Pharma Unit

Pharmacy Law & Ethics

Top 10 Most Repeated Questions with Answers

According to New Syllabus ER 2020-21

2nd Year D. Pharmacy

1) Write a note on medical device?

Ans.

Definition: A medical device is an instrument, apparatus, in vitro reagent, implant or other similar or related article, which is intended for use in the diagnosis of disease or other condition or disease or intended to affect the structure or any function of the body and which does not achieve any of its primary intended purposes through its chemical action within or on the body.

Classification of Medical Devices:

a) Class A: Devices involving low risk levels.
b) Class B: Devices involving low to medium risk.
c) Class C: Devices involving moderate to high risk.
d) Class D: Devices involving high risk.

Applications of Medical Devices:

a) Medical devices have extended the ability of physician to diagnose and treat diseases making great contribution to health and quality of life.
b) Like medicines and other health technologies they are essential for patient care, at the large, specialized hospitals.
c) Medical devices are considered as a fundamental component of health system.
d) Medical devices are essential to prevent, diagnose, treat and rehabilitate illnesses and diseases in a safe and effective way.

2) Write a note on NPPA?

Ans.

Definition

NPPA stands for National Pharmaceutical Pricing Authority. It was constituted by the Government of India on 29th August 1997. NPPA is a government regulatory agency responsible for controlling the prices of pharmaceutical drugs in India. The main purpose of NPPA is to fix or change the cost of bulk medications and to uphold the cost and accessibility of medicines in the country under the Drug Price Control Order, 1995.

Objective

a) To improve basic healthcare facilities and ensure the availability of essential medicines at affordable prices across the country.
b) To empower the NPPA to regulate the prices of 348 essential drugs.
c) To bring all strengths and dosages specified in the NLEM under price control.

Main Features:

a) Coverage: 348 drugs and their 652 formulations are brought under price control.
b) Pricing Mechanism: Uses a market-based pricing mechanism instead of the earlier cost-plus method.
c) Ceiling Price Calculation: Calculated as the simple average of prices of all brands of a drug with a market share of 1% or more.
d) Margins for Wholesalers and Retailers: Reduced to 8% and 16%, respectively.
e) Compliance with Ceiling Prices: Companies selling medicines above the government-mandated ceiling rate must lower their prices. Those selling below the ceiling price cannot raise prices.
f) New Medicine Launches: New medicines can only be sold at or below government-set price caps.
g) Production Continuity: Existing firms cannot stop the production of any drug without government permission.
h) Annual Price Increase: Retail prices may be increased annually in sync with the wholesale price index.

3) Write a note on drug technical advisory board?

Ans.

Definition: DTAB (Drug Technical Advisory Board) It is constituted by central government and consists of ex-officio, nominated and elected members.

Ex-Officio Members of DTAB

a) The Director General of Health Services (Chairman).
b) The Drugs Controller of India.
c) The Director, Central Drug Laboratory (Kolkata).
d) The Director, Central Research Institute, Kasauli.
e) The Director, Central Drug Research Institute, Lucknow.
f) The Director, Indian Veterinary Research Institute, Izatnagar.
g) The President, Pharmacy Council of India.
h) The President, Medical Council of India.

Functions of DTAB

- To advise the central and state governments on the technical matters arising out of the administration of the Act.
- To carry out such other functions as may be entrusted to it by the central government.

4) Write a note on drug inspector?

Ans.

Definition:

In relation to Ayurvedic, Siddha or Unani drugs, an inspector appointed by central or state government under Section 33 G of the Act.
In relation to other drugs and cosmetics, an inspector appointed by central or state government under Section 21 of the Act.
detailed inspection reports and actions to the controlling authority.

Qualification:

A. Must hold a graduate degree in pharmacy, pharmaceutical sciences, or medicine with specialization in clinical pharmacology or microbiology from a recognized university.
B. For inspecting premises licensed for Schedule 'C' drugs:
   - minimum 18 months experience in manufacturing Schedule 'C' substances.
   - Minimum 18 months experience in testing Schedule 'C' substances in an approved laboratory.
   - Minimum 3 years' experience in inspecting firms licensed for manufacturing Schedule 'C' drugs.

