcotic Drugs and Psychotropic Substances Rules, 1985
Gujarat	Excise Department Food and Drugs Control Authority	Excise Department	-
Goa	Excise Department Directorate of Food and Drugs Administration,	Excise Department	Goa, Daman and Diu narcotic drugs and psychotropic substances rules 1987

Pitfalls in Indian NDPS Regulation

- Licensing involved various supervisory authorities.
- Non-uniform licensing procedure from state to state and from district to district.
- Lack of clarity concerning sale and purchase of controlled drugs among dealers and manufacturers.
 - Lack of online licensing facility.
 - Lack of Track and trace system.
 - Small quantity narcotic seizure is a bailable offence, which causes the easy escape of accused.
 - Lack of uniformity in palliative care procedures.
 - Lack of proper implementation of amendments due to lack of training and fear.
 - Various factors like peer group pressure, lack of parental control may lead the youngsters to drug addiction. The Government had taken several attempts in 2018 to combat drug abuse and strengthen the regulatory system, but implementation was very poor, slow and inadequate.
 - Inadequate Rehabilitation /De-addiction centre.

CONCLUSIONS

Amendments are being made to ensure the problems faced by governments by facing practical problems, but there is a need to make further changes in this. This research will be helpful to find out the loopholes and also its solution to make it strong for the benefit of general public. It will be helpful to make opinion or view for the legislature for proper amendment in the Act. It is also expected the study a new dimension of

the issue may be disclosed which give new ground for further research. The study will give new solution to make an equilibrium between the government work and the right to know the public. The research is certainly helpful and important for the scholars who want to further research in this area. Based on the research conducted and feedback of the survey the following recommendations are framed to produce before appropriate authority for fruitful implementation of law.

REFERENCES

1. Roni shye. What Are Controlled Substance [Online]. Available from: <https://www.goodrx.com/blog/what-are-controlled-substances>.
2. Prescription Opioids Drug Facts | National Institute on Drug Abuse [Internet]. National Institute on Drug Abuse. 2020. Available from: <https://www.drugabuse.gov/publications/drugfacts/prescription-opioids>.
3. Han B, Compton W, Blanco C, Crane E, Lee J, Jones C. Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health. 2020. *Annals of internal medicine*. 2017 Sep 5;167(5):293- 301.
4. Regulatory Requirements | legal definition of Regulatory Requirements by Law Insider [Internet]. Lawinsider.com. 2020. Available from: <https://www.lawinsider.com/dictionary/regulatory-requirements>
5. Cancer facts and figures 2018, [Internet] Available from: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>
6. Opioids Market - Growth, Trends, and Forecast (2019 - 2024), [Internet] [cited 10 June 2020]. Available from <https://www.researchandmarkets.com/reports/4622511/opioids-market-growth-trends-and-forecast>,
7. Global Opioid Drug Market Source. [Internet] Available at: <https://www.Maximize market research.com/market-report/global-opioids-drugs-market/23754/>
8. Global Psychoactive Drug Market 2018-2026 [Internet] Available at: <https://www.maximizemarketresearch.com/market-report/global-psychoactive-drug-market/36268/>
9. Global-psychoactive-drug-Market-Segmentation [Internet] Available at: [https://dor.gov.in/narcoticdrugs psychotropic/overview\(different ministries in India\)](https://dor.gov.in/narcoticdrugs psychotropic/overview(different ministries in India))
10. Ray R, Kattimani S, Sharma HK. Opium abuse and its management: Global scenario. World Health Organization Department of Mental Health and Substance Abuse Management of Substance Abuse. National Drug Dependence Treatment Centre All India Institute of Medical Sciences New Delhi, India. 2006:1-3 Available from: https://www.who.int/substance_abuse/activities/opium_abuse_management.pdf.
11. Narcotic drugs and Psychotropic Overview. [Internet] Available at: <https://dor.gov.in/narcoticdrugs psychotropic/overview>.
12. Caraceni A, Hanks G, Kaasa S, Bennett MI, Brunelli C, Cherny N et al Use of opioid analgesics in the treatment of cancer pain: evidence-

based recommendations from the EAPC. The lancet oncology. 2012 Feb 1;13(2): e58- 68.

