

Origin and Nature of Pharmaceutical Legislation in India

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 manufacture 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 any 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.

2 Pharmaceutical Jurisprudence

- 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 about the manufacture, sale and distribution of drugs.
- This bill did not contain any provision relating to drugs and distribution of drugs.
- Thus drug bill was introduced in 1940 in the legislative assembly and Drug and Cosmetic 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.

Drug Enquiry Committee (DEC) (S. 96, 97, 99, 06, 07, 09; W. 98, 99, 01, 02, 05, 07)

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. (S. 04, 05; W. 07)

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.

Origin and Nature of Pharmaceutical Legislation in India 3

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 pharmacist 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/purpose of pharmaceutical legislation in India. (S. 00, 04, 05, 08, 09; W. 03, 07)

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. (S. 04, 07; W. 04, 05, 06)

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 physician 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, pharmacists 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 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.

Chapter

2

The Code of Pharmaceutical Ethics

Q 1. Define the terms.

- **Ethics:** It means a science of morals or "Code of Moral Principles".
- **Morality:** Morality means good conduct or behaviour and consciousness.
- **Law:** Law is defined as, the rules of human conduct binding to all persons in the state or nation.
- **Pharmaceutical ethics:** The ethics in relation to pharmacy profession is called pharmaceutical ethics.

Q 2. What do you mean by code of pharmaceutical ethics? (W. 06)

- The code of pharmaceutical ethics is formulated by PCI for the guidance of Indian pharmacist.
- The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to:

1. His job
2. His trade
3. His fellow pharmacist
4. His physician
5. With medical profession
6. With his profession (pharmacy)
7. With general public.

Q 3. How should a pharmacist handle the prescription as per ethics? OR Describe the ethics for pharmacist in relation to his job during his service. (S. 99, 00, 01, 04, 06, 08, 09; W. 96, 98, 99, 00, 01, 04, 06, 07)

- Pharmacist shall supply commonly required medicines without undue delay.

- Pharmacist also provides emergency supply of drug at all times.
- The premise of pharmacy should be clean in appearance.
- During compounding and dispensing there should not be any type of contamination in the medicines.
- There should be good conduct of owner of pharmacy and pharmacist.
- Pharmacist should receive the prescription and read it carefully and should not discuss merits and demerits of prescription.
- Pharmacist should not show any surprising expression otherwise it may cause anxiety in patients and it may loose faith in their physician.

- Any question asked by the patient should be answered carefully.
- Pharmacist should not disclose any information which may be kept secrete by the physician.
- Pharmacist should not add, omit or substitute any ingredient in the prescription without consulting the doctors.
- If any overdose, or error is in the prescription it is send back for correction to the prescriber.
- Pharmacist should advise the patient about use of medicines as per directions of physician.
- Pharmacist should compound the drugs by taking accurate quantities of ingredients.
- Pharmacist should use the drugs of standard quality.
- Pharmacist should not dispense the drugs which are poisonous or addictive to any person without prescription.
- Pharmacist should give full training to his apprentice pharmacist.

Q 4. Explain the ethics for pharmacist in relation to his trade. (S. 97, 09; W. 02, 08)

- Pharmacist should charge a fair price from the customer for the medicines.
- Pharmacist should give adequate remuneration to fellow pharmacist.
- Fair trade practice (S. 06):
 - Pharmacist should not attempt to capture the business of fellow pharmacist by cut throat competition, i.e. offering any sort of prizes, gifts to the physician.
 - He should not sell the medicines at low prices than those charged by fellow pharmacist.
 - If the prescription contains the name of other than his, he should direct the customer to right place.

- Labels, trademarks, other signs and symbols of the fellow pharmacist should not be imitated or copied.
- Pharmacist should not attempt for saling the drugs from door to door or obtain the orders for medicines.
- He should not carry self-service method for medicines.
- Pharmacist should purchase the drugs from genuine source.
- Pharmacist should not directly or indirectly help the manufacturer for the sale of spurious or substandard drugs.
- Pharmacist should not make advertisement or display of materials which is unethical.

Q 5. How should pharmacist behave with his fellow pharmacist as per ethics? (W. 06)

- Pharmacist should not attempt to capture the business of fellow pharmacist by cut throat competition, i.e. by offering any sort of prizes or gift to the physician.
- He should not charge lower prices for medicines than those charged by fellow pharmacist.
- If the prescription contains name of other dispensary or pharmacy than his, he should not accept such prescription, but should direct the customer to the right place.
- Labels, trademarks and other signs and symbols of the fellow pharmacist should not be imitated or copied.

Q 6. How should pharmacist behave with physician as per code of ethics? OR Give the relation of pharmacist with physician as per code of ethics. (S. 96)

- When pharmacist receives the prescription, he should not discuss the merits and demerits of the prescription.
- Pharmacist should not show any surprising expression on his face otherwise it may loose faith in their physician.
- Pharmacist should not add, omit, substitute or alter the composition of prescription without the permission of prescriber.
- If there is an error in the prescription like overdose, incomplete direction, etc. then such prescription is referred back for correction to the prescriber.
- Pharmacist should not enter into the secrete contract with the physician by offering him any sort of prizes, gifts or commission.

- Pharmacist should not recommend any particular physician to the patient unless it is asked to do so.

Q 7. Give relation of pharmacist to the medical profession. Or Explain how pharmacist is liaison between medical profession and public. (S. 00, 05, 06, 07; W. 00, 03, 07)

- Pharmacist should not undertake medical practice, i.e. diagnosis of disease, prescribing of drugs.
- In emergency cases like accidents, he can give first aid to the victims.
- Pharmacist should not recommend a particular medical practitioner unless asked to do so.
- Clandestine arrangement: Pharmacist should not enter into any secret contract with the physician to offer him any commission, gifts or prizes. This is known as clandestine arrangement.
- Pharmacist is a liaison between medical profession and the people.
- Pharmacist shall obtain the knowledge about the modern developments in the pharmacy.
- Pharmacist should advise the physician, nurses, compounders about new drugs and pharmaceutical matter.
- Pharmacist may be able to educate the people for maintaining healthy and sanitary conditions of living.

Q 8. Describe the code of ethics for pharmacist in relation to his profession (pharmacy). (S. 05; W. 05)

- Pharmacist should increase the status of profession of pharmacy by giving cooperation to fellow members of scientific and technical fields.
- Pharmacist should join the professional organisations, study their aims, objects, etc.
- Pharmacist should not do any unfair deed which is harmful to pharmaceutical profession and discredit the profession.
- Pharmacist should fulfill the provisions of pharmaceutical matters and other laws and regulations.

Q 9. Give the relation of pharmacist with general public as per code of ethics. (W. 06)

- Pharmacist shall supply commonly required medicines without undue delay.

- Pharmacist shall provide emergency supply at all times.
- He shall charge a fair price on medicines.
- Pharmacist shall educate the people for maintaining healthy and sanitary conditions of living.
- In case of emergency or accidents he shall provide first aid treatment to the victims.
- He shall play an important role in family planning programmes and programmes organised by the government and social organisation.
- He shall take part in various social activities, join various organisations and contribute his share in the nation-building activities.

The Pharmacy Act, 1948

Q 1. Give object of Pharmacy Act, 1948. (S. 97, 01, 03, 09; W. 96, 00, 04, 05, 06, 07, 08)

Object

The Pharmacy Act, 1948 was passed with objects:

1. To provide uniform education and training to the 'would be' pharmacist.
2. To maintain control over the persons entering in the profession of pharmacy, by providing their registration in the states.

Q 2. Define the terms.

1. **Central Council:** It means Pharmacy Council of India constituted under Section 3 of the Pharmacy Act, 1948.

2. **State Council:** It means State Pharmacy Council constituted under Section 19 and also includes Joint State Pharmacy Council constituted under Section 20.

3. **Registered pharmacist (S. 99, 08; W. 98, 01, 03, 04, 06, 07):** A person whose name for the time being is entered in the register of pharmacist of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy.

4. **Displaced person (S. 99, 05; W. 98, 01, 03, 05, 06):** It means:
 i. Any person who on account of setting up of the dominion of India and Pakistan or on account of civil disturbances or fear of such disturbances in the area, now forming the part of Pakistan, has left after March 1, 1947 or has been displaced from such place of his residence and since then residing in India.
 ii. Any person who on account of civil disturbances or fear of such disturbances in the area now forming the part of Bangladesh, has left after April 14, 1957 but before March 25,

1971 or has been displaced from such place of his residence and since then residing in India.

5. **Repatriate (S. 05, 08; W. 06):** It means any person of Indian origin who on account of civil disturbances in any area now forming the part of Burma, Sri Lanka or Uganda or any other country has left after March 14, 1957 or has been displaced from such place of his residence and since then been residing in India.
6. **First register (S. 08):** It means the register of pharmacist prepared under chapter IV of the Pharmacy Act, by the state government before constitution of state council.
7. **Subsequent register (S. 08):** It means the register of pharmacist prepared under chapter IV of Pharmacy Act, by the state council after first register.
8. **Central register:** It means the register of pharmacist maintained by the central council.

Q 3. What is PCI? Give the constitution and functions of PCI. (S. 05; W. 99, 03, 07, 08)

Pharmacy Council of India (PCI/Central Council)

- PCI was constituted under section III of Pharmacy Act, 1948.
- The first PCI was constituted by central government in 1949 and council is reconstituted every 5 years.

Constitution of PCI/Central Council (S. 09)

The council consists of elected nominated and ex-officio members.

A. Elected Members

1. Six persons elected by UGC from amongst the teaching staff of a university or affiliated college granting degree or diploma in pharmacy. Amongst these, there shall be one teacher each of pharmacy, pharmaceutical chemistry, pharmacognosy and pharmacology.
2. One person elected by Medical Council of India from amongst its members.
3. One registered pharmacist elected by each state pharmacy council from amongst its members.

B. Nominated Members

1. Six persons nominated by central government of whom at least four should possess degree or diploma in pharmacy or shall be engaged in the practice of pharmacy or pharmaceutical chemistry.

2. One registered pharmacist nominated by each state government.
3. One representative of UGC and AICTE.

C. Ex-officio Members

1. Director, General of health services.
2. The Drugs Controller of India.
3. The Director of Central Drug Laboratory.

Functions of PCI/Central Council (S. 04, 05, 09; W. 06, 07)

1. To prescribe the minimum standards of education required for qualification as pharmacist.
2. To frame the course of study for the pharmacist.
3. To regulate the minimum educational standards.
4. To maintain central register of the pharmacists.
5. To fix the powers and duties of president, vice-president, secretary, etc. of the council.
6. To fix the rates of remunerations and other allowances, payable to its members.
7. To prepare education regulations.
8. To inspect the institutions by appointing inspectors.
9. To give approval to the institution running pharmacy course.
10. Any other function given by central government.

Q 4. Give the constitution and functions of executive committee of PCI. (S. 99, 01; W. 99, 04, 07)

The executive committee of PCI consists of:

A. Ex-officio Members

1. President who shall be the chairman of the committee.
2. Vice-president.

B. Five Members

Elected by central council from its members.

Functions

1. Executive committee is authorised to observe the efficacy of present education regulation.
2. To recommend amendment in the present education regulation.
3. To carry out such other functions as may be entrusted to it by the central council.

Q 5. What are education regulations? Describe different education regulations. OR Write a note on ER. (S. 96, 98, 99, 00, 02, 03, 06, 07, 08, 09; W. 96, 98, 00, 02, 03, 05, 06)

The Pharmacy Council of India has laid down minimum standards of education required for qualification as a pharmacist. These standards are known as education regulations.

These education regulations are:

- i. Minimum qualification for admission to the course.
- ii. The nature and period of course of study.
- iii. The nature and period of practical training that shall be undertaken after the completion of regular course.
- iv. Subjects of the examination and standards to be attained in such examinations.
- v. Equipments and facilities to be provided for the student by the institution running approved course of study.
- vi. Conditions to be fulfilled by the institution giving practical training.
- vii. Conditions to be fulfilled by the authorities holding approved examination.

