

Forensic Pharmacy



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 **NIRALI**
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FORENSIC PHARMACY

(For Pharmaceutical Industry Professionals and Students of
Pharmaceutical Sciences)

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PREFACE

It gives us great pleasure & privilege in presenting this book on 'Forensic Pharmacy' in new form.

Indian Pharmaceutical Industry has made rapid strides in the recent past. The industry is transforming & undergoing continuous changes. It is becoming competitive, vibrant & successful because of the new rules & regulations, amendments in the acts enforced by the Government of India.

Considering the changing scenario, we have made addition of several important topics encompassing the current changes in the field of Pharmacy. We are sure that the added topics will provide value added information to the readers. There may be few mistakes & deficiencies, we will be grateful to the readers if they point them out & revert with their suggestions.

We would like to thank our publisher Mr. D. K. Furia, Mr. Jignesh Furia, Mr. Munde & team members of Nirali Prakashan for publishing this book & extending the wholehearted cooperation. Our sincere thanks to all our well wishers for their support.

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PHARMACEUTICAL LEGISLATION IN INDIA

PHARMACEUTICAL LEGISLATION

Law intends to regulate and control various aspects of social life. The aspects may be classified as social, economical and political legislation. The Pharmaceutical Legislation is such a mixed legislation, which overlappingly covers both social and economic aspects of the society.

The purpose of Pharmaceutical Legislation is to ensure that the patients receive drugs of required quality, tested and evaluated for safety as well as efficacy for their intended use. It means that Pharmaceutical Legislation is associated with the health of the society.

[A] ORIGIN

At the first time in India, a chemists shop was opened in about 1811 by Mr. Bathgate, who came to India with East India Company in Calcutta. After one hundred years (i.e. in 1910), this firm started manufacture of tinctures and spirits.

Another firm Smith Stanistreet and Co. started apothecary shop in 1821 and commenced the manufacturing in 1918. Bengal Chemical and Pharmaceutical works, a small factory was started in Calcutta in 1901, by Acharya Prafulla Chandra Ray. In 1903, under the leadership of Prof. T. K. Gajjar a small factory at Parel was started, which led to the development of other pharmaceutical unit, the Alembic Chemical Works Ltd. at Baroda.

These units were not sufficient to fulfil the requirements of Indian public. In those days most of the medicines were being imported from abroad mainly from U.K, France and Germany.

Then the situation was changed with the First World War. Cheaper drugs were imported from abroad. There was also increasing demands for indigenous drugs. The Indian and Foreign concerns entered in competition with imported medicines producing cheaper drugs. As a result, unhealthy competition grew up and the Indian market got flooded with inferior, substandard and even harmful drugs.

With this issue, the public made the Government to take notice of such situation of drug trade and industry and to think of introducing effective legislation to control the import, manufacture, distribution and sale of drugs.

In those days Opium Act, 1878, Poisons Act, 1919, and Dangerous Drugs Act, 1930 were in existence. But these acts were not comprehensive enough to control the prevailing chaotic and regrettable condition.

Thus, as such there was no legal control on Pharmacy profession at the beginning of this century. With rapid expansion in pharmaceutical industries and market more comprehensive legislation was required. Hence, to have a comprehensive legislation, the Indian Government appointed a '*Drug Enquiry Committee*' under the Chairmanship of Lt. Col. R. N. Chopra in 1931 (D. E. C. 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.

Recommendations of Drug Enquiry Committee :

The committee submitted a comprehensive report with about 90 recommendations.

The main recommendations are as follows :

- (1) The committee recommended the formation of Central Pharmacy Council and the Provincial (state) Pharmacy Councils which would look after the education and training of professionals. These councils would maintain the register containing the names and addresses of the Registered Pharmacists.
- (2) In the recommendations, the Drugs Enquiry Committee suggested the creation of drug control machinery (Departments) at the centre with branches in all the states.
- (3) The committee also recommended the establishment of a well-equipped Central Drug Laboratory (CDL) with competent Staff and experts for an efficient and speedy working of Drug Control Department. It was also suggested that the small laboratories would work under the guidance of Central Drug Laboratory.

Due to Second World War in 1939, there was delay in introduction of legislation as per the recommendations of Drugs Enquiry Committee, which was considered as urgent by Indian Government.

