

**PHARMACEUTICAL
JURISPRUDENCE AND
REGULATORY AFFAIRS
E-BOOK**

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PHAMACEUTICAL JURISPRUDENCE AND REGULATORY AFFAIRS SYLLABUS

1. History of pharmacy legislation in India

Origin and nature of pharmaceutical legislation in India, Its scope and objective, report of commission, new drug policy and the future trends.

2. Study of the followings with latest amendments

1. Pharmaceutical Ethics

Principles and significance of professional ethics, critical study of code of pharmaceutical ethics drafted by PCI regarding to pharmacists in relation to his job, to this trade and to medical profession.

2. Pharmacy act 1948

Introduction, objective, definition, educational regulation and approval, registration of pharmacists, central and state councils, amendment to the Pharmacy act.

3. Drug and cosmetics Act 1940 and Rules 1945

Introduction, definition, general study of the special references to the C, C1, F, G, H, P and X, Salient features of the storage and labeling conditions of drugs, administration, manufacture, sales and import of drug, provisions for Ayurvedic, unani drugs and cosmetics as amended to date.

4. Medicinal and Toilet preparations (Excise duties) Act 1955

Objectives, background, definition, manufacture and warehousing of alcohol preparation, Procedures, offences and penalties as amended to date.

5. Narcotic Drug and Psychotropic substances Act 1985 and Rules

Introduction, objectives, definitions, prohibited and controlled operations, enforcement, manufacture, cultivation of poppy plants, sales of opium, import and export of narcotics as amended to date.

6. Drug Price Control Order

Objective, definitions, schedules to the order, sale prices of bulk drugs, prices and price list, MAPE calculations as amended to date.

7. Patent act

Objective, definitions, types of patents, procedure for patenting, secrecy of certain invention, surrender and revocation of patents as amended to date.

3. A brief study with a special reference to the main provisions

1. Drug and Magic Remedies Act (Objectionable Advertisements) 1954.
2. Medical Termination of pregnancy Act 1970 and Rules 1975.
3. Prevention of cruelty to animals Act 1960.
4. Factories Act 1948.
5. Minimum wages Act 1948.
6. Consumer protection Act with respect to pharmaceutical services

4. Recommended Book for Pharmaceutical Jurisprudence and regulatory affairs:

1. All related Bare Act with latest amendments to date.
2. A textbook of Forensic pharmacy, By N.K. Jain, Vallabh Prakashan, New Delhi, 2002.
3. Latest issues of CIMS, MIMS, PDR, DDR.
4. Latest issues of IDMA Bulletin.
5. The Drug and cosmetics Act and Rules by the Indian drug manufacture association publication
6. ICMR Guidelines.
7. Hand book of Drug Laws: Mehra, Law Publication, Allahabad.
8. CPCACEA guidelines.
9. Pharmaceutical Jurisprudence, By S. P. Agrawal and R. Khanna, Tata Publication.

PHARMACEUTICAL JURISPRUDENCE AND REGULATORY AFFAIRS

1. History of pharmacy legislation in India

Introduction:- In the early part of the 20th century, there was practically no legislative control on drugs as well as on the profession of pharmacy. Although the Opium Act, 1878, the poison act 1919 and the dangerous drugs act, 1930 were in force, these were specific in nature and grossly inadequate in controlling the chaotic conditions prevailing at that time. In 1927, a resolutions was passed by the council of states to recommend to the Governor General in Council to usage all Provisional Governments to take immediate steps to control indiscriminate use of drugs and to legislate for the standardization of the preparation and sale of drugs. 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 set of people known as compounders were filling the gap.

Just after the publication of the report Prof. M.L.Schroff (Prof. Mahadeva Lal Schroff) 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.

1937: Government of India brought 'Import of Drugs Bill'; later it was withdrawn.

1940: Govt. 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: Govt. 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.

1948: Pharmacy Act 1948 published.

1948: Indian Pharmacopoeial Committee was constituted under the chairmanship of late 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.

Govt. of India controls the price of drugs in India by Drugs Price Order changed from time to time.

2. Pharmaceutical Ethics

Introduction :- Ethics may be defined as “the code of moral principles” or as “the science of morals”. The conduct of individuals in any society is governed by governmental controls as well as social customs and duties. The code of ethics framed by the Pharmacy Council of India is meant to guide the Indian Pharmacist as to how he should conduct himself in relation to himself, his patrons and the general public, co-professionals, and members of the medical and other health professions. Profession of Pharmacy is a noble profession as it is indirectly healing the persons to get well with the help of medical practitioners and other co-professionals. Government has restricted the practice of Pharmacy to only Profession Pharmacists i.e registered Pharmacist under the Pharmacy Act 1948. PCI framed the following ethics for Indian Pharmacists, which may be categorised under the following headings:

1. Pharmacist in relation to his job.
2. Pharmacist in relation to his trade.
3. Pharmacist in relation to medical profession.
4. Pharmacist in relation to his profession.

Pharmacist in relation to his job

A pharmacist should keep the following things in relation to his job.

(i) Pharmaceutical services

Pharmacy premises (medicine shops) should be registered. Emergency medicines and common medicines should be supplied to the patients without any delay.

(ii) Conduct of the Pharmacy

Error of accidental contamination in the preparation, dispensing and supply of medicines should be checked in a pharmacy.

(iii) Handling of Prescription

A pharmacist should receive a prescription without any comment on it that may cause anxiety to the patient. No part of the prescription should be changed without the consent of the prescriber. In case of changing the prescription should be referred back to the prescriber.

(iv) Handling of drugs

A prescription should always be dispensed correctly and carefully with standard quality drug or excipients. Drugs that have abusive potential should not be supplied to any one.

(v) Apprentice Pharmacist

Experienced pharmacists should provide all the facilities for practical training of the apprentice pharmacists. Until and unless the apprentice proves himself or herself certificate should not be granted to him / her.

Pharmacist in relation to his trade

Following are the provisions which pharmacist should keep in mind while dealing with his trade:

(i) Price structure

The prices charged should be fair keeping with the quality, quantity and labour or skill required.

(ii) Fair trade practice

Fair practice should be adopted by a pharmacist in the trade without any attempt to capture other pharmacist's business.

If a customer brings a prescription (by mistake) which should be genuinely by some other pharmacy the pharmacist should refuse to accept the prescription.

Imitation or copying of the labels, trade marks and other signs or symbols of other pharmacy should not be done.

(iii) Purchase of drugs

Pharmacists should buy drugs from genuine and reputable sources.

(iv) Advertising and Displays

The sale of medicines or medical appliances or display of materials in undignified style on the premises, in the press or elsewhere are prohibited.

Pharmacist in relation to medical profession.

Following are the code of ethics of a pharmacist in relation to medical profession:

(i) Limitation of professional activity

The professional activity of the medical practitioner as well as the pharmacists should be confined to their own field only.

Medical practitioners should not possess drugs stores and pharmacists should not diagnose diseases and prescribe remedies.

A pharmacist may, however, can deliver first aid to the victim in case of accident or emergency.

(ii) Clarendon arrangement

A pharmacist should not enter into a secret arrangement or contract with a physician by offering him any commission or any advantages.

(iii) Liaison with public.

A pharmacist should always maintain proper link between physicians and people. He should advise the physicians on pharmaceutical matters and should educate the people regarding health and hygiene. The pharmacist should be keep himself / herself up-to-date with pharmaceutical knowledge from various journals or publications.

Any information acquired by a pharmacist during his professional activities should not be disclosed to any third party until and unless required to do so by law.

Pharmacist in relation to his profession

Regarding to the profession the following code of ethics should be fulfilled.

(i) Professional vigilance

A pharmacist must abide by the pharmaceutical laws and he/she should see that other pharmacists are abiding it.

(ii) Law-abiding citizens

The pharmacists should have a fair knowledge of the laws of the country pertaining to food, drug, pharmacy, health, sanitation etc.

(iii) Relationship with Professional Organizations

A pharmacist should be actively involved in professional organization, should advance the cause of such organizations.

(iv) Decorum and Propriety

A pharmacist should not indulge in doing anything that goes against the decorum and propriety of Pharmacy Profession.

(v) Pharmacists Oath

A young prospective pharmacist should feel no hesitation in assuming the following pharmacist's oath:

- "I promise to do all I can to protect and improve the physical and moral well-being of society, holding the health and safety of my community above other considerations. I shall uphold the laws and standards governing my profession, avoiding all forms of misinterpretation, and I shall safeguard the distribution of medical and potent substances.
- Knowledge gained about patients, I shall hold in confidence and never divulge unless compelled to do so by law.
- I shall strive to perfect and enlarge my knowledge to contribute to the advancements of pharmacy and the public health.
- I furthermore promise to maintain my honour in all transactions and by my conduct never bring discredit to myself or to my profession nor to do anything to diminish the trust reposed in my professional brethren.
- May I prosper and live long in favour as I keep and hold to this, my Oath, but if violated these sacred promises, may the reverse be my lot."

3. Pharmacy act 1948

Introduction :- In India there was no restriction to practise the profession of pharmacy. One could practise this profession as any other profession. Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession. Hundreds of cases were brought to the notice of the Government wherein the compounding, mixing, or dispensing of medicines was being done by persons who were not adequately educated in this line. The system was causing great harm to the health of people by wrong compounding, mixing or dispensing. It was found necessary to enact a law for the regulation of the profession and practice of pharmacy. To achieve this goal the Pharmacy Bill, 1947 was introduced in the Legislature which was later referred to the Select Committee. The recommendations of the Selection Committee were incorporated in the Bill.

STATEMENT OF OBJECTS AND REASONS

It is desirable that, as in most other countries, only persons who have attained a minimum standard of professional education should be permitted to practise the Profession of Pharmacy. It is accordingly proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for Pharmacists, and Provincial Pharmacy Councils, which will be responsible for the maintenance of provincial registers of qualified pharmacists. It is further proposed to empower Provincial Governments to prohibit the dispensing of medicine on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a registered pharmacist.

ACT 8 OF 1948

The Pharmacy Bill, 1947, having been passed by the Legislature received its assent on 4th March, 1948.

It came on the Statute Book as THE PHARMACY ACT, 1948 (8 of 1948).

LIST OF AMENDING ACTS AND ADAPTATION ORDERS

1. The Adaptation of Laws Order, 1950.
2. The Adaptation of Laws (No.3) Order, 1956.
3. The Pharmacy (Amendment) Act, 1959 (24 of 1959).
4. The Pharmacy (Amendment) Act, 1976 (70 of 1976).
5. The Pharmacy (Amendment) Act, 1982 (22 of 1982).
6. The Delegated Legislation Provisions (Amendment) Act, 1985 (4 of 1986).

Pharmacy Act 1948 Chapter 1

1. Short title, extent and commencement. -(1) This Act may be called the pharmacy Act, 1948.
- 2 [(2) It extends to the whole of India except the State of Jammu and Kashmir.]
 - (3) It shall come into force at once, but Chapters III, IV and V shall take effect in a particular State from such date
 - 3[***] as the State Government may, by notification in the Official Gazette, appoint in this behalf:
 - 4[Provided that where on account of the territorial changes brought about by the reorganisation of States on the 1st day of November, 1956, Chapters III, IV and V have effect only in a part of a State, the said Chapters shall take effect in the remaining part of that State from such date as the State Government may in like manner appoint]
2. Interpretation.-In this Act, unless there is anything repugnant in the subject or context,
 - (a) "agreement" means an agreement entered into under section 20;
 - (b) "approved" means approved by the Central Council under section 12 or section 14;
 - 5[(c) "Central Council" means the Pharmacy Council of India constituted under section 3;
 - (d) "Central Register" means the register of pharmacists maintained by the Central Council under section
 - 15A;(da) "Executive Committee" means the Executive Committee of the Central Council or of the State Council

Chapter II - The Pharmacy Council Of India

Constitution and Composition of Central Council.- The Central Government shall, as soon as may be, constitute a Central Council consisting of the following members, namely:(a). six members, among whom there shall be at least one teacher of each of the subjects, pharmaceutical chemistry, pharmacy, pharmacology and pharmacognosy elected by the [University Grants Commission] from among persons on the teaching staff provided that for five years from the date on which the Pharmacy (Amendment) Act, 1976. comes into force the Government of each Union territory shall, instead of electing a member under clause (g) nominate one member, being a person eligible for registration under section 31, to represent that territory.

The Pharmacy Council of India consists of the following:

- (i) Six members, among whom at least one teacher of pharmaceutical chemistry, pharmacy. Pharmacology and pharmacology elected by the University Grants Commission.
- (ii) Six members, four of whom are persons possessing a degree or diploma in and practicing pharmacy or pharmaceutical chemistry, nominated by the Central Government .
- (iii) One member elected from amongst themselves by the members of the Medical Council of India.
- (iv) the Director General of Health Services or an authorized person by him.
- (v) the Drugs Controller of India or an authorized person by him,
- (vi) the Director of Central Drugs Laboratory,

- (vii) a representative of the University Grants Commission,
- (viii) a representative of the All India Council for Technical Education.
- (ix) One member to represent each state elected from each state council and who is a registered pharmacist,
- (x) One member to represent each state nominated by the State Government who is a registered pharmacist.’
- (xi) One member to represent each Union territory, nominated by the Union territory Council, being eligible for registration under section 31 of the Act,

The Executive Committee.-(1) The Central Council shall, as soon as may be, constitute an Executive Committee consisting of the President (who shall be Chairman of the Executive Committee) and VicePresident, ex officio, and five other members elected by the Central Council from amongst its members.

(2) A member of the Executive Committee shall hold office as such until the expiry of his term of office as member of the Central Council, but, subject to his being a member of the Central Council, he shall be eligible for re-election.

(3) In addition to the powers and duties conferred and imposed it by this Act the Executive Committee shall exercise and discharge such powers and duties as may be prescribed.

Education Regulations:-

- (1) Subject to the provisions of this section, the Central Council may, subject to the approval of the Central Government, make regulations, to be called the Education Regulations, prescribing the minimum standard of education required for qualification as a pharmacist.
- (2) In particular and without prejudice to the generality of the foregoing power, the Education Regulations may prescribe
 - (a) the nature and period of study and of practical training to be undertaken before admission to an examination;
 - (b) the equipment and facilities to be provided for students undergoing approved courses of study;
 - (c) the subjects of examination and the standards therein to be attained;
 - (d) any other conditions of admission to examinations.
- (3) Copies of the draft of the Education Regulations and of all subsequent amendments thereof shall be furnished by the Central Council to all State Governments, and the Central Council shall before submitting the Education Regulations or any amendment thereof, as the case may be, to the Central Government for approval under subsection (1) take into consideration the comments of any State Government received within three months from the furnishing of the copies as aforesaid.
- (4) The Education Regulations shall be published in the Official Gazette and in such other manner as the Central Council may direct.
- (5) The Executive Committee shall from time to time report to the Central Council on the efficacy of the Education Regulations and may recommend to the Central Council such amendments thereof as it may think fit.

CHAPTER III - STATE PHARMACY COUNCILS

Constitution and Composition of State Councils.-Except where a Joint State Council is constituted in accordance with an agreement made under section 20, the State Government shall constitute a State Council consisting of the following members, namely:--

- (a) six members, elected from amongst themselves by registered pharmacists of the State;
- (b) five members, of whom at least 4[three] shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or 5[registered pharmacists], nominated by the State Government;
- (c) one member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State, as the case may be:
- (d) the chief administrative medical officer of the State ex officio or if he is unable to attend any meeting, a person authorised by him in writing to do so;6[(dd) the officer-in-charge of drugs control organisation of the State under the 7[Drugs and Cosmetics Act, 1940 (23 of 1940)], ex officio or if he is unable to attend any meeting, a person authorised by him in writing to do so;]
- (e) the Government Analyst under the I [Drugs and Cosmetics Act, 1940 (23 of 1940)], ex officio, or where there is more than one, such one as the State Government may appoint in this behalf:

Provided that where an agreement is made under clause (b) of sub-section (I) of section 20, the agreement may provide that the State Council to serve the needs of the other participating States also shall be augmented by not more than two members, of whom at least one shall at all times be a person possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or a 2[registered pharmacist], nominated by the Government of each of the said other participating States, and where the agreement so provides, the composition of the State Council shall be deemed to be augmented accordingly.

The State Pharmacy Council consists of the following:-

- (i) Six members, elected from amongst themselves by registered pharmacists,
- (ii) Five members, of whom three are persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or registered pharmacist, nominated by State Government.
- (iii) one member, elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State,
- (iv) the chief administrative medical officer of the State or his authorised person,
- (v) the officer-in-charge of drugs control organisation of the State or his authorised person,
- (vi) the Government Analyst.

Composition of Joint State Councils:-

- (1) A Joint State Council shall consist of the following members, namely:
 - (a) such number of members, being not less than three and not more than five as the agreement shall provide elected from amongst themselves by the registered pharmacists of each of the participating States;
 - (b) such number of members, being not less than two and not more than four as the agreement shall provide, nominated by each participating State Government;
 - (c) one member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of each participating State as the case may be; .
 - (d) the chief administrative medical officer of each participating State, ex officio, or if he is unable to attend any meeting, a person authorized by him in writing to do so:
[(dd) the officer-in-charge of drugs control organisation of each participating State under the 2[Drugs and Cosmetics Act, 1940], ex officio, or if he is unable to attend any meeting, a person authorised by him in writing to do so;]
 - (e) the Government Analyst under the 2 [Drugs and Cosmetics Act, 1940 (23 of 1940)], of each participating State, ex officio, or where there is more than one in any such State, such one as the State Government may appoint in this behalf.

- (2) The agreement may provide that within the limits specified in clauses (a) and (b) of sub-section (1), the number of members to be elected or nominated under those clauses may or may not be the same in respect of each participating State.
- (3) Of the members, nominated by each State Government under clause (b) of subsection (1), 3 [more than shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or 4 [registered pharmacists].

A Joint State Council consists of the following:

- (i) not less than three and not more than five members elected amongst themselves by the registered pharmacists of each of the participating States,
- (ii) not less than three but not more than four members nominated by each participating State Government
- (iii) one member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of each participating State,
- (iv) the chief administrative medical officer of each participating State or his authorised person,
- (v) the officer in-charge of drugs control organisation of each participating State or his authorised person.
- (vi) the Government Analyst of each participating State.

CHAPTER IV - REGISTRATION OF PHARMACISTS

Preparation and maintenance of register.-

- (1) As soon as may be after this chapter has taken effect in any State, the State Government shall cause to be prepared in the manner hereinafter provided a register of pharmacists for the State.
- (2) The State Council shall as soon as possible after it is constituted assume the duty of maintaining the register in accordance with the provisions of this Act.
- (3) 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.

Preparation of first register.-

- (1) For the purpose of preparing the first register, the State Government shall by notification in the Official Gazette constitute a Registration Tribunal consisting of three persons, and shall also appoint a Registrar who shall act as Secretary of the Registration Tribunal.
- (2) The State Government shall, by the same or a like notification, appoint a date on or before which applications for registration, which shall be accompanied by the prescribed fee, shall be made to the Registration Tribunal.
- (3) The Registration Tribunal shall examine every application received on or before the appointed date, and if it is satisfied that the applicant is qualified for registration under section 31, shall direct the entry of the name of the applicant on the register.
- (4) The first register so prepared shall thereafter be published in such manner as the State Government may direct, and any person aggrieved by a decision of the Registration Tribunal expressed or implied in the register as so published may, within sixty days from the date of such publication, appeal to an authority appointed by the State Government in this behalf by notification in the Official Gazette.
- (5) The Registrar shall amend the register in accordance with the decisions of the authority appointed under sub-section (4) and shall thereupon issue to every person whose name is entered in the register a certificate of registration in the prescribed form.

(6) Upon the constitution of the State Council, the register shall be given into its custody, and the State Government may direct that all or any specified part of the application fees for registration in the first register shall be paid to the credit of the State Council.

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 and if he (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 as the case may be. 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.

Qualifications for subsequent registration. –

- (1) After the date appointed under sub-section (2) of section 30 and before the Education Regulations have, by or under section 11, taken effect in the State, 3[a person who has attained the age of eighteen years shall on payment of the prescribed fee] be entitled to have his name entered in the register if he resides or carries on the business or profession of pharmacy in the State and if he—
- (a) satisfies the conditions prescribed with the prior approval of the Central Council, or where no conditions have been prescribed, the conditions entitling a person to have his name entered on the first register as set out in section 31, or
 - (b) is a registered pharmacist in another State, or
 - (c) possesses a qualification approved under section 14: Provided that no person shall be entitled '[under clause (a) or clause (c)] to have his name entered on the register unless he has passed a matriculation examination or an examination prescribed as being equivalent to a matriculation examination.
- (2) After the Education Regulations have by or under section 11 taken effect in the State, a person shall on payment of the prescribed fee be entitled to have his name entered on the register if he has attained the age of 2[eighteen years], if he resides, or carries on the business or profession of pharmacy, in the State and if he has passed an approved examination or possesses a qualification approved under section 14 '[or is a registered pharmacist in another State.]

Special provisions for , "registration of certain persons.-

- (l) 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:
- (d) the names of persons Who carry on the business or profession of pharmacy in the State. And (i) would have satisfied the conditions for registration as set out in section 31, on the date appointed under sub-section (2) of section 30, had they applied for registration on or before that date; or (ii) have 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 as defined in sub-clause (iii) of clause (f) of section 2 for a total period of not less then five years prior to the date appointed under subse ction (2) of section 30;

- (e) the names of persons who were qualified to be entered in the register for a State as it existed immediately before the 1st day of November, 1956, but who, by reason of the area in which they resided or carried on their business or profession of pharmacy having become part of a State as formed on that date, are not qualified to be entered having in the register for the latter State only by reason of their not having passed either a matriculation examination or an examination prescribed as being equivalent to a matriculation examination or an approved examination or of their not possessing a qualification approved under section 14:
 - (f) the names of persons
 - (i) who were included in the register for a State as it existed immediately before the 1st day of November, 1956; and
 - (ii) who, by reason of the area in which they resided or carried on their business or profession of pharmacy having become part of a State as formed on that date, reside or carry on such business or profession in the latter State;
 - (g) the names of persons who reside or carry on their business or profession of pharmacy in an area in which this Chapter takes effect after the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959), and who satisfy the conditions for registration as set out in section 31.
- (2) Any person who desires his name to be entered in the register in pursuance of subsection (I) shall make an application in that behalf to the State Council, and such application shall be accompanied by the prescribed fee.

