# Pharmaceutical Legislations

**Ms: Manisha K. Gavit**
**Assistant Professor**
**(Department of Pharmaceutical Chemistry)**

**JES's college of Pharmacy,Nandurbar**

# Legislation

- Legislation is law which has been promulgated (enacted) by a legislature or other governing body or the process of making it.
- Law intends for regulation and control of various aspects of life.
- These aspects might be social, economical and political.
- Pharmaceutical legislation is a mixed legislation, which overlapping covers both social and economic aspects.
- Types of Legislation.
- There are four basic types of legislation that are handled by Parliament.
- They include bills, simple resolutions, joint resolutions and concurrent resolutions.
- A bill is the most common type of legislation and can be either permanent or temporary.

# Objective

- To ensure that the patients receive drugs of required quality, tested and evaluated for safety as well as efficacy for their intended use.
- Pharmaceutical legislation is associated with the health of the society.

# A brief review

- In 1811 first chemist shop opened by Mr. Bathgate, who came to India with East India company in Calcutta.
- In 1910 they have started manufacture of tincture and spirits.
- In 1821 another firm, Smith Stanistreet and Co. started apothecary shop and started manufacturing in 1918.
- In 1901 Bengal Chemical and Pharmaceutical works, a small factory was started in Calcutta by Acharya P.C. Ray.
- In 1903 Prof. T. K. Gajjar opens a small factory at Parel for the development of Pharmaceutical units and Alembic chemical works Ltd. at Baroda. 5 Apothecary: a person who prepared and sold medicines and drugs

# A brief review

- These units were not sufficient to fulfil the need of Indian public. Hence most of the medicines were being imported from abroad mainly UK, France and Germany.
- In first world war the need was changed, cheaper drugs were imported from abroad.
- Demand of indigenous drug was also improved.
- Competition becomes unhealthy and Indian marked flooded with inferior, substandard and even harmful drugs

# A brief review

- By considering this issue, public made the government to take a notice of such situation of drug trade and industry and think of introducing an effective legislation to control, manufacture, distribution and sales of drugs.
- The Opium Act, 1878, the poison act 1919 and the dangerous drugs act, 1930 were in force.
- The government of India in pursuance to the resolution appointed a committee known as the **Drugs Enquiry Committee in 1928.**
- Government of India on **11th August 1930,** appointed a committee under the chairmanship of Late Col. R. N. Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken. This committee published its report in 1931. It was reported that there was no recognized specialized profession of Pharmacy.

# A brief review

- A set of people known as compounders were filling the gap. Just after the publication of the report Prof. Mahadeva Lal Schroff (1902-1971 or rightly called as Prof. **M. L. Schroff is** renowned for the title of pioneer and **father of Indian Pharmacy Education**) initiated pharmaceutical education at the university level in the **Banaras Hindu University.**

- In 1935 United Province Pharmaceutical Association was established which later converted into Indian Pharmaceutical Association.

- The **Indian Journal of Pharmacy** was started by **Prof. M.L. Schroff in 1939.**

- All India Pharmaceutical Congress Association was established in 1940.

- The Pharmaceutical Conference held its sessions at different places to publicize Pharmacy as a whole.

# A brief review

- 1937: Government of India brought ‘Import of Drugs Bill’; later it was withdrawn.
- 1940: Government brought ‘Drugs Bill’ to regulate the import, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as ‘**Drugs Act of 1940’.**
- **1941: The first Drugs Technical Advisory Board (D.T.A.B.)** under this act was constituted.
- **Central Drugs Laboratory was established in Calcutta 1945**: ‘Drugs Rule under the Drugs Act of 1940’ was established.
- The Drugs Act has been modified from time to time and at present the provisions of the Act cover Cosmetics and Ayurvedic, Unani and Homeopathic medicines in some respects.
- **1945: Government brought the Pharmacy Bill** to standardize the Pharmacy Education in India,
- **1946: The Indian Pharmacopoeial** List was published under the **chairmanship of late Col. R. N. Chopra.** It contains lists of drugs in use in India at that time which were not included in British Pharmacopoeia.

# A brief review

- **1948: Pharmacy Act** 1948 published.
- 1948: Indian Pharmacopoeial Committee was constituted under the chairmanship of l**ate Dr. B. N. Ghosh.**
- **1949: Pharmacy Council of India** (P.C.I.) was established under Pharmacy Act 1948.
- **1954: Education Regulation** have come in force in some states but other states lagged behind.
- **1954: Drugs and Magic Remedies** (Objectionable Advertisements) Act 1954 was passed to stop misleading advertisements (e.g. Cure all pills).
- **1955: Medicinal and Toilet Preparations (Excise Duties)** Act 1955 was introduced to enforce uniform duty for all states for alcohol products.
- **1955: First Edition of Indian Pharmacopoeia** was published.
- **1985: Narcotic and Psychotropic Substances** Act has been enacted to protect society from the dangers of addictive drugs. Government of India controls the price of drugs in India by Drugs Price Order changed from time to time.