Q 6. How are amendments in education regulations done?

The present ER is framed by PCI with the approval of central government. Amendments to these regulations are first circulated to the state governments for their comments. If the comments are received within three months, then they may be taken in consideration by the central council and then amendments are sent to central government for its approval. After approval by central government it is published in the official gazette. Executive committee shall report to the council from time to time about the efficacy of regulations and may recommend amendments in the present regulation.

Q 7. Give the constitution of state pharmacy councils and joint state pharmacy council. (S. 98, 00, 01, 03, 06, 08; W. 02, 05, 06, 07)

State pharmacy council	Joint state pharmacy council
<p>A. Elected members</p> <ol style="list-style-type: none"> 1. Six registered pharmacists elected among themselves. 	<ol style="list-style-type: none"> 1. 3 to 5 registered pharmacists elected from amongst the pharmacists of each participating state.

State pharmacy council	Joint state pharmacy council
<p>2. One person elected by medical council of state from amongst its members.</p> <p>B. Nominated members 5 persons nominated by state government of whom at least 3 possess a degree/diploma in pharmacy or pharmaceutical chemistry or be the registered pharmacist.</p> <p>C. Ex-officio members 1. Chief administrative medical officer of the state. 2. A government analyst appointed under the D&C Act, 1940. 3. Officer in-charge of the drug control organisation in the state.</p>	<p>2. One person elected by medical council of each participating state from amongst its members.</p> <p>2 to 4 members nominated by each participating state government and more than half should possess a degree/diploma in pharmacy or pharmaceutical chemistry or be the registered pharmacists.</p> <p>1. Chief administrative medical officer of the each participating state. 2. A government analyst of each participating state. 3. Officer in-charge of the drug control organisation of each participating state.</p>

Q 8. How is approval given to the institutions running the course of pharmacy? OR How are the institutions running pharmacy course approved? (W. 00, 01, 04, 07)

- 1. Application:** Any institute or authority which conducts the course of study or examination for the pharmacy has to apply the central council for its approval of the course or examination.
- 2. Inspection:** On the receipt of application, the central council appoints inspectors to visit the institution and to satisfy whether the institution has prescribed facilities or not. Inspector may attend any examination during the course of inspection to judge its standard. After inspection inspectors prepare a detailed report of inspection and send it to central council.
- 3. Approval:** If the central council is satisfied on the report of the inspector that the institution possesses the prescribed facilities as per ER, it may give approval to such institution, conducting pharmacy course.

4. Declaration: Declaration of the approval is made by passing the resolution in the meeting of the council and then it is published in the official gazette.

Q 9. Under what circumstances/conditions/grounds approval of institution can be withdrawn? (S. 05)

If it comes to the notice of PCI that any approved course of study or examination does not continue as per ER, then council may give notice to such institution indicating its intention to withdraw the approval.

In such case the concerned institute should make representation through the state government within 3 months from the date of receipt of notice.

If central council satisfies on the report of state government, it may give approval conditionally.

Q 10. What is central register? How is it prepared? (S. 03, 06, 07; W. 98, 06)

Central Register

It is the register of pharmacist maintained by PCI, containing names of all persons registered as pharmacists in different states of India.

This register has to be maintained by the registrar of the council as per the directions of the council and has to revise from time to time and published in the official gazette.

Preparation of Central Register

For the preparation of central register each state council is required to supply 5 copies of its register to central council after April 1, of each year along with amendments if any for updating the central register.

Q 11. Define state council. Give the functions of state council. (S. 04, 05; W. 04, 05, 08)

State Council

It means state pharmacy council constituted under Section 19 and also includes joint state pharmacy council constituted under Section 20 of the Act.

Functions of State Council

- To register the names of all persons who have approved qualification.

1. To maintain state register of pharmacist.
2. To appoint suitable number of inspectors for the inspection of
3. To appoint where drugs are dispensed and compounded, premise where drugs are dispensed and duties of president, vice-president, secretary,
4. To fix the powers and duties of president, vice-president, secretary, etc.
5. To send five copies of state registers to central council after April 1, of each year for the preparation of central register.

Q 12. What is interstate agreement? Give the provisions under interstate agreement.

Interstate Agreement

Interstate Agreement may enter into agreement (under Section 20) When two or more states will serve the needs of other whereby the state council of one state will serve the needs of other states, such agreement is called interstate agreement.

Provisions

1. Under interstate agreement the membership of the state council may be increased by not more than two persons, out of these one should possess degree/diploma in pharmacy or pharmaceutical chemistry or be registered pharmacist.
2. Agreement provides for the distribution of expenditure between the participating states.
3. It shall also provide which of the state government shall exercise various functions of the participating state governments.
4. It also provides for the consultation between the participating state governments on the general or special matter arising under Act.
5. Such agreement is required to be published in the official gazette of all the participating states.

Q 13. What are the powers of inspector appointed by state council? (S. 04, 05)

1. To inspect premise where drugs are compounded or dispensed.
2. To enquire whether a person who is engaged in compounding and dispensing of drugs is registered pharmacist.
3. To investigate any complain made to him in writing, regarding contravention of the Act.
4. To institute prosecution under the order of executive committee of the state council.
5. To exercise such other powers as may be entrusted to him under the Act.

Q 14. Define first register. How is it prepared? What qualification is required to enter the name in first register? (S. 99, 00, 08; W. 96, 99, 01, 05, 07)

First Register

It means the register of pharmacists prepared under chapter IV of the Pharmacy Act by the state government before constitution of state council.

Preparation of First Register

The first register is required to be prepared in following manner:

1. The state government appoints the 'Registration Tribunal' consisting of 3 persons and also appoints a secretary and registrar of the tribunal.
2. The tribunal then appoints the date before which all applications for registration along with prescribed fees should reach the tribunal.
3. The tribunal examines all applications received within a given date and if it is satisfied that an applicant is duly qualified for registration, it will direct his or her name to enter in the register.
4. The first register so prepared, is then published in a manner directed by state government.
5. The registration certificates in prescribed formates are issued to persons whose names are entered in first register.

Qualification for Entry into First Register

A person for registration should be of at least 18 years of age, and should reside or carry on the business in the state and should have following qualifications:

1. A degree or diploma in pharmacy or pharmaceutical chemistry or a chemist/druggist diploma of an Indian University or a state government or a prescribed qualification granted by an authority outside India.
2. A degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry and has engaged in the compounding of drugs in a hospital or dispensary or other places in which drugs are regularly dispensed on prescription of medical practitioners for the total period of not less than three years.
3. Has passed an examination for compounders and dispensers recognised by state government.

4. Has not less than 5 years experience of compounding and dispensing in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of medical practitioners.

Q 15. Define subsequent register. What qualifications are required for entry of name of the person into subsequent register? (S. 96, 00, 01; W. 96)

Subsequent Register

It means the register of pharmacist prepared under chapter IV of the pharmacy act by the state council after first register.

Qualifications Required Before ER Taken Effect in the State

A person for registration should be of at least 18 years of age and should reside or carry on the business in the state and should have qualification:

- i. Those who possess the qualification required for first register and are at least matriculate.
- ii. Are registered pharmacist in another states.
- iii. Possess qualification for registration recognised by central council and are at least matriculate.

Qualification Required After ER Taken Effect in the State

A person for registration should be of at least 18 years of age and should reside or carry on the business in the state and should have qualifications for entry into subsequent register:

- i. Those who have passed an approved examination.
- ii. Those who possess the qualifications granted by an authority outside India, and which is recognised by central council for the purpose of registration.
- iii. Those who are registered pharmacist in another state.

Q 16. Under what circumstances/conditions/grounds the name of pharmacist can be removed from the register of the state? OR When did the name of pharmacist can be removed from the register of the states? (S. 96, 01, 03, 06; W. 98, 01, 04, 05, 07)

The name of the pharmacist may be removed from the register on the following grounds:

- i. If his name has been entered in the register due to error, misrepresentation, or suppression of material facts.

- ii. If he has been convicted of an offence in any professional respect or has been held guilty of infamous conduct in the professional respect.
- iii. If the person employed by the register pharmacist has been convicted of an offence and such person is registered pharmacist his name may be removed from the register.
 - However, the name of pharmacist can be removed from the register only after an order passed by executive committee of state council after making due enquiries and giving opportunity to the person concerned to explain his conduct.
 - The removal of name may be either permanent or only for the specified period of time.
 - The order passed by executive committee shall be confirmed by the state council and it will take effect only after 3 months from the date of passing order.
 - A person who is dissatisfied by the order about the removal of his name may appeal to the state government within 30 days of the order.
 - Any person whose name has been removed from the register has to surrender the certificate of registration to the registrar of the state of the council.

Q 17. Give the offences and penalties under Pharmacy Act, 1948. (S. 97, 99, 00, 06, 08, 09; W. 99, 02, 03, 07, 08)

1. 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.

Defence

However, if a person is the registered pharmacist of another state and has made application for registration in the state is not deemed to be falsely claiming as a registered pharmacist.

Penalty

Any person who is falsely claimed to be a registered pharmacist is punishable with a fine up to Rs. 500/- on first conviction and to a fine

up to Rs. 1000/- or imprisonment up to 6 months or both on any subsequent conviction.

2. 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 Rs. 1000/- or imprisonment up to 6 months or both.

3. Obstructing the State Council Inspectors in their Duties

Anyone who obstructs state council inspectors from discharging their duties is punishable with the fine of Rs. 500/- on first conviction and fine of Rs. 1000/- or imprisonment up to 6 months or both on any subsequent conviction.

4. 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 Rs. 50/-.

Chapter

4

The Drugs and Cosmetics Act, 1940 and Rules thereunder, 1945

Q 1. Give the aims and objectives of the Drugs and Cosmetics Act, 1940. (W. 01)

Object

The Drugs and Cosmetics Act, 1940 was passed.

1. To regulate the import, manufacture, distribution and sale of drugs and cosmetics.
2. To regulate the import of drugs into India so that no substandard or spurious drugs get imported in India.
3. To regulate manufacture of drugs so that no substandard or spurious drugs get manufactured in the country.
4. This act also provides for the control over the sale and distribution of the drugs by only trained and qualified person.
5. This act also provides for the control over the manufacture, sale and distribution of Ayurvedic, Siddha, Unani and Homeopathic drugs.
6. This act also provides provisions relating to import, manufacturing and sale of cosmetics.

Q 2. Define the terms as per D&C Act, 1940.

1. **Drug (S. 00, 03, 05; W. 96, 05, 08):** It includes:
 - i. All medicines for internal or external use of human being or animals and all the substances intended to be used for or in the diagnosis treatment, mitigation or prevention of any disease or disorder in the human being or animal including the preparation applied on human body for the purpose of repelling insects like mosquito.
 - ii. Such substances other than food, intended to affect the structure or any function of the human body or intended to be

- used for the destruction of vermin or insects which causes disease in human beings or animals.
- iii. All substances intended for use as a component of drug including empty gelatin capsules.
 - iv. Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of the diseases or disorders in human beings or animals.
2. **Ayurvedic, Siddha and Unani drugs (S. 01; W. 00):** It includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in the human beings or animals and manufactured according to formulae described in books of Ayurveda, Siddha and Unani system of medicine specified in first schedule of the Drugs and Cosmetics Act, 1940.
 3. **Homeopathic medicines (S. 04, 09):** It includes drugs recorded in homeopathic literature and their therapeutic efficacy has been established through long clinical experience and which are prepared according to homeopathic technique but does not include medicines for parenteral use.
 4. **Patent and proprietary medicines (S. 96, 98, 00, 01, 02, 05, 08; W. 99, 00, 02, 05, 06):** It means medicines for internal or external use of human beings or animals and prepared according to formulae other than those included in IP or any other book of standards.
 5. **New drug (S. 02, 03):** It means the drug whose composition is generally not recognised as a safe for use under the conditions recommended or suggested in the label and the drugs whose composition is recognised as a safe but which have not been used to any large extent for any appreciable period of time.
 6. **Manufacture (S. 03; W. 96):** It means any process or part of process for making, altering, ornamenting, finishing, labelling, breaking up of any drug or cosmetic for the purpose of their sale and distribution but does not include compounding or dispensing of any drug or the packing of any drug or cosmetic in the ordinary course of retail business.
 7. **Misbranded drug (S. 96, 02, 03, 06; W. 96):** It means a drug which is:
 - i. Coloured, coated, powdered or polished so as to conceal the damage or if it is made to appear of a better therapeutic value than it really is.

