MASTER NOTES FOR D.PHARMA

2ND YEAR STUDENTS

MODULE-6

PHARMACY LAW & ETHICS

Subject Wise Notes

According To PCI Syllabus

Easy To Understand

Prepared By Experts

Learn With Flow Charts

Pharmacy Law & Ethics

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1 GENERAL PRINCIPLES OF LAW

GENERAL PRINCIPLE OF 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 incriment or fine or both.
- The purpose of introducing this subject in the curriculum of pharmacy students is two fold:
  - To aid practicing pharmacist to understand their legal and ethical responsibility and there to avoid the pitfalls that leads to legislation.
  - To serve as a text providing the students with some insight into the legal aspects of the practice of his profession.

History

- The 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.
- Another firm Smith stanistreet and Co. Started abothecar by shop in 1821 and commenced the manufacturing in 1918.
- 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 wark 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.
- With this issue the public made the government to take notice of such situations of drug trade and industry and to think of introducing effective legislation to control the import, manufacture, distribution and sale of the drugs.
- In those day opium Act 1878, Poison Act 1919 and Dangerous Act 1930 where, in existence.
- There was no legal control on Pharmacy profession at the beginning of this century with rapid expansion more comprehensive legislation was required Hence Government appointed a "Drug enquiry committee" (DEC) under chairmanship of **Lt. Col R.N. Chopra in 1931**

- 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.

The Committee recommended the following:

- The central legislation to control drugs and pharmacy.
- Setting up of state drug testing laboratories in order to control the quality of production of drugs. A central Drugs Laboratory to control the quality of imported drugs and final authority in case of disputed samples sent by the count or local Govt.
- Appointment of an Advisory Board to advise the Govt.
- Setting up of courses for training in pharmacy and prescribing minimum qualifications for registration as a pharmacist.
- Registration of every patent and proprietary medicine of undisclosed formula manufactured in India or imported from outside the country.
- The crude single drugs as well as the compounded medicines used in the indigenous systems of treatment, should be brought under control.
- The drugs industry in India should be developed.
- Manufacturing in Medical stores Depots should be gradually reduced.
- Steps should be taken to compile an Indian pharmacopoeia.
- The cinchona Department should cultivate cinchona.

Multiple Choice Questions

1. Jurisprudence is the study of:
(a) Criminal behavior (b) Legal systems and theories
(c) Political science (d) Medical ethics

2. Natural law theory is based on the belief that:
(a) Laws should be based on human reason and moral principles
(b) Laws should reflect societal customs and traditions
(c) Laws should be created by legislative bodies
(d) Laws should be determined by the judiciary

3. Legal positivism emphasizes:
(a) The importance of natural rights
(b) The role of morality in legal decision-making
(c) The authority of legal rules created by a recognized authority
(d) The flexibility of legal principles

4. Legal realism is a legal theory that:
(a) Focuses on the intent of the legislators when interpreting laws
(b) Advocates for a strict interpretation of legal texts
(c) Considers the social and economic context in legal decision-making
(d) Promotes the use of legal precedents in judicial decision-making

5. Which of the following is NOT a source of law?
(a) Legislation
(b) Judicial decisions
(c) Legal textbooks
(d) Custom and tradition

Answer

1-b	**2-a**	**3-c**	**4-c**	**5-c**

2 PHARMACY ACT 1948 & RULES

Introduction

- In order to regulate the practice of pharmacy in India the pharmacy Act was passed in 1948.
- The Act has been divided into 5 chapters and 46 sections.
- It has been amended in a major way by the pharmacy (Amendment) Act, 1976 and in a minor way in 1959 and in 1981.
- The Act extends to the whole of India except the state of Jammu and Kashmir.

