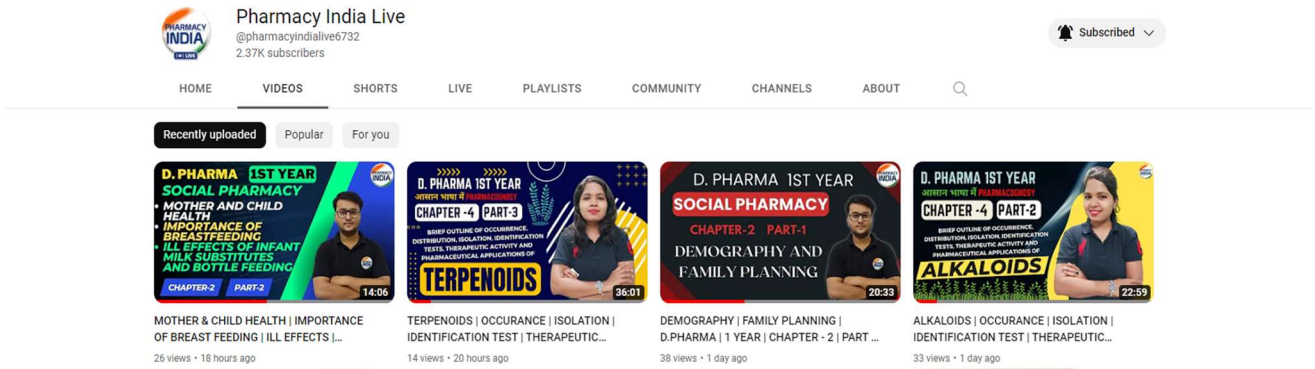
PHARMACY LAW & ETHICS

# MODEL PAPER – 3

## Syllabus to be covered in this module are-

- ❖Chapter- 11 Medical Termination of Pregnancy Act
- ❖Chapter- 12 Role of all the Govt Pharma Bodies
- ❖Chapter- 13 Good Regulatory Practices
- ❖Chapter- 14 Introduction to BCS system
- ❖Chapter- 15 Blood Bank- Basic requirements and functions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# Questions

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# Long Questions-

Ques.1 Explain in detail about the medical termination of pregnancy act rules, 2003.

Ques.2 Discuss medical termination of pregnancy regulations, 2003.

Ques.3 Write in detailed about role of pharma regulatory bodies.

Ques.4 Discuss hospital pharmacy in detail.

Ques.5 Explain detailed about basic requirements & functions of blood bank.

# Short Questions

Ques.1 Write a short note on medical termination of pregnancy act, 1971.

Ques.2 What are the functions of port offices of CDSCO?

Ques.3 Write a short note on Indian Pharmacopoeia Commission (IPC).

Ques.4 What are the principles of Good Regulatory Practices?

Ques.5 Enlist the steps involves in the export procedure.

Ques.6 Write a short note on pharmacy licenses.

Ques.7 What is the basic concept of clinical trials?

Ques.8 What are intellectual property rights & Emergency Use- Authorizations (EUA)?

Ques.9 Explain brand name versus generic name.

Ques.10 Write a short note on orphan drug registration.

Ques.11 Enlist the labels for blood bank bag.

Ques.12 What are the maintenance for the blood bank.

Ques.13 What are the requirements for the records of blood bank?

# Long Answers

## Ques.1 Explain in detail about the medical termination of pregnancy act rules, 2003.

**Ans- Medical Termination of Pregnancy Rules, 2003**

In exercise of the powers conferred by Section 6 of the Medical Termination of Pregnancy Act, 1971 (34 of 1971), the Central Government hereby makes the following rules, namely:

**Rule 01: Short Title and Commencement**

(1) These rules may be called the Medical Termination of Pregnancy Rules, 2003.

(2) They shall come into force on the date of their publication in the Official Gazette.

**Rule 02: Definitions**

"In these rules, unless the context otherwise requires,"

(a) "Act" means the Medical Termination of Pregnancy Act, 1971 (34 of 1971):

(b) "Chief Medical Officer" means the Chief Medical Officer of a District, by whatever name called;

(c) "Form" means a form appended to these rules;

(d) "owner" in relation to a place means any person who is the administrative head or otherwise responsible for the working or maintenance of a hospital or place, by whatever name called, where the pregnancy may be terminated under this Act;

(e) "Committee" means a committee constituted at the district level under the proviso to clause (b) of Section 4 read with Rule 3.

Rule 03: Composition and Tenure Of District Level Committee

(1) One member of the district level committee shall be the Gynaecologist/ Surgeon/ Anaesthetist and other members from the local medical profession, non-governmental organisations, and Panchayati Raj Institution of the district:

Provided that one of the members of the committee shall be a woman.

(2) Tenure of the committee shall be for two calendar years and the tenure of the non- government members shall not be more than two terms.

**Rule 04: Experience and Training Under Clause (D) Of Section 2**

"For the purpose of clause (d) of Section 2, a registered medical practitioner shall have one or more of the following experience or training in gynaecology and obstetrics, namely:"

(a) In the case of a medical practitioner, who was registered in a State Medical Register immediately before the commencement of the Act, experience in the practice of gynaecology and obstetrics for a period of not less than three years;

(b) in the case of a medical practitioner, who is registered in a State Medical Register:

(i) if he has completed six months of house surgency in gynaecology and obstetrics; or

(ii) unless the following facilities are provided therein, if he had experience at any hospital for a period of not less than one year in the practice of obstetrics and gynaecology: or

(c) if he has assisted a registered medical practitioner in the performance of twenty-five cases of medical termination of pregnancy of which at least five have been performed independently, in a hospital established or maintained, or a training institute approved for this purpose by the Government.

(i) This training would enable the Registered Medical Practitioner (RMP) to do only 1st Trimester terminations (up to 12 weeks of gestation);

(ii) For terminations up to twenty weeks the experience or training as prescribed under sub-rules (a), (b) and (d) shall apply.

(d) in case of a medical practitioner who has been registered in a State Medical Register and who holds a postgraduate degree or diploma in gynaecology and obstetrics, the experience or training gained during such degree or diploma.

**Rule 05: Approval of A Place**

(1) No place shall be approved under clause (b) of Section 4,

(i) unless the Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions; and

(ii) unless the following facilities are provided therein, namely: in case of first trimester, that is, up to 12 weeks of pregnancy:" a gynaecology examination/labour table, resuscitation and sterilization equipment, drugs and parenteral fluid, back up facilities for treatment of shock and facilities for transportation; and in case of second trimester, that is up to 20 weeks of pregnancy:"

(a) an operation table and instruments for performing abdominal or gynaecological surgery:

(b) anaesthetic equipment, resuscitation equipment and sterilization equipment;

(c) drugs and parenteral fluids for emergency use, notified by Government of India from time to time.

