PHARMACEUTICAL JURISPRUDENCE

UNIT 5 NOTES

- PHARMACEUTICAL LEGISLATION
- CODE OF PHARMACEUTICAL ETHICS
- TERMINATION OF PREGNANCY ACT
- RIGHT TO INFORMATION ACT
- INTELLECTUAL PROPERTY RIGHTS

IMPERFECT PHARMACY

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Pharmaceutical Legislation Of India

Legislation

- Low intends for regulation & control of various aspects of life.
- These aspects might be social, economic & political.
- Pharmaceutical Legislation is a mixed legislation, which over lapping both social & economic aspects.

History Of Pharmaceutical Legislation

- In 1811, First Chemist shop opened by Mr. Bathgate, who come to India with East India Company in Calcutta.
- In 1821 another team, Smith Stunistreet and Co. started apothecary shop.
- In 1901 Bengal Chemical and Pharmaceutical Works, a small factory was started in Calcutta by Acharya P.C. Roy.
- In 1903 Prof. T.K. Gujjar opens small factory at Parel for the development of pharmaceutical units & Alembic chemical works Ltd. at Baroda.
- After World War I, India's medicine imports changes significantly, with many inexpensive drugs entering the market.
- The rivallary b/w foriegn & Local drug companies led to unethical practices, resulting in low-quality, misbranded & fake drugs.
- The drugs negative effects promoted the Indian Government to regulate the import, export, production, distribution & sale of drugs.

- Acts like the Opium Act, 1910 & the Poison Act 1919, the Dangerous Drugs Act 1930 were enacted as a result.
- These actions failed to ensure safety for the growing population & booming pharmaceutical industries, leading to the formation of Drug Enquiry Committee.

DRUG ENQUIRY COMMITTEE

- On August 11, 1930, the Indian Government establishes the Drug Enquiry Committee, lead by R.N. Chopra, to examine the pharmacy profession, later know nas "Chopra Committee".

KEY GUIDELINES FOR DEC

- The goal is to assess the prevalance of low-quality drugs in British India, particularly those in the British Pharmacopoeia & suggest solutions of public safety.
- The goal is to explain how these recommendations apply to medical products in traditional machine.
- Evaluate the neccesity of laws restricting the pharmacy profession to qualified indivisuals & purpose enhancements based on the findings.
- The Chopra committee investigated key issues & made recommendations, travelling across the country for better insight, & publish its repeat in 1931.
- The committee report noted that India lacked a structured & independent pharmacy profession compared to other regions.

- The profession includes poorly defined compounders who handle drugs & poisons without fully understanding their effects.
- The committee noted minimal focus on basic qualifications, except for the updated compounders course in Bengal & the chemicals & Drugist course in Madras from the late 1920s.
- The simple skill of reading prescriptions in English was seen as enough to work in pharmacy.
- The Drugs Enquiry Committee recommended creating the Indian Pharmacopoeia to detail commonly used drugs & local pharmaceuticals.

HEALTH SURVEY AND DEVELOPMENT COMMITTEE

- This commitee was established by Indian Government in October 1943, lead by **Sir Joseph Bhore**.
- Evaluate India's Health care delivery systems & recommend future improvements, recommendations listed below were suggested :
  - The All India Pharmaceutical Council & Provisional Pharmaceutical Council were created to represent the pharmaceutical industry & education.
  - New laws aim to protect the public from unqualified indivisuals, supports skilled pharmacists & improve medication management standards.
  - Strict regulations were established to manage the field & practice of pharmacy.
  - Revised courses of study are beginning for :
    i) Licentiate Pharmacist
    ii) Graduate Pharmacist
    iii) Pharmaceutical Technologists
  - Establishing the Central Drug Laboratory.
  - Strict application of the D & C Act 1940 across the nation.

HAATHI COMMITTEE AND MODALIAR COMMITTEE

HAATHI COMMITTEE

- This committee was established with Jaisukh Lal Hathi as Chairman.
- To create specific measures for the growth of the pharmaceutical industry in India.
- The committee's report covered topics such as licensing, price control, imports, the foriegn sector's role & quality control.

