Unit-5

Pharmaceutical Jurisprudence

B.Pharma 5th Sem Notes

UNIT 5 TOPICS

- **Pharmaceutical Legislations:** Introduction, Drug Enquiry Committee, Health Survey & Development Committee (Bhore Committee), Hathi Committee, Mudaliar Committee
- **Code of Pharmaceutical Ethics:** Definition, Pharmacist in relation to job, trade, medical profession & his profession, Pharmacist's Oath
- **Medical Termination of Pregnancy Act – 1971:** Objectives, Definitions, Conditions, Practitioners, Records
- **Right to Information Act – 2005:** Objectives, Definitions, Public Information Officers, Procedure, Exemptions, Penalties
- **Introduction to Intellectual Property Rights (IPR):** Patents, Trademarks, Copyrights, Trade Secrets, GI Tags, Regulatory Exclusivity

PHARMACEUTICAL LEGISLATIONS –

Introduction to Pharmaceutical Legislations in India

- Pharmaceutical legislation in India refers to the body of laws, acts, rules, and regulations that govern the discovery, development, manufacture, quality control, distribution, sale, pricing, and use of drugs and medicines. India has one of the most comprehensive drug regulatory frameworks in the world, built over several decades through various committees and legislative enactments.
- The evolution of Indian pharmaceutical legislation began during the British era. The first major step was the Drugs Act of 1940 (now Drugs and Cosmetics Act, 1940). Since independence, several expert committees have recommended improvements to drug policy and legislation. Key legislations include: Drugs & Cosmetics Act 1940, Pharmacy Act 1948, Drugs & Magic Remedies Act 1954, Narcotic Drugs & Psychotropic Substances Act 1985, and the DPCO series.

Pharmaceutical Legislations in India

Year	Legislation / Event
1940	Drugs Act (now Drugs & Cosmetics Act, 1940) – Foundation of Indian drug law; regulates manufacture, distribution, sale of drugs
1945	Drugs & Cosmetics Rules, 1945 – Detailed rules under D&C Act; Schedules A–Y
1948	Pharmacy Act, 1948 – Regulation of pharmacy profession; PCI established
1954	Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954
1955	Medicinal & Toilet Preparations (Excise Duties) Act, 1955
1960	Prevention of Cruelty to Animals Act, 1960; CPCSEA
1970	Patents Act, 1970 – Introduced process patents for pharmaceutical products
1971	Medical Termination of Pregnancy Act, 1971
1985	Narcotic Drugs & Psychotropic Substances Act, 1985
1995	DPCO-1995 (now replaced by DPCO-2013)
1997	NPPA established for drug price control
2002	Patents (Amendment) Act – Transitional TRIPS compliance
2005	Patents (Amendment) Act – Product patents introduced; RTI Act 2005
2013	DPCO-2013 – Market-based ceiling price for NLEM medicines
2019	Drugs & Cosmetics (Amendment) Rules – New Drug Approval, Clinical Trials Rules

2023	Drugs, Medical Devices & Cosmetics Bill (proposed to replace D&C Act 1940)

Drugs Enquiry Committee (Chopra Committee) – 1930

DRUGS ENQUIRY COMMITTEE (CHOPRA COMMITTEE) – 1930

- Year: 1930 | Chairman: Lt. Col. R.N. Chopra
- Appointed by: Government of British India
- Context: Concern over import and use of substandard drugs in India; no uniform drug law existed at the time
- FINDINGS: Large quantity of substandard and spurious drugs being imported and sold; no mechanism to control drug quality; urgent need for a central drug regulatory law
- RECOMMENDATIONS:
- – Enact a comprehensive Central Drugs Act covering manufacture, sale, and import of drugs
- – Establish a Central Drugs Laboratory for testing drug quality
- – Create a Drug Control Organization with Drugs Controllers at Central and State levels
- – Regulate the import of drugs through a licensing system
- – Lay down standards for drug quality (pharmacopoeial standards)
- • OUTCOME: Led directly to the drafting and enactment of the Drugs Act, 1940 (later renamed Drugs & Cosmetics Act, 1940) – the cornerstone of Indian pharmaceutical legislation

Health Survey & Development Committee (Bhore Committee) – 1943–46

HEALTH SURVEY & DEVELOPMENT COMMITTEE – BHORE COMMITTEE

- Year: 1943 (Report: 1946) | Chairman: Sir Joseph Bhore (ICS Officer)
- Appointed by: Government of British India under Health Ministry
- Context: Post-war review of the entire health infrastructure of India; aimed at comprehensive health planning
- SCOPE: Covered all aspects of public health – hospitals, dispensaries, drug supply, pharmacy education, medical education, nutrition, vital statistics

FINDINGS:

- – Gross inadequacy of health services; huge rural-urban disparity
- – Shortage of trained medical and pharmacy personnel

- – Inadequate drug manufacturing capacity in India; excessive dependence on imports
- – Poor nutritional status of Indian population

RECOMMENDATIONS:

- – Establish comprehensive Primary Health Centres (PHCs) at rural level (1 PHC per 10,000–20,000 population)
- – Develop a National Health Service providing free preventive and curative care
- – Strengthen pharmacy education and drug manufacturing in India
- – Develop indigenous pharmaceutical industry to reduce import dependence
- – Integrate all health services under unified command
- – Introduce health insurance and social security for health
- SIGNIFICANCE: Blueprint for Indian public health system; PHC concept adopted; influenced post-independence health planning; often called 'Health Constitution of India'