**Explanation**. In the case of termination of early pregnancy up to seven weeks using RU-486 with Misoprostol, the same may be prescribed by a Registered Medical Practitioner (RMP) as defined under clause (d) of Section 2 of the Act and Rule 4 of MTP Rules, at his clinic, provided such a Registered Medical Practitioner has access to a place approved under Section 4 of the MTP Act, 1971 read with MTP Amendment Act, 2002 and Rules 5 of the MTP Rules. For the purpose of access, the RMP should display a certificate to this effect from the owner of the approved place.

(2) Every application for the approval of a place shall be in Form A and shall be addressed to the Chief Medical Officer of the District.

(3) On receipt of an application under sub-rule (2), the Chief Medical Officer of the District may verify any information contained, in any such application or inspect any such place with a view to satisfying himself that the facilities referred to in subrule (1) are provided, and that termination of pregnancies may be made under safe and hygienic conditions.

(4) Every owner of the place which is inspected by the Chief Medical Officer of the District shall afford all reasonable facilities for the inspection of the place.

(5) The Chief Medical Officer of the District may, if he is satisfied after such verification, enquiry or inspection, as may be considered necessary, that termination of pregnancies may be done under safe and hygienic conditions, at the place, recommend the approval of such place to the committee.

(6) The committee may after considering the application and the recommendations of the Chief Medical Officer of the District approve such place and issue a certificate of approval in Form B.

(7) The certificate of approval issued by the committee shall be conspicuously displaced at the place to be easily visible to persons visiting the place.

(8) The place shall be inspected within 2 months of receiving the application and certificate of approval may be issued within the next 2 months, or in case any deficiency has been noted, within 2 months of the deficiency having been rectified by the applicant.

(9) On the commencement of these rules, a place approved in accordance with the Medical termination of Pregnancy Rules, 1975 shall be deemed to have been approved under these rules.

**Rule 06: Inspection of A Place**

(1) A place approved under Rule 5 may be inspected by the Chief Medical Officer of the District, as often as may be necessary with a view to verify whether termination of pregnancies is being done therein under safe and hygienic conditions.

(2) If the Chief Medical Officer has reason to believe that there has been death of, or injury to, a pregnant woman at the place or that termination of pregnancies is not being done at the place under safe and hygienic conditions, he may call for any information or may seize any article, medicine, ampoule, admission register or other document, maintained, kept or found at the place.

(3) The provisions of the Code of Criminal Procedure, 1973 (2 of 1974), relating to seizure, so far as it may, apply to seizure made under sub-rule

**(2). Rule 07: Cancellation or Suspension of Certificate Of Approval**

(1) If, after inspection of any place approved under Rule 5, the Chief Medical Officer of the District is satisfied that the facilities specified in Rule 5 are not being properly maintained therein and the termination of pregnancy at such place cannot be made under safe and hygienic conditions, he shall make a report of the fact to the committee giving the detail of the deficiencies or defects found at the place and the committee may, if it is satisfied, suspend or cancel the approval provided that the committee shall give an opportunity of making representation to the owner of the place before the certificate issued under Rule 5 is cancelled.

(2) Where a certificate issued under Rule 5 is cancelled, the owner of the place may make such additions or improvements in the place and thereafter, he may make an application to the committee for grant of approval under Rule 5.

(3) In the event of suspension of a certificate, or approval, the place shall not be deemed to be an approved place during the suspension for the purposes of termination of pregnancy from the date of communication of the order of such suspension.

**Rule 08: Review**

(1) The owner of a place, who is aggrieved by an order made under Rule 7, may make an application for review of the order to the Government within a period of sixty days from the date of such order:

Provided that the Government may condone any delay in case it is satisfied that applicant was prevented by sufficient cause to make application within time.

(2) The Government may, after giving the owner an opportunity of being heard, confirm, modify or reverse the order.

**Rule 09: Form of Consent**

"The consent referred to in sub-section (4) of Section 3 shall be given in Form C.

**Rule 10: Repeal and Saving**

"The Medical Termination of Pregnancy Rules, 1975, are hereby repealed except as respects things done or omitted to be done before such repeal.

## Ques.2 Discuss medical termination of pregnancy regulations, 2003.

**Ans- Medical Termination of Pregnancy Regulations, 2003**

**June 13, 2003**

In exercise of the powers conferred by Section 7 of the Medical Termination of Pregnancy Act, 1971(34 of 1971), the Central Government hereby makes the following regulations, namely:

**Regulation 01: Short Title, Extent and Commencement.**

(1) These regulations may be called the Medical Termination of Pregnancy Regulations, 2003.

(2) They extend to all the Union Territories

(3) They shall come into force on the date of their publication in the Official Gazette.

**Regulation 02: Definitions.**

"In these regulations, unless the context otherwise requires,

" (a) "Act" means the Medical Termination of Pregnancy Act, 1971 (34 of 1971);

(b) "Admission Register" means the register maintained under Regulation 5-;

(c) "Chief Medical Officer" means the Chief Medical Officer of a District by whatever name called;

(d) "Form" means a form appended to these regulations,

(e) "Hospital" means a hospital established or maintained by the Central Government or the Government of Union Territory;

(f) "Section" means a section of the Act.

**Regulation 03: Form of Certifying Opinion or Opinions.**

(1) Where one registered medical practitioner forms or not less than two registered medical practitioners form, such opinion as is referred to in sub-section (2) of Section 3 or 5, he or she shall certify such opinion in Form I.

(2) Every registered medical practitioner who terminates any pregnancy shall, within three hours from the termination of the pregnancy certify such termination in Form L.

**Regulation 04: Custody of Forms.**

(1) The consent given by a pregnant woman for the termination of her pregnancy, together with the certified opinion recorded under Section 3 or Section 5, as the case may be and the intimation of termination of pregnancy shall be placed in an envelope which shall be sealed by the registered medical practitioner or practitioners by whom such termination of pregnancy was performed and until that envelope is sent to the head of the hospital or owner of the approved place or the Chief Medical Officer of the State, it shall be kept in the safe custody of the concerned registered medical practitioner or practitioners, as the case may be.

(2) On every envelope referred to in sub-regulation (1), pertaining to the termination of pregnancy under Section 3, there shall be noted the serial number assigned to the pregnant woman in the Admission Register and the name of the registered medical practitioner or practitioners by whom the pregnancy was terminated and such envelope shall be marked "Secret".

(3) Every envelope referred to in sub-regulation (2) shall be sent immediately after the termination of the pregnancy to the head of the hospital or owner of the approved place where the pregnancy was terminated.

(4) On receipt of the envelope referred to in sub-regulation (3), the head of the hospital or owner of the approved place shall arrange to keep the same in safe custody.