- ii. If it is not labelled in the prescribed manner.
 - iii. Its label or container bears the statement which is false and misleading or makes the false claim.
8. **Adulterated drug (S. 99; W. 96, 98, 99, 03, 05):** A drug shall be deemed to be adulterated:
 - i. If it consists, in whole or in part, of any filthy or putrid or decomposed substance.
 - ii. If it has been prepared, packed or stored under insanitary conditions, which are likely to make them injurious to health.
 - iii. If it is packed in the container composed of poisonous substances.
 - iv. If it contains a colour other than prescribed.
 - v. If it contains any harmful or toxic substance which may render it injurious to health.
 - vi. If any substance is mixed with it, so as to render its quality or strength.
 9. **Spurious drug (S. 98, 99, 01, 03, 08, 09; W. 04):** It means a drug:
 - i. Imported under the names of other drugs.
 - ii. The drugs which are an imitation or substitute of the other drugs.
 - iii. It resembles other drugs in a manner likely to cause deception.
 - iv. It bears the name of manufacturer which is fictitious or does not exist.
 - v. Which is supposed to be the product of manufacturer of whom it is not truly a product.
 10. **Drug store:** It means the licensed premises for the sale of drugs which do not require the services of a qualified person.
 11. **Chemist and druggist:** It means premises licensed for sale of drugs which require the services of qualified person but where the drugs are not compounded against the prescription of RMP.
 12. **Pharmacy:** It means the premises licensed for sale of drugs which require services of qualified persons and where drugs are compounded against the prescription of RMP.
 13. **Qualified person (S. 96, 01, 02, 08; W. 98):** Qualified person is a person who:
 - i. Holds a diploma/degree in pharmacy or pharmaceutical chemistry.

- ii. Is a registered pharmacist (under Pharmacy Act, 1948).
 - iii. Has minimum 4 years experience of dispensing and has been approved by licensing authority as a 'qualified person' on or before December 31, 1969.
14. **Drug inspector (S. 97, 05; W. 96, 07):** It means:
- i. In relation to Ayurvedic, Siddha or Unani drug, an inspector appointed by central or state government under Section 33 G of the Act.
 - ii. In relation to other drugs and cosmetics an inspector appointed by central or state government under Section 21 of the Act.
15. **Government analyst (S. 03, 05, 06; W. 07):** It means:
- i. In relation to Ayurvedic, Siddha or Unani drugs a person appointed under Section 33 F.
 - ii. In relation to any other drugs and cosmetics a person appointed by central or state government under Section 20 of the Act.
16. **Repacking of drugs (S. 00):** It means the process of breaking up any drug from a bulk container into small packages and the labelling of each package with a view to its sale and distribution, but it does not include the compounding, dispensing and packing of drugs in the ordinary course of retail business.
17. **Repacking licence:** It is the licence for repacking of drugs and granted for breaking up any drug from the bulk container into small packages and labelling of each package with a view to its sale and distribution.
18. **Loan licence:** It means a licence issued by licensing authority to a person who does not have his own arrangement for manufacture but who intends to avail of the facilities owned by another manufacturer.
19. **Restricted licence:** It is the licence for retail sale of drugs whose sale does not require the supervision of qualified person, it is issued to the travelling agents of the firms or venders of the drugs.
20. **General licence:** It is the licence for retail sale of drugs and issued to the person who has fixed premise for the business and engages the services of qualified persons for sale and compounding, dispensing of drugs.

21. **Retail sale:** It means a sale other than a sale by the way of wholesale dealing.
22. **Sale by the way of wholesale dealing:** It means a sale to a person for the purpose of selling again and also includes the sale to hospitals, dispensaries or medical educational or research institutions.
23. **Cosmetic (S. 97, 99, 00, 02; W. 02, 05):** It means any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or applied to any part of the human body for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as a component of cosmetic.
24. **Misbranded cosmetic (S. 08; W. 00, 02, 07):** It means a cosmetic:
- i. Which contains a colour other than prescribed.
 - ii. It is not labelled in a prescribed manner.
 - iii. Makes any false or misleading claim.
25. **Spurious cosmetic (S. 02; W. 08):** It means:
- i. A cosmetic which is imported under the name of other cosmetic.
 - ii. Cosmetics which are imitations or substitutes for other cosmetics.
 - iii. Resembles other cosmetics in a manner likely to cause deception.
 - iv. Bears the name of manufacturer who does not exist.
 - v. It is claimed to be the product of manufacturer of whom it is not a truly product.

Q 3. What are the schedules to the Drugs and Cosmetics Act, 1940? OR What does the first and second schedule of D&C Act, 1940 prescribe? (S. 04)

1. **First schedule:** It prescribes the list of Ayurvedic, Siddha or Unani drugs.
2. **Second schedule:** It deals with the standards to be complied by the imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution.

Q 4. Give the contents/meaning of the following schedules.

- **Schedule 'A':** List of forms used for making application for issuing licences, granting licences, sending memorandum, etc.

- **Schedule 'B':** Fees for test or analysis by the central drug laboratory or government analyst.
- **Schedule 'C':** List of biological and special products whose import, manufacture and sale are governed by a special provision.
- **Schedule 'C₁':** Other special products whose import, manufacture and sale are governed by special provisions.
- **Schedule 'F':** Provisions applicable to blood bank requirements and licensing to process blood components.
- **Schedule 'F_(b)':** Provisions applicable to production of bacterial and viral vaccines, sera and diagnostic agents.
- **Schedule 'F_(m)':** Standards for surgical dressings.
- **Schedule 'F_(mm)':** Standards for umbilical tapes.
- **Schedule FF:** Standards for ophthalmic preparations.
- **Schedule 'G':** List of substances required to be taken only under supervision of RMP.
- **Schedule 'H':** Prescription drugs which are required to be sold by retail only on the Rx of RMP.
- **Schedule 'J':** List of diseases or ailments, which a drug may not claim to prevent or cure.
- **Schedule 'M':** Current good manufacturing practices (cGMP) and requirements of factory premises, equipment, etc. for the manufacturing of **drug**.
- **Schedule 'M_(b)':** Requirements of factory premises, plant and equipment for the manufacturing of **homeopathic medicines**.
- **Schedule 'M_(mm)':** Requirements of factory premises, plant and equipments for the manufacturing of **cosmetic**.
- **Schedule 'M_(m)':** Requirements of factory premises, plant and equipments for the manufacturing of **medical devices**.
- **Schedule 'T':** Requirements of factory premises and hygienic conditions for the manufacturing of **Ayurvedic, Siddha and Unani medicines**.
- **Schedule 'N':** List of minimum equipments for the efficient running of pharmacy.
- **Schedule 'O':** Standards for disinfectant fluids.
- **Schedule 'P':** Life period of drugs.
- **Schedule 'P₁':** Pack sizes of drugs.
- **Schedule 'Q':** List of coal tar colours permitted to be used in the cosmetics and soaps.

- **Schedule 'R':** Requirements for condoms made of rubber latex intended for single use.
- **Schedule 'S':** Standards for cosmetics.
- **Schedule 'U':** Particulars to be shown in the manufacturing and analytical records of drugs.
- **Schedule 'W':** List of drugs shall be marketed under generic names only.
- **Schedule 'X':** List of habit forming, psychotropic and other such drugs.

Q 5. Give the examples of drugs belonging to following schedules.

- Schedule 'C'**
Sera, toxins, antigens, antitoxins, vaccines, adrenaline, penicillin, streptomycin, tetracyclines, chloramphenicol, ophthalmic preparation, erythromycin.
- Schedule 'C₁'**
Digitalis, adrenaline, vitamins, hormones, vaccines, penicillins, tetracycline, oxytetracycline, chloramphenicol, bacitracin.
- Schedule 'G'**
Chlorthiazide, bleomycin, ethacrynic acid, glibenclamide, phenytoin, insulin, tolbutamide, chlorpheniramine, diphenhydramine.
It includes anticancer, diuretic, antidiabetic, antihistaminic, antiepileptic drugs.
- Schedule 'H' (S. 02; W. 98, 02)**
Analgin, barbituric acid and its salts, betamethasone, bromhexine, chlorpromazine, cimetidine, dapsone, diazepam, ibuprofen, imipramine, mebendazole, metronidazole, oxytocin, paracetamol, phenyl butazone, sulphha drugs.
- Schedule 'X' (S. 02; W. 98, 02)**
Amylbarbitone, amphetamine, barbitone, glutethimide, meprobamate, methaqualone, pentobarbitone, phenobarbitone, secobarbitone.
- Schedule 'W'**
Analgin, aspirin, chlorpromazine, ferrous sulphate, piperazine, paracetamol.

Q 6. Write a note on 'Schedule M'. (S. 98, 00; W. 00, 05)**Schedule 'M'**

It deals with current good manufacturing practices and requirements of factory premises, plant, equipments, etc. for the manufacture of drugs.

- Quality of drug is basically responsibility of manufacturer and GMP provides guidelines so as to assure the quality. To achieve the objectives of GMP the licensee shall comply with the requirements of GMP as laid down in schedule 'M'.

- Schedule 'M' consists of two parts:

Part I

It deals with GMP relating to factory premises.

General Requirements

1. **Location:** It shall be free from contaminants like sewage, drain, soot, dust, smoke, etc.
2. **Construction:** The premises shall be well built, well ventilated. It shall prevent entry of insects and rodents.
3. Manufacturing operations shall be conducted in such a way that mix up and cross contamination shall be avoided.
4. **Working space:** Adequate space shall be provided for working and keeping the materials, etc.
5. Health clothing, and sanitation of workers, medical services like first aid facility, vaccination facility, etc.
6. Requirement of raw material.
7. **Sterile product area:** It shall be separate unit, provided with air locks, well ventilated air supply through HEPA filter.
8. **Master formula records (MFR):** It shall be maintained by licensee which contains all procedures for each product and it shall be prepared and maintained by competent technical staff.
9. Product containers, closures, labels and other printed material.
10. Batch manufacturing records as per schedule 'U'.

Part II

It deals with plant, equipment, etc. for manufacturing of drugs.

It includes the equipments for manufacturing of drugs in sections like:

- i. Ointments, emulsions, lotion and suspension
- ii. Syrup, elixir, solutions

- iii. Ophthalmic preparations
 - iv. Oral liquid preparations
 - v. Tablet, capsule
 - vi. Injectables
 - vii. Granules
 - viii. Powders.
- Minimum area required for parenteral section: 60 sq. metre.
For other sections: 30 sq. metre.

Q 7. Write a note on Schedule 'N'. (S. 96, 04, 06; W. 00, 04, 05, 08)**Schedule 'N'**

It prescribes the list of minimum equipments for the efficient running of pharmacy.

The schedule 'N' prescribes the following minimum requirements.

1. **Entrance:** Front portion of pharmacy shall be indicated as 'PHARMACY'.
2. **Premises:** The premises shall be well built, dry, well ventilated with sufficient dimensions for stocking goods. Poisons shall be stored separately. Dispensing department shall not be less than 6 sq. metre for each pharmacist. The height of premise shall be at least 2.5 metre. The floors and walls should be free from holes, cracks, and surfaces shall be easily washable.
3. **Furniture and apparatus:** Pharmacy shall contain furniture of required size and suitable apparatus. The drugs and chemicals shall be kept in suitable containers to prevent their deterioration. Every container shall be labelled as the name of drug as per pharmacopoeia. Dispensing bench shall be impervious and washable. Poisonous drugs shall be stored in cupboard with lock and key and marked with the word 'POISON' in red letters on white backgrounds.

