PHARMACEUTICAL JURISPRUDENCE

IMPORTANT NOTES

Question-1 Define advertisement. Write objectives of drug and magic remedies Act.

Answer :- Advertisement includes all notices, circulars, labels, wrappers or other documents and all announcements made orally or by means of producing or transmitting light, sounds or smoke.

objectives of drug & magic remedies Act

Drug & Magic Remedies Act (objectionable Advertisements) Act was passed on 1st April 1955. objectives are

1. To control certain type of advertisement related to drugs
2. To prohibit certain type of advertisement related to magic remedies which make false claims & are likely to mislead public.

The Act included prohibition of advertisements related to drugs but also cover all advertisements which are objectionable or unethical and are used to promote self medication or self treatment

Magic Remedies :- includ. talismans, mantras Kavachas & any other charm of any kind which allegied to possess miraculous power for or in the diagnosis, cure, mitigation, treatment of prevention of any disease in human beings or animals or for affecting in any way the structure of any organic function of body of human beings or animals

Q-2 Write various prohibited advertisem -ent. operation as per drug & magic remedies Act.

Answer. Prohibited advertisement :-
The following classes of advertisement are prohibited under act :-

(1) Advertisements, related to drugs which are likely to lead to their use in following ailment of conditions :-

(i) For the procurement of miscarriage of prevention of conception in women.

(ii) For treatment of menstrual disorder in women.

(iii) For improvement of capacity of human beings for sexual pleasure

(iv) The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in schedule (J) of drug & Cosmetic Rules, 1945

(2) Advertisement which
(a) Directly or indirectly give false impression regarding the character of drug
(b) Make a false claim for the drug.
(c) which make false or mislead in any material particular

Advertisement, whose import & Export are prohibited :-

Any document containing any such advertisements and deemed to be goods of which import or export has been prohibited under Sea Custom Act, 1878

Exempted Advertisements - The following classes of advertisements and displays are exempted
(i) sign boards or notices displayed by RMP indicating that treatment is used for disease or disorder, advertisements related to which are otherwise prohibited ..

(ii) Books of treatise related to diseases or cure (medicines) which are prohibited to be advertised, provided published from Social standing.

(iii) Advertisement sent in prescribed manner to RMP's ; such advertisements should contain following words on top : for use of RMP's in Hospital or Laboratory

(iii) Advertisement sent confidentially, in prescribed manner, to RMP's.

(iv) Any advertisement related to drug. printed or published by govt. or by any person with prior permission of govt

(v) Advertisement, label or set of instruction which are permitted under Drug & cosmetic Act

Advertisement Exempted conditionally

Class of Advertisement	Conditions
leaflet	

QUESTION: 3 DISCUSS OBJECTIVES OF MEDICINAL AND TOILET PREPARATION ACT.

ANSWER:

An Act to provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drug or narcotic Be it enacted by Parliament in the Sixth Year of the Republic of India as follows:

1. SHORT TITLE, EXTENT AND COMMENCEMENT. (1) This Act may be called the Medicinal and Toilet Preparations (Excise Duties) Act, 1955.

(2) It extends to the whole of India.

(3) It shall come into force on such date 2, as the Central Government may, by notification in the official Gazette, appoint.

2. DEFINITIONS :- In this Act unless the context otherwise requires, -

(a) "alcohol" means ethyl alcohol of any strength and purity having chemical composition C_2H_5OH;

(aa) "Coca derivative" means - (i) crude cocaine that is any extract of coca leaf which can be used directly or indirectly, for the manufacture of cocaine; (ii) ecgonine, that is laevo-ecgonine, and all the derivatives of laevo-ecgonine from which it can be recovered, and (iii) cocaine, that is, methyl-benzoyl-laevo-ecgonine having the chemical formula, C1H2NO4 and its salts;

(ab) "coca-leaf" means - (i) the leaf and young twigs of any coca plant, that is, of the Erythroxylo coca (Lamk.) and the Erythroxylon novo-granatense (Hiern.) and their varieties, and of any other species of this genus which the Central Government may, by notification in the official Gazette, declare to be coca plants for the purposes of this Act, and (ii) any mixture thereof, with or without neutral materials; (bb) derivative of opium, means - (i) medicinal opium, that is, opium which has undergone the processes necessary to adopt it for medicinal use; (ii) prepared opium, that is, any product of opium obtained by any series of operations designed to transform opium into an extract suitable for smoking and the dross or other residue remaining after opium is smoked ; (iii) morphine, that is, the principal alkaloid of opium having the chemical formula $C_{17}H_{19}NO_8$, and its salts, and its derivatives;

(b) "collecting Government" means the Central Government or, as the case may be, the State Government which is entitled to collect the duties levied under this Act;

(c) "dutiable goods" means the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act;

(d) "excise officer" means an officer of the Excise Department of any State and includes any person empowered by the collecting Government to exercise all or any of the powers of an excise officer under this Act;

(e) "Indian hemp" means - (i) the leaves, small stalks and flowering or fruiting tops of the Indian hemp plant (Cannbis-sativa L), including all forms known as bhang, sidhi or ganja; (ii) charas, that is, the resin obtained from the Indian hemp plant, which has not been submitted to any manipulations other than those necessary for packing and transport; (iii) any mixture, with or without neutral materials, of any of the above forms of Indian hemp or any drink prepared there from; and (iv) any extract or tincture of the above forms of Indian hemp;

(f) "manufacture" includes any process incidental or ancillary to the completion of the manufacture of any dutiable goods;

(g) "medicinal preparation" includes all drugs which are 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 the treatment, mitigation or prevention of disease in human beings or animals;

(h) "narcotic drug" or "narcotic" means a substance which is coca leaf, or coca derivative, or opium or derivative of opium, or Indian hemp and shall include any other substance, capable of causing or producing in human beings dependence, tolerance and withdrawal syndromes and which the Central Government may, by notification in the official Gazette, declare to be a narcotic drug or narcotic;

(i) "opium" means - (1) the capsules of the poppy (Palaver somniferous L), whether in their original form or cut, crushed or powdered and whether or not juice has been extracted there from, (2) the spontaneously coagulated juice of such capsules which has not been submitted to any manipulations other than those necessary for packing and transport; and (3) any mixture, with or without neutral materials of any of the above forms of opium, and includes and derivative of opium;

(j) "prescribed" means prescribed by rules made under this Act;

(k) "toilet preparation" means any preparation which is intended for use in the toilet of the human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes.