(3) The provisions of this section shall remain in operation for a period of two years from the commencement of the Pharmacy (Amendment) Act, 1959 (24 of 1959). Provided that the State Government may, by notification in the Official Gazette, extend the period of operation of clause (a), clause (b) or clause (c) of sub-section (I) by such further period or periods, not exceeding two years in the aggregate, as may be specified in the notification.

Explanation 1.-For the purposes of clause (a) of sub-section (I), "displaced person" means any person who on account of the setting up of the Dominions of India and Pakistan or on account of civil disturbances or the fear of such disturbances in any area now forming part of Pakistan, has, on or after the 1st 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.

Explanation 2.-For the purposes of clauses (b), (c) and (g) of sub-section (i), the period referred to in clause (d) of section 3 I shall be computed with reference to the date of application.]

Removal from register.-

- (1) Subject to the provisions of this section, the Executive Committee may order that the name of a registered pharmacist shall be removed from the register, where it is satisfied, after giving him a reasonable opportunity of being heard and after such further inquiry, if any, as it may think fit to make,--
- (i) that his name has been entered into the register by error or on account of misrepresentation or suppression of a material fact, or
 - (ii) that he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect which in the opinion of the Executive Committee, renders him unfit to be kept in the register, or
 - (iii) that a person employed by him for the purposes of his business of pharmacy [or employed to work under him in connection with any business of pharmacy] has been convicted of any such offence or has been guilty of any such infamous conduct as would, if such person were a registered pharmacist, render him liable to have his name removed from the register under clause (ii): Provided that no such order shall be made under clause (iii) unless the Executive Committee is satisfied
 - (a) that the offence or infamous conduct was instigated or connived at by the registered Pharmacist, or
 - (b) that the registered pharmacist has at any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place committed a similar offence or been guilty of similar infamous conduct, or

- (c) that any person employed by the registered pharmacist for the purpose s of his business of pharmacy [or employed to work under him in connection with any business of pharmacy] has at any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place, committed a similar offence or been guilty of similar infamous conduct, and that the registered pharmacist had, or reasonably ought to have had, knowledge of such previous offence or infamous conduct, or
 - (d) that where the offence or infamous conduct continued over a period, the registered pharmacist had, or reasonably ought to have had, knowledge of the continuing offence or infamous conduct, or
 - (e) that where the offence is an offence under the [Drugs and Cosmetics Act, 1940 (23 of 1940)], the registered pharmacist has not used due diligence in enforcing compliance with the provisions of that Act in his place of business and by persons employed by him [or by persons under his control].
- (2) An order under sub-section (1) may direct that the person whose name is ordered to be removed from the register shall be ineligible for registration in the State under this Act either permanently or for such period as may be specified.
- (3) An order under sub-section (1) shall be subject to confirmation by the State Council and shall not take effect until the expiry of three months from the date of such confirmation.

- (4) A person aggrieved by an order under sub-section (1) which has been confirmed by the State Council may, within thirty days from the communication to him of such confirmation, appeal to the State Government, and the order of the State Government upon such appeal shall be final.
- (5) A person whose name has been removed from the register under this section or under sub-section (2) of section 34 shall forthwith surrender his certificate or registration to the Registrar, and the name so removed shall be published in the Official Gazette.

The name of the registered pharmacist can be removed from the register by the Executive Committee, if it is found that

- (i) his name has been entered by error or on account of misrepresentation or suppression of material fact, or
- (ii) he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect; or
- (iii) a person employed by him for the purposes of his business of pharmacy or employed to work under him in connection with any business of pharmacy has been convicted of any such offence or has been guilty of any such infamous conduct as would, if such person were a registered pharmacist, render him liable to have his name removed from the register.

CHAPTER V - MISCELLANEOUS

Penalty for falsely claiming to be registered.- (1) If any person whose name is not for the time being entered into the register of the State falsely pretends that it is so entered or uses in connection with his name or title any words or letters reasonably calculated to suggest that his name is so entered, he shall be punishable on first conviction with fine which may extend to five hundred rupees and on any subsequent conviction with imprisonment extending to six months or with fine not exceeding one thousand rupees or with both: Provided that it shall be a defence to show that the name of the accused is entered in the register of another State and that at the time of the alleged offence under this section an application for registration in the State had been made.

(2) For the purposes of this section

- (a) it shall be immaterial whether or not any person is deceived by such pretence or use as aforesaid;
- (b) the use of the description "pharmacist", "chemist", "druggist" "Pharmaceuticst", "dispenser", "dispensing chemist", or any combination of such words [or of any such word with any other word] shall be deemed to be reasonably calculated to suggest that the person using such description is a person whose name is for the time being entered in the register of the State;
- (c) the onus of proving that the name of a person is for the time being entered in the register of a State shall be on him who asserts it.

(3) Cognizance of an offence punishable under this section shall not be taken except upon complaint made by order of the State Government or I [any officer authorized in this behalf by the State Government or by order of] the Executive Committee of the State Council.

A person who falsely pretends that his name is entered in the register shall be punishable on first conviction with fine upto five hundred rupees or on any subsequent conviction with imprisonment upto six months or with fine upto one thousand rupees or with both.

Appointment of Commission of Enquiry.-

- (1) Whenever it appears to the Central Government that the Central Council is not complying with any of the provisions of this Act, the Central Government may appoint a Commission of Enquiry consisting of three persons, two of whom shall be appointed by the Central Government, one being the Judge of a High Court, and, one by the Council; and refer to it the matters on which the enquiry is to be made.
- (2) The Commission shall proceed to enquire in such manner as it may deem fit and report to the Central Government on the matters referred to it together with such remedies, if any, as the Commission may like to recommend.
- (3) The Central Government may accept the report or remit the same to the Commission for modification or reconsideration.
- (4) After the report is finally accepted, the Central Government may order the Central Council to adopt the remedies so recommended within such time as may be specified in the order and if the Council fails to comply within the time so specified, the Central Government may pass such order or take such action as may be necessary to give effect to the recommendations of the Commission.

Drug and cosmetics Act 1940 and Rules 1945

CHAPTER I -INTRODUCTORY

1. Short title, extent and commencement. –(1) This Act may be called the Drugs and Cosmetics Act, 1940.

(2) It extends to the whole of India

(3) It shall come into force at once; but Chapter III shall take the effect only from such date as the Central Government may, by notification in the Official Gazette, appoint in this behalf, and Chapter IV shall take effect in a particular State only from such date as the State Government may, by like notification, appoint in this behalf: [Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such date after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 19of 1972, as the Central Government may, by notification in the Official Gazette, appoint in this behalf.]

2. Application of other laws not barred. —The provisions of this Act shall be in addition to and not in derogation of, the Dangerous Drugs Act, 1930 2 of 1930, and any other law for the time being in force.

3. Definitions. —In this Act, unless there is anything repugnant in the subject or context,-- (a) “Ayurvedic, Siddha or Unani drug” includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of [disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine], specified in the First Schedule;]

“the Board” means—

- (i) in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha or Unani Drugs Technical Advisory Board] constituted under section 33C; and
- (ii) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;] 3[4(aaa)] “cosmetic” means 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 ,2* * * ;] 5

(b) “drug” includes—

- (i) 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;
- (ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;
- (iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board

(c) “Government Analyst” means—

- (i) in relation to Ayurvedic, Siddha or Unani drug, a Government Analyst appointed by Central Government or a State Government under section 33F; and
- (ii) in relation to any other drug or cosmetic , a Government Analyst appointed by the Central Government or a State Government under section 20;

(e) “Inspector” means—

- (i) in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and
- (ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21

(f) **“manufacture”** in relation to any drug [or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, 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; and “to manufacture” shall be construed accordingly;

(g) **“to import”**, with its grammatical variations and cognate expressions means to bring into [India];

(h) **“patent or proprietary medicine” means, --**

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

(ii) in relation to any other systems of 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 Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;]] 10[8

[(i)] **“prescribed”** means prescribed by rules made under this Act.]

3. Construction of references to any law not in force or any functionary not in existence in the State of Jammu and Kashmir. —Any reference in this Act to any law which is not in force, or any functionary not in existence, in the State of Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding law in force, or to the corresponding functionary in existence, in that State.]

4. Presumption as **to poisonous substances**. —Any substance specified as poisonous by rule made under Chapter III or Chapter IV [or Chapter IVA] shall be deemed to be a poisonous substance for the purposes of Chapter III or Chapter IV [or Chapter IVA], as the case may be

CHAPTER II - THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABOURATORY AND THE DRUGS CONSULTATIVE COMMITTEE

The Drugs Technical Advisory Board. — (1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

The Board shall consist of the following members, namely: --

- (i) the Director General of Health Services, ex officio, who shall be Chairman;
- (ii) the Drugs Controller, India, ex officio;
- (iii) the Director of the Central Drugs Laboratory, Calcutta, ex officio;
- (iv) the Director of the Central Research Institute, Kasauli, ex officio;
- (v) the Director of Indian Veterinary Research Institute, Izatnagar, ex officio;
- (vi) the President of Medical Council of India, ex officio;
- (vii) the President of the Pharmacy Council of India, ex officio;
- (viii) the Director of Central Drug Research Institute, Lucknow, ex officio;
- (ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

- (x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of Indian University or a college affiliated thereto;
 - xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto;
 - (xii) one person to be nominated by the Central Government from the pharmaceutical industry;
 - (xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;
 - (xiv) one person to be elected by the Central Council of the Indian Medical Association;
 - (xv) one person to be elected by the Council of the Indian Pharmaceutical Association;
 - (xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.]
- (3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:
- (4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

- (5) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the board.
- (6) The functions of the Board may be exercised notwithstanding any vacancy therein.
- (7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

The Central Drugs Laboratory. --

- (1) The Central Government shall, as soon as may be, established a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs [or cosmetic or class of cosmetics] shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs [or such cosmetic or class of cosmetics] shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

- (2) the Central Government may, after consultation with the Board, make rules prescribing—
- (a) the functions of the Central Drugs Laboratory;
 - (d) the procedure for the submission to the said Laboratory [under Chapter IV or Chapter IVA] of samples of drugs [or cosmetics] for analysis or test, the forms of Laboratory's reports thereon and the fees payable in respect of such reports;
 - (e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;
 - (f) the matters necessary to be prescribed for the purpose of the proviso to subsection.

The Drugs Consultative Committee. —

- (1) The Central Government may constitute an advisory committee to be called “the Drugs Consultative Committee” 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.
- (2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.
- (3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

CHAPTER III - IMPORTANCE OF DRUGS AND COSMETICS

Standards of quality. —

(1) For the purposes of this Chapter, the expression “standard quality” means—

(a) in relation to a drug, that the drug complies with the standard set out in [the Second Schedule], and (b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months’ notice of its intention so to do, may by a like notification add to or otherwise amend [the Second Schedule], for the purpose of this Chapter, and thereupon [the Second Schedule] shall be deemed to be amended accordingly.

Misbranded drugs. ---For the purposes of this Chapter a drug shall be deemed to be misbranded---

(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; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular;

Adulterated drugs. -- For the purposes of this Chapter, a drug shall be deemed to be adulterated,-- (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; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Spurious drugs. -- For the purposes of this Chapter, a drug shall be deemed to be spurious— (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 unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

- (d) if it has been substituted wholly or in part by another drug or substance; or
- (e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Misbranded cosmetics. ---For the purposes of this chapter, a cosmetic shall be deemed to be misbranded---

- (a) if it contains a colour which is not prescribed ; or
- (b) if it is not labelled in a prescribed manner; or
- (c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious cosmetics. --For the purposes of this Chapter, a drug shall be deemed to be spurious, --

- (a) if it is imported under the name which belongs to another cosmetic; or
- (b) if it is an imitation of, or is a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly or conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic
- (c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist; or
- (d) if it purports to be the product of a manufacturer of whom it is not truly a product].

Prohibition of import of certain drugs or cosmetics.

From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import—

- (a) any drug [or cosmetic] which is not of standard quality;
- [(b) any misbranded drug or misbranded (or spurious) cosmetic;]
- [(bb) any adulterated (or spurious) drug;]
- (c) any drug [or cosmetic] for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;
- [(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof (the true formula or list of active ingredients contained in it, together with the quantities thereof);]
- (e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;
- [(ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;]

Offences. —(1) Whoever himself or by any other person on his behalf imports,-

(a) any drug deemed to be adulterated under section 9A or deemed to be a spurious drug under section 9B or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10 shall be punishable with imprisonment for a term which may extend to three years and a fine which extend to five thousand rupees;]

(b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which extend to five thousand rupees or both;

(c) any drug or cosmetic in contravention of the provision of any notification issued under section 10A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which extend to five thousand rupees, or both;

(2) Whoever having been convicted of an offence—

(a) under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to ten thousand rupees, or with both;

(b) under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both

(3) The punishment provided by this section shall be in addition to any penalty to which the offender may be liable under the provision of section 11.]

Confiscation. —Where any offence punishable under section 13 has been committed, the consignment of the drugs [or cosmetics] in respect of which the offence has been committed shall be liable to confiscation.

Jurisdiction. —No Court inferior to that of a [Metropolitan] Magistrate or of a [Judicial] Magistrate of the first class shall try an offence punishable under section 13.

CHAPTER IV - MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

Standards of quality. —

- (1) For the purposes of this Chapter, the expression “standard quality” means—
 - (a) in relation to a drug, that the drug complies with the standard set out in [the Second Schedule], and
 - (b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]
- (2) The [Central Government], after consultation with the Board and after giving by notification in the Official Gazette not less than three months’ notice of its intention so to do, may by a like notification add to or otherwise amend [the Second Schedule] for the purpose of this Chapter, and thereupon [the Second Schedule] shall be deemed to be amended accordingly.

Prohibition of manufacture and sale of certain drugs and cosmetics.

—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

- (a) manufacture for sale [or for distribution], or sell, or stock or exhibit [or offer for sale]—
- [(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious; (ii) any cosmetic which is not of a standard quality or is misbranded or spurious;] [(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of [active ingredients contained in it together with the quantities thereof;]] (iv) any drug which by means of any statement, design or device accompanying it or by any other means, purport or claims [to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed; (v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended; (vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made there under;]
- (b) sell, or stock or exhibit [or offer] for sale, or distribute any drug [or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made there under;
- (c) manufacture for sale [or for distribution], or sell, or stock or exhibit [or offer] for sale, or distribute any drug [or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose

Disclosure of the name of the manufacturer, etc.—Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.]

Maintenance of records and furnishing of information. —Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.]

Pleas. —(1) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of drug [or cosmetic] in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

Inspectors. —(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person as it thinks fit, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest [in the import, manufacture or sale of drugs.

Powers of Inspectors—

- (1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed, —
 - (a) inspect**, -- (i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizing and testing the drug or cosmetic;
 - (ii) any premises wherein 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;
 - (c) at all reasonable times, with such assistance, if any, as he considers necessary,--
 - (i) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or
 - (ii) enter and search any place in which he has reason to believe an offence under this Chapter has been, or is being committed; or
 - (iii) stop and search any vehicle, vessel, or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed,

- (cc) examine any record, register, document or any other material object found [with any person, or in place, vehicle, vessel or other conveyance referred to in clause (c)], and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the Rules made there under.
- (cca) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;
- (d) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made there under.

Procedure of Inspectors. —(1) Where an Inspector takes any sample of a drug [or cosmetic] under this Chapter, he shall tender the fair price thereof and may require a written acknowledgement there for. (2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug [or cosmetic] under clause (c) of section 22, he shall tender a receipt therefore in the prescribed form. (3) Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug [or cosmetic] is being manufactured, it shall be necessary to divide the sample into three portions only: Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows: --

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug [or cosmetic];

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

(5) Where an Inspector takes any action under clause (c) of section 22, --

(a) he shall use all despatch in ascertaining whether or not the drug

[or cosmetic] contravenes any of the provisions of the section 18 and, if it is ascertained that the drug [or cosmetic] does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be take , such action as may be necessary for the return of the stock seized;

- (b) if he seizes the stock of the drug [or cosmetic], he shall as soon as may be, inform a [Judicial] Magistrate and take his orders as to the custody thereof;
 - (c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug [or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.
- (6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform a [Judicial] Magistrate and take his orders as to the custody thereof.

Reports of Government Analysts. —(1) The Government Analyst to whom a sample of any drug [or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

- (2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken [and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.
- (3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken [or the person whose name, address and other particulars have been disclosed under section 18A] has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

- (4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.
- (5) The cost of a test or analysis made by the Central Drugs Laboratory under subsection (4) shall be paid by complainant or accused as the Court shall direct.

Purchaser of drugs or cosmetics enabled to obtain test or analysis.— Any person [or any recognized consumer association, whether such person is a member of that association or not] shall, on application in prescribed manner and on payment of prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug [or cosmetic] purchased by him [or it] and to receive a report of such test or analysis signed by the Government Analyst

Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.

Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale—

- (i) any cosmetic deemed to be spurious under section 17D shall be punishable with imprisonment for a term which may extend to three years and with fine;
- (ii) any cosmetic other than a cosmetic referred to in clause (i) above in contravention of any provision of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees or with both.]

Penalty for non-disclosure of the name of the manufacturer, etc.— Whoever contravenes the provisions of section 18A [or section 24] shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to [one thousand rupees], or with both.]

Penalty for not keeping documents, etc., and for non-disclosure of information.

Whoever without reasonable cause or excuse, contravenes the provision of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees or both.

Penalty for use of Government Analyst's report for advertising. —Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug [or cosmetic], shall be punishable with fine, which may extend to five hundred rupees.

Penalty for subsequent offences. --.

- (1) whoever having been convicted of an offence- (a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years with fine which shall not be less than ten thousand rupees: Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than ten thousand rupees;
- (b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees;
- (c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than five thousand rupees, or with both;

Confiscation. (1) Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug [or cosmetic] in respect of which the contravention has been made shall be liable to confiscation [and if such contravention is in respect of—

- (i) manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or
- (ii) manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale, or distribution of any drug without a valid licence as required under clause (c) of section 18;] any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

(2) Without prejudice to the provisions contained in sub-section (1) where the Court is satisfied, on the application of an Inspector or otherwise and after such inquiry as may be necessary that the drug or cosmetic is not of standard quality [or is misbranded, adulterated or spurious drug or misbranded or spurious cosmetic], such drug or, as the case may be, such cosmetic shall be liable to confiscation.]

Power to amend First Schedule. —The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly

SCHEDULE C (1)

[See Rule 23, 61 and 76]

Other Special Products

- 1 Drugs belonging to the Digitalis groups and preparations containing drugs belonging to the Digitalis group not in a form to be administered parentally.
- 2 Ergot and preparations containing Ergot not in a form to be administered parentally.
- 3 Adrenaline and preparations containing Adrenaline not in a form to be administered parenterally.
- 4 Fish Liver Oil and preparations containing Fish Liver Oil.
- 5 Vitamins and preparations containing any vitamins not in a form to be administered parenterally.
- 6 Liver extract and preparations containing liver extract not in a form to be administered parenterally.
- 7 Hormones and preparations containing Hormones not in a form to be administered parenterally.
- 8 Vaccine not in a form to be administered parenterally.[9 Antibiotics and preparations thereof not in a form to be administered parenterally.][10 In-vitro Blood Grouping Sera.
- 11 In-vitro diagnostic Devices for HIV, HbsAg and HCV.]

SCHEDULE C [See Rules 23, 61 and 76 and Part X)

Biological and Special Products

1. Sera.
2. Solution of serum proteins intended for injection.
3. Vaccines for parenteral injections.
4. Toxins.
5. Antigen.
6. Antitoxins.
7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases.
8. Insulin.
9. Pituitary (Posterior Lobe) Extract.
10. Adrenaline and Solutions of Salts of Adrenaline.
11. Antibiotics and preparations thereof in a form to be administered parenterally.]
- 12 Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which a) requires to be stored in a refrigerator; or b) does not require to be stored in a refrigerator.
13. Sterilized surgical ligature and sterilized surgical suture.
14. Bacteriophages.
- 15 Ophthalmic preparations.
- 16 Sterile Disposable Devices for single use only.

[SCHEDULE F (II) (See Rule 124-C)

STANDARDS FOR SURGICAL DRESSING

Synonyms. - Bandage Cloth, bleached Bandage Cloth, Rolled Bandage, Open Wove Bandage, Cotton Bandage Cloth. Bandage Cloth consists of cotton cloth of plain weave made from machine spun yarn of suitable count to comply with a bleached count between 20 tex and 25 tex for wrap and between 25 tex and 30 tex for weft. The fabric contains no filling, sizing or dressing material. It may be supplied uncut and folded or cut to suitable size and rolled. Description for uncut bandages. Uncut bandages are cotton cloth of plain weave, in one continuous length showing no joints or seams, with well-formed selvages. The cloth is bleached to a good white, is clean and odourless and reasonably free from weaving defects and from seed and leaf debris.

Same as for uncut bandages, except for selvages which shall not be included in cut bandages. In addition, both the extremes and edges of cut bandages shall be straight and evenly cut, with reasonable freedom and loose threads. Threads per dim. - Wrap not less than 150 and weft not less than 85. Weight in g/m. - 57 ± 5 .

Length and Width . - The length and width shall not be less than 99 per cent each of the length and width stated on the label. For cut bandages, each of the bandages in a packing complies with this requirement. Foreign matter. - Not more than 2 per cent. Fluorescence When viewed under screened ultra-violet light, not more than occasional points of fluorescence are observed.

