

PHARMACEUTICAL LEGISLATION

Dr. Prakash Chandra Gupta

Assistant Professor

University Institute of Pharmacy,

CSJM University Kanpur

Introduction

Study of fundamental legal principles is called Jurisprudence



Pharmaceutical jurisprudence is concerned with law related to

Drugs

Medicine

Cosmetics

Pharmacist

**Pharmaceutical
profession**

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To ensure that the patients receive drugs of required quality, tested and evaluated for safety as well as efficacy for their intended use

Origin

The 1st chemist shop opened by Mr. Bathgate in Calcutta, who came to India with East India company in 1811.

They have started manufacture of tincture and spirits in 1910.


The firm of Smith Stanistreet and co. started a small apothecary shop in 1821 and started manufacturing in 1918.


Bengal Chemical and Pharmaceuti cal works, a small factory was started in calcutta by Acharya P.C.Ray in 1901.

Prof. T. K. Gajjar started small factory at Parel, Mumbai in 1903 and Alembic chemical works Ltd. at Baroda in 1907.

Reasons for formation of Drug Enquiry Committee (DEC)

- Before independence there was practically no legislative control on drugs and profession of Pharmacy.
- Units were not sufficient to fulfill the requirements of Indian Public
- Drugs were imported from other countries like UK, Germany and France.
- During first world war cheaper drugs were imported into India, which increased the demand for indigenous drugs
- Unhealthy competition grew up and Indian market was flooded with inferior quality drugs.

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

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- Hence to have a comprehensive legislation, the Indian government appointed a ‘ Drug Enquiry Committee’ under the chairmanship of Col. R.N. Chopra in 1928. this was formally known as Chopra Committee. The report of the committee was published in 1931.

Aspects of DEC

To enquire into the extent to which drugs and chemicals of impure quality or defective strength, particularly those recognized by the British Pharmacopoeia are imported, in the public interest, of controlling such importation, manufacture and sale and to make recommendations.

The enquire into the necessity of legislation to restrict the profession of pharmacy to duly qualified persons and to make recommendations.

Recommendation of Drug Enquiry Committee

Central legislation to control drugs and pharmacy

Setting up of test laboratories in all states to control the quality of production of drugs

Appointment of Advisory Board to advise the Govt. in making rules to carry out the objects of the act

Setting up of course for training in pharmacy and prescribing minimum qualifications for registration of pharmacist

The drugs industry in India should be developed

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Registration of every patent and proprietary medicine of undisclosed formula mfg. In India

The manufacturing in medical Stores Depots should be gradually reduced

Step should be taken to compile an Indian Pharmacopoeia.

The Cinchona department should cultivate chinchona.

Health Survey and Development Committee

(Bhore Committee)

- Appointed in 1943 to make a survey of the existing position in respect of health organization under Chairmanship of Sir Joseph Bhore. Committee recommendations were:

Establishment of an All India Pharmaceutical Council and provincial Pharmaceutical Council


Measures for registration of Pharmacist

Maintaining disciplinary control over profession of pharmacy

Setting up of Central drug laboratory

Rigid enforcement of The Drug Act, 1940

Pharmaceutical Enquiry Committee (Bhatia Committee)



Appointed in 1953 under chairmanship of Major-general S.L. Bhatia to make a comprehensive enquiry into the working of pharmaceutical industry

Recommend the steps to be taken by the govt. to establish it on sound line in the interest of country's health and economy

Mudaliar Committee

In 1959, Healthy Survey and Planning Committee appointed under Dr. A. Lakshmanswamy Mudaliar.

Committee recommendation were:

Consolidation of advances made in the 1st two 5 year plans

Strengthening of district hospital to serve as central base for specialist services

Each primary health centre not to serve more than 40,000 population

Integration of medical and health services recommended by the Bhole Committee

To improve the quality of health care provided by the primary health centres

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 facets 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.

Scope and Objectives of Pharmaceutical Legislation

To promote healthcare by regulating the manufacture, supply and distribution of quality drugs

To make these drugs available to the public at reasonable prices and through qualified person

To safeguard the public from misleading advertisements etc. about drugs and remedies

To regulate the profession of pharmacy



Thank You