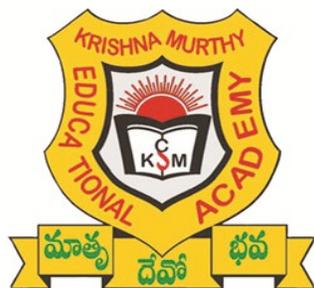


LECTURE NOTES
ON
Pharmaceutical Jurisprudence

(Subject Code:17T00304)

2018 – 2019

III Pharm.D (JNTUA-R17)



KRISHNA TEJA PHARMACY COLLEGE(AF)

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UNIT I- PHARMACEUTICAL LEGISLATIONS

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.

8. 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

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 b e 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 of 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 incase of accident or emergency.

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

(iii)Liasion 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 heath 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 dis 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 c

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: I [(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 sub-section (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 II, 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.- (1) 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 subclause (iii) of clause (f) of section 2 for a total period of not less than five years prior to the date appointed under sub-section (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 subsection (I) by such further period or periods, not exceeding two years in the aggregate, as may be specified in the notification. Explanation I.-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 removed from the register by him

UNIT II

PRINCIPLE AND SIGNIFICANCE OF PROFESSIONAL ETHICS .CRITICAL STUDY OF THE CODE OF PHARMACEUTICAL BY PCI.

INTRODUCTION ;

Purpose of Code of Business Conduct This Code of Ethics ("Code") describes standards of conduct for Morton's board members, officers, managers and all other employees of Morton's, and has been approved by the Morton's Restaurant Group, Inc. Board of Directors. Many of the policies in this Code are based on various laws and regulations. Other are based on business and ethical principles than enhance Morton's ability to conduct its business effectively. Others restate basic work rules and principles contained in the Employee Handbook. The purpose of the Code is to provide guidance and set common ethical standards each of us must adhere to on a consistent basis. It governs the actions and working relationships of Morton's board members, officers, managers and all other employees of Morton's in dealing with fellow employees, guests, competitors, vendors, suppliers, governmental and self-regulatory agencies, the media, and anyone else with whom Morton's has contact.

These relationships are essential to the continued success of Morton's. This Code:

- Requires the highest standards for honest and ethical conduct, including proper and ethical procedures for dealing with conflicts of interest between personal and professional relationships.
- Requires full, fair, accurate, timely and understandable disclosure in reports and documents that Morton's files with, or submits to, governmental and regulatory agencies, and in other public communications made by Morton's.
- Requires compliance with applicable governmental laws, rules and regulations.
- Requires the prompt internal report of any illegal behavior or violations of the Code.
- Establishes accountability for adherence to the Code.
- Provides for methods to communicate violations .

Leadership Responsibilities You are responsible for complying with both the letter and spirit of applicable laws and regulations. You are expected to act fairly and honestly when conducting business on 10257632.1 - 2 - behalf of Morton's and to maintain Morton's high ethical standards. You should avoid any actions that reflect unfavorably on either your own integrity or that of Morton's. Additionally, you are responsible for adhering to the Code and to all additional policies of Morton's. You are responsible for knowing all Morton's policies applicable to you and for complying with them. The Code and any additional policy statements may be modified periodically to reflect Morton's changing needs and the changing environment in which it operates. Supervisors are responsible for ensuring that their employees are aware that Morton's basic operating principle is to conduct business in accordance with the highest level of integrity and ethical standards. This Code cannot provide an answer to all questions that may arise. If you have a question that the Code does not address directly, you should use your good judgment and common sense of what is right, based on the standards set forth in the Code, and seek appropriate guidance from others. You also have a duty to report apparent misconduct by others using appropriate channels, as addressed below, and to assist Morton's in the prevention and correction of these problems.

ADMINISTRATION ;

Periodically, Morton's may require you to acknowledge in writing that you have received and reviewed the Code. In addition, you should disclose any previously unreported transactions, relationships or activities known to you that appear to be in violation of the Code or that the Code requires to be disclosed. If you have a question about whether an event occurring prior to receipt of the Code is reportable, contact Morton's Senior Compliance Officer or one of its Executive Officers. Questions about the Code You should contact Morton's Senior Compliance Officer or one of its Executive Officers with any questions about the Code. Information on how to contact these individuals is set forth in the "Important Contact Information" section of this Code. Please direct all inquiries to those individuals, unless a specific provision of the Code provides otherwise. Reporting Violations You should promptly report to Morton's Senior Compliance Officer or one of its Executive Officers any activity that appears to be fraudulent or illegal or otherwise in violation of the Code. If you would rather contact a resource outside of Morton's management to discuss a perceived violation of the Code, you may contact the chairman of the Audit Committee of the Morton's Restaurant Group, Inc. Board of Directors.

Information on how to contact these individuals is set forth in the "Important Contact Information" section of this Code. You may also follow the procedures outlined in the Employee Handbook. Anonymous reports will be 10257632.1 - 3 - investigated if sufficient information is provided. However, Morton's encourages you to identify yourself in case additional information is necessary during the course an investigation. To the fullest extent possible and appropriate, Morton's will endeavor to keep confidential the identity of anyone who reports a violation. It is Morton's policy to prohibit retaliation against employees, managers, officers, directors or advisors who in good faith report, or cooperate in an investigation of such reports of, possible Code violations by others. However, if you knowingly or recklessly provide false information to Morton's, it may result in disciplinary action, including immediate dismissal. Penalty for Violations Violations of the Code, violations of applicable laws or failure to cooperate with an internal investigation may all constitute grounds for disciplinary action, including immediate dismissal. Supplemental Policies The provisions of the Code cannot include all situations or events likely to occur in the conduct of Morton's business. Therefore, Morton's has issued, and may in the future issue, additional policy statements from time to time, either to address topics not covered in the Code or to provide greater detail on topics already covered by the Code. Definitions Certain terms are defined as follows in the Code: "Board of Directors" refers to members of the Board of Directors of Morton's Restaurant Group, Inc. and/or each subsidiary. "Code" means this Code of Ethics. "Executive Officers" means the Chief Executive Officer, President, Senior Vice Presidents and Vice Presidents of Morton's Restaurant Group, Inc., and the President, Senior Vice Presidents and the Vice President of Human Resources of Morton's of Chicago, Inc. "Immediate Family" means a person's parents, grandparents, spouse, children and dependents, including natural, adoptive, step and in-law relationships, any other individual residing in the same household, and any individual or organization which represents or acts as agent or fiduciary for such individuals. "Managers" or "management" means any management-level position at Morton's offices or its restaurants. "Morton's" means Morton's Restaurant Group, Inc. and/or each subsidiary. "Securities" means any stocks, bonds, notes, debentures or other interests, instruments or documents commonly known as securities, and any rights thereto. 10257632.1 - 4 - "Senior Compliance Officer" means the individual designated by Morton's to manage compliance with this Code, currently the Senior Vice President and General Counsel of Morton's Restaurant Group, Inc.

COMPLIANCE WITH LAWS, RULES AND REGULATIONS

Compliance with Laws Morton's conducts business on a global basis. All board members, officers, managers and all other employees are expected to comply with all applicable laws and regulations in every jurisdiction where Morton's conducts business. However, if any provisions conflict with local law of any jurisdiction in which Morton's operates, Morton's may issue supplemental policies in those jurisdictions. You should consult with Morton's Senior Compliance Officer or one of its Executive Officers when a question arises regarding any law or regulation. While the law prescribes a minimum standard of conduct, this Code may require conduct that exceeds legal standards. Antitrust and Trade Regulation Laws against unfair competition, also known as antitrust, monopoly or fair trade laws, are designed to protect the competitive marketplace. Typically, it is illegal to agree with competitors to do any of the following: • fix prices, terms or conditions; • divide or allocate customers, markets or territories; • refuse to do business with particular sources; or • exchange or discuss nonpublic sales or other information. Improper agreements include not only specific commitments, whether oral or written, but also informal understandings. Consequently, you should never discuss with competitors, even casually, any of the prohibited activities described above or other matters that might be interpreted as an effort to improperly restrict or limit competition. Trade regulation laws also prohibit engaging in false or deceptive advertising or other unlawful or unethical trade practices. You should consult Morton's Senior Compliance Officer or one of its Executive Officers regarding questions about any specific activities or circumstances.

Violations of this policy will not be permitted and will result in disciplinary action, which may include discharge. The procedure for handling complaints of actual or perceived sexual harassment is: STEP 1 If the problem cannot be resolved by speaking with your Manager, or you feel uncomfortable trying to resolve the matter that way, you should report the problem (including all incidents) to the Human Resources Department. To resolve problems quickly, you should report any discriminatory or harassing act immediately after the complaint or incident occurred. STEP 2 The Vice President of Human Resources or his/her designee will make a thorough investigation, in as confidential a manner as is reasonable under the circumstance. Upon completion of this investigation, a determination will be made as to whether the facts establish that sexual harassment occurred. If a violation of this policy took place, corrective action, which may include discharge, will be taken at the discretion of the Vice President of Human Resources. STEP 3 Any incidents of further harassment and/or retaliation should immediately be reported to the Vice President of Human Resources or the Senior Compliance

Officer. Since Morton's is committed to providing a discrimination-free workplace, Morton's encourages you to report all incidents of actual or perceived sexual harassment (or other discrimination or harassment). No one will be retaliated against for having done so, even if the report cannot be verified by Morton's investigation. Morton's reserves the right to initiate disciplinary action against employees who make complaints in bad faith or who fail to cooperate with an investigation. Workplace Violence Morton's is strongly committed to providing a safe workplace. The purpose of this policy is to minimize the risk of personal injury to employees and damage to Morton's and personal property. 10257632.1 - 7 - Morton's does not expect you to become an expert in psychology or to physically subdue a threatening, violent or potentially violent individual. However, Morton's does expect and encourage you to exercise reasonable judgment in identifying potentially dangerous situations.

CORPORATE OPPORTUNITIES Overview Persons covered by this Code owe a duty to Morton's to advance its business interests when the opportunity to do so arises and are prohibited from (i) taking for themselves personally opportunities that are discovered through the use of corporate property, information or position; (ii) using corporate property or information for personal gain; and (iii) competing with Morton's during employment. Business Opportunities Business opportunities that are actively solicited by, or offered to, Morton's, or that were pursued by any persons covered by this Code using Morton's funds, facilities or personnel, belong to Morton's. You should not take for your own benefit, or help others take for their benefit, a business opportunity that belongs to Morton's unless that opportunity is first offered to Morton's and declined, and if your involvement would not pose a conflict. A business opportunity may include a loan, lease, investment or other transaction. You should not use Morton's name or any of its property or resources to enhance your own, or any other person's, economic interest in personal transactions or outside relationships. You should not engage in self-dealing with Morton's, or engage in a business that competes with, or is a supplier to Morton's, unless specifically authorized by the appropriate Board of Directors or an authorized Executive Officer of Morton's Restaurant Group, Inc. Neither you nor your Immediate Family should invest in or purchase personal or real property leased or managed by Morton's, except in situations where no undue advantage 10257632.1 - 10 - arises from your association with Morton's or where Morton's has a specific program that allows for such purchase. General Persons covered by this Code should not solicit, accept or retain any material personal benefit from any client, customer, supplier, vendor or any other firm or individual doing or seeking to do business with Morton's. A

personal benefit may include a gift, gratuity, favor, service, loan, commission, fee or compensation or anything of monetary values, except as otherwise permitted by this Code. This policy is generally not intended to prohibit gifts based on obvious family or close non-business personal relationships where the circumstances make it clear that the personal relationships, rather than the business of Morton's, are the motivating factors. Gifts, Meals and Entertainment

Generally, you should not accept gifts of (i) cash or cash equivalents (such as securities or gift certificates) or (ii) discounts and rebates on goods or services, unless they are available on the same terms to the general public. However, commensurate with your position, you may accept benefits that fall within one of the following categories, provided there is no intent to influence or reward you in connection with any business or any transaction with Morton's, and if the frequency and value of such personal benefits from one source are not excessive or unreasonable:

- gratuities from guests in conjunction with your employment;
- gifts of a reasonable value that are related to commonly recognized holidays or occasions, such as a promotion, business closing, wedding, birth of a child or religious holiday or ceremony;
- normal business courtesies, such as a golf game, attendance at an athletic event or the theater, etc., involving no more than ordinary amenities;
- paid trips or guest accommodations that involve formal representation of Morton's (provided prior written approval is obtained from an authorized Executive Officer), or which can be or are reciprocated on a personal basis;
- advertising or promotional material of a reasonable value;
- civic, charitable, educational, religious or professional organization awards, having a customary or reasonable value, for recognition of service and accomplishments; and
- meals, refreshments and or entertainment, provided there is a demonstrable business purpose and at a level of expense that would be reimbursable by Morton's as a reasonable business expense.

10257632.1 - 11 - Whether a gift, meal or other benefit is of a reasonable value depends on the facts and circumstances. For example, a gift, meal or other benefit would be of a reasonable value if it could have been a reimbursable business expense under Morton's policy if it had not been paid by a third party. This is an example only. If you have any questions whether a particular personal benefit might be considered inappropriate or whether it falls within one of the above categories, you should consult with the Senior Compliance Officer.

INSIDER TRADING It is both illegal and unethical to buy, sell, trade or otherwise participate in transactions involving Morton's securities while in possession of material information concerning Morton's that has not been released to the general public, but which when released may have an impact on the market price of Morton's securities.

Morton's has established a corporate policy relating to insider trading, the Insider Trading Policy and Guidelines, and all board members, officers, managers and all other employees of Morton's are required to comply with such policy. In addition to potential civil and criminal liability under applicable securities laws, violation of the securities laws or the insider trading policy is grounds for disciplinary action, which may include discharge. Any questions concerning the propriety of participating in a Morton's or other company stock or other security transaction should be directed to the Senior Vice President and Chief Financial Officer of Morton's Restaurant Group, Inc.