(5) Every head of the hospital or owner of the approved place shall send to the Chief Medical Officer of the State, in Form II a monthly statement of cases where medical termination of pregnancy has been done.

(6) On every envelope referred to in sub-regulation (1), pertaining to the termination of pregnancy under Section 5, there shall be noted the name and address of the registered medical practitioner by whom the pregnancy was terminated and the date on which the pregnancy was terminated and such envelope shall be marked "Secret".

Explanation. The columns pertaining to the hospital or approved place and the serial number assigned to the pregnant woman in the Admission Register shall be left blank in Form I in the case of termination performed under Section 5.

(7) Where the pregnancy is not terminated in an approved place or hospital, every envelope referred to in sub-regulation (6) shall be sent by registered post to the Chief Medical Officer of the State on the same day on which the pregnancy was terminated or on the next working day following the day on which the pregnancy was terminated:

Provided that where the pregnancy is terminated in an approved place or hospital, the procedure provided in sub-regulations (1) to (6) shall be followed.

**Regulation 05: Maintenance of Admission Register.**

(1) Every head of the hospital or owner of the approved place shall maintain a register in Form III for recording therein the details of the admissions of women for the termination of their pregnancies and keep such register for a period of five years from the end of the calendar year it relates to.

(2) The entries in the Admission Register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished

from the serial number of other years by mentioning the year against the serial number, for example, Serial Number 5 of 1972 and Serial Number 5 of 1973 shall be mentioned as 5/1972 and 5/1973.

(3) Admission Register shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person.

**Regulation 06: Admission Register Not To Be Open To Inspection**

"The Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorised by such head or owner and save as otherwise provided in sub-regulation (5) of Regulation 4-shall not be open for inspection by any person except under the authority of law:

(4) On receipt of the envelope referred to in sub-regulation (3), the head of the hospital or owner of the approved place shall arrange to keep the same in safe custody.

(5) Every head of the hospital or owner of the approved place shall send to the Chief Medical Officer of the State, in Form II a monthly statement of cases where medical termination of pregnancy has been done.

(6) On every envelope referred to in sub-regulation (1), pertaining to the termination of pregnancy under Section 5, there shall be noted the name and address of the registered medical practitioner by whom the pregnancy was terminated and the date on which the pregnancy was terminated and such envelope shall be marked "Secret".

**Explanation.** The columns pertaining to the hospital or approved place and the serial number assigned to the pregnant woman in the Admission Register shall be left blank in Form I in the case of termination performed under Section 5.

(7) Where the pregnancy is not terminated in an approved place or hospital, every envelope referred to in sub-regulation (6) shall be sent by registered post to the Chief Medical Officer of the State on the same day on which the pregnancy was terminated or on the next working day following the day on which the pregnancy was terminated:

Provided that where the pregnancy is terminated in an approved place or hospital, the procedure provided in sub-regulations (1) to (6) shall be followed.

**Regulation 05: Maintenance of Admission Register.**

(1) Every head of the hospital or owner of the approved place shall maintain a register in Form III for recording therein the details of the admissions of women for the termination of their pregnancies and keep such register for a period of five years from the end of the calendar year it relates to.

(2) The entries in the Admission Register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number, for example, Serial Number 5 of 1972 and Serial Number 5 of 1973 shall be mentioned as 5/1972 and 5/1973.

(3) Admission Register shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person.

**Regulation 06: Admission Register Not to be Open To Inspection.**

"The Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorised by such head or owner and save as otherwise provided in

sub-regulation (5) of Regulation 4-shall not be open for inspection by any except under the authority of law:

(1) The consent given by a pregnant woman for termination of her pregnancy, together with the certified opinion recorded under Sec. 3 or Sec.5, as the case may be and the intimation of termination of pregnancy shall be placed in an envelope which shall be sealed by the registered medical practitioner or practitioners by whom such termination of pregnancy was performed and until that envelope is sent to the head of the hospital or owner of the approved place or the Chief Medical Officer of the State, it shall be kept in the safe custody of the concerned registered medical practitioner or practitioners, as the case may be..

(2) On every envelope referred to in sub-regulation (1), pertaining to the termination of the under Sec. 3, there shall be noted the serial number assigned to the pregnant women in the Admission Register and the name of the registered medical practitioner or practitioners by whom the pregnancy was terminated and such envelope shall be marked "secret".

(3) Every envelope referred to in sub-regulation (2) shall be sent immediately after the termination of the pregnancy to the head of the hospital or owner of the approved place where the pregnancy was terminated.

(4) On receipt of the envelope referred to in sub-regulation (3), the head of the hospital or owner of the approved place shall arrange to keep the same in safe custody. (5) Every head of the hospital or owner of the approved place shall send to the Chief Medical Officer of the State, a weekly statement of cases where medical termination of pregnancy has been done in Form II.

(6) On every envelope referred to in sub-regulation (1), pertaining to a termination of pregnancy under Sec. 5, shall be noted the name and address of the registered medical practitioner by whom the pregnancy was terminated and the date on which the pregnancy was terminated and such envelope shall be marked "secret". Explanation: The columns pertaining to the hospital or approved place and the serial number assigned to the pregnant woman in the Admission Register shall be left blank in Form 1 in the case of termination performed under Sec. 5.

(7) Where the pregnancy is not terminated in an approved place or hospital, every envelope referred to in sub-regulation (6) shall be sent by registered post to the Chief Medical Officer of the State on the same day on which the pregnancy was terminated or on the working day next following the day on which the pregnancy was terminated: Provided that where the pregnancy is terminated in an approved place or hospital, the procedure provided in sub-regulations (1) to (6) shall be followed.

**Regulation 05: Maintenance of Admission Register**

(1) Every head of the hospital or owner of the approved place shall maintain a register in Form III for recording therein the admissions of women for the termination of their pregnancies.

(2) The entries in the Admission Register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number, for example, serial number 5 of 1972 and serial number 5 of 1973 shall be mentioned as 5/1972 and 5/1973.

(3) The Admission Register shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person.

**Regulation 06: Admission Register Not To Be Open To Inspection**

The Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorized by such head or owner and save as otherwise provided in

sub-regulation (5) of regulation 4-shall not be open to inspection by any person except under the authority of:

(i) in the case of a departmental or other enquiry, the Chief Secretary to the Government of a Union Territory;

(ii) in the case of an investigation into an offence, a Magistrate of the First class within the local limits of whose jurisdiction the hospital or approved place is situated;

(iii) in the case of suit or other action for damages, the District Judge within the local limits of whose jurisdiction the hospital or approved place is situated: Provided that the registered medical practitioner shall, on the application of an employed woman whose pregnancy has been terminated, grant a certificate for the purpose of enabling her to obtain leave from her employer: Provided further that any such employer shall not disclose this information to any other person.