Health Survey & Planning Committee (Mudaliar Committee) – 1959–61

HEALTH SURVEY & PLANNING COMMITTEE – MUDALIAR COMMITTEE

- Year: 1959 (Report: 1961) | Chairman: Dr. A. Lakshmanaswami Mudaliar (eminent physician)
- Appointed by: Government of India (post-independence review)
- Context: Review the progress since Bhore Committee recommendations; assess health status after 10 years of independence

FINDINGS:

- – Recommendations of Bhore Committee not adequately implemented
- – Hospital-centric approach; rural primary healthcare still neglected
- – Pharmacy education was developing but quality was uneven
- – Medical education quality needed improvement; too many low-quality medical colleges

RECOMMENDATIONS:

- – Consolidation of existing health infrastructure rather than rapid expansion
- – Strengthen Sub-Centres and PHCs; improve quality rather than quantity
- – Improve quality of medical and pharmaceutical education; restrict mushrooming of low-standard colleges
- – Rationalize drug production and strengthen essential drug availability
- – Greater emphasis on preventive medicine and health education
- – Regional coordination of health services for better efficiency
- – Recommended that District Hospitals be upgraded to teaching hospitals
- • SIGNIFICANCE: Mid-course correction of Indian health policy; emphasis on quality of existing facilities; influenced Second Five-Year Plan health priorities

Committee on Drugs and Pharmaceuticals (Hathi Committee) – 1974–75

COMMITTEE ON DRUGS & PHARMACEUTICALS – HATHI COMMITTEE

• Year: 1974 (Report: 1975) | Chairman: Jaisukhlal Hathi (Member of Parliament)

• Appointed by: Government of India (Ministry of Petroleum & Chemicals – then overseeing pharmaceutical industry)

• Context: India's pharmaceutical industry had grown but was dominated by multinational corporations (MNCs); concerns about drug pricing, essential drug availability, and national self-sufficiency in drug production

FINDINGS:

- – MNCs dominated the Indian pharmaceutical market; excessive profits being repatriated
- – Drug prices in India were among the highest in the world
- – Many irrational and hazardous drug combinations available in market
- – Inadequate production of essential medicines; over-reliance on imported APIs
- – Excessive advertising and promotion of drugs; prescribing influenced by commercial interests

RECOMMENDATIONS:

- – Nationalize the top 15–20 pharmaceutical companies to bring them under government control (controversial recommendation)
- – Introduce a core list of essential drugs; restrict production to essential drugs
- – Phase out MNCs from the Indian pharmaceutical market over a defined period
- – Strengthen the public sector pharmaceutical companies (IDPL, HAL, BCPL, etc.)
- – Impose strict price controls on all essential drugs
- – Ban combination products that are irrational or not scientifically justified
- – Develop indigenous capacity for Active Pharmaceutical Ingredient (API) production
- – Overhaul drug regulatory framework; improve drug quality standards
- – Mandatory generic prescribing by all government doctors

OUTCOMES & SIGNIFICANCE:

- – Nationalization recommendation NOT implemented (too controversial)
- – Led to the Drug Policy of 1978 and DPCO-1979 (comprehensive price control)
- – Pushed development of public sector pharma units
- – Concept of Essential Drugs List (later becoming NLEM) introduced in India
- – Most influential pharmaceutical policy committee in independent India

CODE OF PHARMACEUTICAL ETHICS & PHARMACIST'S OATH

CODE OF PHARMACEUTICAL ETHICS

Definition of Pharmaceutical Ethics

Pharmaceutical Ethics refers to the branch of ethics that deals with the moral principles, standards, and codes of conduct governing the professional practice of pharmacy. It defines the professional obligations and responsibilities of a pharmacist toward patients, fellow professionals, the healthcare system, and society at large. The Pharmacy Council of India (PCI) has formulated the Code of Pharmaceutical Ethics to guide the professional conduct of registered pharmacists in India.

> *'Pharmaceutical Ethics is the application of ethical principles to the profession of pharmacy, ensuring that pharmacists act in the best interest of patients and society while adhering to legal requirements and professional standards.'*

Pharmacist in Relation to His Job / Duties

The pharmacist's primary duty is to ensure the safe, effective, and rational use of medicines. The Code of Pharmaceutical Ethics specifies the following duties toward his job:

DUTIES OF PHARMACIST – IN RELATION TO HIS JOB

- DISPENSING ACCURACY: A pharmacist must dispense medicines accurately as per the prescription; must not substitute without the prescriber's consent
- DRUG INFORMATION: Provide correct, unbiased, and up-to-date drug information to patients and healthcare providers
- PATIENT COUNSELING: Counsel patients on the correct use of medicines, storage, potential side effects, and the importance of adherence
- PRESCRIPTION VERIFICATION: Check prescriptions for completeness, legality, therapeutic appropriateness, and drug interactions before dispensing
- RECORD KEEPING: Maintain complete, accurate, and confidential records of all prescriptions dispensed
- EMERGENCY SUPPLY: In emergencies, may supply a limited quantity of prescription medicine to prevent harm to the patient

