Chapter 1

History of Drugs Legislation and Pharmacy Profession in India

INTRODUCTION

- In 1920 and 1930, there were several reports of dangerous imposters and adulterants being sold as substitutes for real medications, and the lethal consequences of these medications were occasionally reported in the Indian press.
- During this time, the manufacturing, sale, and distribution of drugs in India were all completely unregulated, according to articles published in the Indian Medical Gazette. Fake medications have reportedly been blamed for a number of deaths. The usage of croton oil was substituted for eye drops. It was regularly discovered that medicine formulations were adulterated using chalk powder.
- Chalk powder was frequently found to be used for adulteration of drug formulations. There were toxicity reports due to overdose of mercury compounds. In the absence of effective Acts and Rules related to drugs and pharmaceuticals in the country, there was a rat race for manufacturing of sub-standard, spurious and adulterated formulations.
- Finally, on March 9, 1927, as a result of worrying negative reports, deaths caused by phony and tainted medications and demonstrations both inside and outside the nation over the subpar healthcare facilities provided by the British rulers in India. The British government was compelled to start enforcing drug laws.
- To counteract or check malpractice in drug dispensing and medication, the Council of State in British India, presided over by the viceroy, adopted a resolution. Under the leadership of Col RN Chopra, the Drugs Enquiry Committee (DEC) was established on August 11th, 1930. This momentous event marked the start of a new era for drug policy in our nation.
- Prior to the constitution of this Committee, there was no significant piece of legislation regulating the import, manufacture, sale and distribution of medicine. No Act was in vogue prescribing qualification of a pharmacist and there was no systematic procedure adopted for registration as pharmacists.
- Pharmaceutical drug legislation is a mixed legislation which covers both social and economic aspects of the society.

HISTORY OF PHARMACEUTICAL DRUG LEGISLATION IN INDIA

- In ancient years, Ayurveda system of medicines was popular in India. Indians depended on medicines from their indigenous sources. Due to the British conquest, the allopathic medical system was brought to India.

- In the year 1811, Mr Bathgate opened the first pharmacy in Calcutta. This company took roughly 100 years to create the first tinctures and spirits. Smith Stanistreet and Co. founded a new business in 1821, and this company began using the manufacturing technique in 1918. In Calcutta, Bengal Chemical and Pharmaceutical Works was founded in 1901 by Acharya Prafulla Chandra Roy

SCOPES AND OBJECTIVES

- 1940 saw the introduction of the Drug Bill into the Legislative Assembly. The Select Committee's report having been taken into account, the Drug Bill 1940 was approved. After seven years, or in 1947, it became the Drug Act of 1940. Since then, the Drug Act has undergone multiple amendments, and as of right now, it includes provisions pertaining to drugs, cosmetics, ayurvedic, unani, and homoeopathic remedies.
- The present Drugs and Cosmetics Act is an advanced form over the Drug Act, 1940. This Act's main purpose is to regulate the importation, production, distribution, and retail sale of drugs and cosmetics.
- The "Drugs and Cosmetics Rules 1945" are a set of regulations issued by the Central Government that govern the production, sale, and distribution of drugs and cosmetics in India. These laws and regulations are occasionally changed.
- Following DEC's recommendations, the remaining necessary enactments were also passed when India gained its independence in 1947. The purpose of the 1948 Pharmacy Act was to govern the profession of pharmacy in India.
- The Drugs and Magic Remedies (Objectionable Advertisements) Act was passed in 1954 with the prime aim of regulating some sorts of drug advertisements and outlawing certain types of magic remedy advertisements.
- In order to impose and collect excise taxes on medicinal and toilet preparations containing alcohol, opium, Indian hemp, or other narcotic substances and narcotics, the Medicinal Toilet Preparations (Excise Duties) Act, 1955, was passed. Under the terms of this Act, the Central Government established a set of regulations known as "The Medicinal and Toilet Preparations (Excise Duty) Rules 1956."
- The Drugs (Prices Control) Order 1987 was created by the Central Government in accordance with the Essential Commodities Act of 1955 and as a replacement for the Drugs (Prices Control) Order of 1979.
- The "Narcotic Drugs and Psychotropic Substances Act" and the regulations repealing the Opium Act, 1878 and the Dangerous Drugs Act of 1930 were passed in 1985. This Act's major goal is to harmonise and update the law regarding narcotics while also establishing strict guidelines for the management of activities involving narcotics, psychotropic substances, and related issues. This act is supplemented by the 1988 Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act.

