Pharmaceutical Legislation in India

Legislation

- 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 overlappingly covers both social and economic aspects.

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

Origin

- 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 openes small factory at Parel for the development of Pharmaceutical units and Alembic chemical works Ltd. at Baroda

- 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 improved
- Demand of indigenous drug was also improved
- Competition becomes unhealthy and indain marked flooded with inferior, substandard and even harmful drugs.

Drug Enquiry committee

- Appointed by Indian Govt. in 1931
- Committee chairman was Lt. Col. R. N. Chopra
- 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.

Recommendation of DEC

- 90 recommendations with report was submitted by the committee .

Important Recommendations:

1. 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.
2. Creation of drug control machinery (Departments) at the centre and branches in all states.
3. Establishment of a well-equipped Central Drug Laboratory (CDL) with competent staff and experts for an efficient and speedy working of Drug Control Department. Small laboratories would work under its guidance.

Drug Bill

- Because of reluctant approach of Govt. towards implementation of the recommendation of DEC, public pressurised the Govt.
- Ultimately in 1937, Import of Drug bill was introduced in legislative assembly to control the import of drugs.
- However the manufacture, sale and distribution of drug was not included in bill.
- Committee forced the government to include all these aspects.
- As a result in 1940, Drug bill was again introduced in assembly.
- Drug bill 1940 was passed.
- It came into force as Drug Act 1940, later on it was amended many times and at present the act covers provisions related to Drugs, Cosmetics, Ayurvedic, Unani and Homeopathic medicine.

- The present Drug and Cosmetic act is an improved version of Drug act, 1940.
- Objective: to control Import, manufacture, distribution and sale of drugs and cosmetics.
- Central Govt. has made many rules for the same and presented it as Drug and Cosmetic Rules 1945.
- This act and rules were amended from time to time.

Other IMP Act

- After Independence in 1947, the other act were also enacted as per recommendations of DEC.

- Pharmacy Act 1948
- The drugs and magic remedies act 1954
- Medicinal and toilet preparations act 1955 and rules 1956
- Drugs Price Control Order 1979 and changed at 1987
- Narcotic drugs and psychotropic substances act 1985

Miscellaneous Act

- The Industries act 1951
- The industries employment act 1946 and rules
- Factory act 1948
- Indian Patent and Design act 1970
- Trade and Merchandise mark act 1958

Pharmaceutical Ethics

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

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 neighbor in hours of need	Helping neighbors 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 PCI for the guidance of Indian pharmacist. The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to:

His job

His trade

His profession (Pharmacy)

Medical profession

PHARMACIST IN RELATION TO HIS JOB

1. **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.

2. 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.

3. Handling of Prescriptions:

- When a prescription is presented for dispensing. It should be received by a pharmacist without any discussion or comment over it regarding the merits and demerits of its therapeutic efficiency.
- The Pharmacist should not even show any expression on his 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.

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- Any question on a prescription should be answered with every caution and care; it should neither offend a patron nor should it disclose any information, which might have been intentionally, withheld from him.
- It is not within the privilege of a Pharmacist to add, omit or substitute any ingredient or alter the composition of a prescription without the consent of the prescriber, unless the change is emergent or is demanded purely by the technique of the pharmaceutical art and does not cause any alteration in the therapeutic action of the recipe.

- In case of any obvious error in it due to any omission, incompatibility or overdosage, the prescription should be referred back to the prescriber for correction or approval of the change suggested.
- While such an act is imperative in the best interest of the patient, in no case should it be done in a manner, which may hamper the reputation of the prescriber concerned.
- In matter of refilling prescriptions a pharmacist should solely be guided by the instructions of the prescriber aid he should advise patients to use medicines or remedies strictly in accordance with the intention of the physician as noted on the prescription.

4. 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. He should never fill his prescriptions with spurious, sub-standard and unethical preparations.
- A Pharmacist should be very Judicious in dealing with drugs and medicinal preparations used for addiction or any other abusive purposes.

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5. 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.

Pharmacists in Relation to his trade

Pharmacists in Relation to his trade

1. **Price Structure:**

- Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labor 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.

2. 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.

3. 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.

4. 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.

5. 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 his Profession

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

PHARMACIST IN RELATION TO MEDICAL PROFESSION

1. 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,
2. Clandestine Arrangement: No pharmacist should enter into the secret arrangement and contract with the physician to offer him any commission or any other advantage.
3. 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

- *At this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy.*
- *I will consider the welfare of humanity and relief of human suffering my primary concerns.*
- *I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patients I serve.*
- *I will keep abreast of developments and maintain professional competency in my profession of pharmacy.*
- *I will maintain the highest principles of moral, ethical, and legal conduct.*
- *I will embrace and advocate change in the profession of pharmacy that improves patient care.*
- *I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.*

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Pharmacy Act-1948

- Objectives, Definitions, Pharmacy Council of India; its constitution and functions
- Education Regulations, State and Joint state pharmacy councils
- Registration of Pharmacists, Offences and Penalties

Introduction

- Recommendations by **DEC committee**
- Recommendations by **Health Survey and Development committee**
- Pharmacy Act came into force in **4 March 1948.**

Objectives

- **To regulate the profession and practice of pharmacy** and to raise the status of pharmacy in India
- **Constitution of Pharmacy Council of India** (PCI) (Central Council)- responsible for evolving educational standards and regulations for the course in Pharmacy through Education Regulations.
- **Constitution of State Pharmacy Council** of India for registration of Pharmacist and for regulating their professional activities.

Definitions

1. **Central Council:** The pharmacy council of India.
2. **Central Register:** Register of Pharmacist maintained by the central council.
3. **Registered Pharmacist:** A person whose name for time being entered in the register of pharmacist of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy.
4. **University Grant Commission:** It means the University grant commission established under section 4 of the university grant commission act, 1956

Definitions

7. Displaced person:

- Person who on account of the setting up of the Dominions of India and Pakistan or on account of the civil disturbances or the fear of such disturbances in area now forming part of Pakistan has on or after the first day of March 1947, left or been displaced from his place of residence in such area and who has since then been residing in India.
- Any person who on account of the civil disturbances or the fear of such disturbances in any area now forming a part of Bangladesh, has after 14th day of April 1957 but before the 25th day of March 1971, left or has been displaced from his place of residence in such area and who has since then been residing in India.

Definitions

8. Medical Practitioner:

a) A person holding qualifications granted by an authority specified or notified under sec. 3 of Indian Medical Degrees Act, 1916. or specified in the schedules to the Indian Medical Council Act, 1956.

b) A person registered or eligible for registration in a medical register of the state meant for the registration of a person practicing modern scientific system of medicine.

Definitions

8. Medical Practitioner:

c) A person registered in a medical register of the state who although not falling within subclause (a) or (b) is declared by a general or special order made by state government in this behalf as a person practicing the modern scientific system of medicine for the purpose of this act

d) A person who is engaged in the practice of veterinary medicine and who possess qualifications approved by State Government.

Pharmacy Council of India

- Constituted under section 3 of the chapter 1 by the central government
- The first pharmacy council of India (P.C.I) constituted by central government in 1949.
- It is reconstituted every 5 years.
- It consists of three different types of members-

1. Elected member
2. Nominated member
3. EX-Officio Member

Elected members

A. 6 members(teachers), elected by **University Grant Commission** (UGC). There is at least one teacher of each subject i.e., Pharmacy, Pharmaceutical chemistry, Pharmacognosy and Pharmacology.

B. One member, elected by **Medical Council of India**.

C. One member from each state, elected by **State Council**, who shall be a registered pharmacist.

Nominated Members

A. **6** member, nominated by the Central Government of whom at least **4** shall be possessing a degree or diploma in pharmacy and practicing pharmacy or pharmaceutical chemistry.

B. A representative of the U.G.C.

C. A representative of the All India Council for Technical Education (A.I.C.T.E.)

D. One member from each state, nominated by State Government, who shall be a registered pharmacist.

Ex-officio Members

A. DGHS

B. Drug controller of India

C. Director of the Central Drug Laboratory

The **Executive Committee** consists of

1. President
2. Vice president
3. Five other members elected by Central Council from its member's

Apart from this, the council also appoints

1. A registrar/ Secretary
2. Other officers and servants for carrying out its statutory functions

President and Vice-President of Central Council

- Elected by the members of the Council among themselves.
- The President or Vice-President shall hold office as such *for a term* ***not*** **exceeding five** years and ***not extending beyond the expiry of his term*** as member of the Central Council.
- He shall be eligible for re-election.
- **Mode of elections-** Elections under this Chapter shall be conducted in the prescribed manner, and where any dispute arises regarding any such election it shall be referred to the Central Government whose decisions shall be final.