QUESTION: Write note on: Function of PCI and Conduct of pharmacist in relation to his job.

ANSWER:

On 9th March, 1949, the Pharmacy Council of India (PCI) was constituted to fulfil the objectives of the Pharmacy Act, 1948 by way of

i) Prescribing the minimum standard of education required for qualifying as a pharmacist i.e., framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in Pharmacy.

(ii) Ensuring uniform implementation of the educational standards throughout the country.

(iii) Approving the courses of study and examination for pharmacists i.e., approval of the academic training institutions providing pharmacy courses.

(iv)Withdrawing approval, if the course of study does not continue to be in conformity with the educational standards prescribed by the PCI.

(v) Approving qualifications granted outside the territories to which the Pharmacy Act, 1948 extends i.e., the approval of foreign qualification.

(vi)Maintaining the Central Register of Pharmacists.

Pharmacist in relation to his job: A pharmacist should keep the following things in relation to his job. (i)Pharmaceutical services Pharmacy premises (medicine shops) should b e registered. Emergency medicines and common medicines should be supplied to the patients without any delay.

(ii)Conduct of the Pharmacy Error of accidental contamination in the preparation, dispensing and supply of medicines should be checked in a pharmacy.

(iii)Handling of Prescription A pharmacist should receive a prescription without any comment on it that may cause anxiety to the patient. No part of the prescription should be changed without the consent of the prescriber. In case of changing the prescription should be referred back to the prescriber.

(iv)Handling of drugs A prescription should always be dispensed correctly and carefully with standard quality drug or excipients. Drugs that have abusive potential should not be supplied to any one. (v)Apprentice Pharmacist Experienced pharmacists should provide all the facilities for practical training of the apprentice pharmacists. Until and unless the apprentice proves himself or herself certificate should not be granted to him / her.

QUESTION: Write note on Drug and price control order 1995

ANSWER:

Pharmaceutical Jurisprudence

Diploma in Pharmacy second year

Question No. 01 Describe Code of Pharmaceutical Ethics in detail.

Ans: The code of ethics, framed by PCI has been meant to guide the Indian pharmacist as to how, he should conduct himself in relation to his patients, general public, co-professionals and members of the medical and other health professions.

(1) Pharmacist in relation to his job:-

a) Scope of pharmaceutical services: - A pharmacy should provide a good pharmaceutical services including supply of commonly required medicines and emergency supplies at all times without delay.

b) Conduct of pharmacy: - Conditions in the pharmacy should be such that risk of contamination in the preparation, dispensing and supply of medicines are avoided.

c) Handling of prescriptions: - Prescription should be received by a pharmacist without any discussion or comment on it, regarding the merits and demerits of its therapeutic efficacy. Any question on a prescription should be answered with every caution and care. A pharmacist should not add, omit or substitute the ingredient or alter the composition of a prescription.

d) Handling of drugs: - A pharmacist should always use drugs and medical preparations of standard quality and all possible care should be taken to dispense a prescription.

e) Apprentice pharmacist: - Pharmacist incharge should see that the trainees are given full facilities for their work and give them adequate knowledge for dispensing of drugs.

(2) Pharmacist in relation to his trade:-

a) Price structure: - Prices, charged from the customers, should be fair and in keeping with the quality and quantity of drug supplied and the labour and skills required in making it ready for use.

b) Fair trade practice: - A pharmacist should not indulge in cut-throat competitions like offering prizes or gifts or by charging lower prices for any drug than those charged by the competitors.

c) Purchase of drugs: - Drugs should always be purchased from genuine and reputable source.

d) Hawking of drugs: - Hawking of drugs and medicines is not allowed. Self services are also avoided.

e) Advertising and displays: - A pharmacist should not do any type of advertisement regarding sale of drugs.

(3) Pharmacist in relation to medical profession:-

a) Limitation of professional activity: - Pharmacist should not take any medical practice that is to diagnosing disease and prescribing medicine. In case of accidents and emergencies, a pharmacist may however render first aid to the victim.

b) Clandestine arrangements: - No pharmacist should enter into any secrete arrangements or contract with physician, to offer him any commission or any advantage by recommending his dispensary or drug.

c) Liaison with public: - A pharmacist should always aware with the modern developments in pharmacy and other allied sciences by regularly reading books, journals and magazines.

(4) Pharmacist in relation to his profession:-

a) Professional vigilance: - A pharmacist should also fulfill the provisions of the pharmaceutical and others laws and regulation and help to maintain fair name and traditions of pharmacy.

b) Law abiding citizen: - A pharmacist, engaged in profession should have a fair knowledge of the laws of land and abide by them in every phase of life.

c) Relationship with professional organizations: - A pharmacist should join and promote the activities of professional organizations.

d) Decorum and propriety: - A pharmacist should not do anything which spoils the decorum and propriety of pharmaceutical profession.

Question No. 02 Write down the constitution and functions of State and Joint State Pharmacy Council.

Ans: The State and the Joint State Pharmacy Council have the following constitution.

State Pharmacy Council	**Joint State Pharmacy Council**

Elected members 1. Six members elected amongst themselves by Registered Pharmacist of the state. 2. One member elected by the medical council of the state from amongst its members. **Nominated members** 1. Five members nominated by the state government of whom at least three should possess a degree of diploma in pharmacy or pharmaceutical chemistry or be Registered Pharmacist. **Ex-officio members** 1. Chief administrative medical officer of the state. 2. Officer incharge of drugs control administration of the state. 3. Government Analyst of the state or where there is more than one analyst, such one as may be appointed by the state govt.	**Elected members** 1. Six members elected amongst themselves by Registered Pharmacist of each participating State. 2. One member elected by the Medical Council of each state from amongst its members. **Nominated members** 1. Two or five members nominated by each participating state government of whom more than half should have a degree or diploma in pharmacy or pharmaceutical chemistry or be Registered Pharmacist. **Ex-officio members** 1. Chief administrative medical officer of each of the participating state. 2. Officer in-charge of drugs control administration of each participating state. 3. One Government Analyst of each participating state.