[SCHEDULE G] (See Rule 97)

Aminopterin, L-Asparaginase, Bleomycin, Busulphan; its salts

Carbutamide, Chlorambucil; its salts, Chlorothiazide and other derivatives of 1, 2, 4 benzothiadiazine, Chlorpropamide; its salts, Chlorthalidone and other derivatives of Chlorobenzene compound, **[(Cis-Platin)], Cyclophosphamide; its salts

**[(Cytarabine)], Daunorubicin, Di-Isopropyl Eluorophosphate, Disodium Stilboestrol Diphosphate, Doxorubicin Hydrochloride, Ethacrynic acid, its salts

Ethosuximide, Glibenclamide, Hydantoin; its salts, its derivatives, their salts

Hydroxyurea, Insulin, all types, **[(Lomustine Hydrochloride)], Mannomustine; its salts, Mercaptopurine; its salts

Metformin; its salts, Methsuximide, Mustine, its salts, Paramethadione

Phenacemide , Phenformin; its salts, 5-Phenylhydantoin; its alkyl and aryl derivatives, its salts, Primidone, **[(Procarbazine Hydrochloride)]

Quinthazone, Sarcolysine , **[(Sodium 2 Mercaptoethanesulfonate Tamoxifen Citrate)]

Testolactone, Isothipendyl, Mebhydrolin Napadisylate

Meclozine, Pheniramine, Promethazine, Thenalidine, Triprolidine

Substance being tetra-N-substituted derivatives of Ethylene Diamine or Propylenediamine.

Note . – Preparations containing the above substance excluding those intended for topical or external use are also covered by this schedule.

SCHEDULE H - (See Rules 65 and 97)

PRESCRIPTION DRUGS, Acebutolol Hydrochloride, Aclarubicin Inj , Actilyse, Acyclovir
Adrenocorticotrophic hormone (ACTH), Alclometasone Dipropionate, Allopurinol
Alphachymotrypsin, Alprazolam, Amantadine Hydrochloride, Amikacin
Amiloride Hydrochloride, Amineptine, Aminoglutethimide Tab, Aminosalicylic Acid
Amiodarone Hydrochloride, Amitriptyline, its salts, Amoscanate, Amoxapine,
Amrinone Lactate, Analgin, Androgenic, Anabolic, Oestrogenic and Progestational
Substances, Antibiotics, Aprotinin, Organic Compound of Arsenic for injection.
Articaine Hydrochloride, Astemizole, Atenolol, Atracrium Besylate Injection
Auranofin, Azathioprine, Barbituric acid, its salts, derivative of Barbituric acid, their
salts, Bacampicillin, Benserazide Hydrochloride, Betahistine Dihydrochloride
Bethanidine Sulphate, Bezafibrate, Biclotymol, Biperiden Hydrochloride, Bitoscanate
Bleomycin Oil Suspension, Bromhexine Hydrochloride, Bromocriptine Mesylate
Budesonide, Buspirone, Captopril, Carbidopa, Xipamide, Zidovudine Cap, etc.

NOTE :- 1.Preparations exempted under proviso to para 2 of Note to Schedule X shall
also be covered by this Schedule.2.Preparations containing the above substances
excluding those intended for topical/or external use are also covered by this
Schedule. The inclusion of a substance in Schedule H does not imply or convey that
substance is exempted from the provisions of Rule 122-A.

4. Medicinal and Toilet preparations (Excise duties) Act 1955

An Act to provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drug or narcotic
Be it enacted by Parliament in the Sixth Year of the Republic of India as follows:

1. SHORT TITLE, EXTENT AND COMMENCEMENT.

(1) This Act may be called the Medicinal and Toilet Preparations (Excise Duties) Act, 1955. (2) It extends to the whole of India.

(3) It shall come into force on such date 2 , as the Central Government may, by notification in the official Gazette, appoint.

2. DEFINITIONS :- In this Act unless the context otherwise requires, - (a) "alcohol" means ethyl alcohol of any strength and purity having chemical compositions C_2H_5OH ;

(aa) "Coca derivative" means - (i) crude cocaine that is any extract of coca leaf which can be used directly or indirectly, for the manufacture of cocaine;

(ii) ecgonine, that is laevo-ecgonine having the chemical formula, $C_9H_{15}NO_3 \cdot H_2O$, and all the derivatives of laevo-ecgonine from which it can be recovered, and

(iii) cocaine, that is, methyl-benzoyl-laevo-ecgonine having the chemical formula, $C_{17}H_{21}NO_4$ and its salts;

(ab) "coca-leaf" means -

(i) the leaf and young twigs of any coca plant, that is, of the *Erythroxylon coca* (Lamk.) and the *Erythroxylon novo-granatense* (Hiern.) and their varieties, and of any other species of this genus which the Central Government may,

- by notification in the official Gazette, declare to be coca plants for the purposes of this Act, and (ii) any mixture thereof, with or without neutral materials;
- (bb) derivative of opium, means -
- (i) medicinal opium, that is, opium which has undergone the processes necessary to adopt it for medicinal use;
 - (ii) prepared opium, that is, any product of opium obtained by any series of operations designed to transform opium into an extract suitable for smoking and the dross or other residue remaining after opium is smoked ;
 - (iii) morphine, that is, the principal alkaloid of opium having the chemical formula $C_{17}H_{19}NO_8$, and its salts, and its derivatives;
- (b) "collecting Government" means the Central Government or, as the case may be, the State Government which is entitled to collect the duties levied under this Act;
- (c) "dutiable goods" means the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act;
- (d) "excise officer" means an officer of the Excise Department of any State and includes any person empowered by the collecting Government to exercise all or any of the powers of an excise officer under this Act;
- (e) "Indian hemp" means - (i) the leaves, small stalks and flowering or fruiting tops of the Indian hemp plant (*Cannbis-sativa* L), including all forms known as bhang, sidhi or ganja;

- (ii) charas, that is, the resin obtained from the Indian hemp plant, which has not been submitted to any manipulations other than those necessary for packing and transport;
- (iii) any mixture, with or without neutral materials, of any of the above forms of Indian hemp or any drink prepared there from; and
- (iv) any extract or tincture of the above forms of Indian hemp;
- (f) "manufacture" includes any process incidental or ancillary to the completion of the manufacture of any dutiable goods;
- (g) "medicinal preparation" includes all drugs which are a remedy or "prescription" prepared for internal or external use of human beings or animals and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals;
- (h) "narcotic drug" or "narcotic" means a substance which is coca leaf, or coca derivative, or opium or derivative of opium, or Indian hemp and shall include any other substance, capable of causing or producing in human beings dependence, tolerance and withdrawal syndromes and which the Central Government may, by notification in the official Gazette, declare to be a narcotic drug or narcotic;
- (i) "opium" means - (1) the capsules of the poppy (*Palaver somniferous L*), whether in their original form or cut, crushed or powdered and whether or not juice has been extracted there from, (2) the spontaneously coagulated juice of such capsules which has not been submitted to any manipulations other than those necessary for packing and transport; and

(3) any mixture, with or without neutral materials of any of the above forms of opium, and includes and derivative of opium;

(j) "prescribed" means prescribed by rules made under this Act;

(k) "toilet preparation" means any preparation which is intended for use in the toilet of the human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes.

3. DUTIES OF EXCISE TO BE LEVIED AND COLLECTED ON CERTAIN GOODS.

(1) There shall be levied duties of excise, at the rates specified in the schedule, on all dutiable goods manufactured in India.

(2) The duties aforesaid shall be leviable -

(a) where the dutiable goods are manufactured in bond, in the State in which such goods are released from a bonded warehouse for home consumption, whether such State is the State of manufacture or not;

(b) where dutiable goods are not manufactured in bond, in the State in which such goods are manufactured.

4. REBATE OF DUTY ON ALCOHOL, ETC. SUPPLIED FOR MANUFACTURE OF DUTIABLE GOODS.

Where alcohol opium, Indian hemp or other narcotic drug or narcotic had been supplied to a manufacturer or any dutiable goods for use as an ingredient of such goods by, or under the authority of, the collecting Government and a duty or excise on the goods so supplied had already been recovered by such Government under any law for the time being in force, the collecting Government shall, on an application being made to it in this behalf, grant in respect of the duty of excise leviable under this Act, a rebate to such manufacturer of the excess, if any, of the duty so recovered over the duty leviable under this Act.

5. RECOVERY OF SUMS DUE TO GOVERNMENT.

In respect of the duty of excise and any other sums of any kind payable to the collecting Government under any of the provisions of this Act or of the rules made there under, the Excise Officer empowered by the said rules to levy such duty or require the payment of such sums, may deduct the amount so payable from any money owing to the person from whom such sums may be recoverable or due, which may be in his hands or under his disposal or control or may recover the amount by attachment and sale of dutiable goods belonging to such person; and if the amount payable is not so recovered he may prepare a certificate signed by him specifying the amount due from the person liable to pay the sum and sent to it the Collector of the district in which such person resides or conducts his business, and the said Collector on receipt of such certificate shall proceed to recover from the said person the amount specified therein in the same manner as an arrear of land revenue.

CERTAIN OPERATIONS TO BE SUBJECT TO LICENCES.

- (1) The Central Government may, by notification in the official Gazette, provide that from such date as may be specified in the notification, no person shall engage in the production or manufacture of any dutiable goods or of any specified component parts or ingredients of such goods or of specified container of such goods or of labels of such containers except under the authority and in accordance with the terms and conditions of a licence granted under this Act.
- (2) Every licence under sub-section (1) shall be granted for such area, if any, for such period, subject to such restrictions and conditions, and in such form and containing such particulars as may be prescribed.

POWER OF COURTS TO ORDER FORFEITURE.

Any Court trying any offence under Sec. 7 may order the forfeiture to the collecting Government of any dutiable goods in respect of which the Court is satisfied that an offence under this Act has been committed, and may also order the forfeiture of any alcohol, drugs or materials by means of which the offence has been committed and of any receptacles, packages or coverings in which any such goods or articles are contained and the animals, vehicles, vessels or other conveyances used in carrying such goods or articles, and any implements or machinery used in the manufacture of such goods

POWER TO ARREST.

- (1) Any excise officer duly empowered by rules made in this behalf may arrest any person whom he has reason to believe to be liable to punishment under this Act.
- (2) Any person accused or reasonably suspected of committing an offence under this Act or any rules made there under, who, on demand of any excise officer duly empowered by rules made under this Act, refuses to give his name and residence, or who gives a name or residence which such officer has reason to believe to be false may be arrested by such officer in order that his name and residence may be ascertained.

POWER TO SUMMON PERSONS TO GIVE EVIDENCE AND PRODUCE DOCUMENTS IN INQUIRIES UNDER THIS ACT.

- (1) Any excise officer duly empowered by rules made in this behalf shall have power to summon any person whose attendance he considers necessary either to give evidence or to produce a document or any other thing in any inquiry which such officer is making for any of the purpose of this Act.
- (2) A summons to produce documents or other things under sub-section (1) may be for the production of certain specified documents or things or for the production of all documents or things of a certain description in the possession or under the control of the person concerned.

OFFICERS REQUIRED TO ASSIST EXCISE OFFICERS.

All officers of Customs and Central Excise, and such other officers of the Central Government as may be specified in this behalf, and all police officers and all officers engaged in the collection of land revenue are hereby empowered and required to assist excise officers in the execution of this Act.

OWNERS OR OCCUPIERS OF LAND TO REPORT MANUFACTURE OF CONTRABAND DUTIABLE GOODS.

Every owner or occupier of land and the agent of any such owner or occupier in charge of the management of that land, if dutiable goods are manufactured thereon in contravention of the provisions of this Act or the rules made thereunder, shall, in the absence of reasonable excuse, be bound to give notice of such manufacture to a Magistrate or to an officer of the Excise, Customs, Police or Land Revenue Department immediately the fact comes to his notice.

PUNISHMENT FOR CONNIVANCE AT OFFENCES.

Any owner or occupier of land or any agent of such owner or occupier in charge of the management of the land, who willfully connives at any offence against the provisions of this Act or any rules made there under shall, for every such offence, be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both.

SEARCHES AND ARRESTS HOW TO BE MADE.

All arrests and searches made under this Act or under any rules made there under shall be carried out in accordance with the provisions of the Code of Criminal Procedure, 1898 (5 of 1898) 6 , relating respectively to searches and arrests under the Code.

DISPOSAL OF PERSONS ARRESTED.

- (1) Every person arrested under this Act shall be forwarded without delay to the nearest Excise Officer empowered to send persons so arrested to a Magistrate or if there is no such excise officer within a reasonable distance to the officer-in-charge of the nearest police station.
- (2) The officer-in-charge of a police station to whom any person is forwarded under sub-section (1) shall either admit him to bail to appear before a Magistrate having jurisdiction or in default of bail forward him without delay in custody to such Magistrate.

INQUIRY HOW TO BE MADE BY EXCISE OFFICERS AGAINST ARRESTED PERSONS FORWARDED TO THEM.

- (1) When any person is forwarded under Sec. 15 to an excise officer empowered to send persons so arrested to a Magistrate, the Excise Officer shall proceed to inquire into the charge against him.
- (2) For the purpose of sub-section (1), the Excise Officer may exercise the same powers, and shall be subject to the same provisions, as the officer-in-charge of a police station may exercise and is subject to under the Code of Criminal Procedure, 1898 (5 of 1898).

VEXATIOUS SEARCH, SEIZURE, ETC. BY EXCISE OFFICER.

- (1) Any officer exercising powers under this Act or under the rules made there under who - (a) without reasonable ground of suspicion searches or causes to be searched any place, conveyance or vessel; (b) vexatiously and unnecessarily detains, searches or arrests any person; (c) vexatiously and unnecessarily seizes the moveable property of any person on pretence of seizing or searching for any article liable to confiscation under this Act; (d) commits, as such officer, any other act to the injury of any person, without having reason to believe that such act is required for the execution of his duty; Shall, for every such offence, be punishable with fine which may extend to two thousand rupees.
- (2) Any person willfully and maliciously giving false information and so causing an arrest or a search to be made under this Act shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both.

FAILURE OF EXCISE OFFICERS ON DUTY.

Any Excise Officer who ceases or refuses to perform, or withdraws himself from the duties of his office, unless he had obtained the express written permission of his superior officer or has given such superior officer two month's notice in writing of his intention or has other lawful excuse, shall be punishable with imprisonment for a term which may extend to three months, or with fine which may extend to three months' pay, or with both.

BAR OF SUITS AND LIMITATION OF SUITS AND OTHER LEGAL PROCEEDINGS.

- (1) No suit or other legal proceeding shall lie against the collecting Government or against any officer in respect of any order passed in good faith or any act in good faith done or ordered to be done under this Act.
- (2) No suit, prosecution or other legal proceeding shall be instituted against the collecting Government or against any officer for anything done or ordered to be done under this Act after the expiration of six months from the accrual of the cause of action or from the date of the act or order complained of.

REPEALS AND SAVINGS.

If, immediately before the commencement of this Act, there is in force in any State any law corresponding to this Act, that law is hereby repealed : Provided that all rules made, notifications issued, licences or permits granted, powers conferred under any law hereby repealed shall, so far as they are not inconsistent with this Act, have the same force and effect as if they had been respectively made, issued, granted or conferred under this Act and by the authority empowered hereby in that behalf.

Medicinal Preparations

1. Allopathic Medicinal Preparations

- (i) Medicinal preparations containing alcohol which are not capable of being consumed as ordinary alcoholic beverages - (a) Patent or proprietary medicines. Rupees ten per litre of pure alcohol content, whichever is higher. (b) Others. Rupees ten per litre of pure alcohol content.
- (ii) Medicinal preparations containing alcohol which are capable of being consumed as ordinary alcoholic beverages - (a) Medicinal preparations which contain known active ingredients in therapeutic quantities. Rupees twenty per litre of pure alcohol content, whichever is higher.

(b) Others. Twenty per cent. ad valorem or rupees eighty per litre of pure alcohol content, whichever is higher. (iii) Medicinal preparations not containing alcohol but containing narcotic drug or narcotic. ad valorem.

Medicinal preparations in Ayurvedic, Unani or other indigenous systems of medicine -

(i) Medicinal preparations containing Nil self-generated alcohol which are not capable of being consumed as ordinary alcoholic beverages. (ii) Medicinal preparations containing Rupees two and self-generated alcohol which are capable fifty paise per litre of pure alcohol content. (iii) All other containing alcohol Rupees eighty per litre of pure alcohol content. (iv) Medicinal preparations not containing alcohol but containing valorem. narcotic drug or narcotic. 3. Homoeopathic preparations Rupees twenty per litre of pure alcohol content.

TOILET PREPARATIONS

Toilet preparations containing One hundred per cent. ad valorem or rupees twenty per litre of pure alcohol content whichever is higher.

Explanation I : "Patent or proprietary medicines" means any medicinal preparation which bears either on itself or on its container or both, a name which is not specified in a monograph in a pharmacopoeia, formulary or other publications notified in this behalf by the Central Government in the official Gazettee, or which is a brand name, that is, a name or a registered trade-mark under the Trade and Merchandise Marks Act, 1958 (43 of 1958), or any other mark such to a symbol, monogram, label, signature or invented words or any writing which is used in relation to that medicinal preparation for the purpose of indicating or so as to indicate a connection in the course of trade between the preparation and some person having the right either as proprietor or otherwise to use the name or mark with or without any indication of the identity of that person.

5. Narcotic Drug and Psychotropic substances Act 1985 and Rules

An Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances 1[, to provide for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, to implement the provisions of the International Convention on Narcotic Drugs and Psychotropic Substances] and for matters connected therewith. Be it enacted by Parliament in the Thirty-sixth Year of the Republic of India as follows:

CHAPTER 1 - PRELIMINARY

1. Short title, extent and commencement.-

(1) This Act may be called the Narcotic Drugs and Psychotropic Substances Act, 1985.

(2) It extends to the whole of India [and it applies also- (a) to all citizens of India outside India; (b) to all persons on ships and aircrafts registered in India. Wherever they may be.]

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint, and different dates may be appointed for different provisions of this Act and for different States and any reference in any such provision to the commencement of this Act shall be construed in relation to any State as a reference to the coming into force of that provision in that State.

This is a special Act, while adopting the liberal construction of the Act, it is found that the Act has been enacted with a view to make stringent provisions for the control and regulation of operations relating to the narcotic drugs and psychotropic substances; *Gulam Mohiuddin v. State of Jammu and Kashmir*, (1994) 1 Crimes 204 (J & K).

Definitions.-In this Act, unless the context otherwise requires,-- [(i) "addict" means a person who has dependence on any narcotic drug or psychotropic substances;]

(ii) "Board" means the Central Board of Excise and Customs constituted under the Central Boards of Revenue Act, 1963 (54 of 1963);

(iii) "cannabis (hemp)" means-

(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 (excluding the seeds and leaves when not accompanied by the tops), by whatever name they may be known or designated; and (c) any mixture, with or without any neutral material, of any of the above forms of cannabis or any drink prepared therefrom;

(iv) "cannabis plant" means any plant of the genus cannabis; (v) "coca derivative" means

(a) crude cocaine, that is, any extract of coca leaf which can be used, directly or indirectly, for the manufacture of cocaine; (b) ecgonine and all the derivatives of ecgonine from which it can be recovered; (c) cocaine, that is, methyl ester of benzoyl-ecgonine and its salts; and (d) all preparations containing more than 0.1 percent of cocaine;

(vi) "coca leaf" means

(a) the leaf of the coca plant except of a leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed; (b) any mixture thereof with or without any neutral material; but does not include any preparation containing not more than 0.1 per cent. of cocaine;

- (b) the protocol, amending the Convention mentioned in sub-clause (a), adopted by the United Nations Conference at Geneva in March, 1972;
- (c) the Convention on Psychotropic Substances, 1971 adopted by the United Nations Conference at Vienna in February, 1971; and
- (d) any other international convention, or protocol or other instrument amending an international convention, relating to narcotic drugs or psychotropic substances which may be ratified or acceded to by India after the commencement of this Act;
- (x) "manufacture", in relation to narcotic drugs or psychotropic substances, includes
 - (1) all processes other than production by which such drugs or substances may be obtained;
 - (2) refining of such drugs or substances;
 - (3) transformation of such drugs or substances; and
 - (4) making of preparation (otherwise than in a pharmacy on prescription) with or containing such drugs or substances;
- (xi) "manufactured drug" means
 - (a) all coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate;
- (e) all preparations containing more than 0.2 per cent. of morphine or containing any diacetylmorphine;

- (i) A person, who assists a narcotics trafficker in concealing the narcotics in his apartment so that the trafficker may avoid detection, is involved in illicit traffic; *R. v. Jackson*, (1977) 35 CCC (2d) 331.
- (ii) It may be noted that clause (iv) of section 2 (viii a) is independent of other clauses and is in the nature of a residuary provision. It would include an activity of distribution; *R. Parkash v. State of Karnataka*, (1980) Cr LJ 165.
- (iii) The definition of the term 'manufacture' as contained in section. 2(x) is .an inclusive one. where the definition is an inclusive definition, the word not only bears its ordinary, popular and natural sense whenever that would be applicable but it also bears its extended statutory meaning; *S.K. Gupta v. K.P. Jain*, AIR 1979 SC 734.
- (iv) Heroin being an opium is manufactured drug; *I. Paul Kuki v. State of West Bengal*, (1993) 3 Crimes 660 (Cal) (DB).
- (v) It is true that opium is substance, which once seen and smelt can never be forgotten because opium possesses a characteristic appearance and a very strong and characteristic scent. It is possible for people to identify opium without having to subject the product to a chemical analysis. It is only when opium is in a mixture so diluted that its essential characteristics are not easily visible or capable of being apprehended by the senses that a chemical analysis may be necessary; *Baidyanath Mishra v. State of Orissa*, (1967) SCD 1165: 34 Cut LT 1.