Term of Office and Casual Vacancies

- Subject to the provisions of this section, a nominated or elected member shall hold office for a term of five years from the date of his nomination or election or until his successor has been duly nominated or elected, whichever is longer.
- A nominated or elected member may at any time resign his membership by writing under his hand addressed to the President, and the seat of such member becomes vacant.
- A nominated or elected member shall be deemed to have vacated his seat if he is absent without excuse, from three consecutive meetings of the Central Council.

- A casual vacancy in the Central Council shall be filled by fresh nomination or election and the person nominated or elected to fill the vacancy shall hold office only for the remainder of the term.
- Members of the Central Council shall be eligible for re-nomination or re-election.

Staff , Remuneration and Allowances

The Central Council Shall

(a) appoint a **Registrar** who shall act as the Secretary to that Council and who may also, act as the Treasurer.

(b appoint such other **officers and servants** as that Council deems necessary to enable it to carry out its functions under this Act.

(d) with the **previous sanction of the Central Government**, shall fix the **remuneration and allowances** to be paid to the President, Vice-President, and other members of that Council, the pay and allowances and other conditions of service of officers and servants of that Council.

Functions of PCI

1. **To prescribe** minimum standards of education required for qualification as a Pharmacist.
2. **To regulate** the minimum educational standards.
3. **To recognize qualifications granted outside** the territories to which Pharmacy Act, 1948 extends for the purpose of qualifying for registration under the said Act.
4. **To compile and maintain** a central register.
5. All other functions that may be assigned for implementation of the act.

Education Regulations

Subject to the provision of Section 10 of the Pharmacy Act 1948, Central Council after approval of central government may make regulations prescribing the **minimum standards of education required for qualification as pharmacist called *Education Regulations*.**

Education Regulations Prescribes;

1. Minimum qualification for admission to the course.
2. Nature and period of course of study.
3. Nature and period of practical training to be undertaken after completion of course.
4. Subjects of examinations and their standard.
5. The equipment's and facilities to be provided by the Institutions to the students.
6. Conditions to be fulfilled by Institutions giving practical training
7. Conditions to be fulfilled by authorities holding approved examinations.

Approval of Institution/ Authorities providing courses of Study and Examinations

1. Application by Institution/ Authority to the central council
2. Inspection
3. Approval
4. Declaration

Withdrawal of Approval

APPROVAL OF QUALIFICATION GRANTED OUTSIDE INDIA

1. Qualification in pharmacy granted outside India can be recognized by PCI. This is applicable to Indian citizens.
2. Citizens of foreign nationality can be eligible for registration when an Indian national holding the same qualification is allowed to enter an practice in that country.

CENTRAL REGISTER

- Under the provision of pharmacy act (1976), the PCI of India is required to maintain a Central Register.
- Each state govt. has to supply five copies of register for a state to the central council, after the first day of April every year
- The register has to be maintained by the Registrar of PCI.
- Has to be revised suitably from time to time
- Published in the gazette of India.

State Pharmacy Councils

Elected members

- Six members- by registered pharmacist of the state
- One member elected by the members of MCI

Nominated members

- Five members nominated by the State Government from the persons who hold degree or diploma in pharmacy.

Ex-officio members

- Chief administrative Medical Officer of the state
- Officer in charge of Drugs Control Organization of the State
- Government Analyst.

Joint State Pharmacy Councils

Two or more states enter into an agreement to form a joint state pharmacy council

Elected members

- Registered pharmacist- 3 to 5 from each state
- Medical council- 1 from each participating state.

Nominated members

- 2-4 members nominated by each State Government from the persons who hold degree or diploma in pharmacy.

Ex-officio members

- Chief administrative Medical Officer of each participating state
- Officer in charge of Drugs Control Organization of each participating State
- Government Analyst of each participating state.

Election and Terms of office

- The president and vice president are elected by the members from amongst themselves.
- Period of 5 years
- Casual vacancy is filled by nomination or election
- Members are eligible for re-election
- Possess an executive committee similar to the central council.

Inspection

The state council may appoint **Inspectors** having the qualifications as per the Act.

Powers:

1. Inspect any premises where drugs are compounded and dispensed.
2. Enquire whether the person engaged in dispensing is a registered pharmacist or not.
3. Institute prosecution under the order of the Executive Committee of the State Council.
4. Other essential powers.

Registration of Pharmacist

- **Preparation and maintenance of register**

The register shall include the following particulars, namely:

a) the full name and residential address of the registered person;

b) the date of his first admission to the register;

c) his qualifications for registration;

d) his professional address, and if he is employed by any person, the name of such person;

e) such further particulars as may be prescribed.

Qualifications for entry on first register

A person who has attained the age of eighteen years shall be entitled on payment of the prescribed fee to have his name entered in the first register if he resides or carries on the business or profession of pharmacy, in the State

- He must (a) holds a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or a State Government. OR a prescribed qualification granted by an authority outside India.
- OR (b) holds a degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than three years.

- OR (c) has passed an examination recognized as adequate by the State Government for commoners or dispensers
- OR (d) has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than five years prior to the date notified under subsection (2) of section 30.

Special provisions for "registration of certain persons"

Notwithstanding anything contained in section 32, a State Council may also permit to be entered on the register-

- (a) the names of displaced persons who have been carrying on the business or profession of pharmacy as their principal means of livelihood from a date prior to the 4th day of March 1948, and who satisfy the conditions for registration as set out in section 31
- (b) the names of citizens of India who have been carrying on the business or profession of pharmacy in any country outside India and who satisfy the conditions for registration as set out in section 31
- (c) the names of persons who resided in an area which has subsequently become a territory of India and who satisfy the conditions for registration as set out in section 31

Qualifications for entry in register:

- He/ She should hold a diploma in pharmacy or pharmaceutical chemistry.
- He/ She holds a degree in an Indian University other than pharmacy and has been engaged in the compounding of drugs in hospital or dispensary for a total period not less than 3 years.
- Has passed an examination recognized as adequate by the State Government for commoners or dispensers.

Entry and removal of names:

Entry:

- All applicants for the registration should be addressed to the Registrar of SPC.
- If the applicant has the requisite qualifications for registration, he shall direct his or her name to be entered in the register.
- Upon entry, a certificate of registration is issued.

Removal:

- Registration by error.
- If he has been convicted of any offence in any professional aspect.
- 30day period for appealing
- Surrender of certificate of registration and publication in the official gazette.

PRINTING OF REGISTER:

- It is done on the 1st day of April subsequent to the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959).
- Thereafter, each year after the first of April, register will arrange for reprinting showing supplements to the registers.
- These supplements and registers are deemed to be proof that the persons whose names are contained therein, are registered pharmacists.

RENEWAL FEES:

- The state govt. by notification in the official gazette, direct that for the retention of the name in the register.
- In order to retain the name in the register, renewal fee shall be paid to the state government as may be prescribed.
- Where a renewal fee is not paid by the due date, the Registrar shall remove the name of the defaulter from the register.
- On payment of the renewal fee, the Registrar shall issue a receipt and such receipt shall be proof of renewal of registration.

Offences and Penalties

OFFENCES	PENALITIES
Falsely claims to be a registered pharmacist	**First Conviction:** Fine up to Rs.500. **Subsequent Conviction:** Fine up to Rs.1000 and/or 6 months imprisonment.
Dispensing by an unregistered person	6 months of imprisonment **or** a fine of up to Rs1000 **or** both.
Failure to surrender the Certificate of registration	Fine of Rs.50
Obstruction of state pharmacy council inspectors	Imprisonment of up to 6 months or a fine up to Rs1000 or both

DRUG AND COSMETIC ACT 1940

AND RULES 1945

History

- British misrule-Providing poor healthcare system to Indian citizens
- Observations made by-Drugs Enquiry Committee, Indian Medical Association
- Reports in- Indian Medical Gazette during 1920-30
- 1940 – Drugs and Cosmetics Act
- 1945 – Rules under the Act

Extended to whole of India……

Objectives

- To regulate the **import, manufacture, distribution and sale** of drugs & cosmetics through licensing.
- Manufacture, distribution and sale of drugs and cosmetics by **qualified persons only**.
- To prevent **substandard** in drugs.
- To regulate the manufacture and sale of **Ayurvedic, Siddha and Unani drugs.**
- To establish **Drugs Technical Advisory Board(DTAB)** and **Drugs Consultative Committees(DCC)** for Allopathic and allied drugs and cosmetics.

