Last Minute Suggestions - DRx Forum
Pharmacy Law & Ethics, D.Ph 2nd Year - 2026

Q. What is Pharmacy Law? Explain its importance.
Ans. Pharmacy law is the body of laws regulating drugs, pharmacy education and pharmacy practice.
Importance:

- Protects the public from unsafe and poor-quality medicines.
- Controls manufacture, sale, storage and distribution of medicines.
- Defines the duties and responsibilities of pharmacists.
- Maintains professional standards.

Q. Give a brief account of the history and evolution of Pharmacy Law in India.
Ans.

- **Drugs and Cosmetics Act, 1940** → regulates drugs and cosmetics.
- **Pharmacy Act, 1948** → regulates pharmacy education and registration.
- **Drugs & Magic Remedies Act, 1954** → controls objectionable advertisements.
- **NDPS Act, 1985** → controls narcotic and psychotropic substances.
- Later laws covered food safety, clinical establishments, biomedical waste and medical devices.

Q. State the objectives of the Pharmacy Act, 1948.
Ans.

1. Regulate the profession of pharmacy.
2. Prescribe minimum standards of pharmacy education.
3. Regulate registration of pharmacists.
4. Prevent unqualified persons from practising pharmacy.
5. Establish Pharmacy Council of India (PCI) and State Pharmacy Councils.

Q. What is the procedure for registration of a pharmacist?
Ans.

1. Apply to the State Pharmacy Council.
2. Submit educational and identity documents.
3. Pay the prescribed registration fee.
4. Council verifies the qualifications.
5. Name is entered in the State Register.
6. Registration certificate is issued.

Q. State the offences and penalties under the Pharmacy Act.
Ans.
Offences:

- Practising pharmacy without registration.
- Falsely using the title of registered pharmacist.
- Allowing an unregistered person to practise.
- Contravening the Act.

Punishment may include **fine, imprisonment or both**, as provided by law.

Q. What is a Joint State Pharmacy Council?
Ans. A Joint State Pharmacy Council is a council formed by **two or more states jointly**.
It:

- Regulates pharmacy practice in participating states.
- Performs functions similar to a State Pharmacy Council.
- Helps maintain registration and professional standards.

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Q. What is Pharmacy Practice Regulations, 2015?
Ans. It provides standards for professional conduct of pharmacists.
Main points:

- Maintain patient confidentiality.
- Dispense medicines properly.
- Provide counselling.
- Maintain professional ethics.
- Promote safe and responsible pharmacy practice.

Q. Write the constitution of the State Pharmacy Council.
Ans.
Elected members:

- 6 registered pharmacists elected by state pharmacists.
- 1 member elected from the State Medical Council.

Nominated members:

- 5 members nominated by the State Government; at least 3 should be pharmacists.

Ex-officio members:

- State Drug Controller/Registrar.
- Director of Health Services or equivalent official.

The council regulates registration, practice and discipline of pharmacists in the state.

Q. State the functions of the State Pharmacy Council.
Ans.

1. Registers pharmacists.
2. Issues and renews registration certificates.
3. Monitors pharmacy practice.
4. Takes action against professional misconduct.
5. Promotes pharmacy education and professional development.

Q. Discuss the constitution and functions of PCI.
Ans.
Constitution includes:

- Members elected by State Pharmacy Councils.
- Members elected by UGC and Medical Council.
- Members nominated by Central and State Governments.
- Representatives of UGC and AICTE.
- Ex-officio members including DGHS, DCGI and Director of Central Drug Laboratory.

Functions:

1. Sets standards for pharmacy education.
2. Approves pharmacy colleges.
3. Maintains central register of pharmacists.
4. Regulates pharmacy practice.
5. Inspects pharmacy institutions.
6. Advises governments on pharmacy education and profession.

Q. State the objectives of the Drugs and Cosmetics Act, 1940.
Ans.

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- Regulates import, manufacture, distribution and sale of drugs and cosmetics.
- Ensures quality, safety and efficacy.
- Prevents substandard, adulterated and spurious drugs.
- Protects public health.