Objectives

Main objectives of Pharmacy Act, 1948 are:

1. To provide uniform education and training
2. To maintain control over the persons of the pharmacy profession by registering them

Definitions

Central Council	It means the pharmacy council of India.
State Council	State council of pharmacy and includes the Joint state pharmacy councils.
Central Register	Register of pharmacists maintained by the central council.
Medical Practitioner	Person holding-medical qualification as provided in the Indian and Medical Degree's act or Indian Medical Council act.
Registered Pharmacist	A person whose name, is entered in the register of pharmacists of the state.

Pharmacy Council of India

- Constituted by the Central Government every five years.
- First Pharmacy Council of India was constituted in the year, 1949.

Members of Pharmacy Council of India

Elected member (08)	• Six member, at least four member are teacher are elected by UGC. • One member elected by Medical council of India. • One member elected by State pharmacy council who shall be a Registered pharmacist.
Nominated member (08)	• Six member nominated by central govt., including at least four person possessing degree or diploma in pharmacy. • One representative each from UGC and from AICTE • One registered pharmacist to represent each state nominated by State govt. / Union
Ex-officio member (03)	• The Director general of health service • The Director of central drugs laboratory • The Drug controller of India

Functions of Pharmacy Council of India

- To prescribe the minimum standards of education required for qualification as a Registered Pharmacist.
- To regulate the minimum educational standards by inspecting the institutions
- To recognize the qualification granted outside the territory to which the Pharmacy Act, 1948 extends.
- Maintain a Central Register for Pharmacist, containing names of all Registered persons.
- Other function required for the furtherance of the Pharmacy Act, 1948.

Education Regulations for Pharmacy

- The PCI has laid down certain minimum standards of education required as Pharmacist.
- These standards are known as Education Regulations and prescribe:
  1. Minimum qualification for admission to the course of Pharmacy
  2. Duration of course of study and training
  3. Nature and period of practical training to be undertaken after completion of course.
  4. Subjects of examinations and their standard.
  5. Facilities required to be provided by an institution for the conduct of course of examination and practical training.
  6. Conditions to be fulfilled by authorities holding approved examinations.

Main Features of Education Regulations – 91:

- According to ER-91, a candidate has to undergo practical training after having appeared in Diploma in Pharmacy Part II examination in one or more of the following institutions:
  1. Government hospitals/dispensaries.
  2. Other hospitals dispensaries recognized by the PCI.
  3. Licensed pharmacy, chemists and druggists shops.
  4. Licensed drug manufacturing units.
- Practical training should be for a minimum of 500 hours spread over a period of not less than three months out of which not less than 250 hours must be devoted to actual dispensing of preparations.
- These Education Regulations are approved by the central government.

I. **Approval of Institution Providing a Course of Study and Examination for the Pharmacy Profession:**

1. **Application by the institute:** Pharmacy course has to **apply to the PCI.**
2. **Inspection:**
   - PCI deputes its inspectors to **visit the institution and inspect.**
   - Also **attend an examination** without interfering their conduct to inspect the standards.
   - Inspectors **report to the PCI** about the facilities available in the institute.
3. **Approval:** Accord approval and the said course or examination will be claimed to be approved for qualifying registration as Pharmacist.
4. **Declaration:** Once the institute has been approved by PCI, such approval will be published in Gazette.

II. **Withdrawal of Approval:**

- Conformity with the ER, the PCI gives notice to withdraw its approval.
- Institution should make a representation within the 3 months to PCI through state govt
- PCI then decides to either to continue the approval or to withdraw.

III. Approval of Qualification Granted Outside India:

- Approved qualification for the purpose of qualifying for registration as a pharmacist. This is applicable to Indian citizens.
- Citizens holding qualification granted there, shall be eligible for registration in this country when an Indian national holding the same qualification by law allowed to enter and practice in that country.

