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## PHARMACEUTICAL JURISPRUDENCE

UNIT-5

PART-4

Intellectual Property Rights (IPR)









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### Intellectual Property Rights (IPR)

#### Introduction to IPR

- ➤ <u>IPR Definition:</u> Exclusive legal rights granted to creators/inventors for their intellectual creations (patents, trademarks, copyrights, industrial designs, trade secrets).
- Purpose: Protect originality of work, encourage innovation, promote transparency and quality.
- Scope: Covers artistic, literary, scientific, industrial fields; ensures certification and global recognition.







### Objectives of IPR

- Legal Entitlements: Provides various rights over intangible assets (ideas, information, products).
- Exclusive Rights: Holders can control how their creations are used and benefit economically.
- o Innovation Incentive: Encourages new products, processes and creative works.
- Jurisdiction Specificity: Acquisition, registration and enforcement must be pursued separately in each country.
- Example: A company patents a new drug in India and separately in the US to protect it in both markets.







- 3. Types of IPR (Make flowchart of it)
- **Patents** inventions.
- **Trademarks** brand identity and logos.
- **❖ Copyrights & Related Rights –** literary/artistic works.
- Geographical Indications region-specific products (e.g., Darjeeling tea).
- ❖ Industrial Designs ornamental/visual aspects.
- **Trade Secrets** confidential business info.
- ❖ Traditional Knowledge indigenous knowledge protection.







#### 4. Patents

- Definition: Exclusive right for a product or process offering a new solution or improvement.
- Protection: 20 years from filing; after expiry invention enters public domain.
- Rights of Owner:
- Make, use, distribute, license, sell invention.
- > Control over commercial exploitation.
- Public disclosure in exchange for protection (helps build global knowledge).







- Transfer/License: Owner can sell or license patent to others.
- Indian Patent Act Timeline:
  - 1911 Indian Patents and Designs Act.
  - 2005 Amended t1970 Patents Act introduced process patents.
  - o include product patents in food, drugs, chemicals, microorganisms.
- Criteria for Patentability: Novelty, inventive step, industrial applicability.
- Procedure for Grant:







- 1. File application.
- 2. Request examination within 48 months.
- 3. First Examination Report issued.
- 4. Compliance within 6 months (extendable by 3 months).
- 5. If unresolved within 9 months  $\rightarrow$  application abandoned.
- 6. Once requirements met  $\rightarrow$  patent granted & notified in Patent Office Journal.
- Benefits to Society: Innovation, technology transfer, increased public knowledge.







### 5. Trademarks

- > Definition: Distinctive sign identifying goods/services from a specific enterprise.
- Forms: Words, letters, numerals, symbols, 3D shapes, colours, sounds, fragrances.
- **Purpose:** 
  - Protect brand identity.
  - Assure consumers of quality and origin.
  - Exclusive right to use or license in return for payment.







- Registration: Prima facie proof of ownership; rights can be perpetual with 10-year renewals.
- **Examples:** Nike swoosh, Coca-Cola bottle shape, Intel jingle.

- 6. Copyrights & Related Rights
- Definition: Legal rights given to creators of literary and artistic works.
- Works Covered: Books, music, films, architecture, computer programs, databases, choreography, paintings, maps.







- ➤ <u>Automatic Protection:</u> Exists upon creation; registration not mandatory but provides legal evidence.
- **Economic Rights:** Reproduction, distribution, communication, licensing (royalties).
- **Duration**: Life of the author + 60 years.
- ➤ <u>Importance:</u> Encourages creativity, secures financial rewards, prevents plagiarism.







### 7. Industrial Designs

- **Definition:** Protection of ornamental/visual aspects of products; covers creative appearance.
- **Legislation:** New Designs Act, 2000; aligned with TRIPS standards.
- > Purpose:
  - Protects design element of industrial production.
  - Promotes innovation in industry and conformity with international trends.
- **Scope:** Detailed classification system; applied to all fields.
- Example: Unique bottle shapes, furniture design, textile prints.







### 8. Trade Secrets

- **Definition:** Confidential business information giving competitive advantage.
- **Examples:** Manufacturing methods, customer lists, marketing strategies.
- > Features:
  - No registration; protection maintained through secrecy.
  - Less expensive than patents but must remain confidential.
- ➤ <u>Importance</u>: Crucial for companies to retain proprietary know-how and safeguard innovations not suitable for patents.







### 9. Traditional Knowledge

- ➤ Definition: Indigenous knowledge developed over generations (e.g., Ayurveda, Yoga, agriculture).
- ➤ Need for Protection: Prevents biopiracy, promotes benefit-sharing, preserves cultural heritage.
- ➤ Importance in India: Vast availability makes protection crucial to reap economic and social benefits.







- **Patents:** 20 years, public disclosure, innovation incentive.
- > <u>Trademarks:</u> 10-year renewable protection of brand identity.
- **Copyrights:** Automatic, life + 60 years.
- > Industrial Designs: Visual aspect protection under New Designs Act.







- > Trade Secrets: Confidential info, no registration but must remain secret.
- > Traditional Knowledge: Vital to preserve indigenous knowledge.
- Overall Benefits of IPR:
- o Encourages innovation.
- o Protects investments.
- Promotes fair competition.
- Increases global trade credibility.