Q. Define drug, cosmetic, misbranded, adulterated and spurious drug.
Ans.

- **Drug:** Substance used for diagnosis, treatment, prevention or modification of disease.
- **Cosmetic:** Article applied to the human body for cleansing, beautifying or altering appearance.
- **Misbranded drug:** Drug having misleading labelling or appearance.
- **Adulterated drug:** Drug containing harmful/contaminating substances or prepared under improper conditions.
- **Spurious drug:** Drug falsely represented as another drug or made under a false name.

Q. What are the important schedules under the Drugs and Cosmetics Rules?
Ans.

- **Schedule C** → Biological and special products.
- **Schedule C(1)** → Other special products.
- **Schedule G** → Drugs requiring caution on label.
- **Schedule H** → Prescription drugs.
- **Schedule H1** → Certain drugs requiring stricter records.
- **Schedule K** → Exempted drugs/classes under specified conditions.
- **Schedule M** → Good Manufacturing Practices (GMP).
- **Schedule N** → Requirements for pharmacy premises and equipment.
- **Schedule P** → Listed in the PCI syllabus as a schedule to be studied.
- **Schedule X** → Certain habit-forming drugs requiring special control.

Q. What drugs are prohibited from manufacture and sale in India?
Ans. Drugs may be prohibited when they are:

- Misbranded.
- Adulterated.
- Spurious.
- Unsafe or harmful.
- Manufactured or sold in violation of the Act and Rules.
- Not meeting prescribed quality standards.

Q. Explain the import of drugs under the Drugs and Cosmetics Act.
Ans.

- Imported drugs must comply with Indian quality and safety requirements.
- Certain drugs require an import licence.
- Imported drugs may be inspected and tested.
- Substandard, adulterated or prohibited drugs cannot legally be imported.
- Regulatory authorities control their import and distribution.

Q. State the main conditions for manufacture of drugs.
Ans.

1. Proper manufacturing premises and equipment.
2. Qualified technical staff.
3. Compliance with GMP under Schedule M.
4. Proper quality-control testing.
5. Required record maintenance.
6. Valid manufacturing licence.
7. Compliance with the Drugs and Cosmetics Act and Rules.

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Q. What is a loan licence?
Ans. A loan licence allows a person to manufacture drugs using the facilities of another licensed manufacturer.
The manufacturing unit must be properly licensed and quality and legal requirements must be followed.

Q. What is a repacking licence?
Ans. It permits repacking of drugs from bulk containers into smaller containers.
Requirements:

- Approved conditions.
- Proper labelling.
- Quality maintenance.
- Valid licence.

Q. What is a test licence?
Ans. A test licence permits manufacture or import of drugs for **examination, testing or analysis**.
Such drugs are not meant for ordinary commercial sale, and proper records must be maintained.

Q. Explain the various licences issued under the Drugs and Cosmetics Act, 1940.
Ans.

1. **Manufacturing licence** → manufacture of drugs/cosmetics.
2. **Loan licence** → manufacture using another licensed facility.
3. **Import licence** → import of drugs/cosmetics.
4. **Sales licence** → retail and wholesale sale, stock and distribution.
5. **Test licence** → manufacture/import for testing and analysis.
6. **Blood bank licence** → collection, storage and distribution of human blood.

Q. State the general procedure and conditions for obtaining a drug sale licence.
Ans.

Procedure:

1. Submit application to the State Drug Licensing Authority.
2. Submit premises and pharmacist/competent-person documents.
3. Drug Inspector inspects the premises.
4. Licence is issued when requirements are fulfilled.

Conditions:

- Qualified person.
- Proper storage and cold chain where required.
- Separate, well-lit and ventilated premises.
- Display of licence.
- Proper purchase, sale and stock records.
- Prohibited/expired/misbranded drugs must not be sold.
- Renewal and continued compliance are required.

Q. Name the important regulatory authorities under the Drugs and Cosmetics Act.
Ans.

- **CDSCO** → Central drug regulatory organisation.
- **DTAB** → Gives technical advice.
- **DCC** → Promotes uniform implementation.
- **Central/State Licensing Authorities** → Grant and control licences.
- **Drug Inspectors** → Inspect premises and enforce laws.
- **Central Drug Laboratory** → Performs official drug testing.

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Q. What is CDSCO?
Ans. **CDSCO = Central Drugs Standard Control Organization.**
It:

- Regulates important aspects of drugs, cosmetics and medical devices.
- Is involved in new-drug approval.
- Regulates clinical trials and imports.
- Works with State Drug Control authorities.

