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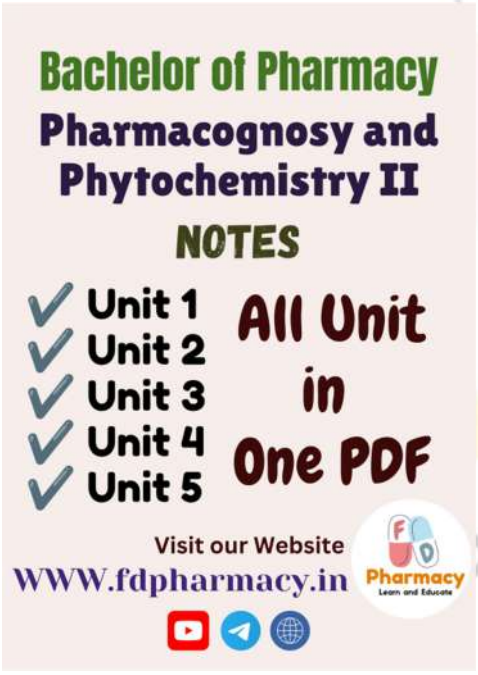
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PHARMACEUTICAL JURISPRUDENCE

UNIT 5

TOPIC :

- **Medical Termination of Pregnancy Act**
  Right to Information Act
  Introduction to Intellectual Property Rights (IPR)

Medical Termination of Pregnancy (MTP) Act, 1971

- The MTP Act, 1971 was enacted in India to provide legal, safe, and accessible abortion services.
- Its purpose is to prevent unsafe abortions, protect the health of women, and reduce maternal mortality due to illegal procedures.

Objectives

1. To legalize abortion under specified conditions.
2. To ensure safe medical procedures for pregnancy termination.
3. To protect the health and life of the pregnant woman.
4. To reduce the incidence of unsafe and clandestine abortions.
5. To regulate facilities and personnel providing abortion services.

Definitions

Term	Definition
Medical Termination of Pregnancy (MTP)	Termination of a pregnancy by medical or surgical means within the limits prescribed by law.
Registered Medical Practitioner (RMP)	A doctor registered under the Indian Medical Council Act, 1956, qualified to perform MTP.
Gestation Period	Duration of pregnancy measured from the first day of the last menstrual period (LMP).

Conditions for Legal Abortion (as per 2021 Amendment)

1. **Up to 20 weeks** of gestation:
   - Abortion can be performed if continuation of pregnancy poses risk to the woman's life or physical/mental health.
   - Abortion can be performed in case of substantial risk that the child may suffer from physical or mental abnormalities.
2. **Between 20–24 weeks** of gestation (special categories):
   - Permitted for rape survivors, minors, and cases of fetal abnormalities.
   - Requires opinion of two RMPs.
3. **Above 24 weeks:**
   - Only allowed if fetal abnormalities are detected and with approval from a Medical Board.

Who Can Perform MTP

- Only a Registered Medical Practitioner (RMP) who has:
  - Recognized qualification in gynecology or obstetrics.
  - Adequate training in MTP techniques.
- Registered Health Facilities:
  - Government hospitals, registered private clinics, and centers approved for MTP.

Procedure

1. **Medical Abortion:**
   - Using drugs (like mifepristone + misoprostol) up to 9 weeks of gestation.
2. **Surgical Abortion:**
   - Methods include manual vacuum aspiration (MVA) or dilatation and curettage (D&C).
   - Usually used for pregnancies beyond 9 weeks.

Record Keeping

- RMPs must maintain detailed records of every MTP procedure:
  - Patient details
  - Gestation period
  - Reason for abortion
  - Consent forms
  - Type of procedure
- Records must be kept confidential and submitted to the authorities as required.

Penalties for Violation

Offence	Penalty
Performing MTP by an unqualified person	Imprisonment up to 3 years and/or fine
Performing MTP without woman's consent	Imprisonment up to 3 years and/or fine
Performing abortion beyond permitted gestation	Imprisonment and revocation of license
Failure to maintain records	Penalty as per State authorities

Right to Information (RTI) Act, 2005

The Right to Information (RTI) Act, 2005 is an Indian law enacted to promote transparency and accountability in public authorities.

It empowers citizens to access information under the control of public authorities to ensure informed participation in democracy and prevent corruption.

Objectives

1. To empower citizens to access information from government or public bodies.
2. To promote transparency and accountability in administration.
3. To prevent corruption and misuse of power.
4. To provide a legal framework for citizens to demand and receive information.

