

## The Indian Laws Relating to Drugs and Poisons

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### Abstract

Drugs are vital means for the prevention and cure of diseases and ailment of different nature. It has played a vital in the health of humanity and improved its life span and quality of life. With the advancement of science and research, new drugs are evolving each year and the pharmaceutical companies are flourishing with business. Therefore various acts have been passed by the Govt. to regulate the manufacture, composition and sale of these drugs. Besides it has made various laws to prevent the misuse of these drugs to harm others. The physicians and the pharmacist should be aware of the various legal acts of drugs and poisons pertaining to its profession. This review article has attempted to bring out all the relevant acts and rules pertaining to drug and poison relevant to the medical practitioners.

**Keywords:** Drugs; Poisons; Laws; Narcotics; Psychotropic substance.

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### Introduction

In India several legal acts have been passed to regulate and control the manufacture, sale, distribution, and possession of drugs and poisons. The WHO (1996) definition, drug [7] is any substance or product that is used or intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient. As per the drug and cosmetic act, drug includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparation applied on human body for the purpose of repelling insects like mosquitoes. Poison is defined as any substance which when introduced into the living body or brought into contact with any part thereof will

produce ill effect or death by its local or systemic action or both. Some of the Indian laws of importance in relation to drugs and poison are as follows:

- The Poison Act, 1919
- The Drugs Act, 1940
- The Drugs and Cosmetics Act, 1940
- The Drugs and Cosmetics Rules, 1945
- The Pharmacy Act, 1948
- The Drugs Control Act, 1950
- The Drugs and Magic Remedies Act, 1954
- The Narcotics Drugs and Psychotropic Substance Act, 1985
- The Indian Penal Code (IPC), 1860
- The Criminal Procedural Code (CrPC), 1973
- The Indian Evidence Act (IEA), 1872

### **The Poison Act (1919)**

This was amended in the year 1958 and repealed in 1960. It regulates the grant of licenses and sale of poisons whether wholesale or retail. It also regulates import of any specified poisons. It extends to whole of all of India.

### ***The Drugs and Cosmetics Act (1940)***

This Act was amended in 1964 to include Ayurveda and Unani drugs and it regulates the drugs of articles of cleansing (except soap), beautifying and promoting attractiveness or altering appearances. It was recently amended in 2008 and today the act is referred to as the Drugs and Cosmetics Amendment Act (2008). This act also demands the fact that every patented or proprietary medicinal preparation under this act must display a label on the container mentioning the exact formula or list of ingredients in it. This act empowers the central Govt. to form a drug technical advisory board and to establish a central drug laboratory to help and advice both the central and states government. It controls the quality, purity and strength of drugs for safety. It regulates the import, manufacture, distribution and sale of these drugs. The amended act has enhanced the scale of punishment for various offences, including sale of spurious drugs, adulteration of drugs and cosmetics, toxic contamination etc.

### ***The Drugs and Cosmetics Rules (1945) [6]***

This is a derivative of Drugs and Cosmetic Act 1940; and it covers all kinds of drugs used in therapeutics under allopathic, Ayurvedic, Unani and Siddha preparations. The rule deals mainly with the standard and quality of drugs. It also controls the drugs by specific regulation laid down for their storage, display, sale, dispensing, labeling, prescription etc. To advise the central and state government on technical matters relating to drug control, the following boards have been set up: The drugs and technical advisory board, The ayurvedic and unani technical advisory boards, and the drugs consultative committee. In order to facilitate the analysis or testing of drug samples to assess their quality, the central drugs laboratory was established in 1962. Stringent punishments have laid down for manufacture, stocking, or sale of substandard or spurious drugs. Guidelines for conducting clinical trials for new drugs have been made more strict (Schedule Y). The drugs and cosmetics rules have classified drugs into various

schedule as follows.

Schedule C and C1- Biological and special products such as serums, vaccines, etc.

Schedule D – Substances not intended for medicinal use – condensed or powdered milk, oats, spices and condiments etc.

Schedule E1- Lists of poisonous substances under Ayurvedic, Siddha and Unani systems of Medicine.

Schedule G- List includes hormone preparations, hypoglycaemic agents, antihistamines and anticancer drugs.

Schedule H and L - These are drugs or poisons which need to be labeled as 'Schedule H Drug Warning- to be sold by retail on the prescription of Registered Medical Practitioner only.' Barbiturates, amphetamines, reserpine, ergot, antibiotics, antibacterials and some of the sulphonamides are listed under this schedule.

Schedule J- Drugs, which should not be advertised for certain diseases (which cannot be announced). This covers list of drugs which are claimed to be cure of conditions such as appendicitis, blindness, cancer, cataract, epilepsy, hydrocoele, etc.