GENERAL PRINCIPLES OF LAW

- No one is above the law, and everyone, regardless of rank or position, is subject to the jurisdiction of ordinary courts of law. According to the rule of law, no one should be treated arbitrarily, harshly, or in an uncivilised manner. It implies that all actions taken by the government must be legal and reasonable. The phrase "rule of law" refers to a situation where legal requirements must be followed at all times.
- It is crucial to remember that the fundamental legal concepts were not created by the legal system; rather, they predated the founding of the legal system and served as its foundation.

The general principles of law are neither the creation nor the part of law. These are the basic norms for formulation of law. Every law is based on following general principles.

Principle of Democracy

- The democratic system of administration was described as "government of the people, by the people, and for the people" by Abraham Lincoln. Democratic forms of government are justified by ideals like equality, independence, and freedom.
- These three justificatory values are combined to create several democratic models. These three justificatory values are combined to create several democratic models.
- Popular democracy
- Participatory democracy
- Deliberative democracy
- Social democracy
- Liberal democracy

Principle of Constitutionalism

- Constitutionalism is "a set of political principles and objectives that reflect the desire to defend freedom via the institution of internal and external checks upon governmental power," according to the Oxford Dictionary.
- The idea of constitutionalism is embodied in the Indian Constitution. By requiring that executive acts adhere to the law and that legislation passed by the legislature adhere to the Constitution, it is hoped to limit the scope of the government's authority.

Principle of Justice

- There is a distinction between "corrective justice" and "distributive justice"; justice is a moral value. Restoration of equality after it has been harmed due to wrongdoing is the focus of corrective justice.
- It aims to bring about justice between the parties. When a wrong is committed, the offender is required to make amends to the victim.
- This is known as corrective justice. Distributive justice, on the other hand, is focused on the more significant distributive issues in society as a whole. The practise of distributing honours and prizes to individuals in accordance with their deservingness is known as distributive justice.

Principle of Liberty

- The definition of liberty is "the right to feel and do as one pleases." A person's right to self-determination in terms of the kind of life they wish to live is crucial.
- The kind of life he/she wants depends not only on circumstances that guarantee no interference with his/her actions, but also on circumstances that make it possible for him/her to realise his/her goals. Thus, liberty has both harmful and beneficial elements.
- In its negative sense, liberty denotes a person's freedom from outside interference or restrictions. Positive aspects of liberty are connected to "the accomplishment of some specific purpose or benefit, typically personal development or self-realization."

Principle of Equality

- It is predicated on the notion that similar things ought to be handled similarly and unlike things differently. It suggests that everyone is subject to the same law and the same courts' jurisdiction regardless of his or her status.

Principle of Fraternity

- In simple language, the word "fraternity" refers to a brotherhood. According to its definition, it is "brotherhood among diverse groups of people unified in their goals, objectives, and so on." One of the main purposes of law is to ensure that people can live in peace with one another, which calls for acknowledging and fostering feelings of brotherhood.
- The law should offer protection from exclusion, discrimination, subordination, and oppression in order to ensure brotherhood. Fraternity is specifically mentioned as one of the goals or guiding concepts in the preamble of the Indian Constitution.

Principle of Supremacy

- The "Principle of Supremacy" states that everyone must follow the law, regardless of their status. Everyone will be treated equally since no one is above the law. All people are subject to the law, even those who create and carry out the law.

ORIGIN AND NATURE OF PHARMACEUTICAL LEGISLATION IN INDIA

- Earlier, the allopathic system of medicine was brought by Britishers to our country and allopathic medicines were mainly imported. To have some control on the import, the British Rules introduced.

Year	*Name of Act*
1857, 1878	The Opium Act enacted
1889	The Indian Merchandise Marks Act enacted
1894	The Indian Tariff Act enacted.
1898	The Sea Customs Act enacted
1906	In USA—Federal Food & Drugs Act introduced.
1919	The Poisons Act enacted.
1920	All India Compounders and Dispensers Association was established.
1920	In Canada—Food and Drugs Act introduced.
1924	The Cantonment Act enacted.
1925	In UK The Therapeutic Substance Act introduced.
1928	In UK Drug Adulteration Act enacted.
1933	The Indian Medical Council Act enacted.
1945	Rules for Drugs & Cosmetic Act framed.
1947	The Indian Nursing Council Act enacted.
1948	The Pharmacy Act, 1948 enacted.
1948	The Dentists Act, 1948 enacted.
1949	First 'Pharmacy Council OJ India' (PCI) constituted under the Pharmacy Act.
1951	The Industries Act enacted.
1954	The Drugs and Magic Remedies (Objectionable Advertisements) Act enacted.
1955	The Medicinal and Toilet Preparations (Excise Duties) Act.

