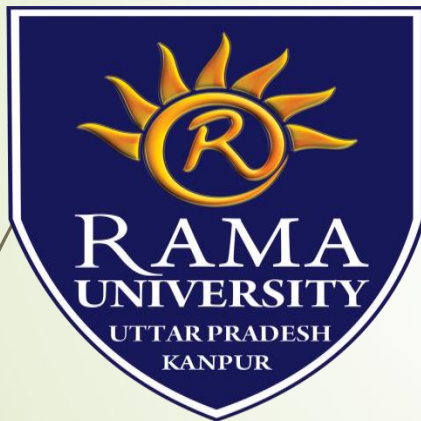


Pharmaceutical Jurisprudence and Ethics



Ms. Pratiksha Jayaswal
Assistant Professor
Rama University, KANPUR

Subject code: 3T6 (Syllabus)

THEORY: 45 Hours (3 Hrs. /week)

1. Historical background of Drug legislation in India.

3 Hrs

Origin and nature of pharmaceutical legislation in India, Its scope and objective, new drug policy and future trends.

2. Code of Ethics for Pharmacists.

2 Hrs

Principles and significance of professional ethics, critical study of code of pharmaceutical ethics drafted by PCI regarding to pharmacist in relation to his job, to his trade, and to medical profession.

3. Pharmacy Act 1948.

6 Hrs

Definition, PCI and State Councils, Composition and Function, Preparation of Registers and qualifications for entry into registers, Educational Regulation and Approval of Courses and Institutions, Offences and Penalties

4. Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976.

4 Hrs

Definitions, restricted and unrestricted preparations, Manufacturing in bond and outside bond

5. Drug Price Control Order

2 Hrs

6. Drugs and Magic Remedies (Objectionable Advertisements) Act 1954.

2 Hrs

Definitions, Prohibited Advertisement, Savings

7. Drugs and Cosmetics Act 1940, Rules 1945.

15 Hrs

Definitions, Advisor bodies DTAB and DCC Composition and function, Drug Control Laboratories and Government Analysts, Drug inspectors, Licensing Authorities, Controlling Authorities and Customs Collectors Provisions Governing Import, Manufacture and Sale of Drugs.

Labeling and Packaging of Drugs. Provisions applicable to manufacture and Sale of Ayurvedic Drugs, Provisions Governing Import, Various offences and corresponding Penalties,

Broad content of various Schedules of the Drugs and Cosmetic Act and Rules.



**8. Narcotic Drugs and Psychotropic Substances Act,
and Rules there under** **6 Hrs**

*Definition, Prohibited and controlled operation,
cultivation of poppy plants, sale of opium, import
and export of*

*narcotics as amended to date, Offences and
corresponding penalties.*

9. Consumer Protection Act **3 Hrs**

**10. Medical termination of pregnancy act 1970 and
rules 1975** **2 Hrs**




*Pharmaceutical
Legislation In India*



What is the purpose of Pharmaceutical legislation ?

× *To ensure that the patients receive drugs of required quality, tested and evaluated for safety and efficacy for their intended result.*




Write a note on origin of pharmaceutical legislation in India.

× History of Pharmaceutical units

Year	Name of Founder	Name of shop/ Industry	Year of commenceme nt of manufacturing
1811	Mr. Bathgate (East India Company)	Chemist Shop in Calcutta	1910
1821	Mr. Smith Stainstreet and Co.	Apothecary Shop	1918
1901	Acharya Praffula Chandra Ray (Calcutta)	Bengal Chemicals and Pharmaceutical Works	
1903	Prof. T.K Gajjar	Factory at Parel	
		Alembic Chemical works, Baroda	

Reasons for formation of Chopra Committee

1. Units were not sufficient to fulfil the requirements of Indian Public.
2. Drugs were imported from UK, Germany and France.
3. During first world war cheaper drugs were imported into India, which increased the demand for indigenous drugs.
4. Unhealthy competition grew up and Indian market was flooded with inferior quality drugs.



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

6. There was no legal and effective control on pharmacy profession.
7. Hence to have a comprehensive legislation, the Indian government appointed a ' Drug Enquiry Committee' under the chairmanship of Col. R.N. Chopra in 1931. this was formally known as Chopra Committee.



What were the recommendations of Drug Enquiry Committee?

× 90 RECOMMENDATIONS.

1. *Formation of Central Pharmacy Council and State Pharmacy Council. (PCI)*
2. *Creation of Drug Control Machinery. (DCM)*
3. *Establishment of well equipped Central Drug Laboratory, and State Drug Laboratory. (CDL)*

Implementations:-

- ⊖ Due to Second World War in 1939, there was delay in introduction of the legislation.
- ⊖ Government was reluctant to implement the recommendations of DEC, and the public was pressurizing the government.
- ⊖ ***Finally an Import of Drug Bill was introduced in 1937.***
- ⊖ This bill dealt with only import of drugs and manufacturing and sale of drugs was not included.

Scope and objective

- × Drug bill was introduced in 1940 in legislative assembly, and Drug Bill 1940 was passed, which came to force in 1947. since then drug act was amended many times and at present it covers the provisions related to Drugs, Cosmetics, Ayurvedic, including Unani and Homeopathic medicines.
- × The present Drug and Cosmetic Act is an improved version of *the Drug Act, 1940*. the main objective of this act was to regulate the import, manufacture, distribution and sale of drugs and cosmetics in India.
- × The Central Government made several rules entitled the *Drug and Cosmetic Rules 1945*. These act and rules were amended from time to time

- × ***The Pharmacy act 1948*** was passed with the main objective to regulate the profession of Pharmacy in India.
- × ***In 1954 the Drug and Magic Remedies Act was passed*** with the main aim to control certain types of advertisements related to drug and to prohibit certain types of advertisements related to magic remedies.
- × ***Medicinal and Toilet Preparations (Excise duty) 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.

- × Central government implemented ***Drug Price Control order 1987.***
- × ***In 1985 the Narcotic and Psychotropic Substance Act, was passed.*** The main objective of this act was to consolidate and amend the laws relating to narcotic drugs and Psychotropic substance.

× Other acts included were:-

- × Prevention of food Adulteration act, 1954 and rules.
- × The Industries (Development and Regulations) Act, 1951.
- × The Industrial Employment (Standing order) Act 1946 and rules.
- × Industrial Dispute Act, 1947.
- × Factory Act, 1948.
- × The Indian Patent and Design Act 1970.
- × The Trade and Merchandise Mark, 1958.
- × The Epidemic Disease Act, 1897.
- × Shops and Establishment acts of respective states.