- COMPOUNDING: Compound medicines accurately using approved formulae and quality raw materials
- AWARENESS OF LIMITATIONS: Must refer patients to a physician when the condition requires medical diagnosis or treatment beyond pharmacy scope
- CONTINUING EDUCATION: Remain updated with new drug developments, therapeutic advances, and regulatory changes
- • REFUSAL OF OBJECTIONABLE PRESCRIPTIONS: Must decline to dispense prescriptions that are illegal, forged, or clinically inappropriate

Pharmacist in Relation to Trade

A pharmacist engaged in the commercial aspects of pharmacy (retail, wholesale, or community pharmacy) must maintain ethical standards in business practices:

PHARMACIST'S ETHICS IN TRADE

- **FAIR PRICING:** Must sell drugs at fair prices; not charge exorbitant prices; not sell above MRP
- **NO SPURIOUS DRUGS:** Must not sell, stock, or supply spurious, misbranded, adulterated, or substandard drugs
- **HONEST LABELING:** Ensure all products are properly labeled with correct information; not mislead consumers
- **NO KICKBACKS:** Must not accept or give kickbacks, commissions, or inducements for prescribing or recommending specific brands
- **PROPER STORAGE:** Maintain appropriate storage conditions for all medicines; ensure cold chain where required
- **EXPIRY CHECK:** Must not sell expired medicines; must remove expired stock promptly
- **RATIONAL SALES:** Must not promote or encourage irrational drug use or self-medication of prescription drugs
- **ADVERTISEMENT:** Must not use unethical advertising; must not make false therapeutic claims
- **RECORD OF CONTROLLED DRUGS:** Maintain proper records of Schedule H, H1, X drugs as required by law
- **TRANSPARENCY:** Be transparent and honest in all business transactions with suppliers, patients, and authorities

Pharmacist in Relation to the Medical Profession

PHARMACIST'S RELATIONSHIP WITH MEDICAL PROFESSION

- **COLLABORATION:** Work collaboratively with physicians, nurses, and other healthcare professionals for optimal patient care
- **RESPECT FOR PRESCRIPTIONS:** Respect and dispense valid prescriptions from registered medical practitioners; do not alter without the prescriber's knowledge and consent
- **DRUG INFORMATION SUPPORT:** Provide accurate, evidence-based drug information to physicians when requested
- **REPORTING ADRs:** Report Adverse Drug Reactions (ADRs) to the concerned physician and pharmacovigilance authorities
- **NO DIAGNOSIS:** A pharmacist must not diagnose disease or prescribe treatment – this is within the domain of the medical profession
- **NO DISPARAGEMENT:** Must not make derogatory comments about physicians or medical treatment to patients
- **THERAPEUTIC CLARIFICATION:** If a prescription appears to have a potential error (dose, drug interaction), contact the prescriber to clarify before dispensing
- **INTERDISCIPLINARY RESPECT:** Maintain mutual respect and professional courtesy with all healthcare team members

Pharmacist in Relation to His Profession

PHARMACIST'S DUTIES TO HIS PROFESSION

- **PROFESSIONAL INTEGRITY:** Maintain high standards of professional conduct; act with honesty and integrity at all times
- **CONTINUING PROFESSIONAL DEVELOPMENT (CPD):** Keep up-to-date with advances in pharmaceutical sciences, therapeutics, and healthcare
- **MENTORING:** Guide and mentor junior pharmacists, pharmacy students, and pharmacy technicians
- **NOT BRINGING PROFESSION INTO DISREPUTE:** Avoid actions that would damage the image or reputation of the pharmacy profession
- **COMPLIANCE WITH LAW:** Obey all applicable pharmaceutical laws, rules, and regulations
- **REGISTRATION COMPLIANCE:** Keep registration current; display registration certificate prominently at place of practice
- **PROFESSIONAL ORGANIZATIONS:** Participate in and support professional pharmacy organizations
- **PUBLICATION & RESEARCH:** Contribute to the body of pharmaceutical knowledge through research and publication with integrity
- **CONFIDENTIALITY:** Maintain confidentiality of patient information; share only with authorized persons

- **PHARMACOVIGILANCE:** Actively participate in drug safety monitoring and adverse drug reaction reporting

Pharmacist's Oath (PCI Oath of a Pharmacist)

At the time of registration, every pharmacist takes a solemn oath (Oath of a Pharmacist) as prescribed by the Pharmacy Council of India. The full text of the oath is:

OATH OF A PHARMACIST

(As Prescribed by the Pharmacy Council of India)

At this moment, I solemnly pledge myself to dedicate my life to the service of humanity through the profession of pharmacy.

I will keep the honor and noble traditions of the pharmacy profession. I will consider the welfare of humanity and relief of suffering my primary concerns.

I will apply my knowledge, experience, and skills to the best of my ability to ensure optimal drug therapy outcomes for the patients I serve.

I will hold in confidence the information entrusted to me by patients and use it only for the purposes intended, to the benefit of those patients.

I will work with other members of the health professions and the public to promote and support measures to meet the health needs of the public.

I will maintain the highest principles of moral and ethical conduct. I will not allow considerations of race, religion, nationality, party politics, social standing, financial reward or personal gain to affect my duty to people.

I will endeavor to keep abreast of developments in my profession. I vow to devote my professional life to the service of others and will not misuse the knowledge gained.

I make these promises solemnly, freely, and upon my honor.

