BP 505 T (Pharmaceutical Jurisprudence) Theory

UNIT-III

- Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties.

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Pharmacy Act –1948

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

Definition

It is an act An Act to regulate the profession of pharmacy whereas it is expedient to make better provision for the regulation of the profession and practise of pharmacy and for that purpose to constitute Pharmacy Council. The Act was promulgated in the Year 1948 [1].

The PCI was first constituted in the year 1949 and reconstituted every 5 years.

In modern perspective, a pharmacist is a regarded as a member of health care team or an essential component of health system. The primary obligation of pharmacy is to safeguard the public health by making available the right medicaments. Medicines are of vital importance and hence their handling, compounding, dispensing and storage etc, need a thorough and specialized knowledge, skill and training of the personnel called pharmacists. The desired knowledge, skill and training are provided through the pharmacy courses [2].

Objectives

- Regulating and Raising the Status of the Profession of Pharmacy in India.
- Providing uniform education and training to the persons willing to enter the profession of Pharmacy.
- Maintaining control over the persons entering the profession of Pharmacy.
- To constituent 'Pharmacy Council of India' for setting new standards in 'Pharmacy Education'.
- To provide constitution and functions of 'State Pharmacy Council' for registration of pharmacists.
- To regulate the activities of pharmacists [3,4].

PHARMACY COUNCIL OF INDIA

In January 2015, the Pharmacy Council of India has published the new pharmacy practice regulations 2015 to regulate pharmacy in India [1]. The important provisions are:

a) The drugs can be dispensed only by a qualified registered pharmacist.
b) Registered pharmacists shall not give his registration certificate at more than one pharmacy.

c) Registered pharmacist shall also comply with the dress code by wearing white coat and apron with a badge displaying the name and registration number.
d) Every registered pharmacist shall dispense only those medicines as prescribed by the registered medical practitioner.
e) Every registered pharmacist shall maintain the medical or prescription records pertaining to the patients for a period of 5 years from the date of commencement of the treatment as per regulations.
f) Pharmacist should promote the rational use of drugs.
g) Other guidelines regarding ethical conduct of pharmacists.

The Central Government constitute a Central Council (Pharmacy Council of India). The PCI was constituted on 9th August, 1949 under section 3 of the Pharmacy Act. The council consisting of the following members:

A. *Elected members*:

a) Six members including at least one teacher each in pharmaceutical chemistry, pharmacology and pharmacognosy on the teaching staff of an Indian University or an affiliated college granting a degree or diploma in pharmacy. These members are elected by the University Grant Commission.
b) One member elected by the Medical Council of India from amongst its members.
c) One member who shall be registered pharmacist to represent each State elected by State Council from amongst its members.

B. *Nominated members*

a) Six members including at least four persons possessing degree or diploma in pharmacy and engaged in the practice of pharmacy or pharmaceutical chemistry, nominated by the Central Government.
b) A representative each of the University Grants Commission and All India Council for Technical Education.
c) One registered pharmacist to represent each State nominated by the State Government / Union Territory Administration.

C. *Ex-officio member*

a) The Director General of Health Services.
b) The Director of Central Drugs Laboratory.
c) The Drugs Controller of India.

If the ex-officio member under C (a) & (b) are unable to attend any meeting they can authorize a person each in writing to attend the meeting.

Function of Pharmacy Council of India (PCI)

The main functions of Pharmacy Council of India are:

a) To prescribe minimum standard of education required as a pharmacist.
b) Drafting of Education of Regulations to be fulfilled by the institutions for the approval, for imparting education in pharmacy.
c) To provide uniform implementation of the educational standards throughout the country.
d) Inspection of Pharmacy Institution to verify availability of the prescribed forms.
e) To recognize the course of study and examination for pharmacists.
f) To withdraw approval, if institution does not confirm educational standards prescribed by the PCI.
g) To approve qualifications granted outside the territories to which the Pharmacy Act extends i.e., the approval of foreign qualification.
h) To compile and maintain Central Register of Pharmacist.

President and Vice-president of Central Council

a) The President and Vice-President of the Central Council are elected by the members of the Council from amongst themselves. They hold office for a period not exceeding five years and not extending beyond the expiry of their term as the members of the Central Council, they are however eligible for re-election.
b) If the term of the President or Vice-President as member of the Central Council expires before the expire of the full term for which he is elected, he shall, if he is re-elected or re-nominated as a member of the Central Council, continue to hold office, as the president or Vice-President for the full term for which he is elected to such office.
c) Elections are to be conducted in the prescribed manner and in case of any dispute the same can be referred to the Central Government whose decision shall be final.

Terms of Office and casual vacancies.

a) Any nominated or elected member shall hold office for a term of five years from the date of his nomination or election or until his successor has been dully nominated or elected.

b) A nominated or elected member can resign his membership by writing under his hand to the President.

c) A nominated or elected member shall be deemed to have vacated his seat if he remains absent, without sufficient reason to the satisfaction of the Central Council, from three consecutive meetings of the Central Council.

d) A casual vacancy in the Central Council shall be filled by fresh nomination or election. The person so nominated or elected to fill the vacancy shall hold office only for the remaining term.

e) Members of the Central Council are eligible for re-nomination or re-election.

The Executive Committee:

The Pharmacy Act provides, constitution of Executive committee by the Central Council. The Executive committee consists of:

a) Ex. Officio members: (i) President who shall be the chairman of this committee and (ii) Vice-president.

b) Five other members elected by the Central Council from amongst its members.

The members of Executive committee holds the office until the expiry of his term as a member of Central Council, but if re-elected as a member of Central Council, he can hold office for residual term.