Containers containing water soluble solutions shall be marked with the words "To Be Diluted".

4. **List of minimum equipment/apparatus:** Dispensing balance minimum 30 mg sensitivity, beakers, bottles, evaporating dish, filter paper, glass funnel, measuring cylinder of 10, 25, 100 ml

and 500 ml, mortar and pestle, ointment slab, spatula, spirit lamp, waterbath, wire gauze, suppository mould, thermometer, etc.

5. **Books**

- i. The pharmacopoeias
- ii. National formulary
- iii. Drugs and Cosmetic Act, 1940 and rules 1945
- iv. The Pharmacy Act, 1948
- v. NDPS Act, 1985.

6. **General provisions:** The conduct of pharmacy shall be under continuous personal supervision of registered pharmacist and his name shall be displayed prominently in the premise. He shall wear white apron. He shall maintain records, registers as per the Act.

Q 8. Mention different administrative bodies of Drug and Cosmetics Act, 1940. (S. 07)

1. **Advisory**

- i. Drugs Technical Advisory Board (DTAB)
- ii. Drugs Consultative Committee (DCC).

2. **Analytical**

- i. Government analyst
- ii. Central Drug Laboratory (CDL)
- iii. Drug control laboratories in the states.

3. **Executive**

- i. Licencing authorities
- ii. Drug Inspectors (DI)
- iii. Custom collectors.

Q 9. What is DTAB? Give the ex-officio members and functions of DTAB. (S. 97, 99, 00, 01, 02, 03, 05, 08; W. 99, 02, 04, 07)

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

1. The Director General of Health Services (Chairman).
2. The Drugs Controller of India.
3. The Director, Central Drug Laboratory (Kolkata).
4. The Director, Central Research Institute, Kasauli.

5. The Director, Central Drug Research Institute, Lucknow.
6. The Director, Indian Veterinary Research Institute, Izatnagar.
7. The President, Pharmacy Council of India.
8. The President, Medical Council of India.

Functions of DTAB (S. 04, 06)

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

Q 10. What is Drug Consultative Committee? Give its constitution and functions. (S. 99, 02; W. 01, 02, 06, 07)

Drugs Consultative Committee (DCC)

DCC is constituted under section 7 of the Act by the central government.

Constitution

It consists of:

1. Two representatives of central government nominated by central government.
2. One representative of state government nominated by each state government.

Functions of DCC

1. To advise the central government, state government and DTAB, on any matters so as to secure uniformity in the administration of the Act.
2. To carry out such other functions as may be entrusted to it by the central government.

Q 11. Give the functions of CDL. What procedure is to be followed for the dispatch of samples to CDL? (S. 97, 03; W. 99, 00, 01, 03)

Central Drug Laboratory (CDL)

Functions (S. 08; W. 05)

1. To analyse or test the samples of drugs or cosmetics sent to it by the court or custom collectors.
2. To carry out such other functions as may be entrusted to it by the central government.

Procedure of Dispatch of Samples to CDL

The samples for test or analysis shall be sent by registered post in a sealed packet along with a copy of memorandum (Form I) and with prescribed fee.

A specimen impression of seal used for sealing the package is also sent separately along with a copy of memorandum by registered post.

On the receipt of package the authorised officer compares the seal with the specimen impressions of seal and then opens the packet and conduct the test or analysis.

After completion of text or analysis the report is supplied in Form II and it is signed by the director or the authorised officer on his behalf.

Q 12. Define government analyst. Give the qualifications required for government analyst. Mention the duties of government analyst. What procedure is to be followed by government analyst on the receipt of sample? (S. 97, 00, 04, 08, 09; W. 98, 99, 03, 05, 06, 07)

Definitions

It means:

1. In relation to Ayurvedic, Siddha or Unani drugs a person appointed by central or state government under Section 33 F.
2. In relation to any other drugs and cosmetics a person appointed by central or state government under Section 20 of the Act.

Qualifications

A person appointed as a government analyst should have following qualifications.

1. A graduate in medicine, science, pharmacy or pharmaceutical chemistry from the recognised university with not less than 5 years experience in testing of drugs or cosmetics.
2. A postgraduate degree in medicine, science, pharmacy or pharmaceutical chemistry from recognised university with not less than 3 years experience in the testing of drugs.
3. Has passed Associateship Diploma of Institution of Chemist (India) with 'Analysis of Drugs and Pharmaceuticals' as one of the subjects and not less than 3 years experience in the testing of drugs under the control of:
 - i. A government analyst.
 - ii. Head of an institution/approved testing laboratory for this purpose.

Duties of Government Analyst (Functions) (W. 04)

1. To analyse or test the samples of drugs or cosmetics sent to him by drug inspectors or private persons and furnish the report in the prescribed formate.
2. To engage in a research or analytical work and send it from time to time to the government with a view of its publication at the discretion of the government.

Procedure Followed by Government Analyst on Receipt of Sample (S. 96, 99, 01, 02)

On the receipt of package of sample, government analyst will record the condition of seal and compare with specimen impression of seal received separately.

On the completion of test or analysis he shall supply the report of analysis in triplicate in Form 13 together with full protocols of the test applied.

If the purchaser wants to analyse or test his sample, he has to make application in Form 14 A along with prescribed fees and report will be supplied in Form 14 B.

Q 13. Define drug inspector. Give the qualifications required for drug inspector. (S. 96, 97, 98, 06)

Drug Inspector

It means:

1. In relation to Ayurvedic, Siddha or Unani drugs, an inspector appointed by central or state government under Section 33 G of the Act.
2. In relation to other drugs and cosmetics, an inspector appointed by central or state government under Section 21 of the Act.

Qualifications

1. A graduate in pharmacy, pharmaceutical sciences or medicine with specialisation in clinical pharmacology or microbiology from the recognised university.
2. Provided for the inspection of premises licensed for manufacture of schedule 'C' drugs a person appointed as drug inspector should have:
 - a. Not less than 18 months experience in the manufacture of at least one substance specified in schedule 'C'.
 - b. Not less than 18 months experience in the testing of any one of the substances specified in schedule 'C' in the approved laboratory.

- c. Not less than 3 years experience in the inspection of firms licensed for manufacture of schedule 'C' drugs during the course of their service as drug inspector.

Q 14. Discuss various powers of drug inspectors as per D&C Act, 1940. (S. 99, 01, 04, 06; W. 99, 07)

Powers of Drug Inspector

1. **To inspect:**
 - i. The premise licensed for sale of drugs.
 - ii. The premises licensed for manufacture of drugs.
2. **To take samples:** To take samples which are manufactured, sold, exhibited for sale or distributed or imported.
3. **To search:** To search any person in connection with the offence at all reasonable times.
4. **To enter and search:** To enter and search any premises in which he has reason to believe that an offence is being committed or has been committed.
5. **To stop and search:** To stop and search any vehicle or other conveyance which he has reason to believe that it used for carrying any drug or cosmetic in respect of which offence has been committed or being committed.
6. **To give order:** To give order in writing to the person in possession of drugs or cosmetics in respect of which offence has been committed, not to dispose off stock of such drug or cosmetic for specific period not exceeding 20 days.
7. **To examine:** The registers, records or other documents which are required to be maintained under the provisions of the Act.

Q 15. Give the duties of drug inspector as per D&C Act, 1940. (S. 96, 02, 03, 04, 05, 07, 08, 09; W. 98, 00, 04, 06, 07, 08)

Duties of Drug Inspector

A. Duties in Relation to Sale of Drugs

1. To inspect at least twice a year all the premises licensed for sale of drugs.
2. To take samples of drugs or cosmetics and send them for test or analysis.
3. To investigate any complain made to him in writing.
4. To examine the register, record and other documents required to be maintained as per the Act.

5. To institute prosecution in respect of breach of the Act and rules.
6. To submit the detail report of inspection and actions taken by him to the controlling authority.

B. Duties in Relation to Manufacture of Drugs and Cosmetics

1. To inspect at least twice a year all the premises licensed for manufacture of drugs or cosmetics.
2. To inspect premises licensed for manufacture of schedule C and C₁ drugs and observe the process of manufacture, the means employed for standardisation, testing, storage, qualification of technical staff and also the location, construction and administration which are likely to affect potency of the product.
3. To take the samples of drugs or cosmetics and send them for test or analysis.
4. To investigate any complain made to him in writing.
5. To examine the register, record and other documents required to be maintained under the Act.
6. To institute prosecution in respect of breach of the Act and rules.
7. To submit the detail report of inspection and actions taken by him to the controlling authority.

Q 16. Give the procedure of drug inspector for taking the samples of drugs or cosmetics and their dispatch to the government analyst. (S. 01, 06; W. 04, 08)

Whenever drug inspector takes any sample of drug or cosmetic:

1. He shall intimate the purpose of taking the sample in the prescribed form (Form 17).
2. He shall tender a fair price of the sample, if the price is refused the inspector shall give receipt in the prescribed form (Form 16).
3. He shall divide the sample in 4 parts in the presence of the person from whom the sample is taken and seal and mark each part. If manufacturer wants to sign and mark, he is also allowed to do so. However, if the sample is taken from manufacturing unit it shall be divided in 3 parts only.
4. The four parts of sample shall be disposed off in the following manner:
 - i. One part shall be sent to the government analyst for testing or analysis.
 - ii. One part shall be given to the person from whom sample is taken.

iii. One part shall be retained by the drug inspector or the production before court if legal proceedings are to be instituted.

iv. One part shall be sent to the warranter if any.
On the receipt of report from the government analyst drug inspector will decide whether further action in this matter is required or not. If the person is dissatisfied with the report of government analyst, it can be challenged within 28 days from the receipt of report. In such case the sample shall be sent to the central drug laboratory and the report supplied by director of CDL is considered to be final.

Q 17. Give the form numbers of licences for the grant of various licences.

- Form no. 19: For sale of drugs other than schedule 'X'.
- Form no. 19 A: For restricted licence.
- Form no. 19 AA: Wholesale or distribute the drugs from motor vehicle.
- Form no. 19 C: For sale of schedule 'X' drugs.
- Form no. 19 B: For sale of homeopathic drugs.

Licence issued	Form numbers		
	For the drugs other than sch. C, C ₁ and X	For the drugs specified in sch. C and C ₁	For schedule 'X' drugs
1. Retail sale	20	21	20 F
2. Restricted	20 A	21 A	-
3. Wholesale	20 B	21 B	20 G
4. Wholesale of drugs through motor vehicle	20 BB	21 BB	-

Q 18. Write a note on restricted licence. (S. 96, 02; W. 98)

Restricted Licence

It is a licence for the sale and distribution of drugs whose sale does not require the supervision of qualified person, and it is issued to the travelling agents of the firms or vendors of drugs.

Conditions for the Grant of Restricted Licence

1. Licensee shall have adequate arrangement for the proper storage of drugs.

2. Licensee shall deal only such drugs that can be sold without supervision of qualified person.
3. The licence shall be displayed at the prominent place of the premise open to the public.
4. In case of vendors of drug they shall possess the licence and should be produced on the demand of inspector.
5. Drugs should be sold in the original containers.

Q 19. What are the conditions to be fulfilled for the grant of general licence?

General Licence

It is the licence for retail sale of drugs and issued to the person who has fixed premise for the sale of drugs and engages the services of qualified person and also do compounding and dispensing of drugs.