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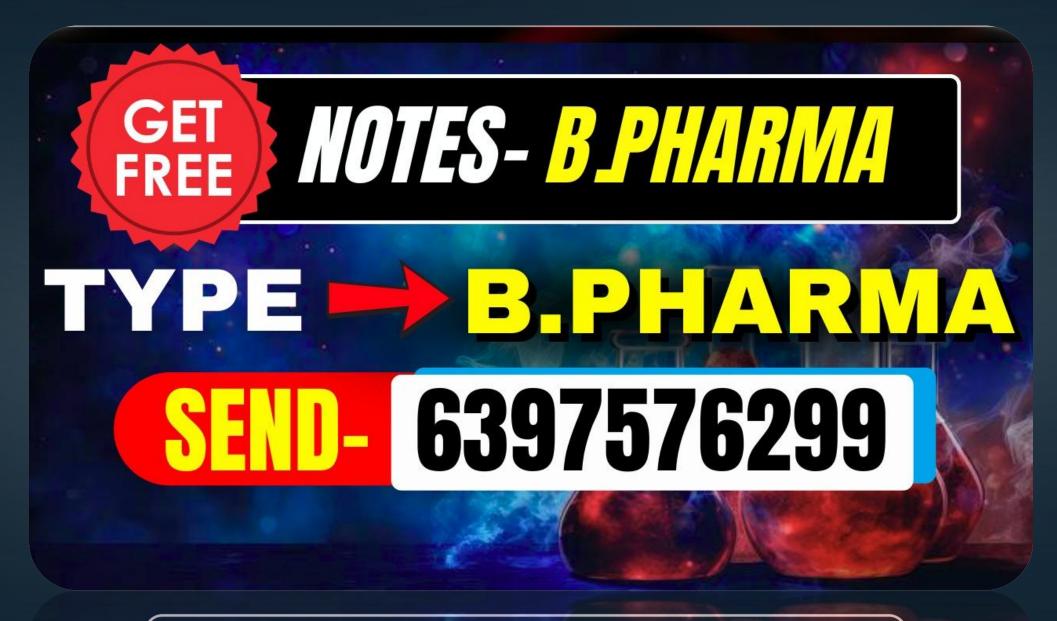
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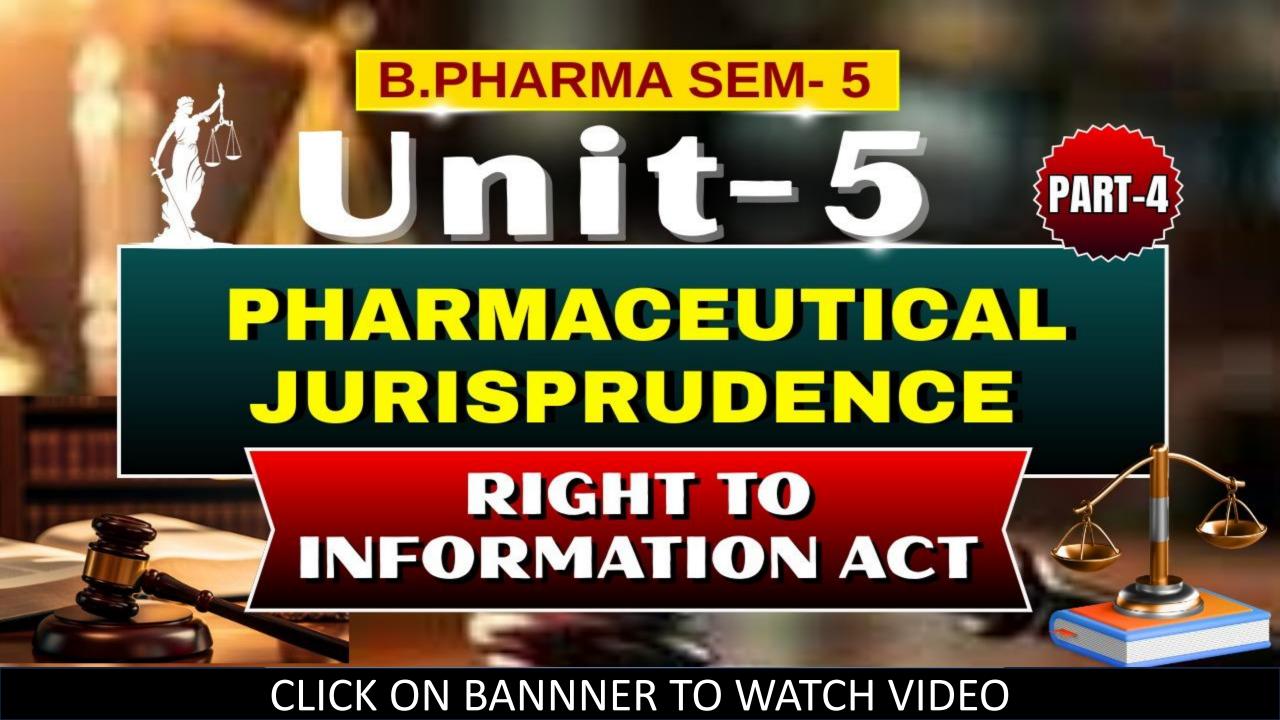
















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## PHARMACEUTICAL JURISPRUDENCE

<u>UNIT-5</u>

PART-4

Right to Information Act (RTI)







## Right to Information Act (RTI)

Topic	Key Points
Introduction	- Enacted in 2005 to give citizens the right to access information under public authorities.
	Promotes transparency, accountability & good governance.
	Extends to the whole of India.







### 2. Key Definitions

- ✓ Appropriate Government:
  - Central Government → Union/UT bodies.
  - $\circ$  State Government  $\rightarrow$  State public authorities.
- **✓ Public Authority:** 
  - Any authority established by the Constitution, Parliament, State legislature, or Government notification/order.
  - Examples: Ministries, Municipal Corporations, Universities, Public Sector Undertakings.







- ✓ Information:
- Any material in any form:
- Records, documents, memos, e-mails, reports, contracts, samples, models, electronic data.
- ✓ <u>Record:</u> Documents, files, microfilm, microfiche, facsimile, computer-generated material.
- ✓ <u>Third Party:</u> Any person or public authority other than the applicant requesting information.
- **✓** Central/State Information Commission:
- Established under Sections 12 and 15 respectively.
- Headed by Chief Information Commissioner (CIC) or State CIC.