MUDALIAR COMMITTEE

- Assigned in June 1959 with Dr. A. Lakshmanswamy Mudaliar as the chairperson.
- The Health survey & Planning Committee recommended including traditional medicines systems under the Drugs Act.
- Traditional medicines (drugs) were included under the D & C Act of 1940 based on its recommendations.
- This committee presented its recommendations report in 1961.

Code Of Pharmaceutical Ethics

Introduction / Definitions

- Ethics is study of moral principles or the science of what is right & wrong.
- The pharmacy profession embodies noble values & a caring unit, allowing indivisuals to earn a living while helping those in need.
- A pharmacist collaborates with healthcare professionals to manage & prepare medical substances, including poisons and strong medications.
- The Pharmacist must priortize the needs of their customers above all else.
- Charaka, an Ancient Indian Philoshoper & Physician, stressed the importance of never betraying or ignoring patient's needs, even at personal risks – a principle all pharmacists should uphold.
- Pharmacy practice limited by the Government to indivisuals who meet the neccessary regulatory qualifications.
- The pharmacists should always be ready to provide guidance to coworkers & uphold the laws of the State & Nation.

Pharmacist In Relation To His Job

① A Scope Of Pharmaceutical Service

- Once registered as a pharmacy, they should offer a wide range of services, including emergency suppliers.

② Conduct Of The Pharmacy

- Accidental contamination in medicine preparation & distribution must be avoided and the pharmacy should reflect a professional appearance.
- Pharmacy services should be clearly visible, with simple signs & notices that are not ovely large or flashy.
- A notice states that scheme dispensing under the Employees State Insurance Scheme (EIS) must be handled by a qualified pharmacist without owner interference.

③ Handling Of Prescription

- Pharmacist should remain neutral & avaid discussing treatment pros and cons when filling prescriptions to prevent patient anxiety.
- Address any prescription questions carefully & don't alter ingredients without the prescriber's approval.
- Patients should contact their doctor for compatibility issues or overdose & issues instructions when filling perscriptions.

④ Handling Of Drugs

- Accurately prepare prescriptions by precisely weighing & measuring each ingredient.
- Always use high-quality drugs & medicines, avoid fake or low-quality products.
- A pharmacist must manage harmful or addictive drugs, which should not be given to eeveryone.

⑤ Apprentice Pharmacist

- A pharmacist must provide trainee with the resources needed to develop essential skills by the end of their training.
- Certificates or credentials should only be awarded when criteria are met & abilities demonstrated.

Pharmacist In Relation To His Trade

① Price Structure

- Customer prices should be reasonable & pharmacists should be fairly compensated for their knowledge skills & responsibilities.

② Fare Trade Price

- Pharmacies should avoid fierce competition by not offering prizes or gifts to doctors.
- Don't fill prescriptions from other pharmacies, direct-customers to the correct location, Avoid replicating labels or trademarks.

③ Purchase Of Drugs

- Always purchase from a trusted source & pharmacies should avoid supporting fake or altered medications.

④ Hawking Of Drugs

- Avoid encouraging or requesting orders, don't promote 'self-service' to prevent self-medications.

⑤ Advertisement Of Drugs

- The pharmacist must not use promotional materials to sell inappropriate medicines or devices, such as:
- Language, design or images that negatively portray other pharmacies.
- Negative mention of other suppliers, products, solutions or treatments.
- False or overstated claims.
- The term "cure" for illness or symptoms, assurance of treatment effectiveness, use of fear tactics, money-back gaurantees & contests or rewards.
- Monitoring healthcare providers or facilities, using titles like "Doctor" or "Nurse" & discussing unapproved treatments for sexual health, aging or vitality.

Pharmacist In Relation To His Medical Profession

① Limitation Of Professional Activity

- Owning drug stores doen't lead to practicing pharmacy, as it eventually result in coded prescriptions.
- Don't practice medicine, including diagnosing or treating illness. In emergencies, pharmacists may provide first aid.

② Clandestine Arrangements

- Pharmacist must not engage in secret deals with doctors for commisions or benefits related to their pharmacy.