Powers of the Central Council to make regulations:

a) The council is authorized to lay down rules for its procedure, fix the rate of allowance payable to its members and members of other committee, which are previously sanctioned by Central Government and also decides modes of election.

b) It also lay down rules for the management of its property, and maintenance and auditing of accounts, holding of meetings, fixing functions, duties and powers of Executive Committee, president and vice-president and qualifications, terms of office, power and duties of secretary, inspectors and other officers of the council.

c) The council may constitute from amongst its members, such committees for general or other special purposes as deemed necessary.

d) The Council has to furnish copies of his minutes and those of Executive committee, together with a summary of annual activities and accounts to the Central Government. The Central Government may publish any reports or abstract in such manner as it thinks proper.

EDUCATION REGULATIONS 1991 (ED)

The Pharmacy Council of India make regulations which is known as Education Regulations 1991 [5]. It prescribe the

a) Minimum qualification for admission to the course.
b) Nature and period of course of study.
c) Nature and period of practical training to be undertaken after the completion of the regular course.
d) The subjects of examination and the standard attained therein.
e) The equipment and facilities to be provided by the institution for the students undergoing approved courses of study.
f) Conditions to be fulfilled by institutions giving practical training.
g) Conditions to be fulfilled by authorities holding approved examinations.

Central council before submitting the Education Regulation or any amendment thereof, as the case may be to the Central Government for approval, sends copies of draft of ER (Education Regulation) and all subsequent amendments to all State Governments and takes into consideration the comments of any State Government received within three months from the furnishing of the copies by Central Council. The ER then is published in Official Gazette by Central Governments as directed by Central Council. The Executive Committee from time to time reports to the Central Council on the efficacy of ER and may recommend to the Central Council such amendments thereof.

Application of Education Regulations to State

After the constitution of the state council under Chapter 3 and after consultation with State Council, the State Government may at any time, by notification in the Official Gazette declare that ER shall take effect in the State. If however, no such declaration has been made, the ER shall take effect in the State after three years from the date of the constitution of the State Council.

PHARM D. REGULATIONS 2008

Pharm D (Doctor of Pharmacy), qualification is considered for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948 [5]. There are two types of PharmD programmes:

i) Pharm D.

ii) Pharm D (Post Baccalareate)

Duration of the course:

Pharm. D: The course is full time of six academic years (5 years of study and one year of internship or residency). Each academic year shall spread overa period of not less than two hundred working days. Six academic years duration is divided into two phases.

a) Phase-I: Phase-I consists of first, second, third, fourth and fifth academic years.
b) Phase-II: Phase-II consists of internship or residency training during sixth year involving posting in speciality units in hospital. During this phase the student is exposed to actual pharmacy practice or clinical pharmacy services.

Pharm. D (Post Baccalaureate): The course is full time of three academic years (2 years of study and one year of internship or residency). Each academic year shall spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases.

a) Phase-I: Phase-I consists of first and second academic years.
b) Phase-II: Phase-II consists of internship or residency training during third year involving posting in speciality units in hospital. During this phase the student is exposed to actual pharmacy practice or clinical pharmacy services.

Minimum qualification for admission:

Minimum qualification for admission to Pharm. D course is:

a) 10 + 2 examination with physics and chemistry as compulsory subjects with mathematics or biology or
b) D. Pharm, from PCI approved institution under section 12 of the Pharmacy Act or
c) Any other qualification approved by PCI as equivalent to any of the above examinations.

Pharm. D. (Post Baccalareate): Minimum qualification for admission to Pharm. D (Post Baccalareate) course is B. Pharm. from PCI approved institution under section 12 of the Pharmacy Act.

Reservation: There shall be reservation for SC, ST and OBC candidates as per the directives of Central Government / State Government / Union Territory Admission as the case may be from time to time.

Number of seats: PCI shall prescribe the number seats to be filled from time to time. Presently it is 30 for Pharm. D. and 10 for Pharm. D. (Post Baccalareate).
Permission: PCI approved institutions under section 12 of the Pharmacy Act running B. Pharm. course will only be permitted to run Pharm. D. programme and institutions running Pharm. D. courses will only be permitted to run Pharm. D. (Post Baccalaureate) programme with prior approval from PCI.

WITHDRAWAL OF APPROVAL

If the executive committee reports to the Central Council that an institution or authority holding an approved course of study or examination does not continue to be in conformity with the ER, the Central Council may give notice to the authority concerned of its intention withdrawing the declaration of approval accorded. The said authority then should make a representation within three months from the receipt of such notice and forward to the Central Council through the State Government.
Taking consideration, representation received from authority concerned, and any observation thereon which the State Government may think to make, the Council may declare that the course of study or examination shall be deemed to be approved only on fulfillment of specified conditions.

THE CENTRAL REGISTER OF PHARMACISTS

Under the provision of the section 15-A of the amendment Act1976, [5]:

a) Central Council has to maintain in a prescribed manner a register of pharmacist to be known as the Central Register which contains the names of all persons whose names are entered in the register for a state.
b) Every State Council has to supply five copies of a State to the Central Council as soon as after the first day of April every year, and Registrar of State Council should also inform all additions and other amendments in the register for a State, without delay to the Central Council.
c) Registrar of the Central Council has to keep the Central Register in accordance with the orders made by Central Council and should revise the Central Register from time to time and publish it in the Gazette of India.
d) The Central Register deemed to be public document within the meaning of the Indian Evidence Act 1872, and may be approved by the production of a copy of the register as published in the Gazette of India.