Schedule L- Antibiotics, antihistaminic and other chemotherapeutic agent of recent origin subjected to same restrictions as Schedule H drugs.

Schedule O – Standards to be followed with regard to disinfectant fluids.

Schedule X drugs – Barbiturates and certain other sedatives, amphetamines, etc.

### ***The Pharmacy Act (1948)***

This Act makes provision for regulation of the profession of pharmacy and for the purpose of constitution of pharmacy council of India, which regulates study of pharmacy throughout the country. Individual states have State Pharmacy Councils for registration of pharmacist. The objective of this act is to allow only registered pharmacists to compound, prepare, mix, or dispense any medicine on the prescription of a registered medical practitioner

### ***The Drugs Control Act (1950)***

This Act regulates the supply and distribution of drugs, and also guides the manufacturer or dealer in fixing the maximum price fix every drug.

### ***The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954***

The objective of this act is to ensure that ethical

standards are maintained when drugs are advertised by manufacturers. This act bans the objectionable advertisements of magical remedial drugs for curing conditions such as venereal diseases, impotency, menstrual disorders, infertility, abortion, misconception, insanity etc. Advertisements offending decency or morality can be banned under this Act.

#### ***The Narcotic Drugs and Psychotropic Substance (NDPS) [2] Act, 1985***

This Act consolidates and amends the law relating to narcotic drugs (The Opium Act, 1857 and 1878; and The Dangerous Drug Act, 1930, both are repealed by this Act), drugs of abuse, penalties for the drug trafficking offenses and control over psychotropic substances. Narcotic drugs under this act include opiates, cannabis and cocaine. The psychotropic drugs under this Act refers to mind alerting drugs such as LSD, phencyclidine, amphetamines, barbiturates, methaqualone, benzodiazepines, mescaline, psilocybin and designer drugs (MDMA, DMT, etc). It was again amended in 1988 and 2001. It prevents trafficking in narcotic drugs and psychotropic substances. It is applicable to all citizens of India even though they may be outside the territory of India and to all persons on ships and aircrafts registered in India, wherever they may be. The NDPS act imposes complete prohibition on the cultivation of coca, poppy, and cannabis plants and the manufacture, sale, purchase, use or transport of any narcotics drugs or psychotropic substance except for medical or scientific purposes.

The minimum punishment for any offence committed under the act is 10 years rigorous imprisonment and fine of Rs 1 lakh, while the maximum punishment is 20 years rigorous imprisonment and fine of Rs 20 lakhs. To constitute an offence the first time around, the minimum quantity seized should be equal to or over 250 mg for heroin, 5 gm for hashish or charas, 5gm for opium, 125 mg for cocaine, and 500 gm for ganja.

The central Government of India constituted a Narcotic control Bureau in 1986 with its head quarter at New Delhi, and Zonal offices at Mumbai, Kolkata, Chennai and Varanasi. In 1988, the central government constitute the Narcotic Drugs and psychotropic substance consultative committee, consisting of a chairman and 18 members from various fields who would among other functions, conduct periodic review of the NDPS act. The NDPS act prohibits cultivation of poppy, cannabis, and coca plant. But it allows restricted cultivation of these

plants under strict control for scientific and medical use.

#### ***Drugs (Price Control) Order, 1995***

The Drugs price control order, 1995 was brought in by Govt. of India to regulate and control the manufacture and pricing of the first schedule drugs. It has the power to fix the maximum sale prices of bulk drugs in the first schedule and also the information to be furnished by the manufacturers in relation to the scheduled bulk drugs and non scheduled bulk drugs. It can also fix the retail price of scheduled formulations. The manufacturers should maintain a proper record of drugs and production for inspection.

#### **List of First Scheduled Drugs**

##### ***The Indian Penal Code (IPC), 1860 [1,3]***

- *Section 176:* Doctors must report all cases of homicidal poisoning to police, if not they are punishable
- *Section 177 :* For furnishing false information
- *Section 193 :* Doctor is punishable for giving false information about poisoning case
- *Section 201:* Causing disappearance of evidence of offence
- *Section 202:* Doctor is punishable for intentional concealing of facts about poisoning case treated by him.
- *Section 272:* Adulteration of food or drink intended for sale
- *Section 273:* Sale of noxious food or drink
- *Section 274:* Adulteration of drugs
- *Section 275:* Sale of adulterated drugs
- *Section 276:* Sale of drugs as a different drug or preparations
- *Section 284:* Lays down penalty for any person causing harm by rash and negligent handling of a poisonous substance so as to endanger human life or to be likely to cause hurt injury to any person.
- *Section 299:* Culpable homicide including that caused through administration of some poisonous substance.
- *Section 300, 302,306,307,309:* Murder including that caused through administration of poisonous substances with the intention of causing death.