The President and Vice President of the council are elected members from amongst themselves for a term of five years. The council usually appoints Registrar and other necessary officers and staff as may be required to carry out its functions.

Functions of the State and Joint State Pharmacy Council

1) Inspection by state council: - They appoint sufficient number of inspectors having prescribed qualification to:

a) Inspect any premises where drugs are compounded or dispensed.

b) Inquiry regarding the registration of the person engaged in compounding and dispensing.

c) Investigate any complaint made in writing regarding contravention of the act.

d) Exercise such other powers as may be deemed necessary in order to give effect to certain provisions of the act.

2) Maintenance of the first and subsequent registers of pharmacists: - Pharmacy Act, 1948 provides for the registration of pharmacists in all the states of India. The first register of pharmacists in a state is required to be prepared by the state govt. After the constitution of the State Pharmacy Council the maintenance of the first and subsequent register becomes the responsibility of the state councils. The state council are (before the end of June each year) required to pay to the PCI a sum equivalent to one-fourth of the fees, collected by them during the period of 12 months ending on the 31st day of March in that year.

The registration of pharmacists includes the following particulars: -

1) Full name and residential address of the registered person.

2) Date of his first entry in the register.

3) Qualification of the person for registration.

4) Professional address of the person and case of employed persons, the name of the employer.

5) Such other particulars as may be prescribed.

Process of registration of Pharmacist:

After the formation of the State Pharmacy Council, all applicants for registration are required to be addressed to the registrar of the state pharmacy council and should be accompanied by the prescribed fee. If upon scrutiny of the application, the registrar is of the opinion that the applicant has the requisite qualification for registration, he shall direct his or her name to be entered into the register. Upon entry of the name of a person in the register, the registrar is required to issue him a certificate of registration in the prescribed form. A person, whose name has been removed from the register of any state, shall not be entitled to registration except with the approval of the state council. Any person, whose application for registration has been rejected by the registrar, may appeal to the state council, within three months of such rejection, whose decision shall be final. Registration is valid up to 31st december of the year of registration. The retention of the name of the register is subject to payment of the prescribed fee annually to the State Council by due date which is the first date of the April of the year to which it relates. Where the renewal fee is not paid by the due date, the registrar shall remove the name of the defaulter from the register which can however be restored on satisfying the prescribed conditions. On payment of the renewal fee, the registrar is required to issue a receipt thereof which shall be a proof of

renewal of registration. A Registered Pharmacist is entitled to have any further professional qualification (acquired after his first registration) entered against his name in the register on payment of the prescribed fee.

Question No. 03 What are the objectives of Pharmacy Act? Write constitution & functions of Pharmacy Council of India.

Ans: Objectives of the Pharmacy Act:

a) Providing uniform education and training to the persons who are willing to enter the profession of pharmacy.

b) Maintaining control over persons entering the profession of pharmacy by providing for their registration in every state and union territory.

Constitution: - PCI in constituted by central government every five years. The first PCI was constituted in 1949.

i) Elected members:-

a) Six members, at least one teacher each of pharmacy, pharmaceutical chemistry, pharmacology and pharmacognosy elected by U.G.C. from teaching staff of an Indian university of college granting a degree of diploma in pharmacy.

b) One member, elected by the Medical Council of India (MCI) from amongst its members.

c) One member, elected by each State Pharmacy Council who, shall be a Registered Pharmacist.

ii) Nominated members:-

a) Six members, nominated by the Central Government, including at least four persons having degree or diploma in pharmacy and engaged in the practice of pharmacy or pharmaceutical chemistry.

b) One representative each of UGC and AICTE.

c) One Registered Pharmacist to represent each state nominated by the State Government.

iii) Ex-Officio members:-

a) Director General of Health Services.

b) Director of Central Drugs Laboratory (CDL)

c) The Drugs Controller of India.

The President and Vice President of the PCI are elected by its members from amongst themselves for a term of five years.

The council appoints: -

a) A Registrar who acts as it Secretary.

b) Other officers and servants for carrying out its functions.

c) The Executive Committee of the PCI consisting of the President (chairman of the committee) and Vice President and five other members elected by the Central Council from amongst its members.

Functions of PCI: -

a) To prescribe the minimum standards of education required for qualification as a Pharmacist.

b) To regulate the minimum educational standards by inspecting the institutions.

c) To compile and maintain a Central Register for Pharmacists containing names of all registered persons.

d) Any other function required for completion of objectives of Pharmacy Act, 1948.

Question No. 04 Write a note on following:-

(a) Poisons Act. (b) Medical Termination of Pregnancy Act, 1971

Ans: 04 (a) Poisons Act was passed on 3rd Sept. 1919 with a view to control the import, possession and sale of poisons. For the purposes of the act, all substances, specified as poisons in this act are to be deemed as poisons.

Import of poisons: - The import of poisons is permitted only to persons who have been granted license for this purpose and such person import poisons in accordance with the conditions.

Possession and sale of poisons or provisions of the act: - The State Govt. may make rules in order to regulate for the store and sale of poisons. Such rules may provide for –

i) The grant of licenses for the possession and sale of any specified class of poisons and fixing of the fees to be paid for grant of such licenses.

ii) The classes of persons to whom the licenses for the permission and sale of poisons are to be granted.

iii) The categories of persons to whom the poisons may be sold.

iv) Maintenance of a sale registers.

v) The safe custody of poisons and labeling of the vessels, packages or coverings, etc. in which poisons are sold or stored.

vi) Inspection and examination of any such poison possessed by a person for sale.

Penalties for offences under the act: - Anyone, who either imports, possesses or sells any poison, except as provided under the act, is punishable with:-

i) Imprisonment up to 3 months or a fine up to Rs. 500/- or both on first time.

ii) Imprisonment up to 6 months or a fine up to Rs. 1000/- or both on any subsequent conviction.

iii) Anyone, who possesses any poison, whose possession has been prohibited by the state govt. shall be liable to imprisonment, which may extend to one year or with a fine up to Rs. 1000/- or both.