Definitions

- **Drugs :**

All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

- **Cosmetic :**

Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

- **Misbranded drugs :**

  (a) if it is so **coloured, coated, powdered or polished** that damage is concealed or if it is made to appear of **better or greater therapeutic** value than it really is; or

  (b) if it is **not labelled** in the prescribed manner.

- **Adulterated drug :**

(a) if it consists, in whole or in part, of any **filthy, putrid** or **decomposed** substance; or

(b) if it has been prepared, packed or stored under **insanitary conditions** whereby it may have been contaminated with filth or whereby it may have been rendered **injurious to health**; or

(c) if its container is composed in whole or in part, of any **poisonous or deleterious substance** which may render the contents injurious to health.

- **Spurious drugs :**

(a) if it is **imported** under a name which belongs to another drug; or

(b) if it is an **imitation** of, or a **substitute** for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the **name of another drug**

- **Manufacture :**

In relation to any drug or cosmetic, it includes any process or part of a process for **making, altering, ornamenting, finishing, pac king, labelling, breaking up or otherwise treating or adopting** any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

- **Patent or Proprietary medicine** :

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is **not included in the edition of the Indian Pharmacopoeia** for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government.

Administration of the act and rules

A) Advisory :

1)Drugs Technical Advisory Board-DTAB

2)Drugs Consultative Committee-D.C.C.

B) Analytical :

1)Central Drugs Laboratory - CDL

2)Drug Control Laboratory in states

3)Government Analysts

C) Executives :

1)Licensing authorities

2)Controlling authorities

3)Drug Inspectors

Drugs Technical Advisory Board(DTAB)

- **Ex-Officio:**

(i) Director General of Health Services (Chairman)

(ii) Drugs Controller, India

(iii)Director of the Central Drugs Laboratory, Calcutta

(iv) Director of the Central Research Institute, Kasauli

(v)Director of Indian Veterinary Research Institute, Izatnagar

(vi) President of Medical Council of India

(vii) President of the Pharmacy Council of India

(viii)Director of Central Drug Research Institute, Lucknow

- **Nominated:**

1) **Two** persons by the **Central Government.**
2) **One** person by the **Central Government** from the **pharmaceutical industry**
3) **Two** persons holding the appointment of **Government Analyst** under this Act,

- **Elected:**

1)one person, to be elected by the Executive Committee of the **Pharmacy Council of India**,

2)one person, to be elected by the Executive Committee of the **Medical Council of India**,

3)one **pharmacologist** to be elected by the Governing Body of the Indian Council of Medical Research;

4)one person to be elected by the Central Council of the **Indian Medical Association**;

5)one person to be elected by the Council of the **Indian Pharmaceutical Association**;

- **Functions:**

To **advise** the Central Government and the State Governments on technical matters.

To carry out the other functions assigned to it by this Act.

- **Elected:**

1)one person, to be elected by the Executive Committee of the **Pharmacy Council of India**,

2)one person, to be elected by the Executive Committee of the **Medical Council of India**,

3)one **pharmacologist** to be elected by the Governing Body of the Indian Council of Medical Research;

4)one person to be elected by the Central Council of the **Indian Medical Association**;

5)one person to be elected by the Council of the **Indian Pharmaceutical Association**;

Drugs Consultative Committee(DCC)

- It is also an **advisory body** constituted by central government.

- Constitution:

  Two representatives of the **Central Government**

  One representative of each **State Government**

- **Functions:**

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure **uniformity throughout India** in the administration of this Act.

- The Drugs Consultative Committee shall **meet when required**

- Has power to regulate its own procedure.

Central Drug Laboratory(CDL)

- Established in **Calcutta**, under the control of a director appointed by the Central Government.

Functions:

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical **Q.C.** of the imported samples.
- Collection, storage and distribution of **internal standards.**
- Preparation of **reference standards** and their maintenance.
- Maintenance of **microbial cultures.**
- **Any other duties** entrusted by Central Government.
- Acting as an **appellate authority** in matter of disputes.

Drug control laboratories in state

In gujarat three laboratories established which collect, analysed and report the various sample of the drugs and food.

1) Baroda: Established in 1959.
2) Bhuj: Established in 1979.
3) Rajkot: Established in 1983

The laboratory has the following devision:-

- Pharmaceutical Chemistry Division
- Immunology Division
- Pharmacology Division
- Pharmacognocy Division
- Food Division
- Ayurvedic Division

Function:

- Testing of drug sample
- Analysis of food sample
- Analysis of exicse sample

Government analyst

- These officers are appointed by the central or state government and perform the duties.

Qualification of government analysist

1 Persons having qualification for appointment as government as govermental Analysis for allopathic drugs ;

2 having a degree in medicine, ayurved, sidha or unani system and not less than three year post graduate experience in the analysis of drugs in a laboratory under control of a government analyst.

Duties:

- *1) The Government Analyst shall cause to be* analysed or tested such samples or drugs and cosmetics as may be sent to him by Inspectors.
- *2)A Government Analyst shall from time to time forward reports to the Government giving* the result of analytical work and research with a view to their publication.

Licencing authority

Qualification:

(i) Graduate in Pharmacy on Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a University established in India by law; and

(ii) Experience in the manufacture or testing of drugs a minimum period of five years, Provided that the requirements as to the academic qualification shall not apply to those inspectors .

Duties:

- *1) The Government Analyst shall cause to be* analysed or tested such samples or drugs and cosmetics as may be sent to him by Inspectors.
- *2)A Government Analyst shall from time to time forward reports to the Government giving* the result of analytical work and research with a view to their publication.

Duties:

(1) to inspect all establishments licensed for the sale of drugs within the area assigned to him;

(2) to satisfy himself that the conditions of the licences are being observed;

(3) to procure and send for test or analysis, if necessary, imported packages.

(4) to investigate any complaint.

(5) to maintain a record of all inspections made and action taken by him in the performance of his duties,

(6) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention to the Act;

Drug Inspector

Qualification

1 Persons having qualification for appointment as government as govermental Analysis for allopathic drugs ; or

2 having a degree in ayurved, sidha or unani system and not less than three year post graduate experience in the analysis of drugs in a laboratory under control of (a) a government analyst, or (b) a chemical examinar, or (c) head of an institution specially approved for this purpose.

Power:

a) **Inspect, --**

(i) any premises where in any drug or cosmetic is being manufactured.

(ii) any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed ;

(b) **Take samples of any drug or cosmetic,--**

(i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

(ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

IMPORT of drugs

- Classes of drugs prohibited to import
- Import of drug under license

  1)Specified in Schedule-C/C_1

  2)Specified in Schedule-X

  3)Imported for Test/Analysis

  4)Imported for personal use

  5)Any new drugs
- Drugs exempted from provisions of import
- Offences and Penalties

Import of the biological drugs(C/C_1)

Conditions to be fulfillled:

- Licensee must have adequate **facility for the storage.**
- Licensee must maintain a **record of the sale.**
- Licensee must **allow an inspector to inspect** premises and to check the records.
- Licensee must **furnish the sample** to the authority.
- Licensee must not sell drugs from which sample is withdrawn and he is advised **not to sale, and recall the batch** from the market.

Import of the Schedule-X drugs (Narcotic & Psychotropic drugs)

Conditions to be fulfilled:

- Licensee must have adequate **storage facility.**
- Applicant must be **reputable** in the occupation, trade or business.
- The license **granted even** before should **not be suspended or cancelled.**
- The licensee has **not been convicted any offence** under the Drugs and Cosmetics Act or Narcotic and Psychotropic Substances Act.

Penalties related to Import

OFFENCES	PENALTIES
Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values	a) 3 years imprisonment and 5000 Rs. fine on first conviction b) 5 years imprisonment OR 1000 Rs. fine OR both for subsequent conviction
Contravention of the provision	a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence

Manufacture

- Prohibition of manufacture
- Manufacture of other than in Sch-C/C_1
- Manufacture of those in Sch-C/C_1
- Manufacture of Sch-X drugs
- Loan license
- Repackaging license
- Offences & Penalties

Manufacture Of Sch-X drugs

Conditions:

- **Accounts of all transactions** regarding manuf. should be maintained in serially.(Preserved for 5 years)
- Have to sent **invoice of sale** to licensing authority every 3 months
- Store drugs in **direct custody of responsible person.**
- Preparation must be labeled with XRx
- Marketed in packings **not exceeding**
  - 100 unit dose –Tablets/Capsules
  - 300 ml- Oral liquid
  - 5 ml - Injection

Loan License

- Definition:

A person(applicant) who does not have his own arrangements(factory) for manufacture but who wish to manufacturing facilities **owned by another licensee**. Such licenses are called Loan licenses.