Central Government to take measures for preventing and combating abuse of and illicit traffic in narcotic drugs, etc.-(1) Subject to the provisions of the Act, the Central Government shall take all such measures as it deems necessary or expedient for the purpose of preventing and combating abuse of narcotic drugs and psychotropic substances and the illicit traffic therein.

- (2) In particular and without prejudice to the generality of the provisions of subsection (1), the measures which the Central Government may take under the subsection include measures with respect to all or any of the following matters, namely:
- (a) coordination of actions by various officers, State Governments and other authorities (i) under this Act, or (ii) under any other law for the time being in force in connection with the enforcement of the provisions of this Act;
 - (b) obligations under the International Conventions;
 - (c) assistance to the concerned authorities in foreign countries and concerned international organisations with a view to facilitating coordination and universal action for prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances;
 - (d) identification, treatment, education, after care, rehabilitation and social re-integration of addicts;
 - (e) such other matters as, the Central Government deems necessary or expedient for the purpose of securing the effective implementation of the provisions of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.

Officers of Central Government.-(1) Without prejudice to the provisions of sub-section (3) of section 4, the Central Government shall appoint a Narcotics Commissioner and may also appoint such other officers with such designations as it thinks fit for the purposes of this Act. (2) The Narcotics Commissioner shall, either by himself or through officers subordinate to him, exercise all powers and perform all functions relating to the superintendence of the cultivation of the opium poppy and production of opium and shall also exercise and perform such other powers and functions as may be entrusted to him by the Central Government. (3) The officers appointed under sub-section (1) shall be subject to the general control and direction of the Central Government, or, if so directed by that Government, also of the Board or any other authority or officer. 6. The Narcotic Drugs and Psychotropic

Substances Consultative Committee.-(1) The Central Government may constitute, by notification in the Official Gazette, an advisory committee to be called "The Narcotic Drugs and Psychotropic Substances Consultative Committee" (hereafter in this section referred to as the Committee) to advise the Central Government on such matters relating to the administration of this Act as are referred to it by that Government from time to time. (2) The Committee shall consist of a Chairman and such other members, not exceeding twenty, as may be appointed by the Central Government. (3) The Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

NATIONAL FUND FOR CONTROL OF DRUG ABUSE

National Fund for Control of Drug Abuse. -(l) The Central Government may, by notification in the Official Gazette, constitute a Fund to be called the National Fund for Control of Drug Abuse (hereafter in this Chapter referred to as the Fund) and there shall be credited thereto-

- (a) an amount which the Central Government may, after due appropriation made by Parliament by law in this behalf, provide;
 - (b) the sale proceeds of any property forfeited under Chapter V A;
 - (c) any grants that may be made by any person or institution;
 - (d) any income from investment of the amounts credited to the Fund under the aforesaid provisions.
- (2) The Fund shall be applied by the Central Government to meet the expenditure incurred in connection with the measures taken for (a) Combating illicit traffic in narcotic drugs, psychotropic substances or controlled substances; (b) Controlling the abuse of narcotic drugs and psychotropic substances; (c) identifying, treating, rehabilitating addicts; (d) Preventing drug abuse; (e) Educating public against drug abuse; (f) supplying drugs to addicts where such supply is a medical necessity.
- (3) The Central Government may constitute a Governing Body as it thinks fit to advise that Government and to sanction money out of the said Fund subject to the limit notified by the Central Government in the Official Gazette.]
- (4) The Governing Body shall consist of a Chairman (not below the rank of an Additional Secretary to the Central Government) and such other members not exceeding six as the Central Government may appoint.
- (5) The Governing Body shall have the power to regulate its own procedure.

Annual report of activities financed under the fund. - The Central Government shall, as soon as may be, after the end of each financial year, cause to be published in the Official Gazette, a report giving an account of the activities financed under section 7-A during the financial year, together with a statement of accounts.

PROHIBITION, CONTROL AND REGULATION

Prohibition of certain operations. -No person shall

(a) cultivate any coca plant or gather any portion of coca plant; or (b) cultivate the opium poppy or any cannabis plant; or 1. Ins. by Act 2 of 1989, sec. 4 (w.e.f. 29-5-1989).

2. Subs. by Act 9 of 2001, sec. 4, for sub-sections (2) and (3) (w.e.f. 2-10-2001).

(c) produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import interState, export inter-State, import into India, export from India or tranship any narcotic drug or psychotropic substance, except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the rules or orders made thereunder and in a case where any such provision, imposes any requirement by way of licence, permit or authorization also in accordance with the terms and conditions of such licence, permit or authorization: Provided that, and subject to the other provisions of this Act and the rules made thereunder, the prohibition against the cultivation of the cannabis plant for the production of ganja or the production, possession, use, consumption, purchase, sale, transport, warehousing, import interState and export inter-State of ganja for any purpose other than medical and scientific purpose shall take effect only from the date which the Central Government may, by notification in the Official Gazette, specify in this behalf: I[Provided further that nothing in this section shall apply to the export of poppy straw for decorative purposes.]

OFFENCES AND PENALTIES

Punishment for contravention in relation to poppy straw. -Whoever, in contravention of any provisions of this Act or any rule or order made or condition of a licence granted thereunder, produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw or removes or does any act in respect of warehoused poppy straw shall be punishable,

- (a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to six months, or with fine which may extend to ten thousand rupees or with both;
- (b) where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years and with fine which may extend to one lakh rupees;
- (c) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees. Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.

Punishment for contravention in relation to coca plant and coca leaves.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder, cultivates any coca plant or gathers any portion of a coca plant or produces, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses coca leaves shall be punishable with rigorous imprisonment for a term which may extend to ten years or with fine which may extend to one lakh rupees.

Punishment for contravention in relation to prepared opium Whoever, in contravention of any provision of this Act or any rule or order made or condition of licence granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses prepared opium shall be punishable,

PROCEDURE

Power to issue warrant and authorisation.-(1) A Metropolitan Magistrate or a Magistrate of the first class or any Magistrate of the second class specially empowered by the State Government in this behalf, may issue a warrant for the arrest of any person whom he has reason to believe to have committed any offence punishable under this Act, or for the search, whether by day or by night, of any building, conveyance or place in which he has reason to believe any narcotic drug or psychotropic substance or controlled substance in respect of which an offence punishable under this Act has been committed or any document or other article which may furnish evidence of the commission of such offence or any illegally acquired property or any document or other article which may furnish evidence of holding any illegally acquired property which is liable for seizure or freezing or forfeiture under Chapter V A of this Act is kept or concealed:

(2) Any such officer of gazetted rank of the departments of central excise, narcotics, customs, revenue intelligence or any other department of the Central Government including the paramilitary forces or the armed forces as is empowered in this behalf by general or special order by the Central Government, or any such officer of the revenue, drugs control, excise, police or any other department of a State Government as is empowered in this behalf by general or special order of the State Government if he has reason to believe from personal knowledge or information given by any person and taken in writing that any person has committed an offence punishable under this Act or that any narcotic drug or psychotropic substance or controlled substance in respect of which any offence under this Act has been committed or any document or other article which may furnish evidence of the commission of such offence or any illegally acquired property or any document or other article which may furnish evidence of holding any illegally acquired property which is liable for seizure or freezing or forfeiture under Chapter V A of this Act is kept or concealed in any building, conveyance or place, may authorise any officer subordinate to him but superior in rank to a peon, sepoy or a constable to arrest such a person or search a building, conveyance or place whether by day or by night or himself arrest such a person or search a building, conveyance or place.

(3) The officer to whom a warrant under sub-section (1) is addressed and the officer who authorised the arrest or search or the officer who is so authorised under sub-section (2) shall have all the powers of an officer acting under section 42.

Power of entry, search, seizure and arrest in offences relating to coca plant, opium poppy and cannabis plant.

-The provisions of sections 41, 42 and 43, shall so far as may be, apply in relation to the offences punishable under Chapter IV and relating to coca plant, the opium poppy or cannabis plant and for this purpose references in those sections to narcotic drugs, or psychotropic substance, [or controlled substance], shall be construed as including references to coca plant, the opium poppy and cannabis plant.

Procedure where seizure of goods liable to confiscation not practicable.-Where it is not practicable to seize any goods (including standing crop) which are liable to confiscation under this Act, any officer duly authorised under section 42 may serve on the owner or person in possession of the goods, an order that he shall not remove, part with or otherwise deal with the goods except with the previous permission of such officer.

Duty of land holder to give information of illegal cultivation.-Every holder of land shall give immediate information to any officer of the police or of any of the departments mentioned in section 42 of all the opium poppy, cannabis plant or coca plant which may be illegally cultivated within his land and every such holder of land who knowingly neglects to give such information, shall be liable to punishment.

Duty of certain officers to give information of illegal cultivation.-Every officer of the Government and every panch, sarpanch and other village officer of whatever description shall give immediate information to any officer of the Police or of any of the departments mentioned in section 42 when it may come to his knowledge that any land has been illegally cultivated with the opium poppy, cannabis plant or coca plant, and every such officer of the Government, panch, sarpanch and other village officer who neglects to give such information, shall be liable to punishment.

Power of attachment of crop illegally cultivated.-Any Metropolitan Magistrate, Judicial Magistrate of the first class or any Magistrate specially empowered in this behalf by the State Government 2[or any officer of a gazetted rank empowered under section 42] may order attachment of any opium poppy, cannabis plant or coca plant which he has reason to believe to have been illegally cultivated and while doing so may pass such order (including an order to destroy the crop) as he thinks fit.

Power to stop and search conveyance.-Any officer authorised under section 42, may, if he has reason to suspect that any animal or conveyance is, or 1. Ins. by Act 9 of 2001, sec. 20 (w.e.f. 2-10-2001). 2. Ins. by Act 2 of 1989, sec. 13 (w.e.f. 29-5-1989).

Power to undertake controlled delivery.- The Director General of Narcotics Control Bureau constituted under sub-section (3) of section 4 or any other officer authorised by him in this behalf, may, notwithstanding anything contained in this Act, undertake controlled delivery of any consignment to (a) any destination in India; (b) a foreign country, in consultation with the competent authority of such foreign country to which such consignment is destined, in such manner as may be prescribed 1

Power of entry, search and seizure :

1. Any Gazetted Officer of the Central Government or of a State Government authorised by a general or special order by the Central Government or, as the case may be, by the State Government in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provision of this Order have been complied with -
 - enter and search any place,
 - seize any drug, alongwith the containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production;
 - seize any document, such as, cash memo or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened.
2. The provision of section 100 of the Code of Criminal Procedure, 1973 (2 of 1974), relating to search and seizure shall, so far as may be, apply to searches and seizures under this Order.

- **Power to review :** Any person aggrieved by any notification issued or order made under paragraphs 3,5,8,9 or 10 may apply to the Government for a review of the notification or order within fifteen days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper :
- Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer, importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government of which a review has been applied for.
- **Power to issue guidelines and directions :**
- The Government, may for the purpose of implementing the provisions of this Order, authorise any Officer, by a general or special order, to inspect the premises of any manufacturer, importer, distributor or dealer and such manufacturer, importer, distributor or dealer shall allow such authorised officer and make available all relevant information required for the purpose.
- The Government may, from time to time, issue such guidelines and directions, consistent with the provisions of this Order to any manufacturer or importer as may be necessary to carry out the provisions of this Order and such manufacturer or importer shall comply with such guidelines and directions.

- **Penalties :**
- Any contravention of any of the provisions of this Order shall be punished in accordance with the provision of the Essential Commodities Act, 1955 (10 of 1955).

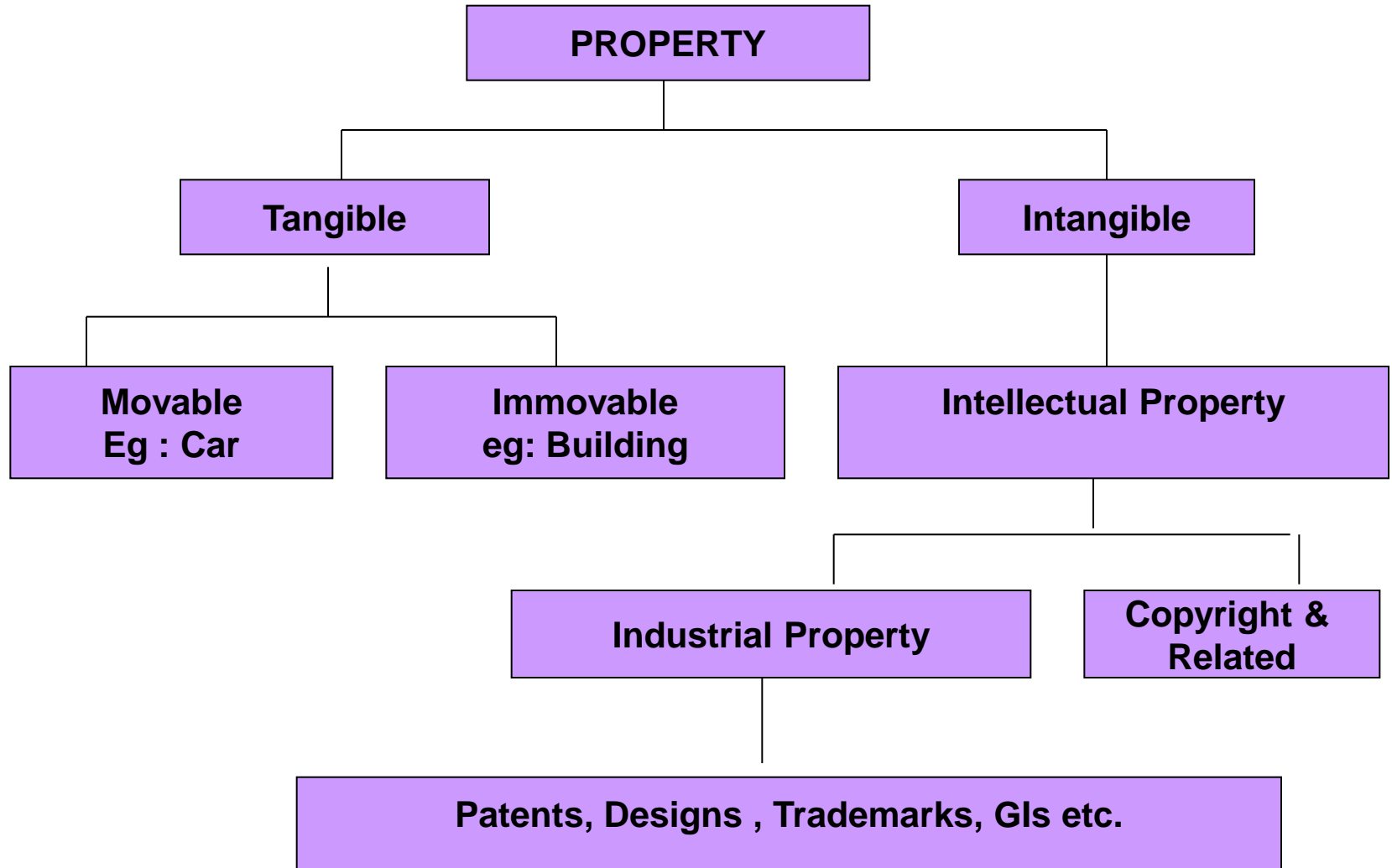
- **Power to exempt :**
- Government may, having regard to the factors mentioned in sub-paragraph (2) and subject to such conditions as it may specify, by an order in the Official Gazette, exempt any manufacturer from the operation of all or any of the provisions of this Order.
- While granting exemption under sub-paragraph (1), the Government shall have regard to all or any of the following factors -
 - number of workers employed;
 - amount of capital Invested;
 - range/group and type of products manufactured;
 - sales turnover;
 - production of bulk drugs from basic stage by a process developed through indigenous research and development, and which is significantly different from known processes and results in cost reduction;
 - production of a new drug which has not been produced elsewhere, if developed through indigenous research and development;

- **Delegation of powers :**
- The Government may, by notification in the Official Gazette, direct that all or any of the powers conferred upon it by this Order, other than those contained in paragraphs 22, 23, and 25 shall, subject to such restrictions, exceptions and conditions, as may be specified in the direction, be exercisable also by such Officer or authority as may be specified in the notification.
- **Repeal and saving :**
- The Drugs (Prices Control) Order, 1987 is hereby repealed.
- Notwithstanding such repeal, anything done or any action taken, including any notification or Order made, direction given, notice issued or exemption granted under the Drugs (Prices Control) Order, 1987, shall, in so far as it is not inconsistent with the provisions of this Order, be deemed to have been done, taken, made, given, issued or granted, as the case may be, under the corresponding provisions of this Order.

7. Patent act

Objective, definitions, types of patents, procedure for patenting, secrecy of certain invention, surrender and revocation of patents as amended to date.

INTELLECTUAL PROPERTY RIGHTS (IPRs)



•Ministry of Commerce & Industry

•Deptt. Of Industrial Policy & Promotion

•O/Controller general patents, designs & trade marks

•Patent & Design
• Office

•Trade Marks
Registry

•Geographical
Indications
Registry

•Patent
Information
System

•Kolkata

•Delhi

•Mumbai

•Chennai

•Mumbai

•Kolkata

•Delhi

•Chennai

Ahmedabad

•Chennai

•NIIPM

•NAGPUR

**Office of the Controller General of Patents,
Designs & Trade Marks,
Boudhik Sampada Bhavan,
Near Antop Hill Post Office, S.M. Road,
Antop Hill,
Mumbai – 400 037
Phone: (91)(22) 24123311,
Fax : (91)(22) 24123322
E-mail: cgpdtm@nic.in**

Address of the Patent Offices/Jurisdictions

Patent Office Mumbai

**The Patent Office,
Government of India,
Boudhik Sampada Bhavan,
Near Antop Hill Post Office, S.M. Road, Antop Hill,
Mumbai – 400 037
Phone: (91)(22) 24137701
Fax: (91)(22) 24130387
E-mail: mumbai-patent@nic.in**

☐ The States of Gujarat, Maharashtra, Madhya Pradesh, Goa and Chhattisgarh and the Union Territories of Daman and Diu & Dadra and Nagar Haveli

Patent office Chennai

**The Patent Office,
Government of India,
Intellectual Property Rights Building,
G.S.T. Road, Guindy,
Chennai – 600 032.**

Phone: (91)(44) 2250 2081-84

Fax : (91)(44) 2250 2066

E-mail: chennai-patent@nic.in

**☐ The States of Andhra Pradesh,
Karnataka, Kerala, Tamil Nadu and the
Union Territories of Puducherry and
Lakshadweep.**

Patent Office New Delhi

**The Patent Office,
Government of India,
Boudhik Sampada Bhavan,
Plot No. 32., Sector-14, Dwarka,
New Delhi – 110075
Phone: (91)(11) 2808 1921 – 25
Fax: (91)(11) 2808 1920 & 2808 1940
E.mail: delhi-patent@nic.in**

**☐ The States of Haryana, Himachal Pradesh,
Jammu and Kashmir, Punjab, Rajasthan, Uttar
Pradesh, Uttaranchal, Delhi and the Union
Territory of Chandigarh.**

Patent Office Kolkatta

The Patent Office (Head Office),

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Boudhik Sampada Bhavan,

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Kolkata- 700 091

Phone: (91)(33) 2367 1943/44/45/46/87

Fax: (91)(33) 2367 1988

E-Mail: kolkata-patent@nic.in

☐ Rest of India

IP BUILDINGS



•**KOLKATA**



•**DELHI**



•**CHENNAI**



•**MUMBAI**

Intellectual Property

- ❑ *Creative thoughts process*
- ❑ *Do some thing better*
- ❑ *Start copying the improvement*
- ❑ *Prevent others from doing the same thing*

PATENT

A Patent is granted

- **Inventor**
- **Invention**
- **Successful solution to technical problems**
- **Not restricted to specific area**
- **Nor limited to improvement**
 - *Novel*
 - *useful*
 - *Non-obvious*

•WHAT IS A DESIGN?

- Design refers to the features of

- Shape

- Configuration

- Pattern

- Ornamentation

- Compositions of lines or colors

•EXTERNAL APPEARANCE OF THE
FINISHED ARTICLE

- Applied to any article in 2-d or 3-d or in both forms; by any Industrial process or means, whether manual,mechanical Or chemical, separate or combined, which in the finished article appeal and are judged solely by the eye.

Industrial Designs

- The ornamental or aesthetic aspect of an article.
- Consist of three dimensional features, such as the shape or surface of an article, or two dimensional feature, such as patterns, lines or color.
- Make as attractive and appealing, and add to its commercial value for that reason.
- Exclusive right against unauthorized copying.
- Protection normally lasts for an initial ten years, after which it can usually be renewed for, in most cases, 15 years.
- Promotes more innovative and aesthetically attractive products



Trade Marks

- Trade marks are commercial source indicators, distinctive signs that identify certain goods or services produced or provided by a specific person or enterprise.
- Trade marks are essentially important when consumers and producers are far away from one another.



SONY



OLYMPUS



TRADEMARKS

- A trade mark is any sign which can distinguish the goods of one trader from those of another. Sign includes, words, logos, pictures, or a combination of these.
- A trade mark is used as a marketing tool so that customers can recognize the product of a particular trader.

What is Copyright ?

Copyright is a legal term describing **rights given to creators** for their literary and artistic works

The **kinds of works covered by copyright** include : literary works such as novels, poems, plays, reference works, newspapers and computer programs; databases; films, musical compositions, and choreography; artistic works such as paintings, drawings, photographs and sculpture; architecture; and advertisements, maps and technical drawings.

Valid for a period lasting 60 year after the creators death.