Exemptions: - The provisions of the Act shall not apply to anything done in good faith by a medical or veterinary prActitioner while giving his duties.

Ans: 04 (b) Medical Termination of Pregnancy Act, 1971:- The Medical Termination of Pregnancy Act was passed by the parliament in 1971 with view to provide for termination of pregnancy by Registered Medical Practitioners for bonafide medical reasons. The Act extends to whole of India due to the following reasons:

i) Legal abortions were difficult at that time and many were being carried out illegally under unhygienic or unsafe conditions resulting in harm to health or life of women.

ii) As a population control measures since it provided for termination of unwanted pregnancy resulting from a failure of any device or method used by the married women or her husband, for limiting the number of children.

Provisions of the act: The Medical Termination of Pregnancy Act provides that pregnancies of women may be terminated by Registered Medical Practitioners under the following circumstances:

i) Pregnancies of women are 18 years of age or more, with their consent or in case of a woman who is less than 18 years of age or are lunatics, with the written consent of their guardian.

ii) A pregnancy which is not more than 12 weeks old and the medical practitioner is of the opinion that its continuance is a grave danger to the life of the woman or to her physical and mental health or the child to be born would be seriously handicapped due to physical or mental abnormalities.

iii) A pregnancy which is more than 12 weeks but not more than 20 weeks old, provided that not less than two registered medical practitioners are of such a opinion.

iv) A pregnancy of any duration provided that the medical practitioner of the opinion that such termination is immediately necessary to save the life of the pregnant woman.

v) A pregnancy which is alleged to have been caused due to rape or due to failure of a contraceptive device used by a woman or her husband for family planning purposes.

vi) In determining health hazards of pregnancy, the women's actual condition in the foreseeable future may be taken into account. The pregnancy of a woman may be terminated by a RMP only at a hospital established or maintained by the government or a place approved by it for the purpose.

Requirement for places approved for termination of pregnancy:

Places approved for termination of pregnancy should have:

i) An operation table with facilities for gynecological or abdominal surgery.

ii) Anesthetic equipment, resuscitation equipment and sterilization equipment.

iii) Drugs and parenteral fluids for emergency use.

iv) Qualified medical personnel.

The application for the approval of a place for the termination of pregnancy should be addressed to the Chief Medical Officer of the district concerned, who shall inspect such place and if satisfied, shall recommend the government to approve the place and issue a certificate of approval. The certificate must be conspicuously displayed at the place so that it is easily visible to persons visiting the place. The certificate can be cancelled or suspended if the prescribed facilities are not maintained and termination of pregnancy at such place cannot be made under safe and hygienic conditions.

Requirement of experience or training for a RMP to terminate pregnancy:

Any RMP having the following experience/training in the practice of gynecology and obstetrics can terminate pregnancy under the act:

i) If the RMP was registered in a State Medical Register before the commencement of this act:

a) An experience in the practice of gynecology and obstetrics for not less than three years.

ii) If the RMP was registered on or after the commencement of this act:

a) Six months of house surgery in gynaecology and obstetrics.

b) In case, he has not done any such house surgery, an experience in the practice of gynecology and obstetrics in any hospital for not less than one year.

c) Experience by way of assistance given by the person to a RMP in the performance of twenty-five cases of medical termination of pregnancy in a hospital established or maintained, or a training institute approved for this purpose, by the government.

Question No. 05 Discuss about Drug and Magic Remedies Act in detail.

Ans: Drug and Magic Remedies: - The Drug and Magic Remedies (Objectionable Advertisements) Act was passed on 1st April, 1955 with the following objectives:

i) To control certain type of advertisements relating to drugs.

ii) To prohibit certain kind of advertisements relating to magic remedies which make false claims and are likely to mislead the public.

Definitions: According to the drugs and magic remedies act,

Advertisement means: - All notices, circulars, labels, wrappers or other documents and all announcements made orally or by means of producing or transmitting light, sound or smoke.

Drug means:

i) A medicine for the internal or external use of human beings or animals.

ii) Any substance included to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals.

iii) Any article, other than food, intended to affect the body of human beings.

iv) Any article intended for use as a component of any medicine, substance or article referred to above.

Magic remedy means: - includes talismans, kavachas and any other charm of any kind which alleged to posses miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting in way the structure or any organic function of the body of human beings or animals.

Prohibited advertisements: - The following classes or advertisements are prohibited to be made under the act:

1) Advertisements, relating to drugs, which are likely to lead to their use in the following ailments or conditions:

i) For the procurement of miscarriage or prevention of conception in women.

ii) For the correction of menstrual disorders in women.

iii) For the maintenance or improvement of capacity of human beings for sexual pleasure.

iv) The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in schedule J of the drugs and cosmetics rules, 1945

v) Advertisements, which; directly or indirectly gives false impression regarding the true character of the drug; make a false claim for the drug;

vi) Advertisements relating to magic remedies claming their efficacy for any of the conditions:

Advertisements whose import and export are prohibited:

Import and export of all documents containing on advertisement of the nature referred to above is prohibited. Any documents containing any such advertisements are deemed to be goods of which import or export has been prohibited the Sea Customs Act, 1878.

Exempted advertisements:-

The following classes of advertisements and displays are exempted from the preview of the Act and hence can be made without any prohibition:

i) Signs, boards or notices displayed by Registered Medical Practitioner (RMP) including that treatment is undertaken for the disease or disorder, advertisements relating to which are otherwise prohibited.

ii) Books or treatises relating to the diseases or ailments, which are otherwise prohibited to be advertised, provided published from bonafide scientific or social standing.

iii) Advertisements sent confidentially, in the prescribed manner, to RMP's. However, such advertisements should bear the following words on top, in a conspicuous manner: for the use only of RMP or a hospital or a laboratory.

iv) Any advertisement relating to a drug, printed or published by the government or by any person with the prior permission of the government.