Multiple Choice Questions

1. The Pharmacy Act-1948 in India regulates:
(a) Medical practice
(b) Pharmaceutical research
(c) Pharmaceutical education and profession
(d) Food and drug manufacturing

2. The Pharmacy Act-1948 establishes which regulatory body in India?
(a) Medical Council of India (MCI)
(b) Pharmacy Council of India (PCI)
(c) Indian Pharmacopoeia Commission (IPC)
(d) Central Drugs Standard Control Organization (CDSCO)

3. The primary objective of The Pharmacy Act-1948 is to:
(a) Ensure the availability of affordable medicines
(b) Promote research and development in the pharmaceutical sector
(c) Regulate the practice of pharmacy and pharmaceutical education
(d) Establish quality standards for pharmaceutical products

4. The Practice Regulations-2015 under The Pharmacy Act-1948 provides guidelines for:
(a) Clinical trials of new drugs
(b) Licensing and registration of pharmacists
(c) Import and export of pharmaceutical products
(d) Pricing and reimbursement of medicines

5. The number of hours of practical training for registered pharmacist is
(a) Not less than 750 hours
(b) Not less than 500 hours
(c) Non less than 250 hours
(d) Not less than 300 hours

Answer

1-c	**2-b**	**3-c**	**4-b**	**5-b**

3 DRUG AND COSMETIC ACT

Introduction

Drugs and Cosmetics Act was passed	10th April 1940	By the Indian Legislature
Rule passed	1945	
This Act was amended	1955	By the Indian Parliament
Subsequently amended	1960, 1962, 1964, 1972, 1982, 1986, 1995, 2008, 2011 and 2018	

OBJECTIVES, DEFINITIONS, LEGAL DEFINATIONS OF SCHEDULES TO THE ACT & RULES

Objectives

- This is an act to regulate the import, manufacture, distribution and sales of drugs, by qualified persons only.
- To prevent substandard in drugs.
- The act also provides for the control over the manufacture, sale & distribution of Ayurvedic, Siddha, Unani & Homeopathic drugs.

Definitions

Drug	All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals.
Cosmetic	Any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or otherwise applied to human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance.
Misbranded drugs	1. If it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value. 2. If not labelled in the prescribed manner. 3. If its label or container or anything accompanying the drug bears any statement, design which makes any false claim for the drug.
Adulterated drugs	1. If it consists, in whole or in part, of any filthy, putrid or decomposed substance. 2. If it has been prepared, packed or stored under insanitary conditions. 3. If its container is composed, in whole or in part, of any poisonous or deleterious substance.

Spurious drugs	1. If it is imported under a name which belongs to another drug. 2. If it has been substituted wholly or in part by another drug or substance. 3. If it purports to be the product of a manufacturer of whom it is not truly a product.
Ayurvedic, Siddha or Unani drug	All medicines intended for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the first Schedule.
Drug Inspector	A Drug Inspector appointed by the Central or a State Govt who is an expert and qualified to monitor the safety, utility, efficacy and quality of a drug from its manufacturing till its sale at the retail shop.
Drug Store	Licensed premises for the sale of drugs, a retail store which do not require the services of a qualified person and sells both prescription and non-prescription drugs.
Pharmacy	Licensed premises for the sale of drugs, which require the services of a qualified person but where the drugs are not compounded against prescriptions.

Schedules to the Act and Rules

Schedules to the Act

First Schedule	Second Schedule
Names of books under Ayurvedic, Siddha and Unani Tibbs systems.	**Standard to be compiled** with by imported drugs and by drugs manufactured for sale, stocked, or exhibited for sale or distributed.

Schedules to the Rules

S. No.	Schedules	Significance
1.	A	Forms for applications of licensing etc.
2.	B	Fee structure for drug analysis by CDL.
3.	C	Biological and special products for parenteral administration whose import, manufacture, sale and distribution are governed by special provisions.
4.	C1	Other special products for non-parenteral administration whose import, manufacture, sale and distribution are governed by special provisions.