# Study of Drugs Enquiry Committee (DEC)

- This committee was appointed by Indian Government in **1931.**
- A Committee chairman was **Lt. Col. R. N. Chopra.**
- This committee is also called as **DEC or Chopra committee.**
- The committee was asked to make enquiries in the said matter and then to make recommendations for smooth control of manufacture, import, distribution and sale of drugs in the interest of public health.

# Reasons for formation of Chopra Committee

- Units were not sufficient to fulfil the requirements of Indian Public.
- Drugs were imported form UK, Germany and France.
- During first world war cheaper drugs were imported into India, which increased the demand for indigenous drugs.
- Unhealthy competition grew up and Indian market was flooded with inferior quality drugs.
- Public pressurized government to introduce effective legislation to control import, manufacture, distribution and sale of drugs.
- There was no legal and effective control on pharmacy profession.
- Hence to have a comprehensive legislation, the Indian government appointed a **'Drug Enquiry Committee'** under the chairmanship of **Col. R. N. Chopra in 1931.** this was formally known as **Chopra Committee.**

# Indigenous Medicine

- Indigenous medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to native cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness including, but not limited to alternative, complementary, holistic, and integrative approaches.

# Recommendations of Drug Enquiry Committee

- 90 recommendations with report was submitted by the committee.
- **Important Recommendations:**

✓ Formation of Central Pharmacy Council and State pharmacy council which would look after the education and training of professionals. Councils would maintain the register containing names and addresses of the registered pharmacist.

✓ Creation of drug control machinery (Departments) at the centre and branches in all states.

✓ Establishment of a well-equipped **Central Drug Laboratory (CDL) at Kolkata** with competent staff and experts for an efficient and speedy working of Drug Control Department. Small laboratories would work under its guidance.

# Overview of Outcomes of DEC

- Enactment of Import of Drugs Bill 1937.
- Drugs and Cosmetic Act 1940 and Rules 1945.
- Pharmacy Act 1948
- Drugs and magic remedies (objectionable advertisement) Act 1954 and Rules 1955.
- Medicinal & Toilet Preparations (Excise Duties) Act 1955 and Rules 1956.
- Publications of first edition of Indian Pharmacopoeia in 1st edition **1955 based on British pharmacopoeia 1948.**
- 1st Edition – 1955, 2nd Edition – 1966, 3rd Edition – 1985, 4th Edition – 1996, 5th Edition – 2007, 6th Edition – 2010, 7th Edition – 2014, 8th Edition – 2018.

# Health Survey and Development Committee

- This committee, known as the Health Survey and Development Committee, was appointed in 1943 with **Sir Joseph Bhore as its Chairman.**
- It laid emphasis on integration of curative and preventive medicine at all levels.
- It made comprehensive recommendations for remodeling of health services in India.
- Aim: The major aim of the committee was to survey then existing position regarding the health conditions and health organization in the country and to make recommendations for future development, in order to improve the public health system in India.

# Guiding principles adopted

- No individual should be denied to secure adequate medical care because of inability to pay,
- Facilities for proper diagnosis and treatment,
- Health programme must lay special emphasis on preventive work,
- As much medical relief and preventive health care should be provided to the vast rural population.
- Health services should be located close to the people to ensure maximum benefit to the community.
- Doctor should be a social physician protecting the people.
- Medical services should be free to all, without distinction.

# Observations made by the Bhore Committee

- Health status of the country as indicated by various indicators was poor,
- Mortality rates were very high,
- Life expectancy at birth was about 27 years,
- Incidence of communicable diseases was very high,
- Many of the health problems were preventable,
- Committee stated that health and development are interdependent,
- Improvement in sector other than health will also lead to improvement in health like water supply, sanitation improvement, nutrition, elimination of unemployment.

# Recommendations by Bhore Committee submitted in 1946

1. Integration of preventive and curative services of all administrative levels.
2. Development of Primary Health Centers in 2 stages including Short-term measure and long-term measures.
3. Major changes in medical education which includes 3 month training in preventive and social medicine to prepare “social physicians”.
4. Abolition of the Licentiate in Medical Practice qualifications and their replacement by a single national standard Bachelor of Medicine and Bachelor of Surgery (MBBS) degree.
5. Creation of a major central institute for post-graduate medical education and research: which was achieved in 1956 with the All-India Institute of Medical Sciences (AIIMS).

# Development of Primary Health Centres in 2 stages

a. **Short-term measure**: One primary health centre as suggested for a population of 40,000. Each PHC was to be manned by 2 doctors, one nurse, four public health nurses, four midwives, four trained dais, two sanitary inspectors, two health assistants, one pharmacist and fifteen other class IV employees. Secondary health centre was also envisaged to provide support to PHC, and to coordinate and supervise their functioning.

b. **A long-term programme**: Also called the 3 million plan) of setting up primary health units with 75 – bedded hospitals for each 10,000 to 20,000 population and secondary units with 650 – bedded hospital, again regionalised around district hospitals with 2500 beds.