Principles of the Oath (Summary)

Principle	Meaning
Service to Humanity	Primary purpose of pharmacy is to serve humanity and relieve suffering
Welfare of Patients	Patient welfare is paramount; place patient interests above personal gain
Competence	Apply knowledge and skills to the best of ability for optimal outcomes

Confidentiality	Maintain confidentiality of patient information at all times
Teamwork	Work collaboratively with other healthcare professionals
Non-Discrimination	Serve all patients without discrimination based on race, religion, caste, gender, or financial status
Continuing Education	Keep knowledge and skills updated throughout professional life
Ethical Conduct	Maintain highest moral and ethical principles in all professional activities

MEDICAL TERMINATION OF PREGNANCY (MTP) ACT – 1971

MEDICAL TERMINATION OF PREGNANCY (MTP) ACT – 1971

Introduction & Background

The Medical Termination of Pregnancy Act, 1971 (Act No. 34 of 1971) was enacted to provide for the termination of certain pregnancies by registered medical practitioners. It came into force on 1st April, 1972. Prior to this Act, abortion was illegal in India under Section 312 of the Indian Penal Code (IPC) 1860. The Act was amended significantly in 2021 (MTP Amendment Act, 2021) to expand access to safe abortion services. The Act extends to the whole of India except Jammu & Kashmir (now also applicable after J&K reorganization).

Objectives of MTP Act – 1971

OBJECTIVES

- To legalize termination of pregnancy under specified conditions and within defined gestational limits
- To make abortion services accessible to women who need them for medical, social, or personal reasons
- To protect women from unsafe and clandestine abortions which were causing high maternal mortality
- To safeguard the rights of women to make decisions regarding their own reproductive health
- To specify the qualifications of medical practitioners authorized to perform abortions
- To specify the conditions of the place where termination of pregnancy can be performed

- To prevent sex-selective abortion (the Act does not permit abortion solely for sex selection – PCPNDT Act governs this separately)
- • To protect the medical practitioner performing the abortion in good faith from criminal prosecution

Definitions

Term	Definition
Registered Medical Practitioner (RMP)	A medical practitioner who possesses a recognized medical qualification under the Indian Medical Council Act and is registered with the Medical Council; for performing terminations, must have specified experience/training in OBG
Gestational Age / Length of Pregnancy	Calculated from the first day of the last menstrual period (LMP)
Guardian	In relation to a minor or a woman of unsound mind – means a person having the care of the minor or that woman
Minor	A person who has not completed 18 years of age
Pregnancy	The condition of having a developing embryo or fetus in the uterus
Termination of Pregnancy	The ending of a pregnancy by medical or surgical means before viability of the fetus
Approved Place	A hospital established or maintained by the Government OR a place approved by the Government for the purpose of termination of pregnancy

When Can Pregnancy Be Terminated?

Section 3 of the MTP Act lays down the conditions under which a registered medical practitioner may terminate a pregnancy:

Gestational Limit	Conditions & Requirements (Post MTP Amendment 2021)
UP TO 20 WEEKS (One RMP required)	Single registered medical practitioner opinion is sufficient. Grounds: (a) Continuation would involve risk to life of pregnant woman, or grave injury to her physical or mental health; OR (b) Substantial risk that child if born would be seriously handicapped due to physical or mental abnormalities; OR (c) Pregnancy resulting from failure of contraceptive used by a married woman or her husband
20–24 WEEKS (Two RMPs required)	Two registered medical practitioners must give their opinion in good faith. Available to specific categories: (i) Survivors of sexual assault or rape; (ii) Minors; (iii) Change of marital status (widowhood/divorce); (iv) Women with disabilities (as defined by

	Rights of Persons with Disabilities Act 2016); (v) Fetal malformation incompatible with life or severe abnormality; (vi) Women in humanitarian settings
BEYOND 24 WEEKS (Medical Board)	Only in cases of fetal anomalies diagnosed post 24 weeks. A Medical Board constituted by every State/UT Government must approve the termination. Board includes: Gynecologist, Pediatrician, Radiologist/Sonologist, and other specialists as required
EXPLANATION 1 (Mental anguish presumed)	For rape survivors: anguish caused by pregnancy resulting from rape shall be presumed to constitute grave injury to mental health of the pregnant woman
EXPLANATION 2 (Contraceptive failure)	Failure of contraceptive extends to UNMARRIED women as well (as per MTP Amendment Act 2021) – this is a major expansion from the original Act

Qualifications of Registered Medical Practitioner for MTP

QUALIFICATIONS OF RMP FOR PERFORMING TERMINATION

- Must possess a recognized medical qualification under Indian Medical Council Act 1956 or under any other corresponding State laws
- Must be registered with the Medical Council of India or State Medical Council
- Must have experience or training in Obstetrics & Gynaecology as specified:
- – Medical Practitioner with postgraduate degree/diploma in OBG (MD/MS/DNB/DGO) – eligible immediately after registration
- – Medical Practitioner with MBBS + at least 6 months' house surgeonship in OBG at an approved hospital
- – In Government-owned hospitals: any medical practitioner with 3 years' experience in a place where MTP is regularly performed
- For medical method of abortion (use of mifepristone + misoprostol up to 9 weeks): MBBS registered practitioner is eligible
- • ASHA workers: Not authorized to independently perform/prescribe MTP; they only provide information and facilitate access

Approved Places for MTP

Termination of pregnancy can be performed only at the following approved places:

APPROVED PLACES FOR PERFORMING MTP

- A hospital established or maintained by the Central or State Government
- A place approved for this purpose by the Central or State Government (a private hospital/clinic that has obtained approval)

- Approval Criteria: The facility must have the required infrastructure – operation theatre, anesthesia equipment, resuscitation equipment, post-operative care facilities
- MTP Amendment 2021: Telemedicine consultations for medical method of abortion (pill-based abortion) permitted at home up to 9 weeks – a major liberalization

Confidentiality & Record Keeping [Section 5A & Rules]

CONFIDENTIALITY & RECORDS

- **STRICT CONFIDENTIALITY:** The registered medical practitioner who terminates a pregnancy is not permitted to disclose the name and other details of the woman to any person other than a person authorized by law
- **RECORDS:** Every approved place must maintain a register of all terminations performed; includes date, gestational age, grounds, method used, practitioner name
- **RETENTION:** Records must be maintained for a period of 5 years
- **ACCESS TO RECORDS:** Only authorized government inspectors/health authorities may access the register
- **VIOLATION:** Disclosure of identity of the woman is an offence punishable under the Act

Offences & Penalties:

Offence	Penalty
Termination of pregnancy by a person not being a registered medical practitioner [Sec 5(1)]	Rigorous Imprisonment not less than 2 years; may extend to 7 years
Termination of pregnancy by RMP in conditions not prescribed (outside law) [Sec 5]	Rigorous Imprisonment not less than 2 years; may extend to 7 years
Termination in a place not approved under the Act	Prosecution; imprisonment up to 7 years
Disclosure of identity of the woman [Sec 5A]	Imprisonment up to 1 year, or Fine, or Both
Sex-selective abortion (covered under Pre-Conception and Pre-Natal Diagnostic Techniques – PCPNDT Act)	Under PCPNDT Act: imprisonment up to 3–5 years + fine

IMPORTANT POINTS – MTP ACT 2021 AMENDMENTS

- Upper gestational limit for single-provider abortions extended from 12 to 20 weeks
- New category of 20–24 weeks created for special categories of women (rape survivors, minors, disabled, etc.)
- Medical Board mechanism introduced for abortions beyond 24 weeks (fetal anomalies)

- Contraceptive failure grounds extended to include UNMARRIED women (previously only married women)
- Confidentiality provisions strengthened; identity of woman must not be disclosed
- • Telemedicine provision for medical abortion (pills) up to 9 weeks introduced

RIGHT TO INFORMATION (RTI) ACT – 2005

RIGHT TO INFORMATION (RTI) ACT – 2005

Introduction:

The Right to Information Act, 2005 (Act No. 22 of 2005) was enacted to provide citizens with the right to access information held by public authorities. It came into force on 12th October, 2005 (except certain provisions which came into force earlier). The RTI Act replaces the Freedom of Information Act, 2002 which was never implemented. The Act is based on the constitutional right of freedom of speech and expression (Article 19(1)(a)) and the right to know, derived from it. The Act extends to the whole of India except Jammu & Kashmir (now also covers J&K after reorganization).

Objectives of RTI Act – 2005

OBJECTIVES

- To promote transparency and accountability in the working of government/public authorities
- To empower citizens with the right to seek information from public authorities
- To combat corruption by bringing government operations under public scrutiny
- To ensure that democracy works for people in the real sense by making information available
- To contain corruption and hold governments and their instrumentalities accountable to the governed
- To protect citizens' right to information as a fundamental right under the Constitution
- To create a system of information officers at all levels of government for effective implementation
- To establish Central and State Information Commissions as quasi-judicial bodies for redressal

Definitions:

Term	Definition
Information	Any material in any form including records, documents, memos, emails, opinions, advices, press releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material held in any electronic form
Right to Information	The right to: inspect works/documents/records; take notes/extracts/certified copies; take certified samples; obtain information in diskette/floppy/tape/video cassette/any other electronic mode
Public Authority	Any authority or body or institution of self-government established or constituted by the Constitution, by any other law made by Parliament or State Legislature, or by notification issued or order made by the Central/State Government; includes bodies substantially financed by government
Public Information Officer (PIO)	A Central/State Government officer designated to receive and respond to RTI applications filed with a public authority
Applicant	Any citizen of India who seeks information under the RTI Act
Central Information Commission (CIC)	Apex body at the central level for appeals and complaints under RTI Act; headed by Chief Information Commissioner
State Information Commission (SIC)	Apex body at the state level; headed by Chief State Information Commissioner
Third Party	A person other than the citizen making the request; a person whose interests may be affected by disclosure of information

Public Information Officer (PIO)

PUBLIC INFORMATION OFFICER (PIO) –FACTS

• DESIGNATION: Every public authority must designate one or more officers as PIO [Section 5]

• ASSISTANT PIOs: Designated at sub-district/sub-divisional level to receive applications and forward to PIOs

• RESPONSIBILITY: The PIO is responsible for providing information to the applicant within the prescribed time limit

• TIME LIMIT: 30 days from receipt of application; 48 hours if information concerns life/liberty of a person

• TRANSFER OF APPLICATION: If the application does not pertain to the PIO's office, must be transferred to the correct PIO within 5 days

• PENALTY FOR DEFAULT: If PIO fails to provide information or gives incorrect/incomplete/misleading information: penalty of Rs. 250 per day (up to Rs. 25,000) + disciplinary action