UNIT III

DRUGS AND COSMETICS ACT, 1940, AND ITS RULES 1945

The **Drugs and Cosmetics Act, 1940** is an [Act](#) of the [Parliament of India](#) which regulates the import, manufacture and distribution of drugs in [India](#).^[1] The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards.^[2] The related [Drugs and Cosmetics Rules, 1945](#) contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.^{[2][3]}

Amendments;

The Act has been amended several times. The following are a list of amending acts:

1. The Drugs (Amendment) Act, 1955 (11 of 1955).
2. The Drugs (Amendment) Act, 1960 (35 of 1960).
3. The Drugs (Amendment) Act, 1962 (21 of 1962) .
4. The Drugs and Cosmetics (Amendment) Act, 1964 (13 of 1964).
5. The Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972).
6. The Drugs and Cosmetics (Amendment) Act, 1982 (68 of 1982).
7. The Drugs and Cosmetics (Amendment) Act, 1986
8. The Drugs and Cosmetics (Amendment) Act, 1995 (71 of 1995)

This Act may be called the Drugs 2 [and Cosmetics] Act, 1940.

It shall come into force at once; but Chapter III shall take effect only from such date⁵ 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 ⁵ as the State Government may, by like notification, appoint in this behalf: 6 [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 (19 of 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, 7 [(a) “ 8 [Ayurvedic, Siddha or Unani] drug” includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of 8 [disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of 9 [Ayurvedic, Siddha and Unani Tibb systems of medicine], specified in the First Schedule;] 9 [(aa) “the Board” means— (i) in relation to 9 [Ayurvedic, Siddha or Unani] drug, the 9 [Ayurvedic, Siddha and 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.

“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. [(b) “drug” includes— 5 [(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 the human body or intended to be used for the destruction of 6 [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;] 7 [(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;] 8 [(c) “Government Analyst” means— (i) in relation to 9 [Ayurvedic, Siddha or Unani] drug, a Government Analyst appointed by the 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 9 [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;] 12[13[(f) “manufacture” in relation to any drug 14[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 14[or cosmetic] with a view to its 15[sale or distribution] but does not include the compounding or dispensing 16[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;] 17[(g) “to import”, with its grammatical variations and cognate

expressions means to bring into 18[India];2 [(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 the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section “prescribed” means prescribed by rules made under this Act.

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 6 [or Chapter IVA] shall be deemed to be a poisonous substance.

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. 7 [(2) 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; 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 an 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 renomination and re-election: 1 [Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.] (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.

6. 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 2 [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 2 [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 4 [under Chapter IV or Chapter IVA] of samples of drugs 2 [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 purposes of the proviso to sub-section (1).

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 1 [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. 2 [7A. Sections 5 and 7 not to apply to Ayurvedic, Siddha or Unani drugs.—Nothing contained in sections 5 and 7 shall apply to 3 [Ayurvedic, Siddha or Unani] drugs.] _ (i) the Director General of Health Services, ex officio; (ii) the Drugs Controller, India, ex officio; 1 [(iii) the principal officer dealing with Indian systems of medicine in the Ministry of Health, ex officio;] (iv) the Director of the Central Drugs Laboratory, Calcutta, ex officio; (v) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government; (vi) one Pharmacognocist to be nominated by the Central Government; (vii) one Phyto-chemist to be nominated by the Central Government; 2 [(viii) four

persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee;] (ix) one teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government; (x) one teacher in ILM-UL-ADVIA and TAKLIS-WA-DAWA-SAZI, to be nominated by the Central Government; 3 [(xi) one teacher in Gunapadam, to be nominated by the Central Government; (xii) three persons, one each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government; (xiii) three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb system of medicine, to be nominated by the Central Government.] (3) The Central Government shall appoint a member of the Board as its Chairman. (4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination. (5) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it. (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.

UNIT IV

PHARMACY ACT -1948

THE 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.

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.

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).

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 4 [University Grants Commission] from among persons on the teaching staff. of an Indian University or a college affiliated thereto which grants a degree or diploma in pharmacy.

(b) Six members, of whom at least 1[four] shall be persons possessing a degree or diploma in, and practicing pharmacy or pharmaceutical chemistry. Nominated by the Central Government.

(c) One member elected from amongst themselves by the members of the Medical Council of India; (d) the Director General, Health Services, ex officio or if he is unable to attend any Meeting, a person authorized by him in writing to do so; 2[(dd) the Drugs Controller, India,

ex officio or if he is unable to attend any meeting, a person authorized by him in writing to do so;]

(e) the Director of the Central Drugs Laboratory, ex officio;

'[(f) a representative of the University Grants Commission and a representative of the All India Council for Technical Education;]

(g) one member to represent each 4 State elected 5 [from amongst themselves] by the members of each State Council, who shall be a registered pharmacist;

(h) One member to represent each 4State nominated by 6[the] State Government, who shall be 7a registered pharmacist:

(i) 8[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,

Incorporation of Central Council.- The Council constituted under section 3 shall be a body corporate by the name of the Pharmacy Council of India, having perpetual succession and a common seal, with power to acquire and hold property both movable and immovable, and shall by the said name sue and be used. The Pharmacy Council of India is a body Corporate having perpetual succession and a common seal with power to acquire and hold property and can sue and be sued.

5. President and Vice-President of Central Council.-(1) The President and Vice-President of the Central Council shall be elected by the members of the said Council from among themselves. 2 [The President] or Vice-President shall hold office as such for a term not exceeding five years and not extending beyond the .expiry of his term as member of the Central Council. but subject to his being a member of the Central Council, he shall be eligible for re-election: 3 [Provided that if his term of office as a member of the Central Council expires before the expiry of the full term for which he is elected as President or Vice-President, he shall. if he is re-elected or re -nominated as a member of the Central Council. continue to hold office as President or Vice-President for the full term for which he is elected to such office.]

6. Mode of elections.-Elections under this Chapter shall be conducted in the prescribed manner, and where any dispute arises regarding any such election it shall be referred to the Central Government whose decision shall be final.

7. Term of office and casual vacancies.-(1) Subject to the provisions of this section, a nominated or elected member 4 shall hold office for a term of five years from the date of his nomination or election or until his successor has been duly nominated or elected. Whichever is longer? (2). A nominated or elected member may at any time resign his

membership by writing under his hand addressed to the President, and the seat of such member shall thereupon become vacant. . (3) A nominated or elected member shall be deemed to have vacated his seat if he is absent without excuse, sufficient in the opinion of the Central Council, from three consecutive meetings of the Central Council or if he is elected under clause (a), (c) or (g) of section 3, if he ceases to be a member of the teaching staff, Medical Council of India or a registered pharmacist.

(4) A casual vacancy in the Central Council shall be filled by fresh nomination or election, as the case may be, and the person nominated or elected to fill the vacancy shall hold office only for the remainder of the term for which the member whose place he takes was nominated or elected.

(5) No act done by the Central Council shall be called in question on the ground merely of the existence of any vacancy in, or any defect in the constitution of the Central Council. (6)

Members of the Central Council shall be eligible for re-nomination or re election. . Staff

,remuneration and allowances.- The Central Council shall-- (a) appoint a Registrar who shall act as the Secretary to that Council and who may also, if deemed expedient by that Council, act as the Treasurer thereof; (b) appoint such other officers and servants as that Council deems necessary to enable it to carry out its functions under this Act; (c) require and take from the Registrar, or any other officer or servant, such security for the due performance of his duties as that Council may consider necessary; and (d) with the previous sanction of the Central Government, fix (i) the remuneration and allowances to be paid to the President, Vice-President, and other members of that Council, (ii) the pay and allowances and other conditions of service of officers and servants of that Council.]

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 Vice-President, 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 by this Act the Executive Committee shall exercise and discharge such powers and duties as may be prescribed.

Other Committees.- (1) The Central Council may constitute from among its members other committees for such general or special purposes as that Council may deem necessary and for

such periods not exceeding five years as it may specify, and may co-opt for a like period persons, who are not members of the Central Council, as members of such committees. (2) The Central Council with the previous sanction of the Central Government shall fix the remuneration and allowances to be paid to the members of such committees. (3) The business before such committees shall be conducted in accordance with such regulations as may be made under this Act.

The Pharmacy Council of India is empowered to constitute from among its members other committees and can also co-opt persons who are not members of the Pharmacy Council of India.

10. 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 recommend to the Central Council the persons who shall be eligible for election to the Central Council.

UNIT V

MEDICINAL AND TOILET PREPARATION 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, $C_9H_{15}NO_3H_2O$, 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, $C_{17}H_{19}NO_8$ 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, 2 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 (*Cannabis 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 3 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 (3) Subject to the other provisions contained in this Act, the duties aforesaid shall be collected in such manner as may be prescribed. Explanation: Dutiable goods said to be manufactured in bond within the meaning of this section if they are allowed to be manufactured without payment of any duty of excise leviable under any law for the time being in force in

respect of alcohol, opium, Indian hemp or other narcotic drug or narcotic which is to be used as an ingredient in the manufacture of such goods

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

6. 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.

7. OFFENCES AND PENALTIES.

If any person - (a) contravenes any of the provisions of a notification issued under Sec. 6; or (b) evades the payment of any duty of excise payable under this Act; or (c) fails to supply any information which he is required by rules made under this Act to supply or (unless with a reasonable belief, the burden of proving which shall be upon him, that the information supplied by him is true) supplies false information; or (d) attempts to commit or abets the commission of any offence mentioned in Cl. (a) or Cl. (b). He 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 two thousand rupees, or with both.

8. 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.

9. 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.

10. 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. (3) All persons so summoned shall be bound to attend either in person or by an authorized agent as such officer may direct and all persons so summoned shall be bound to state the truth on any subject respecting which he is examined or make statements and produce such documents and other things as may be required : Provided that the exemption under Sec. 132 and Sec. 133 of the Code of Civil Procedure, 1908 (5 of 1908), shall apply to requisitions for attendance 7 under this section. (4) Every such inquiry as aforesaid shall be deemed to be a judicial proceeding within the meaning of Sec. 193 and Sec. 228 of the Indian Penal Code (45 of 1860)..

11. 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.

12. 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.

13. 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.

14. 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.

15. DISPOSAL OF PERSONS ARRESTED.

8 (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.

16. 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-incharge of a police station may exercise and is subject to under the Code of Criminal Procedure, 1898 (5 of 1898), when investigating a cognizable case : Provided that - (a) if the Excise Officer is of opinion that there is sufficient evidence or reasonable ground of suspicion against the accused person he shall either admit him to bail to appear before Magistrate having jurisdiction in the case, or forward him in custody without delay to such Magistrate; (b) if it appears to the Excise Officer that there is not sufficient evidence or reasonable ground of suspicion against the accused person, he shall release the accused person on his executing a bond with or without sureties as the Excise Officer may direct, to appear, if and when so required, before the Magistrate having jurisdiction and shall make a full report of all the particulars of the case to him official superior. (3) All officers exercising any powers under Sec. 15 or this section shall so exercise their powers as to ensure that every person who is arrested and detained in custody is produced before the nearest

UNIT VI

NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT

INTRODUCTION ;

The statutory control over narcotic drugs was being exercised under The Opium Act, 1852, The Opium Act, 1878 and The Dangerous Drugs Act, 1930. The provisions of these enactments were found to be inadequate because of the passage of time and developments in the field of illicit drug traffic and drug abuse at national and international level. To consolidate and to amend the existing laws relating to narcotic drugs a comprehensive legislation was considered to be necessary. Accordingly the Narcotic Drugs and Psychotropic Substances Bill was introduced in the Parliament.

STATEMENT OF OBJECTS AND REASONS; The statutory control over narcotic drugs is exercised in India through a number of Central and State enactments. The principal Central Acts, namely the Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drugs Act, 1930 were enacted a long time ago. With the passage of time and the developments in the field of illicit drug traffic and drug abuse at national and international level, many deficiencies in the existing laws have come to notice, some of which are indicated below: (i) The scheme of penalties under the present Acts is not sufficiently deterrent to meet the challenge of well organized gangs of smugglers. The Dangerous Drugs Act, 1930 provides for a maximum term of imprisonment of 3 years with or without fine and 4 years imprisonment with or without fine for repeat offences. Further, no minimum punishment is prescribed in the present laws, as a result of which drug traffickers have been some times let off by the courts with nominal punishment. The country has for the last few years been increasingly facing the problem of transit traffic of drugs coming mainly from some of our neighboring countries and destined mainly to Western countries. (ii) The existing Central laws do not provide for investing the officers of a number of important Central enforcement agencies like Narcotics, Customs, Central Excise, etc., with the power of investigating offences under these laws. It is proposed to amend the existing laws through various provisions.

UNIT VI

NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT

AND RULES

These treaties and conventions which entail several obligations which are not covered or are only partly covered by the present Acts. (iv) During recent years new drugs of addiction which have come to be known as psychotropic substances have appeared on the scene and posed serious problems to national governments. There is no 2 The Narcotic Drugs and Psychotropic Substances Act, 1985 comprehensive law to enable exercise of control over psychotropic substances in India in the manner as envisaged in the Convention on Psychotropic Substances, 1971 to which India has also acceded' 2. In view of what has been stated above, there is an urgent need for the enactment of a comprehensive legislation on narcotic drugs and psychotropic substances which, in all, should consolidate and amend the existing laws relating to narcotic drugs, strengthen the existing controls over drug abuse, considerably enhance the penalties particularly for trafficking offences, make provisions for exercising effective control over psychotropic substances and 'make provisions for the implementation of international conventions relating to narcotic drugs and psychotropic substances to which India has become a party' 3. The Bill seeks to achieve the above objects. ACT 61 OF 1985 The Narcotic Drugs and Psychotropic Substances Bill having been passed by both the Houses of Parliament received the assent of the President on 16th September, 1985.