# Implementation of recommendations of Bhore Committee

- The proposals of the committee were accepted in 1952 by the government of newly independent India. Though most of the recommendations of the committee were not implemented at the time, the committee was a trigger to the reforms that followed.

# Outcomes of Bhore Committee

- The committee was instrumental in bringing about the public health reforms related to peripheral health centres in India.
- Primary Health Centres were built across the nation to provide integrated promotive, preventive, curative and rehabilitative services to entire urban as well as rural population, as an integral component of wider community development programme.

# Significance and Importance of Bhore Committee Report

- Important landmark in public health in India.
- Initiated the concept of integrated development and comprehensive health care.
- Idea of primary health care.
- The three-tier pattern of health care services.

# Hathi Committee

- Government of India constituted a Committee on 08-02-1974 consisting of 15 members under the chairmanship of Mr. Jaisukhlal Hathi.
- The purpose was to take comprehensive look into the drug industry and to enquiry in to the various facets of drugs in India.
- After conducting various meetings, the committee submitted its report in the year 1975.
- The report of this committee covered all aspects ranging from licensing, price control, imports, role of foreign sector and quality control.
- It encouraged the development of indigenous industries, it also further controlled price of a large number of drugs in the interest of the consumer.

# Hathi Committee

- Health is a fundamental human right.
- The Constitution of India directs the State to regard the improvement of public health as among its primary duties.
- The Five-Year Plan have been providing the framework within which the Centre and States have developed their health services infrastructure and programmers.
- The National Health Policy of 1983 marks a significant step in the national Endeavour to improve public health.
- It reiterates India's commitment to the goal of "Health for all by the year 2000 A.D." through the universal provision of comprehensive primary health care service

# Hathi Committee

- The attainment of this goal requires an accelerated development of all inputs to the health care system, including essential and lifesaving drugs and vaccines of proven quality.
- Drugs alone are not sufficient to provide health care.
- However, if rationally used, they do play an important role in protecting, maintaining and restoring the health of the people and in controlling population.
- The Indian Pharmaceutical Industry has, therefore, a vital role in serving the basic health needs of the people.

# Hathi Committee

- The Report of the Hathi Committee (1975) is an important landmark in the development of the Indian Pharmaceutical Industry.
- The Hathi Committee emphasized the achievement of self-sufficiency in medicines and of abundant availability at reasonable prices of essential medicines.
- Since 1975, the Indian Pharmaceutical Industry has grown to be the most diversified and vertically integrated pharmaceutical industry in the entire Third World.
- The country has achieved self-sufficiency in formulations and also in a large number of bulk drugs.

# Mudaliar Committee

- Government of India appointed a ‘Health Survey and Planning committee’ in 1959 towards the end of the 2nd five-year plan to assess the state of the healthcare field and to measure the progress achieved after implementing the suggestions of the Bhore committee of 1946.
- Dr. A. L. Mudaliar was the chairman of the committee. The committee submitted its report in 1962.
- It was appointed to assess the recommendations of Bhore Committee and to suggest the action plan to implement the same.

# Mudaliar Committee

- It recommended that Primary Health Centre should provide with all three public health care services namely curative, preventive and promotive services.
- Each Primary Health Centre would cater to population of 40,000 as suggested by Bhore Committee.
- It also suggested that one health worker should be appointed for every 10,000 persons.
- “All India Health Service” body should replace the earlier “Indian Medical Service”.
- The Committee felt that existing Private Health Centres should be improved before new ones were opened.

# Mudaliar Committee

The committee found out that the level of healthcare provided was unsatisfactory and gave the following recommendations

- Consolidation of advances made in the first two five-year plans,
- Create an ‘All India Health service’ similar to ‘Indian Administrative service’,
- Strengthening of the district hospital with specialist services to serve as central base of regional services,
- Regional organizations in each state between the headquarters organization and the district in charge of a Regional Deputy or Assistant Directors- each to supervise 2 or 3 district medical and health officers.
- Each primary health centre not to serve more than 40,000 population,
- To improve the quality of health care provided by the primary health centres,
- Integration of medical and health services recommended by the Bhore Committee; and constitution of an All India Health Service on the pattern on Indian administrative service.

# Thank you

# Code of Pharmaceutical Ethics

**Ms: Manisha K. Gavit**
**Assistant Professor**
**(Department of Pharmaceutical Chemistry)**

**JES's college of Pharmacy,Nandurbar**

# Definitions

- Ethics: It means moral principles. It is a science of moral duty. Ethics are rules by which a profession regulates actions and sets standard for all its members.
- Pharmaceutical ethics: the ethics in relation to pharmacy profession is called pharmaceutical ethics.
- Morality: Morality means good conduct or behavior and consciousness.
- Law: Law is defined as, the rules of human conduct binding to all persons in a state or nation.

