Chapter

1

# General Principles of Law, History and Various Acts related to Drugs and Pharmacy Profession

## Q.1. Define the terms "jurisprudence" and "pharmaceutical jurisprudence".

#### Jurisprudence

It is the study of fundamental legal principles and is also science and philosophy of law.

#### Pharmaceutical Jurisprudence

It is a branch of pharmacy which deals with the knowledge of laws relating to drugs and pharmaceuticals and about pharmacy profession.

### Q.2. Write a note on origin and nature of pharmaceutical legislation in India.

#### Origin and Nature of Pharmaceutical Legislation in India (History)

- At first time in India a chemist shop was opened in about 1811 by Mr Bathgate who came to India with East India Company in Calcutta.
- The manufacturer of modern drugs in India was started at the end of 19th century.
- At that time drugs were mostly exported in crude form and imported in the finished form.
- There was no control on the drugs and therefore, anything under the name of drug could be made, sold or imported.
- As there was no restriction on the import of the drugs and also quality of drugs, many adulterated and spurious drugs have got entry in India.
- To that effect Sir Haroon Zaffer moved a resolution on March 9, 1927 in the council of state, recommending the Governor-General to take immediate steps to control the quality and standard of drugs.

- Accordingly council of state adopted resolution and recommended to the governments to take such steps as may be necessary so as to control quality of drugs.
- As per the recommendations "Import Drugs Bill" was introduced in 1937 in the legislative assembly to control import of drugs.
- This bill did not contain any provision about the manufacture, sale and distribution of drugs.
- Thus drugs bill was introduced in 1940 in the legislative assembly and the Drugs and Cosmetics Act, 1940 came into force.
- Presently Drug Act, 1940 covers the provisions relating to drugs and cosmetics, Ayurvedic, Siddha and Unani drugs.

#### Q.3. What is DEC? Give the recommendations of DEC. (S. 24)

#### **Drug Enquiry Committee (DEC)**

#### Chopra Committee

Government of India appointed drug enquiry committee under the chairmanship of Col. RN Chopra in 1931. It is also known as Chopra Committee.

#### Recommendations of Chopra Committee

- 1. Central legislation to control drugs and pharmacy.
- 2. Setting up of testing laboratories in all the states so as to control quality of production of drugs and pharmaceuticals and also imported drugs.
- 3. To appoint an Advisory Board to advise the government in making rules.
- 4. Setting up of courses for training in pharmacy and prescribing minimum qualification as a pharmacist.
- 5. Registration of every patent and proprietary medicine.
- 6. Development of drug industries in India.
- 7. Steps should be taken to comply Indian pharmacopoeia.

#### Q.4. Give the scope of pharmaceutical legislation in India.

#### Scope of Pharmaceutical Legislation in India

- 1. The pharmaceutical legislation is related with legal system which regulates the conduct of pharmacy business and practice of profession of pharmacy.
- 2. A thorough understanding of all laws pertaining to pharmacy is essential and all legal aspects must be satisfied by those who wish to practise the pharmacy business.

- 3. The pharmaceutical legislation helps the pharmacists to understand their legal and ethical responsibility and thereby avoid the danger of unnecessary legal proceedings.
- 4. The patient should get the drugs of good quality which are tested and evaluated for safety and efficacy.
- 5. It also covers the legal aspects relating to manufacture of drugs in pharmaceutical industries, their storage, sale and distribution, etc.
- 6. The pharmaceutical legislation safeguards the health of the people by making right medication by controlling pharmacy business and profession.

#### Q.5. Give the objectives/purposes of pharmaceutical legislation in India.

#### Objectives of Pharmaceutical Legislation in India

- 1. To promote health care by regulating the manufacture, supply and distribution of good quality drugs.
- 2. To make these drugs available to public at reasonable prices and through qualified person.
- 3. To safeguard the people from misleading and false advertisements relating to the drugs and magic remedies.
- 4. To regulate the profession of pharmacy.
- 5. To promote the indigenous research technology.
- Q.6. Explain the role of pharmacist in health care system. OR What is the contribution of pharmacist to health care system? OR "Pharmacy is an integral part of health care system." Comment on this statement.

#### Pharmacy and Health Care System

- Pharmacy is an integral and essential part of health care system.
- In olden days, men developed remedies based on experience. Then physician used to diagnose the diseases and treat them in an improvised manner. The pharmacy was not in existence.
- Later on some physicians gave the responsibility of preparing medicines to their assistants known as compounders (apothecaries). The profession of medicine was concerned with both medicine and pharmacy.
- Hindu system of medicine began with 'Atharva-veda' followed by 'Ayurveda' and 'Rigveda'. The ayurvedic system was greatly affected by 'Unani Tibb system' which was brought by Muslims in India. The Britishers brought the most popular system of medicine—"Allopathic system". With the advancement of allopathic system in India, medicine and pharmacy profession got separated.

- With the developing trends in the science and technology, pharmacist's responsibility was increased to give the feedback information to the physician and the patient regarding the drugs.
- Thus, the health care system is not only medical care but also includes services provided to individual or communities by agent of the health services or profession for the purpose of promoting, maintaining or restoring health.
- Pharmacy occupies an important position in the health care system.
  Thus, the pharmacist should be well equipped with knowledge of
  drugs, their handling system and legal aspects as well as principles of
  quality assurance applied to medicines, price structure of medicinal
  products.
- They provide a link between physician and patient.
- They are able to advise the patients with minor illness.
- The profession of pharmacy in our country presently consists of:
  - i. Industrial pharmacist
  - ii. Hospital pharmacist
  - iii. Academic pharmacist
  - iv. Community pharmacist.
- Pharmacist has to play an important role in the areas such as:
  - i. Prescription adherence
  - ii. Storage and distribution of drugs
  - iii. Drug choice
  - iv. Drug monitoring
  - v. Information and education
  - vi. Clinical pharmacokinetics
  - vii. Research and development.

In the chain of health care, the pharmacist is responsible for ensuring that the right patient is receiving the right medicine in the right dose for the right condition in the right dosage form and at right frequency and hence pharmacist is considered as an integral part of the health care system.

#### **OBJECTIVE QUESTIONS WITH ANSWERS IN BOLD LETTERS**

- 1. DEC is appointed under chairmanship of **Col RN Chopra** in 1931.
- 2. In India first chemist shop was opened in Calcutta in 1811, by Scottish chemist and druggist called **Mr. Bathgate**.
- 3. **Pharmacist** is considered as an integral part of health care system.

- 4. 'Import of Drugs Bill' was introduced in **1937** in the legislative assembly to control import of drugs.
- 5. **Jurisprudence** is the study of legal principles and also science of philosophy of law.
- 6. The Drug Bill is introduced in year 1930.
- 7. Sixth edition of Indian Pharmacopoeia was published in year 2010.
- 8. The pharmaceutical Society of India was established in 1923.
- 9. In 1937, the Government of India introduced Import of Drugs Bill.
- 10. A small factory at Parel (Bombay) was initiated by **Prof TK Gajjar** in 1903.