It came on the Statute Book as THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, 1985 (61 of 1985) (Comm: into force on 14-11-1985) . LIST OF AMENDING ACTS;

1. The Narcotic Drugs and Psychotropic Substances (Amendment) Act' 1988 (2 of 1989) (w.e.f. 29-5-1989).

2. The Narcotic Drugs and Psychotropic Substances (Amendment) Act' 2001 (9 of 2001) (w.e.f. 2-10-2001).

3. The Narcotic Drugs and Psychotropic Substances (Amendment) Act' 2014
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.

Definitions:

-In this Act, unless the context otherwise requires, .. a[(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 "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 top 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) mixture, with or without any neutral material, of any of the above forms of cannabis or any drink prepared therefore; (iv) "cannabis plant" means any plant of the genus cannabis; (v) "Central government factories" means -factories owned by the Central Government or factories owned by any company in which the Central Government holds at least fifty-one per cent. of the paid up share capital (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 Per cent 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; (vii) "coca plant" means the plant of any species of the genus *Erythroxylon*; (viii) "commercial quantity", in relation to narcotic drugs and psychotropic substances, means any quantity greater than the quantity specified by the Central Government by notification in the Official Gazette; (viii) "controlled delivery" means the technique of allowing -illicit or suspected consignments of narcotic drugs, psychotropic substances, controlled substances or substances substituted for them to pass out of, or through or into the territory of India with the knowledge and under the supervision of an officer empowered- in this behalf or duly authorised under section 50A with a view to identifying the persons involved in the commission of an offence

under this Act [(viic; "corresponding law" means any law corresponding to the Provisions of this Act) 63];

(viii) "conveyance" means a conveyance of any description whatsoever and includes any aircraft, vehicle or vessel; It (viii a) ;L s s e n t i i i - * t i o i i " drug"; means a narcotic drug notified by the Central Government* for medical and scientific use [3[(viii b) f illicit traffic', in relation to narcotic drugs and Psychotropic substances means- (i) cultivation of coca plant or gathering any portion of coca plant; (ii) cultivation of any cannabis plant; (iii) production, manufacture, possession, sale, 'outright' transportation' warehousing, concealment, use or consumption, import inter-State, export inter-State, import into India, export from India or transshipment, of narcotic drugs or psychotropic substances; (iv) activities in narcotic drugs or psychotropic substances other than those referred to in sub-clauses (i) to (iii); or (v) handling or letting out any premises for the carrying on of any ' ' of the activities referred to in sub-clauses (i) to (iv);- other than those permitted under this Act, or any rule or order made, or any condition of any licence, term or authorisation issued, thereunder. and includes- (1) financing directly or indirectly, any of the aforementioned activities; (2) abetting or conspiring in the furtherance of or in support of doing any of the aforementioned activities; and (3) harboring persons engaged in any of the aforementioned activities- (ix) "International Convention" means- '(a) the Single Convention on Narcotic Drugs, 1953 adopted by the ' ' United Nations Conference at New York in March, 1953; (b) the protocol, amending the Convention mentioned in sub-clause (a), adopted by the United Nations Conference at Geneva in March, 1955; (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 Central Government take measures for preventing and combating abuse of and illicit traffic in narcotic drugs, etc. (2) subject to the provisions ; ; ; t the Central Government shall take all such measures as it deems fit or expedient for the purpose of preventing and combating 31*.of ; ; X t i l ;] ; - ; t ; n i t o p i . * r i ' t t * t e s and the illicit traffic therein [and for ensuring their medical and scientific use] in accordance to the generality of the provisions, of sub-section (1), the measures which the Central Government may take under the sub-section include measures with respect to

all or any of the following matters, namely:- (i) coordination of actions by various officers of State Governments and other authorities- (i) under this Act, or (ii) 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 Convention; (c) 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, rehabilitation and social re-integration of addicts; (e) availability of narcotic drugs and psychotropic substances for medical and scientific use (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. (3) The Central Government may, if it considers it necessary, by order published in the official Gazette constitute an authority or a hierarchy of authorities by such name or names as may be specified in the order for the purpose of exercising such of the powers in such drugs or substances may be obtained; (2) refining of drugs or substances; 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. (a) The Committee may, if it deems it necessary so to do for the efficient discharge of any of its functions constitute one or more sub-committees and may appoint to any such sub-committee, whether generally or for the consideration of any particular matter any person (including a non-official) who is not a member of the Committee. (5) The term of office of, the manner of filling casual vacancies in the offices of and the allowances, if any, payable to, the Chairman and other members of the Committee, and the conditions and restrictions subject to which the Committee may appoint a person who is not a member of the Committee as a member of any of its sub-committees, shall be such as may be prescribed by rules made by the Central Government. 7. Officers of State Government.- (1) The State Government may appoint such officers with such designations as it thinks fit for the purposes of this Act. (2) The officers appointed under sub-section (1) shall be subject to the general control and supervision of the Central Government. (3) The Central Government may also appoint any other officers as it may think fit for the purposes of this Act.

UNIT –VII

STUDY OF SAILENT FEATURES OF DRUGS AND MAGIC REMEDIES ACT AND ITS RULES

In exercise of the powers conferred by section 16 of the Drugs and Magic Remedies

(Objectionable Advertisements) Act, 1954 (21 of 1954), the Central Government hereby makes the following rules, namely:-

1. Short Title and Commencement.–

(1) These rules may be called the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

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

2 . Definitions.

– In these rules, unless the context otherwise requires,–

(1) the “Act” means the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (21 of 1954); and

(2) “section” means a section of the Act.

3. Scrutiny of Misleading Advertisements Relating to Drugs.— Any person authorized by the State Government in this behalf may, if satisfied, that an advertisement relating to a drug contravenes the provisions of section

4], by order, require the manufacturer, packer, distributor or seller of the drug to furnish, within such time as may be specified in the order or such further time as may be allowed in this behalf by the person so authorized 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 order is made, it shall be the duty of the manufacturer, packer, distributor or seller of the drug to which the advertisement relates to comply with the order.

Any failure to comply with such order shall, for the purposes of section

7, be deemed to be a contravention of the provisions of section 4: Provided that no publisher or advertising agency of any medium for the dissemination of any advertisement relating to a drug shall be deemed to have made any contravention merely by reason of the dissemination by him or if any such advertisement, unless such publisher or advertising agency has failed to comply with any discretion made by the authorized 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.

4. Procedure to be followed in prohibiting Import into, and 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 purpose by the Central Government, shall detain the consignment and dispose it of in accordance with the provisions of the Sea Customs Act, 1878 (VIII of 1878), and the rules made thereunder, and shall also inform the importer or exporter of the order so passed:

Provided that if the importer or exporter feels aggrieved by an order passed by the Customs Collector under this sub-rule and makes a representation to him within one week of the date of the order and has given an undertaking in writing not to dispose of the consignment without the consent of the Customs Collector and to return the consignment when so required to do by the Customs Collector, the Customs Collector shall pass an order making over the consignment to the importer or exporter, as the case may be:

Provided further that before passing any order under this sub-rule or under the first proviso thereto, the Customs Collector shall consult the officer appointed for the purpose by Central Government.

(2) If the importer or exporter who has given an undertaking under the first proviso to subrule

(1) is required by the Customs Collector to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

5. 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 wholesale or retail chemist being given. Such document shall bear 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”.

6. 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,

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UNIT VIII

STUDY OF ESSENTIAL COMMODITIES ACT RELEVANT TO DRUGS PRICE CONTROL ORDER .

THE ESSENTIAL COMMODITIES ACT, 1955 ;

The Essential Commodities Act, 1955 (hereinafter referred as the "Act"), aims at maintaining supplies of the essential commodities and to ensure their availability to all people at fair prices. For the fulfillment of its purposes, the Act confers regulatory powers on the central government through licenses, permits or other measures to control production, storage, transport, distribution, acquisition and consumption of any essential commodity falling under the purview of the Act. Provisions have been made under the Act for the seizure of essential commodities traded in contravention of its provisions, and the mechanism thereof. The Act prescribes penalties for any contravention of orders passed under the Act and makes explicit provisions about the liability of companies. Procedure for the trial of persons contravening the orders under the Act has also been laid down. The recognized consumer associations have been empowered to make a report in writing of the facts constituting the offences under the Act for the purpose of taking cognizance by courts.

Commodities Covered by the Act

The Essential Commodities Act provides for the control of the production, supply and distribution of trade and commerce in various commodities, including:2 (i) cattle fodder (including oil cakes and other concentrates); (ii) coal (including coke and other derivatives); (iii)

component parts and accessories of automobiles; (iv) cotton and woolen textiles; (v) drugs; (vi) food stuffs (including edible oil seeds and oils; (vii) iron and steel (including manufactured products of iron and steel); (viii) paper (including newsprint, paperboard and strawboard); (ix) petroleum and its products; (x) raw cotton (whether ginned or unginned) and cotton seed; and (xi) raw jute. These commodities fall into three categories: (1) food for human beings and cattle; (2) raw materials for industries; (3) products of industries controlled by the Parliament. This list of essential commodities is, however, not exhaustive. The central government is authorized to declare, by notified order, any other commodity as an "essential commodity" for the purpose of the Act.

Regulatory Powers of the Central Government

The main provision that determines the process of maintenance of supplies and distribution is section 3 of the Act. It authorizes the central government to regulate or prohibit the production, supply and distribution of an essential commodity, and trade and commerce therein, inter alia, for maintaining or increasing supplies thereof or for securing their equitable distribution and availability at a fair price.⁴ Accordingly, orders can be issued by the central government:⁵ (a) for regulating by licences, permits or otherwise the production or manufacture of any essential commodity ; (b) for bringing under cultivation any waste or arable land for growing thereon food-crops or otherwise maintaining or increasing the cultivation of food-crops; and (c) for controlling the price at which an essential commodity may be bought or sold. The central government can also take steps for regulating by licences, permits or otherwise storage, transport, distribution, disposal, acquisition, use or consumption of any essential commodity; and for prohibiting the withholding from sale of any essential commodity ordinarily kept for sale. Any person holding in stock, or engaged in the production, or in the business of buying or selling of any essential commodity may be required - (i) to sell the whole or a specified part of the quantity held in stock or produced or received by him, or (ii) in the case of any such commodity which is likely to be produced or received by him, to sell the whole or a specified part of such commodity when produced or received by him to the central government or a state government or to an officer or agent of such government or to a corporation owned or controlled by such government or to such other person or class of persons and in such circumstances as may be specified in the order.

The central government can also issue orders for regulating or prohibiting any class of commercial or financial transactions relating to foodstuffs or cotton textiles which are likely to be detrimental to the public interest. Orders can be issued for collecting any information or statistics with a view to regulating or prohibiting any of the aforesaid matters. Any person engaged in the production, supply or distribution of or trade and commerce in any essential commodity can be required to maintain and produce for inspection such books, accounts and records relating to their business and to furnish such information relating thereto, as may be specified in the order. Orders can be issued for the grant or issue of licences, permits or other documents, the charging of fees, deposit of security, the forfeiture of the sum so deposited or any part thereof for contravention of any conditions, and the adjudication about any such matter.

powers of the central government under section 3 of the Act even extend to issuing of orders for any incidental and supplementary matters, including, in particular, the entry, search or examination of premises, aircraft, vessels, vehicles or other conveyances and animals, and seizure by a person authorized to make such entry, search or examination: (i) of any articles in respect of which such person has reason to believe that a contravention of the order has been, is being, or is about to be, committed and any packages, coverings or receptacles in which such articles are found; (ii) of any aircraft, vessel, vehicle or other conveyance or animal used in carrying such articles, if such person has reasons to believe that such aircraft, vessel, vehicle or other conveyance or animal is liable to be forfeited under the provisions of this Act; or (iii) of any books of accounts and documents which in the opinion of such person, may be useful for, or relevant to, any proceeding under this Act and the person from whose custody such books of accounts or documents are seized shall be entitled to make copies thereof or to take extracts therefrom in the presence of an officer having the custody of such books of accounts or documents.

Any person required to sell to the central government or a state government or to any of its officers or agents or a corporation, any grade or variety of food grains, edible oilseeds or edible oils in the absence of a notification having been issued or having been issued, has ceased to be in force, should be paid an amount equal to the procurement price of such commodity. In this respect, consideration should be given to - (a) the controlled price, if any, fixed for commodity; (b) the general crop prospects; (c) the need for making such grade or variety of food grains, edible oilseeds or edible oils available at reasonable prices to the consumers, particularly the vulnerable sections of the consumers; and (d) the recommendations, if any of the Agricultural Prices Commission with regard to the price of the concerned grade or variety of food grains, edible oilseeds or edible oils. Any producer, required to sell any kind of sugar in the absence of the required notification as aforesaid, is to be paid an amount, having regard to: (a) the minimum price, if any, fixed for sugarcane by central government; (b) the manufacturing cost of sugar; (c) the duty or tax, if any, paid or payable thereon; and (d) the securing of a reasonable return on the capital employed in the business of manufacturing sugar. Different prices may be determined from time to time for different areas or for different factories or for different kinds of sugar.