Offences and penalties:-

Contravention of any provisions of the act is punishable with imprisonment up to six months or fine or both on first conviction and imprisonment up to one year or fine or both any subsequent conviction.

Question No. 06 Write about constitution of DTAB.

Ans: - DTAB (Drug Technical Advisory Board) is constituted by the central government to advise the central and state governments on technical matters.

Constitutions: - It consist of 18 members which are –

Ex-officio members –

i) Director General of Health Services (Chairman)

ii) Drug Controller of India.

iii) Director, Central Drug Laboratory, Calcutta.

iv) Director, Central Research Institute, Kasauli.

v) Director, Indian Veterinary Research Institute, Izatnagar.

vi) President, Medical Council of India (MCI).

vii) Director, Central Drug Research Institute, Luckhnow.

Nominated members: -

i) Two persons nominated by the central government from amongst persons who are incharge of drugs centers in states.

ii) One person from the pharmaceutical Industry, nominated by the central government.

iii) Two Government Analysts, nominated by the central government.

Elected Members: -

i) A teacher in pharmacy or pharmaceutical chemistry or pharmacognosy from the staff of an Indian university or college, elected by the executive committee or the Pharmacy Council of India.
ii) A teacher in medicine or therapeutics on the staff of an Indian university or an affiliated college, elected by the executive committee of the Medical Council of India.
iii) One pharmacologist elected by the governing body of the Indian Council of Medical Research.
iv) One person elected by the council of the Central Medical Association.
v) One person to be elected by the council of the Indian Pharmaceutical Association (IPA).
The nominated and elected members hold the office for 3 years but are eligible for re-nomination or re-election. Election governments appoint a secretary and other staff to the board.

Question No. 07 Write qualification and duties of

(a) Government Analyst (b) Drug Inspector (c) Education Regulations (ER)

Ans: 07 (a) Government Analyst: -The state government or the central government may, by notification in the official gazette, appoint such persons as it think fit, having prescribed qualifications to be government analysts for such areas and in respect of such classes of drugs or cosmetics as it may notify. No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics or is directly or indirectly engaged in any trade or business connected with the manufacture of drugs can be appointed as a Government Analyst.

Qualifications of government analyst: - For the appointment of the Government Analyst, a person should be:

i) A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university and have five years post graduate experience in the testing of drugs in a laboratory under the control of a Government Analyst or head of an approved institution or testing laboratory or has completed two years training on testing of drugs, including items in schedule C, in the Central Drugs Laboratory.

ii) A post graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university or Associate-ship Diploma of the Institution of Chemists (India) obtained by passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years

experience in the testing of drugs in a laboratory under the control of a Government Analyst or head of an approved institution or testing laboratory or has completed two years training on testing or drugs, including items in schedule C, in the Central Drugs laboratory.

Duties of government analyst: -

i) To cause to be analyzed or tested samples of drugs and cosmetics sent to him by inspectors or other persons under the act and to furnish reports of the results of test analysis in accordance with the rules.

ii) Forward to the government from time to time, reports giving the results of analysis work and research with a view to their publication at the discretion of government.

Ans: 07 (b) Drug Inspectors: - The Central or State Government is empowered to appoint such persons as it thinks fit, having the prescribed qualifications, to be inspectors for such areas as may be assigned to them. Any person having financial interest in the import, manufacture or sale of drugs or cosmetics cannot be appointed as Drug Inspector.

Qualifications of Drug Inspector: -

For appointment as the Drugs Inspector a person must possess a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law. However only those Inspectors shall be authorized to inspect the manufacture of the substances mentioned in schedule C:-

i) Who have not less than 18 months experience in the manufacture of at least one of the substances specified schedule C; or

ii) Who have not less than 18 months experience in testing of at least one of the substances in schedule C in a laboratory approved for this purpose by the licensing authority; or

iii) Who have gained experience of not less than three years in the inspection of firms manufacturing any of the substances specified in schedule C during the tenure of their services as Drug Inspector.

Duties of Inspectors:-

Inspection of premises licensed for sale: -

Subject to the instructions of the following authority it shall be duty of an inspector to:

i) Inspect not less than twice a year all establishments licensed for the sale of drugs within the area assigned to him and to satisfy himself that the conditions of the license are being observed.

ii) To investigate any complaint made to him in writing and to institute prosecutions in respect of breaches of the act or rules there under.

iii) To maintain a record of all inspections made and action taken by him.

Inspection of manufacture of drugs: -

Subject to the instructions of the controlling authority following shall be the duty of an inspector.

i) To send to the controlling authority after each inspection a detailed report indicating the conditions of the license and provisions of the act and rules there under which are be observed and the conditions and provisions, if any, which are not being observed.

ii) To take the samples of the drugs manufactured on the premises and send them for test or analysis.

iii) To institute prosecutions in respect of breaches of the act and rules.

Ans: 07 (c) Education regulations (ER)

The Pharmacy Council of India has laid down certain minimum standards of education required for qualification as Pharmacist. These standards are known as Education Regulations and prescribe.

i) Minimum educational qualification required for admission to the course of Pharmacy.

ii) Duration of course of study and training.

iii) Nature and period of practical training to be undertaken after the completion of regular course.

iv) Subjects of examination and the standards to be attained therein for qualification.

v) Conditions to be fulfilled by the authorities holding approved examinations.

Main features of Education regulations – 91 are:

According to ER-91 a candidate has to undergo practical training after having appeared in Diploma in pharmacy part II examination in one or more following institutions:

i) Government hospitals/dispensaries.

ii) Other hospitals/ dispensaries recognized by PCI.

iii) Licensed pharmacy, chemists and druggists shop.

iv) Licensed drug manufacturing units.

Practical should be for a minimum of 500 hours spread over a period of not less than three months out of which not less than 250 hours must be devoted to actual dispensing of prescriptions.

Question No. 08 Define following terms with examples wherever possible.