③ Liaison With Public

- A pharmacist connects healthcare professionals & the public, staying informed through regular reading & contributing to nation-building activities.
- Promote learning & contribute to education while keeping information private & maintaining the trust of supporters.

PHARMACIST IN RELATION TO HIS PROFESSION

① PROFESSIONAL VIGILANCE

- He should follow the law, avoid harmful actions, comply with regulations, & reports wrongdoers.
- A pharmacist should support a obllegue's genuine scientific or technical needs to maintain their reputation.

② LAW - ABI DING CITIZEN

- Those working in pharmacy must understand the laws related to foods, drugs, health & sanitation.
- A pharmacist is a complete indivisual, & their life can't be separated into different parts.

RELATION WITH PROFESSIONAL ORGANIZATION

- A pharmacist should support & promote the goals of organizations that benefit the scientific, ethical & cultural welfare of pharmacits.

DECORUM AND PROPRIETY

- A pharmacist must avoid actions that undermine the profession's standard or reputation.

PHARMACIST OATH'S

- I pledge to adhere to the pharmacy Council of India's Code of Ethics & be an integral part of the healthcare team.
- I'll follow the rules & standards of my profession.
- I'll strive to enhance my knowledge to advance pharmacy & public health.
- I'll follow the system I believed is best for pharmaceutical care & patient counselling.
- I'll work hard to find & create quality medicines to help ease human suffering.
- I'll kept patient information private & only share it if required by law.
- I'll work with organizations that aim to improve the pharmacy profession & help them achieve their goals.
- I pledge to uphold this oath & strive for respect in my pharmacy work, if I fail, May I face the consequences.

Medical Termination Of Pregnancy Act

Introduction

- The Medical Termination of Pregnancy Act of 1971, along with the 1975 Rules & Regulations.
- It outlines the rules that licensed medical professionals must follow to perform pregnancy terminations.
- This law applies to all states In India, except for Jammu & Kashmir.

Definitions

① Registered Medical Practioner

- A RMP is a qualified medical professional listed in a State Medical Register, with required experience or training in gynaecology & Obstetrics as per the Indian Medical Council Act.

② Hospital

- A Hospital is operated by the Central Government of the Union Territory Government.

③ Lunatic

- A Lunatic is a person with a material mental illness who may be dangerous, silly, or unpredictable, as defined in Section 3 of the Indian Lunacy Act.

④ GUADIAN

- A Gaurdian is someone responsible for looking after a child or a person who is mentally ill.

⑤ MINOR

- A minor is a person not yet an adult, also known as an infant, with the age definition varying by location.

TERMINATION OF PREGNANCIES

- During pregnancy, an embryo or foetus develops in woman's body.
- Common signs include missed periods, morning sickness, larger breasts and a growing belly.
- Abortion is the termination of a pregnancy before the foetus can survive independently.

- Only RMPs with gynaecology & obstretics training can end pregnancies, following specific rules :

- Pregnancies under 12 weeks that threaten a woman's life or health, or involve serious foetal issues, can be concerning. Unplanned pregnancies or those resulting from rape may also cause significant metal health challenges.
- Pregnancy can be terminated with written consent from women aged 18 or older. Those under 18 or deemed mentally ill require gaurdian consent.
- A pregnancy b/w 12 to 20 weeks can only be terminated if two doctors agree it's neccessary due to complications, Immediate te to protect the woman's life can occur at any age, even by specialist doctors.

- The district CMO should regularly check the approved sites & obtain the approval certificates during each visit.
- The CMO can request more information, remove items from unsafe locations, especially those that have harmed women & cancel or pause approval certificates.
- The hospital owner securely maintain an admission register accessible only to authorized indivisuals like the Chief secretory, First class magistrate or District Judge.
- Consent forms & RMPs opinions should be securely stored & sent in "Secret" envelops to the hospital head, location owner, state CMO.
- Number at each entry in order.