GEOGRAPHICAL INDICATION

- ✓ Consists the name of the place of origin
- ✓ It originates from a definite geographical territory.
- ✓ It is used to identify agricultural, natural or manufactured goods
- ✓ The manufactured goods should be produced or processed or prepared in that territory.
- ✓ It should have a special quality due to geographical environment or reputation or specific manufacturing skills & traditions

GEOGRAPHICAL INDICATION

- Examples of Indian Geographical Indications.
 - Basmati Rice
 - Darjeeling Tea
 - Kanchipuram Silk Saree
 - Alphanso Mango
 - Nagpur Orange
 - Kolhapuri Chappal
 - Bikaneri Bhujia
 - Agra Petha



GEOGRAPHICAL INDICATION

- Registration is not compulsory
- To claim damages registration is must
- Valid for a period of 10 years
- Can be renewed continuously for further period of 10 years at each subsequent renewals
- If not renewed it is liable to be removed from the register
- Can not be assigned, transmitted, licensed, pledged, mortgaged

Legislations In force

- **The Patents Act 1970 (amended in 2005)**
- **The Designs Act, 2000**
- **The Trademarks Act 1999**
- **The GI Act, 1999**
- **The Copyrights Act, 1957**

RELATIONS BETWEEN IPR

- The logo *Coca-Cola* is an example for TRADEMARK.
- Shape of the bottle – an INDUSTRIAL DESIGN.
- PATENTS may have been obtained in respect of bottling equipment.
- COPYRIGHT - in respect of the text, database or artistic work appearing on its website.



i.e a single product can be protected
by more than one IPR

PATENT

If an automatic exposure control mechanism is invented for first time such invention (i.e. new technology) can be protected by patent law for **20 years**

TRADEMARK

Trademark “Canon” can be protected by Trademark law for **10 yrs** extendable for next 10 yrs for any number of times.



DESIGNS

A Design of camera's appearance can be protected by Design Law. Design right is valid for **10 years** from the date of its registration and it is extendable for another period of 5 years.

TYPES OF PATENT APPLICATION; UNITY OF INVENTION, PROVISIONAL AND COMPLETE SPEC.

THE PATENT OFFICE

*D/O Industrial Policy & Promotion; M/O Commerce &
Industry*

SECTOR 14, DWARKA, NEW DELHI- 110045

TEL. NO. 28034312

EMAIL-nrmeena.ipo@nic.in

KINDS OF APPLICATIONS

- ORDINARY APPLICATION (WITH P.S & WITH C.S)
- CONVENTION APPLICAIION
- DIVISIONAL APPLICATION
 - Patent of addition APPLICATION

PROVISIONAL SPECIFICATION

- SECURES PRIORITY DATE
- MAY BE FILED AS SOON AS PATENTABLE IDEA COMES IN MIND
- DISCLOSES ESSENTIAL FEATURES OF INVENTION
- PATENT IS GRANTED ON COMPLETE SPECIFICATION ONLY
- TIMELIMIT TO FILE C.S.: 12 MONTHS FROM P.S.

COMPLETE SPECIFICATION

- EXAMINED BY THE PATENT OFFICE
- CONTAINS FULL DISCLOSURE OF INVENTION
- CLAIMS – THE MOST IMPORTANT PART
 - DETERMINES THE EXACT BOUNDARIES OF INVENTION
 - RIGHT IS LIMITED TO WHAT IS CLAIMED
 - 1ST CLAIM – THE BASIC CLAIM

CONVERSIONS OF PROVISIONAL SP.

- TWO OR MORE P.S. RELATING TO SAME INVENTION ON REQUEST MAY BE COGNATED AND ONE C.S. MAY BE FILED: 12 MONTH PERIOD IS COUNTED FROM EARLIEST P.S.
- ANY C.S ON REQ.WITHIN 12 MONTHS FROM DATE OF FILING OF CS MAY BE CONVERTED TO P.S.
- THE P.S FILED OR CONVERTED P.S.FROM C.S. MAY BE CANCELLED ON REQUEST ANY TIME BEFORE GRANT OF PATENT - & THEREBY POSTDATING THE APPLICATION

POST DATING OF APPLICATION

- UPTO 6 MONTH BUT SUBJECT TO PROVISIONS OF SEC 9

ELEMENTS OF COMPLETE SPECIFICATION

- **TITLE OF THE INVENTION**
- **FIELD & USE OF THE INVENTION**
- **PRIOR ART**
- **DRAW BACKS OF PRIOR ART**
- **COMPARISON BETWEEN PRIOR ART AND PRESENT INVENTION**
- **SUMMARY OF THE PRESENT INVENTION**
- **STATEMENT OF INVENTION**
- **DETAILED DESCRIPTION OF INVENTION DRAWINGS
&WORKING EXAMPLES**
- * **CLAIMS**

USE OF BIOLOGICAL MATERIAL

- SHOULD BE DEPOSITED IN INT. DEPOSITORY PRIOR TO FILING OF APPLICATION AND REF. THEREOF SHOULD BE IN SPECIFICATION
- SPECIFICATION SHOULD CONTAIN ALL DETAILS SAID MATERIAL
- GEOGRAPHICAL ORIGIN OF THE SAID MATERIAL SHOULD BE DISCLOSED

FORMAT OF CLAIMS

- 1. Claims may be as many in numbers .**
- 2. First claim is called as principal claim and subsequent claims called preferred embodiments.**
- 3. PRINCIPAL CLAIM SHOULD DEFINE ALL ESSENTIAL NOVEL FEATURES OF THE INVENTION.**
- 4. OPTIONAL FEATURE MAY BE CLAIMED IN SUBORDINATE CLAIMS**
- 5. SHOULD BE CLEAR AND CONCISE**
- 6. CLAIMS SHOULD RELATE TO SINGLE INVENTION**
- 7. SHOULD BE FAIRLY BASED ON MATTER DICLOSED IN THE SPECIFICATION**
- 8. Should comply with requirement of section 2i(j), 3,4,5&10.**
- 9. The claim should consist of one sentence . No full stop within the claim.**

COMPLETE SPECIFICATION

1. [Title]

BED SHEET TENSIONER

2. [Technical field]

This invention relates to improvement in device for tensioning of bed sheets of the invention

3. [Background and the 'prior art']

For many people the lack of smoothness in the lower sheet on a bed causes discomfort which can result any problem with in lack of sleep.

There have been many proposals to tension a bed sheet, but these have all required that omen fitting or other be provided on the bed sheet on which to fasten some form of retaining strap For example one previous device proposes buttonholes or similar apertures along the length of the sheet and an elastic strap having a button at each end to fasten underneath the mattress to keep the bed sheet tensioned These proposals have the disadvantage that a standard bed Sheet bought from a shop cannot be used until it has been modified by including button holes (or other fastening arrangements) on the sheet

COMPLETE SPECIFICATION

4. [Summary of the invention, which provides a bed sheet tensioning invention]

These problems are overcome by the present device comprising a resilient strap with releasable fasteners at each end thereof, each of the releasable fasteners being adapted to fasten the strap to the cloth material of a bed sheet by gripping the cloth material without any part of the fasteners being included on the cloth material

5. [List of preferred and optional features] :In one form of the invention, the releasable fasteners comprise a plate having a projection with an enlarged head and an engagement clip thereon, the clip adapted to realizably engage the projection under the enlarged head with the cloth material of the bed sheet trapped there between. 11

In another form of the invention, the releasable fasteners may comprise a pair of jaws resiliency biased towards each other such that the jaws may grip between them the edge of a bed sheet or a portion of material within a bed sheet to tension the bed sheet as required. Such jaws may include serrations to assist with gripping of the bed sheet material.

The resilient strap may be made of rubber or elasticized cloth or any other resilient material such as a spring. Such a spring may be encased in a cloth sleeve to prevent it attaching itself to mattress covers or sheets.

The fasteners may be made of any suitable material, such as metal, or molded plastic. To assist with understanding the invention, reference will now be made to the accompanying drawings, which show one example of the invention.



COMPLETE SPECIFICATION

6. Brief description of the drawing: Summary of the device according to this invention is :

FIG. 1 shows one example of a bed sheet tensioning drawings FIG.2 shows the application of such a bed sheet tensioning device to a corner of a mattress.

7. Detailed description of the preferred embodiments:

Referring to FIG. 1 can be seen that the bed sheet tensioning device according to this invention comprises an elongate resilient strap 1 comprised of an elasticized cloth strap having loops 2 and 3 at each end thereof. The loops 2 and 3 are formed by sewing at 4 and 5 respectively, after an elongate slot 6 and 7 respectively has had the loop passed there through.

The elongate slots 6 and 7 are on end fastener assemblies 8 and 9 respectively. The end fastener assembly 8 comprises essentially a planar base 10 having at one end a slot 6 substantially transverse to the direction of elongation of the planar base 10 and at the other end a substantially mushroom shaped projection 11. The projection 11 comprises a stalk portion 12 and a head 13. A wire clip 14 is pivotally mounted to a projection 15 on the base 10 and includes a loop portion 16 to just fit over the head 13 of the projection 11. When a sheet of cloth is placed between the clip 14 and the planar base 10 the extra thickness of cloth over the projection 11 causes the loop 16 to have an interference fit with the head 13 which enables releasable retention of the cloth of the bed sheet to the fastener assembly.

COMPLETE SPECIFICATION

A similar end fastener assembly is provided at the other end of the resilient strap 1.

FIG.2 shows the bed sheet tensioning device in operation. It can be seen that a mattress 20 has a bed sheet 21 over it, and at one corner the bed sheet tensioning device is fastened at one end to a bed sheet portion 22 at one side underneath a mattress and to a bed sheet portion 23 on the adjacent side around the corner of the mattress.

By the use of four bed sheet tensioning devices of this type, the sheet may be tensioned at four corners of the bed. The sheet as a whole will then be held firmly in position, rumpling of the sheet will be prevented, and the bed will be more comfortable.



COMPLETE SPECIFICATION

8. I/We claim,

1. A bed sheet tensioning device comprising a of claim] resilient strap with releasable fasteners at each end thereof, each of the releasable fasteners being adapted to fasten the strap to the cloth material of a bed sheet by gripping the cloth material without any part of the fasteners being included on the cloth material.
2. The device as claimed in claim1 wherein plate having a projection with an enlarged head and an engagement clip thereon, the clip adapted to engage the projection under the enlarged head with the cloth material of the bed sheet there between such that the fastener is engaged onto the bed sheet.
3. The bed sheet tensioning device of claim 1 wherein the releasable fasteners comprise a pair of jaws resiliency biased towards each other.
4. The bed sheet tensioning device of claim 3 wherein the fastener's jaws include serrations to assist in gripping the bed sheet.
5. The bed sheet tensioning device of any one of claims 1 to 4 wherein the resilient strap is a spring enclosed in a cloth sleeve.
6. The bed sheet tensioning device of any one of claims 1 to 4 wherein the resilient strap is made of rubber.
7. A bed sheet tensioning device substantially as herein described and illustrated in the figures of the accompanying drawings.

Dated this _____5thday of jan 2010

Signature

1 ST PAGE OF C.S.

FORM-2
THE PATENTS ACT, 1970
(39 OF 1970)

COMPLETE SPECIFICATION
SECTION-10

A PROCESS OF PREPARING PLANT BASED
AYURVEDIC FORMULATION
FOR THE TREATMENT OF PARKINSON'S DISEASE
NAME OF THE APPLICANT

THE FOLLOWING SPECIFICATION
**PARTICULARLY DESCRIBE THE
NATURE OF THIS INVENTION AND THE
MANNER IN WHICH IT IS TO BE
PERFORMED:-**

Unity of invention

- The c.s. may disclose more than one invention;
- The claims have to be restricted to only to a group of invention having single inventive concept;
- Single Inventive Concept
- Examples

Concept of Unity

Example

- 1. Product comprising $A + B + C$
- 2. Product comprising $A + C + D$
- 3. Product comprising $A + C + D + E$
- 4. Product comprising $A + B + C + E$
- 5. Product comprising $A + B + C + D + E$

Concept of Unity

Example

All May have unity IF A + C is novel

If A + B are novel and inventive then claim
1 to 5 are in single inventive concept

The Concept of Unity

Allowed combinations

- Product +
- Process specially adapted for the manufacture of product +
- Use of product.

The Concept of Unity

Allowed Combinations

- Process +
- Apparatus or means specifically designed for carrying out the process

The Concept of Unity

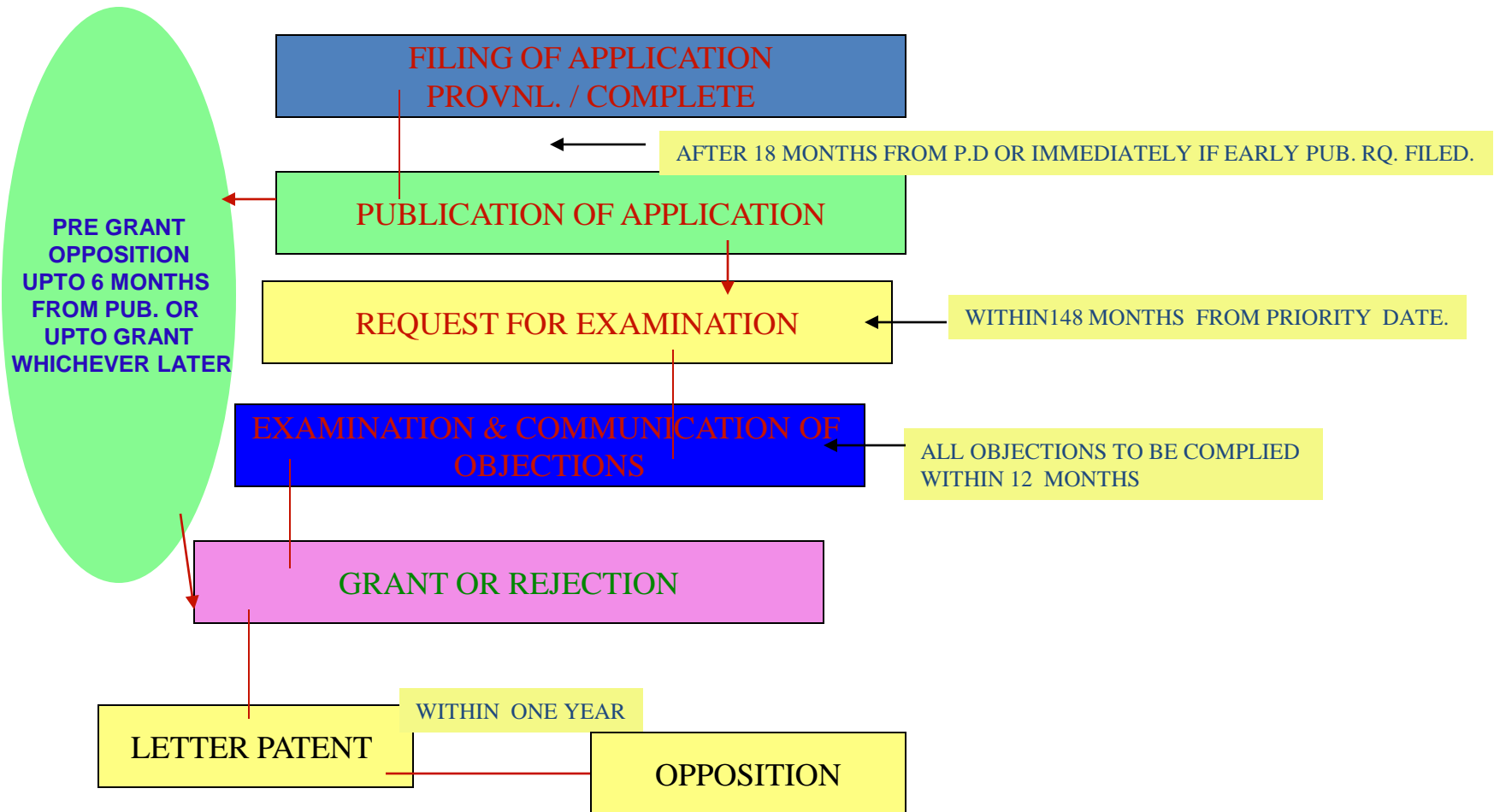
Allowed Combinations

- Product +
- Process specially adapted for manufacture of product +
- Apparatus or means specifically designed for carrying out the process.

What if claims define multiple inventions

- Divide out the application & file divisional application for distinct sets of the invention;
- If fails to do so .
- The controller may ask to divide out the application
- File divisional application before grant of the main application (sec 16)
- Claims cannot go beyond the scope of the parent application

STEPS FROM FILING TO GRANT OF PATENT



ADDRESS OF PATENT OFFICES

- **1. The Patent office, I.P.Building, CP-2, sector 5, Salt Lake City, *Kolkata*-700091 Tel 033-23671945/1946/1987, Fax-03323671988, [email-kolkata-patent@nic.in](mailto:kolkata-patent@nic.in)**
- **2. The Patent office, I.P.Building, GST Road, Guindy, *Chennai*-600032 Tel 04422322824/25; Fax 04422322878 Email Chennai-patent@nic.in**
- **3. The Patent office, I.P.Building, Plot No.32, Sector 14, Dwarka, *New Delhi*, 110075 Tel 011 28081922-25, Fax 01128081920/40 email delhi-patent@nic.in**
- **4. The Patent office, I.P.Building, Near Antop Hill Post Office, S.M.Road, Antop Hill *Mumbai*, 400037; Tel 24137701, 24141026, 24150381, 24148165, 24171457, Fax 24130387**

WHERE TO FILE (jurisdiction)

- If THE APPLICANT/FIRST MENTIONED APPLICANT-RESIDES/HAS DOMICILE/HAS PLACE OF BUSINESS/HAS ORIGIN OF INVENTION/HAS SERVICE ADDRESS(in case of foreign applicant) **IN STATES** JURISDICTION
- **NORTHERN** PATENT OFFICE DELHI
- **SOUTHERN** PAT. OFFICE CHENNAI
- **WESTERN** PAT. OFFICE MUMBAI
- **REST OF INDIA** PAT. OFF. KOLKATTA

THE APPLICANT ?

- THE INVENTOR
- ASSIGNEE OF THE INVENTOR
 - * THE NATURAL PERSON
 - * THE LEGAL ENTITY
- THE LEGAL REPRESENTATIVE OF THE DECEASED APPLICANT
- **FOR PCT INT. APPLICATION:- THE APPLICANT OR ATLEAST ONE APPLICANT SHOULD BE A RESIDENT OR NATIONAL OF INDIA**

Requirement for filing a patent application

- Application form 1 (in duplicate)
- Complete/provisional specification
- Fees Rs. 1000/4000
- Extra claim (beyond 10) & pages (beyond 30) fee: @Rs. 200/800 per claim & Rs. 100/400 per page
- Form 9(if early pub.is to be requested) with fees rs 2500/10000
- Form 18 after publication of the invention with fees rs 2500/10000

PUBLICATION

- UNEXAMINED APPLICATION
- AFTER GRANT

TIME LIMIT FOR PUBLICATION

- **Ordinary application:** PROMPTLY AFTER 18 MONTHS OF FILING
- **Conventional applications :**PROMPTLY AFTER 18 MONTHS FROM PRIORITY
- **Applications for which secrecy directions are issued:**AFTER 18 MONTH OR PROMPTLY AFTER CESSATION OF THE SECRECY DIRECTIONS WHICHEVER IS LATER
- **Divisional application:** 18 months from priority of parent application/immediately after filing divisional application whichever is later
- **National phase PCT application:** immediately after filing
- **Patent of addition :** 18 months from priority of main application or immediately after filing Patent of addition application whichever is later
- **Early Publication**

WHAT IS PUBLISHED ?

- Date of application
- Number of application identified with word "A"
- Name and address of the applicant
- Abstract
- INTERNATIONAL CLASSIFICATION

Effects of publication

- Determines details of the application such as priority, applicants, inventors, abstract of technology described
- Invention becomes prior art
- No other can file similar application for patent
- Interested parties may contact applicant for commercialization

Effects of publication

- Interested parties may file pre grant opposition to the grant of patent
- Infringers will not be innocent Infringers and damages will be recoverable from the date of notification u/s 11 (a)
- Except for the applications filed u/s 5(2) prior to 1.1.2005 where the right shall accrue from date of the grant of the Patent

EFFECTS OF PUBLICATION

- Biological material mentioned in the specification becomes available for inspection to public
- Patent specification and drawings becomes available to the public for inspection

Applications not to be published

- For Provisional applications in respect of which complete specification not filed
- Application has been withdrawn within 15 months from the date of priority/filing whichever is earlier
- Application for withdrawal shall be made in writing to controller.