Power of Drug inspector:

a) Inspection: Check the premises licensed for drug sale. Check the premises licensed for drug manufacture.
b) Sampling: Can take samples of manufactured, sold, exhibited, or distributed drugs or cosmetics.
c) Search: Can search any person related to an offense at reasonable times.
d) Entry and Search: Can enter and search premises where offenses are suspected.
e) Stop and Search: Can stop and search vehicles suspected of carrying illegal drugs or cosmetics.
f) Issuing Orders: Can order the possession holder of offending drugs or cosmetics not to dispose of stock for up to 20 days.
g) Examination: Can examine registers, records, or documents mandated by the Act.

Duties of Drug Inspector

A. Duties Related to Sale of Drugs:

a) Inspection: Inspect drug sale premises at least twice a year.
b) Sampling: Take samples of drugs or cosmetics for testing.
c) Investigation: Investigate written complaints.
d) Documentation: Examine required registers and records.
e) Prosecution: Institute prosecution for Act and rule breaches.
f) Reporting: Submit detailed inspection reports and actions to the controlling authority.

B. Duties Related to Manufacture of Drugs and Cosmetics:

a) Inspection: Inspect manufacturing premises at least twice a year.
b) Observation: Observe manufacturing processes, standardization means, testing, storage, technical staff qualifications, and facility conditions affecting product potency.
c) Sampling: Take samples of drugs or cosmetics for testing.
d) Investigation: Investigate written complaints.
e) Documentation: Examine required registers and records.
f) Prosecution: Institute prosecution for Act and rule breaches.
g) Reporting: Submit detailed inspection reports and actions to the controlling authority.

5) Write a note on blood bank?

Ans.

Definition: A blood bank stores blood or its components from donations for later transfusions. Charles Richard Drew pioneered blood banking.

Objectives:

a. Collect, process, and store blood for medical use.
b. Ensure donated blood is safe for transfusions.
c. Save lives by providing blood.
d. Separate blood components for specific patient needs.
e. Identify patients and blood products during transfusions.
f. Connect blood banks, volunteers, donors, and patients.

Functions:

a) Collect, process, and store blood for medical purposes.
b) Provide quick service for urgent blood requests.
c) Check pre-transfusion samples and requests.
d) Ensure compatibility between donors and patients.
e) Choose suitable blood components for each condition.
f) Match blood groups.
g) Safely handle blood components.
h) Provide blood components for transfusion.
i) Integral part of hospitals, managing donor registration to storage.

General Requirements for Blood Banks:

i. Blood banks must have their own rules defining management roles.
ii. They need a qualified physician overseeing medical, technical, and administrative aspects.
iii. Licensed by State Drug Controller and approved by Drugs Controller General (India).
iv. Must adhere to Drugs and Cosmetics Rules for donor recruitment, collection, processing, and distribution.
v. Maintain a quality policy and manual.
vi. Keep detailed standard operating procedures and records.
vii. Staffing must meet regulatory standards.
viii. Ensure adequate space, environment, and equipment for safety.
ix. Maintain equipment calibration and validation records.
x. Use sterile, pyrogen-free, disposable materials stored in a controlled environment.
xi. Containers and preservatives must meet regulatory and quality standards.
xii. Implement and maintain a quality assurance system.

6) What is medical termination of pregnancy act and rule? What are the provisions under which RMP may terminate the pregnancies of women?

Ans.

Definition: The Medical Termination of Pregnancy Act, 1971 was passed to provide for the termination of pregnancies of women by Registered Medical Practitioners (RMP) for bonafide medical reason and for the matter concerned therewith.

Objectives:

- The termination of pregnancy during certain period is harmful to the health of pregnant woman or it may cause serious effects on the child of such woman.
- Pregnancy should be terminated under hygienic conditions along with the required facilities in specified premises under the supervision of Registered Medical Practitioners.