Loan licenses are issued for:

1) Drugs other than specified in C/C_1 & X.

2) Drugs specified in Schedule-C/C_1

Repackaging license

- Definition:

Process of **breaking up** any drug from a bulk container into small packages and labeling with a view to their sale and distribution.

Repackaging of drugs is granted of drugs other than Schdule-C/C_1 and X.

Penalties related to Manufacture

OFFENCES	PENALTIES
Manufacture of any spurious drugs	a) 1-3 years imprisonment and Rs.5000 fine b) 2-6 years imprisonment & Rs.10000 fine on subsequent conviction
Manufacture of adulterated drugs	a) 1 year imprisonment & Rs.2000 fine b) 2 years imprisonment & Rs.2000 fine for subsequent conviction
Manuf. of drugs in contravention of the provisions	a) Imprisonment up to 3 months & Rs.500 fine b) Imprisonment up to 6 months & Rs.1000 fine on subsequent conviction

Sale of Drugs

- Classes of drugs prohibited to be sold
- Wholesale of biological (C/C_1)
- Wholesale of other than those specified in C/C_1 and X

Wholesale of biological (C/C_1)

- Adequate premises, with **greater than 10 M^2 area**, with proper storage facility
- Drugs sold **only to retailer having license**
- Premises should be in charge of competent person who is **Reg. Pharmacist**.
- **Records** of purchase & sale
- Records preserved for 3 years from date of sale
- License should **displayed on premises**

whole sale from other than specified in c/c1 and x

- All the conditions as discussed in for biological.
- Compounding is made by or under the direct and personal **supervision of a qualified person.**

Schedules to the act

- **First schedule** – Names of **books** under **Ayurvedic** and **Siddha** systems

- **Second schedule** – **Standard to be complied** with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution

Schedules to the rules

TYPE	CONTENT
"A"	Performa for **forms**(Application, issue, renewal, etc.)
"B"	**Rates of fee** for test or analysis by CDL or Govt. analysts
"C"	List of **Biological and special products (Injectable)** applicable to special provisions.
"C_1"	List of Biological and special products **(nonparenteral)** applicable to special provisions.
"D"	List of drugs that are **exempted** from provisions of **import**
"E_1"	List of poisonous substances under the **Ayurvedic , Siddha and Unani systems**
"F"	Provisions applicable to **blood bank**

Schedules to the rules

TYPE	CONTENT
"F_1"	Special provision applicable to biological and special products, eg. Bacterial and viral vaccines, sera from living animals, bacterial origin diagnostic agents
"F_2"	Standards for **surgical dressings**
"F_3"	Standards for **umbilical tapes**
"FF"	Standards for **ophthalmic preparations**
"G"	List of substances required **to be used under medical supervision** and labelled accordingly
"H"	List of substances (**prescription**) that should be sold by retail only on prescriptions of **R.M.P.**

Schedules to the rules

TYPE	CONTENT
"J"	List of **diseases and ailments** that drug should **not claim to cure**
"K"	List of drugs that are **exempted** from certain provisions regarding **manufacture**
"M"	Requirements of manufacturing premises, **GMP requirements** of factory premises, plants and equipments
"M_1"	Requirements of factory premises for manufacture of **Homeopathic medicines**
"M_2"	Requirements of factory premises for manufacture of **cosmetics**
"M_3"	Requirements of factory premises for manufacture of **medical devices**
"N"	List of **equipment to run a Pharmacy**
"O"	Standards for **disinfectant fluids**

TYPE	CONTENT
"P"	**Life period(expiry)** of drugs
"Q"	**Coal tar colors** permitted to be used in cosmetics
"R"	Standards for **mechanical contraceptives**
"R_1"	Standards for **medical devices**
"S"	Standards for **cosmetics**
"T"	Requirements (GMP) of factory premises for **Ayurvedic, Siddha, Unani** drugs
"U"	Manufacturing and analytical records of **drugs**

DRUG PRICE CONTROL ORDER (DPCO)

Group 01
Akshay, Gaurav, Anjana, Mukta, Mayur

DPCO

- The drug price control order (DPCO) is an order issued by the government under the Essential Commodities Act which enables it to fix the prices of some essential bulk drugs and their formulations.
- The origin of this control dates back to 1970 when for the first time the government placed limits on profitability of pharmaceutical companies.

DPCO

- The drug price control order (DPCO) is an order issued by the government under the Essential Commodities Act which enables it to fix the prices of some essential bulk drugs and their formulations.
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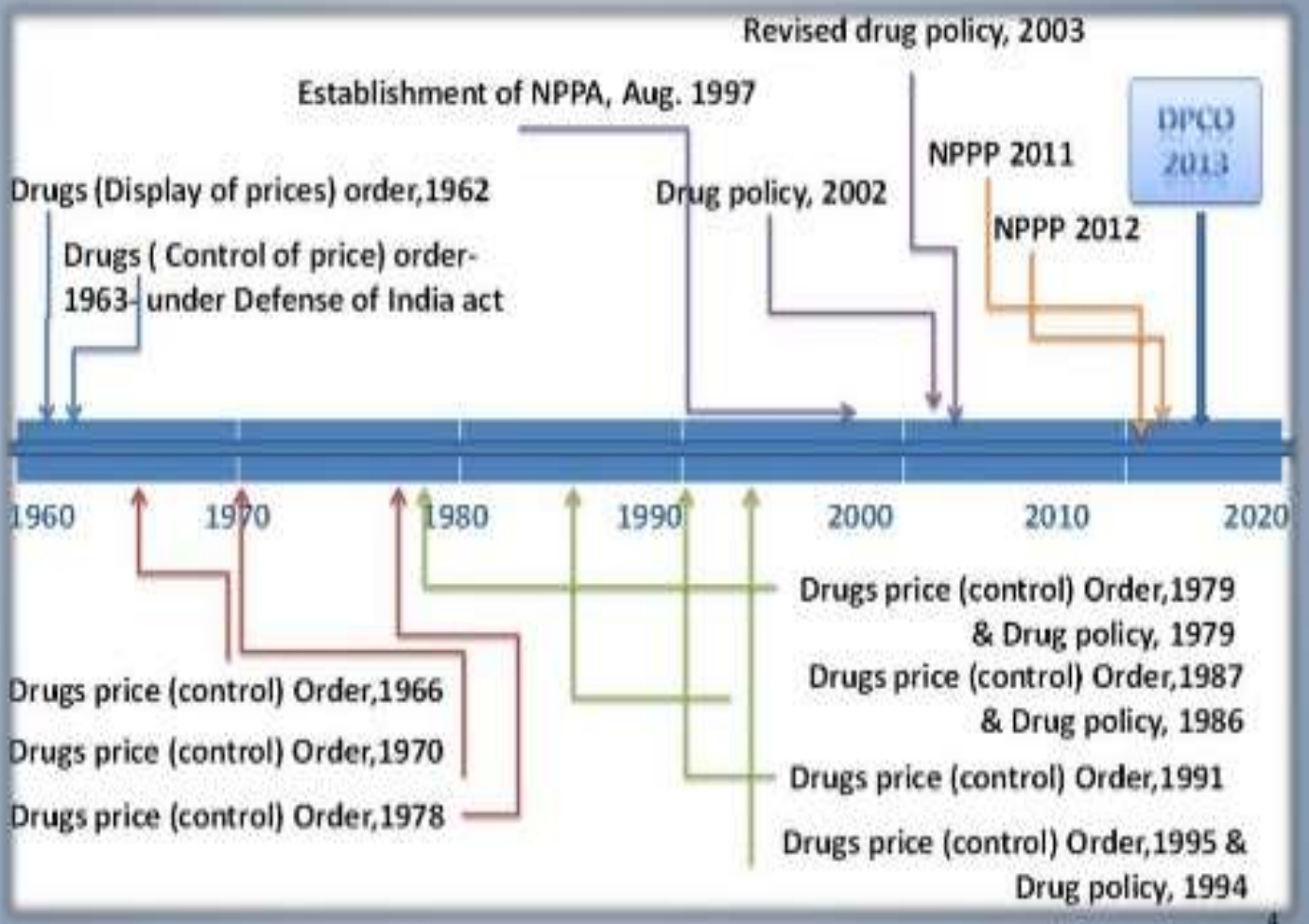
History of Price regulation in India



Objective of DPCO

- To ensure availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality.
- Promoting the rational use of drugs in the country To encourage cost-effective production with economic sizes OBJECTIVE

DPCO provides

- The list of price controlled drugs.
- Procedures for fixation of prices of drugs.
- Method of implementation of prices fixed by Government.
- Penalties for contravention of provisions

**All formulations containing the bulk drugs either in a single or combination form fall under the price control category.