Confiscation of Essential Commodities

Procedure Whenever an essential commodity is seized in pursuance of an order made under section 3 a report of such seizure should be made to the collector concerned without unreasonable delay.¹⁷ Where such orders have been contravened, then irrespective of initiation, collector can direct that such a commodity may be produced for inspection before him, and if satisfied that there has been a contravention, he may order confiscation of such essential commodity; any package, covering or receptacle in which such essential commodity is found ; and any animal, vehicle, vessel or other conveyance used in carrying such essential commodity.¹⁸ However, no foodgrains or edible oil seeds can be confiscated under this section in pursuance of an order made under section 3 from a producer, if the seized foodgrains or edible oilseeds have been produced by him.¹⁹ In case any animal, vehicle, vessel or other conveyance

used for the carriage of goods or passengers for hire, the owner of such animal, vehicle, vessel or other conveyance shall be given an option to pay, in lieu of its confiscation, a fine not exceeding the market price at the date of seizure of the essential commodity sought to be carried by such animal, vehicle, vessel or other conveyance.

Appeal against confiscation order If any person is aggrieved by an order of confiscation he can, within one month from the date of the communication to him of such order, appeal to any judicial authority appointed by the state government concerned. Such a judicial authority can, after giving an opportunity to the appellant to be heard, confirm, modify or annul the order appealed against, as it may deem proper.

Penalties for Contravention of Orders Section 7 of the Act deals with penalties and prescribes punishments for contravention of various kinds of orders and directions. Punishment for contravention of an order made with reference to section 2(h)(i) regarding collection of information, and producing for inspection books, accounts, records etc. is imprisonment for a term which may extend to one year and fine. In the case of any other order, the punishment is imprisonment for a term not less than three months but which may extend to seven years and shall also be liable to fine. However, for any adequate and special reasons to be mentioned in the judgment, imprisonment for a term of less than three months may be awarded.

Recovery of Payments on Default;

If any amount becomes due from a person in pursuance of an order made under section 3, or is required to deposit any amount to the credit of any account or fund constituted by or in pursuance of any order made under that section, but such person makes any default in paying or depositing the whole or any part of such amount, the amount will be recoverable by the government together with simple interest at the rate of fifteen per cent per annum as arrears of land revenue or as a public demand.

Summary Trials the central government;

can, in the interests of production, supply or distribution of any essential commodity or trade or commerce therein and other relevant considerations, direct by notification that the contravention of any order under section 3 in relation to an essential commodity be tried summarily. Every such notification is to be laid before both Houses of Parliament.

Judicial Scrutiny of the Regulations;

As section 3 of the Act gives very wide powers to the central government, many cases have come before courts to find out whether these powers have been used fairly. For example, in *Reghu Seeds and Farm v. Union of India*?* while considering the validity of the Seeds (Control) Order, 1983, the court held that it is very much within the competence of central government.

UNIT IX

**DRUG PRICE CONTROL ORDER AND NATIONAL
DRUG POLICY (CURRENT).**

in exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order, namely:-

1. Short title and commencement :

(1) This Order may be called the Drugs (Prices Control) Order, 1995

(2) It shall come into force on the date of its publication in the Official Gazette.

2. Definitions :

In this Order, unless the context otherwise requires, - (a) "bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation; (b) "capital employed" means net fixed assets plus working capital of a manufacturer in relation to manufacture of bulk drugs; (c) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph 9; (d) "dealer" means a person on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business and includes his agent; (e) "distributor" means a distributor of drugs or his agent or a stockist appointed by a manufacturer or an importer for stocking his drugs for sale to a dealer; (f) "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, intended to affect the structure or any function of the human or animal 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 Government by notification in the official Gazette; and (iii) bulk drugs and formulations; (g) "Form" means a form specified in the Second Schedule; (h) "formulation" means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or

prevention of disease in human beings or and, but shall not include - (i) any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines. (ii) any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply; (i) "free reserve" means a reserve created by appropriation of profits, but does not include reserves provided for contingent disputed claims, goodwill, revaluation and other similar reserves; (j) "Government" means the Central Government; (k) "import" with its grammatical variations and cognate expressions means bringing into India from a place outside India, and "importer", in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer; (kk) "local taxes" means any tax or levy (except excise duty included in retail price) paid and/or payable to the Central Government or State Government or any local authority under any law by the manufacturer or his agent or dealer; (l) "manufacture" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly; (m) "manufacturer" means any person who manufactures a drug; (n) "net-worth" means the paid-up share capital of a company plus free reserve, if any, and surpluses excluding outside investments which are not readily available for operational activity; (o) "non-Scheduled bulk drug" means a bulk drug not specified in the First Schedule; (p) "non-Scheduled formulation" means a formulation not containing any bulk drug specified in the First Schedule; (q) "pre-tax return" means profits before payment of Income-tax and surtax and includes such other expenses as do not form part of the cost of formulation; (r) "price list" means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list; (s) "retail price" means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price; (t) "retailer" means a dealer carrying on the retail business of sale of drugs to customers; (u) "Scheduled bulk drug" means a bulk drug specified in the First Schedule; (v) "Scheduled formulation" means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name; (w) • "sale turn-over" means the product of units of formulations sold by a manufacturer or an importer, as the case

may be, in an accounting year multiplied retail price inclusive of sales tax, if any, paid or direct sales by the manufacturer or importer but does not include excise duty and local taxes, if any; (x) "Schedule" means a Schedule annexed to this Order; (y) "wholesaler" means a dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities of drugs.

3. Power to fix the maximum sale prices of bulk drugs specified in the First Schedule :

1. The Government may, with a view to regulate the equitable distribution and increasing supplies of a bulk drug specified in the First Schedule and making it available at a fair price, from different manufacturers, after making such inquiry as it deems fit, fix from time to time, by notification in the Official Gazette, a maximum sale price at which such bulk drug shall be sold: Provided that for the purpose of enquiry, in addition to the information required to be furnished by the manufacturers under this Order, the manufacturers shall provide any such additional information as may be required by the Government, and shall allow for inspection of their manufacturing premises for verification through on the spot study of manufacturing processes and facilities and records thereof, by the Government. 2. While fixing the maximum sale price of a bulk drug under subparagraph (1), the Government shall take into consideration a post-tax return of fourteen per cent on net worth or a return of twenty-two percent on capital employed or in respect, of a new plant an internal rate of return of twelve percent based on long term marginal costing depending upon the option for any of the specified rates of return that may be exercised by the manufacturer of a bulk drug: Provided that where the production is from basic stage, the Government shall take into consideration a post-tax return of eighteen percent on net worth or a return of twenty-six percent on capital employed : Provided further that the option with regard to the rate of return once exercised by a manufacturer shall be final and no change of rates shall be made without the prior approval of the Government. 3. No person shall sell a bulk drug at a price exceeding the maximum sale price fixed under sub-paragraph (1) plus local taxes, if any: Provided that until the price of a bulk drug is fixed, by the Government under sub-paragraph (1), the price of such bulk drug shall be the price which prevailed immediately before the commencement of this Order and the manufacturer of such bulk drug shall not sell the bulk drug at a price exceeding the price prevailing immediately before the commencement of this Order. 4. Where, after the commencement of this Order, any manufacturer commences Production of any

bulk drug specified in the First Schedule, he shall within fifteen days of the commencement of production of such bulk drug, furnish the details to the Government in Form I, and any such additional information as may be required by the Government and the Government may after receipt of the information and after making such inquiry as it may deem fit, may fix the maximum sale price of bulk drug by notification in the Official Gazette. 5. Any manufacturer, who desires revision of the maximum sale price of a bulk drug fixed under sub-paragraph (1) or (4) or as permissible under sub-paragraph (3), as the case may be, shall make an application to the Government in Form 1, and the Government shall after making such enquiry, as it deems fit within a period of four months from the date of receipt of the complete information, fix a revised price for such bulk drug or reject the application for revision for reasons to be recorded in writing.

4. Information to be furnished by the manufacturer in relation to the Scheduled bulk drugs

Every manufacturer, producing a Scheduled bulk drug shall furnish to the Government : (a) a list of all Scheduled bulk drugs produced by him within days of the commencement of this Order and indicate the details of the cost of each of such bulk drug in Form I; (b) the details of the cost of each Scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form I by the 30th September, every year.

5. Information to be furnished by the manufacturer in relation to the non-Scheduled bulk drugs :

Every manufacturer, producing a non-Scheduled bulk drug shall furnish to the Government : (a) a list of all such bulk drugs produced by him within thirty days of the commencement of this Order and indicate the details of the cost of each of such bulk drugs in Form II; (b) the details of the cost of each non-Scheduled bulk drug produced by him, including such bulk drug which has been produced after the commencement of this Order, in Form II: Provided that, for the purpose of this paragraph, the Government, may after making such inquiry as it may deem necessary in public interest, fix or revise the price of any non-Scheduled bulk drug and the manufacturer or importer of such bulk drug shall give effect to the price so fixed or revised, within fifteen days of receipt of the order and not sell such non-scheduled bulk drug at a price exceeding the price so fixed or revised thereafter.

6. Power to direct manufacturers of bulk drugs to sell bulk drugs to other manufacturers of formulations :

1. With a view to achieving adequate production and regulating the equitable distribution, the Government may, from time to time, by general or special order, direct any manufacturer of any bulk drug to sell such bulk drug to such other manufacturers of formulations as may be specified in such order: Provided that while making any such order, the Government shall have regard to all or any of the following factors, namely: - (i) the requirement for captive consumption of such manufacturer, and; (ii) the requirement of other manufacturers. 2. For the purpose of making any order under sub-paragraph (1), the Government may call for such information from manufacturer, importer or distributor, of bulk drugs, as it may consider necessary and such manufacturer, importer or distributor shall be bound to furnish such information within such time as may be specified by the Government.

7. Calculation of retail price of formulation :

The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely: $R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + ED$. where "R.P." means retail price; "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf; "C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf; "P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations; "E.D." means excise duty: Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price alongwith such margin to cover selling and distribution expenses including interest and importer's profit which shall not

exceed fifty percent of the landed cost. Explanation - For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

8. Power to fix retail price of Scheduled Formulations:

1. The Government may, from time to time, by order, fix the retail price of a Scheduled formulation in accordance with the formula laid down in paragraph 7. 2. Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilises such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation. 3. The retail price of a formulation once fixed by the Government under (1) and (2) shall not be increased by any manufacturer the prior approval of the Government. 4. Any manufacturer, who desires revision of the retail price of a formulation fixed under sub-paragraph (1), shall make an application to the, Government in Form III or Form IV, as the case maybe, and the Government shall after making such enquiry, as it deems fit within a period of two months from the date of receipt of the complete information, fix a revised price for such formulation or reject the application for revision for reasons to be recorded in writing. 5. Notwithstanding anything contained in the foregoing sub-paragraphs, the retail price of a Scheduled formulation, of a manufacturer shall until the retail price thereof is fixed under the provisions of this Order, be the price which prevailed immediately before the commencement of this Order, and the manufacturer of such formulation shall not sell the formulation at a price exceeding the price prevailing immediately before the commencement of this Order. 6. No manufacturer or importer shall market a new pack, if not covered under sub-paragraph 3 of para 9, or a new formulation or a new dosage form of his existing Scheduled formulation without obtaining the prior approval of its price from the Government. 7. No person shall sell or dispose of any imported Scheduled formulation without obtaining the prior approval of its price from the Government.

9. Power to fix ceiling price of Scheduled formulations :

1. Notwithstanding anything contained in this Order, the Government may, from time to time, by notification in the Official Gazette, fix the ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale

price for all such packs including those sold under generic name and for every manufacturer of such formulations. 2. The Government may, either on its own motion or on application made to it in this behalf by a manufacturer in Form III or Form IV, as the case may be, after calling for such information as it may consider necessary, by notification in the Official Gazette, fix a revised ceiling price for a Scheduled formulation. 3. With a view to enabling the manufacturers of similar formulations to sell those formulations in pack size different to the pack size for which ceiling price has been notified under the sub-paragraphs (1) and (2), manufacturers shall work out the price for their respective formulation packs in accordance with such norms, as may be notified by the Government from time to time, and he shall intimate the price of formulation pack, so worked out, to the Government and such formulation packs shall be released for sale only after the expiry of sixty days after such intimation: Provided that the Government may, if it considers necessary, by order revise the price so intimated by the manufacturer and upon such revision, the manufacturer shall not sell such formulation at a price exceeding the price so revised. Explanation - For the purpose of this paragraph the "Scheduled formulation" includes single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name.

10. Power to revise price of bulk drugs and formulations :

Notwithstanding anything contained in this order : (a) the Government may, after obtaining such information as may be considered necessary from a manufacturer or importer, fix or revise the retail price of one or more formulations marketed by such manufacturer or importer, including a non-Scheduled formulation, in such manner as the pre-tax return on the sales turnover of such manufacturer or importer does not exceed the maximum pre-tax return specified in the Third Schedule; (b) the Government may, if it considers necessary so to do in public interest, after calling for such information by order fix or revise the retail price of any formulation including a nonScheduled formulation; (c) the Government may, if it considers necessary so to do in public interest, by order include any bulk drug in the First Schedule and fix or revise the prices of such a bulk drug and formulations containing such a bulk drug in accordance with the provisions of paragraphs 3, 7, 8 and 9, as the case may be.

11. Fixation of price under certain circumstances :

Where any manufacturer, importer of a bulk drug or formulation falls to submit the application for price fixation or revision, as the case, may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be.