Registration in the Central Register: After receiving the report of registration of a person in the register for a State, the Registrar of Central Council enters the name of such person in the Central Register.

STATE AND JOINT STATE PHARMACY COUNCILS

State Council: Means, a State Council of Pharmacy constituted under the Act and includes a Joint State Council of Pharmacy in accordance with an agreement under section 20 of the Act [2].

State Government shall constitute a State Council consisting of the following members [1]:

a) Six members, elected from amongst themselves by registered pharmacists of the State.
b) Five members, of whom at least three shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or registered pharmacists.
c) One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State.
d) Ex-officio members
   i) The chief administrative medical officer of the State.
   ii) The officer-in-charge of drugs control organization of the State.
   iii) The Government Analyst.

The joint State Pharmacy Council consists of following members

a) Not less than three members and not more than five members as the agreement shall provide elected from amongst themselves by the registered pharmacists of each of the participating States.
b) Not less than two members and not more than four members 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.
d) Ex-officio members
   i) The chief administration medical officer of each participating State.
   ii) The officer-in-charge of drug control organization of each participating State.
   iii) The Government analyst.

Two or more State Government may agree to establish a joint State Council for all participating State or agree that the State Council of State must respond to the needs of

participating States. The membership of the State Pharmacy Council may be augmented by not more than two persons nominated by each of the State Governments of which at least one always have a degree or diploma in Pharmacy or pharmaceutical chemistry or registered pharmacist. The amount os expenditure to be shared between the State and may make other provisions for giving effect to the agreement. The inter-state agreement shall be published in the official Gazette of the participating States.

The President and Vice-President of the State Council are elected by the members from amongst themselves provided that for five years from the first constitution of the State Council, the President shall be a person nominated by the State Government who shall hold office for five years. The President and Vice-President shall hold office as such for a term not exceeding five years and not exceeding beyond the expiry of his term as a member of the State Council. He shall be eligible for re-election.

Terms of office and casual vacancies

a) Nominated or elected member hold office for a term of five years from the date of his nomination or election.
b) A nominated or elected member at any time resigns his membership by writing to the president and such seat thereupon become vacant.
c) If any member is absent, without excuse sufficient in the opinion of the State Council, for three consecutive meeting of the State Council, he shall be deemed to have vacated his seat.
d) The member who is elected from amongst themselves either by the registered pharmacist or by the members of Medical Council of the State or council of Medical Registration of the state as the case may be shall have to vacate his seat as a member of State council if he ceases to be a Registered Pharmacist or ceases to be a member of Medical Council or council of Medical Registration of the State as the case may be.
e) A casual vacancy in the State Council filled by fresh nomination or election as the case may be and the person nominated or elected to fill such vacancy, holds office only for the remainder of the term for whose place he takes.
f) Member of the State Council can be eligible for re-nomination or re-election.

Staff, remuneration and allowances

With previous sanction of the State Government, State Council may

a) Appoint Registrar, who also acts as a secretary and treasurer of the State Council, for a period of four years from the first constitution of State Council. Registrar is appointed by State Government.

b) Appointment of such other officers and servant may be required to enable State Council to carry out its functions.
c) Fix the remuneration and allowances to be paid to the President, Vice-president and other members of that Council.
d) Fix the pay and allowances and other conditions of service of officers and servants of that Council.

Inspector

A State Council with previous sanction of the State Government may appoint sufficient number of inspectors having prescribed qualifications.

Power of inspector: An inspector may

a) Inspect any premises where drugs are compounded and dispensed.
b) Enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist or not
c) Inspect any complaint made in writing in respect of any contravention of this Act.
d) Institution prosecution under the order of the Executive Committee of the State Council.
e) Exercise such other power as may be necessary to give effect to some provisions of the Act.

Every inspector shall be deemed to be public servant within the meaning of section 21 of Indian Penal Code. Any person willfully obstructing an inspector in the exercise of the powers conferred on him by or under this Act or any rules made there under shall be punishable with imprisonment for a term which may extend to six months or fine of rupees thousand or both.

The State Council constitutes an Executive Committee consisting of the President (who shall be chairman of the Executive Committee) and Vice President and other members elected by the State Council from amongst them. The member of the Executive Committee shall hold office until the expiry of his term of office as member of the State Council. He shall br eligible for re-election.

REGISTRATION OF PHARMACISTS

Registered Pharmacist: Means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy [2].

The Pharmacy Act, 1948 under the chapter 4 provides for the registration of pharmacists in all the State in India. As soon as after this chapter has taken effect in the State, the first register of

pharmacist is required to be prepared by State Government concerned. The State Pharmacy Council is to be constituted soon after the preparation of first register and once State Council has been constituted the register is to be handed over to it. The State Council then has to be responsible for the maintenance of register. The register shall include the following particulars:

a) The full name and residential address of the registered persons.
b) The date of his first entry in the register.
c) His qualification 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:

a) For the preparation of first register, State Government by notification in official Gazette constitute a Registration Tribunal consisting three persons, and also appoints Registrar who acts as a secretary of Registration Tribunal.
b) The State Government then by notification specify a date on or before which, application for registration accompanied with prescribed fee is made to the Registration Tribunal.
c) The Registration Tribunal examines every application received on or before the specified date and if satisfied that the applicant is qualified for registration, directs the entry of the name of the applicant on the register.
d) The first register so prepared is then published in a manner directed by State Government. Any person aggrieved by the decision of Registration Tribunal expressed on implied in the published register, may appeal within 60 days of publication to the authority appointed by State Government in this behalf.
e) The registrar amend the register accordingly with the decision of authority mentioned above and thereupon issues to every person a certificate of registration in prescribed form whose name is entered in the register.
f) After constitution of State Council, this register is to be given into its custody and Government directs to direct to credit application fee collected to State Council.