DPCO 2013

- The government has notified the DPCO 2013 under the Essential Commodities Act, 1955, which will give power to the NPPP 2012 to regulate prices of 348 essential drugs along with their specified strengths and dosages under NLEM 2011.

❖ Main Features of the DPCO 2013

1) The new order will bring 348 drugs & their 652 formulations under price control.

2) The new policy uses a market-based pricing mechanism against the earlier proposed cost-plus method. The ceiling price would be calculated by taking the simple average of prices of all brands of a drug with a market share of 1% or more.

3) Margins of wholesalers & retailers have been cut down to 8% & 16% respectively.

4) Companies selling medicines above the government-mandated ceiling rated would have to slash prices to meet the demands of new rules, but those selling drugs below the ceiling price wouldn't be allowed to raise prices.

5) Firms that launch new medicines can sell them at or below government-set price caps.

6) Existing firms will not be allowed to stop production of any drug without permission from the government.

7) Drug producers will be permitted an annual increase in the retail price in sync with the wholesale price index.

› **Which drugs will come under price control?**

› This order doesn't cover **patented** drugs. Earlier in March this year the Department of pharmaceuticals (DOP) had issued a draft proposal on price negotiation of patented drugs.

› Prices of 652 formulations spanning over 27 therapeutic classes are regulated by DPCO 2013.Prices of some additional anti-cancer drugs including the much talked about Imatinib, Carboplatin, Dacarbazine, Daunorubicn, Chlorambucil, Oxaliplatin and some anti-retroviral cocktails like Zidovudine-Lamivudine-Nevirapine and Stavudine- Lamivudine will now be regulated by the current order.

How prices are calculated & fixed....

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step1: First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

***P(c) = P(s).(1+M/100)**, where*

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16

Margin to retailer: *While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.*

Maximum retail price:

(1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Ceiling price + Local Taxes as applicable

(2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Retail Price + Local Taxes as applicable

EFFECT ON PHARMA INDUSTRY

- DPCO covers a majority of the antibiotics, cough syrups, vitamin and mineral supplement which together comprise over 25% of the market in value terms.
- The bigger players in antibiotics and vitamins such as Glaxo, Ranbaxy, Cipla, Hoechst and E. Merck derive almost 60% of their revenues from products that are under price control.

MEDICINAL & TOILET PREPARATION ACT

1955

INTRODUCTION

- Alcohol has always been a fascinating friend of the mankind.
- Drinking alcohol for pleasure’s sake is an abuse.
- Use of alcohol for preparation of medicines is necessity.
- Alcohol used either for drinking or manufacture of perfumes is subjected to higher duties than that of used in medicine preparation.
- Affordability of alcohol is to be controlled.
- This is the reason to take this Act in existence.

Cont…..

- The Excise Duties Act came in force in 1955.
- For excise duty to be an effective alcohol control measure, duty increases need to increase annually in relation to inflation and income.
- It has found that increasing the level of a minimum price per unit leads to steep reductions in alcohol consumption and related harms.

What is an Excise?

- An **excise** or **excise tax** is an inland tax.
- It is different from Customs duties.
- In other words, an excise is considered an indirect tax.
- In common terminology (but not necessarily in law), an excise is distinguished from a sales tax or VAT in three ways:
- (i) an excise typically applies to a narrower range of products;
- (ii) an excise is typically heavier, accounting for a higher fraction of the retail price of the targeted products; and
- (iii) an excise is typically a per unit tax, costing a specific amount for a volume or unit of the item purchased, whereas a sales tax or VAT is an ad valorem tax and proportional to the price of the good.

- In India, an excise is described as an indirect tax levied and collected on the goods manufactured in India.
- The Act is extended throughout India.
- The Excise Duties Act is sometimes referred as “Sin tax”

❑ **Types of Excise duty**

- Basic
- Additional
- Special

❑ Excisable Goods

The term 'excisable goods' means the goods which are specified in the first schedule and the second schedule to the Central Excise Tariff Act, 1985, as being subject to a duty of excise

Objectives of Act

- Levy and collection of duties
- Curb all irregularities of previous Act

Definitions under the Act

- Alcohol- alcohol means ethyl alcohol of any strength and purity having chemical composition C2H6OH

- Dutiable goods- it includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act

- Medicinal Preparation- It includes the drugs used as a remedy or prescription prepared for internal or external use of human being or animals and all substances intended to be used for or in treatment, mitigation or prevention of disease in human being or animals

Definitions under the Act (Continue…)

- Toilet Preparation- the preparation intended to be used in the toilet of human body or in perfuming apparel of any description, or any substances intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes

Definitions under the Rules (Continue…)

- Denaturated Spirit or Denatured alcohol- it means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the central Govt. or by the State Govt. with the approval of the Central Govt.

- Spirit Store- it is the part of the bonded or non- bonded manufactory used for the storage of alcohol, opium, Indian hemp, and other narcotic drugs or narcotics purchased free of duty or at prescribed rates of duty specified in the Schedule to the Act.

Definitions under the Rules (Continue…)

- Restricted Preparation- These are medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages

- Unrestricted Preparation- These are medicinal preparations which are considered to be not capable of being, misused as ordinary alcoholic beverages

- Standard preparations- It includes:
  - A pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum i.e. requirement
  - A proprietary medicines, not conforming to the formula displayed on the label

Manufacture

- There are two modes of manufacture of medicinal and toilet preparation containing alcohol,
  - Manufacture in bond; and
  - Manufacture outside bond

    - In first case, alcohol on which duty has not been paid shall be used under the excise supervision and in the case of manufacture outside bond, only the alcohol on which duty has already been paid shall be used.

Licensing procedure

- For the preparation containing alcohol and narcotic substances
- Obtained from narcotic commissioner
- Applied with prescribed fee and format

- Details required:

- Name and address of applicant
- Place/site of the bonded laboratory
- If applicant is a firm then name and address of partners
- If applicant is a company then name address of directors, managers and managing agents and reg. no. of company.
- Amount of capital proposed.
- Number and full description of vats, stills and other apparatus and machinery.
- Maximum quantity of alcohol remain at one time in the form of finished and unfinished preparations

- Approximate date of starting production
- Statement indicating that excise officer required full time or part time
- Site and elevation plant of laboratory building
- Incase of firm copy of partnership deed
- Incase of company list of directors managers, copies of memorandum of association, articles of association and latest balance sheet
- On receiving application licensing authority verify

1. Qualification and experience of technical staff
2. Equipments
3. Suitability of proposed building
4. Soundness of applicant financial position

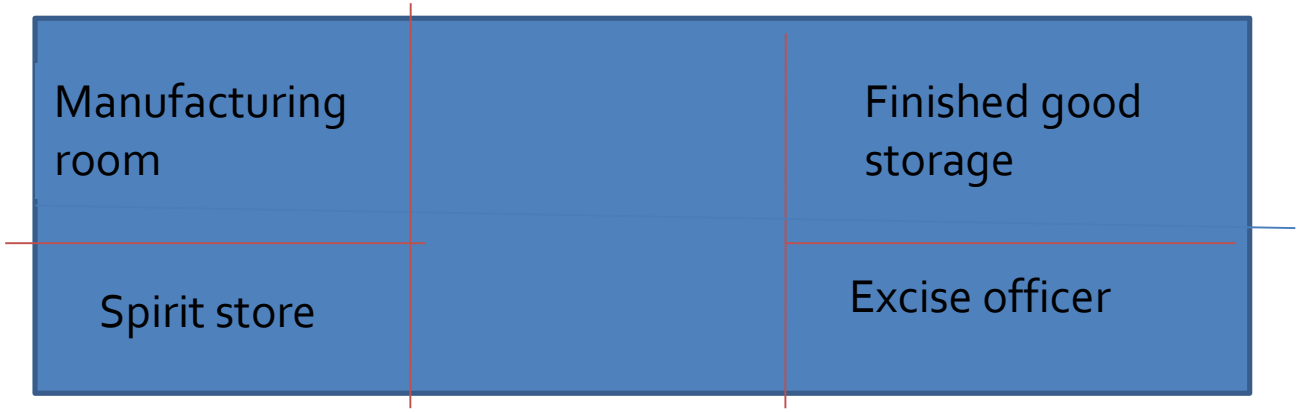
Differences in payment of fees

Manufacture in bond	Manufacture outside bond
Consumption of alcohol < 4000 liter/ year---Rs. 100	Consumption of alcohol is 125 liter/ year---Rs. 10.
Consumption of alcohol ≥ 4000 liter/ year---Rs. 200	Consumption of alcohol is 126-499 liter/ year---Rs. 25
Self generating alcohol by distillation in Ayurvedic & Unani medicines---Rs.25	Consumption of alcohol < 4000 liter/ year---Rs. 100
	Self generating alcohol by distillation in Ayurvedic & Unani medicines---Rs.25