EXPERIENCE OR TRAINING

The Act requires the RMP to have atleast one experience or training. gynaecologist & Obstretics :

- If the RMP was in the State Medical Register before the Act, they must have at least 3 years of experience in gynaecology & obstretics.
- If the RMP was listed in a State Medical Register on or after the start of the Act :
  - He needs to have 6 months of experience in house surgery related to gynaecology & Obstetrics.
  - He should have atleast a year of hospital experience in gynaecology & Obstetrics if he hasn't performed any surgeries.
  - He has assisted a registered medical practioner with 25 medical terminations of pregnancy in a government - approved facility.
- A registered medical practioner must hold a post-graduate deg diploma in pregnancy & Obstetrics, along with relevant experience

Approval Of Place

- An RMP can only end a pregnancy at an approved location, which requires submitting an application to the District CMO for inspection & approval includes:
  - The location needs to have a surgical table & the tools needed for abdominal or gynaecological surgery.
  - The location needs to have anaesthetic tools, resuscitation tools, & sterilisation tools.
  - The location needs to have the neccessary medications & IV fluids for emergencies.

- The Government reviews the District CMOs applications & suggestions, approves the location, & issues a visible approval certificates for visitors.
- The district CMO can check the approved locations as needed & must report to the goverment if facilities & safety standards are lacking.
- After recieving the report, the government allows the owner to present their case before diciding or deciding to revoke or suspend the approval certificate.
- The owner can renew or obtain a new certificate after making neccessary improvements, if suspended the location is no longer approved for pregnancy termination.

ADMISSION REGISTER

- The hospital director or owner of the authorized facility must keep a log to track the women admitted for pregnancy terminations.
- The records in this leg should be organized in a yearly serial order.
- The Admission Register must remain confidential, with pregnant women's details securely stored & stored only with authorized indivisuals.

i) The Chief Secretory of a Union Territory will manage departmental inquireis.
ii) A First - class Magistrate in the hospital's area will investigate the offense.
iii) The District Judge where the hospital is located will handled any lawsuits for damages.

- The RMP should issue a certificate to an employed woman post-pregnancy for leave, while the employer must maintain confidentially. Admission records must be destroyed five years after the last entry, & other documents three years after the pregnancy ends.
- Only pregnant women's names & their assigned serial numbers should be recorded in hospitals documents, specifically in the admission register.

Custody Of Forms

- The pregnant woman's consent to terminate her pregnancy should be placed in an envelope with the official opinion.
- The RMP who ended the pregnancy should seal his envelope & store it safely until it is sent to the hospital head, facility owner or State CMO.
- Label the envelope "SECRET" & include the pregnant woman's serial number & name of the RMP (Doctor) who performed the termination.
- The envelope is swiftly sent to the hospital director or facility owner where the pregnancy ended.
- The hospital head or facility owner must securely store the envelope & submit a weekly report of medical termination of pregnancy cases to the State CMO.

Power To Make Rules

- The Central Government can establish rules for this Act, including the experience of training needed for an RMP to perform a pregnancy termination.
- The Central Government must present the rules made under this Act to both issues of parliament within 30 days during a session, which may be one or two consecutive sessions.
- If both houses agree to change the rule or decide against it before the end of the current or next session, the rule will either be valid in its new form or not at all.
- Changes made will not impact the validity of actions taken under the original rule.

POWER TO MAKE REGULATIONS

The State Government can create rules for it:

- Collecting opinions, certifying them with RMP & managing certificate shortage or disposed.
- Any RMP who terminates a pregnancy must modify about it & provide required details.
- Sharing hints or information with unauthorized indivisuals is prohibited.
- Ayone who intentionally breaks the rules should face a fine of arround one thousand rupees (Rs. 1000).

OFFENCES AND PENALTIES

① OFFENCES

i) Offences by Companies:

- If a company violates this Act, all responsible indivisuals the company itself are deemed guilty & subject to legal action.
- If a company violates this Act, any director, manager, secratory or officer involved or negligent in their duties is also guilty & liable for legal action.

ii) Offences to be cognizable

- An offense under this Act is deemed congnizable, regardles of the Code of Criminal Procedure, 1898.

② PENALTIES

- Anyone who breaks the rules of this Act will be punished as:
  - First time may face 6 months in prison, a fine or both.
  - If convicted again, they may face a one year prison, a fine or bo

RIGHT TO INFORMATION ACT

INTRODUCTION

- Every Indian citizen have the rights to information under section 3 of the Right to Information Act 2005, enacted on June 15, 2005, applicable throughout India except Jammu & Kashmir.