12. Power to recover dues accrued under the Drugs (Prices Control) Order, 1979 and to deposit the same into the Drugs Prices Equalisation Account :

1. Notwithstanding anything contained in this Order, the Government may by notice, require the manufacturer, importer or distributor, as the case maybe, to deposit the amount which has accrued under the provisions of the drugs (Prices Control) Order, 1979 on or before the commencement of this Order, into the Drugs Prices Equalisation Account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount into the said Account within such time as the Government may specify in the said notice. 2. The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this Order, and the amount deposited under sub-paragraph (1) shall be utilised for : (a) paying to the manufacturer, importer or distributor, as the case may be, the shortfall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs; (b) meeting the expenses incurred by the Government in discharging the functions under this paragraph; and (c) promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes incidental thereto.

13. Power to recover Overcharged Amount :

Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importers or distributors, as the case maybe, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and under the provisions of this Order.

14. Carrying into effect the price fixed or revised by the Government, its display and proof there of :

1. Every manufacturer or importer shall carry into effect the price of a bulk drug or formulation, as the case may be, as fixed by the Government from time to time, within fifteen days from the date of notification in the Official Gazette or receipt of the order of the Government in this behalf by such manufacturer or importer. 2. Every manufacturer, importer or distributor of a formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the retail price of that formulation, notified in the Official Gazette or ordered by the Government in this behalf, with the words 'retail price not to exceed' preceding it, and "local taxes extra" succeeding it, in the case of Scheduled formulations. Provided that in the case of a container consisting of smaller saleable packs, the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the prorata retail price of the main pack rounded off to the nearest paisa. 3. Every manufacturer or importer shall issue a price list and supplementary price list, if required, in Form V to the dealers, State Drugs Controllers and the Government indicating reference to such price taxation or revision as covered by the order or Gazette notification issued by the Government, from time to time. 4. Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

15. Display of prices of non-Scheduled formulations and price list thereof :

1. Every manufacturer, importer or distributor of a non-Scheduled formulation intended for sale shall display in intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the retail price of that formulation with the words "retail price not to exceed" preceding it "local taxes extra" succeeding it, and the words "Not under Price Control" on a green strip: Provided that in the case of a container consisting of smaller saleable packs, the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the prorata retail price of the main pack rounded off to the nearest paisa. 2. Every manufacturer or importer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations in Form V to the dealers, State Drugs Controllers and the Government indicating changes, from time to time. 3. Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous

part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

16. Control of sale prices of bulk drugs and formulations:

No person shall sell any bulk drug or formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less, plus all local taxes, if any, payable.

17. Sale of split quantities of formulations :

No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation plus 5 percent thereof.

18. Manufacturer, distributor or dealer not to refuse sale of drug :

Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the Rules framed thereunder - (a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons; (b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

19. Price of formulations sold to the dealer :

1. A manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this Order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in the case of Scheduled drugs. 2.

Notwithstanding anything contained in sub-paragraph (1), the Government may by a general or special order fix, in public interest, the price of formulation sold to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order.

20. Maintenance of records and production thereof for inspection

1. Every manufacturer and importer shall maintain in such form as may be specified by the Government, records relating to the sales turnover of individual bulk drugs manufactured or imported by him, as the case may be, and the sales turnover of formulations pack-wise and also such other records as may be directed from time to time by the Government and the Government

shall have the power to call for such records or to inspect such records at the premises of the manufacturer or importer. 2. Every manufacturer or importer shall, within six months of the close of the accounting Year, submit to the Government information in respect of turnover and allocation of sales and expenses for that year in Form VI. 3. Every dealer, manufacturer or importer shall maintain the cash memo or credit memo, books of account and records of purchase and sale of drugs and shall make available such records for inspection by the

UNIT X

PREVENTION OF CRUELTY TO ANIMALS ACT -1960

To prevent the infliction of unnecessary pain or suffering on animals and for that purpose to amend the law relating to the prevention of cruelty to animals. Be it enacted by Parliament in the Eleventh year of the Republic of India as follows:

1. Short title, extent and commencement:

(1) This Act may be called the Prevention of Cruelty to Animals Act, 1960. (2) It extends to the whole of India except the State of Jammu and Kashmir. , (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 States and for

.2.Definitions:

In this Act, unless the context otherwise. requires, (a) "animal" means any living creature other than a human being, 1 [(b) "Board" means the Board established under Section 4. and as reconstituted from time to time under Section 5A] (c) "captive animal" means any animal (not being a domestic animal) which is in captivity or confinement, whether permanent or temporary, or which is subjected to any appliance of contrivance for the purpose of hindering or preventing its escape from captivity or confinement or which is pinioned or which is or appears to be maimed; (d) "domestic animal" means any animal which is tamed or which has been or is being sufficiently tamed to serve some purpose for the use of man or which, although it neither has been nor is intended to be so tamed, is or has become in fact wholly or partly tamed-, (e) "local authority" means a municipal committee, district board or other authority for the time being invested by law with the control and administration of any matters within a specified local area;

(f) "owner", used with reference to an animal, includes not only the owner but also any other person for the time being in possession or custody of the animal, whether with or without the consent of the owner. (g) "phooka" or "doom dev" includes any process of introducing air or any substance into the female organ of a milch animal with the object of drawing off from the animal any secretion of milk; (h) "prescribed" means prescribed by Rules made under this Act; (i) "street" includes any way, road, lane, square, court, alley, passage or open space, whether a thoroughfare or not to which the public have access.

3. Duties of persons having charge of animals:

It shall be the duty of every person having the care or charge of any animal to take all reasonable measures to ensure the well-being of such animal and to prevent the infliction upon such animal of unnecessary pain or suffering.

4. Establishment of Animal Welfare Board of India:

(1) For the promotion of animal welfare generally and for the purpose of protecting animals from being subjected to unnecessary pain or suffering, in particular, there shall be established by the Central Government, as soon as may be after the commencement of this Act, a Board to be called the 3 (Animal Board of India.) (2) The Board, shall be a body corporate having perpetual succession and a common seal with power, subject to the provisions of this Act, to acquire, hold and dispose of property and may by its name sue and be sued.

5. Constitution of the Board :

(1) The Board shall consist of the following persons, namely: (a) the Inspector General of Forests, Government of India, ex-officio, (b) the Animal Husbandry Commissioner to the Government of India, ex-officio; 4 (ba) two persons to represent respectively the Ministries of the Central Government dealing with Home Aff airs and Education, to be appointed by the Central Government; (bb) one person to represent the Indian Board for Wild Life, to be appointed by the Central Government; (bc) three persons who, in the opinion of the Central Government, are or have been actively engaged in animal welfare work and are well-known humanitarians, to be nominated by the Central Government;) (c) one person to represent such association of veterinary practitioners as in the opinion of the Central Government ought to be represented on the Board, to be elected by that association in the prescribed manner; (d) two

persons to represent practitioners of modern and indigenous systems of medicine, to be nominated by the Central Government; 5 [(e) one person to represent each of such two municipal corporations as in the opinion of the Central Government ought to be represented on the Board, to be elected by each of the said corporations in the prescribed manner (f) one person to represent each of such three organisations actively interested in animal welfare as in the opinion of the Central Government ought to be represented on the Board, to be chosen by each of the said organisations in the prescribed manner; (g) one person to represent each of such three societies dealing with prevention of cruelty to animal as in the opinion of the Central Government ought to be represented on the Board, to be chosen, in the prescribed manner; (h) three persons to be nominated by the Central Government, (i) six Members of Parliament, four to be elected by the House of the People (Lok Sabha) and two by the Council of States (Rajya Sabha). (2) Any of the persons referred to in clause 9a) or 6 [clause (b) or clause (ba) or clause (bb) of sub-section (1) may depute any other person to attend any of the meetings of the Board. 7 [(3) The Central Government shall nominate one of the members of the Board to be its Chairman and another member of the Board to be its Vice-Chairman.)

5A. Reconstitution of the Board :

(1) In order that the Chairman and other members of the Board hold office till the same date and that their terms of office come to an end on the same date, the Central Government may, by notification in the Official Gazette, reconstitute, as soon as may be after the Prevention of Cruelty to Animals (Amendment) Act, 1982 comes into force, the Board. (2) The Board as reconstituted under sub-section (1) shall be reconstituted from time to time on the expiration of every third year, from the date of its reconstitution under sub-section (1). (3) There shall be included amongst the members of the Board reconstituted under sub-section (1), all persons who immediately before the date on which such reconstitution is to take effect, are Members of the Board but such persons shall hold office only for the unexpired portion of the term for which they would have held office if such reconstitution had not been made and the vacancies arising as a result of their ceasing to be Members of the Board shall be filled up as casual vacancies for the remaining period of the term of the Board as so reconstituted: Provided that nothing in this sub-section shall apply in relation to any person who ceases to be member of the Board by virtue of the amendment made in sub-section (1) of section 5 by sub-clause (ii) of clause (a) of section 5 of the Prevention of Cruelty to Animals (Amendment) Act, 1982). 9

6. Term of office and conditions of service of Members of the Board :

(1) The term for which the Board may be reconstituted under section 5A shall be three years from the date of the reconstitution and the Chairman and other Members of the Board as so reconstituted shall hold office till the expiry of the term for which the Board has been so reconstituted. (2) Notwithstanding anything contained in sub-section (1): (a) the term of office of an ex-officio Member shall continue so long as he holds the office by virtue of which he is such a Member; (b) the term of office of a Member elected or chosen under clause (c), clause (e), clause (g), clause (h) or clause (i) of section 5 to represent anybody of persons shall come to an end as soon as he ceases to be a Member of the body which elected him or in respect of which he was chosen; (c) the term of office of a Member appointed, nominated, elected or chosen to fill a casual vacancy shall continue for the remainder of the term of office of the Member in whose place he is appointed, nominated, elected or chosen; (d) the Central Government may, at any time, remove for reasons to be recorded in writing a member from office after giving him a reasonable opportunity of showing cause against the proposed removal and any vacancy caused by such removal shall be treated as casual vacancy for the purpose of clause (c). (3) 'The members of the Board shall receive such allowance, if any, as the Board may, subject to the previous approval of the Central Government, provided by regulations made in this behalf, (4) No act done or proceeding taken by the Board shall be questioned on the ground merely of the existence of any vacancy in, or defect in the constitution of the Board and in particular, and without prejudice to the generality of the foregoing, during the period intervening between the expiry of the term for which the Board has been reconstituted under section 5A and its further reconstitution under that section, the ex-officio members of the Board shall discharge all the powers and function of the Board.)

7. Secretary and other employees of the Board :

(1) The Central Government shall appoint 10xxxxx the Secretary of the Board. (2) Subject to such rules as may be made by the Central Government in this behalf, the Board may appoint such number of other officers and employees as may be necessary for the exercise of its powers and the discharge of its functions and may determine the terms and conditions of service of such officers and other employees by regulations made by it with the previous approval of the Central Government.

8. Funds of the Board :

The funds of the Board shall consist of grants made to it from time to time by the Government and of contributions, subscriptions, bequests, gifts and the like made to it by any local authority or by any other person.

9. Functions of the Board :

The functions of the Board shall be Board (a) to keep the law in force in, India for the prevention of cruelty to animals under constant study and advise the Government on the amendments to be undertaken in any such law from time to time; (b) to advise the Central Government on the making of rules under this Act with a view to preventing unnecessary pain or suffering to animals generally, and more particularly when they are being transported from one place to another or when they are used as performing animals or when they are kept in captivity or confinement; (c) to advise the Government or any local authority or other person on improvements in the design of vehicles so as to lessen the burden on draught animals; (d) to take all such steps as the Board may think fit for 11(amelioration of animals) by encouraging or providing for, the construction of sheds, water-troughs and the like and by providing for veterinary assistance to animals: (e) to advise the Government or any local authority or other person in the design of slaughter-houses or the maintenance of slaughter houses or in connection with slaughter of animals so that unnecessary pain or suffering, whether physical or mental, is eliminated in the pre-slaughter stages as far as possible, and animals are killed; wherever necessary, in as humane a manner as possible; (f) to take all such steps as the Board may think fit to ensure that unwanted animals are destroyed by local authorities, whenever it is necessary to do so, either instantaneously or after being rendered insensible to pain or suffering. (g) to encourage by the grant of financial assistance or otherwise, 12(the formation or establishment of pinjrapoles, rescue homes, animal shelters, sanctuaries and the like) where animals and birds may find a shelter when they have become old and useless or when they need protection: (h) to co-operate with, and co-ordinate the work of, associations or bodies established for the purpose of preventing unnecessary pain or suffering to animals or for the protection of animals and birds; (i) to give financial and other assistance to animal welfare organisations functioning in any local area or to encourage the formation of animal welfare organisations in any local area which shall work under the general supervision and guidance of the Board; (j) to advise the Government on matters relating to the medical care and attention which may be provided in animal hospital, and

to give financial and other assistance to animal hospitals whenever the Board thinks it necessary to do so; (k) to impart education in relation to the humane treatment of animals and to encourage the formation of public opinion against the infliction of unnecessary pain or suffering to animals and for the promotion of animal welfare by means of lectures, books, posters, cinematographic exhibitions and the like; (l) to advise the Government on any matter connected with animal welfare or the prevention of infliction of unnecessary pain or suffering on animals.

10. Power of Board to make regulations:

The Board may, subject to the previous approval of the Central Government, make such regulations as it may think fit for the administration of its affairs and for carrying out its functions.

