THE EVOLUTION OF DRUGS LAWS

There are two types of drug laws-

a) Pre-constitution laws.

b) Post constitution laws.

Pre-constitution laws

The laws were passed before independence. In Pre-constitution laws, the state governments are empowered to make changes as their requirements with prior assent of the president.

There is four such type of act-

a) The Opium Act-1857, 1878.

b) The Poison Act -1919.

c) The Dangerous Drug Act- 1930.

d) The Drug Act- 1940, 1949, 1950, 1951, 1955, 1960, 1962, 1964, 1972, 1982, 1986, 1995.

Post constitution laws

These laws are passed after independence, as per Indian constitution. The state governments are not empowered to make any changes. Such types of act are as follows.

a) The Pharmacy act- 1948.

b) The Drug and Magic Remedies (Objectionable Advertisement) Act- 1954.

c) The Medicinal and Toilet Preparation (Excise Duties) Act- 1955, 1976.

d) The Drug (Prices Display and Control) Order- 1966, 1969, 1970, 1987, 1995.

e) Insecticides Act- 1968.

f) Medicinal Termination of Pregnancy Act- 1971, 1975.

g) The Narcotic Drugs and Psychotropic Substance Act- 1985.

HEALTH SURVEY AND DEVELOPMENT COMITTEES

1. **Mudaliar Committee:** The concern of the Health Survey and Planning Committee (Mudaliar Committee 1962) was limited to the development of the health services infrastructure and the health care at the primary level. It felt the growth of infrastructure needed radical transformation and further investment. Another major shift came in the Third Plan (1961-66) when family planning received priority for the first time. Increase in the population became a major worry and was seen as a hurdle to the development process.

Although the broad objective was to bring about progressive improvement in the health of the people by ensuring a certain minimum level of physical well-being and to create conditions favourable for greater efficiency, there was a shift in focus from preventive health services to family planning. During the Fourth Plan (1969-74), efforts were made to provide an effective base for health services in rural areas by strengthening the PHCs. The vertical campaigns against communicable diseases were further intensified.

2. **Bhatia Committee:** Government of India in 1953 appointed a committee under the chairmanship of Major General S.L.Bhatia which is called as Bhatia committee to make comprehensive enquiry into the working of Pharmaceutical industry & to recommend what steps the Government should take to establish it on sound lines in the interest of the country 's health care delivery & economy.

3. **Hathi Committee:** Indian Government has setup Hathi committee under the chairmanship of Jaysukhlal Hathi to take comprehensive look into the drug industry and to enquiry in to the various facts of drugs in India. The report of this committee covered all aspects ranging from licensing, Price control, Imports, role of foreign sector and quality control. It encouraged the development of indigenous industries, It also further controlled price of a large number of drugs in the interest of the consumer.

4. **Bhore committee:** In 1943, Indian Government appointed a committee under the chairmanship of Sir Joseph Bhore to make a survey of existing position of Drug industries in respect to the health care delivery organization in India and to make recommendation for future developments.

Recommendation of Bhore committee

a) Setting up Central Drug Laboratory (CDL).

b) Establishment of all India Pharmaceutical council and provincial Pharmaceutical Council representing the pharmaceutical trade, education.

c) Starting of revised courses of study for:

- Licentiate Pharmacist.
- Pharmaceutical Technologist.
- Graduate Pharmacist.

d) Rigid enforcement of the Drugs and cosmetic act, 1940 throughout the country.

Drug Enquiry Committee: The government of India pursuance to the resolution appointed a committee known as Drug Enquiry Committee with Col.Ramnatha.N.Chopra as its chairman in, 1928.

Recommendation of Chopra Committee

1. A central law to control drug and pharmacy profession.
2. Setting up of testing laboratories in all states to control quality of production of drugs and pharmaceutical and a central laboratory to control the quality of imported drugs and also to act as expert a referee in case of sample sent by local government.
3. Appointment of advisory board to advice the government in making rules to carry out the objectives of the act.
4. Setting up the course for training of pharmacist and prescribe minimum qualification for the registration as the pharmacist.
5. Registration of every pattern and proprietary medicine manufacture in India or imported from outside country.
6. Bringing of crude single drug as well as compounded medicine used in the indigenous system of treatment under control.
7. Development of the drug industry in India.
8. Gradual reduction of manufacturing in medical stores.
9. Completion of an Indian Pharmacopoeia.