Definitions

Term	Definition
Information	Any material in electronic, paper, or other form held by a public authority.
Public Authority	Any government body, body funded or controlled by the government, or any organization substantially financed by the government.
Right to Information (RTI)	The right of a citizen to access information from a public authority as provided by the Act.
Central Information Commission (CIC)	An independent authority to hear appeals and complaints regarding information requests.
State Information Commission (SIC)	State-level authority for hearing RTI appeals and complaints.

Applicability

- Applies to all government bodies, including central, state, and local authorities.
- Includes public sector undertakings and government-funded organizations.
- Citizens can seek information about policies, decisions, expenses, and functioning of public authorities.

Key Provisions

1. **Right to Access:**
    - Citizens can request information in writing from public authorities.
    - Authorities must respond within 30 days (or 48 hours in case of life or liberty urgency).
2. **Exemptions:**
    - Information affecting national security, sovereignty, or integrity.
    - Personal information that violates privacy unless in public interest.
    - Trade secrets or intellectual property confidential to the government.
3. **Obligations of Public Authorities:**
    - Maintain records in a systematic manner.
    - Provide information proactively (Sec. 4).
    - Designate a Public Information Officer (PIO) to handle RTI requests.
4. **Appeals and Complaints:**
    - First Appeal: To senior officer within the department.
    - Second Appeal: To Central or State Information Commission if first appeal is unsatisfactory.
5. **Penalties:**
    - Rs. 250 per day for delay or refusal to provide information.
    - May lead to disciplinary action against officers.

Importance in Healthcare and Pharmacy

1. **Access to Drug Information:**
    - Citizens can seek info on drug approvals, clinical trials, price controls, and safety regulations.
2. **Transparency in Public Health Programs:**
    - RTI ensures transparency in vaccine distribution, essential drug availability, and government health schemes.
3. **Accountability of Regulatory Authorities:**
    - Ensures DGCI, NPPA, CDSCO, and health departments function transparently.

Introduction to Intellectual Property Rights (IPR)

Intellectual Property Rights (IPR) are legal rights granted to creators and inventors to protect their creations, inventions, and innovations.

IPR ensures that the creator has exclusive rights to use, produce, and commercialize their work for a specific period.

It encourages innovation, research, and development in science, technology, and pharmaceuticals.

Objectives of IPR

1. Protection of innovations and creations from unauthorized use.
2. Encourage research and development in technology, medicine, and industry.
3. Promote fair competition and prevent counterfeit products.
4. Economic growth by enabling commercialization and licensing of innovations.
5. Legal recognition for inventors, authors, and creators.

Importance of IPR in Pharmaceuticals

1. Protection of new drugs and formulations from unauthorized manufacture.
2. Encourages R&D in drug discovery, vaccines, and biotechnology.
3. Promotes quality standards and discourages counterfeit drugs.
4. Enables patent licensing, technology transfer, and commercialization.
5. Protects trade secrets, trademarks, and proprietary knowledge of pharmaceutical companies.

Types of Intellectual Property Rights

Type	Definition	Example in Pharma
Patents	Exclusive rights to an invention for a fixed period (usually 20 years)	New drug molecule, drug delivery system, formulation
Copyright	Protection of original literary, artistic, or scientific work	Research publications, educational material, software
Trademarks	Protection of brand names, logos, and symbols	Brand name of drugs (e.g., Crocin, Metformin)
Industrial Design Rights	Protection of visual/design features of a product	Packaging design, inhaler design, tablet shape
Trade Secrets	Protection of confidential business information	Manufacturing process, formula, R&D data
Geographical Indications (GI)	Protection of products associated with a specific region	Herbal medicines like "Kashmir Saffron"
Plant Variety Protection	Protection of new plant varieties	Genetically modified medicinal plants

Patent in Pharmaceuticals

- Definition: A patent gives exclusive rights to the inventor to manufacture, use, and sell an invention.
- Requirements for Patentability:
    1. Novelty: Must be new and not disclosed before.
    2. Inventive Step: Must involve innovation beyond existing knowledge.
    3. Industrial Applicability: Must be useful and capable of industrial application.
- Duration: Usually 20 years from the date of filing.
- Examples: New drug molecules, novel drug delivery systems, medical devices.

Copyright in Pharmaceuticals

- Protects scientific publications, textbooks, software, and multimedia.
- Prevents unauthorized reproduction or distribution.

Trademarks in Pharmaceuticals

- Protect brand names, logos, or symbols used to identify pharmaceutical products.
- Prevents confusion in the market and ensures authenticity.