11. Treating animals cruelly :

(1) If any person (a) beats, kicks, over-rides, over-drives, over-loads, tortures or otherwise treats any animal so as to subject it to unnecessary pain or suffering or causes, or being the owner permits, any animal to be so treated; or (b) employs in any work or labour or for any purpose any animal which, by reason of its age or any disease) infirmity; wound, sore or other cause, is unfit to be so employed or, being the owner, permits any such unfit animal to be employed; or (c) wilfully and unreasonably administers any injurious drug or injurious substance to 14(any animal) or wilfully and unreasonably causes or attempts to cause any such drug or substance to be taken by 15(any animal;) or (d) conveys or carries, whether in or upon any vehicle or not, any animal in such a manner or position as to subject it to unnecessary pain or suffering; or (e) keeps or confines any animal in any -cage or other receptacle which does not measure sufficiently in height, length and breadth to permit the animal a reasonable opportunity for movement; or f) keeps for an unreasonable time any animal chained or tethered upon an unreasonably short or unreasonably heavy chain or cord; or (g) being the owner, neglects to exercise or cause to be exercised reasonably any dog habitually chained up or kept in close confinement; or (h) being the owner of (any animal) fails to provide such animal with sufficient food, drink or shelter; or (i) without reasonable cause, abandons any animal in circumstances which tender it likely that it will suffer pain by reason of starvation thirst; or (j) wilfully permits any animal, of which he is the owner, to go at large in any street, while the animal is affected with contagious or infectious disease or, without reasonable excuse permits any diseased or disabled animal, of which he is the

owner, to die in any street; or (k) offers for sale or without reasonable cause, has in his possession any animal which is suffering pain by reason of mutilation, starvation, thirst, overcrowding or other ill-treatment; or 16{(1) mutilates any animal or kills any animal (including stray dogs) by using the method of strychnine injections, in the heart or in any other unnecessarily cruel manner or;} 17{(m) solely with a view to providing entertainment (i) confines or causes to be confined any animal (including tying of an animal as a bait in a tiger or other sanctuary) so as to make it an object or prey for any other animal; or (n) 18[xxxx] organises, keeps uses or acts in the management or, any place for animal fighting or for the purpose of baiting any animal or permits or offers any place to be so used or receives money for the admission of any other person to any place kept or used for any such purposes; or (o) promotes or takes part in any shooting match or competition wherein animals are released from captivity for the purpose of such shooting: he shall be punishable 19(in the case of a first offence, with fine which shall not be less than ten rupees but which may extend to fifty rupees and in the case of a second or subsequent offence committed within three years of the previous offence, with fine which shall not be less than twenty-five rupees but which may extend, to one hundred rupees or with imprisonment for a term which may extend, to three months, or with both.) (2) For the purposes of section (1) an owner shall be deemed to have committed an offence if he has failed to exercise reasonable care and supervision with a view to the prevention of such offence; Provided that where an owner is convicted permitting cruelty by reason only of having failed to exercise such care and supervision, he shall not be liable to imprisonment without the option of a fine. (3) Nothing in this section shall apply to - (a) the dehorning of cattle, or the castration or branding or noseroping of any animal in the prescribed manner, or (b) the destruction of stray dogs in lethal chambers 20[by such other methods as may be prescribed] or (c) the extermination or destruction of any animal under the authority of any law for the time being in force; or (d) any matter dealt with in Chapter IV; or (e) the commission or omission of any act in the course of the destruction or the preparation for destruction of any animal as food for mankind unless such destruction or preparation was accompanied by the infliction of unnecessary pain or suffering.

12. Penalty for practising phooka or doom dev :

If any persons upon any cow or other milch animal the operation called practising phooka or 21[doom dev or any other operation (including injection of any or doom dev. substance) to improve lactation which is injurious to the health of the animal] or permits such operation being

performed upon any such animal in his possession or under his control, he shall be punishable with fine which may extend to one thousand rupees, or with imprisonment for a term which may extend to two years, or with both, and the animal on which the operation was performed shall be forfeited to the Government.

13. 'Destruction of suffering animals':

(1) Where the owner of an animal is convicted of an offence under section 11, it shall be lawful for the court, if the court is satisfied that it would be cruel to keep the animal alive, to direct that the animal be destroyed and to assign the animals to any suitable person for that purpose, and the person to whom such animal is so assigned shall as soon as possible, destroy such animal or cause such animal to be destroyed in his presence without unnecessary suffering: and any reasonable expense incurred in destroying the animal may be ordered by the court, if the court is satisfied that it would be cruel to keep the animal alive, to direct that the animal be destroyed and to assign the animal to any reasonable expense incurred in destroying the animal may be ordered by the court to be recovered from the owner.

UNIT XI

PATENTS AND DESIGN ACT -1970

PATENTS AND DESIGN ACT

(1) This Act may be called the Patents Act, 1970.

(2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint: PROVIDED that different dates may be appointed for different provisions of this Act, and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision. 2. Definitions and interpretation (1) In this Act, unless the context otherwise requires,— 1[(a) "Appellate Board" means the Appellate Board referred to in section 116; (ab) "assignee" includes an assignee of the assignee and the legal representative of a deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person;

2[(aba) "Budapest Treaty" means the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure done at Budapest on 28th day of April, 1977, as amended and modified from time to time;] (ac) "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry;] (b) "Controller" means the Controller-General of Patents, Designs and Trade Marks referred to in section 73; (c) "convention application" means an application for a patent made by virtue of section 135; 1[(d) "convention country" means a country or a country which is member of a group of countries or a union of countries or an Inter-governmental organisation preferred to as a convention country in section 133;] (e) "district court" has the meaning assigned to that expression by the CPC, 1908; (f) "exclusive licence" means a licence from a patentee which confers on the licensee, or on the licensee and persons authorised by him, to the exclusion of 1 Substituted by Patents (Amdt.) Act, 2002, w.e.f. 20-5-2003 vide S.O. 561(E), dt. 20-5-2003. 2 Inserted by the Patents (Amdt.) Act, 2005, w.e.f. 1-1-2005. 3 Substituted for "notified as such under sub-section (1) of section 133" by the Patents (Amdt.) Act, 2005, w.e.f. 1-1-2005. 2 THE PATENTS ACT, 1970 SECTION 2 all other persons (including the patentee), any right in respect of the patented invention, and "exclusive licensee" shall be construed accordingly; (g) [Clause (g) omitted by the Patents (Amdt.) Act, 2005, w.e.f. 1-1-2005] (h) "government undertaking" means any industrial undertaking carried on— (i) by a department of the government; or (ii) by a corporation established by a Central, Provincial or State Act, which is owned or controlled by the government; or (iii) by a government company as defined in section 617 of the Companies Act, 1956(1 of 1956) 1 [;or] 1[(iv) by an institution wholly or substantially financed by the Government;] [Certain words omitted by the Patents (Amdt.) Act, 2005, w.e.f. 1-1-2005] 2[(i) "High Court", in relation to a State or Union territory, means the High Court having territorial jurisdiction in that State or Union territory, as the case may be;] 3[(ia) "international application" means an application for patent made in accordance with the Patent Cooperation Treaty;] 4[(j) "invention" means a new product or process involving an inventive step and capable of industrial application; 2 [(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;] (k) "legal representative" means a person who in law represents the estate of a deceased person; 2 [(1) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world

before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art; (m) "patent" means a patent for any invention granted under this Act;] 1 [(ia) "pharmaceutical substance" means any new entity involving one or more inventive steps;] 2 [(la) "Opposition Board" means an Opposition Board constituted under sub-section (4) of section 25;] (n) "patent agent" means a person for the time being registered under this Act as a patent agent; (o) "patented article" and "patented process" mean respectively an article or process in respect of which a patent is in force; 3 [(oa) "Patent Co-operation Treaty" means the Patent Cooperation Treaty done at Washington on the 19th day of June, 1970 as amended and modified from time to time;] 1

Inserted by Patents (Amdt.) Act, 2005, w.e.f. 1-1-2005. 2 Substituted, *ibid.* 3 Inserted by Patents (Amdt.) Act, 2002, w.e.f. 20-5-2003 vide SO 561(E), dt. 20-5-2003. 4 Substituted, *ibid.*

SECTION 2 THE PATENTS ACT, 1970 3 (p) "patentee" means the person for the time being entered on the register as the grantee or proprietor of the patent; (q) "patent of addition" means a patent granted in accordance with section 54; (r) "patent office" means the patent office referred to in section 74; (s) "person" includes the government; (t) "person interested" includes a person engaged in, or in promoting, research in the same field as that to which the invention relates; 1 [(u) "prescribed" means,— (A) in relation to proceedings before a High Court, prescribed by rules made by the High Court; (B) in relation to proceedings before the Appellate Board, prescribed by rules made by the Appellate Board; and (C) in other cases, prescribed by rules made under this Act;] (v) "prescribed manner" includes the payment of the prescribed fee; (w) "priority date" has the meaning assigned to it by section 11; (x) "register" means the register of patents referred to in section 67; (y) "true and first inventor" does not include either the first importer of an invention into India, or a person to whom an invention is first communicated from outside India. (2) In this Act, unless the context otherwise requires, any reference— (a) to the Controller shall be construed as including a reference to any officer discharging the functions of the Controller in pursuance of section 73; (b) to the patent office shall be construed as including a reference to any branch office of the patent office. COMMENTS Appellate Board Section 116 of the Act provides that the Appellate Board established under section 83 of the Trade Marks Act, 1999 shall be the Appellate Board for the purposes of the Act and the said Appellate Board shall exercise the jurisdiction, power and authority conferred on it by or under the Act. Section 83 of the Trade Marks Act, 1999 provides that the Central Government shall, by notification in the Official Gazette, establish an Appellate Board to be known as the Intellectual Property

Appellate Board to exercise the jurisdiction, powers and authority conferred on it by or under that Act. The provisions for composition of the said Board are contained in section 84 of the said Act. Assignee Assignment is the act of transferring to another all or part of one's property, interest or rights. It is a transfer or making over to another of the whole of any property, real or personal, in possession or in action, or of any estate or right therein. It includes transfers of all kinds of property, including negotiable instruments. In other words, it is the transfer by a party of all the rights to some kind of property, usually intangible property such as rights in a lease, mortgage, agreement of sale or a partnership. Tangible property is more often transferred by possession and by instruments conveying title such as a deed or a bill of sale. —Black's Law Dictionary. "Assignment" means the transfer of the claim, right or property to another. The Commissioner of Gift Tax, Madras v. N.S. Getty Chettiar, AIR 1971 SC2410. 1 Substituted by Patents (Amdt.) Act, 2002, w.e.f. 20-5-2003 vide SO 561(E), dt. 20-5-2003. 4 THE PATENTS ACT, 1970 SECTION 2 An "assignee" is a person to whom an assignment is made; grantee. Assignee in fact is one to whom an assignment has been made in fact by the party having the right; and assignee in law is one in whom the law vests the right, as an executor or administrator. Assignee means a person appointed by another to do any act or perform any business; also a person who takes some right, title or interest in things by an assignment from an assignor. They are divided into—(1) assignees by deed, as when a lessee of a term sells or assigns it to another, and (2) assignees by law, as when property devolves upon an executor without any specific appointment, the executor is assignee in law to the testator.—Wharton's Law Lexicon. Capable of industrial application An invention, in order to be patentable, must be capable of being made or used in some kind of industry. In this context, "industry" should be understood in its broadest sense as including any useful, practical activity as distinct from purely intellectual or aesthetic activity, and does not necessarily imply the use of a machine or the manufacture of an article. An "invention" within the meaning of the Act is an invention for a manner of new manufacture that is in some way associated with trade and commerce; meaning traffic in goods, i.e., exchange of commodities for money or other commodities—Sri Gajalakshmi Ginning Factory Ltd. v. CIT (1952) 22ITR 502 (Mad). Trade or commerce is carried with profit motive. The expression "invention" has, therefore, been defined in the Patents Act, 1970 to mean manner of manufacture; machine; substance produced by manufacture. The invention relates to the skill (art), series of action (process) or the particular way (method) or the way (manner) of making a product or thing. It also relates to machine or apparatus by which a thing is made and also the

product which is the result of act of making. All these are associated with "manufacture", which word: • denotes either a thing made which is useful for its own sake and vendible as such; or • means an engine or instrument to be employed either in the making of some previously known article or in some useful purpose or extending to new process to be carried on by known implements or elements acting upon known substances and ultimately producing some other known substance, but producing it in a cheaper or more expeditious manner, or of a better or more useful kind. [See R. v. Wheeler (1819) 26 & Aid345, quoted with approval in BombayAgarwal Co. v. RamchandAIR 1953 Nag. 154]. The focus is on "manufacture". Controller Under section 3(1) of the Trade Marks Act, 1999, the Central Government may, by Notification in the Official Gazette, appoint a person to be known as the Controller-General of Patents, Designs and Trade Marks, who shall be the Registrar of Trade Marks for the purposes of that Act. The said officer shall be the Controller for the purposes of the Patents Act also. Convention application Convention is an agreement or compact; especially, international agreement; e.g. Geneva Convention. It is an assembly or meeting of members or representatives of political, legislative, fraternal, etc. organisations. Under section 135 of the Patents Act, where a person has made an application for a patent in respect of an invention in a convention country and that person or the legal representative or assignee of that person makes an application under the Act for a patent within 12 months after the date on which the basic application was made, the priority date of a claim of the complete specification being a claim based on matter disclosed in the basic application, is the date of the basic application. Convention country With regard to international arrangements in respect of patents, with a view to the fulfilment of a treaty, convention or arrangement with any country outside India which affords to applicants for patents in India or to citizens of India similar privileges as are granted to its own citizens in SECTION 2 THE PATENTS ACT, 1970 5 respect of the grant of patents and protection of patent rights, the Central Government may declare such country to be a convention country for the purposes of the Act, vide section 133. District Court Section 2(4) of the Code of Civil Procedure, 1908 says that, "district" means the local limits of the jurisdiction of a Principal Civil Court of original jurisdiction (called a "District Court") and includes the local limits of the ordinary original civil jurisdiction of a High Court. Exclusive licence The expression "exclusive" is explicit and significant when the expression is explicit, it is conclusive, alike in what it says and in what it does not say. This is corroborated by the use of the expression "claim" for all purposes—Charan Lal Sahu v. Union of India AIR 1990 SC 1480 (In the context of Bhopal Gas Leak Disaster