NEW DRUG POLICY

In September 1994, a new drug policy was announced with an intension of liberalization of economy and to attract foreign capital. This policy was modified in 1986.

Features of new drug policy

1. Abolished licensing requirements except-
   - Bulk drugs Vit-B1, Vit-B6, folic acid, tetracycline, oxytetracycline.
   - Bulk drug produced by the use of recombinant DNA technology.
   - Bulk drug requiring use of nucleic acids.
2. Replaces two lists of 142 price controlled drugs by single list of 76 drugs.
3. Set up National Drug Authority.
4. A National Pharmaceutical Pricing Authority set up for fixing and revising drug prices.
5. Exemption from price control for ten years for a new drug produced with indigenous technology,
6. Provides incentive for Pharmaceutical Research and Development,
7. Provides for automatic approval of Foreign Technology agreement.
8. Foreign equity ceiling raise from 40% to 50%.

PHARMACY AS A HEALTH CARE SYSTEM

Pharmacy renders a health service and pharmacists are the health professionals. Pharmacists are useful in health services as follows,

1. Preservation of drugs.
2. Prescription adherence.
3. Drug monitoring.
4. Selection of essential drugs.
5. Clinical pharmacological research.
6. Provide information and educate the patients regarding proper use of drugs.

PERD) has been set up at Sarkhej-Gandhinagar Highway, Ahmedabad.

1.2 DRUGS AND PHARMACEUTICAL INDUSTRY

DRUGS

A drug is "a chemical" substance used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being." Drugs may be prescribed for a limited duration, or on a regular basis for chronic disorders.

When drug is absorbed into the body of a living organism, alters normal bodily function. There is no single, precise definition, as there are different meanings in drug control law, government regulations, medicine, and colloquial usage.

Recreational drugs are chemical substances that affect the central nervous system, such as opioids or hallucinogens. They may be used for perceived beneficial effects on perception, consciousness, personality, and behavior. Some drugs can cause addiction and habituation.

A medication or medicine is a drug taken to cure and/or ameliorate any symptoms of an illness or medical condition, or may be used as medicine that has future benefits but does not treat any existing or pre-existing diseases or symptoms.

Drugs are usually distinguished from endogenous biochemicals by being introduced from outside the organism. For example, insulin is a hormone that is synthesized in the body; it is called a hormone when it is synthesized by the pancreas inside the body, but if it is introduced into the body from outside, it is called a drug.

Many natural substances such as beers, wines, and some mushrooms, blur the line between food and drugs, as when ingested they affect the functioning of both mind and body.

Drugs can be administered in a number of ways:

1. Bolus, a substance into the stomach to dissolve slowly.
2. Inhaled, (breathed into the lungs), as an aerosol or dry powder.
3. Injected as a solution, suspension or emulsion, either: intramuscular, intravenous, intraperitoneal, intraosseous.
4. Insufflations, or snorted into the nose.
5. Orally, as a liquid or solid, that is absorbed through the intestine.
6. Rectally as a suppository, that is absorbed by the rectum or colon.

7. Sublingually, diffusing into the blood through tissues under the tongue.
8. Topically, usually as a cream or ointment. A drug administered in this manner may be given to act locally or systemically.
9. Vaginally as a suppository, primarily to treat vaginal infections.

CLASSIFICATION OF DRUGS

Medications can be classified in various ways, such as by chemical properties, mode or route of administration, biological system affected, or therapeutic effects. An elaborate and widely used classification system is the Anatomical Therapeutic Chemical Classification System (ATC system). The World Health Organization keeps a list of essential medicines.

A sampling of classes of medicine includes:

1. Antipyretics: reducing fever (pyrexia/pyresis)
2. Analgesics: reducing pain (painkillers)
3. Antimalarial drugs: treating malaria
4. Antibiotics: inhibiting germ growth
5. Antiseptics: prevention of germ growth ear burns, cuts and wounds.

The table below gives a list of drugs and the systems of the body on which it is effective.