### 3. Right to Information

- ✓ Every citizen has the right to access information held or controlled by public authorities.
- ✓ This includes the right to inspect works, take notes, certified copies, samples, or receive information in various formats (printed, digital, etc.).
- 4. Obligations of Public Authorities
- **✓** Record Management:
- ✓ Must maintain records catalogued, indexed, and computerised for easy access.







- ✓ Publish Information within 120 Days:
- Organisation & Functions: Name, duties, powers of officers.
- Decision-Making Process: Channels of supervision, accountability, rules, regulations, manuals, and categories of documents.
- > Financial Details: Budgets, expenditures, subsidy programmes, concessions.
- Personnel Details: Remuneration of officers, directory of staff, names of Public Information Officers.
- Public Consultation: Boards, councils, committees, and policies with public participation.







- ✓ Transparency:
- Publish facts while formulating policies.
- Provide reasons for administrative or quasi-judicial decisions to affected persons.
- 5. Designation of Public Information Officers
- > Every public authority must appoint:
- Central Public Information Officers (CPIOs) or State Public Information Officers (SPIOs) in all offices within 100 days.
- Assistant Public Information Officers at sub-divisional levels to accept applications and appeals.
- This decentralises RTI, making it easier for citizens to apply.







- 6. Request for Information
- **✓** Application Format:
- > Written or electronic, in English, Hindi, or the regional language.
- Applicant need not give reasons.
- **✓** Transfer of Application:
- > If connected to another authority, must be transferred within 5 days.







- ✓ Time Limit:
- 30 days for normal cases.
- **o** 48 hours if it concerns life or liberty.
- ✓ Assistance:
- Disabled persons or illiterate applicants get help in reducing request to writing.
- BPL (Below Poverty Line) applicants get free access.







### 7. Disposal of Requests & Fees

- ✓ Decision within 30 days; otherwise deemed refusal.
- ✓ Fees must be reasonable; none for BPL applicants or if authority delays beyond time limit.
- ✓ Applicant to be informed of additional fees with calculation details.
- ✓ Rejection must include:
- o Reasons.
- Appeal timeframe.
- Appellate authority details.







### 8. Exemptions from Disclosure

- **✓** No obligation to give information on:
- Security & Sovereignty: Information harming India's integrity, foreign relations, or leading to incitement.
- Parliamentary Privilege: Breach of privilege of Parliament or State Legislature.
- Trade Secrets/Commercial Confidence: If disclosure harms competitive position.
- Fiduciary Relationships: Unless larger public interest overrides.







- Foreign Government: Information received in confidence.
- Life & Safety: Disclosure endangering life or identifying informants.
- Investigations: Interfering with investigations or prosecutions.
- Cabinet Papers: Until decision is taken.
- Copyrighted Information of private persons.
- ✓ Severability:
- Non-exempt part of a record must still be shared.







- 9. Third Party Information
- ✓ If information concerns a third party:
- Notice to be given within 5 days.
- Third party's views considered before disclosure.
- Decision communicated to applicant and third party.







#### 10. Central Information Commission

- ✓ Constitution: By notification in the Official Gazette.
- **✓** Composition:
- Chief Information Commissioner + up to 10 Information Commissioners.
- **✓** Appointment Committee:
- PM (Chair), Leader of Opposition, Union Cabinet Minister.







- > Headquarters: Delhi (with approval, offices can be elsewhere).
- > Independence: Can act autonomously without government direction.
- ➤ Eligibility: Eminence in public life—law, social service, journalism, management, mass media, science/tech.
- Cannot hold political or profit office.







#### 11. Term of Office & Service Conditions

- ✓ CIC: Holds office as prescribed, not beyond 65 years, no reappointment.
- ✓ Information Commissioners: Same terms; can be promoted to CIC.
- ✓ Aggregate tenure as IC + CIC not more than 5 years.







#### 12. Key Highlights for Exams / Recap

- $\circ$  30 days → normal information; 48 hours → life or liberty.
- No reasons needed from applicant.
- Free for BPL; disabled applicants assisted.
- $\circ$  120 days  $\rightarrow$  authorities must publish proactive disclosures.
- Third party consultation mandatory.
- Independent Central & State Information Commissions ensure enforcement.







#### 13. Conclusion

- RTI Act is a powerful tool for transparency and accountability.
- Encourages citizen participation and reduces corruption.
- Public authorities are bound to proactively disclose information, not just respond to RTI queries.









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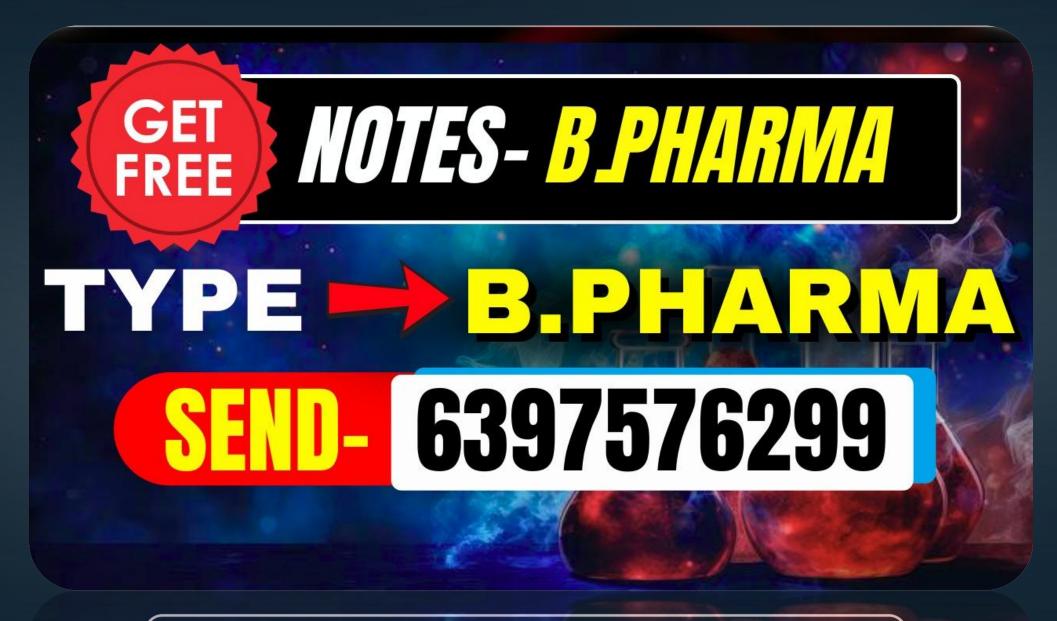




