

Dept. of PharmTech



Pharmaceutical Legislation in India

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Legislation

- law intends for regulation and control of various aspects of life.
- These aspects might be social, economical and political.
- Pharmaceutical legislation is a mixed legislation, which overlapping both social and economic aspects.



Objective

- To ensure that the patients receive drugs of required quality, tested and evaluated for safety as well as efficacy for their intended use.
- Pharmaceutical legislation is associated with the health of the society



Origin

- In 1811 first chemist shop opened by Mr. Bathgate, who came to India with East India company in Calcutta.
- In 1910 they have started manufacture of tincture and spirits.
- In 1821 another firm, Smith Stanistreet and co. started apothecary shop and started manufacturing in 1918.
- In 1901 Bengal Chemical and Pharmaceutical works, a small factory was started in calcutta by Acharya P.C. Ray.
- In 1903 Prof. T. K. Gajjar opens small factory at Parel for the development of Pharmaceutical units and Alembic chemical works Ltd. at Baroda



Health Survey and Development Committees

- Mudaliar Committee: Also known as Health survey and planning committee
- Established: 1962
- Chairman: Dr. A.L. Mudaliar
- Objective: to assess the performance in health sector
- Recommendation: Family planning, Strengthening the PHCs, inclusion of indigenous system of medicine



Health Survey and Development Committees

- Bhatia Committee: Chairman- Major General S. L. Bhatia
- Established: 1953
- Objective: To enquire into the work of pharmaceutical industries and to recommend what steps to be taken for the country's benefit and economy
- Recommendation: intensive research in indigenous drugs of Ayurveda



Health Survey and Development Committees

- Bhole Committee: Also known as Health survey and development committee
- Chairman- Sir Joseph Bhole
- Established: 1943
- Objective: To survey of existing position of pharmaceutical industries in respect to the health care delivery organization in India and to recommend
- Recommendation: Formation of PCI, Course curriculum for Pharmacist, CDL, rigid enforcement of Drugs & Cosmetics Act, 1940



Health Survey and Development Committees

- Hathi Committee:
- Chairman- Jaysukhlal Hathi
- Established: 1974
- Objective: To enquire pharmaceutical industries in respect to the various facts of drugs in India and to recommend
- Recommendation: self-sufficiency in medicines and of abundant availability at reasonable prices of essential medicines



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- These units were not sufficient to fulfill the need of Indian public. Hence most of the medicines were being imported from abroad mainly UK, France and Germany.
- In first world war the need was improved.
- Demand of indigenous drug was also improved.
- Competition becomes unhealthy and Indian market flooded with inferior, substandard and even harmful drugs.



Drug Enquiry committee

- Appointed by Indian Govt. in 1931
- Committee chairman was Lt. Col. R. N. Chopra
- Also called as DEC or Chopra committee
- The committee was asked to make enquiries in the said matter and then to make recommendations for smooth control of manufacture, import, distribution and sale of drugs in the interest of public health.



Recommendation of DEC

- 90 recommendations with report was submitted by the committee.
- Important Recommendations:
 1. Formation of Central Pharmacy Council and State pharmacy council which would look after the education and training of professionals. Councils would maintain the register containing names and addresses of the registered pharmacist.
 2. Creation of drug control machinery (Departments) at the center and branches in all states.
 3. Establishment of a well-equipped Central Drug Laboratory (CDL) with competent staff and experts for an efficient and speedy working of Drug Control Department. Small laboratories would work under its guidance.



Drug Bill

- Because of reluctant approach of Govt. towards implementation of the recommendation of DEC, public pressurized the Govt.
- Ultimately in 1937, Import of Drug bill was introduced in legislative assembly to control the import of drugs.
- However the manufacture, sale and distribution of drug was not included in bill.
- Committee forced the government to include all these aspects.
- As a result in 1940, Drug bill was again introduced in assembly.
- Drug bill 1940 was passed.
- It came into force as Drug Act 1940, later on it was amended many times and at present the act covers provisions related to Drugs, Cosmetics, Ayurvedic, Unani and Homeopathic medicine.



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- The present Drug and Cosmetic act is an improved version of Drug act, 1940.
- Objective: to control Import, manufacture, distribution and sale of drugs and cosmetics.
- Central Govt. has made many rules for the same and presented it as Drug and Cosmetic Rules 1945.
- This act and rules were amended from time to time.



Other Important Acts

- After Independence in 1947, the other act were also enacted as per recommendations of DEC.
- Pharmacy Act 1948
- The drugs and magic remedies act 1954
- Medicinal and toilet preparations act 1955 and rules 1956
- Drugs Price Control Order 1979 and changed at 1987
- Narcotic drugs and psychotropic substances act 1985



Miscellaneous Acts

- The Industries act 1951
- The industries employment act 1946 and rules
- Factory act 1948
- Indian Patent and Design act 1970
- Trade and Merchandise mark act 1958