# Difference between Law and Ethics

| Law | Ethics |
| --- | --- |
| Rules of human conduct binding to all persons in a state or nation. | Rules by which a profession regulates actions and sets standard for all its members. |
| If law is broken, a violator may be subjected to punishment, a fine or imprisonment. | If rules are broken, the professional body may subject the violator to loss professional privileges. |
| Standards of Law | Standards of Conduct |
| Law may prevent one from causing injury to other. But it can't force him to help his neighbour in hours of need. | Helping neighbours is the function of ethics. |
| Selling misbranded or adulterated drug is prevented by law | Selling medicines at cheaper rate than that of the fellow pharmacist in his area is not ethical |

# Code of Pharmaceutical Ethics

- The code of pharmaceutical ethics is formulated by Pharmacy Council of India (PCI) for the guidance of Indian pharmacist.
- The code of pharmaceutical ethics helps to guide the pharmacist as to how pharmacist should conduct himself/herself in relation to:

✓ Job

✓ Trade

✓ Profession (Pharmacy)

✓ Medical profession.

# Pharmacist in relation to Job

- Scope of Pharmaceutical Services
- Conduct of Pharmacy
- Handling of Prescriptions
- Handling of Drugs
- Apprentice Pharmacists

# Pharmacist in relation to Job

- **Scope of Pharmaceutical Services:**

- When premises are registered under statutory requirements and opened as a pharmacy, a reasonably comprehensive pharmaceutical service should be provided.
- This involves the supply of commonly required medicines of this nature without undue delay.
- It also involves willingness to furnish emergency supplies at all times.

# Pharmacist in relation to Job

- **Conduct of Pharmacy:**

- The condition in a pharmacy should be such as to preclude avoidable risk or error or of accidental contamination in the preparation, dispensing and supply of medicines.
- The appearance of the premises should reflect the professional character of the pharmacy.
- It should be clear to the public that the practice of pharmacy is carried out in the establishment.
- Signs, notices, descriptions, wording on business, stationary and related indications, should be restrained in size, design and terms.

# Pharmacist in relation to Job

- **Handling of Prescriptions:**

- A received prescription should be checked for therapeutic efficiency.
- The Pharmacist should not even show any expression on face of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may lose their faith on physician.
- Any question on a prescription should be answered with every caution and care.
- A guidance should be given on refilling of prescriptions, a pharmacist should solely be guided by the instructions of the prescriber aid should advise the patient to use medicines or remedies strictly in accordance with the intention of the physician as noted on the prescription.

# Pharmacist in relation to Job

- **Handling of Drugs:**

- All possible care should be taken to dispense a prescription correctly by weighing and measuring all ingredients in correct proportions by the help of scale and measures: visual estimations must be avoided.
- Always use drugs and medicinal preparations of standard quality available.
- Pharmacist should never fill his prescriptions with spurious, substandard and unethical preparations.
- A Pharmacist should be very Judicious in dealing with drugs and medicinal preparations used for addiction or any other abusive purposes.

# Pharmacist in relation to Job

- **Apprentice Pharmacists:**

- While in-charge of a dispensary, drugstore or hospital pharmacy where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training they have acquired sufficient technique and skill to make themselves dependable pharmacists.
- No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

# Pharmacist in relation to trade

- Price Structure
- Fair Trade Practices
- Purchase of Drugs
- Hawking of Drugs
- Advertising and Displays

# Pharmacist in relation to trade

- **Price Structure:**

- Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labour and skill required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist taking into consideration his knowledge, skill, the time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

# Pharmacist in relation to trade

- **Fair Trade Practices:**

- No attempt should be made to capture the business of a fellow pharmacist by cut-throat competition, that is, by offering any sort of prizes or gifts or by knowingly charging lower prices for medical commodities than those charged by fellow pharmacist.
- In case any order or prescription genuinely intended to be served by some dispensary is brought by mistake to another, the latter should refuse to accept it and should direct the customer to the right place.
- Labels, trademarks and other signs and symbols of contemporaries should not be imitated or copied.

# Pharmacist in relation to trade

- **Purchase of Drugs:**

- Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub- standard drugs.

# Pharmacist in relation to trade

- **Hawking of Drugs:**

- Hawking of drugs and medicinal should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
- `Self-service` method of operating pharmacies and drug - stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self-medication, which is highly undesirable

# Pharmacist in relation to trade

- **Advertising and Displays:**

- No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public of medicines or medical appliances which is undignified in style or which contains:

a. Any offer about refund of money,

b. Misleading, or exaggerated statements or claims,

c. The word "Cure" in reference to an ailment or symptoms of ill-health,

d. A guarantee of therapeutic efficacy, e. An appeal to fear

# Pharmacist in relation to Profession

- Extend help to fellow pharmacist in emergency need.
- Should Maintain Standard of the profession.
- Should try to weed out corruption in profession and society.
- Should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession.
- Should have up to date Knowledge of Professional matters.
- Should have fair knowledge of laws related to his profession.