OBJECTIVES

- The goal is to establish a clear system for citizens to access information held by public authorities.
- To encourage openness & responsibility in the operations of all public authorities.
- To establishment of Central & State Information Commisions & related matters.

DEFINITIONS

There are some definitions under the RTI Act :

- **RECORDS** Any document, manuscript, file, microfilm, microfiche, image reproduction or material created by a computer or device.
- **STATE CHIEF INFORMATION COMMISSIONER** The State Chief Information Commisioner & State Information commissioner are appointed per subsection (3) of section 15.

State Medical Public Information Officer

- He is a person other than the citizen making a request for information & includes a public authority.

Third Party

- A person who is not a citizen & is asking for information, which also includes a public authority.

Right To Information And Obligations Of Public Authorities

- Organize & index all records for easy access under this Act.
- Public authorities must appoint Central or State public information officers within 100 days of this Act's passage.
- To give details about any event that took place 20 years before the request for information.
- Keep the information or records for the past & the next 20 years to help enforce the RTI Act.
- A request must be submmitted in writting or electronically in English, Hindi or the local official language, along with any required fee :-
  i) The Central officer or the State Public Information Officer, depending on the situation, of the relevant public authority.
  ii) The Assistant Public Information Officer may need to specify the requested information.
- An applicant asking for information doesn't need to provide a reason for their request.

THE CENTRAL INFORMATION COMMISSION

- The Central Government will establish the Central Information Commission to exercise its powers & fullfil the tasks assigned by this Act.
- The Central Information Commission will include:
  a) The Chief Information Commissioner
  b) Up to ten Central Information Commissioners, as needed.
- The President will appoint the Cheif Information Commissioner & Information Commisioners based on a committee's advice:
  a) The Prime Minister will be serve as the Chairperson of the committee.
  b) The head of the opposition in the Lok Sabha.
  c) A Union Cabinet Minister will be appointed by the Prime Minister.
- The Cheif Information Commisioner will serve a five-year term starting from the day he begins his role & can't be reappointed.
- No Chief Commisioner can committee in office after reaching the age of sixty-five (65).

THE STATE INFORMATION COMMISSION

- The State Government will create group called the Information commision to use the powers given to it:
- It will include:
  a) The State Chief Information Commisioner and
  b) Up to ten State Information Commisioners, as needed.
- The Governer will appoint the State Chief Information Commisioner & the State Information Commissioners based on the advice of a committee made up of:
  a) The Chief Minister, who will lead the committee.
  b) The Leader of the opposition in the Legislative Assembly.
  c) A cabinet Minister chosen by the Chief Minister.
- The State Chief Information Commisioner will lead the State Information Commissioner, supported by State Information Commissioners with neccessary authority.
- A person can't be a member of parliament or a State/Union Territory Legislature, hold a profitable position, or be affiliated with any political party.
- The State Information Commission will have a main office designated by the State Government & may set up additional offices in other locations.
- The State Chief Information Commissioner serves a 5 years term but can't continue past age 65.

JURISDICTION OF COURTS

- No court shall consider any lawsuits or actions related to orders made under this Act, such orders can only be challenged through an appeal under this Act.
- Lower courts can't hear cases related to this Act, but the supreme court & High courts retain their write jurisdiction.

INTELLECTUAL PROPERTY RIGHTS

- Intellectual property is something produced using human intellect which has commercial value.
- Examples of IPR are, an invention, relating to a product or process, a new design, an article, a literary or artistic work & a trademark.
- Intellectual Property Right can be defined as the Right held by a person over the creation of his mind or intellect.
- IPR are the statutory rights once granted allows the creator (s) or owners (s) of the intellectual property to exclude others from expoliting the same commercially for a given period of time.

SCOPE

- Patents
- Trade Secrets
- Copyrights
- Trademarks
- Design
- Geographical Indications

Importance Of IPR

- IPR can be used to establish the goodwill & brand value in the Market.
- Inventor, creator or author of an IP can mention about the IP in his/her resumes & thus show their competence.
- IPR Certificate establishes legal & valid ownership about an intellectual property.
- It encourages new industry & Research.
- Faciliate technology transfer.