13. Commission on Narcotic Drugs takes decisive step to help prevent deadly fentanyl overdoses, Available at: <https://www.unodc.org/en/commission-on-narcotic-drugs-takes-decisive-step-to-help-prevent-deadly-fentanyl-overdoses.html>.
14. Definition of Controlled Substance.[Internet] Available at: <https://www.dictionary.com/browse/controlled-substance>
15. What are narcotics and why are they addictive. Available at: <https://www.foundationsrecoverynetwork.com/what-are-narcotics-and-why-are-they-addictive/>
16. <https://www.linkedin.com/pulse/statutory-regulatory-requirements-quality-management-system>
17. http://www.investorwords.com/4150/regulatory_requirements.html
18. http://www.emcdda.europa.eu/publications/topic-overviews/classification-of-controlled-drugs/html_en
19. <http://nicfs.gov.in/wp-content/uploads/2017/01/Narcotics-Drugs-and-Psychotropic-Substances.pdf>
20. Rexed B, Edmondson K, Khan I, Samsom RJ. Guidelines for the control of narcotic and psychotropic substances: in the context of the international treaties 1984. Available at: <http://www.who.int/publications/m/item/guidelines-for-the-control-of-narcotic-and-psychotropic-substances-in-the-context-of-the-international-treaties-1984>
21. Kilmer B., U.S. Department of Justice, Drug Enforcement Administration Available at: <http://www.ritalindeath.com/Methylphenidate.MethylPhenidate> (A background paper), October 1995.
22. Marshall D., Narcotic Drug Treatment Programme Best Practice Guidelines, US Department of Justice Drug Enforcement Administration, April 2000.
23. Howard A. Heit and Aaron M. Gilson, Federal Regulations for Prescribing Scheduled Controlled Substances Available at: <http://www.asam.org/pain-and-addiction/>
24. Drug Law Reform in Latin American Countries, Available at: <http://druglawreform.info/en/country-information/latin-america/argentina>.
25. Michele Leonhart et.al Pharmacist's Manual: An Informational Outline of the Controlled Substances Act. Springfield: United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control. 2010 edition Available at: www.gpoaccess.gov.
26. Boiteux L. Drugs and prisons: the repression of drugs and the increase of the Brazilian penitentiary population. Systems overload-drug laws and prisons in Latin America. Amsterdam/Washington: Transnational Institute/Washington Office Latin America. 2011:30-8.
27. Nakanishi, T., Pharmaceutical Regulation in Japan, Evaluation and Licensing Division Pharmaceutical Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare Available at: [CPhlJapan2012_siryou_E1.pdf](http://www.cphl-japan2012.siryou.e1.pdf).
28. Xiaoqiong Zheng. Information Centre, State Food and Drug Administration, Beijing, China. WHO Drug Information Vol. 26, No. 1, 2012 The State Council (2005). Regulation for control of narcotics and psychotropics Available at: <http://www.sfda.gov.cn/WS01/CL0784/23500>.

29. EU drug markets report — a strategic analysis Available at: www.europol.europa.eu.
30. International Narcotic Control Strategy Report 2013, March 5 2013. Available at: <https://2009-2017.state.gov/r/pa/prs/ps/2013/03/205998.htm>.
31. Rémuzat C, Toumi M, Falissard B. New drug regulations in France: what are the impacts on market access? Part 2—impacts on market access and impacts for the pharmaceutical industry. *Journal of market access & health policy*. 2013 Jan 1;1(1): 20892, Available at: <http://www.jmahp.net/index.php/jmahp/article/viewFile/20891/29560>.
32. Meyer S. Animal Health market in the BRIC countries and comparison of its regulatory requirements for veterinary medicinal products with EU legislation (Doctoral dissertation, Master's Thesis). Available at: <http://dgra.de/deutsch/studiengang/master-thesis/2014-Sybille-Meyer-Health-market-in-the-BRIC-countries-and-comparison-of-its%3Fnav%3Dstudiengang>
33. Marcelo Ribeiro., The Brazilian Drug Policy Situation: The Public Health Approach Based on Research Undertaken in a Developing Country, *Public Health Reviews*, 2014, Vol. 35, No 2.
34. Linda A. Johnson., IMS Health: Drug spending to jump 30 pct. to \$1.3T in 2020, 18 November 2015. Available at: <https://www.canadianbusiness.com/business-news/ims-health-new-drugs-more-generic-use-in-poor-countries-to-push-spending-to-1-3t-in-2020/>
35. Rosen LW. International drug control policy: background and US responses. Congressional Research Service; 2015 Mar 16. Available at: <https://scholar.google.com/scholar?um=1&ie=UTF-8&lr&cites=4378840739655118916>
36. Miraglia P, Drugs and Drug Trafficking in Brazil: Trends and Policies, Available at: <https://www.brookings.edu/wp-content/uploads/2016/07/miraglia-brazil-final.pdf>
37. Dragic L, Lee E, Wertheimer A. Classifications of Controlled Substances: Insights from 23 Countries. *INNOVATIONS in pharmacy*. 2015 Jan 1;6(2). Available at: <http://pubs.lib.umn.edu/innovations/vol6/iss2/6>.
38. Guidelines on the regulation of Therapeutic products in New Zealand, MEDSAFE, Ministry of Health, Part 5, Edition 1.4, Feb 2015. Available at: <http://legislation.govt.nz/act/public/1981/0118/latest/whole.html#DM53795>
39. NATIONAL POLICY ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES Available at: <http://cbn.nic.in/html/NationalPolicyEnglish.pdf> –
40. Dr Colin Tidy, CONTROLLED DRUGS, Document ID 234 (v8) Available at: www.patient.co.uk/doctor/controlled-drugs
41. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA: a cancer journal for clinicians*. 2018 Nov;68(6):394-424. Available at: <https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21492>.