# Pharmacist in relation to Medical Profession

- Limitation of Professional Activities: Pharmacist under no circumstances, take to medical practice i.e. diagnosing drug and prescribing medicines. In emergency he can give first aid to the person. Should not recommend a medical practitioner,
- Clandestine (Concealed/ Secret) Arrangement: No pharmacist should enter into the secret arrangement and contract with the physician to offer him any commission or any other advantage.
- Liaison with Public: Being a liaison between medical profession and people, a pharmacist will always keep himself updated with the modern development of pharmacy by regular reading of books, magazines etc

# 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 the 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 my 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 organizations.
- While I continue to keep this oath unviolated, 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!

*Thank you*

# MEDICAL TERMINATION OF PREGNANCY ACT, 1971 AND RULES THEREUNDER 1975

**Ms: Manisha K. Gavit**
**Assistant Professor**
**(Department of Pharmaceutical Chemistry)**



**JES's college of Pharmacy,Nandurbar**

# Object

Termination of certain pregnancies by registered medical practitioner and for the matters connected there with

# DEFINITIONS

- **Guardian:** A person having the care of a minor or lunatic
- **Minor:** A person who under the provision of the Indian Majority act 1875 is to be deemed not to have attained his majority
- **Registered Medical Practitioner:** A medical Practitioner who possesses any recognized medical qualifications as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956, whose name has been entered in a state medical register and who has such experience or training in gynecology and obstetrics as may be prescribed by rules made under this act.
- **Place:** It is a building tent, vehicle or vessel or part there of used for the establishment or maintenance therein of hospital or clinic which is used or intended to be used for the termination of pregnancy.
- **Owner:** In relation to place, means any person who is administrative head or otherwise responsible for the working or maintenance of such hospital or clinic.

# Circumstances for termination of Pregnancy by RMP

1. **Pregnancy is not more that 12 weeks old:** Conditions: a-Serious injury to physical or mental health of the woman and b- Child to be born would be seriously handicapped.
2. **More than 12 weeks but less than 20 weeks:**

   If pregnancy caused because of rape or as a result of failure of any contraceptive device used by any married woman or her husband for the purpose of family planning, it may presumed to constitute a grave injury to the mental health of pregnant woman

- Woman with 18 years or more: with her written consent
- Woman with less than 18 years: lunatic with written consent of her guardian

# Experience or Training

This act prescribes the experience and training in gynecology and obstetrics for RMP who should have to terminate the pregnancy.

1. Before commencement of the act: Should have registration in state medical register and have more than 3 years of experience and practice in mentioned field.
2. After Commencement of the act:

- ✓ should have Completed 6 months of house surgency in gynecology and obstetrics
- ✓ More than 1-year experience in the practice of gynecology and obstetrics at any hospital.
- ✓ Assisted RMP in the performance of 25 cases of medical termination of pregnancy in a hospital established or maintained by govt. for this purpose

3. RMP who holds post-graduate degree or diploma in gynecology and obstetrics, the experience or training gained during the course of such degree or diploma.

# Places for Pregnancy Termination

- Should have approval from government.
- Termination of pregnancies may be done under safe and hygienic conditions
- Facilities required: Operation table, instruments, anesthetics equipment, resuscitation equipment, sterilization equipment, Drugs and parenteral fluids for emergency use.

# MAINTENANCE OF ADMISSION REGISTER

1. Head of the hospital or owner of the approved place should maintain register in prescribed form of the admission of women for the termination of their pregnancies.
2. Serial number should be given to each entry in the register.
3. Fresh serial number need to be given in each calendar year
4. Serial number of each year should be distinguishable
5. Information should not be disclosed.

# Offences and Penalties

| Offences | Penalties |
|---|---|
| Termination of pregnancy by a person who is not RMP | Punishable under IPC |
| Any person who willfully contravenes or fails to comply with the requirements of any regulations made by state govt. | 1000 rupees |

# Thank you

# RIGHT TO INFORMATION ACT

**Ms: Manisha K. Gavit**
**Assistant Professor**
**(Department of Pharmaceutical Chemistry)**

**JES's college of Pharmacy,Nandurbar**

# Establishment of the Act

- The Right to Information Act, 2005, received the assent of the President on the 15th June, 2005.
- It came into force w.e.f. October 12, 2005.
- It extends to the whole of India except the State of Jammu and Kashmir.