Inspection of published applications

- After date of publication
- Application ,Complete sp.drawings and abstract may be inspected
- Request in writing
- Fees : individual:Rs. 200 & L.E. Rs. 800
- Photocopy may be obtained
- @ Rs. 4/- each page

withholding publication

- A request in writing to controller for withdrawal of application
- Within 15 months from date of priority/filing whichever is earlier

REQUEST FOR EXAMINATION

- EXAMINATION: NOT AUTOMATIC
- REQUEST TO BE MADE ON F/18
- BY APPLICANT OR THIRD PARTIES
- EXAMINATION REPORT TO APPLICANT ONLY
- FEES: RS 2500/ 10000
- TIMELIMIT:
 - > 48 MONTHS FROM DATE OF PRIORITY
 - > EXPRESS REQUEST FOR EXAMINATION (ONLY FOR PCT N.P.CASES WHICH ARE FILED PRIOR TO 31 MONTHS FROM THE DATE OF PRIORITY)
 - > FORM 18 , FEES 3500/14000

HEARING U/S 14

- Patent office not satisfied with compliance
- Applicant not satisfied with objection
- Ask for hearing from controller
- At least 10 days prior to normal Date
- Controller issue decision
- Appealable in IPAB in Patent Office

On what payable	Form	Individual	Company
•APPLICATION FORM	1	1000	4000
•Prov./Comp spec.	2		
•PAGES EXCEEDING 30	-	100	400
•CLAIMS EXCEEDING 10	-	200	800
*Request for extension of time	4	300 PER MONTH	1200 PER MONTH
SUBSTITUTION OF APPLICANTS	6	500	2000
REQUEST FOR EARLY PUBLICATION	9	2500	10000
AMENDMENTS OF SP. & APP. FORM	13	200/500/1000	800/2000/4000
•Request for Examination	18	2500	10000
•EXPRESS REQUEST FOR EXAMN.	18	3500	14000
*Change of Applicant	6	500	2000
*Notice of Opposition	7	1500	6000
*Certified Copy\Certificate	-	1000	4000
*On a petition	-	1000	4000
*Restoration of lapsed patent	15	1500	6000
RENEWAL FEES		500	2000
3 rd to 6 th Year(per year)		1500	6000
6 th to 10 th Year—do--		3000	12000
11 th to 15 th Year----do---		5000	20000
16 th to 20 th year-----do----			

IMPORTANT TIME LIMITS

ACTIVITY	T.L. (MTH)	EXT. (MONTHS)
PROVISIONAL TO COMPLETE SPECIFICATION	12	NIL
SUBMISSION OF PROOF OF RIGHT TO APPLY	3	TILL ACCEPT WITH PET. U/R 138.
STATEMENT REG. FOREIGN FILING U/S 8 REQUEST FOR EXAMINATION SEC 11(b)	3 48 FROM DATE OF PRIORIT Y	-DO- NIL
COMPLIANCE OF OBJECTIONS AFTER F.E.R.	12	nil
NOTICE OF OPPOSITION AFTER NOTFCN.	1YEAR	
RESTORATION OF LAPSED PATENT	18	NIL
RENEWAL FEES	END OF PRECEDI NG YEAR	6

Important websites for conducting free prior art search

- <http://www.surfip.gov.sg>
- <http://patft.uspto.gov>
- <http://pk2id.delhi.nic.in>
- <http://www.ipdl.wipo.int>
- <http://www.indianpatents.org.in>
- <http://ep.espacenet.com>
- <http://www.ipindia.nic.in>
- <http://www.european-patent-office.org>

Requirement for filing a patent application

- Application form 1 (in duplicate)
- Complete/provisional specification
- Fees Rs. 1000/4000
- Extra claim (beyond 10) & pages (beyond 30) fee: @Rs. 200/800 per claim & Rs. 100/400 per page
- Form 9(if early pub.is to be requested) with fees rs 2500/10000
- Form 18 after publication of the invention with fees rs 2500/10000

SUBSCRIPTION FOR JOURNAL

- Rs. 400 per vol
- Also available in CD form
- Rs. 250/- per CD
- Published every Friday
- Rs.. 20000/- per annum printed form
- Rs.. 12000/- in CD form
- Available free of cost at website www.ipindia.nic.in

FOREIGN FILING

- DIRECT FOREIGN FILING NOT ALLOWED
- EITHER FILE APPLICATION FIRST IN INDIA, and file abroad after 6 weeks OR
- SEEK PERMISSION FROM CONTROLLER OF PATENTS

DEFENCE RELATED INVENTION

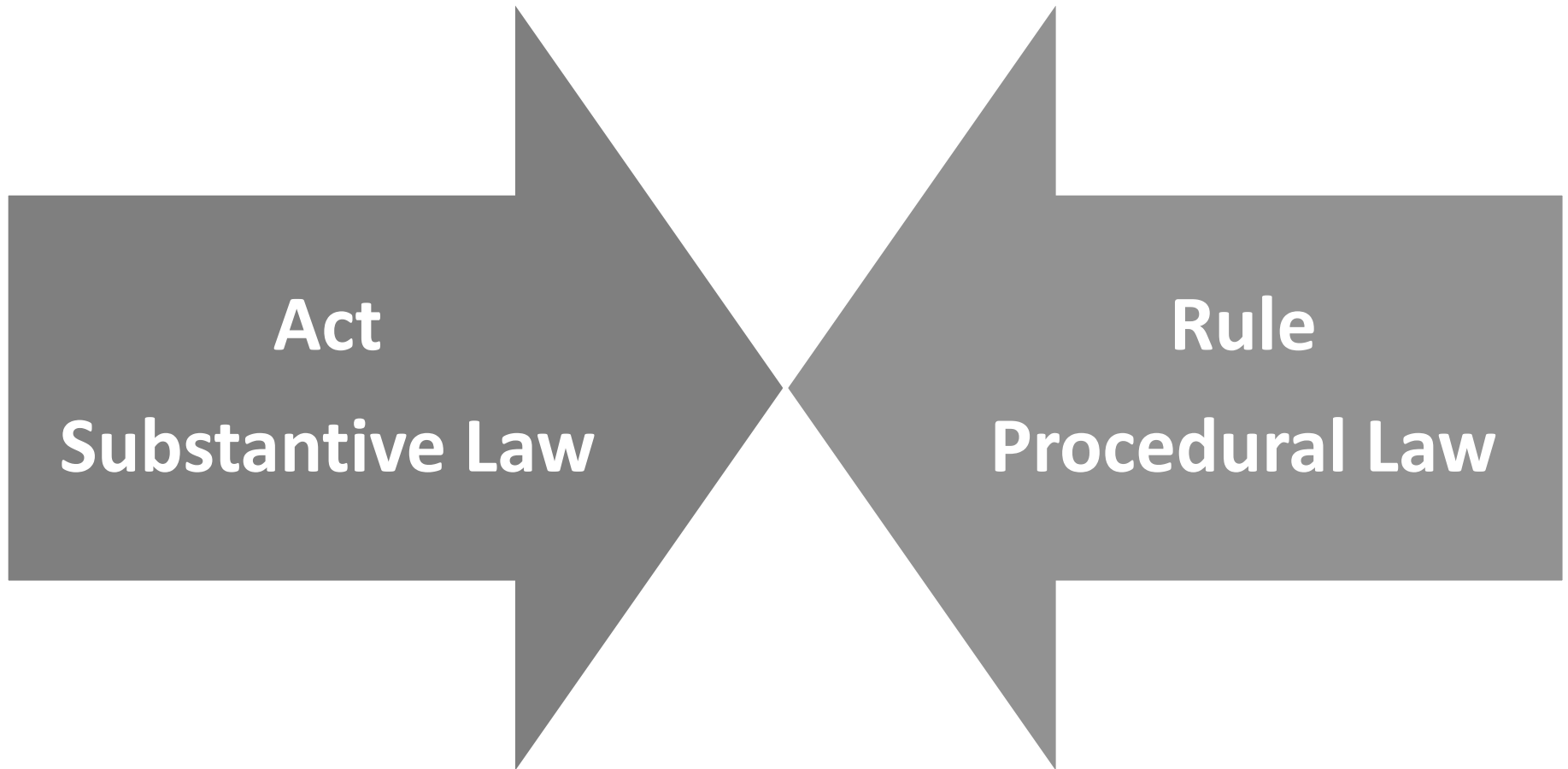
- SECRECY DIRECTIONS ARE ISSUED
- REVIEWED 6 MONTHLY
- NO PUBLICATION TILL CESSATION OF SEC. DIRECTION
- NO PUB.=NO PATENT

The Drugs and Magic Remedies
(Objectionable Advertisements) Act
1954 & Rules, 1955.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is an Act No. 21 of 1954.

The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

Act & Rule



**The Drugs and Magic Remedies
(Objectionable Advertisements)
Act, 1954 is an Act No. 21 of
1954.**

Structure of the act

Section

Contents

1

Short title, extent &
Commencement

2

Definitions

3,4,5,6

Prohibitions

7

Penalty

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Power of entry, search etc

9

Offences by companies

9 A

Offences to be cognizable

10

Jurisdiction to try offences¹⁶⁵

Structure of the act

Section

Contents

11	Officers to be deemed to be public servants
12	Indemnity
13	Other laws not affected
14	Savings
15	Power to exempt from application of act
16	Power to make rules

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is an Act No. 21 of 1954 (Section 1)

It extends to the whole of India, except the state of Jammu & Kashmir.

It was came into force by Gazette notification on 1st April, 1955.

Definitions

'drug' includes –

- (i) A medicine for the internal or external use of human beings or animals;

- (i i) Any substance intended to be used for or in the diagnostic, cure, mitigation , treatment or prevention of disease in human beings or animals;

Definitions

'drug' includes –

- (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), (i) and (iii);

Definitions- D & C act

“drug” includes—

- (i) 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;**
- (ii) such substances (other than food) intended to affect the structure or any function of human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]**

Definitions- D & C act

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board

Definitions

'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;

Definitions

‘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;

Definitions

‘Taking any part in the publication of any advertisement’ includes -

(i) the printing of the advertisement;

(ii) the publication of any advertisement outside the territories to which this Act extends by or at the instance of a person residing within the said territories;

PROHIBITIONS -Section 3

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for –

- (a) 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

PROHIBITIONS -Section 3

(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 rules made under this Act.

Provided that no such rules shall be made except –

(i) in respect of any disease, disorder or condition which requires timely treatment in consultation with a registered medical practitioner or for which there are normally no accepted remedies, and

(ii) after consultation with the Drug Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and, if the Central Government considers necessary, with such order persons having special knowledge or practical experience in respect of Ayurvedic or Unani systems of medicines as that Government deems fit.

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 character of the drug; or
- (b) make a **false claim** for the drug; or
- (c) is otherwise **false or misleading in any material particular**.

How to Grow Hair Fast

How to Grow Hair Fast

Increase The Length of Your Hair, Up to 5X Faster!

DISCOVER THE TIME-PROVEN EFFECTIVE SYSTEM!

"Achieve your desired hair length without waiting for months"

Just what you need to stop menstruation

A "new" Brazilian pill to stop menstruation?

Just what you need to stop menstruation

STOP Vitiligo

Herbal Medical

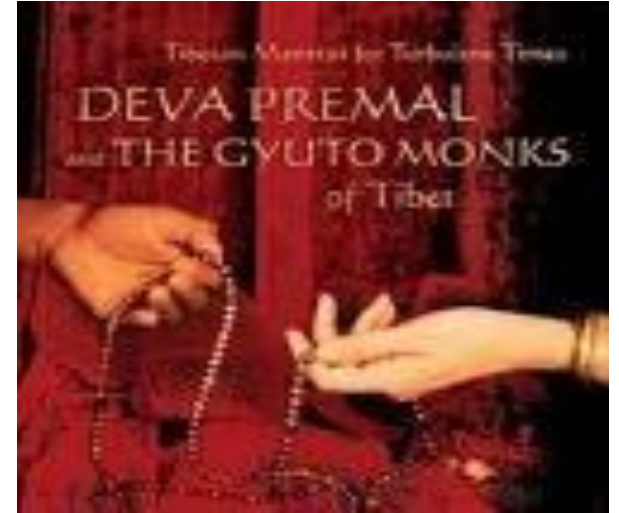
Stop Vitiligo Oil

\$55

Natural Treatments for Psoriasis and Psoriatic Arthritis

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 purpose specified in Section 3.



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 Section 3, or Section 4, or Section 5, and any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under Section 19 of the Sea Customs Act, 1878 (8 of 1878) and all the provisions of that Act shall have effect accordingly.

Penalty

Whoever contravenes any of the provisions of this Act [or 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**.

Powers of entry, search etc

- (1) Subject to the provisions of any rules made in this behalf, **any Gazetted officer authorised by the state Government** may, within the local limits of the area for which he is so authorised –
- a) **enter and search at all reasonable times**, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this act has been or is being committed;
 - b) **seize any advertisement** which he has reason to believe contravenes any of provisions of this act;

Powers of entry, search etc

- c) **Examine any record, register, document** or any other material object found in any place mentioned in clause (a) and **seize** the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this act.
- (2) Provisions of the code of criminal procedure, 1898 shall may apply to any search under this act.
- (3) Where any person seizes anything under clause (b) or clause (c) of sub section (1), he shall, as soon as may be inform a Magistrate and take his orders as to the custody thereof.

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:
- (2) Notwithstanding anything contained in sub-section (1) where an offence under this act has been committed by a company and it is proved 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 be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Jurisdiction to try offences

No court inferior to that of a Presidency Magistrate or a Magistrate of first class shall try any offence punishable under this Act.

Forfeiture

Where a person has been convicted by any court for contravening any provision of this Act or any rule made there under, the court may direct that any document (including all copies thereof), article or thing, in respect of which the contravention is made, including the contents thereof where such contents are seized under clause (b) of sub-section (1) of section 8, shall be forfeited to the Government.

Officers to be deemed to be public servants

Every person authorized under section 8, shall be deemed to be a public servant within the meaning of section 21 of Indian Penal Code (Act 45 of 1860).

Indemnity

No suit, persecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.

Other laws not affected

The provisions of this Act in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Savings – Nothing in this Act shall apply to :

- (a) any signboard 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
- (b) any treatise or book dealing with any of the matters specified in Section 3 from a bonafide scientific or social standpoint; or
- (c) any advertisement relating to any drug sent confidentially in the manner prescribed under Section 16 only to a registered medical practitioner; or

Savings – Nothing in this Act shall apply to :

- (d) any advertisement relating to a drug printed or published by the Government; or
- (e) 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);

Power to exempt from application of Act

If in the opinion of the Central Government public interest requires that the advertisement of any specified drug or class of drugs ¹[or any specified class of advertisements relating to drugs] should be permitted; it may, by notification in the Official Gazette, direct that the provisions of sections 3, 4, 5 and 6 or any one of such provisions shall not apply or shall apply subject to such conditions as may be specified in the notification to or in relation to the advertisement of any such drug or class of drugs ¹[or any specified class of advertisement relating to drugs].

Power to make rules

- (1) The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.
- (2) In particular and without prejudice to the generality of the foregoing power, such rules may-
 - (a) specify any [disease, disorder or condition] to which the provisions of section 3 shall apply;
 - (b) prescribe the manner in which advertisements of articles or things referred to in clause (c) of section 14 may be sent confidentially.

Power to make rules

(3) Every rule made under this Act shall be laid as soon as may be after it is made, before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions and if before the expiry of session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

Notification No.S.R.O.512,dt.26-02-1955

Structure of the rule

Rule	Content
1	Short title & Commencement
2	Definitions
3	Scrutiny of misleading misleading advertisements relating to drugs
4	Procedure to be followed in prohibiting import into & export from, India of certain advertisements
5	Manner in which advertisements may be sent confidentially
6	Prohibition of advertisement of drugs for treatment of disease, etc
	The Schedule
	Notifications

Scrutiny of misleading advertisements relating to drugs

Any person authorised by the state Government in this behalf may, if satisfied, that an advertisement relating to a drug contravenes the provisions of section 1 by order, require the manufacturer, packer, distributor or seller of the drug to furnish within such time as may be allowed in this behalf by the person so authorised information regarding the composition of the drug or the ingredients thereof or any other information in regard to that drug as he deems necessary for holding the scrutiny of the advertisement, and where any such the drug to which the advertisement relates to comply with the order.

Scrutiny of misleading advertisements relating to drugs

Provided that no publisher or advertising agency of any medium for the dissemination of an advertisement relating to a drug shall be deemed to have made any such contravention merely by reason of the dissemination by him or it of any such advertisement, unless such publisher or advertising agency has failed to comply with any direction made by the authorised person in this behalf calling upon him or it to furnish the name and address of the manufacturer, packer, distributor, seller or advertising agency, as the case may be, who or which caused such advertisement to be disseminated.

Procedure to be followed in prohibiting import into & export from, India of certain advertisements

(1) If the customs collector has reasons to believe that any consignment contains documents of the nature referred to in section 6, he may, and if requested by an officer appointed for the purposes by the Central Government, shall detain the consignment and dispose it of in accordance with the provisions of the Sea Customs Act 1878 and shall also inform the importer or exporter of the order so passed.

Manner in which advertisements may be sent confidentially

All documents containing advertisements relating to drugs referred to in clause (c) of sub –section (1) of section 14, shall be sent by post to a registered medical practitioner by name, or to a wholesale or retail chemist, the address of such registered medical practitioner or wholesaler or retail chemist being given. Such document shall be at the top, printed in indelible ink in a conspicuous manner, the words “For the use only of registered medical practitioners or a hospital or a laboratory.

Prohibition of advertisement of drugs for treatment of disease, etc

No person shall also take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule annexed to these rule.

The Schedule

1. Asthma
2. AIDS

Notifications:

- 1. Permitted class of advertisements relating to drugs
(Notification: G.S.R.843)**
- 2. Permitted advertisements of Chemical contraceptives
(Notification No.G.S.R. 46 (E), dated 30-04-1992)**

Medical Termination of Pregnancy (MTP) Act

**Legal Update
is it in conflict with
PCPNDT?**

Action Research and Training for Health (ARTH)

MTP Act: addressing a public health priority

MTP Act - an enabling act which

- 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
- De-criminalizes the abortion seeker
- 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?

- Up to 20 weeks gestation
- With the consent of the women. If the woman 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: Indications

- 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: Indications

- *“In determining whether the continuance of pregnancy would involve such risk of injury to the health (as mentioned above), account may be taken of the pregnant woman’s actual or reasonable foreseeable environment”*

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 Mifepristone (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

Implications of amendments

- Simplifies registration of sites which can be done at district level now
- Providers can get their sites approved for providing abortions under the MTP Act for 1st trimester only or up to 20 weeks and thereby come under the protective cover of the MTP Act

Implications of amendments

- Approved providers can provide medical abortions from their clinic, as long as they have access to an approved site
- Offers potential to increase number of approved sites, which would enable women to access safe abortion services
- Effective implementation will help to bring all abortions within legal frame work

MTP rules: what are they for?

- Enable proper implementation of the provisions of the Act
- Ensure that MTP services are provided by qualified persons in safe and hygienic settings
- Help to monitor quality of services

MTP rules: what do they cover?

- Experience & training required for providers
- Approval of a place for terminating pregnancy under the Act
- Composition & tenure of District Level Committee
- Inspection, cancellation or suspension of approval; review
- Consent form

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

MTP rules: training requirement - 2

For termination up to 20 weeks

- A practitioner who holds a post-graduate degree or diploma in Obstetrics and Gynecology
- A practitioner who has completed six months house job in Obstetrics and Gynecology
- A practitioner who has at least one-year experience in practice of Obstetrics and Gynecology at a hospital which has all facilities
- A practitioner registered in state medical register immediately before commencement of the Act, experience in practice of Obstetrics and Gynecology for a period not less than three years.

Approval of a place by trimester

For sites up to 12 weeks (1st trimester)

- Gynecology examination/ labor table
- Resuscitation and sterilization equipment
- Drugs & parental fluids
- Backup 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

Application form for Approval (Form A)

प्ररूप क

[नियम 5 का उपनियम (2) देखिए]

गर्भ का चिकित्सीय समापन (संशोधन) अधिनियम, 2002 (2002 का 64). के धारा 4 के खंड (ख) के अधीन स्थान के अनुमोदन के लिये आवेदन का प्रारूप :-

अनुमोदित जगह का प्रवर्ग

(अ) 12 सप्ताह तक के गर्भ का समापन किया जा सकता है ।

(आ) 20 सप्ताह तक के गर्भ का समापन किया जा सकता है ।

1. स्थान का नाम (स्पष्ट अक्षरों में)

2. पूरा पता

3. गैर-सरकारी/प्राइवेट/नर्सिंग होम/अन्य संस्थाएं :

4. कृपया बताइए कि क्या इस स्थान पर निम्नलिखित सुविधाएं उपलब्ध हैं —

प्रवर्ग अ

- (i) स्त्री रोग विज्ञान परीक्षण/प्रसव पीड़ा पटल ।
- (ii) पुनरुज्जीवन उपस्कर ।
- (iii) निर्जमीकरण उपस्कर ।
- (iv) प्रघात के उपचार के लिए सुविधाएं जिसके अंतर्गत आपात औषधियां भी हैं ।
- (v) परिवहन के लिए सुविधाएं यदि अपेक्षित हो ।

प्रवर्ग आ

- (ii) शल्य क्रिया वाली पटल और उदरीय या स्त्री रोग विषयक शल्य — चिकित्सा करने के लिए उपकरण
- (iii) आपातिक दशाओं के लिए पर्याप्त मात्रा में औषधियां और जनकीय तरल
- (iv) निश्चेतक उपस्कर, पुनरुज्जीवन उपस्कर और निर्जमीकरण उपस्कर

स्थान :

तारीख :

स्थान के स्वामी के हस्ताक्षर

Certificate for Approval (Form B)

प्ररूप ख

[नियम 5 का उपनियम (6) देखिए]

अनुमोदन का प्रमाण - पत्र

नीचे वर्णित स्थान को गर्भ का चिकित्सीय समापन अधिनियम, 1971 (1971 का 34) के प्रयोजनार्थ अनुमोदित किया जाता है :

.....सप्ताहों के भीतर पड़े गए रूप में

स्थान का नाम

पता तथा अन्य वर्णन

स्वामी का नाम

स्थान :

तारीख :

सेवा में.....सरकार

Approval Process

- Place to be inspected within 2 months of receiving application
- Certificate to be issued within 2 months of inspection
- If deficiency found, within 2 months of deficiency having been rectified

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

MTP regulations

- Power to states to make regulations regarding MTP services
- Regulations for Union Territories by Central Govt.
- Application of central govt. regulations in the absence of state regulations.

MTP regulations: What do they cover?