5.	D	Drugs exempted from the provision of import of drugs.
6.	E1	Poisonous substances under Ayurvedic, Siddha and Unani system of medicines.
7.	F & F1	Special provisions applicable for the production, testing, storage, packing and labelling of biological and other special products.
8.	F2	Standards of surgical dressings.
9.	F3	Standards of sterilized umbilical tapes.
10.	FF	Standards for ophthalmic preparations.
11.	G	Various drugs/ substances to be used under the medical supervision.
12.	H	Various drugs to be sold on prescription of an RMP.
13.	J	diseases that cannot be treated by any drug.
14.	K	Drugs exempted from provisions related to manufacture of drugs.
15.	M	Requirements of Good Manufacturing practices (GMP) and factory premises and the requirements of plant and equipments.
16.	M1	Requirements for factory premises, etc. for the manufacture of Homeopathic drugs.
17.	M2	Requirements for factory premises for the manufacture of cosmetics.
18.	M3	Requirements for factory premises for the manufacture of medical devices.
19.	N	List of manufacture equipments for the efficient running of a pharmacy.
20.	O	Standard for disinfectant fluids.
21.	P	Life period and storage of various drugs.
22.	P1	Regulations regarding retail package size.
23.	Q	Permitted dyes and coal tar colours in cosmetics.
24.	R	Standards for condoms and mechanical contraceptives.
25.	R1	Standards for medical devices.
26.	S	Standards for cosmetics.
27.	T	Requirements for factory premises and manufacture of Ayurvedic, Siddha and Unani products.
28.	U	Maintenance of manufacturing and analytical records of drugs.
29.	U1	Maintenance of manufacturing and analytical records of cosmetics.
30.	V	Standards for patent and proprietary medicines.

31.	W	List of drugs which can be marketed under generic names only.
32.	X	List of drugs which are habit forming, psychotropic, to be misused for addictive purposes.
33.	Y	Requirement and guidelines for clinical trials.

Multiple Choice Questions

1. CDRI is located at
(a) Kolkata (b) Izatnagar (c) Lucknow (d) Kasauli

2. The regulatory body established under the Drugs and Cosmetics Act, 1940, is called the:
(a) Drug Regulatory Authority of India (DRAI)
(b) National Pharmaceutical Pricing Authority (NPPA)
(c) Central Drugs Standard Control Organization (CDSCO)
(d) Food Safety and Standards Authority of India (FSSAI)

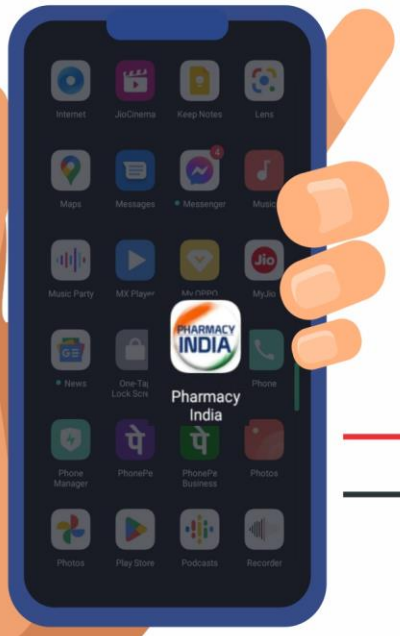
3. The primary objective of the Drugs and Cosmetics Act, 1940, is to:
(a) Regulate the manufacture, sale, and distribution of drugs and cosmetics
(b) Control the pricing of essential medicines
(c) Promote research and development in the pharmaceutical industry
(d) Establish quality standards for food products

4. Schedule U, of D & C Act and Rules deals with.....
(a) Requirements and guidelines on clinical trials for import and manufacture of new drugs
(b) Standards for patent or proprietary medicines
(c) Particulars to be shown in the manufacturing, raw materials and analytical records pertaining to cosmetics
(d) GMP for Ayurvedic, Siddha and Unani medicines

5. If a drug is so coloured, coated or polished that it would appear, of better or greater therapeutic value than it really has is known as
(a) Adulterant drug (b) Spurious drug
(c) Misbranded drug (d) True drug

Answer

1-c	**2-c**	**3-a**	**4-c**	**5-c**



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