



## An overview of regulations of controlled substances in different countries: United States, Europe, Australia and India

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### Abstract

Narcotics and psychoactive drugs are among highly abused and highly regulated substances under controlled substances regulations. To protect the public health and safety by preventing diversion and abuse of controlled substances without prohibiting their appropriate and effective use, regulation of such is required. The purpose of this study was to describe substance abuse and to critically review the regulations regarding to manufacturing and import-export of controlled substances.

**Keywords:** controlled substances, regulations, narcotics, drug abuse, drug prevention

### Introduction

#### Controlled substances

Controlled substances are drugs or chemicals whose manufacture, sale, possession or use is strictly regulated by a government under legislative control. Controlled substances are useful in severe pain, for its mental and physical effects and as steroids, analgesics, euthanasia and anesthetics<sup>[1]</sup>.

Controlled substances have varying degrees of medicinal properties and addictive properties. These substances are regulated to control the danger of addiction, abuse, physical and mental harm, the trafficking by illegal means, and the dangers from actions of those who have used the substances.

The term Controlled substances most commonly used, other terms that have been used by various groups are controlled drugs and controlled medications. Controlled substances include narcotic drugs, psychoactive drugs and precursor chemicals.

Controlled substances such as Narcotics are drugs which induce drowsiness, stupor or insensibility and relieve pain, causing loss of feeling or paralysis. Narcotic analgesics are used for severe pain. Examples of some narcotics are opium, opium derivatives, their semi-synthetic substitutes and cocaine.

Psychoactive drugs are chemical substances that changes brain function and results in alterations in perception, mood, consciousness or behavior. They are also known as psycho pharmaceutical or psychotropic. They are used in neuropsychiatric disorders. Examples of psychoactive substances are cocaine, crack cocaine, methylphenidate, dextrolysergic acid diethylamide tartrate (LSD), codeine, cannabis, ephedrine etc. Precursor chemicals are substance which can be used to make illicit drugs. Precursor chemicals include precursors, reagents and solvents. Some examples of precursor chemicals are methamphetamines, amphetamines, fentanyl and analogues, phencyclidine etc.

Controlled substances are mainly used as pain killers or in

pain management. Medical uses of controlled substances are as follows:

Opioid analgesics, such as codeine and morphine, and antiepileptic, such as lorazepam and Phenobarbital, are considered as essential medicines by the World Health Organization.

Controlled substances such as narcotics are useful to relieve extreme pain which is not controlled by milder substances. They cannot be used for longer than 4 months because they are highly addictive in nature. Morphine is given near death situation to ease pain and discomfort. Psychoactive drugs are mainly used in anesthesia to undergo medical procedures like surgery without the feelings of physical pain or emotional trauma. They are also used as stimulants, mood stabilizers, antidepressants, hallucinogens, anxiolytics and antipsychotics.

#### History of Controlled Substances<sup>[5, 6]</sup>

Medicines are as old as mankind and the concept how their quality has to be ensured has evolved gradually over the time. During the nineteenth century, there was very little governmental control over drugs. The federal government regulated the smallpox vaccine in 1813 (2 Stat. 806) and established some controls through the Imported Drugs Act of 1848 (9 Stat. 237, repealed by Tariff Act of 1922 [42 Stat. 858, 989]).

Some addictive substances such as opium and cocaine were legal. Heroin, discovered in 1888, was prescribed for treating other addictions. California began restricting opium in 1875, but widespread criminalization of the substance would not come for decades.

States began a widespread movement toward control of legal and illegal controlled drugs at the turn of the twentieth century. The federal government joined this process with the Pure Food and Drug Act of 1906 (34 Stat. 768, 1906, Ch. 3915, §§ 1-13, repealed by Federal Food, Drug, and Cosmetics Act of 1938), which primarily sought to protect

consumers from "misbranded or poisonous" drugs and medicines. It established federal jurisdiction over the domestic manufacture and sale of drugs and also regulated drug imports.

Nevertheless, when Congress passed the Harrison Act of 1914 (Pub. L. No. 223, 38 Stat. 785), which imposed a tax on opium and cocaine; it stopped short of declaring either drug illegal.

Despite numerous amendments, flaws in the Pure Food and Drug Act spurred Congress to replace the statute. In 1938, federal law makers enacted the Federal Food, Drug, and Cosmetics Act (FFDC) (21 U.S.C.A.), which established the Food and Drug Administration (FDA) as the federal agency charged to enforce the law.