**Regulation 07:** Entries In Registers Maintained In Hospital or Approved Place No entry shall be made in any care-sheet, operation theatre-register, follow-up card or any other document or register (except the Admission Register) maintained at any hospital or approved place indicating therein the name of the pregnant woman and reference of the pregnant woman shall be made therein by the serial number assigned to such woman in the Admission

**Register. Regulation 08:** Destruction of Admission Register and Other Papers Save as otherwise directed by the Chief Secretary to the Union territory Administration or for inrelation to any proceeding pending before him, as directed by a District Judge or a Magistrate of the first class, every Admission Register shall be destroyed on the expiry of a period of five years from the date of the last entry in that Register and other papers on the expiry of a period of three years from the date of the termination of the pregnancy concerned.

## Ques.3 Write in detailed about role of pharma regulatory bodies.

**Ans- CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)**

The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control.

**Broad functional activities and duties of zonal and sub-zonal offices of CDSCO**

**Technical**

- To participate in joint inspection for issuance / revalidation of Certificate of Pharmaceutical Products (COPPS) as per WHO certification scheme.
- To participate in joint inspection for grant/renewal of Blood Bank, LVP, r-DNA, Medical Devices, Vaccines and sera licences under CLAA scheme.
- To participate in inspection of Clinical Trial facilities as directed by Drugs Controller General (India) from time to time.
- To carry out auditing/verification/post certification of manufacturers pertaining to preferred bidders.
- To carry out surprise checks/raids/ jointly and independently on the basis of complaints received under Whistle Blower scheme and also from other sources.

- To carry out joint inspection of Testing Laboratories for approval to carry out tests or analysis on drugs, cosmetics and raw materials used in the manufacturer for sale of drugs/cosmetics.
- Drawing drugs samples for testing at central laboratories, and carrying out investigation and launching prosecutions in cases where they do not conform to quality requirements.
- Deputation of drugs samplers to various places of suspicion and collect samples through them as surrogate patient from the sales premises by way of survey to monitor the quality of drugs,

**Functions of Port offices of CDSCO**

- Scrutiny of bills of entry with a view to ensuring that imported drugs comply with the provisions of Chapter III of the Drugs and Cosmetic Act and Rules there under and Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules and Narcotic Drugs and Psychotropic Substances Act and Rules thereunder.
- To check the shipping bills for export for statistical data and keep control under Narcotic Drugs and Psychotropic Substances Act & Rules and Drugs & Magic Remedies (Objectionable Advertisements) Act and the Rules thereunder.
- To ensure that no New Drug is imported into the country unless its import is permitted by the Drugs Licensing Authority under Rules 122 A & 30-AA.
- To ensure that small quantities of drugs imported for clinical trials or for personal use are duly permitted under Test License (11 or 11-A) or Permit Licence as (12 B) as the case may be.
- Maintenance of Statistics regarding import and export of drugs and cosmetics
- Coordination with Customs authorities.
- Coordination with States Drugs Controllers and Zonal Offices for post-import checks.
- Preparation of monthly/quarterly/annual reports.
- To draw samples from import/export and re-import consignments.

**INDIAN PHARMACOPOEIA COMMISSION (IPC)**

Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India. The set of standards are published under the title Indian Pharmacopoeia (IP), which has been modelled over and historically follows from the British Pharmacopoeia. The standards that are in effect since 1 December 2010[4] are the Indian Pharmacopoeia 2010 (IP 2010). The Pharmacopoeia 2014 was released by Health Minister Ghulam Nabi Azad on 4 November 2013.

| | |
|---|---|
| Formation | 1956 |
| Headquarters | Ghaziabad |
| Chairman | P.K. Pradhan, secretary (health & family welfare |
| Website | Ipc.hov.in |

**Mission**: To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients. excipients and dosage forms, used by health professionals, patients, and consumers.

**Vision**: To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis.

**Major Functions**

(i) Publishing Indian Pharmacopoeia (IP) and its Addenda at regular intervals.

(ii) Preparation, certification, and distribution of IP Reference Substances (IPRS) to the stakeholders.

(iii) Publishing National Formulary of India (NFI) for rational use of medicines by health professionals.

(iv) Running Pharmacovigilance Programme of India (PVPI) through National Coordination Centre (NCC) at IPC.

(v) Analysis of the new drug candidate materials by Indian Pharmacopoeia laboratory

(IPL) for their marketing authorization. materials by Indian

(vi) Skill development, international collaborations etc.

IP is the officially recognised book of standards for drugs included therein, in terms of the second schedule to the Drugs and Cosmetics Act, 1940 to specify the standards of identity, purity and strengths for the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. The standards prescribed in IP are authoritative. The standards in IP are in the form of general monographs (e.g. Tablets, Capsules, Injections) and specific drug monographs such as of active pharmaceutical ingredients and their dosage forms (e.g. Paracetamol, Paracetamol Oral Suspension), pharmaceutical aids etc.

To fulfil the intended purpose of IP monographs, IPC also establishes and supplies the IPRS both for drug substances as well as the impurities to the stakeholders. These are highly characterized materials used for the purpose of comparison. IPC is accredited as Reference Material Producer in accordance with the ISO Guide 34.

Furthermore, IPC promotes the rational use of generic medicines by publishing NFI which is a guidance document essentially meant for the healthcare professionals, students, nurses and pharmacists for appropriate selection of medicines. The NFI covers the drugs based on their therapeutic merit, the extent of their use in the current medical practices, drugs listed in National List of Essential Medicines of India, and drugs used in National Health Programmes.

In line with the objectives of 'Skill Development', IPC provides hands-on training to the regulators, researchers, scientists, analysts, academicians, and students in the areas related to standard setting for drugs, drug analysis, pharmacovigilance, and other related areas. As a part of training IPC also organises seminars, conferences, and hands-on workshops throughout the year for the benefit of stakeholders. For the sake of harmonisation, IPC collaborates with its international counterparts on pharmacopoeia related matters.

## Ques.4 Discuss hospital pharmacy in detail.

**Ans- HOSPITAL PHARMACY**

Hospital pharmacy is a specialised field of pharmacy which forms an integrated part of patient health care in a health facility.

Hospital pharmacy is the profession that strives to continuously maintain and improve the medication management and pharmaceutical care of patients to the highest standards in a hospital setting.

**Definition:** The practice of pharmacy within the hospital under the supervision of a professional pharmacist is known as hospital pharmacy.

**Functions of Hospital Pharmacy**

1. Dispensing of drugs, chemicals, and pharmaceutical supplies.

2. Dispensing of all narcotic drugs, alcohol & maintaining running stock account of the same.

3. Filling and labelling of all drug containers.

4. Inspection of all pharmaceutical supplies.

5. To maintain satisfactory system of record and book keeping of all products available in hospital pharmacy.

6. To maintain stock of approved drugs.

7. To maintain adequate control over dispensing of all drugs.

8. To maintain correct specification of drugs.

9. To maintain correct costing of drug

10. To prepare large volume Parenteral & other parenteral preparations & to maintain aseptic condition while manufacturing.