Trademark

- A Trademark is any design that can distinguish the goods of one trader from those of another, it includes symbols, words, logos, pictures, colour or combination of these.
- In Pharmaceutical Arena, trade names for certain drug may be registered as a trademark Eg. Viagra.
- It is covered under the Act called Trademark Act 1999.
- It replace Trade & Merchandise Act 1958, it extends to whole India.

Different Symbols Of Trademark

- ® Registered Trademark
- TM intent to use application filled for product.
- SM intent to use application filled for service.

Duration Of Trademark

- Trademark - 10 years + renewable
- Service Mark - 17 years + renewable

COPYRIGHTS

- The term originated in the copyright law means that the work originated with the author.
- It is right which grant protection to the unique expression of Idea.
- India has a very strong & comprehensive copyright law based on Indian Copyright Act 1957, which has amended in 1982, 1984, 1992, 1994 & 1999.

WHAT COVERED BY COPYRIGHT

- Literary
- Films
- Dramatic
- Musical
- Artistic
- Sound recording
- Books
- Broadcast

DURATION OF COPYRIGHT

- Authors life + 60 years for literary work (Books)
- 60 years (Films, Photographs)
- 25 years (Broadcasting)

SYMBOL OF COPYRIGHT

- © + Year + Name

Example : © 2021 Pharmaceutical Education & Research

PATENT

- Patent is an exclusive right granted to an applicant by the Govt. for a limited period to practice the invention (Manufacture, Use & Sale), in lieu of the information disclosed to the Govt. with regard to an invention.
- The patent confers rights to the patentee to exploit the patent for commercial gains & also to stop others from manufacturing, & selling the patented products / process.
- An invention in general means a law discovery, relating to the product (machine) or process, even to an existing module or Idea.

WHAT IS NOT PATENTABLE

- A method for agriculture & horticulture.
- Any methods of treatment of human beings or animals.
- Plants & Animals in whole or any part therefore other than micro-organism.
- A mathematical or bussiness method or a computer program.
- A literary, dramatic, musical, artistic work etc.
- A scheme or rule or method of performing mental act or method of playing game.
- A presentation of Information.
- Topography or Integrated circuits
- An invention relating to the traditional knowledge
- An invention relating to Atomic Energy (Sec.4)

What Is Patentable

- A product
- The Appratus for producing product
- The process
- The Composition of Matter

Patent Jurisdiction

Office	Territorial Jurisdiction
Patent Office Branch, Chennai	The States of Andhra Pradesh, Karnatka, Kerala, Tamilnadu & Union Territories of Pondicherry and Lakshwadeep.
Patent Office Branch, Mumbai	The States of Maharastra, Gujrat, MP, Goa & Chattisgarh and the Union Territories of Daman & Die and Dadra & Nagar Haweli.
Patent Office Branch, New Delhi	The states of Haryana, HP, J & K, UP, Punjab, Uttrakhand, Rajasthan, Delhi & Union Territory of Chandigarh.
Patent Office, HO Kolkata	The rest of India

Basic Requirement For Petantability

- Novelty
- Utility
- Non Obviousness
- Industrial Application

Importance Of Patent

- It encourages research
- Induce an inventor to disclose his invention.
- Encourage establishment of new industries.
- Reasonable assurance of commercialization
- Faciliate technology transfer
- Stimulate R&D at universties and Research center.

Industrial Design

- Industrial Design Act 2000
- Term for Industrial Design is for 15 years
- It protects the ornamental appearance of object exactly as, shown in drawing supplied with patient application.
- Protects ornamental or non- functional features.

Type Of IP	Subject Matter	Main Fields
Patent	New, Non- obvious, Industrial applicable	Chemical, Drugs, Plastics, Engines, Turbines, Scientific Equipment
Trademark	Sign or Symbol	All Industries
Copyright	Original work of authorship	Printing, Entertainment (audio, video, motion pictures), softwares, Broadcasting
Industrial Design	Ornamental Design	Clothing, Automobiles, Electronics
Geogaphical indication	Geographical origin of Goods & Services	Food products & other products

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