Conditions for the Grant of General Licence

1. Licensee must have adequate premise and proper storage facilities for the drugs.
2. Sale and distribution of drugs shall be conducted under the supervision of qualified person.
3. The requirements prescribed for pharmacy should be as per schedule 'N'.
4. Licensee should allow inspector to inspect premise, register, records, etc.
5. Any changes in qualified staff shall be reported within 1 month to the licensing authority.

Q 20. Define wholesale of drugs. Mention general conditions required for the grant of licence for wholesale of drugs.

Wholesale of Drugs

It means sale of drugs to the hospitals, dispensaries, medical, educational and research institutions and to the person who purchases it for selling again.

General Conditions for the Grant of Wholesale Licence

1. Licensee must have adequate premise which should not be less than 10 sq. metre and which is well equipped for the storage of schedule C and C₁ and schedule 'X' drugs.
2. Incharge of the premise should be competent person.

3. Licence shall be displayed at the prominent place of the premise open to the public.
4. Drugs should be purchased only from licensed dealer or manufacturer.
5. The record of purchase and sale of drugs shall be maintained as per the provisions of the Act.
6. The drug should be sold only to those persons who are licensed to sale the drug by retail.

Q 21. Write in brief about storage of schedule 'X' drugs. (W. 01, 05)

Storage of Schedule 'X' Drugs

The substances specified in schedule 'X' kept in the retail shop shall be stored.

1. Under lock and key in the cupboard or drawer separately reserved for the storage of these substances.
2. In the part of premise which is separate from the remaining premise where responsible persons are allowed to enter.

Q 22. Write in short about storage of drugs for veterinary use.

Storage of Drugs for Veterinary Use (W. 01, 05)

The medicines for treatment of animal should be labelled as "Not for Human Use, For the Treatment of Animal Use Only."

Veterinary drugs should be stored in the cupboard or drawer separately reserved for the storage of veterinary drugs or in the part of premise separated from the remaining part of the premise where customers are not permitted to enter.

Q 23. Name the classes of drugs prohibited for import, manufacture and sale and distribution as per Drug and Cosmetic Act, 1940. (S. 00, 04, 07, 08, 09)

The following are the classes of drugs which are prohibited for import, manufacture and sale and distribution as per Drug and Cosmetic Act, 1940.

1. Any drug which is not of standard quality.
2. Adulterated, misbranded or spurious drug.
3. Any patent and proprietary medicine whose true formula is not disclosed on the label.
4. Any drug which claims to cure or prevent any of the diseases specified in schedule 'J'.

5. Any drug in contravention of any of the provisions of the Act and rules.
6. Physician samples are also prohibited for distribution.

Q 24. Name the places/routes through which drug may be imported into India. (S. 00)

Route of import	Places
1. By air	Mumbai, Delhi, Kolkata, Chennai
2. By sea	Mumbai, Kolkata, Chennai, Vishakhapatnam
3. By rail	Ferozpur, Amritsar

Q 25. Write a note on loan licence. (S. 97, 98, 00, 03, 06; W. 03, 08)

Loan Licence

It is the licence for manufacture of drugs and issued to the person who does not have his own premises and facilities for the manufacturing of drugs but who intends to avail of facilities owned by another person or licensee.

Loan licence is issued for the manufacture of drugs other than those specified in schedule 'X'.

Conditions for the Grant of Licence

1. The applicant should submit the documentary consent of the licensee whose facilities are to be availed for the manufacturing.
2. The requirements of factory premises, plant, equipment, etc. shall be as per schedule 'M'.
3. The licensee shall provide for testing of batch of raw materials and finished goods and maintain the records as per schedule 'U'.

Q 26. Write a note on repacking licence. (S. 98, 00, 03, 07; W. 05)

Repacking Licence

It is the licence for breaking of any drug from the bulk container into small packages and labelling of these packages with a view to sale and distribution.

Repacking licence is issued for the drugs other than schedule 'C' and 'C₁'.

Conditions for the Grant of Repacking Licences

1. Repacking shall be conducted under supervision of at least one "competent person".

Competent person: It means:

- i. Who holds diploma in pharmacy or is registered pharmacist under Pharmacy Act, 1948.
 - ii. Has passed matriculation examination or its equivalent examination and with not less than 4 years experience in the manufacturing, dispensing or repacking of drugs.
2. The factory premises should comply with requirements of schedule 'M'.
 3. The licensee should maintain adequate arrangement for testing of each batch of raw material and repacked drugs.
 4. The licence should be kept in the licensed premise and should be produced to inspector on his demand.
 5. The repacked drugs in addition to other particulars should be labelled with repacking licence number.

Q 27. State the general conditions for labelling of drugs as per Drug and Cosmetics Act, 1940. (S. 04, 09)**General Conditions for Labelling of Drugs**

1. Proper name of the drug along with trade name (if any).
2. Statement of net contents in terms of weight, volume, number of units, etc.
3. Quantity of active ingredient expressed in terms of amount per single dose. For example:
 - i. For oral liquid content per single dose or per 5 ml or multiple thereof.
 - ii. For liquid parenterals content per ml or content per single dose or % by volume.
 - iii. For any dosage forms like tablet, capsule, contents per tablet or capsule, etc.
4. Name and address of the manufacturer.
5. Distinctive batch number: It can be written as batch number or lot number.
6. Manufacturing licence number: Mfg Lic. No.
7. Date of manufacture.
8. Date of expiry or potency.

9. Alcoholic preparation should be labelled with percentage of alcohol by volume in the product.
10. If the drug is distributed as a free sample to medical practitioners, it shall be labelled as "physician sample, not to be sold".

Q 28. Give the labelling conditions for following schedules.

Labelling conditions for the given schedules are as follows:

1. Schedule 'G' (S. 96)**Caution**

It is dangerous to take the preparation except under medical supervision.

It should be conspicuously printed and surrounded by a line.

2. Schedule 'H' (S. 01; W. 04)**Warning**

- i. To be sold by retail on the R_x of RMP.
- ii. Symbol R_x conspicuously displayed on the left top corner of the label.

3. Schedule 'H' Drugs (Under NDPS Act)

- i. Symbol NR_x displayed on left top corner of the label.
- ii. Schedule 'H' drug.

Warning

"To be sold by retail only on the Rx of RMP."

4. Schedule 'C' Drugs (S. 96, 97)

- i. Proper name of the drug.
- ii. Statement of potency in units.
- iii. Name and address of manufacturer.
- iv. Date of manufacturer.
- v. Batch number.
- vi. Date of expiry.
- vii. Name and percentage of preservative if added.
- viii. Precautions regarding preserving the potency of product.
- ix. When the test for maximum toxicity is prescribed a statement that the drug has passed such test.

5. Schedule 'X' Drugs (S. 96, 97, 09; W. 04, 05, 08)

- i. *Warning:* "To be sold by retail only on the Rx of RMP."
- ii. Symbol XR_x in a red on left hand top corner of the label.

6. Ophthalmic Preparations (S. 06; W. 99, 05, 07)

Ophthalmic Solutions and Suspensions

- For external use only.
- Not for injection.
- Warning:**
 - If irritation persists or increases discontinue the use of drug and consult the physician.
 - Do not touch the tip of dropper or any other dispensing tip to any surface, since it may contaminate the solution.
 - Use the solution within 1 month after opening the container.

Ophthalmic Ointment

- For external use only.
- Warning:** If irritation persist or increases discontinue the use of drug and consult the physician.

Q 29. Give the specimen lables for certain drugs.

- Give the specimen label for 10 × 10 tab of Analgin IP (S. 97)
- Prepare a specimen label for vial of Insulin 80 units/cc.

10 × 10 Tablets ANALGIN TABLETS I.P.
Rx Each tablet contains Analgin IP 500 mg Date of mfg Mfg LIC No. Batch No. Date of Expiry RP (not to be exceeded)
Schedule 'H' drug
Warning: To be sold by retail on the prescription of RMP only.
Dosage: As directed by physician ABC PHARMA PVT. LTD., SATARA

10 cc INSULIN 80 Units/cc
Date of mfg Mfg LIC No. Batch No. Date of Expiry RP (not to be exceeded) Date of Expiry RP (not to be exceeded)
Schedule 'G' Drug
Caution: It is dangerous to take the preparation except under medical supervision.
Dosage: As directed by physician PQR PHARMA PVT. LTD., MUMBAI

- Prepare a specimen label for 100 tablets of Phenobarbitone sodium. (S. 99)
- Prepare a specimen label for 100 tablets of Ethyl morphine hydrochloride.

10 × 10 Tablets PHENOBARBITONE SODIUM TABLETS	10 × 10 Tablets ETHYL MORPHINE HCl TABLETS
XRx Each tablet contains Phenobarbitone sodium 30 mg Date of mfg Mfg LIC No. RP (not to be exceeded) Batch No. (LT Extra)	NRx Date of mfg Mfg LIC No. RP (not to be exceeded) Batch No. (LT Extra)
Schedule 'X' Drug	Schedule 'H' Drug
Warning: To be sold by retail only on the prescription of RMP.	Warning: To be sold by retail on the prescription of RMP.
Dosage: As directed by physician XYZ PHARMA PVT. LTD., PUNE	Dosage: As directed by physician UPS PHARMA PVT. LTD., PUNE

Q 30. Give specimen label for hair dye containing paraphenylyene diamine 4% or coaltar colour. (W. 98, 01)

40 ml HAIR DYE
Date of Mfg. Mfg LIC No. Batch No. It contains: Paraphenylyene diamine
Expiry date MRP Rs..... (inclusive of all taxes) 4%
POISON
FOR EXTERNAL USE ONLY
Caution: This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to accompanying direction should first be made. This product should not be used for dying eyelashes eyebrows as such use may cause blindness.
Warning: Keep the product away from reach of children.
Direction: Apply as directed. COLOURS PVT. LTD., MUMBAI

Preliminary Test

This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists.

To make the test cleanse a small area of skin behind the ear or upon the inner surface of the forearm using soap and water or alcohol. Prepare the dye as per the instructions and apply a small quantity of hair dye to the area and allow it to dry for 24 hours. After that wash the area with soap and water. If no irritation or inflammation exists, it may be assumed that there is no hypersensitivity to the dye.

Q 31. Give the offences and penalties under Drug and Cosmetics Act, 1940.

- Penalty for the use of government analyst report for advertising (S. 96, 02; W. 98, 02, 06):** Any one who uses the report of test or analysis supplied by CDL or government analyst for advertising, shall be punishable with fine up to Rs. 500/-, on first conviction and with imprisonment up to 10 years or fine or both on any subsequent conviction.
- Penalty for nondisclosure of the name of manufacturer:** Any one 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.
- 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.

Q 32. What does the schedule 'J' prescribe for? Give examples.

Schedule 'J' prescribes the list of diseases and ailments to which the drug may not claim to prevent or cure.

Examples: Cancer, blindness, leprosy, epilepsy, plague, diabetes, obesity, deafness, paralysis, rheumatism.

Q 33. Mention the schedules to which the following drugs fall.