11. To check quality of manufactured product.

12. To give information concerning to medicines to physicians, interns & nurses

13. To prepare periodic & annual report about working of Hospital pharmacy.

14. To implement decisions of PTC.

15. To implement programme of education for pharmacist, nurses and interns.

**Objective of Hospital Pharmacy**

The primary mission of hospital pharmacy is to manage the use of medications in hospitals and other medical centres. Goals include the selection, prescription, procuration, delivery, administration, and review of medications to optimize patient outcomes. It is important to ensure that the right patient, dose, route of administration, time, drug, information, and documentation are respected when any medication is used.

**Location and Layout of Hospital pharmacy**

The location of hospital pharmacy should be such that it is convenient for providing service to all departments of hospital and personal who make daily use of such service. In general hospital of less than 200 beds the pharmacy should be located on the first floor in the centre and near to the outpatient department. This will increase the efficiency and reduce the man hours of work.

**Infrastructure:**

1. Located in the ground floor or in the first floor.

2. Sufficient space for seating of patients.

3. Waiting room for out-patients. It should contain educative posters on health, hygiene and offer literature for reading.

4. Suitable space routine manufacturing of bulk preparations (stock solutions, bulk powders, and ointments etc.

5. Office of the chief
6. Packaging and labelling area
7. Cold storage area
8. Research wing
9. Pharmacy store room
10. Library
11. Radio isotope storage and dispensing area

**ROLES AND RESPONSIBILITIES OF HOSPITAL PHARMACIST INDOOR PHARMACISTS**

**In Central dispensing area:**

1. To ensure that all drugs are stored and dispensed correctly.
2. To check the accuracy of the dosages prepared.
3. Maintain proper records
4. Preparation of bills
5. Co-ordinate over all pharmaceutical needs of the patient
6. Framed policies and procedures are followed
7. Maintain professional competence
8. Communicate with all pharmacy staffs

**In Patient care areas:**

1. Maintain liaison with nurses
2. Reviewing of drug administration
3. Provide instruction and assistance to the junior pharmacist

**In Direct patient areas:**

1. Identification of drugs brought into the hospital
2. Obtaining patients medication history
3. Assist in the selection of drug products
4. Monitor patients total drug therapy
5. Counselling patients
6. Participating in cardio-pulmonary emergencies

**In General responsibilities:**

1. Ensure that all drugs are handled properly
2. Participate in cardio-pulmonary emergencies

3. Provide education and training for pharmacists

**Outdoor pharmacist responsibilities:**

**(a) Central dispensing area:**

1. To ensure that all drugs are stored and dispensed correctly.

2. To check the accuracy of the dosages prepared.

3. Maintain proper records

4. Preparation of bills

5. Keeps the pharmacy neat and tidy manner

**(b) Patient care areas**

1. Inspect periodically the medication areas

2. Identify the drugs brought into the hospital

3. Monitoring of drugs

4. Counsel the patients

**(c) General responsibilities:**

1. Ensure that all drugs are handled properly

2. Participate in cardio-pulmonary emergencies

3. Provide education and training for pharmacists

4. Co-ordinate overall pharmaceutical need of the outdoor services

## Ques.5 Explain detailed about basic requirements & functions of blood bank.

**Ans- BASIC REQUIREMENTS AND FUNCTIONS OF BLOOD BANK**

**1. Location and Surroundings:** The blood bank shall be located at a place which shall be away from open sewage, drain, public lavatory or similar unhygienic surroundings.

**2. Building:** The building(s), used for operation of a blood bank and/or preparation of blood components shall be constructed in such a manner to permit the operation of the blood bank and preparation of blood components under hygienic conditions and shall avoid the entry of insects, rodents and flies. It shall be well lighted, ventilated and

screened (mesh), wherever necessary. The walls and floors of the rooms, where collection of blood or preparation of blood components or blood products is carried out shall be smooth, washable, and capable of being kept clean. Drains shall be of adequate size and were connected directly to a sewer, shall be equipped with traps to prevent back siphonage.

**3. Health, clothing, and sanitation of staff:** The employees shall be free from contagious or infectious diseases. They shall be provided with clean overalls, head-gears, foot-wears, and gloves, wherever required. There shall be adequate, clean, and convenient hand washing and toilet facilities.

**Accommodation for A Blood Bank**

A blood bank shall have an area of 100 square metres for its operations and an additional area of 50 square metres for preparation of blood components. It shall be consisting of a room each for:

1. Registration and medical examination with adequate furniture and facilities for registration and selection of donors.

2. Blood collection (air-conditioned).

3. Blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degrees centigrade to 25 degree centigrade).

4. Laboratory for blood group serology. (Air-conditioned).

5. Laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV-antibodies (air-conditioned).

6. Sterilization-cum-washing.

7. Refreshment-cum-rest room (air-conditioned).

8. Store-cum-records.

**PERSONNEL**

Every blood bank shall have following categories of whole time competent technical staff:

(a) Medical Officer, possessing the qualifications specified in condition.

(b) Blood Bank Technician(s), possessing:

(i) Degree in Medical Laboratory Technology (M.L.T.) with six months' experience in the testing of blood and/or its components; or

(ii) Diploma in Medical Laboratory Technology (MLT) with one year's experience in the testing of blood and/or its components, the degree or diploma being from a University/Institution recognised by the Central Government or State Government.

(c) Registered Nurse(s).

(d) Technical Supervisor (where blood components are manufactured), possessing:

(i) Degree in Medical Laboratory Technology (M.L.T.) with six months' experience in the preparation of blood components, or

(ii) Diploma in Medical Laboratory Technology (M.L.T.) with one year's experience in the preparation of blood components, the degree or diploma being from a University/Institution recognised by the Central Government or State Government.

**Maintenance**

The premises shall be maintained in a clean and proper manner to ensure adequate cleaning and maintenance of proper operations. The facilities shall include-

1. Privacy and thorough examination of individuals to determine their suitability as donors.

2. Collection of blood from donors with minimal risk of contamination or exposure to activities and equipment unrelated to blood collection.

3. Storage of blood or blood components pending completion of tests.

4. Provision for quarantine, storage of blood and blood components in a designated location, pending repetition of those tests that initially give questionable serological results.

5. Provision for quarantine, storage, handling and disposal of products and reagents not suitable for use.

6. Storage of finished products prior to distribution or issue.

7. Proper collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.

8. Adequate and proper performance of all procedures relating to plasma pheresis, platelet pheresis and leukapheresis.

9. Proper conduct of all packaging, labelling and other finishing operations.

10. Provision for safe and sanitary disposal of:

(i) Blood and/or blood components not suitable for use, distribution or sale.