Q. Write a short note on Central Drug Laboratory (CDL).

Ans. CDL is the national drug testing laboratory of India and is located in **Kolkata**.
Functions:

- Tests drugs, vaccines and medical devices.
- Checks quality, purity and safety.
- Examines imported medicines.
- Supports CDSCO.
- Detects spurious and substandard medicines.

Q. Write the qualifications, duties, responsibilities and powers of a Drug Inspector.
Ans.

Qualification:

- Degree in Pharmacy/Pharmaceutical Sciences, or Medicine with specialisation in Clinical Pharmacology or Microbiology.
- Either **18 months' experience** in manufacture/testing of a Schedule C substance **OR 3 years' experience in drug testing**.

Duties:

- Inspect shops, factories and companies.
- Collect drug samples.
- Take legal action against violations.

Powers:

- Inspect pharmacies, factories and warehouses.
- Collect drug samples.
- Examine and seize spurious, misbranded, adulterated or expired drugs.
- Check licences, registers and sales records.
- Take legal action against violators.
- Check compliance of imported medicines.

Q. Write the qualifications of a Government Analyst.
Ans.

- Degree in Medicine, Science, Pharmacy or Pharmaceutical Chemistry.
- Chemistry, Microbiology or Biochemistry as a relevant subject.
- At least **5 years' experience** in drug analysis as stated in the notes.
- Special training in Microbiology where required.
- Appointment/approval by government.

Q. State the objectives, offences and punishment under the NDPS Act, 1985.
Ans.
Objectives:

1. Control illegal manufacture, sale and transport.

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2. Regulate narcotic and psychotropic substances for medical/scientific purposes.
3. Prevent drug abuse and addiction.
4. Provide strict punishment.
5. Promote international cooperation.

Offences:

- Illegal production, sale or purchase.
- Illegal possession.
- Smuggling.
- Helping or encouraging illegal drug activities.
- Financing illegal drug activities.

Punishment according to the quantities given in the notes:

- **Small quantity:** Jail up to 1 year or fine up to ₹10,000 or both.
- **More than small but less than commercial quantity:** Jail up to 10 years and fine up to ₹1 lakh.
- **Commercial quantity:** Jail from 10–20 years and fine from ₹1–2 lakh.
- Repeat offenders may receive higher punishment.
- The notes also mention death penalty for certain repeated large-scale trafficking cases.

Q. State the objectives of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
Ans.

- Controls misleading advertisements of drugs and remedies.
- Prohibits advertisements claiming treatment of certain diseases.
- Prevents false claims about magic remedies.
- Protects the public from fraudulent medical claims.

Q. What classes of advertisements are prohibited under this Act?
Ans. Advertisements are restricted when they claim to:

- Cure or prevent certain serious diseases.
- Promote magic remedies.
- Mislead people about efficacy of drugs.
- Encourage improper or harmful use of medicines.

Q. Define Magic Remedy, Advertisement and Registered Pharmacist.
Ans.

- **Magic Remedy:** Medicine, device or treatment falsely claimed to cure or prevent diseases without scientific proof.
- **Advertisement:** Public notice or message used to promote a product or service.
- **Registered Pharmacist:** A person whose name is enrolled in the State Pharmacy Council.

Q. What is CPCSEA? State its functions.
Ans. **CPCSEA = Committee for the Purpose of Control and Supervision of Experiments on Animals.**
Functions:

- Registers animal-breeding and research establishments.
- Ensures ethical use of laboratory animals.
- Inspects animal houses.
- Regulates animal experiments.
- Minimises unnecessary pain and suffering.

Q. State the important requirements for animal experimentation.
Ans.

- Scientific purpose should be present.

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- Proper ethical approval should be obtained.
- Animals should receive proper care and housing.
- Pain and suffering should be minimised.
- Proper records should be maintained.

Q. Write the constitution and functions of the Institutional Animal Ethics Committee (IAEC).
Ans.
Constitution:

- Chairperson.
- Outside scientists.
- Biological scientist.
- Veterinarian.
- Scientist-in-charge of animal house.
- Socially aware person.
- CPCSEA nominee.