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (21 U.S.C.A.), which continues to be the primary source of federal law on controlled substances.

In 1980, antidrug abuse act was passed by US congress which prohibited controlled substances analogue.

Sense of any illegal drug was first recorded in 1926, Amer. Eng. There are many kinds of narcotics from which two most common are morphine and codeine which are synthesized from opium for pain management. Some other drugs which

are used in pain management are fentanyl, oxycodone, tramadol, hydrocodone, methadone and hydromorphone. The newest drug is ZOHYDRO which came out in 2014. It is an intense dosage of hydrocodone medication created for pain management. The first psychoactive drug was chlorpromazine which was used in the treatment of acute and chronic psychoses, schizophrenia and bipolar disorder. Psychoactive substances include stimulants, depressants and hallucinogens. Recently new psychoactive drugs have been synthesized such as synthetic cathinones and cannabinoids, derivatives of piperazine and aminoindans.

**Classification of controlled substances**

To control the use of dangerous drugs, federal law and most state statutes use a classification system outlined by the Uniform Controlled Substances Act, based on the federal Comprehensive Drug Abuse Prevention and Control Act. This system includes both illegal and legal controlled substances.

It uses five groups, called schedules, to organize drugs according to their potential for medical use, harm, or abuse, and it imposes a series of controls and penalties for each schedule.

**Drugs are scheduled under Federal law according to their effects, medical use, and potential for abuse**

DEA Schedule	Abuse Potential	Examples of Drugs Covered	Some of the Effects	Medical Use
I	Highest	heroin, LSD, hashish, marijuana, methaqualone, designer drugs	Unpredictable effects, severe psychological or physical dependence, or death	No accepted use; some are legal for limited research use only
II	High	morphine, PCP, codeine, cocaine, methadone, Demerol, benzadrine, dexedrine	May lead to severe psychological or physical dependence	Accepted use with restrictions
III	Medium	codeine with aspirin or Tylenol, some amphetamines, anabolic steroids	May lead to moderate or low physical dependence or high psychological dependence	Accepted use
IV	Low	Darvon, Talwin, phenobarbital, Equanil, Miltown, Librium, diazepam	May lead to limited physical or psychological dependence	Accepted use
V	Lowest	Over-the-counter or prescription compounds with codeine, Lomotil, Robitussin A-C	May lead to limited physical or psychological dependence	Accepted use

**Fig 1:** classification of controlled substances showing the schedules of controlled substances

Heroin, hallucinogens, and marijuana are placed on schedule I, as they are thought to have a high potential for harm and no medical use. Other types of opiates and cocaine are on schedule II. Most depressants and stimulants are on schedule

III. Some mild tranquilizers are on schedule IV. Schedule V is for drugs that are considered medically useful and less dangerous but that can cause limited physical and psychological dependence, such as cough-syrup mixtures that

contains codeine.

Under the law, drugs may be rescheduled as new evidence of their uses or risks become apparent, and the attorney general has the authority to add new drugs to the schedules at anytime. In Europe controlled substances are classified in five schedules same as US with minor changes. While in Australia controlled drugs are classified in the national classification system of schedule 8. According to revised regulations, changes have been added to classification system.

### Regulations of controlled substances

Regulatory agencies are established to protect and prevent public health. Current regulation of controlled substances has two main objectives. First, it regulates the manufacture, sale, and use of legal drugs such as aspirin, sleeping pills, and antidepressants. Second, it prohibits and punishes the manufacture, possession, and sale of illegal drugs from marijuana to heroin, as well as some dangerous legal drugs.

Controlled substances legislation is to protect and promote public health by measures targeted at preventing poisoning, medicinal misadventure, and abuse of drugs.

Based on the need of strict regulations for controlled substances amendments and revised regulations are provided by various regulatory authorities.

### Regulations as per us

The U.S. Food and Drug Administration is the oldest federal agency dedicated to consumer protection. The controlled substances regulation is governed by FDA. Policy implementation involves both federal and state agencies, including the Department of Justice, the Drug Enforcement Administration (DEA), the Federal Bureau of Investigation (FBI), and the State Department, branches of the Armed Services and the U.S. Coast Guard, and local police departments.

The Drug Enforcement Administration (DEA) is a United States federal law enforcement agency under the U.S. Department of Justice. The regulations regarding to controlled substances are given within 21 CFR (Code of Federal Regulations).

