



Pharmaceutical Legislation In India



What is the purpose of Pharmaceutical legislation ?

- ➔ *To ensure that the patients receive drugs of required quality, tested and evaluated for safety and efficacy for their intended result.*
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Write a note on origin of pharmaceutical legislation in India.

➤ History of Pharmaceutical units

Year	Name of Founder	Name of shop/ Industry	Year of commencement of manufacturing
1811	Mr. Bathgate (East India Company)	Chemist Shop in Calcutta	1910
1821	Mr. Smith Stainstreet and Co.	Apothecary Shop	1918
1901	Acharya Praffula Chandra Ray (Calcutta)	Bengal Chemicals and Pharmaceutical Works	
1903	Prof. T.K Gajjar	Factory at Parel	
Alembic Chemical works, Baroda			

Reasons for formation of Chopra Committee

1. Units were not sufficient to fulfil the requirements of Indian Public.
2. Drugs were imported from UK, Germany and France.
3. During first world war cheaper drugs were imported into India, which increased the demand for indigenous drugs.
4. Unhealthy competition grew up and Indian market was flooded with inferior quality drugs.



Public pressurized government to introduce effective legislation to control import, manufacture, distribution and sale of drugs.

6. There was no legal and effective control on pharmacy profession.
7. Hence to have a comprehensive legislation, the Indian government appointed a ' Drug Enquiry Committee' under the chairmanship of Col. R.N. Chopra in 1931. this was formally known as Chopra Committee.

What were the recommendations of Drug Enquiry Committee? (V.I.P)

➤ *90 RECOMMENDATIONS.*

- 1. Formation of Central Pharmacy Council and State Pharmacy Council. (PCI)*
- 2. Creation of Drug Control Machinery. (DCM)*
- 3. Establishment of well equipped Central Drug Laboratory, and State Drug Laboratory. (CDL)*

Implementations:-

- ❑ Due to Second World War in 1939, there was delay in introduction of the legislation.
- ❑ Government was reluctant to implement the recommendations of DEC, and the public was pressurizing the government.
- ❑ ***Finally an Import of Drug Bill was introduced in 1937.***
- ❑ This bill dealt with only import of drugs and manufacturing and sale of drugs was not included.

Scope and objective

- Drug bill was introduced in 1940 in legislative assembly, and Drug Bill 1940 was passed, which came to force in 1947. since then drug act was amended many times and at present it covers the provisions related to Drugs, Cosmetics, Ayurvedic, including Unani and Homeopathic medicines.
- The present Drug and Cosmetic Act is an improved version of *the Drug Act, 1940*. the main objective of this act was to regulate the import, manufacture, distribution and sale of drugs and cosmetics in India.
- The Central Government made several rules entitled the *Drug and Cosmetic Rules 1945*. These act and rules were amended from time to time

The Pharmacy act 1948 was passed with the main objective to regulate the profession of Pharmacy in India.

- ***In 1954 the Drug and Magic Remedies Act was passed*** with the main aim to control certain types of advertisements related to drug and to prohibit certain types of advertisements related to magic remedies.
- ***Medicinal and Toilet Preparations (Excise duty) Act, 1955*** was passed providing for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium Indian hemp or other narcotic drugs.



Central government implemented ***Drug Price Control order 1987.***

➔ ***In 1985 the Narcotic and Psychotropic Substance Act, was passed.*** The main objective of this act was to consolidate and amend the laws relating to narcotic drugs and Psychotropic substance.

Other acts included were:-

- ▶ Prevention of food Adulteration act, 1954 and rules.
- ▶ The Industries (Development and Regulations) Act, 1951.
- ▶ The Industrial Employment (Standing order) Act 1946 and rules.
- ▶ Industrial Dispute Act, 1947.
- ▶ Factory Act, 1948.
- ▶ The Indian Patent and Design Act 1970.
- ▶ The Trade and Merchandise Mark, 1958.
- ▶ The Epidemic Disease Act, 1897.
- ▶ Shops and Establishment acts of respective states.



Frequently asked questions.

- What is the objective of Pharmaceutical Legislation in India?
- Write a note on origin/ history of Pharmaceutical Legislation in India.
- **What were the recommendations of Drug Enquiry Committee?**
- Write a short note on scope and objectives of Pharmaceutical Legislation in India.