• FIRST APPELLATE AUTHORITY: An officer senior to the PIO within the same organization – hears appeals from applicant when dissatisfied with PIO's response

Procedure for Filing RTI Application

Step	Details
Step 1: Identify PIO	Identify the Public Information Officer of the concerned public authority from which information is sought
Step 2: File Application	Submit written application (in English/Hindi/official language of area) to the PIO; online filing available at rtionline.gov.in
Step 3: Pay Fee	Application fee: Rs. 10 (Central Govt.); State fees vary; BPL card holders are exempt from fee
Step 4: PIO Processes	PIO must respond within 30 days (48 hours for life/liberty matters); may transfer to correct PIO within 5 days if needed
Step 5: Response	PIO provides information or gives reasoned rejection citing relevant exemption clauses
Step 6: First Appeal	If dissatisfied: file first appeal with First Appellate Authority within 30 days of PIO's response (or non-response); FAA must decide within 30 days (extendable to 45 days)
Step 7: Second Appeal	If still dissatisfied: file second appeal with CIC/SIC within 90 days of FAA decision
Step 8: CIC/SIC Order	Information Commission hears appeal; can impose penalty on PIO; order compliance

Exemptions from Disclosure:

Section 8 lists the categories of information that are exempt from disclosure under RTI:

INFORMATION EXEMPT FROM DISCLOSURE [SECTION 8]

- (a) Information that would prejudicially affect the sovereignty, integrity, security, strategic, scientific, or economic interests of India; relation with foreign states; or lead to incitement of offence
- (b) Information expressly forbidden to be published by any court of law or whose disclosure may constitute contempt of court
- (c) Information, disclosure of which would cause a breach of privilege of Parliament or State Legislature
- (d) Commercial confidence, trade secrets, or intellectual property of a third party, disclosure of which would harm their competitive position (unless the public interest overrides)
- (e) Information available to a person in his fiduciary relationship, unless the public authority is satisfied that the larger public interest warrants disclosure
- (f) Information received in confidence from a foreign government

- (g) Information that would endanger life or physical safety of any person, or identify the source of information given in confidence
- (h) Information that would impede the process of investigation, apprehension or prosecution of offenders
- (i) Cabinet papers including records of deliberations of the Council of Ministers, Secretaries, and other officers
- (j) Information which relates to personal information, disclosure of which has no relationship to any public activity or which would cause unwarranted invasion of the privacy of an individual
- • NOTE: Notwithstanding these exemptions, any information that cannot be denied to Parliament or State Legislature cannot be denied to a citizen

Penalties:

Violation	Penalty
PIO fails to receive RTI application without reasonable cause	Rs. 250 per day of delay; Maximum Rs. 25,000
PIO fails to furnish information within time limit	Rs. 250 per day of delay; Maximum Rs. 25,000
PIO denies request for information without reasonable cause	Rs. 250 per day; Maximum Rs. 25,000
PIO knowingly gives incorrect, incomplete, or misleading information	Penalty up to Rs. 25,000
PIO destroys information requested	Rs. 25,000 penalty + disciplinary action under service rules
PIO obstructs furnishing of information	Fine + disciplinary action

RTI and Pharmaceutical Sector

RELEVANCE OF RTI TO PHARMACY

- Drug approval data: Citizens can seek information about drug approval decisions, committee reports from CDSCO/DCGI
- Drug pricing: RTI can be used to seek information from NPPA on ceiling price calculations, notifications
- Drug recalls: Information about drug recall orders from State/Central Drug Controllers
- Clinical trial data: Information about clinical trial approvals, adverse events reported (subject to exemptions for commercial confidentiality)

- NPPA enforcement: Information on overpricing complaints and action taken
- Pharmacy College approvals: Information from PCI/State Pharmacy Councils about inspection reports, approvals/rejections
- • Government hospital procurement: Drug procurement data from public hospitals/ESIC/Railways pharmacies

INTRODUCTION TO INTELLECTUAL PROPERTY RIGHTS (IPR)

INTRODUCTION TO INTELLECTUAL PROPERTY RIGHTS (IPR)

What are Intellectual Property Rights?

Intellectual Property Rights (IPR) are legal rights that protect creations of the mind – inventions, literary and artistic works, symbols, names, images, and designs used in commerce. IPRs give the creator or inventor an exclusive right to use their creation for a defined period, in exchange for public disclosure of the invention. The World Intellectual Property Organization (WIPO) administers international IPR treaties. In India, IPRs are governed by several statutes and aligned with the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) of the WTO.

> *'Intellectual Property Rights are legal protections granted by governments to creators and inventors, giving them exclusive control over the use of their creations for a specified period, in exchange for public disclosure.'*

Importance of IPR in Pharmacy & Pharmaceutical Sciences

WHY IPR IS IMPORTANT IN PHARMACEUTICAL SCIENCES

- **INCENTIVIZES INNOVATION:** Patents protect the enormous investment (Rs. 1000–5000 crores) required to develop a new drug; without protection, no company would invest in R&D
- **ENABLES TECHNOLOGY TRANSFER:** IPR framework facilitates licensing of pharmaceutical technology between countries and companies

- **GENERIC DRUG ENTRY:** When patents expire, generic manufacturers can produce affordable versions – critical for healthcare access
- **BRANDING & QUALITY ASSURANCE:** Trademarks protect brand identity and assure consumers of consistent quality
- **REGULATORY EXCLUSIVITY:** Data exclusivity protects clinical trial data submitted for drug approval, separate from patent protection
- **TRADITIONAL KNOWLEDGE PROTECTION:** GI tags and biodiversity laws protect India's traditional medicinal knowledge from biopiracy
- **COMPULSORY LICENSING:** Allows governments to override patents in public health emergencies to ensure access to essential medicines (e.g., HIV antiretrovirals)

Types of Intellectual Property Rights

◆ A. PATENTS

A patent is an exclusive right granted for an invention – a product or process that provides a new way of doing something, or offers a new technical solution to a problem. In India, patents are governed by the Patents Act, 1970 (as amended in 1999, 2002, and 2005).