(a) Cannabis (b) Drug (c) Misbranded drugs (d) Psychotropic substances (e) Qualified Pharmacist (f) Spurious drugs (g) Advertisements (h) Adulterated drugs (i) First register

Ans: 08 (a) Cannabis (hemp): - Means

i) Charas i.e. the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish.

ii) Ganja i.e. the flowering or fruiting tops of the cannabis plant, by whatever name they may be known.

iii) Any mixture, with or without any neutral material, or any of the above forms or cannabis or any drink prepared there from.

Ans: 08 (b) Drug: - All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquito.

i) Such substances other than food intended to affect the structure of any function of human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals.

ii) All substances intended for use as components of a drug including empty gelatin capsules.

iii) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

Ans: 08 (c) Misbranded drugs: - A drug is termed as misbranded.

i) If it is so colored, coated, powdered or polished that damage is cancelled or if it is made to appear of better or greater therapeutic effect than it really is.

ii) If it is not labeled in prescribed manner.

iii) If it label or container or package bears any statement, design or device which makes any false claim for the drug or which false or misleading in any way.

Ans: 08 (d) Psychotropic substances: - Means any substance, natural or synthetic or any natural material or any salt or preparation or such substance or materials include in the list of psychotropic substances as specified in the schedule.

Ans: 08 (e) Qualified Pharmacist or Registered Pharmacist: - A person whose name for the time being is entered in the register of pharmacists of the state in which he is for the time being residing or carrying on his profession or business of pharmacy.

Ans: 08 (f) Spurious drug: - It includes

i) If it is imported under a name which belongs to another drug or if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such drugs.

iii) If the label or containers bears the name of an individual or company purporting to be the manufacture of the drug which is fictitious or does not exist.

iv) If it has been substituted wholly or in part by another drug or substance.

v) If it purports to be the product of a manufacturer of whom it is not truly a product.

Ans: 08 (g) Advertisements: - Include all notices, circulars, labels, wrappers or other document and all announcements made orally or by means of producing or transmitting light, sound or smoke.

Ans: 08 (h) Adulterated drugs:- A drug is said to be adulterated

i) If it consists, in whole or in part of any filthy, putrid or decomposed substance.

ii) If it has been prepared, packed or stored under in sanitary conditions whereby it may have been contaminated with filthy or it may be injurious to health.

iii) If its container is composed in whole or part of any poisons of deleterious substances which may render the contents injurious to health.

iv) If it bears or contains, for purpose of coloring only a color other than one, which is prescribed.

v) If it contains any harmful or toxic substances which may render it injurious to health.

Question No.9. Write a short note on:-

(a) Chopra committee (Drugs enquiry committee)

(b) Drugs (price control) order, 1995

(c) Manufacture of alcoholic preparations in bond

Ans: 09 (a) Chopra committee (Drugs enquiry committee):- The government of India in pursuance to the resolution appointed a committee known as the Drugs Enquiry Committee with Col. R.N. Chopra as its Chairman in 1928 to:

i) Enquire the extent to which drugs of impure quality or defective strength were being imported, manufactured or sold in India, and

ii) Recommend steps for controlling such import, manufacture and sale in public interest.

iii) Enquire into the necessity of legislation to restrict the profession of pharmacy to qualified persons and to make recommendations.

Recommendations of the Chopra Committee: - The Drugs Enquiry Committee also known as the Chopra committee recommended the following:

i) A central law to control drugs and pharmacy profession.

ii) Development of the drug industry in India.

iii) Gradual reduction of manufacturing in Medical stores/depots.

iv) Compilation of an Indian Pharmacopoeia.

v) Appointment of an advisory board advises the government in making rules to carry out the objectives of the act.

Actions taken by the Government on the recommendations of the Chopra Committee:

Even though it has taken many years before the above recommendations could be enacted in law or otherwise implemented, it is a matter of great satisfaction that the valuable recommended of Chopra Committee shaped the future of the profession of pharmacy and pharmaceutical industry in India. The following pharmaceutical legislation and actions of the Central Government can traced to the above recommendations:

i) Drug testing laboratories have been set up at State and Central Government level.

ii) Registration of all drugs and formulations sold in India.

iii) Pharmacopoeias for drugs used in indigenous systems of medicine are being developed.

iv) As more formulations of standard quality are available commercially, manufacturing in medical stores and hospital pharmacies has been minimized.

v) Passage of Drugs Act in 1940 to regulate the import, manufacture, distribution and sale drugs. The drugs rules were framed in 1945 to give effect to the provisions of the act.

Ans: 09 (b) Drugs (Price Control) Order, 1995: - The Drug (Price Control) order, 1995 was passed by the central government in price of this power. The order extends to the whole of India and replaces the drugs order, 1987. It is effective from the date of its publication in the official gazette.

Sale Prices of bulk drugs: - The government may fix from time to time, by notification in the official gazette, the maximum sale price at which any bulk drug specified in the first schedule can be sold. No person can sell a bulk drug at a price exceeding the fixed price plus local taxes, if any.

Any manufacturer who commences the production of any bulk drug specified in the First schedule, after the commencement of this order, is required to finish the necessary details in from I within fifteen days of the commencement of the necessary inquiries, fix the maximum sale price of the bulk drug by notification in the official gazette. Any manufacturer, who desire revision of the maximum sale price of a bulk drug should make an application to the government in form I. the government, shall then, within four months from the date of receipt of the complete information, fix a revised price for such bulk drug or reject the application for reasons to be recorded in writing.

Every manufacturer of a scheduled bulk drug or a non- scheduled bulk drug has to submit to the government a list of all bulk drug produced by him indicating the details of the cost of each such bulk drug within thirty days of the commencement of the order and by 30th September thereafter, every year.

The government may, in public interest, fix or revise the price of any non-scheduled bulk drug and the manufacturer or such bulk drug shall not sell the same at a price exceeding the price or revised, within fifteen days of receipt of the order.

Calculation of retail price of formulations: - The retail price of a formulation can be calculated in accordance with the following formation

$$\mathbf{R.P. = (M.C. + C.C. + P.M. + P.C.)\ (1 + MAPE/100) + E.D.}$$

Where, **R.P.** - retail price, **M.C.** - material cost, **C.C.** - conversion cost, **P.M.** - cost of the packing material

P.C. - packing charges

M.A.P.E. - Means all cost incurred by manufacturer from the stage of ex-factory cost to retailing and included trade margin for the manufacturer and it shall not exceed 100% of indigenously manufactured scheduled formulations.