- Forms to be required for making opinion, admission register and reporting of MTPs
- Custody of forms
- Prevention of disclosure of information

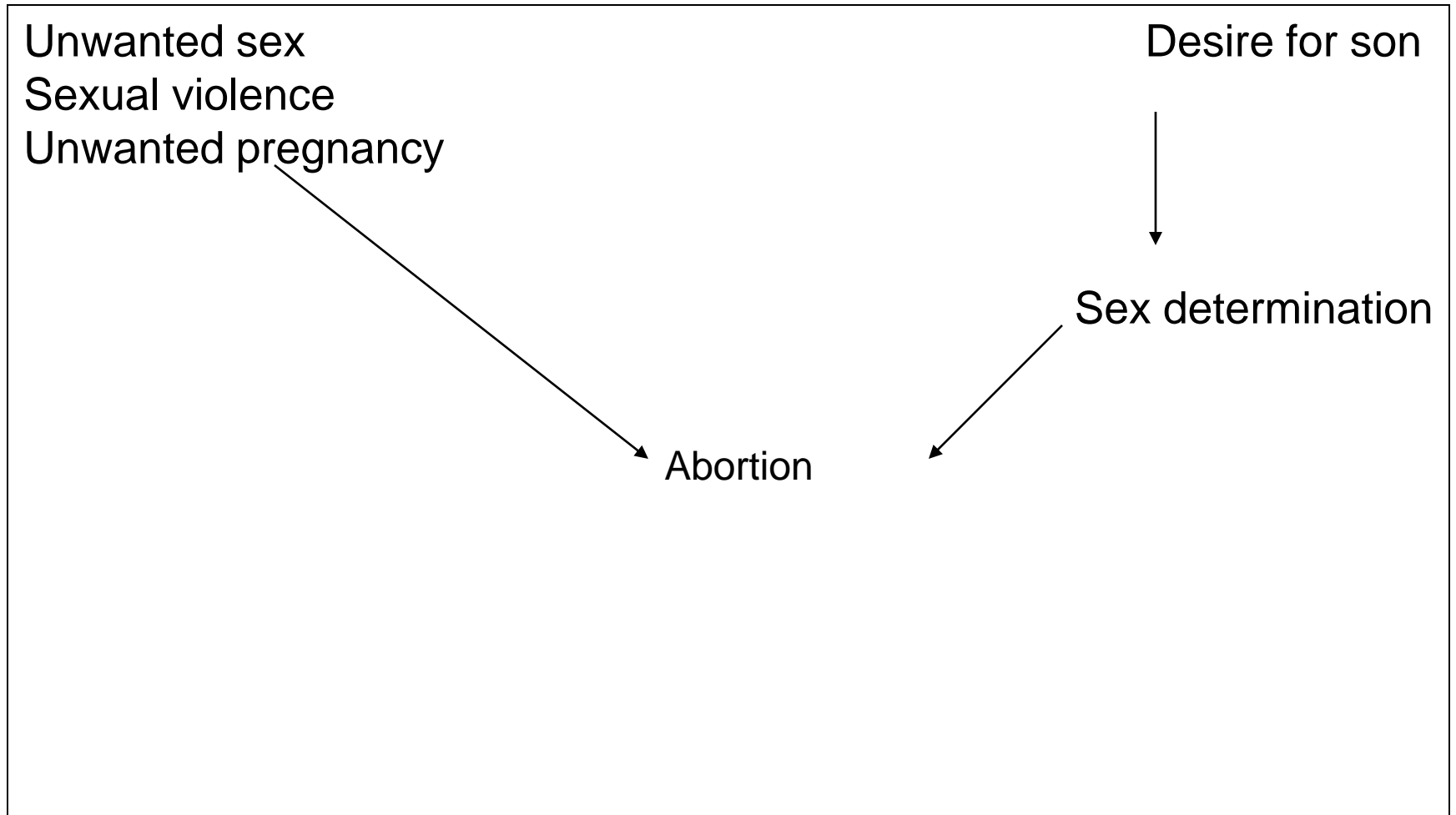
MTP regulations: opinion forms

- For an MTP, opinion of an approved RMP (2 RMPs for 2nd trimester) is required.
- The provider(s) is required to certify his/her opinion in Form I within three hours of terminating a pregnancy.

Declining sex ratios...

- Census 2001 confirmed apprehensions of declining juvenile sex ratios.
- Parallel with steep increase in availability of ultrasound machines and use during pregnancy
- Sex determination testing followed by second trimester abortion- major pathway for sex selection
- Public interest litigation triggered amendments in Act of 1994
- Focus on “female feticide” as having attained endemic proportions

Safe Abortion and Sex Selection Pathways



The thin edge.....

- The recent incidents in Rajasthan have shown that the distinction between two public policy issues – sex selection (“female feticide”) and safe abortion – have become extremely blurred
- Choices along the thin edge separating the two are:
 - Restricting access to abortion to prevent sex selection
 - Dealing with the two issues separately
 - Developing a integrated strategy to address both sex selection and unsafe abortion together

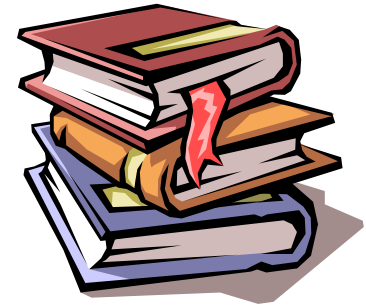
“We speak for those who cannot
speak for themselves”

George Thorndike Angell, 1869



Why Are There Laws About Animals?

Paradigm Shift
Social responsibility
Harmony



What Are The Animal Laws?

Cruelty – Wildlife – Control



- The Constitution of India
- The Indian Penal Code, 1860
- The Criminal Procedure Code, 1973
- **The Prevention of Cruelty to Animals Act, 1960**
- The Wildlife Protection Act, 1972
- The Police Acts
- The Municipal Corporation Acts.

The Constitution of India

- The DPSP – Part IV – Art. 48 & 48A
- The Fundamental duties – Part IVA – Art. 51A (g)
 - “It shall be the duty of every citizen of India ... to protect and improve the natural environment including forests, lakes, rivers and wildlife, and to have compassion for living creatures.”
- Fundamental to governance – so – highest priority



The Indian Penal Code, 1860

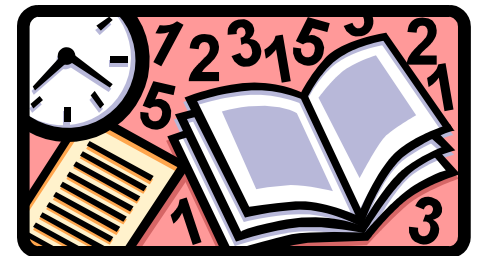
On Animals



- S. 47 – Definition of “animal”
- S.289- Negligent conduct with respect to an animal
- S.428- Mischief by killing or maiming animal of the value of ten rupees.
- S. 429 – Mischief by killing or maiming cattle etc of any value or any animal of the value of fifty rupees-up to five years.

Other Animal Laws

- The prevention of cruelty to Animals Act, 1960 – pertains to captive animals and domestic animals – S. 11 definition of cruelty
- The Wildlife Protection Act, 1972 – pertains to wild animals – both flora and fauna – aimed at conservation of animal and habitat.



Police Acts

- Empowers Police Officers with respect to offences under the PCA Act, 1960 or WPA, 1972
- Empowers Police Officers with respect to offences otherwise e.g. nuisance
- State Laws – enacted and enforced by various States



Municipal Corporation Acts

- Deal with:-
 - Prohibition of nuisances, dead animals
 - Establishment & maintenance of veterinary hospitals, cattle pounds, farms, diaries, municipal markets and slaughter houses;
 - licenses to private markets and slaughter houses, theatre circus etc.
 - State Acts – enforced by State agencies.



Salient Features of the Prevention of Cruelty to Animals Act, 1960

- Central Act- in force throughout the territory of India.
- Rules under the Act- in force throughout India unless specified otherwise.
- Applies only to “captive” and “domestic” animals.
- S.11 enumerates the various forms of cruelty on animals which are prohibited



Salient Features of the Prevention of Cruelty to Animals Act, 1960

- **Chapter IV- experimentation on animals- CPCSEA-to regulate experimentation- general objectives laid down- non-cognizable offences**
- **Chapter V – performing animals- registration mandatory- procedure laid down in S.23- S.26 offence and punishment- non-cognizable offence**



Salient Features of the Wildlife Protection Act, 1972



- Applicable all over India except Jammu and Kashmir which has its own Act.
- Hunting of any scheduled animal prohibited-
Exceptions- mice, rats, common crow and fruit bats.
- Hunting- also includes capturing and trapping a wild animal

Salient Features of the Wildlife Protection Act, 1972



- Schedules I,II,III & IV list different protected species, the killing or trade of which prohibited.
- Schedule V lists vermin which may be killed
- Schedule VI lists protected plants
- A Schedule I offence can earn a repeat offender 6 years in prison and a fine of Rs.25,000.
- Rules of a protected area

Why Should Wildlife Crime be Prevented?



- Species face extinction because of demands from the wildlife trade wild plants-provide genetic variation for crops-natural source for many medicines-threatened by the trade.
- Wildlife commodity should not be over exploited.
- Illegal wildlife trade-part of the crime syndicate-must be prevented. *

* Wildlife Crime- An Enforcement Guide By Vivek Menon & Ashok Kumar, 1998.

Wildlife crime



- Live animals only form a small part of the trade.
- The trade occurs at all levels
- Only second to narcotics -Second largest illegal occupation in the world.



How Large Is Wildlife Crime?



- Numbers in Global Trade

- Monkeys- 25-30,000*
- Live birds- 2-5 million*
- Reptile skin- 10 million*
- Orchids-10 million*

- Record Global Prices

- Trained Falcon- up to US \$ 10,000*
- Rare parrot- up to US \$ 40,000*
- Rare butterfly- up to US \$ 30,000*
- Rare orchid- up to US \$ 2,000.*

* Wildlife Crime- An Enforcement Guide By Vivek Menon & Ashok Kumar, 199

CITES



- Convention on International Trade in Endangered Species of Wild Flora and Fauna.
- Regulates international trade in endangered species & export-import of endangered species between member Countries- species
- Authority- Directorate of CITES & officers of the WPA

Animal Law- How & Why

- Performing Animals
- Draught and Pack Animals
- Transporting animals
- Slaughter- issues
- Pet animals and strays
- Wild animals and the WPA
- Fishing
- Zoos
- Experimentation on animals



Performing Animals



- The law under the PCA, 1960
- Chapter V- prohibits exhibiting or training any performing animal unless registered s.23-- “prescribed authority” - see Rules
- S.26- Penalties
- Downside- “exhibit” - narrow definition- “sale of tickets” clause-needs amendment

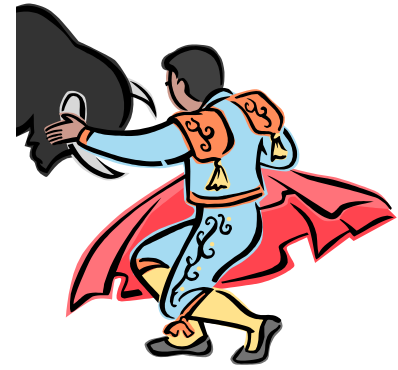


Performing Animals



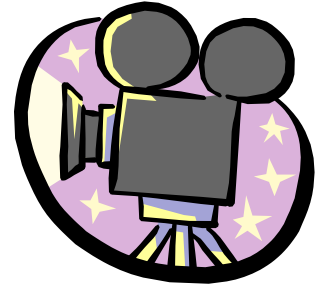
- The law under the WPA, 1972
- All wild animals under Act- Govt. property
- permission in writing of the CWW to keep such property-No guidelines to CWW to issue License-proof that animal was bred in captivity to be given by the licensee-loop-hole
- Permission from the local Corporation to carry on business.Issues-snakes, bears etc.

Performing Animals Instances



- Animal racing- S.11(1)(a), PCA, 1960
- Bull-fighting (Goa)- S.11(1)(n), PCA, 1960
- Cockfights- S.11(1)(m)(ii) & (n) PCA, 1960
- Partridge fights- S.11(m)(ii)(n), PCA, 1960 – also a grave offence under the WPA, 1972- Scheduled bird.

Animals in Films



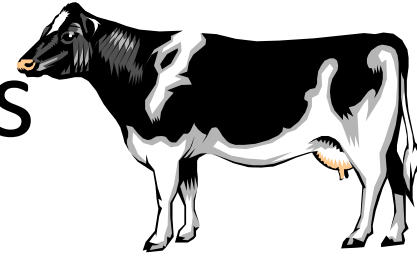
- Could violate S.11(c), (e), and (m), S.23 & Rules thereunder of the PCA.
- Violates Cinematograph Act, 1952
- During shooting & After release-how should you act?
- Compel submission of certificate granting permission to exhibit performing animal.

Animals in the Circus



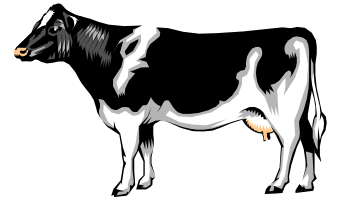
- Banned in many Countries
- Registration under PCA mandatory
- Gather evidence.
- Write to the MOEF, AWBA, SPCA, CWW & WW, MC or the ICF.
- Violative of S.11 & S.23, PCA, 1960

Draught & Pack Animals



- PCA, 1960- S.11(1)(a) & (b)
- S.38- “Prevention of Cruelty of Draught and Pack Animals Rules, 1965” - prescribe maximum load etc.
- Take action- Gather evidence- report to police- prosecution under PCA.

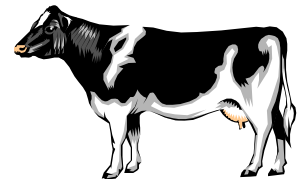
Transporting Animals



- PCA Act, 1960- S.11(a), (d), (e) & (h)-
Transport of Animal Rules, 1978-ISI
Code for Transport of Cattle by Rail
and Road, 1968
- Checklist-Gather evidence.
- Number- subject matter of local law.
- Take action

Transporting Animals- Instances

- Carrying chicken upside down- S.11(a), (d), (e) and (f) of the PCA- ISI Code for Transport of Poultry.
- Carrying Partridge upside down- PCA, WPA, Police Acts & Municipal Corporation Acts- Multiple crime



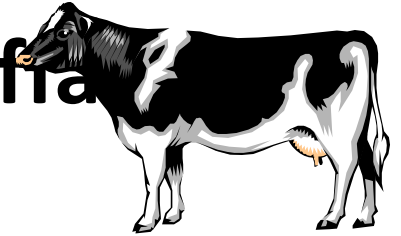
Transporting Animals- Instances

- **Inter-state transportation of cows, calves, calf of the buffalo, bulls and bullocks for slaughter-**
- All States except Kerala and W. Bengal prohibit export and slaughter – inter-state transportation prohibited- permit for export under State Cattle Preservation Acts- mandatory-also declaration that cattle concerned is not for slaughter to be made-punishable for a term up to three years.

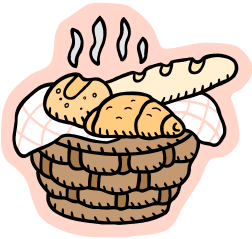


Transportation-Issues

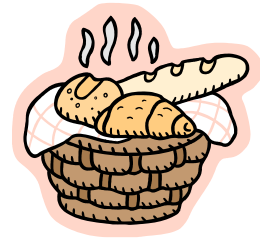
- **Inter-state transportation of Buffalo for slaughter-**



- Transportation permissible by all States unless Notification to the contrary.
- conditions laid down in ISI Code for the Transport of Cattle by Rail and Road.- Slaughter illegal unless certified by concerned authority.



Slaughter



- Prohibited in any Corporation or Municipal area without license
- Environmental pollution-Duty of Corporation to provide space
- Goat and bird sacrifice- prohibited some States through local Acts- priest and sacrificer can be arrested

Poultry Farms

- Hen, Chicken, Turkey and Ducks can be slaughtered- Poultry farms- follow norms under PCA, 1960- S.11(e), (h) & (l)- ISI Code of Practice for poultry housing
- Action-lodge FIR and accompany police-entry & search provisions



Pet Animals & Strays

General Issues



- PCA, 1960- S.11- gather evidence
- Killing of animal
 - willfully-S.428 IPC- punishment, 2 years- lodge FIR with police
 - accidentally- lodge FIR -fact of accident mitigating factor.

Pet Animals & Strays

General Issues



- Random execution of stray animals by the MC- S.11(1)(l)- justification
- MC Rules and Bye-laws- stipulate measures to register and control dogs- done by the MC workers.
- See whether notification of CG on method by which stray dogs may be destroyed

Wild Animals & The Wildlife Protection Act, 1972

- WPA, 1972- applicable to everyone, including tribes
- Wild animal or bird being sold in local market- hunting- legal presumption-lodge FIR-involve senior official- accompany police- option -use S.43



Wild Animals & The Wildlife Protection Act, 1972

- Scheduled animal or bird under WPA or CITES may not be taken out of the Country without permission by authority-
- Other animals- Live Animal Regulations and Container Requirements of the International Air Transport Association, Customs Act, 1962, PCA, 1960, Foreign Trade (Development and Regulation) Act, 1992 etc.



Wild Animals & The Wildlife Protection Act, 1972

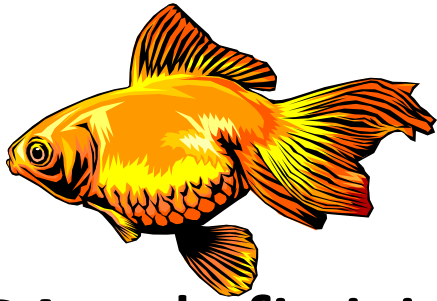
- Cutting of tree having nests- offence of hunting.
- Cannot Manufacture, deal or carry on business in animal articles, trophies etc- cannot display in any commercial premises- could entail up to 7 years imprisonment- contact authority under WPA & lodge an FIR.



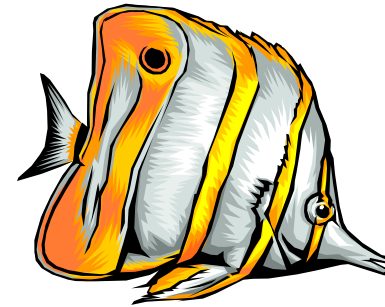
Wild Animals & The Wildlife Protection Act, 1972



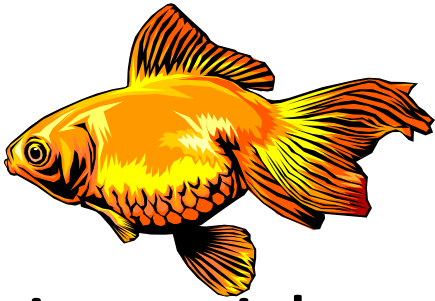
- Collection of specimens- hunting may be allowed under S.12 of the WPA by the CWW - only recognized Zoos and Museums- Transfer or commercial sale of such specimens prohibited-
- Specimens not under Schedule-can be netted but can attract PCA, 1960-Netting in Forest-Indian Forest Act-forest produce.



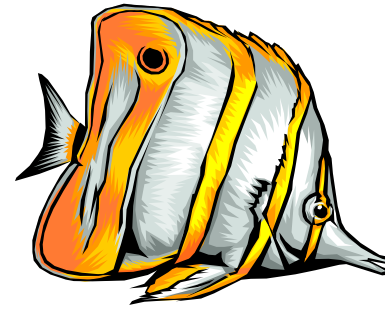
Fishing



- WPA –definition of animal should include fish & separate Schedule should list protected sea animals.
- Indian Fisheries Act, 1897 –archaic law- diverse notification varies from State to State-
- Enforcers lack adequate knowledge and skill to identify type of marine animal.



Fishing



- Fishing without valid permit/license illegal unless provisions of local State fishing laws state otherwise.
- Fishing by use of dynamite illegal- S.11(1)(I)) of the PCA, 1960.
- Fish sold by an aquarium- varies from State to State- codification of the fish an aquarium can sell also varies.

Zoos



- Prior to 1991 -Zoos not governed by specific legislation- 1991 amendment- all Zoos brought under its purview.
- CG framed and notified the Central Zoo Authority and Recognition of Zoo Rules- to be registered under the Act- to comply with the Recognition of Zoo Rules

Zoos- What Can You Do?

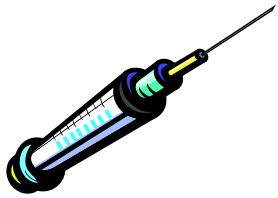


- Government zoos- collect evidence- file Writ Petition- Court can order closure of Zoo-relocation of animals
- Teasing animal in Zoo- S.38-J of the WPA- punishable with imprisonment- three years or with fine which may extend to Rs.25,000/-use citizen's arrest-complain to Zoo Director -officer under WPA.

Traveling Zoos

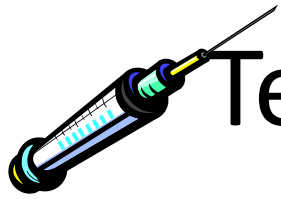


- Traveling Zoos- law acknowledges existence of mobile/traveling Zoos- subject to recognition by the Zoo authority-stringent conditions for upkeep of animals
- No mobile zoo has thus far been recognized- report to nearest PS or WA.
- Are Madaris “travelling Zoos” ?



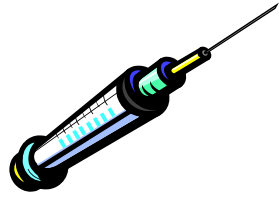
Animal Experimentation

- Chapter IV- Section 15-experimentation on animals- confers power on the CG to appoint CPCSEA- set up to regulate experimentation - general objectives laid down.
- CPCSEA not advisory committee but a statutory committee- Hence Rules framed by this Committee are binding- breach- offence under the PCA, 1960.



Testing Cosmetics On Animals

- Amendment in Aug, 1996-CPCSEA recommended that the testing of cosmetics on animals be made optional
- If not tested- statement to that effect on the product label



Dissection

- S.17 calls for avoiding experiments where ever possible
- CPCSEA- statutory body- right to prohibit & regulate dissection.
- Identify offence & gather evidence
- Explore alternatives- Eg: educational aids
- Write to policy makers.

FACTORY ACT, 1948

OBJECTIVE OF THE ACT

The Act has been enacted primarily with the object of protecting workers employed in factories against industrial and occupational hazards.

For that purpose, it seeks to impose upon the owner or the occupier certain obligations to protect the workers and to secure for them employment in conditions conducive to their health and safety.

APPLICABILITY OF THE ACT

At any place wherein manufacturing process is carried on with or without the aid of power or is so ordinarily carried on, not with standing that:

- The number of persons employed therein is less than ten, if working with the aid of power and less than twenty if working without the aid of power, or
- The persons working therein are not employed by the owner thereof but are working with the permission of, or under agreement with, such owner.