1956	Essential Commodities Act enacted.
1956	The University Grants Commission Act enacted.
1960	Prevention of Cruelty to Animals Act passed.
1968	Insecticides Act enacted.
1970	Indian Patents Act enacted.
1971	Medicinal Termination of Pregnancy Act enacted.
1973	Homoeopathy Central Council Act enacted.
1985	The Narcotic-Drugs & Psychotropic Substances Act enacted.
1986	Consumer Protection Act enacted.

RUGS ENQUIRY COMMITTEE (DEC), 1930

- Col RN Chopra served as the organization's chairman, Shri C Govindan Nair served as secretary, and Dr B Mukherjee served as assistant secretary. Maulvi Abdul Matin Chowdhary, Mr H Cooper, and Fr JF. Caius made up the other three members of the Committee.
- The Committee accomplished wonderful work for the country's pharmaceutical profession. The Committee travelled to numerous locations throughout the nation and spoke with physicians and other experts about the country's healthcare system, the standard of the medications provided, etc.
- The Committee distributed questionnaires to medical professionals, customs agents, manufacturers, medical associations, and other parties involved in the medical industry.

The terms of references for the committee were as follows:

1. To examine the quality of medications being imported, produced, and sold, particularly those that are legal in BP.
2. To propose corrective actions for preventing the import, production, sale, or distribution of substandard or fake medications and their formulations.
3. To investigate locally made vegetable medication formulations and recommend corrective actions to keep the quality of such formulations.
4. To investigate all other factors those are directly or indirectly related to the pharmaceutical profession.

Some of the recommendations of the Chopra Committee are as follows:

- According to DEC, the country does not have a systematic profession like pharmacy. Most of the time, untrained individuals handled and distributed the medications.
- The drug control machinery departments were established at the centre in all states as a result of the committee's recommendation.
- This council also developed the Central and State Pharmacy Council, whose role it was to oversee the training and education of pharmacy professionals as well as to maintain the register containing the name and address of the registered pharmacist.
- The group also advocated for the requirement of an expertly staffed, well-equipped Central Drug Laboratory (CDL).
- The group also advocated for the need of a Central Drug Laboratory with certified personnel.

- The Committee suggested appointing an advisory board to advise the government in making rules to carry out the objectives of the Act.
- Framing the academic curriculum for educating pharmacy students and also providing training for them to become registered pharmacists.
- The Committee provided a basis for registration of patent and proprietary medicines manufactured in India or imported from outside the country.

HEALTH SURVEY AND DEVELOPMENT COMMITTEE

- The Health Survey and Development Committee, established in 1945 and presided over by Justice Bhore, reiterated the need for pharmacists who were qualified and trained as well as for their registration, the establishment of councils to oversee the profession at the federal and provincial levels, the strengthening of the Drugs Act's provisions, the expansion of drug control facilities for the purpose of bolstering the infrastructure for drug regulation, etc.
- The Pharmacy Act of 1948 was founded on the suggestions of the Drugs Enquiry Committee and the Health Survey and Development Committee. The Pharmacy Council of India was established in 1949, and the requirements for registration as a pharmacist were outlined, along with the registration procedure.
- After independence, it was felt to regulate the advertisements of drugs, which were in exaggerated form and misleading. A number of manufacturers were making exaggerated claims for their medicines and also exploiting the human weaknesses especially, in relation with advertisements pertaining to sexually transmitted diseases, menstrual disorders, loss of vigour, stamina, etc.
- The magic remedies were freely advertised for the cure of *Bhanamati*, epilepsy or fits, diabetes and number of other diseases.
- The magic remedies in the form of *Kavachas*, Taits, Talisman, Sacred Bones, Sacred *Bhasmas, Mantras*, etc., were freely practiced and the poor and illiterate people were exploited. It is to control such objectionable trends; "The Drugs and Magic Remedies (Objectionable Advertisements) Act" was passed by the Parliament in 1994.
- Alcohol is an important solvent in pharmaceutical industry. Alcohol is required for manufacturing of drugs and also for drug formulations as vehicle, preservative and therapeutic agent. At the time of independence, manufacturing, sale and distribution of alcohol was controlled by provinces/states.
- The rates charged by the provinces/states in the form of excise duties were different for different regions. Alcohol was also being misused and it was drug of abuse. It is to regulate the production, sale and distribution of alcohol and to bring uniformity in the excise duties to be paid, the Medicinal and Toilet preparations (Excise Duties) Act was passed by the Parliament in 1955.
- The Drugs Price Control Order, 1970 and subsequently at subsequent intervals, was intended to fix the prices for drugs and their formulations classified into essential and non-essential groups in order to maintain uniform retail rates for certain categories of drugs and control the prices of life-saving medications.
- The Indian Patents Act of 1970, which was based on process patents, provided the country's pharmaceutical industry a boost and led to a rise in domestic drug and pharmaceutical output. The Indian pharmaceutical business is experiencing a rapid metamorphosis to meet the difficulties of the globalisation of pharmaceutical commerce in the post-WTO era with the new product patent regime coming into place.