Functions:

1. Reviews and approves animal experiments.
2. Ensures ethical treatment and minimum pain.
3. Monitors animal welfare.

Q. State the main provisions of the Poisons Act, 1919.
Ans.

- Regulates possession and sale of poisons.
- Controls possession for sale.
- Regulates storage.
- Requires proper labelling and precautions.
- Prevents poisoning and misuse.

Q. State the conditions for sale of poisons.
Ans.

- Sale only by an authorised person.
- Proper labelling and storage.
- Required records must be maintained.
- Prescribed restrictions must be followed.
- Poisons must not be sold to unauthorised persons.

Q. What is FSSAI? State its functions.
Ans. **FSSAI = Food Safety and Standards Authority of India.**
Functions:

- Regulates food safety and standards.
- Prescribes food standards.
- Regulates food manufacture, storage and sale.
- Controls food labelling and safety requirements.
- Protects consumers from unsafe food.

Q. State the important labelling requirements for food supplements.
Ans. Label should generally contain:

- Name of product.
- Ingredients.
- Nutritional information.
- Recommended use.
- Batch number.

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- Manufacturing/expiry information.
- Manufacturer's details.
- Warnings and precautions.

Q. Write the qualifications of a Food Safety Officer.
Ans.

- Recognised degree in a relevant field such as Food Technology, Dairy Technology, Biotechnology, Agriculture, Veterinary Science, Biochemistry or Microbiology.
- Knowledge of food laws.
- Relevant experience where required.
- Required examination/interview or selection process.

Q. What is NPPA? State its functions.
Ans. **NPPA = National Pharmaceutical Pricing Authority.**
Functions:

- Fixes/revises prices of controlled medicines.
- Implements DPCO provisions.
- Monitors medicine prices.
- Ensures manufacturers follow price limits.
- Recovers overcharged amounts where applicable.

Q. What is DPCO? State its objectives.
Ans. **DPCO = Drug Price Control Order.**
Objectives:

- Controls prices of selected medicines.
- Fixes ceiling prices of scheduled formulations.
- Helps make essential medicines affordable.
- Prevents unreasonable pricing.
- Price-control provisions are implemented by NPPA.

Q. Calculate the ceiling price of a scheduled formulation.
Ans.
Formula:
Ceiling Price = Average Price to Retailer × (1 + 16/100)
The Average Price to Retailer is determined using the price data specified in the DPCO framework; the source notes mention brands having at least **1% market share**.

Example:
Average Price to Retailer = ₹100
Ceiling Price = 100 × 1.16 = **₹116**.

Q. What is NLEM? State its importance.
Ans. **NLEM = National List of Essential Medicines.**
It contains medicines considered essential for basic healthcare needs.
Importance:

- Ensures availability of essential medicines.
- Promotes rational use.
- Supports affordability.
- Supports applicable price-control measures.
- Is periodically revised according to healthcare needs.

Q. Write a short note on DPCO, 1995.
Ans. DPCO, 1995 was a government order for controlling prices of essential medicines.
Main points:

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- Price control of essential medicines.
- Government-fixed prices.
- Revision of prices.
- Monitoring of medicine prices.
- Action against overpricing.

Q. What is the Code of Pharmaceutical Ethics?
Ans. It is a set of ethical rules guiding pharmacists in professional conduct.
Main principles:

- Serve patients honestly.
- Maintain confidentiality.
- Dispense medicines correctly.
- Avoid misleading claims.
- Maintain good relations with healthcare professionals.
- Follow laws and professional standards.

Q. State the duties of a pharmacist towards patients, medical profession, trade and his own profession.
Ans.

- **Patients:** Provide safe and proper pharmaceutical care.
- **Medical profession:** Maintain respectful cooperation with doctors.
- **Own profession:** Maintain dignity and professional standards.
- **Trade:** Avoid unfair competition and unethical practices.
- Always give priority to patient welfare.

Q. Write the Pharmacist's Oath.
Ans. It is a professional commitment to:

- Serve patients honestly.
- Maintain professional ethics.
- Keep patient information confidential.
- Avoid harmful and unethical practices.
- Continuously improve professional knowledge.
- Work for the health and welfare of society.

Q. Define Code of Ethics. Explain receiving and handling of prescriptions by pharmacists.
Ans. Code of Ethics is a set of rules guiding pharmacists to behave honestly, ethically and professionally.