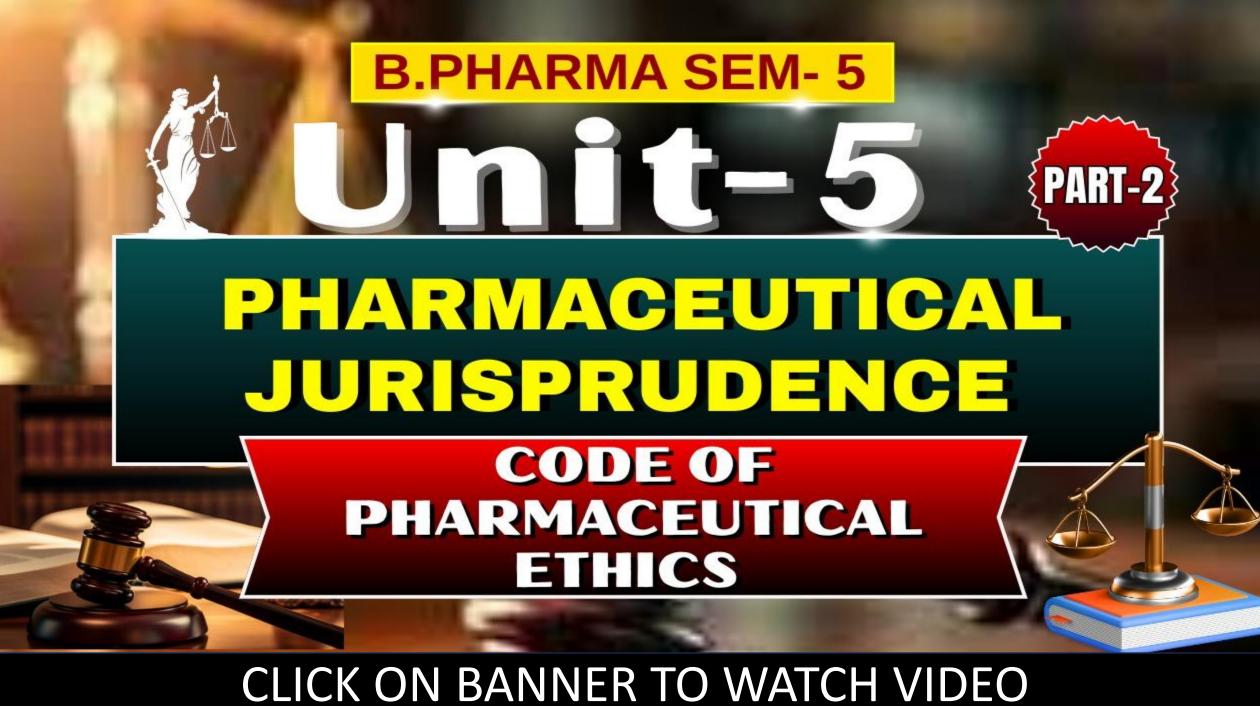
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# JURISPRUDENCE

**UNIT-5 PART-2** 

**CODE OF PHARMACEUTICALS ETHICS** 









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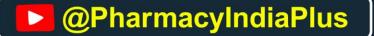
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#### **LAW**

- Defined as rules of human conduct binding on all people in a state or nation.
- If Law is broken, a violator may be subjected to punishment, a fine or imprisonment or both.







#### **ETHICS**

- Ethics means moral principle it is a science of moral duties.
- Defined as rules by which a profession regulate action and sets standard for all its member.
- If rule of ethics (professional conduct) are broken the professional body may subject the violator to loss of professional privileges.







#### Note:

- Law may prevent one from causing injury to another but it can't force him to help his neighbor in hour of need.
- Helping the neighbor is the function of ethic.







#### PHARMACEUTICAL CODE OF ETHICS

- Student in professional education must become competent in their profession, so he must be able to place his skills with the context of society
- The code of ethics formulated by the PCI for the guidance of Indian pharmacist
- As to how he should conduct himself in relation to himself his partrons and the general public his co-professional and the member of the medical and other health profession







#### **DEFINITION**

- **1. Pharmaceutical science:** Pharmacist provides efficient and reasonably comprehensive pharmaceutical service through medical stores, Involve
  - Commonly required medicine without delay.
  - Emergency supply at all time.
- **2. Pharmacy / Drug store:** Include avoidable risk be discussed with patient or other in the prescription, dispensing and supply of medicine







- **3. Prescription:** Prescription dispensing should be discussed with patient or other regulates merit and demerit of drugs.
- **4. Drug/Ingredient:** While dispensing the prescription the ingredients or drug must be weighted or measured correctly.
- **5. Apprentice pharmacist:** No certificate should be granted to the trainee pharmacist before completion of prescribed periods for training.







#### PHARMACIST IN RELATION TO HIS TRADE

- 1. Price structure: Charge from customer should be fair.
- 2. Fair trade practice: Should not make any attempt to capture the business of fellow pharmacist by unhealthy competition or cutthrough competition. Trademark symbol, another sign-should not be copied







#### 3. Hawking of drugs

- Hawking of drugs and medicines should not be practiced and any attempt should not be made to collect the orders from door to door.
- Self-service method in the pharmacy or drug store not be permitted encourage self-medication

#### 4. Advertisement and display:

 There should not be any display or advertisement on the premises in the newspaper.