Aspect	Details
Governing Law	Patents Act, 1970 (amended 2005 for TRIPS compliance)
Duration	20 years from the date of filing of the patent application
Types of Patents	(1) Product Patent – for a product (introduced for pharma in 2005); (2) Process Patent – for a method of making a product
Criteria for Patent	(1) Novelty – must be new; (2) Inventive step/Non-obviousness; (3) Industrial applicability/Usefulness
Section 3(d) of Patents Act	A landmark Indian provision: enhanced forms of known substances are not patentable unless they show significantly enhanced efficacy; prevents 'evergreening' of pharmaceutical patents
Compulsory Licensing [Sec 84]	After 3 years, if a patent is not worked at reasonable price, any person can apply for compulsory license; India granted first CL in 2012 (Bayer's Sorafenib/Nexavar to Natco)
Patent Office	Controller General of Patents, Designs & Trade Marks; offices at Mumbai, Delhi, Chennai, Kolkata
Pharmaceutical Relevance	Patents on new chemical entities (NCEs), drug delivery systems, synthesis processes, formulations, combinations

◆ B. TRADEMARKS

A trademark is a sign (word, name, symbol, design, or combination) that distinguishes the goods or services of one enterprise from those of others. In pharmacy, brand names of drugs are registered as trademarks.

TRADEMARKS –

- **Governing Law:** Trade Marks Act, 1999; Trade Marks Rules, 2017
- **Duration:** 10 years; renewable indefinitely for every 10 years on payment of renewal fee
- **Registration:** Application to Trade Marks Registry (under CGPDTM); 45 classes of goods/services
- **Pharmaceutical Trademarks:** Brand names like Crocin, Combiflam, Disprin, Augmentin are registered trademarks
- **Section 135 IPC:** Counterfeiting a trademark is a criminal offence – imprisonment up to 3 years + fine
- Generic Names: Generic (INN) names of drugs cannot be trademarked – they belong to the public domain
- **Well-Known Marks:** Trademarks that are very famous (like Aspirin brand) get enhanced protection across all classes

◆ C. COPYRIGHTS

COPYRIGHTS –

- **Governing Law:** Copyright Act, 1957 (amended 2012)
- **Duration:** Life of the author + 60 years (for literary, artistic, musical works); 60 years for films, sound recordings, broadcasts
- **What is Protected:** Literary works (textbooks, drug information databases), computer software, artistic works, sound recordings, films
- **No Registration Required:** Copyright arises automatically on creation; registration provides evidence in legal disputes
- **Pharmaceutical Relevance:** Protects drug information compendia (like drug interaction databases), educational materials, pharmaceutical software, package insert content
- **Fair Use:** Limited use of copyrighted material for education, research, and criticism is permitted

◆ D. TRADE SECRETS

TRADE SECRETS –

- **Definition:** Confidential business information that provides a competitive advantage; not publicly disclosed

- **Governing Law:** No specific statute in India; protected under contract law and common law; Information Technology Act 2000 partially covers
- **Duration: Indefinite** – as long as the information remains secret
- **Pharmaceutical Examples:** Manufacturing process details, formulation know-how, analytical methods, customer lists
- **Protection Mechanism:** Confidentiality agreements (NDAs), non-compete clauses, access restrictions, employment contracts
- **Loss of Protection:** Once disclosed to the public (by accident or publication), trade secret protection is lost
- **Difference from Patent**: No public disclosure required; no time limit; no registration; but cannot prevent independent discovery

◆ E. GEOGRAPHICAL INDICATIONS (GI Tags)

GEOGRAPHICAL INDICATIONS (GI TAGS)

- **Governing Law:** Geographical Indications of Goods (Registration & Protection) Act, 1999
- **Definition:** A GI tag is a sign used on products that have a specific geographical origin and possess qualities, reputation, or characteristics attributable to that origin
- **Duration:** 10 years; renewable
- **Pharmaceutical/Medicinal Relevance:** Darjeeling Tea, Assam Tea (health products); Malabar Pepper; Traditional medicinal herbs with specific geographic origin
- **Protection:** Prevents unauthorized use of a GI designation on products from other regions
- **TRIPS Article 22-24:** International protection of GIs under TRIPS Agreement

◆ F. REGULATORY DATA EXCLUSIVITY

Regulatory data exclusivity is a form of intellectual property protection that prevents regulatory authorities from relying on the originator's clinical trial data to approve generic competitors for a specified period, separate from patent protection.