Manufacture in bond

- Without payment of duty rectified spirit is issued with sufficient securities and bond.
- Bonded laboratory:
- Ideal requirements

1. Spirit store
2. Room for manufacturing of medicinal preparations.
3. Room for storage of finished preparations.
4. Room for manufacturing and storage of Toilet preparations
5. Accommodations for excise officer with furniture.



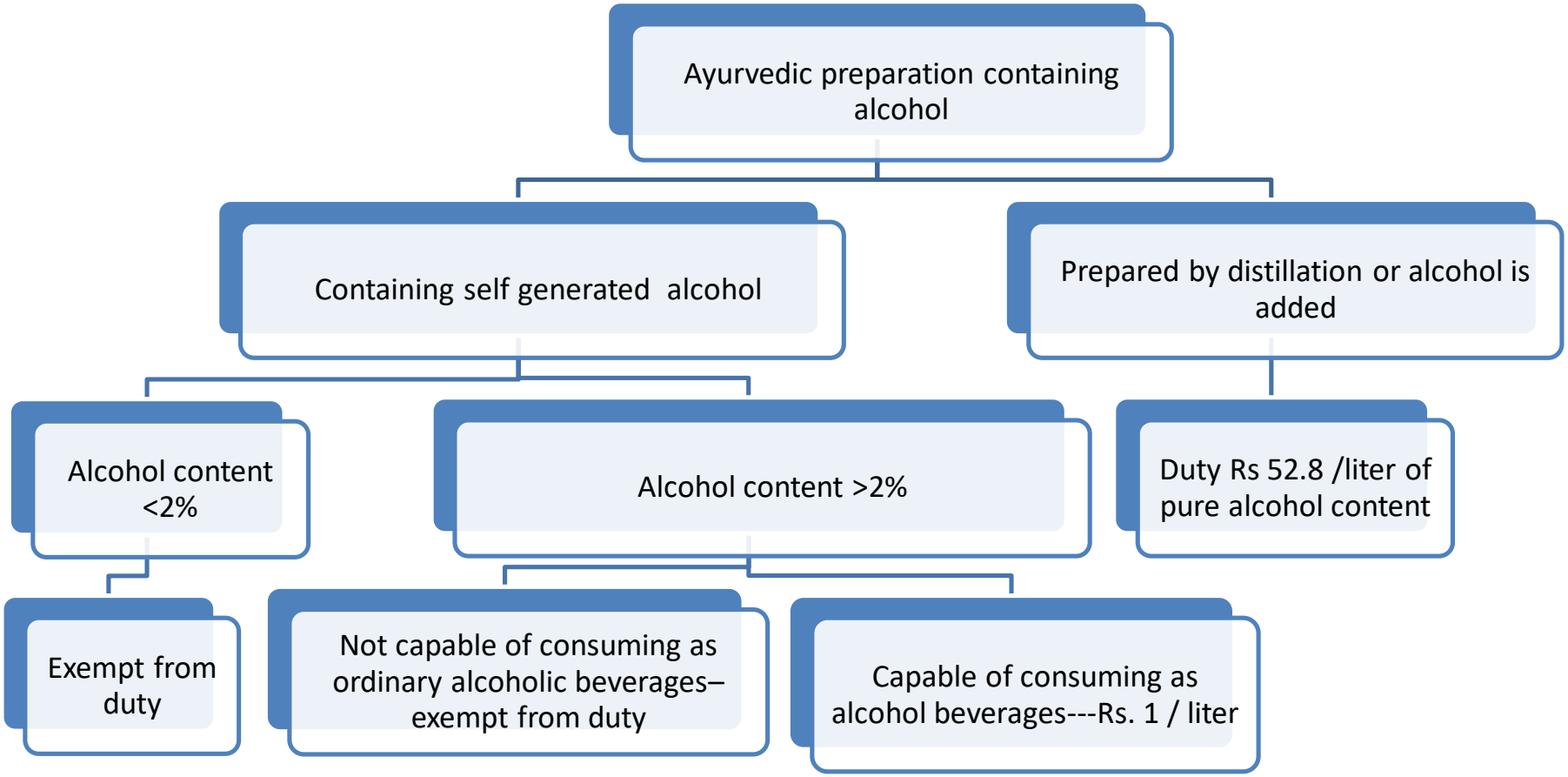
1. Obtaining the spirit
2. Verification and storage of received spirit
3. Issue of spirit from spirit store to manufacturing
4. Wastage of spirit in manufacture.
5. Storage of finished product.
6. Issue of alcoholic preparations from bonded laboratory.
7. Exemptions

Manufacture outside bond

- With payment of duty
- Non –bonded laboratory:
  - A spirit store
  - A finished good store
  - A laboratory
- Manufacturing:

1. Obtaining the spirit
2. Manufacture, storage and sale
3. Sampling
4. Returns
5. Employees
6. Inspection

Manufacture Of Ayurvedic, Homeopathic And Patent And Proprietary Preparations



Warehousing Of Alcoholic Preparations

- To store alcoholic preparation on which duty has not been paid.
- License can be issued by payment of fees Rs.25 with bond and security.
- Duty will be paid at the time of removal of goods from warehouse.
- All goods should be weighed, gauged and assessed the duty and recorded.
- No goods can be issued without payment of duty except export from India or transfer to another bonded warehouse.
- Movement of goods between two warehouse should be done by bond and security of twice amount of duty.
- Goods can be stored for maximum period of 3 years.

Export under bond	Export outside the bond
Without payment of duty	With payment of duty
Exporter apply in triplicate to excise officer	Exporter apply in duplicate to excise officer
Exporter should mention the means export either by land, sea, air or post	Export should give 48 hour notice before exporting date
Exporter Should give separate application for different means of export	Exporter should present entire consignment to excise officer
	Excise officer take samples and send for analysis on the basis of it permit for export
All goods should contain serial no., owners name & mark, total qty of dutiable goods, alcoholic strength, name & address of consignee, gross wt of each package	All goods should contain serial no., owners name & mark, total qty of dutiable goods, alcoholic strength, name & address of consignee, gross wt of each package
Excise officer puts his official seal on each package	Excise officer puts his official seal on each package
Excise officer return the duplicate copy of application to exporter	Excise officer return the duplicate copy of application to exporter

Power, Duties And Responsibility Of Excise Officer

- Powers:

1. Inspection
2. Entry, search and seizure
3. Detention of person.
4. Suspension-revoke of license.
5. Summons/ notices.
6. Prosecutions.
7. Disposal of seized article/ arrested persons.
8. Power to arrest
9. Power to make rules.

- Duties:

1. Checking the qualifications and experience of technical staff, equipments, suitability of building and applicants financial position.
2. Visit the premises at regular intervals
3. Countersign on indent to get alcohol from distillary

- Responsibility

1. Correct collection of duty and penalty
2. Articles seized should handed over to officer in charge of police station
3. Articles seized should be disposed speedily.
4. Persons arrested should be forwarded without delay to excise officer who is empowered to produce against magistrate.

NARCOTICS DRUGS AND PSYCHOTROPIC SUBSTANCES ACT

INTRODUCTION[1]

- The Central Acts like Opium Act, 1857,the Opium Act ,1878 and the Dangerous Drugs Act,1930 were enacted a long time ago. With the changing circumstances and the developments in the field illicit drug traffic and drug abuse at national and international level ,many drawbacks have come to notice in the said Acts.
- The Government of India has repealed these old Acts and passed "The Narcotic Drugs and Psychotropic Substances Act,1985".
- These Acts established in 14 November 1985.