E.D. - Means Excise duty. Provided that in the case of an imported formulation, the landed cost shall from the basic from fixing its price along with such margin to cover selling and distribution expenses including interest and importer profit which shall not exceed fifty per cent of the landed cost.

Price and Price List: - Every manufacturer, importer or distributor of a formulation intended for sale is required to display in indelible print mark, on the label of container of formulation and the maximum pack thereof, the retail price of that formulation. The retail price should be indicated as "Retail price not to exceed Rupee…. Local taxes extra". In case of non-scheduled formulation offered for sale the retail price should be indicated as "Maximum retail Rupees ….. Inclusive of all taxes".

Ans: 09 (c) Manufacture of alcoholic preparations in bond

1) Procurement of spirit from a distillery or spirit warehouse:- Rectified spirit for the manufacture of medicinal and toilet preparations can be obtained on an indent counter signed by the officer-incharge of the laboratory, from any approved distillery or spirit warehouse either situated in the same state or in another state. The officer of the distillery or spirit warehouse, on receipt of the duplicate copy on the indent, shall issue the spirit in duly sealed containers and send an advice of the consignment to the Excise officer–in–charges of the bonded laboratory.

2) Verification and storage of spirit received:- Consignments of spirit received at the laboratory have to be verified in volume and strength by the Excise officer and then stored in the spirit store from where it can be issued form time to time the manufacturer, according to his requisition.

3) Issue of spirit from the spirit store for manufacture: - Calculated quantities of spirit can be obtained by the manufacturer on a requisition to the officer-in-charge who shall then issue the same from the spirit store. The spirit so issued has to be immediately mixed with other ingredients of the preparation in the presence of the officer-in-charges. The percolators or other vessels charged with the spirit should be labeled with the following particulars:

i) Name and batch number of the preparation.

ii) Description and quantity of alcohol put in it.

iii) Date of removal of preparation and the quantity of such preparation removed. As soon as the manufacture of a preparation has been completed, it should be removed in the finished goods store, measured and stored in the vessels provided for the purpose. Details of the preparation should also be entered in a register and it should be given a batch number. The excise officer-in-charge may permit the manufacture to take a sample of not more than 250 ml for analysis purpose free of duty. A separate

account must be maintained by the manufacturer regarding the amount of samples used by him for analysis and amount left over after analysis should be mixed with the main bulk of batch.

4) Storage of finished product:- All finished preparation should be stored in bulk in jars or bottles, each containing not less then 2.255 liters of the preparation every container should be labeled with the name of the preparation, its batch number strength date of storage and actual content in bulk liters. The containers should be so arranged in suitable racks so as allow ready identification of each batch. A record of all deficiencies in bull content of finished preparation should be kept by the officer-in-charge and reported to the excise commissioner quarterly. If the excise commissioner is satisfied that the deficiency reported was due to some unavoidable reasons he may remit the duty payable otherwise such loss is subject to levy of duty at penal rate which shall not be more then double the prescribed rates.

Question No. 10 Describe Narcotics and Psychotropic Substances Act and various offences coming under this Act.

Ans: Narcotics Drugs and Psychotropic Substances Act was passed in 1985 with the following objectives:-

i) To consolidate and amend the existing laws relating to narcotic drugs.

ii) To make strong provisions for the control and regulation of operation relating Narcotic drugs Psychotropic substances.

iii) To considerably enhance the penalties particularly for trafficking offences.

iv) To make provisions for the implementations of international conventions relating to Narcotic drugs and Psychotropic substances to which India is a party.

The Narcotic drugs and Psychotropic Substances consultative committee-

The Central Government may constitute this advisory committee to advice it on such matters relating to the administrations of this Act.

Prohibition, control and regulation- the following operations are totally prohibited under this Act-

i) Cultivations of any coca plant or gathering of any portion of coca plant.

ii) Cultivation of opium poppy or any cannabis plant.

iii) Production, manufacture, possession, sale, purchase, transportation, warehousing, consumption, import-export etc. of any Narcotic Drug or Psychotropic Substance, except for medical or scientific purposes.

Offences and penalties:-

Offences punishable with rigorous imprisonment for 10 to 20 years and a fine of not less than one lakh rupees on first conviction and with rigorous imprisonment for 15-30 years and a fine of not less than two lakh rupees on second and subsequent conviction.

i) Contravention of provisions of the act or rules in relation to poppy straw, coca plant and coca leaves, opium poppy and opium, prepared opium, manufactured drugs and Psychotropic substances.

ii) Embezzlement of opium by cultivator.

iii) Contravention in relation to cannabis plant and cannabis other than ganja.

iv) Illegal import into India, export from India of Narcotic Drugs and Psychotropic Substances.

v) External clearings in Narcotic Drugs and Psychotropic Substances.

vi) Financing illicit traffic and hard pouring offenders.

Death penalty for certain offences after previous conviction:-

Notwithstanding the above, if any person who has been convicted of the commission of, or attend to commit, or criminal conspiracy to commit, any of the offences listed above, is subsequently convicted of similar offences with respect to the Narcotic Drug or Psychotropic Substances and which is equal to or more than the quantity specified in this behalf shall be awarded death penalty.

Offences punishable with rigorous imprisonment up to 5 years and fine up to 50000 rupees on first conviction and with rigorous imprisonment up to 10 years and fine up to 1 lakh rupees on second and subsequent conviction on contravention in respect to cannabis plant and cannabis related to ganja.

Offences by licensees of their employees punishable with imprisonment up to 5 years or fine or both:-

i) Failure, without any reasonable cause, to maintain accounts or to submit any return in accordance with provisions of this act.

ii) Failure to produce, without any reasonable cause, license permit on demand by an authorized person.

iii) Keeping of false accounts or making of false statements.

iv) Willful and deliberate indulgence in branch of any of the conditions of this act.

Offences punishable with imprisonment up to 1 year or fine or both:-

Illegal possession in small quantities for personal consumption or consumption of cocaine, morphine or any other Narcotic Drug or Psychotropic Substances specified in this behalf.