The provisions under which RMP may terminate the pregnancies of women are as follows:

1. Those who are 18 years of age or more with their written consent.
2. Those who are less than 18 years of age or more than 18 years but are lunatic, with the written consent of their guardians.
3. The pregnancy may be terminated if it is not more than 12 weeks old and RMP is of opinion that continuation of pregnancy is dangerous to the life of the woman, or it may affect the physical or mental health of the pregnant woman or child to be born may suffer with physical or mental abnormalities.
4. Further pregnancy which is more than 12 weeks but less than 20 weeks old may also be terminated if at least two RMPs are of above opinion.
5. If pregnancy is caused because of rape can be terminated by RMP as per provisions.
6. If pregnancy is caused because of failure of contraceptive used by woman or her husband such unwanted
7. pregnancy is found to affect physical and mental health of pregnant woman and therefore, it may be terminated.
8. The pregnancy of any duration may be terminated by RMP, if it is immediately necessary to save the life of a pregnant woman.

7) Write offences and penalties under Drug and cosmetics act 1940 and pharmacy act 1948?

Ans.

A. Offences and penalties under Drug and cosmetics act 1940

a) **Penalty for the use of government analyst report for advertising:** Anyone who uses the report of test or analysis supplied by CDL or government analyst for advertising, shall be punishable with fine up to ` 500/-, on first conviction and with imprisonment up to 10 years or fine or both on any subsequent conviction.

b) **Penalty for nondisclosure of the name of manufacturer:** Anyone who does not disclose the name of the manufacturer or his agent when asked by inspector shall be punishable with imprisonment up to 1 year or fine up to Rs. 1000/- or both.

c) **Offences and penalty for manufacture for sale or for distribution of stocks or exhibits for sale or offers for sale or distribution of cosmetics:**

- Any spurious cosmetics shall be punishable with imprisonment up to 3 years and with fine.
- Any cosmetic in contravention of the provisions of the Act and rules thereunder shall be punishable with imprisonment up to 1 year or fine up to Rs.1000/- or with both, on first conviction and with imprisonment up to 2 years and with fine up to Rs. 2000/- or with both on subsequent conviction.

B. Offences and penalties under pharmacy act 1948

a) **Falsely Claiming to be a Registered Pharmacist:** Any person whose name is not entered in the register of pharmacist and uses the words like “pharmacist”, “chemist”, “druggist”, “dispenser” or combination of such words like “chemist and druggist”, “dispensing chemist”, etc. which likely suggest that the person is registered pharmacist. Such person is said to be falsely claiming to be a registered pharmacist. Any person who is falsely claimed to be a registered pharmacist is punishable with a fine up to ` 500/- on first conviction and to a fine up to ` 1000/- or imprisonment up to 6 months or both on any subsequent conviction.

b) **Dispensing by Unregistered Person:** Any person who is not registered pharmacist but engages in the compounding and dispensing of drugs on prescription of RMP is punishable with a fine of ` 1000/- or imprisonment up to 6 months or both.

c) **Obstructing the State Council Inspectors in their Duties:** Anyone who obstructs state council inspectors from discharging their duties is punishable with the fine of ` 500/- on first conviction and fine of ` 1000/- or imprisonment up to 6 months or both on any subsequent conviction.

d) **Failure to Surrender the Certificate of Registration:** Anyone who fails to surrender the certificate of registration after removal of his name from the register is punishable with the fine of 50/-.

8) Define magic remedy? write objectives, and prohibition of certain advertisement as per magic and remedies act 1954?

Ans.

Definition: It includes Talisman, mantras, Kavachas and other charm of any kind which claim to possess miraculous power, for diagnosis, cure, mitigation, treatment, and prevention of any diseases in human beings or animals or altering any organic function of human or animal bodies.

Objectives

- This Act is passed to control and prohibit the advertisements related to drugs and magic remedies which make false claim and mislead the public.
- This Act covers all the advertisements which are objectionable and unethical, and which are used to promote self-medication and self-treatment.