Drugs	Schedule	Drugs	Schedule
1. Diazepam	Schedule H	16. Heparin	Schedule H
2. Phenobarbital	Schedule X	17. Meprobamate	Schedule X
3. Chlorpheniramine	Schedule G	18. Ampicillin	Schedule H
4. Insulin	Schedule C	19. Sera	Schedule C
5. Cyclobarbital	Schedule X	20. Chlorpropamide	Schedule G
6. Analgin	Schedule H	21. Ibuprofen	Schedule H
7. Streptomycin	Schedule P	22. Salbutamol sulphate	Schedule H
8. Secobarbital	Schedule X	23. Chlordiazepoxide	Schedule H
9. Erythromycin	Schedule C ₁	24. Pituitary extract	Schedule C
10. Vasopressin	Schedule H	25. Fish liver oil	Schedule C ₁
11. Penicillin	Schedule C	26. Polio vaccine	Schedule P
12. Amphetamine	Schedule X	27. Methaquinolone	Schedule X
13. Toxins	Schedule C	28. Dexamphetamine	Schedule X
14. Chloral hydrate	Schedule H	29. Primidone	Schedule G
15. Tolbutamide	Schedule G	30. Tetracycline	Schedule C ₁

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

Q 1. Give the objectives of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954. (S. 08, 09; W. 01, 02, 07)

Object

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

Q 2. Define the terms as per DMR (O.A) Act, 1954.

a. Advertisement (S. 97, 98, 00, 03, 09; W. 99, 02, 04, 08)

It means:

- i. Any notice, circular, label, wrapper or other document.
- ii. Any announcement made orally or by means of producing or transmitting light, sound or smoke.

b. Drug (W. 06): It includes:

- i. The medicines for internal or external use for human beings or animals.
 - ii. Any substance intended to be used for the diagnosis, cure, mitigation, treatment or prevention of diseases in human beings or animals.
 - iii. Any article other than food, if affects any structure or organ function of the body of human beings.
 - iv. Any article used as a component of any medicine or substances used in (i), (ii) and (iii) as above.
- c. "Magic remedy" (S. 96, 97, 98, 99, 00, 02, 05, 06, 09; W. 98, 99, 01, 02, 03, 04, 05, 06):** 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.

d. "Taking part in the publication of any advertisement" (W. 03)

It includes:

- i. The printing of advertisement.
- ii. The publication of any advertisement in the area to which this Act extends.

Q 3. State the classes of prohibited advertisement as per OA Act, 1954. OR Give the classes of advertisement which are prohibited under the DMR Act, 1954. OR What are the classes of advertisement to which provisions of Act are applicable? OR Name the classes of advertisement of which import and export are totally prohibited under DMR (OA) Act, 1954. (S. 96, 99, 00, 02, 03, 05, 06, 07, 09; W. 99, 00, 01, 05, 06, 07, 08)

Following classes of advertisements are prohibited under the Act:

- I. **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.
 - b. The correction of menstrual disorders in women.
 - c. The maintenance or improvement of capacity of human being for sexual pleasure.
 - d. Diagnosis, cure, mitigation, treatment or prevention of any disease or disorder specified in schedule 'J' of the Act.
- Schedule 'J' diseases:**
Appendicitis, blindness, cataract, cancer, deafness, diabetes, epilepsy, gallstone, kidney stone, leprosy, obesity, paralysis, sexual impotence, smallpox, tuberculosis, venereal diseases, etc.
- II. **Advertisements relating to drug**
 - i. Which directly or indirectly give false impression regarding true character of the drug.
 - ii. Make false claim for it.
 - iii. Are otherwise false and deceptive.
- III. **Advertisements relating to magic remedies** claiming their efficacy mentioned in clause (I) by the person who carries on the profession of administering magic remedies.

Q 4. Give the classes of advertisements and displays which are exempted from the provision of DMR Act, 1954. OR Name the classes of advertisements to which DMR Act, 1954 is not applicable. (S. 02, 06; W. 96, 98, 00, 01, 03)

The following classes of advertisements are exempted from the provisions of DMR Act:

- Any notice, signboard displayed by RMP on his premise indicating that the treatment is undertaken for disease.
- Any book or treatise dealing with matter relating to the disease or conditions and which is published from bona fide scientific or social standpoint.
- Advertisements relating to drugs which are sent confidentially in the prescribed manner to the RMP.
Such advertisements are required to be sent confidentially and if sent by post then following matter should be written at the top. "For the use of registered medical practitioner or hospital."
- Advertisements relating to drugs which are printed or published by government or by any other person with previous permission of government.
- Any advertisements, labels or sets of instructions which are permitted under the Drug and Cosmetics Act and rules thereunder.
- Any advertisement which is prohibited under Act, and central government feels that particular advertisement shall be in the interest of public, then it may be permitted by notification in the official gazette.

Q 5. How scrutiny of misleading advertisements relating to the drugs is done as per DMR (OA) Act, 1954?

- The scrutiny of misleading advertisement is done by person authorised by state government.
- If the person authorised feels that a particular advertisement has been made in contravention of the provisions of the Act, he may order to the manufacturer, packer, distributor or seller to submit the information regarding composition of drug or its ingredient.
- Such other information which may be necessary for scrutinising the advertisement.
- The manufacturer, packer, or seller shall bound to comply with order.
- The publishers and advertising agencies shall furnish the information like name and address of manufacturer, packer and seller, etc.

- From the above information advertisement is scrutinised and if it is found misleading then it shall be punishable under this Act.

Q 6. Give the offences and penalties under DMR (OA) Act, 1954. (S. 01, 02, 04; W. 07)

- Anyone who contravenes any of the provisions of Act shall be punishable with imprisonment up to 6 months or a fine or both on first conviction and with imprisonment up to 1 year or a fine or both on subsequent convictions.
- If company contravenes any of provisions of Act, every person who at the time of offence was incharge of company or responsible person shall be deemed to be guilty and punishable under the Act.

Q 7. Enlist any 10 diseases or ailments of which advertisements are prohibited under DMR (OA) Act, 1954. OR Mention any seven diseases or ailments of which no advertisement should be made to claim their cure as per Drugs and Magic Remedies (OA) Act. (S. 97)

- | | | |
|-----------------|-----------------|---------------------|
| 1. Tuberculosis | 6. Paralysis | 11. Blindness |
| 2. Epilepsy | 7. Deafness | 12. Rheumatism |
| 3. Leprosy | 8. Appendicitis | 13. Kidney stone |
| 4. Cancer | 9. Obesity | 14. Cataract |
| 5. Smallpox | 10. Deafness | 15. Heart diseases. |

Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules (NDPS Act, 1985)

Q 1. Give the object of narcotic Drugs and Psychotropic Substances Act, 1985. (S. 98, 04, 05; W. 01, 06, 08)

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

Q 2. Define the terms.

1. **Addict (S. 98, 99, 02, 03, 09; W. 99, 01):** It means a person addicted to any narcotic drug and psychotropic substances.
2. **Psychotropic substances (S. 98, 99, 02, 03, 05, 07, 08; W. 99, 01, 03, 05, 08):** It means any substance, natural or synthetic or any salt or preparation of such substances or material, which is included in the list of psychotropic substances in the schedule. For example, mescaline, diazepam, nitrazepam, phenobarbitone, chlordiazepoxide, amphetamine.
3. **Narcotic drugs (S. 98, 99, 02, 03, 09; W. 99, 01, 05):** It means coca leaf, cannabis, opium, poppy straw and includes all manufactured drugs.
4. **Medicinal cannabis (hemp):** It means any extract or tincture of cannabis (hemp).
5. **Coca plant:** It means the plant of any species of genus *erythroxylon*.
6. **Coca leaf (S. 00, 03, 09; W. 98, 04, 07):** It means:
 - i. The leaf of coca plant except a leaf from which all ecgonine, cocaine have been removed.

- ii. Any mixture with or without neutral material except any preparation containing not more than 0.1% of cocaine.
7. **Coca derivative (S. 97, 98, 04, 08; W. 02, 07, 08)**
It means:
 - i. Crude cocaine
 - ii. Ecgonine and all its derivatives
 - iii. Cocaine and its salts
 - iv. All the preparations containing more than 0.1% of cocaine.
8. **Opium (S. 00, 03; W. 98, 04)**
It means:
 - i. Coagulated juice of opium poppy
 - ii. Any mixture with or without neutral materials of coagulated juice but not includes any preparation containing not more than 0.2% of morphine.
9. **Opium poppy:** It means the plant of *papaver somniferum* and other species of *papaver* from which opium or any phenanthrene alkaloids can be extracted.
10. **Poppy straw:** It means all parts of opium poppy (except seeds) after harvesting whether in their original form, or cut, crushed or powdered and whether or not juice has been extracted from it.
11. **Poppy straw concentrate:** It means the material obtained when poppy straw is subjected for the concentration of its alkaloids.
12. **Opium derivatives (S. 97, 99, 02, 04, 05, 08; W. 03, 04, 05):**
It means:
 - i. *Medicinal opium:* It is the opium confirming with requirement as per Indian pharmacopoeia or any other pharmacopoeia and mixed with or without neutral materials.
 - ii. *Prepared opium:* It means the opium manipulated to make it suitable for smoking and the residue left after it has been smoked.
 - iii. Morphine, codeine, thebain and their salts.
 - iv. Heroin and its salts.
 - v. Preparation containing more than 0.2% of morphine.
13. **Cannabis (Hemp) (S. 00, 04; W. 98, 04):** It means:
 - i. *Charas:* The resin in the crude or purified state obtained from cannabis plant including concentrated preparations and the resin known as Hashish oil or liquid Hashish.

- ii. *Ganja*: Means flowering and fruiting tops of cannabis plant except seeds and leaves.
- iii. Any mixture with or without neutral material of the above forms or any drink prepared from them.

14. **Illicit traffic (S. 99, 06; W. 99, 03)**: It includes:

- i. Cultivating any coca plant or gathering any portion of coca plant.
- ii. Cultivating the opium poppy or any cannabis plant.
- iii. Engaging in production, manufacture, possession, sale, purchase, transport, warehousing, consumption, interstate import or export, import into India, export from India, transshipment of narcotic drugs or psychotic substances.
- iv. Engaging in the activities in the narcotic drugs or psychotic substances other than those specified in (i) to (iii) above.
- v. Giving premises for the above activities except as permitted under the Act.
- vi. Financing directly or indirectly for any of the above activities.
- vii. Harboring the persons engaged in the above activities.

Q 3. Give the operations controlled and regulated by central government as per NDPS Act, 1985. (S. 01, 99, 08; W. 04, 08)

Central government by making rules controls and regulates following operations:

1. Cultivation and gathering of any portion of coca plant, only on behalf of central government.
2. Cultivation of opium only on behalf of central government.
3. Production and manufacture of opium and production of poppy straw.
4. Manufacture of manufactured drugs except prepared opium and medicinal hemp.
5. Sale of opium and opium derivatives.
6. The manufacture, possession, transport, interstate export, import, sale, purchase, consumption or use of psychotropic substances.

Q 4. What are the operations controlled and regulated by state government. (S. 08, 09; W. 08)

State government by making rules controls and regulates following operations:

1. Possession, transport, interstate import, export, warehousing, sale, purchase, consumption and use of poppy straw.
2. Cultivation of any cannabis plant, production, manufacture, possession, transport, interstate import, export, sale, purchase, use of cannabis (except charas).
3. Manufacture of medicinal opium or preparation containing manufactured drugs.
4. Possession, transport, purchase, sale, interstate import, export, use or consumption of manufactured drugs.
5. The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with state government on medical advice or his personal consumption.

Q 5. Give the offences and penalties under NDPS Act. (S. 01, 06, 09; W. 00, 01)

1. Offences

- i. Operations relating to poppy straw.
- ii. Cultivating coca plant and gathering its portion.
- iii. Operations relating to prepared opium.
- iv. Operations relating to opium poppy and opium.
- v. Operation relating to cannabis plant except ganja.

Penalty

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

2. Offences

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

Penalty

- i. Rigorous imprisonment not less than 10 to 20 years and fine not less than 1 to 2 lakhs on first conviction.

- ii. With rigorous imprisonment for not less than 15 to 30 years and fine not less than 1.5 to 3 lakhs.

3. Penalty for Illegal (Unlawfully) Possession in Small Quantity of any Narcotic and Psychotropic Substances for Personal Consumption Under NDPS Act, 1985

Shall be punishable with:

- i. Imprisonment up to 1 year or fine or both where narcotic drug or psychotropic substance consumed is—cocaine, morphine, heroin, etc.
- ii. Imprisonment up to 6 months or fine or both where narcotic or psychotropic substance consumed is other than above.

Chapter

7

Drugs Price Control Order (DPCO)

DRUGS PRICE CONTROL ORDER (DPCO) (S. 07)

The drug price control order is passed by central government under Section III of Essential Commodity Act, 1955.