Main points

- Health
- Safety
- Welfare
- Working Hours Of Adults
- Annual Leave With wages

HEALTH

- 11 - [Cleanliness](#)
- 12 - [Disposal of wastes and effluents](#)
- 13 - [Ventilation and temperature](#)
- 14 - [Dust and fume](#)
- 15 - [Artificial humidification](#)
- 16 - [Overcrowding](#)
- 17 - [Lighting](#)
- 18 - [Drinking water](#)
- 19 - [Latrines and urinals](#)
- 20 - [Spittoons](#)

SAFETY

- 21 - Fencing of machinery
- 22 - Work on or near machinery in motion
- 23 - Employment of young persons on dangerous machines.
- 24 - Striking gear and devices for cutting off power
- 25 - Self-acting machines
- 26 - Casing of new machinery
- 27 - Prohibition of employment of women and children near cotton-openers
- 28 - Hoists and lifts
- 29 - Lifting machines, chains, ropes and lifting tackles
- 30 - Revolving machinery
- 31 - Pressure plant

SAFETY

Cont...

- 32 - Floors, stairs and means of access
- 33 - Pits, sumps openings in floors, etc
- 34 - Excessive weights
- 35 - Protection of eyes.
- 36 - Precautions against dangerous fumes, gases
- 36A - Precautions regarding the use of portable electric light.
- 37 - Explosive or inflammable dust, gas, etc
- 38 - Precautions in case of fire
- 39 - Power to require specifications of defective parts or tests of stability
- 40 - Safety of buildings and machinery
- 40A - Maintenance of buildings
- 40B - Safety Officers
- 41 - Power to make rules to supplement this Chapter

WELFARE

- 42 - [Washing facilities](#)
- 43 - [Facilities for storing and drying clothing](#)
- 44 - [Facilities for sitting](#)
- 45 - [First-aid appliances](#)
- 46 - [Canteens](#)
- 47 - [Shelters, rest rooms and lunch rooms](#)
- 48 - [Creches](#)
- 49 - [Welfare officers](#)
- 50 - [Power to make rules to supplement this Chapter](#)

WORKING HOURS FOR ADULTS

- 51 - [Weekly hours](#)
- 52 - [Weekly holidays](#)
- 53 - [Compensatory holidays](#)
- 54 - [Daily hours](#)
- 55 - [Intervals for rest](#)
- 56 - [Spread over](#)
- 57 - [Night shifts](#)
- 58 - [Prohibition of overlapping shifts](#)
- 59 - [Extra wages for overtime](#)
- 60 - [Restriction on double employment](#)
- 61 - [Notice of periods of work for adults](#)
- 62 - [Register of adult workers](#)
- 63 - [Hours of work to correspond with notice under section 61 and register under section 62.](#)
- 64 - [Power to make exempting rules](#)
- 65 - [Power to make exempting orders](#)
- 66 [Further restrictions on employment of women](#)

ANNUAL LEAVE FOR WAGES

- 78 - [Application of Chapter](#)
- 79 - [Annual leave with wages](#)
- 80 - [Wages during leave period](#)
- 81 - [Payment in advance in certain cases](#)
- 82 - [Mode of recovery of unpaid wages](#)
- 83 - [Power to make rules](#)
- 84 - [Power to exempt factories](#)

PAYMENT OF GRATUITY ACT, 1972

OBJECTIVE OF THE ACT

- The objective of the act is to provide for a scheme for the payment of gratuity to employees engaged in factories, mines, oilfields, plantations, ports, railway companies, shops or other establishments and for matters connected therewith or incidental thereto.

APPLICABILITY OF THE ACT

The act is applicable to :

- Every factory, mine, oilfield, plantation, port and railway company.
- Every shop or establishment within the meaning of any law for the time being in force in relation to shops and establishments in a state, in which ten or more persons are employed on any day of the preceding twelve months.
- Other establishments or class of establishments, in which ten or more employees are employed or were employed, on any day of the preceding twelve months, as the central government may notify.

PAYMENT OF GRATUITY.-

- Gratuity shall be payable to an employee on the termination of his employment after he has rendered continuous service for more than five years,-
- (a) on his superannuation, or
- (b) on his retirement of resignation, or
- (c) on his death or disablement due to accident or disease:

EMPLOYEE PROVIDENT FUND ACT

OBJECTIVE OF THE ACT

- The Objective of the Act is to provide for the institution of provident funds, pension fund and deposit linked insurance fund for employees in factories and other establishments.

APPLICABILITY OF THE ACT

- Every establishment which is a factory engaged in any industry specified in Schedule I and in which twenty or more persons are employed.
- Any Establishment employing twenty or more persons or class of such establishments which the central government may by notification in the official gazette specify in this behalf.
- Any other establishment employing less than twenty persons, if the central government extent the applicability by way of notification in the official Gazette.
- Where an establishment Consists of different departments or has branches, whether situate in the same place or in different places, all such departments or branches shall be treated as parts of the same establishments.

FOR NEW ENTRANTS

- An employee is eligible for membership from the day he joins the covered establishment.
- If the employee's emoluments exceed Rs. 6,500/- per month, he has the option to join the Scheme's) with the consent of employer.
- Declare previous employment details, if any, in Form No. 11 to the employer.
- On becoming a member of the Schemes file details in Form No. 2 (family particulars/ nominations) through the employer.
- Rate of contribution payable by a member shall be @ 12% of his emoluments.
- A member can contribute statutorily over and above the prescribed rate.

FOR EXISTING MEMBERS:

- Enrolment:
- Any change in the family status, such as, -
 - marriage of the member.
 - additions / deletion in the family.
 - Legal adoption of the children.
 - Change of nominee, is to be filed in Form No. 2 through the employer.
- In the event the member is holding a Scheme Certificate (under EPS, 95), he should surrender the same to the concerned EPFO office, through his employer.
- A member is entitled to various benefits & facilities such as withdrawals, advances, pensions, death insurance etc.

EMPLOYEE STATE INSURANCE ACT,19

OBJECTIVE OF THE ACT

- The objective of the act is to provide for certain benefits to employees in case of sickness, maternity and “employment injury” and to provide for certain other matters in relation there to.

APPLICABILITY OF THE ACT

- The Act is applicable to all factories including factories belonging to the Government other than seasonal factories.
- ESI is applicable to the employee drawing salary of less than 10,000/- in a month.

Contribution:

Employer: 4.75 % of salary.

Employee: 1.75% of salary

BENEFIT COVERED

- SICKNESS BENEFIT
- MATERNITY BENEFIT
- DISABLEMENT BENEFIT
- **Presumption as to accident arising in course of employment**
- **Accidents happening while acting in breach of regulations, etc.**
- **Accidents happening while travelling in employer's transport**
- **51D. Accidents happening while meeting emergency**
- **Dependants' benefit**

Minimum wages Act, 1948

- A tripartite Committee Viz., "The Committee on Fair Wage" was set up in 1948 to provide guidelines for wage structures in the country. The report of this Committee was a major landmark in the history of formulation of wage policy in India. Its recommendations set out the key concepts of the 'living wage', "minimum wages" and "fair wage" besides setting out guidelines for wage fixation.
- Article 39|- The State shall, in particular, direct its policy towards securing (a) that the citizen, men and women equally shall have the right to an adequate livelihood and (b) that there is equal pay for equal work for both men and women.

- Article 43 |- The State shall endeavor, by suitable legislation or economic organization or in any other way, to give all workers, agricultural, industrial or otherwise, work, a living wage, conditions of work ensuring a decent standard of life and full enjoyment of leisure, and social and cultural opportunities.

CONSUMER PROTECTION ACT, 1986

(With amendments of the Act effected from
15.3.2003
and rules from 5.3.2004)

CONSUMER PROTECTION ACT, 1986

- Enacted to provide for the better protection of the interest of consumer
- Act applies to whole of India except Jammu and Kashmir
- Chapter I, II and IV came into force on 15.4.1987. Chapter III came into force on 1.7.1987
- The act was amended in 2002 and the amendments came into force w.e.f. 15th March 2003.

WHAT IS A COMPLAINT?

“Complaint” means any allegation in writing made by a complainant that :

- I. An unfair trade practice or a restrictive trade practice has been adopted by any trader or service provider;
- II. The goods bought by him or agreed to be bought by him suffer from one or more defects ;
- III. The services hired or availed of or agreed to be hired or availed off by him suffer from deficiency in any respect;

WHAT IS A COMPLAINT?

- IV. A trader or service provider as the case may be has charged for the goods or for the services mentioned in the complaint, a price in excess of the price
- a) fixed by or under any law for the time being in force;
 - b) displayed on the goods or any package containing such goods;
 - c) displayed on the price list exhibited by him by or under any law for the time being in force;
 - d) agreed between the parties .

WHAT IS A COMPLAINT?

- V. Goods which will be hazardous to life and safety when used are being offered for sale to the public –
 - a) In contravention of any standards relating to safety of such goods as required to be complied with, by or under any law for the time being in force;
 - b) If the trader could have known with due diligence that the goods so offered are unsafe to the public;

WHAT IS A COMPLAINT?

- VI. Service which are hazardous or likely to be hazardous to the life and safety of the public when used, are being offered by the service provider which such person could have known with due diligence to be injurious to life and safety.

WHO IS A CONSUMER ?

- Any person who buys goods or avails services for consideration
- Consideration may be fully paid, partially paid or fully promised to be paid or partially promised to be paid
- Any body who uses the goods or services with the consent of the consumer

WHO IS A CONSUMER ?

- Legal heir of consumer in case death of consumer
- Does not include any person who buys goods for resale or commercial purpose and services for commercial purpose
- However any person who buys goods for commercial use but exclusively for his livelihood by means of self employment is a consumer.

WHAT IS A DEFECT ?

- Fault
 - Imperfection
 - Shortcoming
- In the
- Quality
 - Quantity
 - Potency
 - Purity Or
 - Standards

Which is required to be maintained by or under any law for the time being in force

WHAT IS A DEFICIENCY ?

- Fault
 - Imperfection
 - Shortcoming Or
 - Inadequacy
- In the
 - Quality
 - Standard and
 - Manner of performance

Which is required to be maintained by or under any law for the time being in force

WHAT IS A SERVICE?

“Service” means service of any description, which is made available to potential users and includes, but not limited to the provisions of the facilities in connection with

- 1) banking
- 2) financing
- 3) insurance
- 4) transport
- 5) processing
- 6) supply of electrical or other energy
- 7) boarding or lodging or both
- 8) house construction
- 9) entertainment
- 10) amusement or
- 11) the purveying or new or other information

But does not include the rendering of any service free of charge or under a contract of personal service

CONSUMER DISPUTE REDRESSAL AGENCIES

- 1) A Consumer Dispute Redressal Forum at the District level.
- 2) A Consumer Dispute Redressal Commission at the State level.
- 3) A National Consumer Dispute Redressal Commission at national level.

JURISDICTION

Forum / Commission	Where the value of the goods or services and the compensation, if any claimed,
District Forum	Does not exceed Rs. 20 lakhs
State Commission	Rs. 20 lakhs and above but not exceeding One Crore
National Commission	Above One Crore
Besides, State and National Commission have appellate jurisdiction also.	

FILING OF COMPLAINTS

A complaint may be filed by

- a) The consumer to whom the goods are sold or services are provided
- b) Any recognised consumer association
- c) One or more consumers with same interest
- d) The central government or state government

FILING OF COMPLAINTS

The Fee for filing the Complaint for the district forum is as under

Sr. No.	Value of Goods / Service and Compensation	Amount of Fees
1)	Upto Rs. 1 lakh rupees	Rs. 100
2)	Rs. 1 Lakh and above but less than Rs.5 lakhs	Rs. 200
3)	Rs. 5 Lakhs and above but less than Rs. 10 lakhs	Rs. 400
4)	Rs. 10 lakhs and above but less than Rs. 20 lakhs	

The fees shall be paid by Cross demand Draft drawn on a nationalized bank or through crossed Indian postal order drawn in favour of the Registrar of the State Commission and payable at the place of the State Commission (w.e.f. 5.3.2004.)

POWER OF CIVIL COURT TO DISTRICT FORUM

The District Forum shall have the powers of Civil Court while trying a suit in respect of the following matters ;

- a) The summoning and enforcing attendance of any defendant or witness and examining the witness on oath.
- b) The discovery and production of any document or other material object producible as evidence.
- c) The reception of evidence on affidavit
- d) The requisition of the report of the concerned analysis or test from the appropriate laboratory or from any other relevant source.
- e) Any other matter which may be prescribed.

RELIEF TO THE COMPLAINANT ?

IF THE COMPLAINT IS PROVED THE FORUM SHALL ORDER

- a) to remove defect pointed out by the appropriate laboratory from the goods in question;
- b) to replace the goods with new goods of similar description which shall be free from any defect;
- c) to return to the complainant the price, or , as the case may be, the charges paid by the complainant;
- d) to pay such amount as may be awarded by it as compensation to the consumer for any loss or injury suffered by the consumer due to negligence of the opposite party;
- e) To remove the defect in goods or deficiency in the services in question.

RELIEF TO THE COMPLAINANT ?

- f) to discontinue the unfair trade practice or the restrictive trade practice or not to repeat them;
- g) not to offer hazardous goods for sale;
- h) to withdraw the hazardous goods from being offered for sale;
- ha) to cease manufacture of hazardous goods and to desist from offering services which are hazardous in nature;
- hb) to pay such sum as may be determined by it, if it is of the opinion that loss or injury has been suffered by a large number of consumers who are not identifiable conveniently.
- hc) to issue corrective advertisements to neutralize the effect of misleading advertisement at the cost of the opposite party responsible for issuing such misleading advertisement;
- i) To provide for adequate cost to parties.

APPEAL

- shall be filed within thirty days.
- Delay in filing appeal may be condoned if there is sufficient cause.

LIMITATION PERIOD

Within two years from the date on which the cause of action has arisen.

DISMISSAL OF FRIVOLOUS OR VEXATIOUS COMPLAINTS

- Where a complaint instituted before the District Forum, the State Commission or the National Commission, is found to be frivolous or vexatious, it shall, for reasons to be recorded in writing, dismiss the complaint and make an order that the complainant shall pay to the opposite party such Cost, not exceeding ten thousand rupees, as may specified in the order.

PENALTIES

Where a trader or a person against whom a complaint is made (or the complainant) fails or omits to comply with any order made by the District Forum, the State Commission or the National Commission, such trader or person (or complainant) shall be punishable with imprisonment for a term which shall not be less than one month but which may extend to three years or with fine which shall not be less than two thousand rupees but which may extend to ten thousand rupees, or with both.

NOTE ON CONSUMER PROTECTION ACT, 1986

- A person may be consumer of goods, or services. When I purchase a fan, a gas stove or a refrigerator, I could be the consumer of goods.
- When I open a bank account, take an insurance policy, get my car repaired, I could be the consumer of services.
- The consumer protection Act, 1986 tries to help a consumer when for example, the goods purchased are defective or the services rendered to him are subject to so deficiency.
- Prior to the consumer Protection Act, 1986 for any consumer complaint one had to go to an ordinary Civil Court. He had to engage a lawyer, pay the necessary fee, and be harassed for years or decades before any outcome, positive or negative, was there in that litigation.
- Under the Consumer Protection Act, no Court fee has to be paid and the decision on the complaint is much quicker, as the Court can evolve a summary procedure in disposing off the complaint.

CASE LAWS ON THE ACT.

PECUNIARY JURISDICTION

- **In Krishan Dass Chaurasia V. State Bank of India (1995)** the total claim in a complaint did not exceed Rs. 1,00,000/-. It was held that the matter was not within the jurisdiction of the State Commission and such a claim was rejected by the State Commission. The Complainant could seek the remedy from the District Forum. Therefore, jurisdiction, which is vested in a district Forum cannot be created for State Commission by merely exaggeration of a claim.
- **In B. Raghunath Vs Trans India Tourism (1996)** the complainant had suffered a loss of Rs. 5,000/-, according to his own statement. He claimed compensation of Rs. 5,00,000. It was evident that he had purposely boosted his claim to bring the matter within the pecuniary jurisdiction of the State Commission. The complaint was returned by the State Commission for presentation in proper District Forum with necessary correction.

CASE LAWS ON THE ACT.

NO ACTION WHERE NO TERRITORIAL JURISDICTION

In **J. K. Synthetics Vs. Smt. Anita Bhargava (1993)** the registered office of the Opposite Party was situated at Kanpur. Payment was made through Bank in Delhi.

The complaint filed in Calcutta was held to be outside the territorial jurisdiction of the District Forum. The Order passed by the Calcutta District Forum was set aside in Appeal

CASE LAWS ON THE ACT.

EVIDENCE THROUGH AFFIDAVITS IS LEGAL & SUFFICIENT EVIDENCE.

- In **Union of India Vs. Ramswaroop Chandil (1998)** the complainant? Respondent had a circular ticket in his possession during journey which was locked in his box. He was not allowed to break open the lock and produce the ticket and was forced to pay excess charge for four persons. The District Forum awarded compensation in his favour for refund of fare and excess charge and for inconvenience, humiliation and Advocates fee, etc.
- In appeal by the Railway Authorities it was pleaded that the complainant had not produced any witness to support his claim. Dismissing the appeal it was held that he had narrated his case in the affidavit and the same was not rebutted by the Opposite party.
- It was held that the evidence by affidavit was legal and sufficient to support the complainant's case.

CASE LAWS ON THE ACT.

AFFIDAVITS PERMITTED TO DETERMINE DEFICIENCY IN SERVICE AS WELL AS DAMAGES.

- The Consumer Protection Act contemplates speedy disposal of complaints, which are required to be disposed off within 90 days of service of notice to Opposite Party. The Consumer Protection Act, therefore, does not contemplate regular trial as is usually done in civil suits.
- In **Prem Prakash Mehra Vs. Oriental Insurance Co. Ltd., (1995)** it has been held that the parties can be called upon to lead evidence on affidavits not only on question of deficiency in service but also on subject of determination of damages. This is in consonance with the objective of the Consumer Protection Act, for speedy disposal of cases.

CASE LAWS ON THE ACT.

NON-SPEAKING ORDER CAN BE SET ASIDE

- **In S.D.O. Telephone Vs. Rama Shankar Pandey (1997)** the District Forum, Hanoi, allowed the complaint and directed that the telephone bills of the complainant be revised on the basis of average consumption and awarded Rs. 200/- compensation to the complainant. No reasons were given for such order.
- The State Commission held that the order of the District Forum should be a speaking one. It should give, however briefly, the essential facts and material, considered by it as well as the reasons for the conclusion. Else the order becomes arbitrary in the eyes of law.
- The order of the District Forum was set aside and the case was sent back to the District forum for re-consideration in accordance with law after notice to the parties.

CASE LAWS ON THE ACT.

REMAND WHEN ORDER SIGNED BY PRESIDENT ONLY

- In **S. Ravisankar Vs. Aslo Steel Ltd.**, the order of the District forum was signed only by the President of the Forum. No other member had signed it.
- Section 14 requires that every order shall be conducted/signed by the President and at least one member. The present order was held to be invalid, and the matter was remanded to the District Forum.

CASE LAWS ON THE ACT.

PRESIDENT SITTING SINGLY

- It has been held by the National Commission that the orders passed by the President of the State Commission sitting singly without the junction of any other member is contrary to Section 14(2) of the Consumer Protection Act, 1986. Such an order is invalid (**Raj kumar Mangla Vs. R.S. Singh (1995)**)

CASE LAWS ON THE ACT.

PRESIDENT SITTING SINGLY

- In **Haryana Urban Development Authority Vs. Avtar Krishan Ambedkar (1998)** the revision petition was filed against the order of the President of the District Forum, Gurgaon dated 11.7. 1997, which was passed by the President sitting singly, i.e. without associating any of the two companion members.
- It was held that Section 14(2) requires that all proceedings shall be conducted by the President of District Forum and at least one member thereof sitting together. It was held that the President sitting singly was acting without jurisdiction. The said order was set aside and the case was referred back to the District Forum for fresh decision in accordance with law.

CASE LAWS ON THE ACT.

PREGNANCY NO GROUND FOR CONDONATION OF DELAY

- In **Registrar, University of Pune Vs. Mrs. Puja Pravin Wagh (1999)** the complainant filed a complaint 3 1/2 months after the expiry of the limitation period of 2 years against the University of Pune for the wrong declaration of result. The reason for delay in filing the complaint given by the complainant was her pregnancy. The District Forum condoned the delay and awarded compensation of Rs. 2,5000/- to the complainant. On appeal it was held that the fact of pregnancy was no justification for the delay. The complaint being time barred the order of the District Forum was set aside.

CASE LAWS ON THE ACT.

DAMAGES

- In **Charan Singh Vs. Healing Touch Hospital (2000)** it has been held by the Supreme Court that while quantifying damages, Consumer Forums are required to make an attempt to serve the ends of justice so that compensation is awarded, in an established case, which not only serves the purpose of recompensing the individual, but which also at the same time, aims to bring about a qualitative change in the attitude of the service provider. Indeed, calculation of damages depends on the facts and circumstances of each case. No hard and fast rule can be laid down for universal application. While awarding compensation, a Consumer Forum has to take into account all relevant factors and assess compensation on the basis of accepted legal principles, on moderation.

CASE LAWS ON THE ACT.

DAMAGES

- **In Patel Roadways Ltd. Vs. Birla Yamaha Ltd. AIR 2000** the Supreme Court has held that Consumer Forums have jurisdiction to entertain complaints against carriers regarding loss of or damage to goods entrusted to carrier for transportation.
- **In Provident Fund Commissioner Vs. Shiv Kumar Joshi (2000)** the Supreme Court has held that an employee, who is a member of the Employees' Provident Fund Scheme, is a consumer and duties performed by the Regional Provident Fund Commissioner under such scheme is "service" and thus, in case of delay in release of provident fund, complaint for deficiency in service, is maintainable.

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THE END