#### Pharmacist should not make such advertisement

- a) Misleading or exaggerated statement or claims.
- b) A guarantee pf therapeutic efficacy
- c) An offer to refund money paid
- d) An appeal to fear
- e) The word cure in reference to the ailment or symptoms of ill health.
- f) A price competition or similar scheme.







#### C. PHARMACIST IN RELATION TO MEDICAL PROFESSION

- **1. Limitation of professional activities:** A pharmacist under no circumstance should practice medicine that is diagnosis disease and prescribing medicine.
- **2. Clandestine arrangement:** No any secret agreement with physician, to after him commission.
- **3. Liaison with public:** Being liaison between medical profession and public. Update him by modern development reading books, journals, magazines, periodicals etc.







#### D. PHARMACIST IN RELATION TO HIS PROFESSION

- 1. A pharmacist should observe the law and ethical principle to maintain the standard of the profession.
- 2. A pharmacist should extend the help and co-operation to his fellow pharmacist in an emergency.
- 3. A pharmacist should have for knowledge of laws of the state and nation.
- 4. A pharmacist should have up to date knowledge, he should associate himself with various pharmacist organization.
- 5. A pharmacist should not perform such act which will bring to his profession or to himself.





#### PHARMACIST'S OATH

- ☐ I Swear by the code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of health care team.
- ☐ I shall uphold the laws and standards governing my profession.
- ☐ I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
- I shall follow the system, which I consider best for pharmaceutical care and counseling of patients.
- ☐ I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.







- ☐ I shall hold in confidence the knowledge gained about the patients in connection with professional practice and never divulge unless compelled to do so by the law.
- ☐ I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organisations.
- While I continue to keep this Oath inviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times!
- ☐ Should I trespass and violate this oath, may the reverse be my lot!









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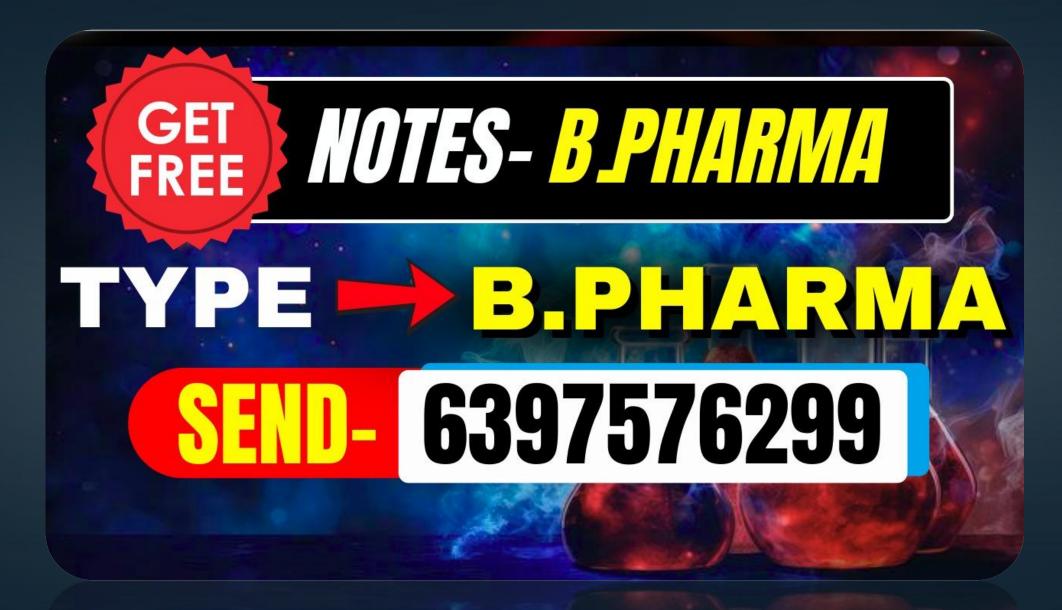




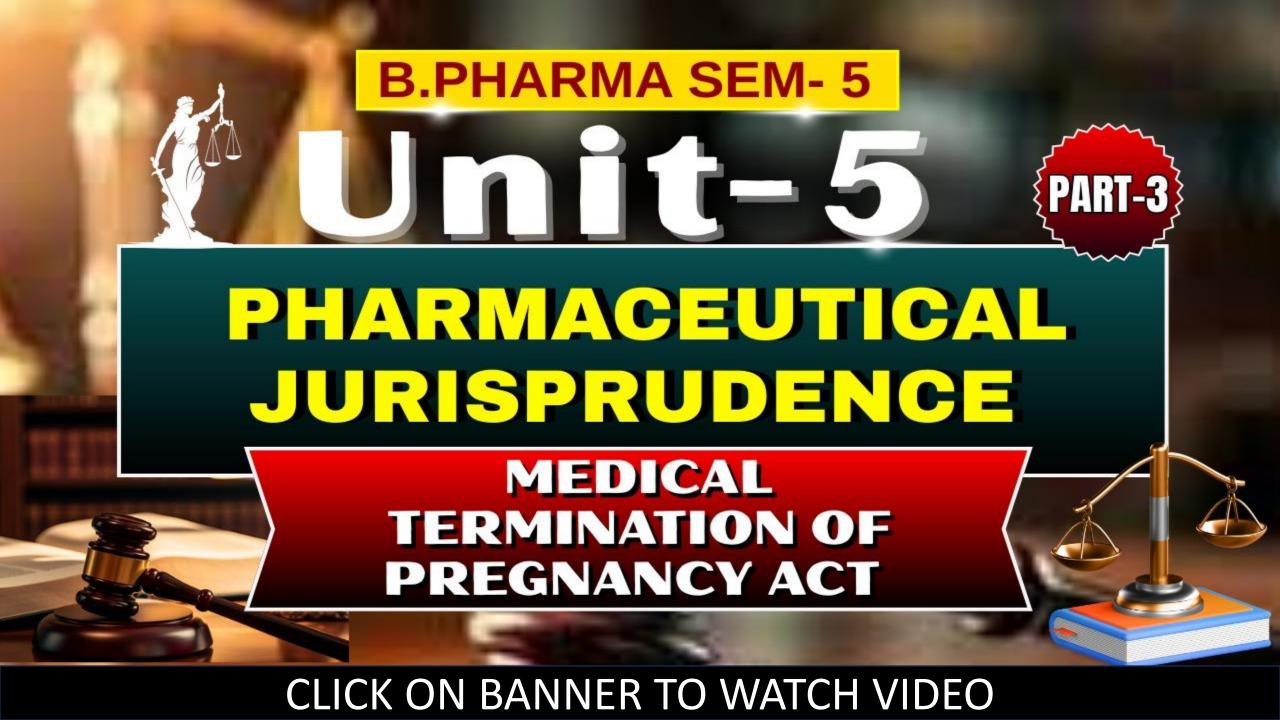
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### <u>JURISPRUDENCE</u>