Prescription handling:

1. Check patient's name, age, date and doctor's signature.
2. Ensure the prescription is clear and complete.
3. Clarify doubtful information with the doctor.
4. Check medicine and dosage.
5. Dispense correctly.
6. Cross-check label and expiry date.
7. Counsel the patient about dose, timing, side effects and precautions.
8. Maintain prescription records and confidentiality.

Q. Write a short note on the Medical Termination of Pregnancy (MTP) Act, 1971.
Ans. The **Medical Termination of Pregnancy (MTP) Act, 1971** provides a legal framework for the termination of certain pregnancies by qualified **Registered Medical Practitioners (RMPs)** under specified conditions. The Act was amended in **2002 and 2021** to improve access to safe and legal abortion services.

Main features:

- Protects women by providing a framework for **safe and legal termination of pregnancy**.

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- Termination may be allowed when continuation of pregnancy involves risk to the woman's life or serious injury to her physical or mental health.
- It may also be permitted in cases of substantial fetal abnormalities, rape, and specified contraceptive failure.
- Up to **20 weeks** → opinion of **one RMP**.
- **20–24 weeks** → opinion of **two RMPs** for specified categories of women.
- In cases of substantial fetal abnormalities diagnosed by a **Medical Board**, the usual gestational limit does not apply as provided by the Act.
- MTP must be performed by an eligible RMP at an **approved place/facility**.

Q. Under what circumstances is termination of pregnancy legal? Who can perform it?
Ans. Termination may be permitted under the MTP framework in circumstances such as:

- Risk to the woman's physical or mental health.
- Serious fetal abnormalities.
- Pregnancy resulting from rape.
- Contraceptive failure in specified circumstances.

Time limits given in the notes:

- Up to **20 weeks** → opinion of one Registered Medical Practitioner.
- **20–24 weeks** → specified special cases with opinion of two doctors.
- Beyond **24 weeks** → specified severe fetal-abnormality cases with medical-board approval.

It should be performed by an eligible **Registered Medical Practitioner (RMP)** at an approved facility.

Q. Write a brief note on the Clinical Establishments Act, 2010.
Ans. It aims to regulate and improve healthcare establishments.

Main features:

- Registration of clinical establishments.
- Minimum standards for facilities, staff and services.
- Proper and transparent charges.
- Proper record maintenance.
- Government inspection and monitoring.

Q. What are Good Regulatory Practices (GRP)? State their requirements.
Ans. GRP are practices that ensure medicines and healthcare regulations are clear, effective and properly implemented.

Requirements:

1. Clear and transparent rules.
2. Consistency.
3. Scientific basis.
4. Public and professional involvement.
5. Regular monitoring and improvement.

Q. Mention the important areas covered under GRP.
Ans.

- Proper documentation.
- Valid licences and timely renewal.
- Transparent regulatory procedures.
- E-governance.
- Regular inspections.
- Proper records.
- Manufacturing and wholesale compliance.

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- Import/export regulation of drugs and medical devices.

Q. State the basic steps in new drug development.
Ans.

Discovery → Pre-clinical → Clinical trials → Approval → Marketing → Post-marketing monitoring

- Discovery → identify potential drug.
- Pre-clinical → laboratory/animal studies.
- Clinical trials → human studies.
- Approval → regulatory review.
- Marketing → introduction after approval.
- Post-marketing → safety monitoring.

Q. What is a New Drug Application (NDA)?
Ans. NDA is an application submitted to the regulatory authority for approval of a new drug.

It contains information about:

- Quality.
- Safety.
- Efficacy.
- Manufacturing.
- Pre-clinical studies.
- Clinical studies.

Q. Write a short note on New Drugs and Clinical Trials Rules, 2019.

Ans.

- Provides a framework for new drugs and clinical trials in India.
- Specifies requirements for clinical-trial applications and approvals.
- Promotes safety of trial participants.
- Regulates new-drug approval and clinical research.
- Works under the Drugs and Cosmetics Act.

Q. Explain the phases of clinical trials.
Ans.

Phase	Main purpose
Phase I	Safety, dose and side effects
Phase II	Effectiveness and short-term side effects
Phase III	Large-scale confirmation and comparison
Phase IV	Post-marketing safety and rare/long-term effects

Q. Explain Emergency Use Authorization (EUA).
Ans. Emergency Use Authorization is special permission for use of a medicine or vaccine during a serious health emergency when available evidence supports its use.