Continue..

- It also provides the licensing system for both Central and State Government .

OBJECTIVE [1]

- The main objective of this Acts is to consolidate and amend the law relating to narcotic drugs, to make stringent provision for control and regulate the operation relating to narcotic drugs and psychotropic substance and matter connected there with.

DEFINATION[1,2]

- (1)Addict : A person habitual to regular use of any narcotic drug or psychotropic substance.
- (2)Cannabis :
- (a) charas, that is, the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish.
- (b) ganja, that is, the flowering or fruiting tops of the cannabis plant .
- (3) Medicinal Cannbis : It is any extract or tincture of cannabis.

Continue…

- Coca Derivative : It include :
- (I) Crude cocaine which can be used directly or indirectly for manufacture of cocaine .
- Cocaine is methyl ester of benzoyl-ecogonine and it`s salts.
- (4) Opium : it means the coagulated juice of the opium poppy and it`s mixture with or without neutral material.
- (5) Opium Poppy : It includes the plant of Papaver somniferum L and other species of papaver from which opium and phenanthrene alkaloid can be extacted.
- (6) Psychotropic Substance :It means any substance natural or synthetic or any salt or preparation of such substance or material ,which is included in list of psychotropic substance specified in the schedul .eg.DET, Clonazepam,Amphetamine, Pentobarbital,Pentazocine

Narcotic Control Bureau (NCB)[I]

- NCB was established on 17th March 1986 to enable the full implementation of the NDPS Act 1985.
- Headquarter at Delhi.
- It is the chief law enforcement and intelligence agency of India.
- Director general.

AUTHORITIES AND OFFICERS[1]

- **[A] Central Government to take measure for Preventing and Combating abuse of narcotic drugs and illicit traffic therein :**
- Co-ordination of action by various officers,state government and other authorities under this Act.or under any other law for the enforcement of the provision of this Act.
- Obligations under the International Conventions.
- Assistance to concerned authorities for prevention and suppression of illicit traffic in NDPS
- Treatment, education ,aftercare ,rehabilitation and social re-interaction of addicts.

Power of Central Government to Permit, Control, and Regulate :

- The cultivation ,or gathering of any portion of coca plant (only on account of the Central Government),or the production ,sale ,purchase ,transport ,import inter-state ,export inter- state, use or consumption of coca leaves.
- The cultivation of the opium poppy (only on account of the Central Government).
- The production and manufacture of opium and production of poppy straw;
- The sale of opium and opium derivative from the Central Government factories for export from India or sale to State Government or to manufacturing chemists;

Continue…

- **[B] Officers of Central Government :**

They appoint Narcotic Commissioner and other officers as it think .

Function : a) the supervision of cultivation of opium poppy;

b) production of opium ;

- **[C] NDPS Consultative committee**
- This committee consists of chairman and other members not exceeding 20.
- Committee shall advice the central government on the matters relating to the administration of this Act.

- The import into India and export from India transhipment of NDPS ;
- The manufacture, possession, transport ,import inter-state ,export inter- state, sale ,purchase , consumption or use of psychotropic substance;
- **(c) Central government control on certain operation : According to the rules :**
- Govt. shall fix the limit of licences for cultivation.
- The product cultivated by cultivator shall delivered to the authorised officer.
- Govt. shall fix the price to be paid to the cultivator for the opium delivered.

Offence and Penalties[1]

- ❖ Punishment for contravention in relation to ;
- Poppy straw .
- Coca plant and leaves.
- Prepared opium.
- Opium poppy and opium.
- Manufacture drug and preparation.
- Psychotropic substances.
- Cannabis plant and cannabis.
- ❖ Punishment for illegal import into India , export from India or transhipment of NDPS.
- ❖ Punishment for external dealing in NDPS in contravention of the provision of this act.

Conclusion

- This act provide stringent provisions relating to narcotic drugs and psychotropic substances due to this no person can posesses,consume ,import and export of this drugs, it ultimetly protects public health by preventing drug abuse.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

- OBJECT

-An Act to control the advertisement of drugs in certain cases,

-To prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith.

DEFINITIONS

- 1. Advertisement:

  advertisement' ***includes any notice, circular, label, wrapper, or other document,*** and any announcement made orally or by any means of producing or transmitting light, sound or smoke.

- 2. Magic Remedy:

  magic remedy' includes a ***talisman, mantra, kavacha***, and any other charm of any kind which is alleged to possess miraculous ***powers for or in the diagnosis, cure, mitigation***

  treatment or prevention of any disease in human beings or animals ,or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals.

2 Drug: includes-

- (i) a medicine for the internal or external use of human beings or animals;
- ii) any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals
- (iii)any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals
- (iv)any article intended for use as a component of any medicine, substance or article, referred to in sub-clauses (i), (ii) and (iii);

- 4.'Registered Medical Practitioner' means any person,–

i)who holds a qualification granted by an authority specified in, or notified under, section 3of the Indian Medical Degrees Act, 1916 (7 of 1916) or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

ii) who is entitled to be registered as a medical practitioner under any law for the time being in force in any State to which this Act extends relating to the registration of medical practitioners

CLASSES OF PROHIBITED ADVERTISEMENTS

- SECTION 3:
- 1.Prohibition of Advertisement of Certain Drugs for Treatment of Certain Diseases and Disorders.
- a) For the procurement of miscarriage in women or prevention of conception in women; or
- b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or
- c) the correction of menstrual disorder in women; or
- d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition (by whatsoever name called) which may be specified in the schedule, or in rules made under this Act:

- 2.Prohibition of Misleading Advertisements Relating to Drugs.

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which-

- a) directly or indirectly gives a false impression regarding the true nature or character of the drug; or
- b) makes a false claim for the drug; or
- c) is otherwise false or misleading in any material particular are prohibited.

- 3.Prohibition of Advertisement of Magic Remedies for Treatment of Certain Diseases and Disorders.
- No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in section 3.

- 4. Prohibition of Import into, and Export from, India of Certain Advertisements.
- No person shall import into, or export from, the territories to which this Act extends any document containing an advertisement of the nature referred to in 2,3 above.

CLASSES OF EXEMPTED ADVERTISEMENT/PROVISION FOR SAVINGS

- The following classes of advertisement are not prohibited under this act:

1. Any advertisement relating to the drugs printed or published by the Government or any other person with prior permission of the Government.
2. Any advertisement relating to a drug which is sent confidentially in prescribed manner to Registered Medical Practitioner.
3. Advertisement including any book or treatise (a written or printed composition) dealing with any matter relating to the diseases.

•Any sign board or notice displayed by a registered medical practitioner on his premises indicating that treatment for any disease, disorder or condition specified in section 3; the Schedule or the rules made under this Act, is undertaken in those premises; or

•Any advertisement relating to a drug printed or published by any person with the previous sanction of the Government granted prior to the commencement of the Drugs and magic Remedies (Objectionable Advertisement) Amendment Act, 1963 (42 of 1963).

•Provided that the Government may, for reasons to be recorded in writing withdraw the sanction after giving the person an opportunity of showing cause against such withdrawal.

- i) Advertisement relating to the drugs which comply with the required conditions as follows:
- A) Leaflets or literature along with packings of drug; or

Advertisements of drugs in medicinal, pharmaceutical, scientific and technical journals.

B) Therapeutic index or price list published by licensed manufacturer, importer, or distributor of drug; or Medical literature distributed by Medical representatives.

With the condition that:

the advertisement should contain only the information, required for the guidance of registered medical practitioner regarding:

- a) therapeutic indications;
- b) route of administration,
- c) dosage and side effects of such drug or drugs ; and
- d) the precaution to be taken in treatment with the drug

- ii) The distribution of such literature should be given to registered medical practitioner,dispensaries,hospitals,medical and research institutions, chemists and druggists or pharmacies.