**UNIT-5 PART-3** 

### MEDICAL TERMINATION OF PREGNANCY ACT









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First provision 1860: Under the provision it was deemed to be a crime for mother as well as for person doing this except done for safe mother life.

#### PHARMACIST'S OATH

Act passed	1971
Rules passed	1975







#### **IMPORTANT POINTS**

- ☐ Pregnancy termination consent shall be given in form C.
- □ Every RMP terminate pregnancy should certify such termination in the prescribed in form 1 within 3 hour from termination of pregnancy.
- Chief medical officer of the district approved the place.







#### **DEFINITION**

**Guardian:** Means a person having the care of minor or a lunatic (mentally ill person).

**Lunatic:** It has the meaning assigned to it in section 3 of the Indian lunacy act.

**Approved place:** It means the place approved under rule 4 of the medical termination of pregnancy act and rules.









# LAW REGARGING ABORTION SPECIALLY KEEPING THE FOLLOWING BACKGROUNDS

1.	Humanitarian aspects	Pregnancy arises due to sex crime, intercourse with a lunatic woman
2.	Health achects	Pregnancy gave risk to life or physical or mental health of a woman
3.	Huganic achacte	Where chile to be born is likely to have deformalities and/ or serious defects







#### **TERMINATION OF PREGNANCIES**

- Length of pregnancy does not exceed 12 weeks.
- The RMP may terminate a pregnancy where if it is more than the 12 weeks but not more than 20 weeks:- terminate only if it at least two medical practitioners are there.
- The RMP may terminate a pregnancy of a woman of 18 year of age or more with her written consent







- If less than 18 year of age or is lunatic (as defined in lunatic act 1972) with written consent of her guardian.
- No pregnancy shall be terminated without the consent of pregnant woman expect:
- The pregnant woman is less than 18 years in age.
- The pregnant woman lunatic although she has attained the age 18







#### **EXPERIENCE OF PERSON DOING ABORTION**

- (a) Medical practitioner registered before commencement of act:
  - Not less than 3 Year of experience in gynecology and obstetric.
- (b) Medical practitioners registered after commencement of act:
  - 1. Completed at least 6-month house surgery in gynecology and obstetric.
  - 2. He/she had experience at any hospital for not less than 1 year in practice of gynecology and obstetrics
  - 3. He has assisted a RMP in the performance pregnancy of 25 cases of medical termination of pregnancy in hospital by govt.
- (c) Hold post graduate degree or diploma in pregnancy in gynecology and obstetrics.







#### PLACE WHERE PREGNANCY MAY BE TERMINATED

- 1. Government hospital (safe and hygienic)
- 2. Place approved the purpose of this act (safe and hygienic)

#### Following facilitated are provided:

- (a) Operation table and instrument for surgery
- (b) Anaesthetic equipment, resuscitation equipment, sterilize
- (c) Drugs and parenteral fluid are emergency use.







#### **INSPECTION OF A PLACE FOR TERMINATION OF PREGNANCY**

- Inspected by CMO of district
- CMO may seize and article if he feels that death & injury to a woman has been caused and place does not have safe and hygiene condition







#### **MAINTENANCE OF ADMISSION REGISTER**

Admission of woman for the termination of pregnancies maintained in register and kept in safe custody by owner of hospital (should not open to inspect by any one)

#### **Except**

- 1. Chief Secretary of the state
- 2. First class magistrate
- 3. District judge







#### **OFFENCES AND PENALTIES**

S.NO	OFFENCES	PENALTIES
1.	Termination of pregnancy by a person other than RMP or termination of pregnancy other than prescribed place	Imprisonment for not less than 2 up to 7year.
2.	Willful contravention or willful failure to comply with the requirement of any regulation	Fine up to 1000









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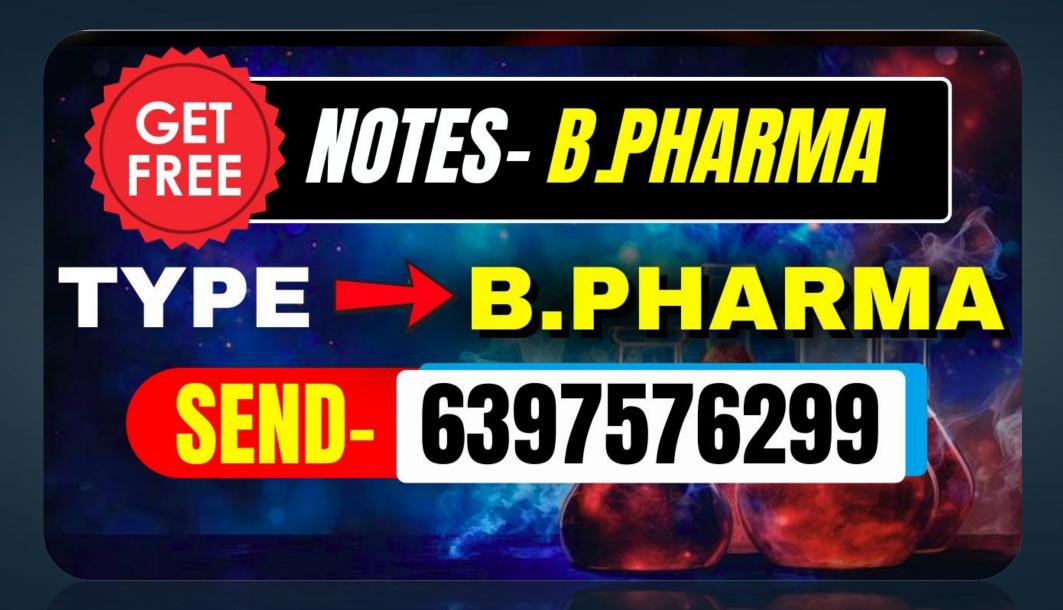