Main points:

- Used during emergencies.
- Allows faster access.

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- Based on available data.
- Temporary/emergency use is followed by continued monitoring and further evaluation.
- The notes give COVID-19 vaccines as examples.

Q. Describe generic medicines.
Ans. A generic medicine has the same active ingredient, strength, dosage form and therapeutic effect as the corresponding branded medicine and is marketed under a non-proprietary name.

Main points:

- Same active ingredient.
- Different/non-proprietary name.
- Usually lower cost.
- Must meet required quality and safety standards.

Q. Write the BCS classification of drug substances.
Ans.

Class	Solubility	Permeability
I	High	High
II	Low	High
III	High	Low
IV	Low	Low

Examples:

- Class I → Paracetamol, Metoprolol
- Class II → Ibuprofen, Ketoconazole
- Class III → Ranitidine, Atenolol
- Class IV → Hydrochlorothiazide, Furosemide

BCS helps predict drug absorption and bioavailability.

Q. What are Intellectual Property Rights? Mention their types.
Ans. IPR are legal rights protecting inventions and other creations.
Types:

1. **Patent** → protects inventions.
2. **Trademark** → protects brand names/logos.
3. **Copyright** → protects original written/artistic works.
4. **Trade secret** → protects confidential business information.

Q. What is a patent? Why is it important in pharmacy?
Ans. A patent gives an inventor an exclusive legal right over an invention for a limited period.
Importance:

- Protects new drugs.
- Protects formulations and processes.
- Prevents unauthorised commercial use.
- Encourages research and innovation.

Q. Which inventions are not patentable under the Patent Act?
Ans.

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- Natural discoveries.
- Scientific theories and mathematical methods.
- Certain plant/animal-related biological processes.
- Methods of treatment, diagnosis and surgery.
- Traditional or already-known public knowledge.

Q. What is a blood bank? State its functions.
Ans. A blood bank is a place where blood is **collected, tested, stored and supplied** for transfusion.

Functions:

- Blood collection.
- Blood-group and infection testing.
- Storage and preservation.
- Cross-matching.
- Safe issue of blood.
- Record maintenance.

Q. State the criteria for blood donation given in the notes.
Ans.

- Age: **18–65 years**.
- Weight: **at least 50 kg**.
- Haemoglobin: **12.5 g/dL or more**.
- Should not have infections such as HIV, hepatitis or malaria.
- The notes also mention avoiding alcohol or medications during the preceding 24 hours.

Q. State the objectives of Biomedical Waste Management Rules, 2016.
Ans.

- Safe handling of biomedical waste.
- Prevention of infection and environmental pollution.
- Proper segregation, collection, treatment and disposal.
- Protection of healthcare workers, patients and the public.

Q. Explain colour-coded segregation of biomedical waste.
Ans.

- **Yellow** → Anatomical/soiled waste, expired medicines etc.
- **Red** → Contaminated recyclable plastic waste.
- **White** → Sharps such as needles and blades.
- **Blue** → Glassware and metallic implants.

Q. How is biomedical waste managed?
Ans.

- Segregate at the point of generation.
- Use correct colour-coded containers.
- Store safely.
- Use authorised treatment/disposal facilities.
- Maintain records.

Q. What is Bioethics? State its principles.
Ans. Bioethics is the study of ethical issues in healthcare, medicine and biological research.

Four principles:

1. **Autonomy** → patient's right to decide.
2. **Beneficence** → work for patient's benefit.

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3. **Non-maleficence** → do no harm.
4. **Justice** → fair and equal treatment.

Q. State the ethical requirements for biomedical research involving human participants.
Ans.

- Informed consent.
- Privacy and confidentiality.
- Minimum possible risk.
- Benefits should justify risks.
- Voluntary participation.
- Ethics committee approval.
- Respect for dignity and rights.

Q. State the objectives of the Consumer Protection Act.
Ans.

- Protect consumer rights.
- Prevent fraud, unfair pricing and defective goods/services.
- Provide consumer dispute resolution.
- Control misleading advertisements and unfair trade practices.
- Create consumer awareness.