Offences punishable with imprisonment up to 6 months or fine or both:-

i) Illegal possession in small quantities for personal consumption or consumption of substance other than those mentioned above.

ii) Offences for which no penalty is provided separately in this Act.

Punishment for attempt to commit offence or criminal conspiracy:-

Same as that for the commitment of the offence itself.

Punishment for preparation of an offence but where circumstances have prevented the commitment of the offence itself-

Half of that for the commitment of the offence itself.

Question No. 11 Write a note on following schedules:-

(a) Schedule X (b) Schedule C (c) Schedule M (d) Schedule G

Ans:11 (a) Schedule X: - List of drugs whose import; manufacture and sale, labeling and packaging are governed by special provisions.

E.g. Phenobarbitone Sodium Injection I.P.

Analgin and Pentobarbital Sodium Injection

Ans:11 (b) Schedule C: - list of biological and special products whose import, sale, distribution and manufacture are governed by special provisions.

C_1 – list of other special products whose import, sale, distribution and manufacture are governed by special provisions.

Ans:11 (c) Schedule M: - Good manufacturing practices (GMP) requirements of factory, premises, plant and equipment for pharmaceutical products.

Part I – G.M.P. for premises and materials.

Part I-A – Specific requirements for manufacture of sterile products, parenteral and sterile ophthalmic preparations.

Part I-B – Specific requirements for manufacture of oral solid dosage forms (Tablets, Capsules).

Part I-C - Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsion, and suspensions).

Part I-D - Specific requirements for manufacture of topical (External) products (creams, ointments, pastes, emulsions, lotions, solutions and identical products).

Part I-E - Specific requirements for manufacture of metered dose inhalers (MDI).

Part I-F - Specific requirements for premises. Plants and materials for manufacture of active pharmaceutical ingredients (bulk drugs).

Part –II– Requirements of plant and equipments.

M_1 - Requirements of factory premises etc.

M_2 - Requirements of factory premises for manufacture of cosmetics.

M_3 - Requirements of factory premises for manufacture of medical devices.

Ans:11 (d) Schedule G :– List of substances that are required to be used only under medical supervision and which are to be labeled accordingly.

Question No. 12 Discuss conditions of license for whole sale of drug.

Ans: General licenses under the following three categories are granted for the wholesale of drugs:

(A) License for the wholesale of schedule C and C1 drugs.

(B) License for the wholesale of drugs other than those specified in schedule C, C1 and X.

(C) License for the wholesale of schedule X drugs.

(A) License for the wholesale of schedule C and C1 drugs:

1. The licensee should have adequate premises equipped with facilities for the proper storage of drugs.

2. The license shall be displayed in a prominent part of the premises open to the public.

3. No drug would be sold unless due precautions have been taken in order to ensure its preservation.

4. The drug would only be sold to the person licensed to retail them. Condition shall not apply to:

a) Hospitals, medical and research institutions or a RMP for the purpose of supply to his patients.

b) An officer or authority purchasing on behalf of the government.

c) Manufacturer of hydrogenated vegetable oils, beverages, confectionery or other non-medicinal products where such drugs are needed for processing their products.

5. The licensee would obtain prior permission of the licensing authority for the purpose of selling any additional category of drugs not specified in his license.

6. The licensee would maintain records of all purchases and sales of schedule C drugs under:

a) Date of purchase and sale.

b) Name and address of the firm from whom purchased and to the firm to whom sold.

c) Name and quantities of drugs and their batch numbers.

d) Name of the manufacturers of the drugs.

7. Such records would be preserved for a period of at least three years from the date of sale.

(B) License for the wholesale of drugs other than those specified in schedule C, C1 and X.

1. The license shall be displayed in a prominent part of the premises to open to the public.

2. Drugs would be purchased only from a duly licensed dealer or manufacturer.

3. The drug would only be sold to the person licensed to retail them. Condition shall not apply to:

a) Hospitals, medical and research institutions or a RMP for the purpose of supply to his patients.

b) An officer or authority purchasing on behalf of the government.

c) Manufacturer of hydrogenated vegetable oils, beverages, confectionery or other non-medicinal products where such drugs are needed for processing their products.

4. The license would comply with the provision of the Drugs and Cosmetics Act and Rules, as applicable.

(C) license for the wholesale of schedule X drugs.

1. The license shall be displayed in a prominent part of the premises open to the public.

2. Drugs would be purchased only from a duly licensed dealer or manufacturer. Condition shall not apply to:

a) Hospitals, medical and research institutions or a RMP for the purpose of supply to his patients.

b) An officer or authority purchasing on behalf of the government.

3. The license would comply with the provisions of the Drugs and Cosmetics Act and Rules, as applicable.

4. The drug would only be sold to the person licensed to sell or distribute drugs specified in schedule X.

Question No. 13 Discuss the penalties provided for following under medicinal and toilet preparation Act, (1954) for: (a) Improper keeping of accounts (b) Obstructing the excise officer in discharging his duties. (c) Failure to observe correlations of license or to pay duty.

Ans: 13 (a) Improper keeping of accounts: All dutiable goods are required to be stored in an orderly manner as directed by the excise commissioner. Breach of this rule shall be punishable with fine up to Rs. 1000. All accounts of goods must also be maintained in the prescribed manner. Any person who makes false entries or tears out pages from the stock book shall be liable to a fine up to Rs. 2000 and goods, for which due entries have not been made shall be liable to confiscation.

Ans: 13 (b) Obstructing the excise officer in discharging his duties.

Any person who willfully obstruct or offers any resistance or gives any false or misleading information to any excise officer, shall be liable to a fine of up to Rs. 5000/-.

Ans: 13 (c) Failure to observe correlations of license or to pay duty: Any person who:

1. Either manufactures dutiable goods without a license or fails to observe any condition of the license granted to him.

2. Evades any payment of duty due from him.

3. Fails to supply information asked for or supplies false information.

4. Attempts or commits or abets the commission of any offence shall be liable to imprisonment up to six months or a fine up to Rs. 2000 or both.