Finding the Government, reluctant to implement the recommendations of DEC, the demand and pressure from the public was increased to implement the said recommendations. Ultimately, an *Import of Drugs Bill* was introduced in Legislative Assembly, to control import of drugs. The Government preferred to refer the Bill to Select Committee. The Bill was limited only to the import of drugs and the question of manufacture and sale of drugs was left untouched. Hence, the Select Committee pressed for comprehensive legislation not only to control imports but also to control and regulate manufacture, sale and distribution of drugs in the country.

[B] SCOPE AND OBJECTIVES

As a result Drug Bill was introduced in 1940 in Legislative Assembly. After considering the report of Select Committee, Drug Bill 1940 was passed. It came into force as *Drug Act 1940* after seven years i.e. in 1947. Since then the Drug Act has been amended many times and at present the Act covers the provisions related to Drugs, Cosmetics, Ayurvedic, including Unani and Homoeopathic medicines. The present Drugs and Cosmetics Act is an improved version over the Drug Act, 1940. The main object of this Act is to regulate the import, manufacture, distribution and sale of Drugs and Cosmetics. The Central Government has made a number of Rules for the manufacture, distribution and sale of drugs and cosmetics in India entitled '*The Drugs and Cosmetics Rules 1945*'. This act and rules were amended from time to time.

With the achievement of Independence in 1947, the rest of the required enactments were also passed following the recommendations of DEC.

The *Pharmacy Act, 1948* was passed with the object to regulate the profession of Pharmacy in India.

In 1954, '*The Drugs and Magic Remedies (Objectionable Advertisements) Act*' was passed with the main aim to control certain types of advertisements relating to drugs and to prohibit certain kinds of advertisements relating to magic remedies.

The *Medicinal and Toilet Preparations (Excise Duties) 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 and narcotics. The Central Government has framed certain Rules under the provisions of this Act, called as '*The Medicinal and Toilet Preparations (Excise Duty) Rules 1956*'.

Under the essential commodities Act, 1955, and in supersession of the Drugs (Prices Control) Order 1979, the Central Government made the *Drugs (Prices Control) Order 1987*.

In 1985, the '*Narcotic Drugs and Psychotropic Substances Act* was passed along with the Rules repealing the Dangerous Drugs Act, 1930 and Opium Act, 1878. The main object of this act is to consolidate and amend the law relating to Narcotic Drugs and to make stringent provisions for the control and regulations of operations relating to Narcotic Drugs and Psychotropic Substances and for the matters connected there with. The Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Ordinance, 1988 is supplemented to this act.

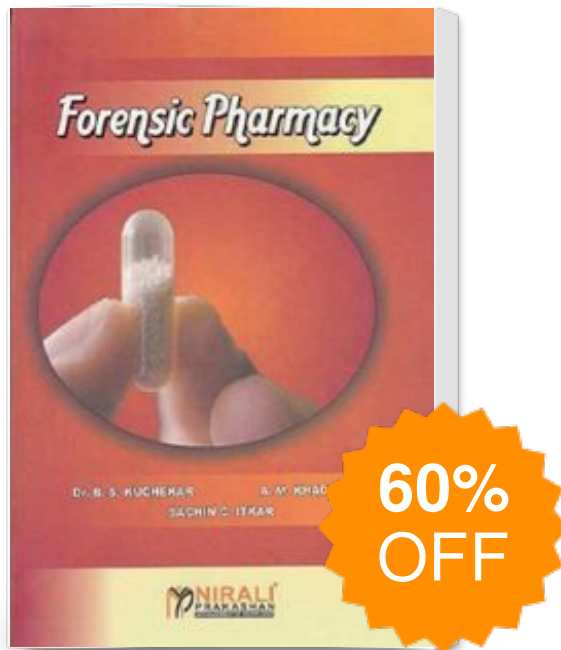
There are also some other enactments, which are directly or indirectly related to manufacture, distribution and sale of Drugs and Pharmaceuticals in India. These are :

- (1) The Industries (Development and Regulations) Act, 1951.

- (2) The Industrial Employment (Standing Order) Act, 1946 and rules.
- (3) Industrial Dispute Act, 1947.
- (4) Factory Act, 1948.
- (5) The Indian Patent and Design Act 1970.
- (6) The Trade and Merchandise Mark Act, 1958.
- (7) The Epidemic Diseases Act, 1897.
- (8) Shops and Establishments Acts of respective states.



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