(ii) Trash and items used during the collection, processing and compatibility testing of blood and/or blood components.

**Equipment**

Equipment used in the collection, processing, testing, storage and sale/distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance. The equipment shall be observed, standardised, and calibrated on a regularly scheduled basis as described in the Standard Operating Procedures Manual and shell operate in the manner for which it was designed so as to ensure compliance with the official requirements (the equipment's) as stated below for blood and its components.

**Supplies and Reagents**

All supplies and reagents used in the collection, processing, compatibility, testing, storage and distribution of blood and blood components shall be stored at proper temperature in a safe and hygienic place, in a proper manner and in particular:

(a) All supplies coming and contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency, or effectiveness of the product.

(b) Supplies and reagents that do not bear an expiry date shall be stored in a manner the oldest is used first.

(c) Supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer.

(d) All final containers and closures for blood and blood components not intended for transfusion shall be clean and free of surface solids and other contaminants.

(e) Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling. Such examination shall include inspection for breakage of seals, when indicated, and abnormal discoloration. Where any defect is observed, the container shall not be used or, if detected after filling, shall be properly discarded.

**Records**

The records which the license is required to maintain shall include inter alia the following particulars, namely:

1. Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer In-charge.

2. Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L., Hepatitis B surface antigen and Hepatitis C virus antibody and irregular antibodies (if any), name and address of the donor with particulars, utilisation issue number, components prepared or discarded and signature of the Medical Officer Incharge.

3. Issue register: It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion.

4. Records of components supplied: quantity supplied; compatibility report, details of recipient and signature of issuing person.

5. Records of A.C.D/C. P. D/CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply, and results of testing.

6. Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.

7. Blood bank must issue the cross-matching report of the blood to the patient together with the blood unit.

8. Transfusion adverse reaction records.

9. Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.

**LABELS**

The labels on every bag containing blood and/or component shall contain the following particulars, namely:

1. The proper name of the product in a prominent place and in bold letters on the bag.

2. Name and address of the blood bank

3. Licence number

4. Serial number

5. The date on which the blood is drawn and the date of expiry as prescribed under Schedule P to these rules.

6. A coloured label shall be put on every bag containing blood. The following colour scheme for the said labels shall be used for different groups of blood.

7. The results of the tests for Hepatitis B surface antigen, and Hepatitis C virus antibody, syphilis, freedom from HIV I and HIV II antibodies and malarial parasite.

8. The Rh group.

9. Total volume of blood, the preparation of blood, nature, and percentage of anti-coagulant.

10. Keep continuously temperature at 2 degrees centigrade to 6 degrees centigrade for whole human blood and/or components as contained under III of Part XII B. dub

11. Disposable transfusion sets with filter shall be used in administration equipment.

12. Appropriate compatible cross matched blood without a typical antibody in recipient shall be used.

13. The contents of the bag shall not be used if there is any visible evidence of deterioration like haemolysis, clotting or discoloration.

14. The label shall indicate the appropriate donor classification like "Voluntary Donor" or "Replacement Donor" in no less prominence than the proper name.

# Short Answers

## Ques.1 Write a short note on medical termination of pregnancy act, 1971.

**Ans- INTRODUCTION**

Medical Termination of Pregnancy Act was passed by the parliament in 1971 with the objective to provide for the termination of pregnancy by Registered Medical Practitioner (R.M.P.) for bona fide reasons.

**Objective**

- To improve the maternal health scenario by preventing large number of unsafe abortions and consequent high incidence of maternal mortality & morbidity.
- Legalizes abortion services
- Promotes access to safe abortion services to women
- Decriminalize the abortion seeker

**Statement of Objects and Reasons:**

1. The provisions regarding the termination of pregnancy in the Indian Penal Code which were enacted about a century ago were drawn up in keeping with the then British Law on the subject. Abortion was made a crime for which the mother as well as the abortionist could be punished except where it had to be induced in order to save the life of the mother. It has been stated that this very strict law has been observed in the breach in a very large number of cases all over the country. Furthermore, most of these mothers are married women, and are under no necessity to conceal their pregnancy.

2. In recent years, when health services have expanded and hospitals are fully availed of by all classes of society, doctors have often been confronted with gravely ill or dying pregnant women whose pregnant uterus have been tampered with, a view to causing an abortion and consequently suffered very severely.

3. there is thus avoidable wastage of the mother's health, strength and, sometimes, life. The proposed measure which seeks to liberalise certain existing provisions relating to termination of pregnancy has been conceived

(1) as a health measure when there is danger to the life or risk to physical or mental health of the woman;

(2) on humanitarian grounds- such as when pregnancy arises from a sex crime like rape or intercourse with a lunatic woman, etc.; and

(3) eugenic grounds - Where there is substantial risk that the child, if born, would suffer from deformities and diseases. -Gaz, of Ind., 17-11-1969, Pt. II, section 2, Ext., p. 880.

## Ques.2 What are the functions of port offices of CDSCO?

**Ans- Functions of Port offices of CDSCO**

- Scrutiny of bills of entry with a view to ensuring that imported drugs comply with the provisions of Chapter III of the Drugs and Cosmetic Act and Rules there under and Drugs and Magic

Remedies (Objectionable Advertisements) Act and Rules and Narcotic Drugs and Psychotropic Substances Act and Rules thereunder.

- To check the shipping bills for export for statistical data and keep control under Narcotic Drugs and Psychotropic Substances Act & Rules and Drugs & Magic Remedies (Objectionable Advertisements) Act and the Rules thereunder.
- To ensure that no New Drug is imported into the country unless its import is permitted by the Drugs Licensing Authority under Rules 122 A & 30-AA.
- To ensure that small quantities of drugs imported for clinical trials or for personal use are duly permitted under Test License (11 or 11-A) or Permit Licence as (12 B) as the case may be.
- Maintenance of Statistics regarding import and export of drugs and cosmetics
- Coordination with Customs authorities.
- Coordination with States Drugs Controllers and Zonal Offices for post-import checks.
- Preparation of monthly/quarterly/annual reports.
- To draw samples from import/export and re-import consignments.

## Ques.3 Write a short note on Indian Pharmacopoeia Commission (IPC).

**Ans- INDIAN PHARMACOPOEIA COMMISSION (IPC)**

Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India. The set of standards are published under the title Indian Pharmacopoeia (IP), which has been modelled over and historically follows from the British Pharmacopoeia. The standards that are in effect since 1 December 2010[4] are the Indian Pharmacopoeia 2010 (IP 2010). The Pharmacopoeia 2014 was released by Health Minister Ghulam Nabi Azad on 4 November 2013.

| | |
|---|---|
| Formation | 1956 |
| Headquarters | Ghaziabad |
| Chairman | P.K. Pradhan, secretary (health & family welfare |
| Website | Ipc.hov.in |

**Mission**: To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients. excipients and dosage forms, used by health professionals, patients, and consumers.

