

## Chapter – 1 General Principles of Law, History and various Acts related to Drugs

### 1.1

### Introduction

#### Law:

- ❖ Law are the sets of rules and regulation to control, conduct of human individual in society.
- ❖ Law are the statutory binding on every person in the state or nation.
- ❖ Law are mandatory violation of which may result in punishment in term of fine.

The purpose of introducing this subject in the curriculum of pharmacy students is two fold

1. To aid practicing pharmacist to understand their legal and ethical responsibility and there to avoid the pitfalls that leads to legislation
2. To serve as a text providing the students with some insight into the legal aspects of the practice of his profession.

### 1.2

### History

- He first time in India a chemist shop was opened in about 1811 by Mr. Bathgate who come in India with East India company in Calcutta.
- After one hundred years this firm started manufacture of tincture and spirits.
- Bengal chemical and pharmaceutical works a small factory was started in Calcutta in 1901 by Achary Prafulla Chandra Ray.
- In 1903 under the leadership of prof. TK. Gajjar a small factory at Parel was started which led to the development of other pharmaceutical units the alembic chemical work Ltd at Baroda.
- These units were not sufficient to fulfill 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 were also increasing demands for indigenous drugs. The Indian and Foreign concern entered in competition grew up and the Indian market got flooded with inferior substandard and even harmful drugs.
- **1930:** Government of India on 11th August 1930, appointed a committee under the chairmanship of Late Col. R.N.Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken.

- **1931:** R.N. Chopra committee published its report in 1931. It was reported that a set of people known as compounders were filling the gap.
- **1932:** Just after the publication of the report Prof. M. L. Schroff (Prof. Mahadeva Lal Schroff) initiated pharmaceutical education at the university level in the Banaras Hindu University. The Department of Pharmaceutical Engineering and Technology (Formerly Department of Pharmaceutics) was established in 1932 in BHU.
- **1935:** In 1935 United Province Pharmaceutical Association was established which later converted into Indian Pharmaceutical Association.
- **1939:** The Indian Journal of Pharmacy was started by Prof. M.L. Schroff in 1939.
- **1940:** All India Pharmaceutical Congress Association was established in 1940.
- **1940:** Drug and cosmetics Act 1940 and Rules 1945
- The primary objective of the Act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to prescribed quality standards. The Drugs Act was formulated in 1940 in pursuance of recommendations of Chopra Committee constituted in 1930 by Government of India.
- **1940:** Central Drugs Laboratory was established in Calcutta
- **1941:** The first Drugs Technical Advisory Board (D.T.A.B.) under this Drugs act 1940 was constituted.
- **1948:** Pharmacy Act 1948
- An Act to regulate the education and profession of pharmacy. Constitution of national pharmacy council and state pharmacy councils for the aforesaid purpose.
- **1948:** Indian Pharmacopoeial Committee was constituted under the chairmanship of late Dr. B.N. Ghosh.
- **1949:** Pharmacy Council of India (P.C.I.) was established under Pharmacy Act 1948.
- **1954:** The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
- This act control advertisement of Drugs In India. It prohibit advertisement of magical remedies. It also prohibit advertisement for the cure of certain disease conditions.
- **1955:** First Edition of Indian Pharmacopoeia was published.
- **1955:** The Medicinal & Toilet Preparations (Excise Duties) Act 1955
- It is an Act with provision for levy and collection of excise duties on medicinal and toilet preparations containing alcohol, opium, Indian hemp (cannabis) or other narcotic drugs.

- **1960:** The Prevention of Cruelty to Animals Act, 1960
- **1971:** Medical Termination of Pregnancy Act 1971
- Recently, the Union Cabinet has approved the Medical Termination of Pregnancy (MTP) (Amendment) Bill, 2020. The Bill seeks to extend the termination of pregnancy period from 20 weeks to 24 weeks, making it easier for women to safely and legally terminate an unwanted pregnancy.
- **1985:** The Narcotic Drugs and Psychotropic Substances Act 1985
- **1995:** Drugs Price control Order 1995
- The objective of DPCO is to ensure availability of essential and life saving and prophylactic medicine of good quality at the reasonable prices. For the purpose of implementing provisions of DPCO, powers have been vested in NPPA.
- **2005:** With the establishment of WTO and India being signatory to the Agreement on TradeRelated Aspects of Intellectual Property Rights (TRIPS), several new legislations were passed for the protection of intellectual property rights to meet the international obligations. Patents Act, 1970 has been amended in the year 1995, 1999, 2002 and 2005 to meet its obligations under the TRIPS agreement. Thus, the Patent Amendment Act, 2005 is now fully in force and operative.
- **2008:** Guidelines for Taking Action on Samples of Drugs Declared Spurious or Not of Standard Quality In The Light of Enhanced Penalties under The Drugs and Cosmetics (Amendment) Act, 2008
- **2011:** The National Commission for Human Resources for Health Bill, 2011.
- **2015:** New Pharmacy Practice rules 2015 seek to address the rights of pharmacists. These regulation allow concept of Pharma clinic and finally gives pharmacists their rightful role in healthcare.
- **2019:** CPA, Consumer protection Act First came in India in 1986, New act came in 2019

### 1.3

### Various Acts related to Drugs and Pharmacy Profession

There are some act which are directly or indirectly related to drugs and pharmacy profession.

1. Industrial employment (Standing order) Act 1946
2. Industrial dispute Act 1947
3. Factory Act 1948

4. Minimum wages Act 1948.
5. Development and regulation Act 1951
6. Drug and Magic Remedies Act (Objectionable Advertisements) 1954.
7. Prevention of Food adulteration Act 1954
8. Trade and merchandise mark Act 1958
9. Prevention of cruelty to animals Act 1960.
10. Indian patent design Act 1970.
11. Medical Termination of pregnancy Act 1970 and Rules 1975.
12. Shops establishments, Act of respective State.