Qualification for entry on first register

A person who has attend age of 18 years, entitle to have his name in first register on pay ment of prescribed fee, if he resides or carries on the business or profession of pharmacy in the State and should have the following qualification:

a) A degree or diploma in pharmacy, or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University, or a State Government or prescribed qualification granted by an authority outside India, or
b) 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 prescription of Medical Practitioners for a total period of not less than three year.
c) Has passed an examination recognized as adequate by the State Government for compounders and dispensers.
d) Has not less than five years experience of compounding and dispensing in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of Medical Practitioners, prior to the date notified by the Registration. Tribunal for receipt of the application for entry of the names on first register.

Subsequent Register

After appointment of date to invite application for registration, to enter names in first register by State Government and before the Education Regulations have taken effect in the State, a person who has completed his 18 years of age shall on payment of prescribed fee, be entitle to have his name in the register, if he resides or carries on the business or profession of pharmacy in the State and if he has following qualifications:

a) Satisfies the conditions prescribed for registration and where no such conditions have been prescribed satisfies the conditions entitled to have his name enter on first register and are at least matriculate, or
b) Is a registered pharmacists in another State, or
c) Possesses qualification for registration granted outside the territories to which this Act extends and are at least matriculate.

After the Education Regulation have taken effect in the State, a person who has attained age of 18 years, shall on payment of prescribed fee, be entitled to have his name entered on the register and if he resides or carries on the business or profession of pharmacy in the State and if he –

a) Has passed an approved examination, or
b) Possesses a qualification granted outside the territories to which this Act extends, or
c) Is a registered pharmacist in another State.

Special provision for Registration of certain persons

The Pharmacy (Amendment) Act 1959, made certain special provisions for the registration of certain classes of persons besides the persons those who are eligible to register their name in subsequent register. This class of persons include particularly those who had been affected by the partition of the country in 1947 or by reorganization of States in 1956 or by transfer of certain foreign settlement to India or those who since passage of the Act migrated to India. By virtue of these provisions, a State Council may permit to enter on the register, the name of following classes of persons:

a) Displaced persons who had been carrying on the business or profession of pharmacy from a date prior to the 4th day of March 1948 and who satisfies the necessary conditions for registration in first register of a State.
b) Citizens of India who had been carrying on the business or profession of pharmacy in any country outside India and who satisfies the necessary conditions for registration in first register of a State.
c) Persons who resided in such area which at the time of the passage of Pharmacy Act not parts of India but which subsequently become a territory of India and who satisfies the necessary conditions to have their names in a first register of a State.
d) Person who carry on the business or profession of pharmacy in the State and who satisfy the conditions for registration in first register and had applied for registration on or before the date appointed, but did not get registered for some reasons.
e) Persons who carry on the business or profession of pharmacy in the State and who have been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of medical practitioners for a total period not less than five years before the date appointed by State Government.
f) Persons who were qualified to be registered in a State existing before the 1st day of November 1956, but who, because of the transfer of the area in which they resided or carries on their business or profession of pharmacy, to another State on that day and are not qualified to be registered in the latter State only by the reason that they are not matriculates or do not possess a qualification obtained from outside India, which is recognized by the Pharmacy Council of India.
g) Persons who were registered in a State existing before 1st November 1956 and later it becomes part of another State and residing or carrying on the business or profession of pharmacy in later State.

h) Persons who resides or carry on their business or profession of pharmacy in an area in which the chapter relating to the registration applies after the commencement of the Pharmacy (Amendment) Act, 1959; and who satisfies condition for registration in first register.

Any person desiring to enter his name under special provisions in the register may apply in that behalf to the State Council. Such application should be accompanied with prescribed fee. These provisions remain in operation for a period of two years from the commencement of Pharmacy (Amendment) Act, 1959. The State Government however by notification, extend the period of operation of clause 1, 2 and 3, not exceeding two years in aggregate.

Scrutiny of applications for registration:

After the date appointed applications for registration accompanied by the prescribed fee shall be addressed to the Registrar of the State Pharmacy Council. If upon such application Registrar is of the opinion that the applicant has requisite qualifications for registration, he may direct to enter the name of the applicant in the register. Persons whose name has been removed from the register of any State shall not be entitled to have his name entered in the register except with the approval of State Council recorded at a meeting. Any persons whose application for registration is rejected by the Registrar, may appeal to the State Council within three months from the date of rejection. The decision of the State Council thereon is final. Upon entry of name in the register, registrar issues a certificate of registration in a prescribed form.

Renewal fees:

The retention of the name on the register after 31st December of the year following the year in which the name is first entered in the register, subject to the payment of prescribed fee annually before the 1st day of April. If a renewal fee is not paid by the due date, the Registrar shall remove the name of defaulter from the register. The name so removed however may be restored to the register on the prescribed conditions having satisfied. On payment of the renewal fee, the Registrar issues a receipt therefore, and such receipt deemed to be proof of renewal of registration. Any additional qualifications obtained by register pharmacist shall be entered in the register on payment of prescribed fee.

Removal of the names from the register:

The Executive Committee after giving an opportunity to a concerned to explain his conduct and on sufficient inquiry if satisfied, orders to remove the name of a registered pharmacist on following conditions:

a) If his name has been entered in the register by error or on account of misrepresentation or suppression of material fact or,
b) If 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,
c) That a person employed by him to work under him, in connection with any business of pharmacy has been convicted of an offence or held guilty of any such infamous conduct, if such person is a registered pharmacist, he is liable to remove his name from register.