MUDLIAR COMMITTEE

- This Committee, also known as the Health Survey and Planning Committee, was appointed in June 1959 and led by Dr A Lakshman Swamy Mudliar and this committee was also known as Health Survey and Planning Committee which recommended the inclusion of indigenous systems of medicine under the supervision of the Drugs Act.
- Based on its recommendations, drugs prepared according to indigenous systems of medicine were brought within the purview of Drugs and Cosmetics Act, 1940.
- In 1961, the Committee sent in its final report and recommendations.

HATHI COMMITTEE

- Important milestone in pharmaceutical legislation history is Hathi Committee Chairman-Jaisukh Lal Hathi
- This Committee covered all the aspects of Licensing, price control, imports, role of foreign sector quality control.

Self-assessment Exercises
MCQs

1. Pharmaceutical legislation is:

a. Social aspects of the society.
b. Economic aspects of the society
c. Both a and b
d. None of the above

2. Drug Enquiry Committee was appointed on:

a. 11th May 1930
b. 11th August 1930
c. 11th August 1945
d. 11th August 1945

3. Drug Enquiry Committee under the chairmanship of:

a. Col RN Chopra
b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudliar
d. Jaisukh Lal Hathi

4. Drug Enquiry Committee also called as

a. Health Survey Committee
b. Viceroy Committee
c. Chopra Committee
d. Both b and c

5. Which of following is the name of advisory boards?

a. Drugs Technical Advisory Board
b. Drugs Consultative Committee
c. Both a and b
d. Hathi Committee

6. What is the full for of DTAB?

a. Drugs Technical Advisory Board
b. Drugs Technical Advertisement Board
c. Drugs Technical Administrative Board
d. None of the Above

7. What is full form of DCC?

a. Drugs Cosmetic Committee
b. Drugs Commission Committee
c. Drugs Consultative Committee
d. None of the above

8. Health Survey and Development Committee was set up in:

a. October 1930 b. October 1943
c. October 1945 d. October 1946

9. Health Survey and Development Committee was set up under the chairmanship of:

a. Col RN Chopra b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudliar d. Jaisukh Lal Hathi

10. Mudliar Committee was appointed in:

a. June 1930 b. June 1943
c. June 1945 d. June 1959

11. Mudliar Committee was appointed under chairmanship of:

a. Col RN Chopra b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudliar d. Jaisukh Lal Hathi

12. Mudliar Committee also called as:

a. Health Survey and Planning Committee
b. Viceroy Committee
c. Chopra Committee
d. None of the Above

13. The Mudliar Committee submitted its report of recommendations in:

a. 1930 b. 1943
c. 1961 d. 1959

14. Hathi Committee was set up under the Chairmanship of:

a. Col. RN Chopra b. Sir Joseph Bhore
c. Dr A Lakshmanswamy Mudliar d. Jaisukh Lal Hathi

ANSWERS

1. c	**2. b**	**3. a**	**4. d**	**5. c**
6. a	**7. c**	**8. c**	**9. b**	**10. d**
11. c	**12. a**	**13. c**	**14. d**	

SHORT QUESTIONS

1. Write a note on origin and nature of pharmaceutical legislation in India.

2. Explain about Health Survey and Development Committee.

LONG QUESTION

1. Explain in detail about Drug Enquiry Committee.

2. Explain general principles of law.