PROGRAM:D.PHARM **UNIT**:4
COURSECODE:2.4

DRUGS AND COSMETICS ACT, 1940, AND ITS RULES 1945

The in **Drugs and Cosmetics Act, 1940** is an act, which regulates the import, manufacture and distribution of drugs 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.

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 0f 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 entral 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 commencementof 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. 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.