Such order shall be made only if Executive Committee is satisfied that:

a) The offence or infamous conduct was instigated or conceived at by the registered pharmacist or,
b) The register pharmacist has any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place, committed similar offence or guilty of infamous conduct or,
c) Any person employed by the registered pharmacist in connection with any business of pharmacy has been guilty of similar offence during the preceding twelve months and that the registered pharmacist had knowledge of such previous offence or infamous conduct or
d) The offence or infamous conduct continued over a long period and then to the registered pharmacist had or reasonable ought to have had knowledge of continuing offence or infamous conduct or,
e) The offence is an offence under the Drugs and Cosmetics Act, and the registered pharmacist did not use his intelligence to see that the provision of this Act were being observed at his place of business by persons under his control.

The removal of names from the register may either be permanent or only for a specified period of time. The order of Executive Committee directing removal of a name from the Register should be confirmed by the State Pharmacy Council and it takes effect only after three months of the date of such information. This period is probably given to allow the person to find an alternative means of livelihood. A person aggrieved by the order directing the removal of his

name, may appeal to the State Government within thirty days from the date on which he received such order and the decision of the State Government shall be final. A person whose name has been removed from the register is required to surrender his certificate of registration to the Registrar of the Pharmacy Council concerned and the name so removed shall be published in Official Gazette.

Restoration of the names to register:

The State Council may at any time for reasons appearing sufficiently to it, orders that upon payment of the prescribed fee, the name of a person removed from the register shall be restored to the register. Where an appeal against removal was made and rejected by State Government the name cannot be restored unless confirmed by State Government.

Issue of duplicate certificates of registration:

If it is shown to the satisfaction of the Registrar that a certificate of registration has been lost or destroyed, the Registrar may on payment of prescribed fee, issue a duplicate certificate in prescribed form.

OFFENCES AND PENALTIES

Falsely claiming to be Registered Pharmacist:

Any person whose name is not entered in the register, falsely claims to be a Registered Pharmacist or uses in connection with his name any words or letters to suggest that his name is so entered in the register, is punishable with fine up to five hundred rupees on first conviction and with imprisonment up to six months or fine up to thousand rupees or both on any subsequent conviction.

The use of description such as 'Pharmacist', 'Chemist', 'Druggist', 'Pharmaceutist', 'Dispenser', 'Dispensing Chemist' or any combination of such words by a person indicates that his name is entered in the register of a state.

If a person who is registered pharmacist in another state and who at the time of making claims to registration in the State has filed an application for registration shall not be deemed to be guilty of the offence. Cognizance of an offence punishable under this section shall not be taken except upon complaint made by order of the State Government or the Executive Committee of the State Council.

Dispensing by unregistered persons:

The persons other than registered pharmacists, dispensing any medicine for patients is liable for punishment with imprisonment up to six months or with fine up to six months or with fine up to one thousand rupees or with both.

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Medicinal and Toilet Preparations (excise duties) Act, 1955 and Rules thereunder 1976

The present Act prescribes uniform rules for whole of the country regarding duty leviable on such preparations. Alcohol may be used in the manufacture of medicines and toilet preparations. The alcohol required for this purpose can be obtained at lower rate of duty than required for drinking as ordinary alcoholic beverages.

This Act extends to the whole of India and provides legal binding on the use of alcohol.

A. Objective

It provides for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp, or other narcotic drugs and narcotics.

B. Definations

Alcohol: Alcohol means ethyl alcohol of any strength and purity having chemical composition C_2H_6OH.

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

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

Toilet Preparation: The preparation intended to be used in the toilet of 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.

Bonded Manufactory: It means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has not been paid.

Non-bonded manufactory: It means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol opium, Indian hemp and other narcotic drugs or narcotics on which duty been paid.

Denatured Spirit or Denatured alcohol: It means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the Central Government or by the State Government with the approval of the Central Government.

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

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

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

Substandard Preparations: It includes:

(a) A pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum i.e. requirement.

(b) A proprietary medicine, not conforming to the formula displayed on the label.

C. Manufacture

Manufacturer gets the rectified spirit required for manufacture of medicinal and toilet preparations from a distillery or a spirit warehouse of the state. If there is a loss of rectified spirit due to the wastage in transit, and if the Excise Commissioner satisfies that the loss is bonafide and due to negligence by the manufacturer, the duty payable in respect of such loss may be waived in full or in part depending on the circumstances.

Permission of State Government is necessary to claim the concessions in duty in case of the issues of rectified spirit made to non-bonded manufactories.

There are two modes of manufacture of medicinal and toilet preparation containing alcohol,

(i) Manufacture in bond; and
(ii) Manufacture outside bond.

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

Procedure for license:

Every person, desiring to manufacture Medicinal and Toilet preparation containing alcohol or other narcotic substances is required to obtain a license,

(1) From the Excise Commissioner in case of a Manufacture in Bond; and

(2) From the officer as the State Government may authorise in this behalf in case of manufacture outside bond.

The application for grant of license should be submitted in the prescribed form together with prescribed fee (treasury chalan) so as to reach the licensing authority at least two months before the proposed date of the commencement of the manufacture.

Such application should contain the following particulars:

(1) The name or names and address or addresses of the applicant or applicants.

In case of a firm, the name and address of every partner. In case of a company, its registered name and address, the names and addresses of it's Directors, Managers and Managing agents.

(2) Name and address of the place and the site on which the Bonded or Non-bonded Laboratory is situated or to be constructed.

(3) The amount of capital proposed to be invested.