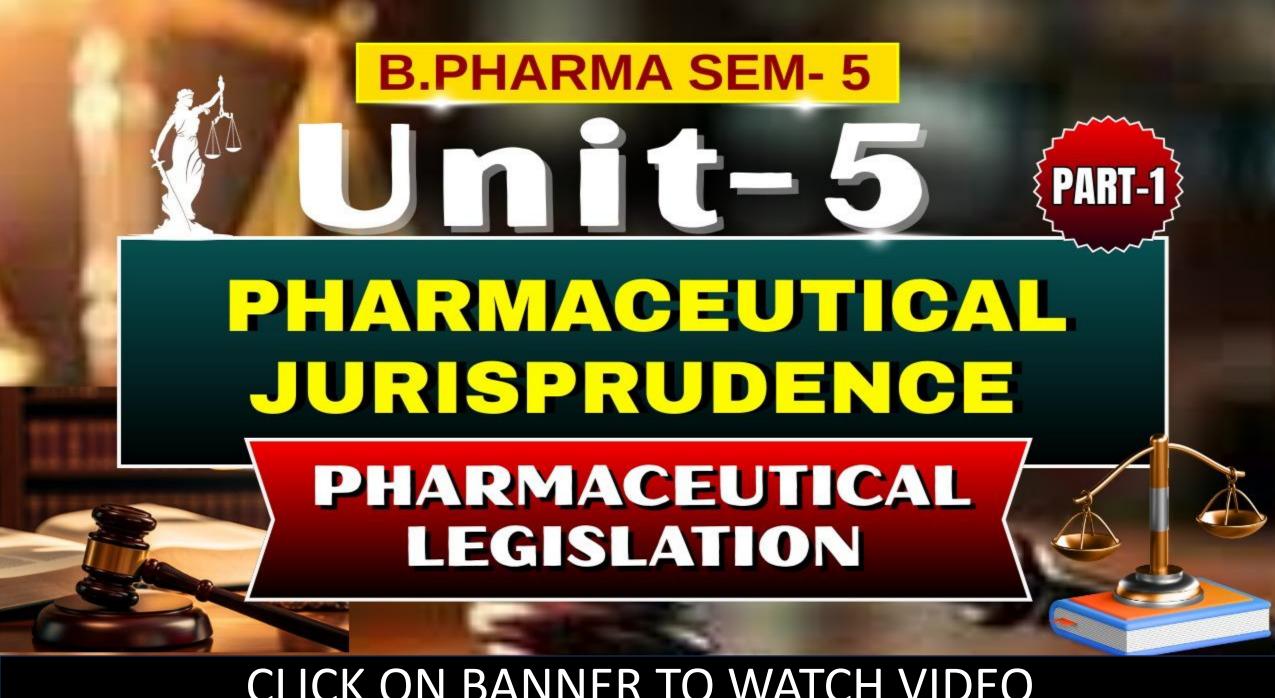
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# <u>JURISPRUDENCE</u>

**UNIT-5 PART-1** 

PHARMACEUTICAL JURISPRUDENCE









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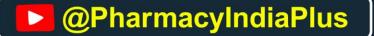
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#### PHARMACEUTICAL LEGISLATIONS

- Pharmaceutical legislation is a legislation which covers various laws enacted from time to time by the Government for the regulation of education, practice and pharmaceutical industry for promoting health care system and safeguarding public health.
- It is concerned with the social, economic and health aspects of the society.







- Jurisprudence is a place of inter assembly for judicial and other pharmacy.
- Pharmaceutical jurisprudence is the study of laws regulating the profession of pharmacy in India.







## **OBJECTIVES**

- To promote the health care system by regulating the manufacture and supply of good quality drugs
- To regulate the profession and business of pharmacy
- To promote the indigenous research technology
- To control the prices of drugs.
- To safeguard the public from such advertisements of drugs
- Makes false claim for the drug or gives the misleading information about the drug







### HEALTH SURVEY AND DEVELOPMENT COMMITTEES

#### **Bhore Committee:**

Government of India set up Health Survey and Development Committee in October 1943 under the chairmanship of Sir Joseph Bhore.

#### **Bhatia Committee:**

Government of India in 1953 appointed the pharmaceutical enquiry committee under the Chairmanship of Major General S. L. Bhatia to make enquiry into the working of pharmaceutical industry.







#### **Mudaliar Committee:**

Government of India in June 1959 under the Chairmanship of Dr. A. Lakshman Swamy Mudaliar appointed a Health Survey and Planning Committee.

#### **Hathi Committee:**

Government of India under the Chairmanship of Jaisukhlal Hathi appointed a committee. The report of this committee covered all aspects ranging from licensing, price control, import, role of foreign sector, quality control etc.







#### **BEFORE 1940**

**1664:** The first hospital was opened at Fort St. George, Madras.

**1820:** Lord Cornwallis started Opium factory at Ghazipur (U.P.).

**1824:** Hindustani versions (Devnagri and person scripts) of the London Pharmacopoeia were prescribed

**1857, 1878:** The Opium Act enacted.

**1868:** The Pharmacopoeia of India published under the authority of Secretary of State for India.

1889: The Indian Merchandise Marks Act enacted.