Q 1. Give the object of DPCO. (S. 99, 04, 07; W. 03)

Object of DPCO

1. To regulate equal distribution of bulk drugs and making it available at a fair price.
2. To fix maximum sale price of bulk drugs.
3. To fix maximum retail price of drug formulation.

Q 2. Define the terms.

1. **Retailer (W. 98):** It means a dealer carrying on retail business of sale of drugs to the customers.
2. **Distributor (W. 98, 99):** It means a distributor of drugs or his agent or a stockist appointed by manufacturer or an importer for stocking his drugs for resale to a dealer.
3. **Dealer (W. 98, 99):** It means a person carrying on business of purchase or sale of drugs whether as a wholesaler or retailer including his agent.
4. **Wholesaler:** It means a dealer or his agent or stockist appointed by manufacturer or an importer for sale of drugs to retailer, hospital dispensary and medical, educational or research institutions who purchase drugs in bulk quantities.
5. **Ceiling price (leader price) (S. 04, 08, 09; W. 06, 08):** It means the price fixed by government for scheduled formulations according to provisions of DPCO.

6. **Free reserve:** It means a reserve created by appropriation of profit but does not include the reserve provided for contingent liability, disputed claims, good will and other similar reserves.
7. **Net worth (S. 04):** It means the paid up capital share of a company plus free reserve if any and surpluses excluding outside investments which are not readily available for operational activity.
8. **Bulk drug (S. 97, 01, 02, 05, 06, 08; W. 99, 02, 03, 05, 08):** It means any pharmaceutical, chemical, biological or plant product including its salts, esters and derivatives confirming to the pharmacopoeial standards and which is used as such or as an ingredient in any formulation.

Q 3. How is fixation of price of bulk drugs done? (S. 08; W. 00)

Fixation of Price of Bulk Drugs

- Under the provisions of DPCO, government has power to fix the maximum sale price of bulk drugs.
- For this purpose government asks the manufacturer or importer of the bulk drugs to submit necessary information required for fixing the price.
- Government after taking into consideration other factors fixes maximum sale price of bulk drugs.
- Once the price is fixed, no person shall sale the bulk drug at a price exceeding maximum sale price fixed by the government plus local taxes extra, if any.
- If the manufacturer wants revision of maximum sale price of bulk drugs which is fixed earlier as per provision of DPCO, he has to make application in form I to the government.
- The government will fix the revised price for such bulk drugs within specified period.

Q 4. How is "retail price" of formulation calculated as per DPCO? (S. 96, 97, 98, 99, 00, 03, 06, 07, 09; W. 96, 98, 99, 00, 02, 04, 05, 07)

1. As per DPCO 1979

$$RP = [MC + CC + PC] \times \left[1 + \frac{MU}{100} \right] + ED$$

Where,

RP = Retail price

MC = Material cost

CC = Conversion cost
 PC = Packaging charges
 MU = Marks up
 ED = Excise duty

2. As per DPCO, 1987 or 1995

$$RP = MC + CC + PM + PC \times \left[1 + \frac{MAPE}{100} \right] + ED$$

Where,

RP = Retail price
 MC = Material cost
 CC = Conversion cost
 PM = Packaging material cost
 PC = Packaging charges
 MAPE = Maximum allowable post manufacturing expenses
 ED = Excise duty

Q 5. Give regulations regarding the sale of "split quantities of formulation," under the drug price control order, 1979. (S. 96, 98, 01; W. 04, 08)

Sale of "Split Quantities of Formulations"

No dealer can sell loose quantities of formulation drawn from pack of such formulation at a price which exceeds as per the proportion of retail price of formulation plus 5% thereof.

Q 6. What are different schedules to the drug price control order, 1995? (S. 05)

There are three schedules to the drug price control order, 1995.

1. **First schedule:** It gives the list of bulk drugs.
2. **Second schedule:** It gives the different types of forms (total six).
3. **Third schedule:** It specifies the maximum pre-tax return on sales turnover of manufacturer or importer of formulations.

Q 7. Write a note on drug price equalisation account (DPEA). (S. 06; W. 01, 04, 07)

Government may, by notice, ask manufacturer, importer or distributor, as the case may be, to deposit the amount which has accrued under the provisions of the drug price control orders into drug prices.

The amount available with DPEA shall be utilised for:

1. Paying to the manufacturer, importer or distributor the shortfall between his retention price and the common selling price for the purpose of increasing production, proper distribution and availability at fair prices of drugs.
2. Meeting expenses of government during discharging its functions.
3. Promoting higher education and research in pharmaceutical sciences and technology.

Q 8. Define the terms.

1. **Sale turnover:** It means the products of units of formulations sold by a manufacturer or an importer for the sale of his drugs to a retailer hospital dispensary, medical, educational or research institutions, purchasing bulk quantities of drugs.
2. **Formulation (S. 99):** Formulation means a medicine processed out of or containing one or more bulk drugs with or without the use of any pharmaceutical aid for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals but does not include:
 - i. Any medicine included in any bona fide Ayurvedic (including Siddha) or Unani (Tibb) systems of medicines.
 - ii. Any medicine included in the homeopathic system of medicine.
 - iii. Any substance to which the provisions of Drugs and Cosmetics Act, 1940 do not apply.

Chapter

8

The Poison Act, 1919

Q 1. Give the aim and object of Poison Act, 1919. (S. 99, 01, 02, 06, 08; W. 96, 98, 02, 04, 06)

Object

The Poison Act, 1919 was passed with a view to regulate and control import, possession for sale and sale of a poison.

Q 2. Define 'poison' as per Poison Act, 1919. Give examples of list A and list B poisons. (S. 96, 99, 06, 07; W. 99, 03, 08)

Poison

It means all the substances notified as a poison under the Poison Act, 1919.

List A

Morphine, atropine, arsenic, heroin, potassium cyanide, belladonna, coca, strychnine, barbituric acid.

List B

Chloroform, zinc chloride, oxalic acid, carbolic acid.

Q 3. Write a note on "import of poison".

Import of Poison

- Central government regulates import of poisons in India.
- The import of poisons into India is permitted only under the authority of licence issued by the central government.
- The persons licensed to import poisons must observe the conditions of licence.
- The person licensed to import poisons, should import them across one of the defined customs frontiers and in accordance with the conditions of the licence.

Q 4. How does state government regulate possession for sale and sale of poison under Poison Act, 1919? OR Explain in brief the restrictions imposed by the Poison Act on possession for sale and sale of poison in India. OR Mention different conditions to be satisfied for wholesale or retail sale of poison in a state. (S. 03, 04, 05, 07, 09; W. 00, 01, 02, 03, 05, 06)

Possession for Sale and Sale of Poison

The rules made by state government for possession and sale of poison.

1. To grant of licences to possess any specified poison for wholesale or retail.
2. Fixing the fees for the licence.
3. The classes of persons to whom the poison may be sold.
4. The classes of persons to whom the poison can be sold to any one person.
5. The maximum quantity of poison that can be sold to any one person.
6. Maintenance of sale register by the vendors of poisons, particulars to be entered in the register and its inspections.
7. Safe custody of such poisons and labelling of vessels, packages or coverings in which the poison is sold or possessed for sale.
8. Inspection and examination of such poison by the inspectors appointed by state government when poison is possessed for the sale by the vendors.

Q 5. Give the offences and penalties under Poisons Act, 1919. (S. 96, 98, 99, 00, 06; W. 98, 99, 02, 04, 07, 08)

1. **Penalty for unlawful (illegal) importation, possession for sale and sale of any poison:** Anyone who unlawful imports, possesses or sells any poison, shall be punishable with imprisonment up to 3 months or fine up to Rs. 500/- or both on first conviction and with imprisonment for 6 months or a fine up to Rs. 1000/- or both on any subsequent conviction.
2. **Penalty for illegal possession of any poison:** Anyone who possesses any poison whose possession is banned by the state government is punishable with imprisonment up to 1 year or a fine up to Rs. 1000/- or both.
3. Any poison in respect of which offence has been committed is liable to confiscation along with any vessel packages, coverings, etc. in which the poisons have been stored.

Chapter

9

The Medicinal and Toilet Preparation (Excise Duties) Act, 1955 and Rules thereunder 1976 [MTP (ED) Act, 1955]

Q 1. Give the object of Medicinal and Toilet Preparation Act, 1955.

The act is passed to provide for the levy and collection of duties of excise on the medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics.

Q 2. Define the terms.

1. **Alcohol (S. 96, 99; W. 98, 99, 01):** It means ethyl alcohol of any strength and purity having chemical composition C_2H_5OH .
2. **Denatured alcohol/spirit (S. 97, 07):** It means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the central or state government.
3. **Rectified spirit (S. 07):** It means plain undenatured alcohol of strength not less than 50° over proof and includes absolute alcohol.
4. **Absolute alcohol:** It means alcohol confirming to the British pharmacopoeial specification for dehydrated alcohol.
5. **Spirit store:** It means that portion of bonded or nonbonded laboratories which is said a part for the storage of alcohol, opium, Indian hemp or other narcotic drugs and on which duty has been paid or not.
6. **Dutiable goods (S. 99, 01, 05; W. 98, 99, 02, 04):** It means medicinal and toilet preparation specified in the schedule on which duties of excise are levied under the MTP Act, 1955.
7. **Warehouse:** It means any place or premise licensed under the rule 70.
8. **Medicinal preparations (S. 99, 01, 04; W. 98, 99, 02):** It includes the drugs used as a remedy or prescription prepared for

internal or external use of human beings or animals and all substances intended to be used for or in treatment, mitigation or prevention of diseases in human beings or animals.

9. **Toilet preparation (S. 96, 99, 06, 08, 09; W. 98, 99, 01, 03, 04, 05, 08):** It means any preparation intended to be used in the toilet of human body or in perfuming apparel of any description or any substance intended to cleanse, improve or alter the complexion, hair, skin, teeth and includes deodorants and perfumes.

10. **Narcotic drugs/narcotics:** It means substance which is a coca leaf or coca derivative or opium or opium derivative or Indian hemp and includes any other substance capable of causing or producing in human beings dependence, tolerance and withdrawal syndromes and those substances which are declared to be narcotic drugs or narcotics by central government in the official gazette.

11. **Restricted preparations (S. 96, 05; W. 99, 01, 02):** It means the medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages.

12. **Unrestricted preparations (S. 96, 05; W. 99, 01, 02):** It means the medicinal preparations which are not capable of being misused as ordinary alcoholic beverages.

13. **Manufacture in-bond (under bond):** It means alcohol or any other narcotic drug on which duty has not been paid, is used for the manufacture of medicinal and toilet preparations and is carried out in bonded laboratory.

14. **Manufacture outside bond (without bond):** It means alcohol or any other narcotic drug on which duty has been paid, is used for manufacture of medicinal and toilet preparations and is carried out in nonbonded laboratory.

15. **Bonded laboratory/manufactory (S. 04; W. 07):** It means premise or any part of the premise approved and licensed for the manufacture and storage of medicinal and toilet preparation containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has not been paid.

16. **Nonbonded laboratory/manufactory:** It means premise or part of the premise approved and licensed for the manufacture and

storage of medicinal and toilet preparation containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has been paid.

Q 3. Explain the procedure of obtaining licence to bonded/non-bonded laboratory.

- For obtaining licence, application along with prescribed fees shall be made to the excise commissioner of the concerned state at least two months before the proposed date of starting the manufacturing.

- In the application following particulars shall be mentioned.

- i. Name and address of the applicant: If applicant is a firm, name and address of the firm along with addresses of directors and managers should be mentioned.
- ii. The amount of capital proposed to be invested.
- iii. The full description regarding the apparatus and permanent machinery.
- iv. The list of preparations which are to be manufactured along with % of alcohol that may remain in the finished preparation.
- v. The plan of bonded/nonbonded laboratory should be submitted along with plan of quarters provided for excise officer.
- vi. The approximate date of starting manufacturing.
- vii. In case of firm, a copy of partnership deed is to be enclosed.