REGULATORY DATA EXCLUSIVITY

- **Under TRIPS Article 39.3:** Protection of undisclosed regulatory data submitted for drug approval
- **New Drug Data Exclusivity:** Typically 3–5 years in different countries; in India, New Drug Rules 2019 provide exclusivity to innovators
- **Pharmaceutical Significance:** Even after patent expiry, generic companies cannot reference innovator's clinical data during the exclusivity period
- **TRIPS-Plus provisions in FTAs:** Some bilateral trade agreements require longer data exclusivity periods – concern for generic drug access in India

TRIPS Agreement & India

Aspect	Details
Full Name	Trade-Related Aspects of Intellectual Property Rights Agreement
Organization	World Trade Organization (WTO)
Year	1994 (Uruguay Round); came into force 1995
India's Obligation	As a WTO member, India was required to amend IP laws to comply with TRIPS by 1st January 2005 for product patents in pharmaceuticals
Change in India	Patents Amendment Act 2005 introduced product patents for drugs (previously only process patents since 1970)
Section 3(d)	India's shield against 'evergreening' – enhanced forms of known substances not patentable unless significantly enhanced efficacy
Compulsory Licensing	TRIPS allows compulsory licensing for public health emergencies (Doha Declaration 2001)
TRIPS Flexibilities	Used by India to ensure generic drug production for HIV/AIDS medicines supplied to developing countries

EXAM-ORIENTED MCQs – PHARMACEUTICAL JURISPRUDENCE UNIT 5

Q1. Which committee's recommendations directly led to the enactment of the Drugs Act, 1940?

a) Bhore Committee b) Mudaliar Committee c) Chopra (Drug Enquiry) Committee d) Hathi Committee

✓ **Answer: c) Chopra (Drug Enquiry) Committee**

Q2. The Bhore Committee (1943–46) is primarily remembered for recommending:

a) Drug price controls b) Essential drugs list c) Primary Health Centre (PHC) concept and comprehensive health planning d) Pharmacy Act

✓ **Answer: c) Primary Health Centre (PHC) concept and comprehensive health planning**

Q3. Which committee recommended nationalization of top pharmaceutical companies?

a) Bhore Committee b) Hathi Committee c) Mudaliar Committee d) Chopra Committee

✓ **Answer: b) Hathi Committee**

Q4. The concept of Essential Drugs List in India was first proposed by:

a) Chopra Committee b) Bhore Committee c) Mudaliar Committee d) Hathi Committee

✓ **Answer: d) Hathi Committee**

Q5. The Pharmacist's Oath is administered at the time of:

a) Qualifying D.Pharm examination b) Graduation c) Registration with State Pharmacy Council d) Joining a hospital

✓ **Answer: c) Registration with State Pharmacy Council**

Q6. Under the MTP Act 1971 (as amended in 2021), up to how many weeks can a single registered medical practitioner terminate a pregnancy?

a) 12 weeks b) 20 weeks c) 24 weeks d) 28 weeks

✓ **Answer: b) 20 weeks**

Q7. Under the MTP Amendment Act 2021, termination up to 24 weeks is available to which of the following?

a) All married women b) Rape survivors, minors, women with disabilities c) Any woman on request d) Only government hospital patients

✓ **Answer: b) Rape survivors, minors, women with disabilities**

Q8. Penalty for termination of pregnancy by a non-registered medical practitioner under MTP Act is:

a) Fine only b) 6 months imprisonment c) Rigorous imprisonment 2–7 years d) 1 year imprisonment

✓ **Answer: c) Rigorous imprisonment 2–7 years**

Q9. The RTI Act, 2005 came into full force on:

a) 15th August 2005 b) 12th October 2005 c) 26th January 2006 d) 1st April 2006

✓ **Answer: b) 12th October 2005**

Q10. Under RTI Act 2005, the time limit for furnishing information where it concerns life or liberty of a person is:

a) 7 days b) 48 hours c) 15 days d) 30 days

✓ **Answer: b) 48 hours**

Q11. The penalty imposed on a PIO under RTI Act for delay in providing information is:

a) Rs. 100 per day up to Rs. 10,000 b) Rs. 250 per day up to Rs. 25,000 c) Rs. 500 per day up to Rs. 50,000 d) Rs. 1000 per day

✓ **Answer: b) Rs. 250 per day up to Rs. 25,000**

Q12. Section 3(d) of the Patents Act, 1970 is significant in pharmaceutical patents because it:

a) Allows product patents for all drugs b) Prevents 'evergreening' by not allowing patents on enhanced forms unless significant efficacy improvement shown c) Provides compulsory licensing d) Allows data exclusivity

✓ **Answer: b) Prevents 'evergreening' by not allowing patents on enhanced forms unless significant efficacy improvement shown**

Q13. Duration of a patent in India is:

a) 10 years b) 14 years c) 20 years d) 25 years

✓ **Answer: c) 20 years**

Q14. Under which section of the Patents Act can compulsory licensing be sought after 3 years of grant?

a) Section 3 b) Section 48 c) Section 84 d) Section 92

✓ **Answer: c) Section 84**

Q15. India's first compulsory license (2012) was granted for which drug?

a) Imatinib (Gleevec) b) Sorafenib (Nexavar) by Bayer to Natco Pharma c) Dasatinib d) Erlotinib

✓ **Answer: b) Sorafenib (Nexavar) by Bayer to Natco Pharma**

END OF UNIT 5 NOTES | BEST OF LUCK FOR EXAMS!

Prepared by Noteskarts | www.noteskarts.com | YouTube: @Noteskarts