1894: The Indian Tariff Act enacted.

**1898:** The Sea Customs Act enacted.

1899: The Compounders training course started in Madras.

**1901:** Acharya P.c. Roy along with Kartik Chandra Bose established Bengal Chemical and Pharmaceutical Works at Calcutta.

1919: The Poisons Act enacted.

**1920:** All India Compounders and Dispensers Association was established.

**11-8-1930:** Drugs Enquiry Committee (D.E.C.) headed by Col R. N. Chopra constituted.







1932: A two-year Degree Course in Pharmaceutical Chemistry for B.Sc.

- Beginning of pharmacy education at Banaras Hindu University by Prof. Mahadev Lal Schroff (Father of Pharmacy Education in country),

1-11-1933: The Indian Medical Council Act enacted.

**1937:** Biological Standardization Laboratory (B.S.L.) established at Calcutta.

**1940:** Biological Standardization Laboratory was named as Central Drugs Laboratory (CDL) under DCA.







#### **AFTER 1940**

**1943:** Health Survey and Development Committee constituted under the chairmanship of Sir Justice Joseph Bhore.

**1944:** First I. P. Committee constituted.

**1949:** Dr. K.C.K.E. Raja was nominated by the Central Government as the first President of Pharmacy Council of India.

**1953:** First Education Regulations (E.R) as approved by the Ministry of Health & F.W., Government of India were notified.







**1954:** The Pharmaceutical Enquiry Committee recommended appointment of graduates in Pharmacy as Chief Pharmacists for all large hospitals.

**1954:** The first B. Pharmacy Course approved by Pharmacy Council of India at Birla College, Pilani.

**1955:** The first Diploma in Pharmacy Course approved by P.C.I. at Government Medical College, Amritsar.

**1963:** The Indian Hospitals Pharmacists Association (IHPA) was launched at Pilani, Rajasthan.

**2001:** The first pharmacist (Prof. C.K. Kokate) appointed as Vice-Chancellor of Indian University, (Kakatiya University A.P.),







## **Drugs Enquiry Committee (D.E.C.)**

headed by Col R. N. Chopra and Dr. B. Mukherjee as its assistant secretary.

Following are the terms of reference to the drugs enquiry committee;

- Examine the import, manufacture, and sale of impure or substandard drugs/chemicals (including those in British Pharmacopoeia) and recommend controls.
- Recommend extending such controls to other approved medicinal preparations and indigenous medicines.
- Assess the need for legislation to restrict pharmacy practice to qualified persons and give recommendations.







### The Committee finally recommended:-

- 1. Central legislation to control drugs and pharmacy. The legislation may consist of either a combined Drugs and Pharmacy Act or separate Drugs Act and separate Pharmacy Act.
- 2. Setting up of testing laboratories in all States to control the quality of production of drugs and pharmaceuticals and a control laboratory to control the quality of imported drugs and also to act as expert referee in case of disputed samples sent by local Governments.
- 3. Appointment of an Advisory Board to advise the Government in making rules to carry out the objects of the Act.
- 4. Setting up of courses for training in pharmacy and prescribing minimum qualification for registration as a pharmacist.







- 5. Registration of every patent and proprietary medicine of undisclosed formula manufactured in India or imported from outside the country.
- 6. The crude single drugs as well as compounded medicines used in the indigenous system of treatment should be brought under control.
- 7. The drugs industry in India should be developed.
- 8. The manufacturing in Medical Stores Depots should be gradually reduced.
- 9. Steps should be taken to compile an Indian Pharmacopeia.
- 10. The Cinchona Department should cultivate cinchona.









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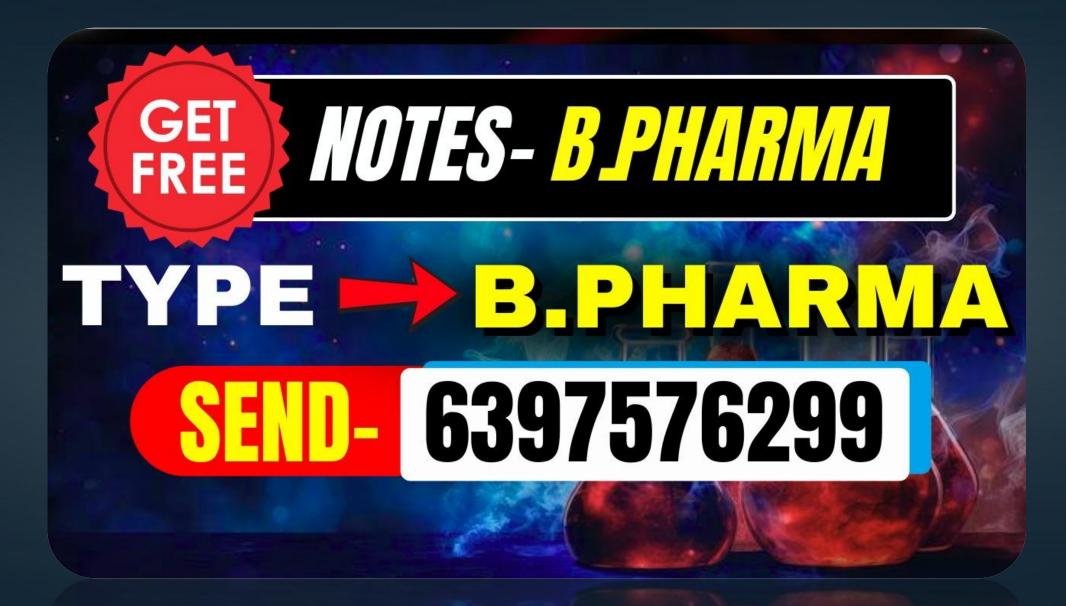




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