# Objectives of the Act

- To secure access to information under the control of public authorities
- To promote transparency and accountability in the working of every public authority
- To contain corruption
- To increase citizens' awareness and ability to exercise their other rights
- To equip them to participate meaningfully in the development process

# Definitions

- **" Public Authorities " Sec 2(h) means**
- Any body constituted under the Constitution or a law made by Parliament or State Legislatures.
- Any body constituted by a notification or order issued by the Central/State Governments.
- Any body owned, controlled or substantially financed by the Central Government or the State Government.

- **"Information" Sec 2(f) means:**

  any material in any form, including records, documents, memos, e-mails, opinions, advices, press releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material held in any electronic form and information relating to any private body which can be accessed by a public authority under any other law for the time being in force;

- **“Right to Information" Sec 2(j) means** the right to information accessible under this Act which is held by or under the control of any public authority and includes the right to

(i) inspection of work, documents, records;

(ii) taking notes, extracts or certified copies of documents or records;

(iii) taking certified samples of material;

(iv) obtaining information in the form of floppies, tapes, video cassettes or in any other electronic mode or through printouts where such information is stored in a computer or in any other device.

- **“Record” Sec 2(j)**

- Any document, manuscript and file;
- Any microfilm, microfiche and facsimile copy of a document;
- Any reproduction of images or images embodied in such microfilm and
- Any other material produced by a computer or any other device .

# What is RTI Act?

- Provides a legal framework of citizens' democratic right to access to information under the control of public authorities.
- To promote transparency and accountability in the functioning of every public.

# Who is a Public Authority?

"Public authority means any authority or body or institution established or constituted"

- By or under the constitution ;
- By any other Law made by the Parliament;
- By any other Law made by State Legislature
- By notification issued or order made by the appropriate Government and includes any

I. Body owned, controlled or substantially financed,

II. Non-Government organization substantially financed directly or indirectly by funds provided by the appropriate Government;

# What does 'Information' mean?

- Records
- Documents
- Memos
- Opinions and advices
- Press releases
- Circulars orders & log books
- Contracts
- Reports, papers, samples & models

# Need for RTI Act

**Because it helps to:**

- Promote openness, transparency and accountability in the working of every public authority.
- Reduce corruption
- Prevent administrative arbitrariness
- Bridge the gap between providers and recipients of public services.
- Make citizens part of decision making
- Make administrative responsive
- Strengthen the foundations of Democracy

# Procedure for requesting Information

- Apply in writing or through electronic means in English or Hindi or in the official language of the area, to the Public Information Officer (PIO) specifying the particulars of the information sought for.
- Reason for seeking information are not required to b given;
- Pay fees may b as prescribed.

# Fees and Charges

- Application fee Rs.10/-
- information is required in electronic media- floppy/CD, etc., additional charges will be applicable.
- Photocopy charges of Rs.2/- per page
- Inspection charges of relevant files, documents and records:
- ✓ no fee for first hour of inspection.
- ✓ Rs,5/- for every subsequent hour of fraction thereof.
- Processing expenses incurred by the Public Information Officer to be intimated in writing.
- Applicant can seek review of the decision on fees charged by the PIO by applying to the appropriate Appellate Authority;
- No fees from people living below the poverty line
- Free of cost if the IPO fails to comply within the time limit as prescribed under the RTI Act.

# Time limits to get the information

- 30 days if application is filed with the PIO
- 35 days in case it is filed with the Assistant PIO
- 48hours in case the matter to which the information pertains affects the life and liberty of an individual.

# Coverage

RTI Act came into force on 12TH October 2005

- Covers Central, State and Local Governments and all bodies owned, controlled or substantially financed by the respective Governments; Section 2(h)
- Non-Government organization substantially financed directly or indirectly by funds provided by the appropriate Government; Section 2(e)
- Executive, Judiciary and Legislature.
- Includes information relating to private body which can be accessed by under any other law for the time being in force; Section 2(f)

# Exemptions from disclosure of Information

a) National security
b) Contempt of court
c) Parliamentary privilege
d) Trade secrecy
e) Fiduciary relationship
f) Foreign government
g) Safety of informer in Law enforcement
h) Investigation
i) Cabinet papers
j) Privacy
k) Copyright- disclosure which would involve an infringement of copyright subsisting in a person other than the State may be rejected. (Section 9)

# ILLUSTRATIONS

- Personal details, income, pan, sources of fund, partnership details
- Marks awarded by individual panel experts under different parameters
- Property return and details of property
- Assessment reports
- Medical report
- Details of the bank accounts
- Answer sheets
- Frivilous queries that are prefixed with wholly unsubstantiated adjective such as ‘fake’
- Queries asking for an explanation from the authority

# Appeal

- First appeal with the senior in the department.
- Second appeal with the Information Commission.
- Envisages an independent Information Commission at the central and state level to be an appellate authority and to oversee the functioning of the Act. Has various powers under RTI Act.

# PENALTIES

- The penalty levied under the RTI Act at the rate of Rs.250/- a day, up to maximum of Rs.25000/- is recovered from the salary of officials.