On the receipt of application excise commissioner will verify the statements made in the application and if satisfied he will issue the licence to the applicant.

Q 4. Give the plan/requirements/outline/construction of bonded laboratory. (S. 97, 98, 99, 01, 02, 03, 05, 07, 08, 09; W. 98, 00, 02, 03, 04)

The bonded laboratory should consist of following compartments:

1. A spirit store.
2. A room for manufacturing of medicinal preparations.
3. One or more rooms for the storage of finished medicinal preparations.
4. A separate room for manufacture of toilet preparation.
5. A separate room for storage of finished toilet preparations.
6. Accommodation facilities with necessary furniture for the excise officer incharge of the bonded laboratory near its entrance.

Requirements

1. There shall be only one entrance to the laboratory and only one door for each of its compartments.
2. Every room in the bonded laboratory should have a board indicating the name of the room and serial number.
3. The pipes from sinks or wash basins in the laboratory should be connected to the general drainage of the laboratory.
4. The arrangements of gas and electric connections should be such that their supply can be cut off at the end of the days work.
5. Every window in bonded laboratory would be provided with specific arrangement of malleable iron rods of prescribed dimensions and the window should be covered on the inside with strong wire netting of a mesh not exceeding 25 mm.
6. All the doors shall be secured with excise ticket locks in the absence of excise officer in-charge.
7. All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial number and full capacity.

Q 5. How are the finished goods removed from the bonded laboratory?

Whenever manufacturer wants to remove his preparations from bonded laboratory, he should apply in the prescribed form to the officer in-charge of the laboratory and pay the duty on it.

Excise officer checks the entries and duty paid and allows the manufacturer to remove his preparation from the bonded laboratory.

However, if the preparations are issued:

- i. To the bonded warehouse.
 - ii. For export outside India.
 - iii. To the institutions authorised to receive them duty-free.
 - iv. For research/experimental purposes.
- the duty should not be required to pay.

Q 6. Write a note on Excise staff of bonded laboratory. (S. 99; W. 99)

Excise Officer

He is the officer of the department or the person appointed by state government to exercise all or any of the powers of excise officer.

The manufacture in bond shall be conducted under the supervision of excise officer in-charge.

The excise commissioner after consulting with the owner of the bonded laboratory determines the type of staff to be provided for the laboratory.

The accommodation facilities of the excise officer should be situated near the entrance of bonded laboratory.

Functions of the Excise Officer

1. To supervise the manufacturing of alcoholic preparations.
2. To take the samples from the finished preparations and send them to the chemical examiner for the determination of alcoholic strength.
3. To issue alcoholic preparations from the bonded laboratory on which duty has not been paid.
4. To obtain a spirit from distillery or warehouse.

Q 7. Differences between: (S. 96, 06, 08; W. 01, 02, 04, 05, 06, 08)

A. Bonded and nonbonded laboratory/manufactory.

<i>Bonded laboratory/manufactory</i>	<i>Nonbonded laboratory/manufactory</i>
1. It means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, Indian hemp or narcotic drug on which duty has not been paid.	1. It means premises approved and licensed for manufacture and storage of medicinal and toilet preparations containing alcohol, Indian hemp or narcotic drug on which duty has been paid.
2. Only manufacturing is carried out in the laboratory without any restriction.	2. Manufacturing as well as sale of the preparation is carried out in the laboratory between sunrise and sunset and on those days fixed by the excise commissioner.
3. Manufacturing is conducted under the supervision of excise officer in-charge of the laboratory.	3. Excise officer in-charge is not required.
4. Accommodation for excise officer is required.	4. Accommodation is not required.
5. Duty on finished preparation is paid at the time of removal of preparations from bonded laboratories.	5. Duty is paid in advance.

B. Manufacture in bond and manufacture outside bond.

<i>Manufacture in bond</i>	<i>Manufacture outside bond</i>
<ol style="list-style-type: none"> 1. The alcohol or narcotic drugs on which duty has not been paid are used in the manufacture of medicinal and toilet preparations. 2. Manufacturing is conducted in bonded laboratory. 3. Supervision of excise officer is required. 4. Accommodation for excise officer is required. 5. Duty on finished preparation is paid at the time of removal of preparation from bonded laboratory. 6. Only manufacturing is conducted. 	<ol style="list-style-type: none"> 1. The alcohol or any other narcotic drugs on which duty has been paid are used in manufacture of medicinal and toilet preparations. 2. Manufacturing is conducted in non-bonded laboratory. 3. Supervision of excise officer is not required. 4. Accommodation for excise officer is not required. 5. Duty is paid in advance. 6. The manufacture as well as sale is conducted between sunrise and sunset.

Q 8. What are the provisions for exemption of duty on medicinal and toilet preparations? (S. 01; W. 00)

The duty on medicinal preparation is exempted if they are supplied direct from a bonded laboratory to:

- i. Hospital and dispensaries under government.
- ii. Charitable hospitals and dispensaries under local bodies.
- iii. Medical stores of government.
- iv. Any institution certified by district medical officer supplying medicines free to the poor people.
- v. Export outside India.
- vi. For experimental purposes.

Q 9. Give the offences and penalties under medicinal and toilet preparations. (S. 01, 05; W. 07)

1. **Offences relating to warehousing:** An owner of the warehouse or his servant, who commits any of the following offenses shall be punishable with a fine extending up to Rs. 2000/-.

The offences are:

- a. Opens any lock or door in absence of excise officer.
 - b. Makes any alteration in the warehouse without the consent of excise officer.
 - c. Deposits or removes the goods in contravention of the rules.
 - d. Conceals the contraband goods or goods other than dutiable, etc.
- Vexatious search, seizure, etc. by excise officer:**
2. **Penalty:** The officer will be punishable up to Rs. 2000/-.
 3. **Malicious information:** Anyone who gives malicious information is punishable with imprisonment up to 2 years or fine up to Rs. 2000/- or both.
 4. **Obstructing to the officer and giving false information:** Anyone who obstruct the officer appointed by the government while performing his duties or provides false information to the officer shall be punishable with fine up to Rs. 500/-.
 5. **Maintaining false accounts of stock of goods in a warehouse or manufactory or not following the provisions of this Act, while maintaining such accounts:** Punishable with a fine up to Rs. 2000/-.

Q 10. How does the movement of dutiable goods from one bonded warehouse to another bonded warehouse take place? (S. 00, 02, 04; W. 01, 05, 06, 07)

- When the goods are to be removed from one warehouse to another, the consigner should have to make an application in triplicate to the officer in-charge of the warehouse with the other necessary information at least 24 hours before the removal of goods.
- The officer in-charge takes the accounts of goods and sends duplicate copy to the officer in-charge of the warehouse of destination and triplicate copy is to be sent to the consignee.
- On arrival of goods at destination, the consignee should present such goods along with the triplicate application and transport permit to the officer in-charge.
- Then he prepares rewarehousing certificate on duplicate and triplicate and returns the duplicate to the officer in-charge of warehouse (destination) and triplicate to the consigner.
- The consigner shall then present such triplicate copy of application with warehousing certificate to the officer in-charge of his warehouse within 90 days of the issue of the transport permit to him.

Medical Termination of Pregnancy Act, 1971 (MTP Act, 1971)

Q 1. Give the aim and object of the Medical Termination of Pregnancy Act, 1971 (MTP Act, 1971). (S. 04, 06; W. 96, 99, 01)

Object

The Medical Termination of Pregnancy Act, 1971 was passed to provide for the termination of certain pregnancy of women by registered medical practitioners (RMP) for bona fide medical reasons and for the matter concerned therewith.

Q 2. Define the terms under MTP Act, 1971.

1. **Guardian:** It means a person having the care of minor or lunatic.
2. **Minor:** It means a person who is deemed to be not attending the age of majority under the provisions of Indian Majority Act.
3. **Lunatic:** It means as specified under section 3 of Indian Lunacy Act, 1972.
4. **Admission register:** It means a register maintained as per regulation V of the MTP Act, 1971.
5. **Approved place:** It means a place approved under rule IV of the MTP Act, 1971 and rules thereunder.
6. **Registered medical practitioner (RMP) (S. 01, 03, 08; W. 06):**
It means a person who possesses any recognised medical qualification as defined under Indian Medical Council Act and whose name has been entered in a state medical register and has an experience of training in gynaecology and obstetrics as prescribed by rules made under the MTP Act, 1971.

Q 3. Name the approved places for termination of pregnancy. OR Name the places where termination of pregnancy is done as per MTP Act, 1971. (S. 97, 99, 08; W. 99, 01, 02, 04, 07, 08)

Termination of pregnancy should be made only at:

1. Hospital established and maintained by government.
2. Any place approved by government for this purpose.

Q 4. How are the places for termination of pregnancy approved as per provisions of the MTP Act, 1971? (S. 08; W. 06)

Approval of Place

- For the approval of the place application shall be made to the chief medical officer of the district.
- CMO shall verify and inspect the premise and if he satisfies that applicant has prescribed facilities for termination of pregnancies, he will submit the report to the government.
- If the government satisfies on the report of CMO, it may approve such place and issue a certificate of approval.
- This certificate shall be displayed at the prominent place of the premise.
- CMO inspects the approved place whenever necessary and submit the report to government.
- If the CMO report not complying with conditions under Act, government may suspend the approval until specified conditions are satisfied.

Q 5. What are the facilities/equipment provided at approved place as per the MTP Act, 1971? (W. 04)

The owner of approved place shall provide following facilities for termination of pregnancy.

- i. Operation table
- ii. Instruments for abdominal and gynaecological operations or surgery
- iii. Anaesthetic equipment
- iv. Sterilization equipment
- v. Resuscitation
- vi. Emergency drugs
- vii. Parenteral fluids IP, IV saline, dextrose solution, etc.

Q 6. What is admission register? How is it maintained? (S. 01)

Admission Register

It means a register maintained under regulation-V of the MTP Act, 1971.

- Every head of the hospital or owner of the approved place shall maintain the register containing the information about pregnancies.

- The entries in the admission register shall be made serially and year-wise.
- The admission register is a secret document and the information contained in it should not be disclosed to any person.
- The register shall be kept in the custody of head of the hospital or owner of the approved place.

Q 7. Under what circumstances/conditions/grounds pregnancy of a woman can be terminated by RMP as per MTP Act, 1971? OR Give the bona fide reasons for termination of pregnancy by RMP under MTP Act, 1971. (S. 96, 99, 00, 01, 02, 03, 05, 08, 09; W. 99, 01, 02, 03, 05, 07)

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

- Those who are 18 years of age or more with their written consent.
- Those who are less than 18 years of age or more than 18 years but are lunatic, with the written consent of their guardians.
- 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.
- 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.
- If pregnancy is caused because of rape can be terminated by RMP as per provisions.
- If pregnancy is caused because of failure of contraceptive used by woman or her husband such unwanted pregnancy is found to affect physical and mental health of pregnant woman and therefore, it may be terminated.
- The pregnancy of any duration may be terminated by RMP, if it is immediately necessary to save the life of a pregnant woman.

Q 8. Give the offences and penalties under MTP Act, 1971. (S. 97, 99, 01; W. 00, 01, 03)

1. Termination of pregnancy by person other than RMP is an offence and is punishable under Indian Penal Code (IPC).

2. Anyone who purposefully contravenes or fails to comply with the requirements of any regulation, shall be liable to be punished with a fine extending up to Rs.1000/.

Q 9. Whether the termination of pregnancies at the residence of a registered medical practitioner will be supposed to be legal? If not, state the places where it will be legal. (S. 97, 99; W. 02)

The termination of pregnancies at the residence of a registered medical practitioner will not be legal, because residential place does not come under the approved place as per provisions of MTP Act, 1971. It will be legal at the following places.

- Any hospital established and maintained by government.
- Any place approved by government for this purpose.