NAMES OF THE DISEASES ,DISORDER AND CONDITIONS AS PER SCHEDULE

- **1** Appendicitis
- 2. Arteriosclerosis
- 3. Blindness
- 4. Blood poisoning
- 5. Bright's disease(kidney)
- 6. Cancer
- 7. Cataract
- 8. Deafness
- 9. Diabetes
- 10. Diseases and disorders of the brain
- 11. Diseases and disorders of the optical system
- 12. Diseases and disorders of the uterus
- 13. Disorders or menstrual flow
- 14. Disorders of the nervous system
- 15. Disorders of the prostatic gland
- 16. Dropsy(oedema)
- 17. Epilepsy
- 18. Female diseases (in general)
- 19. Fevers (in general)
- 20 Fits
- 21 Form of structural changes of female bust
- 22 Gall stones, kidney stones and bladder stones
- 23 Gangrene

24 Glaucoma
25. Goitre
26. Heart diseases
27. High or low blood pressure
28. Hydrocele
29. Hysteria(uncontrolled emotion)
30. Infantile paralysis
31. Insanity(mentally ill)
32. Leprosy
33. Leukoderma
34. Lockjaw
35. Locomotor atoxia
36. Lupus
37. Nervous debility
38. Obesity
39. Paralysis
40. Plague
41. Pleurisy(inflammation of pleura)
42. Pneumonia
43. Rheumatism
44. Ruptures
45. Sexual impotence
46. Small pox
47. Stature of persons
48. Sterility in women
49 Trachoma
50 Tuberculosis
51 Tumors
52 Typhoid Fever
53 Veneral Diseases

Penalty. - Whoever contravenes any of the provisions of this Act of the rules made there under shall, on conviction, be punishable-

(a) In the case of a first conviction, with imprisonment which may extend **to six months, or with fine, or with both;**

(b) In the case of a **subsequent conviction**, with imprisonment **which may extend to one year, or with fine, or with both.**

Offences by companies-

- (1) If the person contravening any of the provisions of this Act is a company, every person who, at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly;

- Provided that nothing contained in this sub section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

2)Notwithstanding anything contained in sub section (1) where an offence under this Act has been committed by a company and it is prove that the offence was committed with the consent or connivance of or is attributable to any neglect on the part of any director or manager secretary or other officer of the company such director manager secretary or other officer of the company shall also he deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(a)"**Company" means** - body corporate and includes a firm or other association of individuals, and **Director"** in relation to a firm means a partner in the firm.

Medical Termination of Pregnancy (MTP) Act,1971

MTP Act: Objectives

MTP Act

- Aims to improve the maternal health scenario by preventing large number of unsafe abortions and consequent high incidence of maternal mortality & morbidity
- Legalizes abortion services
- Promotes access to safe abortion services to women
- Offers protection to medical practitioners who otherwise would be penalized under the Indian Penal Code (sections 315-316)

Legal framework

- MTP Act
  - lays down when & where pregnancies can be terminated
  - Grants the central govt. power to make rules and the state govt. power to frame regulations
- MTP Rules
  - lays down who can terminate the pregnancy, training requirements, approval process for place, etc.
- MTP Regulations
  - lays down forms for opinion, maintenance of records
  - custody of forms and reporting of cases

Legal abortions

Abortions are termed legal only when all the following conditions are met:

- Termination done by a medical practitioner approved by the Act
- Termination done at a place approved under the Act
- Termination done for conditions and within the gestation prescribed by the Act
- Other requirements of the rules & regulations are complied with

When can pregnancies be terminated?

- RMP shall not be guilty of offence under law
- Up to 20 weeks gestation
- With the consent of the women. If the women is below 18 years or is mentally ill, then with consent of a guardian
- With the opinion of a registered medical practitioner, formed in good faith, under certain circumstances
- Opinion of two RMPs required for termination of pregnancy between 12 and 20 weeks

MTP Act: Application

- Continuation of pregnancy constitutes risk to the life or grave injury to the physical or mental health of woman
- Substantial risk of physical or mental abnormalities in the fetus as to render it seriously handicapped
- Pregnancy caused by rape (presumed grave injury to mental health)
- Contraceptive failure in married couple (presumed grave injury to mental health)

MTP Act: Place for conducting MTP

- A hospital established or maintained by Government

or

- A place approved for the purpose of this Act by a District-level Committee constituted by the government with the CMHO as Chairperson

MTP Act amendment 2002

- Decentralizes site registration to a 3-5 member district level committee chaired by the CMO/DHO
- Approval of sites that can perform MTPs under the act can now be done at the district level
- Stricter penalties for MTPs being done in a un-approved site or by a persons not permitted by the act

Medical Abortion

- MTP using Mifepristrone (RU 486) & Misoprostol approved for up to 7 weeks termination
- Only an RMP (as defined by the MTP Act) can prescribe the drugs
- Has to follow MTP Act, Rules & Regulations
- Can prescribe in his/her clinic, provided he/she has access to an approved place
- Should display a certificate from owner of approved place agreeing to provide access

MTP rules: Who can perform?

A medical practitioner (RMP)

- who has a recognized medical qualification as defined in clause (h) of section 2 of 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 prescribed by Rules made under the Act

MTP rules: training requirement - 1

For termination up to 12 weeks:

- A practitioner who has assisted a registered medical practitioner in performing 25 cases of MTP of which at least 5 were performed independently in a hospital established or maintained or a training institute approved for this purpose by the Government

Approval of a place by trimester

For sites up to 12 weeks (1st trimester)

- Gynecology examination/ labor table
- sterilization equipment
- Drugs & parental fluids
- Back up facilities for treatment of shock
- Facilities for transportation

Approval of a place by trimester

For sites up to 20 weeks (1st and 2nd trimester):

- All requirements for up to 12 weeks +
- Operation table and instruments for performing abdominal or gynecological surgery
- Anesthetic equipment, resuscitation equipment and sterilization equipment
- Drugs & parental fluids notified for emergency use, notified by Government of India from time to time

Regulatory body: D L C

- District level MTP Committee
  - Minimum of 3 & Maximum of 5 members including chairperson (CM H O)
- Composition of the committee:
  - One medical person (Gyne/Surgeon/Anestheist)
  - One member from local medical profession; NGO & Panchayati Raj Institution of the district.
  - At least one member shall be a woman.
- Tenure 2 calendar years
  - NGO members shall not have more than 2 terms

Approval Process

- Application in Form A to be addressed to CMHO by place seeking approval
- CMHO verifies or inspects the place to satisfy that termination can be done under safe & hygienic conditions
- CMHO recommends approval to the committee
- Committee considers application & recommendation and approve and issue certificate of approval in Form B

Inspection

- CMHOs to inspect to ensure safe & hygienic conditions for conduction of MTPs.
- Call for information and seize in case found otherwise

Cancellation/ Suspension

- CMHO to report the committee for unsafe and unhygienic conditions.
- Committee can suspend or cancel approval after giving the owner an opportunity for representation
- Owner can reapply to the committee after making additions and improvements.
- During suspension the place be deemed as non-approved

POISON ACT 1919

CONTENT

- INTRODUCTION
- OBJECTIVE
- IMPORT OF POISON
- POSSESSIONS, POSSESSION OF SALE AND SALE AND SALE OF ANY POISON
- LIST OF POISONOUS SUBSTANCES
- ISSUE WARRANTS

INTRODUCTION

- This Act was passed in 3rd September , 1919 in India .
- To control the possession for sale and the sale whether wholesale or retails , of any specified poison .
- Need of poison act ?
- The act extends to the whole of India except the state of Jammu and Kashmir where only certain provisions related to the importation of specified poisons into are applicable.

OBJECT OF POISON ACT

- Regulate and control the import , possession and sale of poisons.
- Central government regulates imports
- State government regulates possession , possession for sale and sale poisons.

IMPORT of POISON

- The import of poisons is permitted only by person to have been granted liecence for the purpose by the central Government .
- Such persons may import poison across one of the defined custom frontiers and in accordance with the condition of the liecence

Possession, Possession for sale and sale of any poison

1. Possession for sale and sale of any of any poison:
2. Possession any poison
3. Import of poison

Inspection and Examination of any such poison possessed by a vendor for sale

- The poisons the record maintained for their sale are subject to inspection , by persons authorised in this behalf by the state governments.
- The state government are also empowered to regulate the possession of any specified poison in any local area .

List of Poisonous substances

- List A:- Aconite , Arsenic , Coca , Digitalis , lead etc
- List B:- Essential oils of almonds Chloroform , Carbolic acid , All oxides of mercury , Sulphonal Zinc Chloride etc .

Issue of Warrants

The District Magistrate , Sub –divisonal Magistrates and the Commissioner of police have been empowered to issue warrants for the search of any place , where they have reasons to believe or suspect that a contraband poison is sold , kept or concealed.