(4) Approximate date from which the applicant desires to start the manufacture if the required license is granted.

(5) The number and full description of the vats, stills and other permanent apparatus and machinery which the applicant wishes to set up.

(6) The maximum quantities in L.P. Liters of alcohol and alcoholic content in unfinished and finished preparations are likely to remain in the laboratory at any one time; and Maximum quantities by weight of opium, Indian hemp or other narcotic drug and their content in unfinished and finished preparations are likely to remain in the laboratory at one time.

(7) In case of Bonded laboratory, whether the proposed bonded manufactory will require the services of a whole-time or part-time excise officer.

(8) A list of all preparations, that the licensee proposes to manufacture showing,

(i) The percentage or proportion of alcohol in such preparation containing alcohol.

(ii)The quantities of opium, Indian hemp or other narcotic drugs in terms of weight in preparations containing these substances.

(9) The kind and number of licences held by the applicant under the Drugs and Cosmetics Act, 1940.

(10) Site and elevation plans of the manufactory building or buildings showing the location of the different rooms with doors and windows therein.

(11) In case of a firm, a true copy of the partnership deed. And in case of a company, the list of the Directors and Managers together with copies of Memorandum of Association and Articles of Association.

On receipt of such application the licensing authority makes the following enquiries:

(a) The qualifications and experience of the technical persons.

(b) The equipment of the bonded or non-bonded laboratories,

(c) Suitability of the proposed building for the establishment of a laboratory.

After satisfying that the applicant is eligible for the issue of a license, the licensing authority (the Excise Commissioner) shall issue a license and approve the plans of buildings submitted along with the application by the applicant. After constructing the buildings and establishing the laboratory as per the approved plans, the planning authority shall verify the plans to ascertain whether the construction is as per the approved plan or not.

In some cases where security is required to be furnished the licensing authority shall fix the amount of such security before granting the license. The security shall be either in cash or in interest bearing securities like Government Promissory Notes, National Savings Certificates, etc.

I. Bonded Laboratory or Bonded Manufactory

Following are the requirements of the bonded laboratory:

1. A spirit store, (if a distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory).
2. Room or rooms for the manufacture of medicinal preparations.
3. One or more rooms for the storage of the finished medicinal preparations.
4. A separate room or arrangement for the manufacture of toilet preparations.

5. The storage room for the finished toilet preparations.
6. Accommodation near the entrance for the officer-in-charge with necessary furniture.
7. Every room in the bonded laboratory should bear a board indicating the name of the room and serial number.
8. The pipes from sinks or wash basins in the laboratory should be connected with the general drainage of the laboratory.
9. The arrangements of gas and electric connections should be such that their supply can be cut off at the end of the day's work.
10. Every window in the bonded laboratory would be provided with specific arrangement of malleable iron rods of prescribed dimensions and the window should be covered on the inside with strong wire netting of a mesh not exceeding 25 mm.
11. There shall be-only one entrance to the bonded laboratory and one door to each of it's compartments. All the doors shall be secured with excise ticket locks in the absence of the officer-in-charge. No alterations in the bonded premises shall be made without the previous orders of the Excise Commissioner.
12. All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial number and full capacity.
13. The vessels for the storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks.

For the manufacture in bonded laboratory, the rectified spirit shall be issued without previous payment of duty subject to the condition that the manufacturer enters into a bond in prescribed form with sufficient security.

Obtaining the rectified spirit from the Distillery or spirit warehouse approved the Excise Commissioner:

The spirit required for the manufacture in bond shall be obtained on an in prescribed form countersigned by the officer in-charge of the laboratory from the approved spirit store or distillery. After receiving the duplicate of indent from the officer in-charge of the bonded laboratory, the distillery or warehouse officer shall issue the spirit under the appropriate permit, and send the advice portion of such permit to the officer-in-charge. The cost price of such rectified spirit shall be paid by the licensee to the distiller warehouse officer.

Verification and Storage of rectified spirit received:

After receiving the rectified spirit, it is verified in volume and strength and entered in the register. Then the spirit is stored in the spirit store.

Issue of the rectified spirit from the spirit store for manufacture:

The licensee should calculate the requirement of spirit on the basis of the formula of the preparation in pharmacopoeia or formula displayed on the label and hand it over to the officer-in-charge. Officer-in-charge shall then issue the spirit to the manufacturer. All rectified spirit issued shall be added immediately to the other ingredients of the preparation in presence of the officer-in charge.

The manufacturing vessels like percolators charged with alcohol should bear a label indicating

(a) The name and batch number of the preparation.

(b) Description and quantity of alcohol placed in it.

(e) Date of removal of the preparation and the quantity of such preparation removed.

On completion of the manufacture of a medicinal and toilet preparation, it should be removed to the finished goods store. With the permission of officer-in-charge, the licensee shall take specified quantity of the free sample for analysis in his laboratory.

Storage of finished products:

1. Finished preparations should be stored in bulk in jars or bottles each containing not less than 2,273 ml.
2. The preparations ready for issue may be filled in the containers of not less than 57 ml capacity. In some cases the Excise Officer may authorize issue in smaller containers.
3. Every container should be labeled and the label should contain:

(a) Name of the preparation.

(b) Batch number.

(e) Alcoholic strength; and

(d) Name of the manufacture.

4. The label on the container in which the preparation is stored in bulk should in preparation is stored in bulk should in addition indicate alcoholic content in liters, alcoholic strength and the date of storage.

5. The containers are so arranged on the rack so as to allow ready identifications of each batch.

6. The finished preparations may be stored in a store room for a period of three years or more with the permission of Excise Commissioner.