**Vision**: To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis.

**Major Functions**

(i) Publishing Indian Pharmacopoeia (IP) and its Addenda at regular intervals.

(ii) Preparation, certification, and distribution of IP Reference Substances (IPRS) to the stakeholders.

(iii) Publishing National Formulary of India (NFI) for rational use of medicines by health professionals.

(iv) Running Pharmacovigilance Programme of India (PVPI) through National Coordination Centre (NCC) at IPC.

(v) Analysis of the new drug candidate materials by Indian Pharmacopoeia laboratory

(IPL) for their marketing authorization. materials by Indian

(vi) Skill development, international collaborations etc.

## Ques.4 What are the principles of Good Regulatory Practices?

**Ans- Principles of Good Regulatory Practices**

**Legality:** Regulation should have a sound legal basis and should be consistent with existing legislation, including international norms or agreements.

**Impartiality:** Regulation and regulatory decisions should be impartial in order to be fair and to avoid conflicts of interest, unfounded bias or improper influence from stakeholders. **Consistency:** Regulations should be clear and predictable; both the regulator and the regulated party should understand the behaviour and the conduct that are expected and the consequences of noncompliance.

**Proportionality:** Regulations and regulatory decisions should be proportional to the risk and should not exceed what is necessary to achieve the objectives.

**Flexibility**: Regulations should not be prescriptive; they should allow flexibility in responding to a changing regulated environment and different or unforeseen circumstances.

**Effectiveness**: Regulations should produce the intended result.

**Efficiency**: Regulations should achieve their goals within the required time, effort, and cost.

**Clarity:** Regulations should be accessible to, and understood by, the users.

**Transparency:** Regulatory systems should be transparent; requirements and decisions should be made known to affected parties and, where appropriate, to the public in general.

## Ques.5 Enlist the steps involves in the export procedure.

**Ans- The export procedure includes several steps:**

1. Receipt of indent
2. Receipt of license for export
3. Procurement of goods
4. Packing and labelling
5. Appointment of forwarding agent
6. Dispatch of goods.
7. Foreign customs permit
8. Shipping order
9. Export duty and shipment bill
10. Dock dues or challan
11. Loading the goods
12. Mate's receipt
13. Bill of loading
14. Marine insurance
15. Forwarding agent advice
16. Preparation of export invoice
17. Payment
18. Advice to importer

## Ques.6 Write a short note on pharmacy licenses.

**Ans- PHARMACY LICENCES**

**Granting a licence**

A licence is needed to open and operate a community pharmacy in all countries in the WHO European Region.

Applications for licences can be made directly or through electronic government systems, as in Armenia, Azerbaijan, Georgia and Kazakhstan. Most licences are attached to a given location and premises, which may be subject to inspection prior to the licence being granted, as in Iceland and Malta.

Two different concepts govern pharmacy licences.

1. A facility-based pharmacy licence is an authorization to operate a pharmacy in a specific location. The licence can be transferred (sold) automatically when the pharmacy is sold to another owner (provided the new owner meets all other requirements); it is therefore time unlimited and transferrable. This model is usually used in countries that combine limiting the establishment of community pharmacies (for health planning) with limiting ownership to pharmacists

2. A licence to operate a community pharmacy concerns the legal running of the pharmacy. which may be associated with a specific responsible pharmacist (as in Leland). When the operator/responsible pharmacist changes, the licence is cancelled and a new one must be issued. This licence is personal and non-transferrable.

**Documents Required**

- A challan of 3,000
- Affidavit of the proprietor on 20 stamp paper
- Self-attested copies of education certificate and identity proof of proprietor
- Affidavit of a registered pharmacist or competent person
- Self-attested copies of education certificate and identity proof of registered pharmacist or competent person
- Experience certificate of a competent person
- Blueprint of a plan layout of proposed premises
- Electricity bill of proposed premises
- Copy of refrigerator bill
- Either rent agreement or ownership document of the premises
- Covering letter
- 5 photos each of proprietor, and either the registered pharmacist or competent person

## Ques.7 What is the basic concept of clinical trials?

**Ans- Basic Concept of Clinical Trials**

Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioural intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device.

Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects. If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the FDA approves it for clinical use and continues to monitor its effects.

Clinical trials of drugs are usually described based on their phase. The FDA typically requires Phase I, II, and III trials to be conducted to determine if the drug can be approved for use.

- A Phase I trial tests an experimental treatment on a small group of often healthy people (20 to 80) to judge its safety and side effects and to find the correct drug dosage.
- A Phase II trial uses more people (100 to 300). While the emphasis in Phase I is on safety, the emphasis in Phase II is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.
- A Phase III trial gathers more information about safety and effectiveness, studying different populations and different dosages, using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people. If the FDA agrees that the trial results are positive, it will approve the experimental drug or device.
- A Phase IV trial for drugs or devices takes place after the FDA approves their use. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug may not become clear until more people have taken it over a longer period.

## Ques.8 What are intellectual property rights & Emergency Use-Authorizations (EUA)?

**Ans-** **INTELLECTUAL PROPERTY RIGHTS**

Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property.

Intellectual property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical, or scientific creation. Intellectual property rights (IPR) refer to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time. These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize his invention/creation for a given period.

Intellectual and Industrial Property Rights are the rights associated with "products of the mind".

The rights are:

- Trade Marks
- Patents
- Copyright
- Registered Design Rights Unregistered Design Rights; and
- Know-how/Confidential Information

**EMERGENCY USE AUTHORIZATIONS (EUAS)**

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including

infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when the Secretary of HHS declares that an emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives. The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretary of HHS, Homeland Security, or Defence.

## Ques.9 Explain brand name versus generic name.

**Ans- BRAND NAME VERSUS GENERIC NAME**

Generic drugs are copies of brand-name drugs that have the same dosage, intended use, effects, and side effects, route of administration, risks, safety, and strength as the original drug. In other words, their pharmacological effects are the same as those of their brand-name counterparts.

- Manufacturers formulate generic drugs to work the same way and provide the same benefits as their branded counterparts.
- Once a brand-name drug's patent has expired, a drug company can file an "abbreviated new drug application" (ANDA).
- The generic drug must meet strict standards before the FDA will approve it.
- Researchers have found that many branded drugs have regular annual or biannual price increases.
- According to the FDA. generic drugs may cost 80% less than their brand-name equivalents.

**Patent Law in India**

The Patents Act 1970, along with the Patents Rules 1972, came into force on 20th April 1972, replacing the Indian Patents and Designs Act 1911. The Patents Act was largely based on the recommendations of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. One of the recommendations was the allowance of only process patents about inventions relating to drugs, medicines, food, and chemicals.