(Processing of Claims) Act, 1985). Exclusive license is the exclusive right granted by patent holder to licensee to use, manufacture, and sell patented article. It is the permission to do a thing and contract not to give leave to any one else to do the same thing—Overman Cushion Tire Co. v. Goodyear Tire and Rubber Co. C.C.A. N. Y. 59 F. 2d 998, 999. It is a licence which binds the licensor not to enlarge thereafter the scope of other licences already granted, or increase the number of licences, is an exclusive licence—Mechanical Ice Tray Corporation v. General Motors Corporation, C.C.A.N. Y. 144 F. 2d 720,275. An "exclusive licensee" is one granted exclusive right and licence to use, manufacture, and sell patented article; one having exclusive right to use patented method and apparatus in designated territory.—De/te/ v. Chisholm, C.C.A.N.Y. 42 F. 2d 172, 173; Paul E. Hawkinson Co. v. Carnell, C.C.A. Pa. 119 F. 2d 396, 398 Food Food is a nutritive material absorbed or taken into the body of an organism which serves for purposes of growth, work or repair and for the maintenance of the vital processes.— Webster's International Dictionary. Under section 2(v) of the Prevention of Food Adulteration Act, 1954, "Food" means any article used as food or drink for human consumption other than drugs and water and includes — (a) any article which ordinarily enters into, or is used in the composition or preparation of human food, and (b) any flavouring matter or condiments. Within the meaning of the Prevention of Food Adulteration Rules, 1955, "food" means the composite preparations which normally go to constitute a meal.—Collector of Central Excise v. Parle Exports (Pvt.) Ltd. AIR 1989 SC 644 The expression 'food' has generally been understood to mean nutritive material absorbed or taken into the body of an organism which serves for purposes of growth, work or repair and for the maintenance of the vital process. What human beings consume is styled as food and what animals consume is described as animal feed. This distinction has to be borne in mind. Expression 'food-stuffs' is made of two expressions, 'food' plus 'stuff. In other words, the stuff which is used as food would be foodstuff. Therefore, foodstuff is that which is taken into the system to maintain life and growth and to supply waste of tissue. If the raw foodstuff with a view to making it consumable by human beings undergoes a change of its conditions by the process of cooking, the derivative is none the less foodstuff.—Welcome Hotel v. State of Andhra Pradesh, AIR 1983 SC 1015: Food means an article which normally a man eats or drinks to nourish his body and also an article which normally is not considered food but which normally enters into or is used in the composition or preparation of human food.—Khedar Lal v. State of U.P. 1981 FAJ 192 (All) Government undertaking Undertaking means business, project or works undertaken; something undertaken; a prom- 6 THE PATENTS ACT, 1970 SECTION 2 ise, a pledge. Under

section 2(v) of the Monopolies and Restrictive Trade Practices Act, 1969, "undertaking" means an undertaking which is engaged in the production, supply, distribution or control of goods of any description or the provision of service of any kind. Undertaking means the entire organization. A company whether it has a plant or whether it has an organization is considered as one whole unit, and the entire business of the going concern is embraced within the word 'undertaking'.—Rustom Cavasjee Cooper v Union of India AIR 1970 SC 564: (1970) 1 SCJ 564: (1970)2 SCA 37. The term "undertaking" must be defined as any business or any work or project resulting in material goods or material services and which one engages in or attempts as an enterprise analogous to business or trade.—Secretary, Madras Gymkhana Club Employees' Union v. Management of the Gymkhana Club, AIR 1968 SC 554. The word "undertaking" as used in Section 25-FFF of the Industrial Disputes Act used its ordinary sense, connoting thereby any work, enterprise, project or business undertaking. It is not intended to cover the entire industry or business of the employer.—Workmen of the Straw Board Manufacturing Co. Ltd. v. Straw Board Manufacturing Co. Ltd., AIR 1974 SC 1132. According to its dictionary meaning as given by Webster, "undertaking" means anything undertaken; any business, work or project which one engages in or attempts; an enterprise.—The Workmen of Indian Standards Institution v. The Management of Indian Standards Institution, AIR 1976 SC 145. Invention Invention is the act or operation of finding out something new; the process of contriving and producing something not previously known or existing, by the exercise of independent investigation and experiment. Also the article or contrivance or composition so invented—Smith v. Nichols, 88 U.S. (21 Wall.) 112, 22 LEd. 566; Hollister v. Mfg. Co., 113 U.S. 59, 5 S.Ct. 717, 28 LEd. 901. Invention is a concept; a thing involved in the mind; it is not a revelation of something which exists and was unknown, but is creation of something which did not exist before, possessing elements of novelty and utility in kind and measure different from and greater than what the art might expect from skilled workers—Pursche v. Atlas Scraper & Engineering Co. C.A. Cal., 300 F.2d467, 472. The finding out—The contriving, the creating of something which did not exist, and was not known before, and which can be made useful and advantageous in the pursuits of life, or which can add to the enjoyment of mankind. Not every improvement is invention; but to entitle a thing to protection it must be the product of some exercise of the inventive faculties and it must involve something more than what is obvious to persons skilled in the art to which it relates. Mere adaptation of known process to clearly analogous use is not invention.—Firestone Tire and Rubber Co. v. U.S. Rubber Co., C.C.A. Ohio, 79 F.2d 948, 952, 953. Inventive skill has

been defined as that intuitive faculty of the mind put forth in the search for new results, or new methods, creating what had not before existed, or bringing to light what lay hidden from vision; it differs from a suggestion of that common experience which arose spontaneously and by a necessity of human reasoning in the minds of those who had become acquainted with the circumstances with which they had to deal.—*Hollister v. Mfg. Co.*, 113 U.S. 59, 5 S.Ct. 717, 28 L.Ed. 901. Invention, in the nature of improvements, is the double mental act of discerning, in existing machines, processes or articles, some deficiency, and pointing out the means of overcoming it. Under section 2(8) of the Patents and Designs Act, 1911, "invention" means any manner of new manufacture and includes an improvement and an allied invention. Unlike the Patents Act, 1970, the 1911 Act does not specify the requirement of being useful in the definition of "invention". But courts have always taken the view that a patentable invention, apart from being a new manufacture, must also be useful. The foundation for this judicial interpretation is to be found in the fact that section 26(1)(f) of the 1911 Act recognises lack of utility as one of the grounds on which a patent can be revoked.—*Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* AIR 1982 SC 1444. Legal representative The term "legal representative" in its broadest sense means one who stands in place of, and represents the interests, of another. He is a person who oversees the legal affairs of another. A "legal representative" ordinarily means a person who in law represents the estate of a deceased person or a person on whom the estate devolves on the death of an individual.—*Gujarat State Road Transport Corporation v. Ramanbhai Prabhat Bhai*, AIR 1987 SC 1690: "Legal representatives" include heirs as well as persons who represent the estate even without title either as executors or administrators in possession of the estate of the deceased.—*Custodian of Branches of BANCO National Ultramarino v. Nalini Bai Naique*, AIR 1989 SC 1589: Legal representative is a person who in law represents the estate of a deceased person, and includes any person who intermeddles with the estate of the deceased and where a party sues or is sued in a representative character, the person on whom the estate devolves on the death of the party so suing or sued.—Civil Procedure Code 1908, s. 2(11); Arbitration Act 1940, s. 2(d); Gift-Tax Act 1958, s. 2(xvi) (b). The term conveys of two distinct categories. Firstly, the heirs or persons, who in law represent the estate of the deceased person. However, at par with them and in a class by itself is any person who intermeddles with the estate of the deceased. Such a person is equally a legal representative.—*Sudama Devi v Jogendra Choudhury* AIR 1987 Pat 239. Medicine or drug Drug includes 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 disease in human beings or animals.—Sk. Amir v. State of Maharashtra AIR 1974 SC 469 Under section 3(b) of the Drugs and Cosmetics Act, 1940, "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 disease in human beings or animals; and (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins 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. '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 treatment, mitigation or prevention of disease in human beings or animals other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine; and (ii) such substance (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins 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. Drugs Act 1940, s. 3(b).

'Drug' includes— (i) a medicine for the internal or external use of human beings or animals; (ii) any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals; (iii) any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals; (iv) any article intended for use as a component of any medicine, substance or article, 8 THE PATENTS ACT, 1970 SECTION 2 referred to in sub-clauses (i), (ii) and (iii). Drugs and Magic Remedies (Objectional Advertisements) Act, 1954, s. 2(b). 'Drug' means any drug as defined in clause (b) of section 3 of the Drugs Act, 1940 (XXIII of 1940), in respect of which a declaration has been made under s. 3. Drugs (Control) Act 1950. Patent Patent is a grant or right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it. It is an official document conferring a right or privilege, letters patent; writing securing to an inventor for a term of years the exclusive right to make, use and sell his invention; the monopoly or right so granted.—Webster's Ninth New Collegiate Dictionary. The effect of the grant of patent is quid pro quo, quid'ts the knowledge disclosed to the public and quo is the monopoly granted for the term of the patent. Section 12, Patents and Designs Act sets out that a Patent once granted confers upon the patentee the exclusive privilege

of making, selling and using the invention throughout India and of authorising others so to do. This is quo. The quid is compliance with the various provisions resulting in the grant of patent.—Raj Parkash v Mangat Ram Choudhary AIR 1978 Del 1: Patentee "Patentee" is he to whom a patent has been granted. The term is usually applied to one who has obtained letters patent for a new invention. Patentee includes assignee of patent whose name is entered into the register of patents.—Luxmi Dutta v. Nankaus AIR 1964 All 27 Person In general usage, a human being (i.e. natural person), though by statute term may include labor organizations, partnerships, associations, corporations, legal representatives, trustees, trustees in bankruptcy, or receivers. 'Person' shall include any company or association or body of individuals, whether incorporated or not.—General Clauses Act 1897, s. 3(42); Indian Penal Code 1860, s. 11. The definition of the term in the General Clauses Act is not exhaustive. It is hardly a definition. It only indicates the intention of legislature to treat artificial persons as persons.—Jabbar v State of UP. AIR 1966 All 590. Section 11, I.P.C. defining a person includes within its ambit a company or association or body of persons whether incorporated or not. It may seem prima facie that a corporate body or a body of unincorporated persons is punishable as an ordinary individual. But, the clause "unless there is anything repugnant to the subject or context" must always be understood to exist in the context of the definition given in Penal Code. So a corporate body or a company shall not be indictable for offences which can be committed only by a human individual (e.g., rape, bigamy etc.) or for offences which must be punished by imprisonment (e.g. cheating).—Sfate of Maharashtra v Syndicate Bank AIR 1964 Bom 95: (1964) 2 Cr U 276. In general, a corporation is in the same position in relation to criminal liability as a natural person and may be convicted of common law and statutory offences including those requiring mens rea. There are, however, crimes which a corporation is incapable of committing or of which a corporation cannot be found guilty as principal; nor can a corporation be convicted of a crime for which death or imprisonment are the only punishments. Criminal liability of a corporation arises where an offence is committed in the course of corporation's business by a person in control of its affairs to such a degree that it may fairly be said to think and act through him so that his actions and intent are the actions and intent of the corporation.—Halsbury's Laws of England, 4th Ed. Vol. 11, para 34, p. 30. Under section 2(31) of the Income Tax Act, 1961 "person" includes— (i) an individual, SECTION 3 THE PATENTS ACT, 1970 9 (ii) a Hindu undivided family, (iii) a company, (iv) a firm, (v) an association of persons or a body of individuals, whether incorporated or not, (vi) a local authority, and (vii) every artificial juridical person, not falling

within any of the preceding sub-clauses. Income-tax Act 1961, s. 2(31). In Order 30, Rule 10, Code of Civil Procedure 1908, the word 'person' does not include a company, because such a construction will be repugnant to the context.—Modi Vanaspati v Khaitan Jute Mills AIR 1969 Cat 496. The General Clauses Act, 1897 defines that "person" shall include any company, or association or body of individuals whether incorporated or not". The word "person" in section 4 of the Indian Partnership Act which has replaced section 239 of the Indian Contract Act contemplates only natural or artificial, that is, legal persons and therefore a firm, is not a person and as such is not entitled to enter into Partnership with another firm or Hindu undivided family or individual.— Dulichand Laxminarayan v. Commissioner of Income Tax, Nagpur.