Classes of advertisements are prohibited under the Act:

A. Advertisements relating to drugs which are likely to be used in the following diseases or conditions for:
   a) The procurement or miscarriage (abortion) or the prevention of conception (pregnancy) in women. The correction of menstrual disorders in women.
   b) The maintenance or improvement of capacity of human being for sexual pleasure.
   c) Diagnosis, cure, mitigation, treatment or prevention of any disease or disorder specified in Schedule 'J' of the Act.
   d) Schedule 'J' diseases: Appendicitis, blindness, cataract, cancer, deafness, diabetes, epilepsy, gallstone, kidney stone, leprosy, obesity, paralysis, sexual impotence, smallpox, tuberculosis, venereal diseases, etc.

B. Advertisements relating to drug,
   a) Which directly or indirectly give false impression regarding true character of the drug.
   b) Make false claim for it.
   c) Are otherwise false and deceptive.

C. Advertisements relating to magic remedies claiming their efficacy mentioned in clause (I) by the person who carries on the profession of administering magic remedies.

9) Write a note on narcotic drugs and psychotropic substance act 1985?

Ans.

Objectives

- The Act was passed to fight against the fast-increasing use of addictive materials.
- The Act provides very stringent provisions for the control and regulation of operations relating to the narcotic and psychotropic substances and concerned matters.

Offences and penalties

A. Offences:

- Operations relating to poppy straw.
- Cultivating coca plant and gathering its portion.
- Operations relating to prepared opium.
- Operations relating to opium poppy and opium.
- Operation relating to cannabis plant except Ganja.

Penalties

- Rigorous imprisonment for not less than 10–25 years and fine not less than 1 to 2 lakhs on first conviction.
- With rigorous imprisonment for not less than 15 to 30 years and fine not less than 1.5 to 3 lakhs.

B. Offences:

- Operations of manufactured drugs and their preparations.
- Operations relating to psychotropic substances.
- Illegal import–export or transhipment of narcotic drugs and psychotropic substances.
- External dealing in narcotic drugs and psychotropic substances.
- Allowing premise, vehicle, vessel, etc. to be used for the commission of offences.

Penalties

- Rigorous imprisonment not less than 10 to 20 years and fine not less than 1 to 2 lakhs on first conviction.
- With rigorous imprisonment for not less than 15 to 30 years and fine not less than 1.5 to 3 lakhs.

C. Penalty for Illegal (Unlawfully) Possession in Small Quantity of any Narcotic Drugs and Psychotropic Substances for Personal Consumption under NDPS Act, 1985 Shall be punishable with:

- Imprisonment up to 1 year or fine or both where narcotic drugs or psychotropic substances consumed is cocaine, morphine, heroin, etc.
- Imprisonment up to 6 months or fine or both where narcotic drugs and psychotropic substances consumed is other than above.

10) Write definition, principles and scope of Bioethics?

Ans.

Definition: Bioethics is the study of ethical issues emerging from advances in biology and medicines

Principles:

a) Patients should have an equal share in the costs and benefits of the healthcare system.
b) The rights of individuals to make decisions regarding their own health must be respected.
c) Healthcare providers should act in the best interests of their patients and strive to provide benefits.
d) Healthcare providers must avoid causing harm to their patients.

Scope:

a) The Human Genome Project and its implications.
b) Stem Cell Research and its potential for treating diseases.
c) Artificial Reproductive Technologies such as IVF and surrogacy.
d) Pre-Implantation Genetic Diagnosis to screen for genetic conditions in embryos.
e) The Synthesis of New Life Forms through synthetic biology.
f) The possibility of Reproductive Cloning and its ethical consequences.

Extra Questions:

1) Explain about Consumer Protection Act?
2) Write a note on Disaster Management Act?
3) Write a note on Biomedical Waste Management Rules 2016?
4) Write a note on Clinical Trials and ANDA, NDA?
5) Explain Good Regulatory practices?
6) Explain CDSCO?
7) Write about Code of Pharmaceutical Ethics?
8) Write a note on FSSAI?
9) Explain poison act 1919?
10) Explain Prevention of Cruelty to Animals Act-1960?
11) Write definitions and objectives of pharmacy act 1948?
12) Write a note on Drugs and Cosmetics Act 1940?

All The Best For Your Exam

Very Imp Note:

- Please Read All the chapters very carefully before Pharmacy Law and Ethics Exam.
- These questions are only for the reference purpose.