In Chapter: 2 of title 21 of DEA, dept. of justice, controlled substances regulations for registration, manufacturing, labeling and packaging, importation and exportation are published.

The regulations that most directly affect controlled substances are contained in:

- 21 CFR chapter: 2, browse parts:1300-1399
- 1301: Registration of manufacturers of controlled substances
- 1302: labeling and packaging of controlled substances
- 1308: schedules
- 1312: Importation and Exportation of controlled substances
- 21 CFR chapter: 2, subchapter: 13(Drug Abuse Prevention and Control)
- These regulations have been amended recently in 2012.

### Regulations as per Europe <sup>[9, 10]</sup>

The European Union is a politico-economic union of 27 member states that are primarily located in Europe. The EU

operates through European Medicine Agency for evaluation of medicinal products (abbreviated to European Medicines Evaluation Agency, or EMEA).

EMA was first named in 1993 by EC regulation no. 2309/93 as the European Agency for the Evaluation of Medicinal Products. It was renamed in 2004 by EC Regulation no. 726/2004 as the European Medicines Agency, but retained the acronym EMEA. At the end of 2009, it was changed the acronym EMA.

In Europe, the manufacture and import-export of controlled substances are regulated by several European bodies and by national authorities.

Act on Narcotic Drugs and Psychotropic Substances and precursors regulated controlled substances manufacturing and import-export.

The legislation for precursor control is to be found in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988.

EU legislation implements controlled substances regulation through:

- Regulation (EC) No 111/2005 on trade in drug precursors between EU and third countries, amended by Regulation (EC) No 1259/2013.
- Regulation (EC) No 271/2004 on trade in drug precursors within the EU amended by Regulation (EC) No 1258/2013.

As national authority United Kingdom regulates controlled substances by The Misuse of Drugs Act 1971 which aimed to control numerous listed drugs and drug-like substances as a controlled substance. The act allowed and regulated the use of some Controlled Drugs. The Misuse of Drugs Act 2001 was recreated under the Act 1971.

Recently implemented regulation in UK is The Psychoactive Substances Act 2016.

### Regulations as per australia

Therapeutic Goods and Administration (TGA) regulates controlled substances by office of Drug Control. The Office of Drug Control provides advice and legislation on manufacturing, import and export of controlled substances.

Legislation implemented by Australia are as follows:

The Customs (prohibited imports) Regulation 1956: Regulation 5,5A, 5G, 5H.

The Customs (prohibited exports) Regulation 1958: Regulation 10, 10A, 10B, 10AB.

Narcotic Drugs Legislation Amendment Act 2016

Narcotic Drug (License Charges) Act 2016

Narcotic Drug (License Charges) Regulation 2016

Narcotic Drugs Legislation Amendment Act 2016

Narcotic Drugs Amendment Bill 2016

Therapeutic Goods Order No.93

### Regulations as per india

In India, the major drug laws on controlled substances come under Drug Policy of India. The regulations implemented for controlled substances are the Narcotic and Psychoactive Substances Act 1985(NDPS Act) and the Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act.

The NDPS Act covers regulations of production/manufacture/cultivate and transport of controlled substances.

The Act has been amended three times – in 1988, 2001, and most recently in 2011.

The Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act is a drug control law which was passed in 1966 to enable the full implementation and enforcement of the Narcotic and Psychoactive Substances Act. The Narcotic Control Bureau (NCB) is the chief law enforcement and intelligence agency of India. This agency is mainly responsible for preventing drug trafficking and the abuse of illegal substances- controlled substances.

It was created on 17 march 1986 to enable the full implementation of the Narcotic and Psychoactive Substances Act 1985 (NDPS Act) and the Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act.

### **Conclusion**

In this study, it is observed that United States, European countries and Australia have very stringent regulations for controlled substances while in India there are very few regulations for controlled substances which can affect the public health. In order to strengthen the regulation system of medical and scientific use of controlled substances, to eliminate its risk of abuse and to reduce the rate of morbidity and mortality stringent control by regulation is necessary.

### **Acknowledgement**

The authors are thankful to Dr. K. Pundarikakshudu, Director of L. J. Institute of Pharmacy; Ahmedabad, India for providing all the facilities and encouragement to carry out the work and also thankful to Dr. Jignesh S. Shah for providing support and knowledge.

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