Issue of preparations from bonded laboratory:

For taking out the preparations from a bonded laboratory, the licensee should apply in prescribed form to Excise Officer-in-charge. After checking the entries and realizing the duty payable, the officer-in-charge shall issue a permit and allow the required quantities to be removed. However, the issue to another bonded warehouse may be made without payment of duty under proper security governed by the rules under this Act.

II. Non-Bonded Laboratory or Non- Bonded Manufactory

The manufacture and sale in the non-bonded laboratory should be conducted between sunrise and sunset only and on such days and hours as may be fixed by the Excise Commissioner.

Building Arrangements:

1. The portion of the non-bonded laboratory should be separated from the other portion used for other business.
2. There should be separate 'spirit store', laboratory' and finished store' and these should have the windows fitted with malleable iron bars of specific dimensions and the windows should be covered on the inside with strong wire netting of mesh not exceeding 25 mm.
3. There should be only one entrance to the non-bonded manufactory and one door to each of the above-mentioned departments.
4. All the pipes from sinks and wash-basins inside the non-bonded laboratory should be connected with the general drainage system of the premises.
5. The arrangements of gas and electric supply should be such that their supply can be cut off at the end of day's work.
6. There should be separate spirit store for the rectified spirit purchased at different rates of duty.
7. There should be separate finished stores for medicinal and toilet preparations falling under each item of the schedule to the act e.g., pharmacopoeial preparations with the items like, Aquas, Elixirs, Lotions, spirits etc., and Non-phamacopoeial preparations.

The State Government may relax the provisions in case of small manufacturers whose annual consumption of alcohol is not more than 500 litres and in the case of those who prepare medicinal preparations for dispensing to their patients only and not for sale.

Obtaining the rectified spirit-duty paid:

To obtain the spirit for manufacturing medicinal and toilet preparations from approved distiller or a spirit warehouse, the licensee should send the indent along with treasury chalan (evidence of duty payable) to the officer-in-charge of the distillery. The cost of such rectified spirit shall be paid by the licensee to the distillery or spirit-warehouse-keeper.

The officer-in-charge of the distillery, after satisfying himself that the correct amount of duty has been paid shall order the issue of rectified spirit required together with a permit covering the issue. After entering in the proper register, the spirit so obtained should be transferred to the respective spirit store.

Manufacture and storage of the preparations:

1. The manufacture of preparations from duty paid spirit should be carried out only at the licensed premises.
2. Each preparation should be registered after its manufacture and given a distinctive batch number.
3. All finished preparations should be transferred from the laboratory to the finished store and so arranged that they can be easily checked from the account register.
4. Finished preparations prepared from rectified spirit obtained at different rates of duties should be stored separately in the finished store.
5. The finished preparation stored in bulk should be measured in the storage vessel to the nearest fluid ounce (28.350 ml) and sealed.
6. The quantities from the bulk storage taken out by the manufacturer from time to time should be entered in the stock-card attached thereto. The Excise Officer, without any previous notice to the manufacturer may take samples at least once a month for analysis.

D. Exemption from Duty

The followings are exempted from duty on medicinal preparations containing alcohol manufactured in India and supplied direct from a bonded manufactory or warehouse.

1. Hospitals and dispensaries under Government or subsidized by the Government (State or Central).
2. Charitable hospitals and dispensaries under local bodies,
3. Medical Stores of Government.
4. Any institution certified by District Medical Officer supplying medicines free to the poor.

The Government has power to exempt any dutiable goods from the levy of the duty in the interest of the trade or in public interest.

E. Classification of Medicinal and Toilet Preparations Containing Alcohol

(A) Allopathic Preparations:

(a) Official allopathic preparations.

(b) Non-official allopathic preparations (Patent and Proprietary Preparations).

(B) Homoeopathic Preparations.

(C)Ayurvedic Preparations.

Medicinal and Toilet preparations are also classified as

(i) Restricted preparations.

(ii) Un-restricted preparations.

Allopathic Preparations:

Official preparations are made according to the formulae given in official books like I.P, B.P, B.P.C., U.S.P., N.F., Veterinary Codex (Government of India) etc.

Non-official allopathic preparations are prepared according to the allopathic system of medicine and confirm strictly to the formula displayed on the label. The official and non-official preparations, capable of being consumed as ordinary alcoholic beverages are known as 'Restricted Preparations'. Central Government may declare the unrestricted preparations as restricted preparations if they are widely misused.

Proprietary preparation which is newly put in the market is presumed to be a restricted preparation unless declared to be otherwise by the Central Government on the advice of the Standing Committee.

Any manufacturer intending to manufacture a new non-official alcoholic preparation should submit two samples of such preparations with the recipe to the State Government. The State Government, on advice of the Standing Committee, shall declare the class of such preparation, whether restricted or unrestricted.

Homoeopathic Preparations:

American, British and general pharmacopoeias shall be recognized as standard pharmacopoeia for Homoeopathic preparations.

Ayurvedic Preparations:

Ayurvedic preparations containing alcohol may be of two types:

(1) Those containing self-generated alcohol e.g. Asavas and Aristas.

(2) Those prepared by distillation or to which alcohol is added at any stage of manufacture.

Duty shall not be levied on Ayurvedic preparation containing self generated alcohol in which the alcoholic content is less than 2 per cent. In case of the preparation, the alcoholic content of which is more than 2% and if it is capable of being consumed as ordinary alcoholic beverages, the duty shall be paid, otherwise not.

Registered Ayurvedic Practitioners are allowed to manufacture and dispense (except by distillation or by addition of alcohol during the process) such preparations are free of duty, provided:

(a) They take a license.