Q. State the rights of consumers.
Ans.

1. Right to safety.
2. Right to information.
3. Right to choose.
4. Right to be heard.
5. Right to seek redressal.
6. Right to consumer education.

Q. What is Disaster Management? State its objectives.
Ans. Disaster management is organised action to **prevent, prepare, respond and recover** from disasters.
Objectives:

- Reduce loss of life and property.
- Prepare people and healthcare systems.
- Provide quick emergency response.
- Restore essential services.
- Support rehabilitation and recovery.

Q. What are medical devices? Give examples.
Ans. Medical devices are instruments, machines, implants or tools used for diagnosis, treatment, prevention or monitoring of diseases.

Examples:

- **Diagnostic:** Blood glucose meter, ECG.
- **Therapeutic:** Insulin pump, pacemaker.
- **Surgical:** Scalpel, endoscope.
- **Implants:** Artificial heart valve, hip implant.
- **Monitoring:** BP monitor, pulse oximeter.

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Important Schedules under Drugs & Cosmetics Rules, 1945

Schedule	Short description
Schedule C	Biological and special products
Schedule C(1)	Other special products
Schedule G	Drugs to be used under medical supervision
Schedule H	Prescription drugs — sold only on prescription of RMP
Schedule H1	Certain antibiotics, anti-TB and habit-forming drugs; stricter sale/record requirements
Schedule K	Drugs exempted from certain provisions of the Rules
Schedule M	Good Manufacturing Practices (GMP) and requirements for premises/equipment
Schedule N	Requirements for running a pharmacy
Schedule P	Life period (shelf life) of drugs
Schedule X	Certain habit-forming/controlled drugs with stricter prescription, storage and record requirements

Important Acts & Regulations – Quick Revision

Act / Regulation	Year	Main purpose / topic
Pharmacy Act	**1948**	Regulation of pharmacy profession and registration of pharmacists
Drugs and Cosmetics Act	**1940**	Regulation of import, manufacture, distribution and sale of drugs and cosmetics
Drugs and Cosmetics Rules	**1945**	Rules for licensing, manufacture, sale, storage and control of drugs/cosmetics
Pharmacy Practice Regulations	**2015**	Professional standards and responsibilities of pharmacists

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Narcotic Drugs and Psychotropic Substances (NDPS) Act	**1985**	Control and regulation of narcotic drugs and psychotropic substances
Drugs & Magic Remedies (Objectionable Advertisements) Act	**1954**	Control of objectionable advertisements of drugs and magic remedies
Prevention of Cruelty to Animals Act	**1960**	Prevention of cruelty and regulation of animal experimentation
Poisons Act	**1919**	Regulation of possession and sale of poisons
Food Safety and Standards Act (FSSAI)	**2006**	Regulation of food safety, including food supplements
DPCO	**2013**	Control of prices of essential medicines
National List of Essential Medicines (NLEM)	—	Identification of essential medicines for healthcare and price regulation
Medical Termination of Pregnancy (MTP) Act	**1971**	Legal framework for termination of certain pregnancies
New Drugs and Clinical Trials Rules	**2019**	Regulation of new drugs and clinical trials
Patents Act	**1970**	Protection of inventions and patent rights
Clinical Establishments Act	**2010**	Registration and regulation of clinical establishments
Biomedical Waste Management Rules	**2016**	Safe handling and disposal of biomedical waste
Consumer Protection Act	**2019**	Protection of consumer rights and grievance redressal

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Disaster Management Act	**2005**	Legal framework for disaster management
Medical Devices Rules	**2017**	Regulation of manufacture, import and sale of medical devices

Ultra-short memory list:

1948 → Pharmacy Act
1940 → Drugs & Cosmetics Act
1945 → Drugs & Cosmetics Rules
2015 → Pharmacy Practice Regulations
1985 → NDPS Act
1954 → Drugs & Magic Remedies Act
1960 → Prevention of Cruelty to Animals Act
1919 → Poisons Act
2006 → FSSAI Act
2013 → DPCO
1971 → MTP Act
2019 → New Drugs & Clinical Trials Rules
1970 → Patents Act
2010 → Clinical Establishments Act
2016 → Biomedical Waste Rules
2019 → Consumer Protection Act
2005 → Disaster Management Act
2017 → Medical Devices Rules

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