# Thank you

# Intellectual Property Rights

**Ms. Manisha K. Gavit**
**Assistant Professor**
**(Department of Pharmaceutical Chemistry)**

**JES's college of Pharmacy,Nandurbar**

# Introduction

- Intellectual property rights is a term used for various legal entitlements which attach to certain types of information, ideas or other intangible in their expressed form.
- The term intellectual property reflects the idea that this subject matter is the product of the mind or the intellect and the intellectual property rights may be protected at law in the same way as any other form of property.

# Intellectual Property

- Intellectual property is an intangible creation of the human mind, usually expressed or translated into a tangible form that is assigned certain rights of property.
- Intellectual property include music, literature and other artistic works, discoveries and inventions and words, phrases, symbols and designs.

# Categories of Intellectual Property

- **Industrial property-** It includes inventions (patents) trademarks, industrial designs and geographical indications of source.
- **Copyright-** It includes literary and artistic works such as novels, poem and plays, films musical works, artistic works such as drawing, paintings, photographs and sculptures and architectural designs.

# Intellectual Property Rights

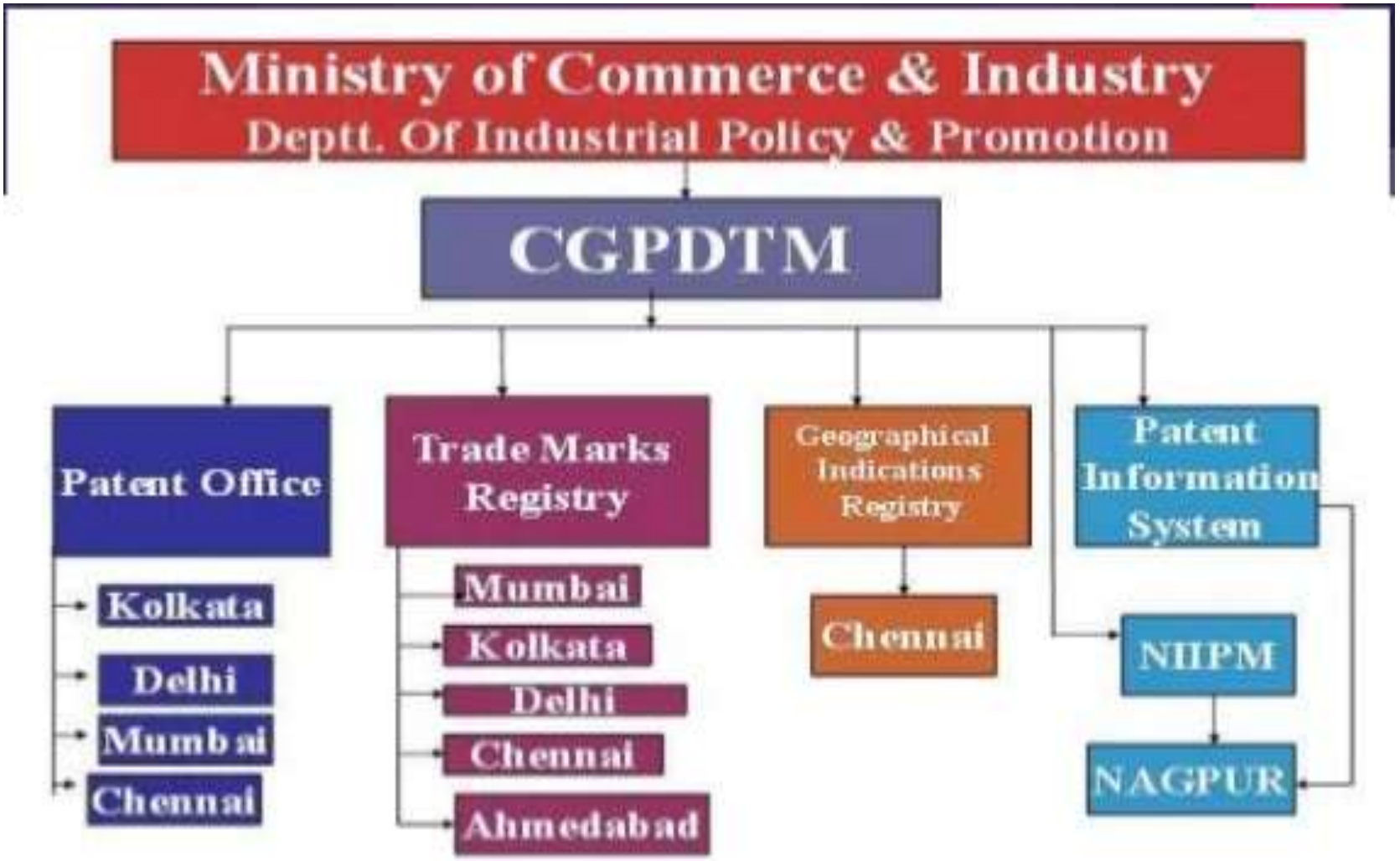
- The rights given to people over the creation of their minds. They usually give the creator an exclusive right over the use of his/her creations for a certain period of time.