UNIT –XII

BRIEF STUDY OF PRESCRIPTION AND NON PRESCRIPTION

OVER-THE-COUNTER MEDICATIONS: USE IN GENERAL AND SPECIAL POPULATIONS, THERAPEUTIC ERRORS, MISUSE, STORAGE AND DISPOSAL A Resource from the American College of Preventive Medicine A Clinical Reference The following Clinical Reference provides the evidence to support the Over-the-Counter (OTC) Medications Time Tool. The following bookmarks are available to move around the Clinical Reference. 1. Introduction 2. Clarifying Terminology 3. Use in the General Population 4. Use in Special Populations 5. Therapeutic Errors and Misuse 6. Storage and Disposal 7. Doctor/Patient Communication Gaps 8. Physician's Role – What Doctors Should Tell Their Patients 9. Bottom Line 10. Resources/Links 11. References © 2011. American College of Preventive Medicine. All rights reserved. 2 1. INTRODUCTION Over-the-counter (OTC) medications—drugs available to consumers without a prescription—play an increasingly vital role in our healthcare system and are the most prevalent means of treating the majority of common health problems in the United States. There are over 80 therapeutic categories of OTC drugs which can be grouped in 12 broad therapeutic classes. [1,2] (See Table 1) Table 1. Broad Therapeutic Classes of OTC Medications

- Analgesics and antipyretics
- Cold, cough, and allergy products
- Nighttime sleep-aids
- Gastrointestinal products
- Dermatological products
- Other topical products (including dermal and vaginal antifungals, anorectal medications, head lice products, hair loss products, and otics)
- Ophthalmic products
- Oral health care products
- Menstrual products
- Nicotine replacement products
- Weight loss aids
- Vaginal contraceptives and emergency contraceptives

OTC retail

sales totaled \$17 billion (excluding Walmart sales) in 2010. [3] Currently, 35% of adult Americans use OTC medications on a regular basis and there is a trend for increasing use as more drugs move from prescription to OTC status. [4] The Center for Drug Evaluation and Research (CDER) division of the Food and Drug Administration (FDA) regulates OTC medications to ensure that they are properly labeled, their benefits outweigh their risks, their potential for misuse and abuse is low, and that health practitioners are not needed for their safe and effective use. [1] The benefits of over-the-counter availability include: [5,6] • Direct, rapid access to effective medicines • Wide availability • Decreased healthcare system utilization (fewer physician visits, lower healthcare system costs) • Allowing individuals to be in charge of their own health However, there are risks associated with OTC use, such as: [5,6] • Incorrect self-diagnosis delaying diagnosis and treatment of serious illnesses (delay in seeking advice from a healthcare professional) • Increased risk of drug-drug interactions • Increased risk of adverse events when not used appropriately • Potential for misuse and abuse

2. CLARIFYING TERMINOLOGY One area of confusion is the definition of and demarcation between drugs, dietary supplements, and cosmetics. FDA's definitions of these categories are provided in the following. While FDA does not use the term "OTC medications," we use it in this material interchangeably with "OTC drugs." Drugs / OTC Drugs Drugs (prescription and OTC drugs) are substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. OTC drugs are defined as safe and effective for use by the general public without a doctor's prescription. [7] © 2011. American College of Preventive Medicine. All rights reserved. 3 Dietary Supplements (including Herbal Ingredients) A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. Permitted ingredients of dietary supplements include vitamins, minerals, herbs or other botanicals, and amino acids. [8] Cosmetics Cosmetics are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body... for cleansing, beautifying, promoting attractiveness, or altering the appearance." [9] Another area of confusion exists around the terms therapeutic error, misuse, and abuse. In order to clarify these terms, the following definitions by the American Association of Poison Control Centers (AAPCC) are supplied. [10] Therapeutic error: An unintentional deviation from a proper therapeutic regimen that results in the wrong dose, incorrect route of administration, administration to the wrong person, or administration of the wrong substance. Intentional misuse: An exposure resulting from the intentional improper or incorrect use of a substance for reasons other than the pursuit of a psychotropic or euphoric

effect. Intentional abuse: An exposure resulting from the intentional improper or incorrect use of a substance where the individual was likely attempting to achieve a euphoric or psychotropic effect.

3. USE IN THE GENERAL POPULATION The use of OTC medications is one aspect of a growing movement toward medical self-care and has become a tool in gaining control over one's health. The findings of a 1999 Slone survey of adult Americans demonstrated the important role OTC medicines have in the general population. In this study, OTC analgesics were the most frequently used of all medications (OTC or prescription), taken by approximately 20% of the population in a given week. OTC decongestants and antihistamines followed analgesics in frequency of use. [11] Female individuals are more likely to use OTC medications. [12] In a 2002 survey, 87% of women reported the use of an OTC pain medication in the past year compared to 80% of men. [13] A study conducted in 2011 confirmed that OTC medications are American's most popular treatment choice for common ailments such as headache, heartburn, allergies, and colds. [14] (See Figure 1) Figure 1. Percentages of Individuals Who Treated a Condition With OTC Products Only (n=1,880; January 2011) [14] © 2011. American College of Preventive Medicine. All rights reserved.

| Condition | Percentage |
|--|------------|
| Headaches, Migraines | 40 |
| Upper Respiratory Infections, Cough, Cold, Flu | 10 |
| Heartburn, Acid Reflux | 20 |
| Muscle & Joint Pain, Arthritis | 30 |
| Allergies, Asthma | 40 |

The most commonly used OTC products in the United States according to 2009 sales data are (expressed as number of pack units sold in 2009; excluding Walmart data): [15]

- OTC MEDICATIONS FOR ORAL INGESTION
 - o Cough/cold and allergy remedies (711,604,074)
 - o Analgesics (430,254,703)
 - o Antacids and anti-gas products (173,320,632)
 - o Laxatives (114,872,050)
 - o Diarrhea remedies (22,663,194)
- OTC MEDICATIONS FOR TOPICAL USE
 - o Toothpastes (458,370,150)
 - o Oral antiseptics and rinses (178,368,512)
 - o First aid treatments* (157,717,515)
 - o Lip remedies (151,111,158)
 - o Eye care products (62,401,048)

* Including germicidal antiseptics and topical hydrocortisone

4. USE IN SPECIAL POPULATIONS Children. The number of children ages 12 and younger being administered an OTC medication in a given time period is more than twice that of prescription medications. The most commonly used OTC medications in children are the analgesics/antipyretics acetaminophen and ibuprofen. [16] Adolescents. Compared to the general population, adolescents 12–17 years of age use more OTC products for acne and less for allergies and pain relief. Use by adolescents accounts for 38% of acne remedies' sales volume, but for only 7% of the total internal analgesics category volume. [17] Of particular concern are adolescents who abuse alcohol, illicit drugs, and medications including OTC cough medicines

containing dextromethorphan. The 2011 Monitoring the Future survey, which looks at 8th, 10th, and 12th graders nationwide, showed that in 2010 approximately 5% of the survey participants reported past year use of OTC cough medicine “to get high.” For comparison, the ratio of 8th, 10th and 12th graders in this survey reporting the abuse of other substances within the past year was 49% for alcohol, 25% for marijuana, 6% and 4% for the prescription analgesics Vicodin® and OxyContin®, respectively. [18] Older adults. Adults ages 65 years and over generally have more medical problems and use more medications, both prescription and OTC, when compared to younger adults. In this group, polypharmacy is common including multiple OTC preparations and prescription drugs. Age-related changes occur in the elderly, predisposing this population to greater risks of adverse events, drug-drug interactions, therapeutic errors, and misuse. [19,20,21] Physicians should refer to the Beers List of drugs potentially inappropriate © 2011. American College of Preventive Medicine. All rights reserved. 5 for the elderly when prescribing and counseling patients regarding OTC drug use. The latest update of Beers List has been published in the Archives of Internal Medicine and is available at:

<http://archinte.amaassn.org/cgi/content/full/163/22/2716#ACK>. [21] OTC medications of particular concern include diphenhydramine (can cause confusion and sedation), nonsteroidal anti-inflammatory drugs (renal dysfunction, gastrointestinal bleeding, hypertension, exacerbation of heart failure), ferrous sulfate (constipation), and mineral oil (aspiration, lipid pneumonia) due to their increased risk of adverse events in older adults. 5. THERAPEUTIC ERRORS AND MISUSE While the public acknowledges the need to be careful with using OTC medications, therapeutic errors and misuse occur with these products. The root causes of therapeutic errors and misuse of OTC medicines are attributable to inaccurate attitudes and wrong beliefs. For instance:

- One third (33%) of Americans admit that they have taken more than the recommended dose of an OTC medicine [22]
- thinking it will bring more relief more quickly,
- thinking it will help with severe symptoms, or
- because they did not obtain relief after taking the recommended dose.
- While 95% of Americans read some portions of the OTC label, only half (51%) say they seek out the packaging label for usage information when they plan to take an OTC medication for the first time. [22]
- Given the scale of OTC medication use, a significant number of individuals are likely to take more than one prescription or OTC drug simultaneously, which can increase the risk of drug-drug interactions. [23]
- Areas of intentional incorrect use or misuse of OTC medicines include:
 - using more than the recommended doses of pain relievers [13],
 - using laxatives to lose weight and to “feel thin” (in particular by individuals with eating

disorders) [24], and o using first-generation H1-antihistamine allergy medicines to sedate young children. [25] Therapeutic errors and misuse of OTC medications are associated with medication overdoses and adverse events. • In 1999, the FDA estimated the ratio of hospitalizations due to adverse events from all medications (prescription and OTC) to be 5.5%, and the ratio of hospitalizations due to adverse events specifically from OTC drugs to be 0.55% (corresponding to 170,500 of 31 million annual hospitalizations). [26] • A study of 2004/2005 data by the Centers for Disease Control and Prevention (CDC) showed that over 70,000 children annually were brought to emergency departments for medication overdoses (in more than 26,000 of these cases, OTC medications were implicated). Four fifths (82%) of emergency department visits for medication overdoses resulted from resulting from unsupervised ingestions of prescription and OTC drugs, with peak incidence in two-year-olds. [27]

6. STORAGE AND DISPOSAL

Medications need to be properly stored for maximal safety and efficacy. If incorrectly stored, children may ingest harmful doses of OTC drugs. As the aforementioned study by the CDC showed, medication © 2011. American College of Preventive Medicine. All rights reserved. 6 overdoses resulting from unsupervised ingestions of OTC and prescription products is a main cause of emergency department visits by young children. [27] For proper disposal, the Environmental Protection Agency recommends that drugs be taken out of their containers, mixed with undesirable substances, (e.g., cat litter, used coffee grounds) and put into a disposable container with a lid or into a sealed bag before putting in the trash. Advise patients to remove any personal information from any labels by covering the information with black marker, or duct tape, or by scratching it off. [28] Environmentally, it is irresponsible to “flush” OTC medications. Most sewage treatment plants are not equipped to extract pharmaceutical compounds from wastewater and the impact of these drugs in public drinking water is unknown. [28]

7. DOCTOR/PATIENT COMMUNICATION GAPS

As common as OTC use is, there appear to be significant challenges for doctors to communicate with their patients about it. For instance: • While three-quarters of physicians report that they ask their patients directly about OTC drug use, one-quarter waits for patients to volunteer this information. [22] • Americans are least likely to talk with a medical professional about taking more than the recommended dose of an OTC medication (30%), the use of leftover prescription antibiotics (33%), the use of OTC pain relievers (36%), and the use of more than one OTC product at a time. [22] • Only 18% of physicians educate their patients about safe drug taking, storing, and disposal practices. [29]

8. PHYSICIAN’S ROLE – WHAT DOCTORS SHOULD TELL THEIR PATIENTS

Due to the

high prevalence of OTC medication use, physicians need to stay abreast of the trends in OTC usage patterns as well as the risks associated with incorrect use and storage of OTC drugs. Physicians need to participate in efforts to prevent adverse events, therapeutic errors, misuse, and unsupervised pediatric ingestions of OTC medicines. • Routinely document OTC use in the medical history: o to detect incorrect use, o to detect potential drug-drug interactions, and o to identify therapeutic duplication. • Discuss with patients the potential risks of the OTC medications they have disclosed during history taking. • Provide alternative medication choices if you suspect misuse of an OTC medication. • Teach patients how to read package labeling with special emphasis on the sections “Warnings” and “Directions” (dosage instructions). • Teach parents and caregivers about the use of OTC medications in children. o Emphasize the importance of heeding the dosage instructions of the package labeling. © 2011. American College of Preventive Medicine. All rights reserved. 7 • Teach parents and caregivers about the handling and storage of OTC medications. o Tell your patients to put the entire container up, away, and out of sight after every use. o Tell your patients to correctly replace the child-resistant caps on all medicines. • Refer patients to Internet educational resources (See Patient Guide and Patient Education Resources). Following are a few scripted conversations that may help with the discussion. Ten Important Conversations: 1. “Tell me about the types of OTC medications you take.” 2. “Read the entire package label and follow its instructions each time a dose is taken. In particular, if you take more than one medicine, pay attention to the active ingredients stated on the label to avoid taking too much of the same active ingredient.” 3. “Contact me at any time if you have questions about the choice or use of an OTC medication.” 4. “Contact me if you feel you need a dose that is higher than the one recommended on the package label.” 5. “Keep all medications in their original container.” 6. “Correctly replace the child-resistant caps on all medicines after every use.” 7. “Keep OTC and prescription drugs out of reach and sight of children after every use.” 8. “Make a general house policy that all drugs are stored in one well-controlled location such as a locked drawer or cabinet, and that no drugs are stored in bedrooms, automobiles, backpacks, or school lockers.” 9. “Discard all medications that have expired. Regardless of the expiration date, discard any medications that show changes in shape, size, color, or odor; show signs of softening, cracking, or hardening; when tablets or capsules stick together; or when a liquid has become cloudy.” 10. “To discard drugs take them out of their containers, mix them with undesirable substances (e.g., cat litter, used coffee grounds), and put them into a disposable container with a lid or into a sealed bag before putting in the trash.

Remove any personal information by covering the information with black marker, or duct tape, or by scratching it off.” 9. BOTTOM LINE OTC medications represent a diverse group of widely available drugs. OTC use is ever increasing and expected to continue to rise. These drugs are safe and effective when used as directed. However, physicians must be aware that some people--with or without intention--use OTC medications incorrectly. Instruct all patients on the safe and appropriate storage and disposal of all types of medicines. Stay abreast of trends in OTC usage, therapeutic errors, misuse, and abuse. Routinely incorporate OTC conversations during office visits. A list of physician and patient resources is below. Each of these efforts will help your patients to get the maximum benefit out of OTC use while minimizing the risks of incorrect OTC use.