Later, India became signatory to many international arrangements with an objective of strengthening its patent law and coming in league with the modern world. One of the significant steps towards achieving this objective was becoming the member of the Trade Related Intellectual Property Rights (TRIPS) system.

**History**

India had to meet the first set of requirements on 1st January 1995 to give a pipeline protection till the country starts granting product patent.

On 26th March, 1999, Patents (Amendment) Act, 1999 came into force retrospective effect from 1st January, 1995.

The second phase of amendment was brought in by the Patents (Amendment) Act, 2002 which came into force on 20th May 2003.

The third and final amendment to the Patents Act, 1970 came by way of Patents (Amendment) Ordinance, 2004, which was later replaced by The Patent (Amendment) Act, 2005, and Patents (Amendment) Rules, 2006 with retrospective effect from 1st January, 2005.

**Current Position**

The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 (hereinafter referred to as the Act) and Patents Acts Rules, 2006 (hereinafter referred to as the Rules).

The Head Patent Office is located at Kolkata and its branch offices are located at Delhi, Mumbai, and Chennai. Patent system in India is administered by the Controller General of Patents, Designs, Trademarks and Geographical Indications. Each office has its own territorial jurisdiction for receiving patent applications and is empowered to deal with all sections of Patent Act.

## Ques.10 Write a short note on orphan drug registration.

**Ans- Orphan Drug Registration**

New Rules, 2019 define orphan drugs as a "drug intended to treat a condition which affects not more than five lakh (500,000) persons in India." To promote research in orphan drugs, there have been favorable provisions in New Rules, 2019 as follows:

- Provision for fast-track approval process and special status for orphan drugs, including a complete fee waiver for CT filing.
- Provision for expeditious review process. In situations where the evidence for clinical safety and efficacy have been established. Even if the drug has not completed all clinical trial phases, the sponsor or applicant may apply to the CLA for expedited review process. After accelerated approval, applicants could be required to conduct post marketing trials for validating anticipated clinical benefits.
- Provision for waiver of local clinical study and Phase IV on satisfaction of CLA

**Post-Trial Access**

New Rules, 2019 defines post-trial access as "making a new drug or investigational new drug available to a trial subject after completion of clinical trial through which the said drug has been found beneficial to a trial subject during clinical trial, for such period as considered necessary by the investigator and the ethics committee." These drugs should be free-of-charge upon approval of the ethics committee.

If the clinical trial is being conducted for an indication for which no alternate therapy is available, and the investigational new drug or new drug has been found to be beneficial to the trial subject by the investigator, the sponsor has no liability for post-trial use of an investigational new drug or new drug to which the patient commits in writing.

**Ethics Committees (ECs)**

As per new rules, ECs need to include at least one female member and 50% of membership must consist of those who are not affiliated with the institution or organization in which the committee is constituted. The new rules also mandate each EC member to undergo such training and development programs as may be specified from time-to-time by CLA. Further, any change in membership or constitution of registered

E. is to be reported to CLA in writing within 30 working days. ECs will have to go through reconstitution (and subsequent re-registration) to comply with new rules before taking up any new CTs for review.

**Increased Fees for Various Applications**

Fees for all types of applications have been increased. Some have increased substantially. For example, the application fees for a Phase III Clinical Trials have increased to INR 200,000 from INR 25,000. While previously there were no fees for a Phase IV study, the applicant must now pay INR 200,000 for a Phase IV study. There are also some new categories for which fees have been included.

## Ques.11 Enlist the labels for blood bank bag.

**Ans- LABELS**

The labels on every bag containing blood and/or component shall contain the following particulars, namely:

1. The proper name of the product in a prominent place and in bold letters on the bag.

2. Name and address of the blood bank

3. Licence number

4. Serial number

5. The date on which the blood is drawn and the date of expiry as prescribed under Schedule P to these rules.

6. A coloured label shall be put on every bag containing blood. The following colour scheme for the said labels shall be used for different groups of blood.

7. The results of the tests for Hepatitis B surface antigen, and Hepatitis C virus antibody, syphilis, freedom from HIV I and HIV II antibodies and malarial parasite.

8. The Rh group.

9. Total volume of blood, the preparation of blood, nature, and percentage of anti-coagulant.

10. Keep continuously temperature at 2 degrees centigrade to 6 degrees centigrade for whole human blood and/or components as contained under III of Part XII B. dub

11. Disposable transfusion sets with filter shall be used in administration equipment.

12. Appropriate compatible cross matched blood without a typical antibody in recipient shall be used.

13. The contents of the bag shall not be used if there is any visible evidence of deterioration like haemolysis, clotting or discoloration.

14. The label shall indicate the appropriate donor classification like "Voluntary Donor" or "Replacement Donor" in no less prominence than the proper name.

## Ques.12 What are the maintenance for the blood bank.

**Ans- Maintenance**

The premises shall be maintained in a clean and proper manner to ensure adequate cleaning and maintenance of proper operations. The facilities shall include-

1. Privacy and thorough examination of individuals to determine their suitability as donors.

2. Collection of blood from donors with minimal risk of contamination or exposure to activities and equipment unrelated to blood collection.

3. Storage of blood or blood components pending completion of tests.

4. Provision for quarantine, storage of blood and blood components in a designated location, pending repetition of those tests that initially give questionable serological results.

5. Provision for quarantine, storage, handling and disposal of products and reagents not suitable for use.

6. Storage of finished products prior to distribution or issue.

7. Proper collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.

8. Adequate and proper performance of all procedures relating to plasma pheresis, platelet pheresis and leukapheresis.

9. Proper conduct of all packaging, labelling and other finishing operations.

10. Provision for safe and sanitary disposal of:

(i) Blood and/or blood components not suitable for use, distribution or sale.

(ii) Trash and items used during the collection, processing and compatibility testing of blood and/or blood components.

## Ques.13 What are the requirements for the records of blood bank?

**Ans- Records**

The records which the license is required to maintain shall include inter alia the following particulars, namely:

1. Blood donor record: It shall indicate serial number, date of bleeding, name, address, and signature of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer In-charge.

2. Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L., Hepatitis B surface antigen and Hepatitis C virus antibody and irregular antibodies (if any), name and address of the donor with particulars, utilisation issue number, components prepared or discarded and signature of the Medical Officer In charge.

3. Issue register: It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipients, unit/institution, details of cross-matching report, indication for transfusion.

4. Records of components supplied: quantity supplied; compatibility report, details of recipient and signature of issuing person.

5. Records of A.C.D/C. P. D/CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply, and results of testing.

6. Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.

7. Blood bank must issue the cross-matching report of the blood to the patient together with the blood unit.

8. Transfusion adverse reaction records.

9. Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.