# Types of Intellectual Property Rights

- Patents
- Trademarks
- Copyrights
- Geographical indications
- Industrial designs
- Trade secrets
- Layout designs for integrated circuits
- Protection of new plant variety

# Patents

- A patent is an exclusive right granted for an invention.
- In exchange for this right, the patent owner makes technical information about the invention publicly available in the published patent document.
- Patent duration-
- Term of every patent in India is 20 years.

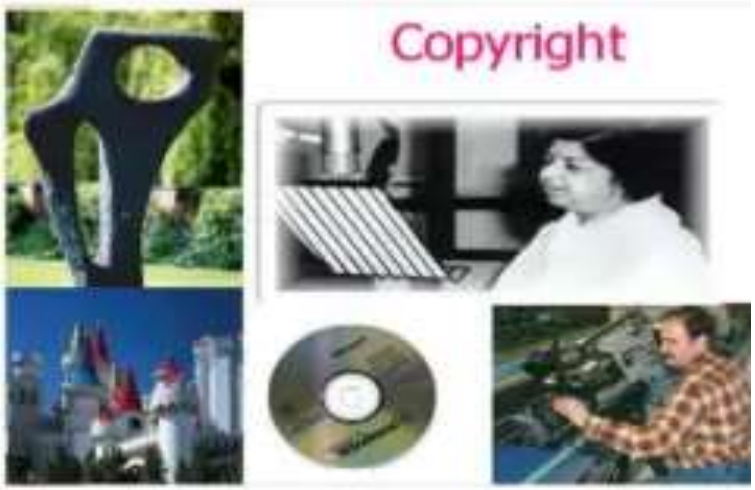

Ministry of Commerce & Industry
Deptt. Of Industrial Policy & Promotion
CGPDTM
Patent Office
Kolkata
Delhi
Mumbai
Chennai
Trade Marks Registry
Mumbai
Kolkata
Delhi
Chennai
Ahmedabad
Geographical Indications Registry
Chennai
Patent Information System
NIIPM
NAGPUR

# Trademarks

- A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises.
- It protects the public from confusion and deception by identifying the source or origin of products as distinguished some other similar products.
- It may consist of drawings, symbols, three- dimensional signs such as the shape and packaging of goods.

# Copyrights

- Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings.



# Geographical Indications

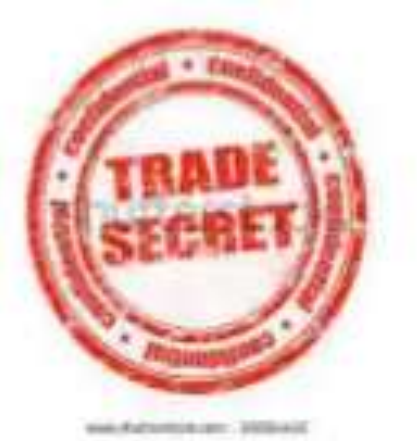
- Indications which identify a good as originating in the territory of a member, or a region or a locality in that territory, where a given quality, reputation or characteristic of the good is essentially attributable to its geographic origin
- More importantly, it identifies the product's special characteristics, which are the result of the product's origins.
- Examples-
- Darjeeling tea
- In Rajasthan- Bikaneri Bhujia.
- In Andhra Pradesh- Tirupati Laddu.
- In Maharashtra- Mahabaleshwar strawberry.

# Industrial designs


- An industrial design constitutes the ornamental or aesthetic aspect of an article.
- Owners of protected designs must be able to prevent the manufacture, sale or importation of articles bearing or embodying a design which is a copy of the protected design.
- It consists of :
- Three-dimensional features, such as the shape of a product;
- Two-dimensional features, such as ornamentation, patterns, lines or colour of a product.
- Industrial designs are applied to a wide variety of industrial products and handicrafts: from technical and medical instruments to watches, jewellery and other luxury items; from house wares and electrical appliances to vehicles and architectural structures.

# Trade Secrets

- Usually these are manufacturing or industrial secrets and commercial secrets.
- These include sales methods, distribution methods, consumer profiles, advertising strategies, lists of suppliers and clients, and manufacturing processes. Contrary to patents, trade secrets are protected without registration.



# Layout Design for Integrated Circuits

- The aim of the Semiconductor Integrated Circuits Layout-Design Act 2000 is to provide protection of Intellectual Property Right (IPR).
- The main focus of SICLD Act is to provide for routes and mechanism for protection of IPR in Chip Layout Designs created and matters related to it.

# Protection of New Plant Variety

- The Plant Variety Protection and Farmers Rights act 2001 was enacted in India to protect the New Plant Variety.
- The act has come into force in 2005 through the Authority.

Thank you