- *Section 304A*: Rash and negligent act including that caused through poisoning
- *Section 320*: Causing grievous hurt
- *Section 324*: Causing hurt by dangerous weapons or means (including Poison or any corrosive substance)
- *Section 326*: Causing grievous hurt by dangerous weapons or means (including poison)
- *Section 326 A*: Voluntarily causing grievous hurt by use of acid(vitriolage )
- *Section 326 B*: Voluntarily throwing or attempting to throw acid.
- *Section 328*: Causing hurt by means of poison or stupefying intoxicating or unwholesome drug or other thing with the intent to commit an offence.

### **The Code of Criminal Procedure (CrPC), 1973**

Section 39: Every person aware of the commission of, or of the intention of any other person to commit any offence punishable under IPC shall forthwith give information to the nearest magistrate or police officer of such commission or intention.

Section 40: Every employed officers aware of the commission of, or of the intention of any other person to commit any offence punishable under IPC shall forthwith give information to the nearest magistrate or police officer of such commission or intention.

Section 175: Power to summon persons by police officer proceeding under section 174

### *The Indian Evidence Act (IEA), 1872*

Section 32, Clause 1, under the Indian Evidence Act (IEA) allows a doctor to record dying declaration when the death of the patient is imminent and arrival of magistrate is delayed.

### **Recent Amendments of IPC Dealing with Acid Attack Case, 2013 [4,5]**

*IPC 326 A (Voluntarily Causing Grievous Hurt by Use of Acid, etc.)*

Whoever causes permanent or partial damage or deformity to, or burns or maims or disfigures or disables, any part or parts of the body of a person or causes grievous hurt by throwing acid on or by administering acid to that person, or by using any

other means with the intention of causing or with the knowledge that he is likely to cause such injury or hurt, shall be punished with imprisonment of either description for a term which shall not be less than ten years but which may extend to imprisonment for life, and with fine: provided that such fine shall be just and reasonable to meet the medical expenses of the treatment of the victim: provided further that any fine imposed under this section shall be paid to the victim. The section was introduced on the basis of the recommendation of justice J.S Verma committee.

### *IPC 326 B (Voluntarily Throwing or Attempting to Throw Acid)*

Whoever throws or attempts to administer acid on any person, or attempts to use any other means, with the intention of causing permanent or partial damage or deformity or burns or maiming or disfiguring or disability or grievous hurt to that person, shall be punished with imprisonment of either description for a term which shall not be less than five years but which may extend to seven years, and shall also be liable to fine.

For the purposes of section 326 A and this section, acid includes any substance which has acidic or corrosive character or burning nature, that is capable of causing bodily injury leading to scars or disfigurement or temporary or permanent disability. For the purposes of section 326 A and this section, permanent or partial damage or deformity shall not be required to be irreversible.

Supreme court in Laxmi Vs Union of India directed the state to consider (1) Enactment of appropriate provisions for effective regulation of sale of acid in the states/Union territories (2) Measures for proper treatment, after care and rehabilitation of the victims of acid attack and needs of acid attack victims (3) Compensation payable to acid victims by the state/ or creation of some separate fund for payment of compensation to acid attack victims. In a subsequent order in the same case the supreme court issued many directions to curb the menace of acid attacks.

### *Supreme Court Guidelines to Prevent Acid Attacks*

1. Over the counter, sale of acid is completely prohibited unless the seller maintains a log/register recording the sale of acid which will contain the details of the person(s) to whom acid(s) is/are sold and the quantity sold. The log/register shall contain the address of the person to whom it is sold.
2. All sellers shall acid only after the buyer has

shown:

- a. A photo ID issued by the government which also has the address of the person.
  - b. Specifies the reason/purpose for procuring acid.
3. All stocks of acid must be declared by the seller with the concerned Sub Divisional Magistrate (SDM) within 15 days
  4. No acid shall be sold to any person who is below 18 years of age.
  5. In case of undeclared stock of acid, it will be open to the concerned SDM to confiscate the stock and suitably impose fine on such seller upto 50,000-
  6. The concerned SDM may impose fine upto 50,000/- on any person who commits breach of any of the above directions.

The educational institutions, research laboratories, hospitals, Government departments and the departments of public sector undertakings, who are required to keep and store acid, shall follow the following guidelines:

1. A register of usage of acid shall be maintained and the same shall be filed with the concerned SDM.
2. A person shall be made accountable for possession and safe keeping of acid in their premises.
3. The acid shall be stored under the supervision of this person and there shall be compulsory checking of the students/personnel leaving the

laboratories/place of storage where acid is used.

### Conclusion

In India we have various acts and laws to regulate drugs and poisons. It is important to know its legal aspects when we prescribe and dispense these drugs in hospital or pharmacy. Its awareness can help us to avoid negligence due to our ignorance of these rules and also provide prudent medico-legal opinion related to drug and poison.

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