(b) Use such preparations only for the patients of the practitioners and not for sale to the general public.

(c)They should allow Excise Officer to draw samples of such preparations to ensure that the preparations contain only self-generated alcohol; and

(d) They should maintain accounts of the preparations manufactured or dispensed to the patients together with the names and addresses of the patients. The Ayurvedie preparations may be manufactured in bond or without bond.

F. Warehousing of Alcoholic Preparations

The manufacturers or dealers in dutiable goods are allowed to establish bonded warehouses anywhere in India to deposit dutiable goods. The persons who intend to establish a warehouse should apply in prescribed form along with prescribed fees to Excise Commissioner of State and obtain a license for the purpose from him. The Excise Commissioner may require the licensee to furnish a bond in prescribed form with surety or security, binding him to pay duty on the goods deposited or for removal of such goods to another warehouse or for the due observance of the terms, conditions and requirements of the Act. All such goods brought for warehousing should be produced to the officer-in-charge of the warehouse with the relative transport permit. Before the entry in the warehouse, the goods should be weighed, gauged and assessed to duty and the particulars should be recorded in the register maintained for the purpose. The bonded warehouse should be locked and secured as per the directions of Excise Commissioner.

Goods shall not be removed from any warehouse without payment of duty. Duty shall not be paid for the removal of goods to other warehouse or for export. Goods shall remain in the warehouse in which they are deposited for three years or more as the Excise Commissioner allow.

G. Export of Medicinal and Toilet

Preparations (Alcoholic Preparations):

No duty shall be paid on alcoholic preparations which are exported from India. The preparations can be exported by two methods:

(1) Duty paid goods shall be exported under claim for rebate of duty.

(2) Goods (without payment of duty) shall be exported under bond.

I. Export of Duty Paid Goods:

Export of Duty paid goods shall be made under claim for rebate of duty. The owner of the non-bonded manufactory or a wholesale dealer who wants to export duty paid goods should give minimum 48 hours' notice to the concerning Excise-Officer to supervise the packing of the goods which are to be exported. The manufacturer or dealer should present the consignment to be exported to the concerning officer who shall send the samples of such dutiable goods to the Chemical Examiner for analysis to confirm the alcoholic contents of these goods. From the report of Chemical Examiner, the officer shall enter the alcoholic contents (strength) in the

duplicate copy of the application which shall be presented to Excise Commissioner by the exporter for claiming rebate of excise duty.

After verifying the application, the officer-in-charge or concerning officer shall get the following particulars noted on the packages:

(1) Name and address of the consignee.

(2) Total quantity of the goods packed.

(3) Description of the goods packed.

(4) Alcoholic strength of the goods in London-proof (L.P.) liters.

(5) A Gross weight of each package.

The Officer-in-charge shall then seal each package with his official seal and endorse all the copies of the application specifying the period within which the goods shall be actually exported. The Officer shall return the duplicate to the consignor, who has to enter the number and date of the railway receipt or bill of landing in duplicate copy, after dispatching the goods. The consignor should inform these particulars to the concerning officer for entry in the other copies. On arrival of the goods at the consignee's place (place of export) the goods should be presented to the Customs Collector, Border Examiner etc. for examination, along with duplicate application. After such examination the Customs Collector, Border Examiner such officers of customs may allow export. For obtaining the payment of rebate the exporter should produce to the Excise Commissioner, the duplicate application along with the certificate of the officer who examined the goods. The Excise Commissioner if satisfied from the comparison of duplicate and original application that the claim is in order, he shall sanction the rebate claimed by the exporter.

II. Export under Bond:

The owners of the bonded manufactory or bonded warehouse can export the alcoholic preparations under bond. The exporter should present an application in triplicate to the Excise Officer-in-charge of the bonded laboratory or warehouse, giving the statements that the goods are to be exported by sea or air or by parcel post. The packages of the goods to be exported should be marked in ink or oil color with the particulars like serial number, owners name and special mark if any and total quantity of the dutiable goods with their alcoholic strength in L.P. liters.

On verification of the particulars in the application, the Officer-in-charge also note the following particulars on the packages,

(1) Name and address of the consignee (to whom the goods are to be exported).

(2) Description of goods.

(3) Total quantity of the goods packed.

(4) Gross weight of the package.

The officer may seal each package with his official seal. The packages can be exported in the same way as that of duty-paid goods.

Inter-State movement of Medicinal and Toilet Preparations under the Act:

Medicinal and Toilet preparation under this Act can be moved from one State to another after payment of duty as per the rules. Such dutiable goods can also be transferred from a bonded warehouse of one State to the bonded warehouse of the other State. The procedure for the same is described in the further paragraph.

Movement of dutiable goods from one Bonded Warehouse to another Bonded warehouse:

When the goods are to be removed from one warehouse to another, the consignor or the consignee should enter into a bond with surety or sufficient (prescribed) security. Such bond shall be furnished to the officer-in-charge of the warehouse of removal or of the warehouse of destination as the case may be. Such bond shall remain valid until the Officer-in-charge of the warehouse of removal has received a re-warehousing certificate (stating that the goods have been re-warehoused) from the Officer-in-charge of warehouse of destination. The consignor should make an application in triplicate for removal of goods from one warehouse to another warehouse to the officer-in-charge of the warehouse together with other necessary information as the Excise Commissioner may require at least 24 hours before the removal of goods.

The officer-in-charge shall take the account of goods and send the duplicate copy after giving remark for removal to the officer-in-charge of the warehouse of destination. And the triplicate copy shall be given to the consignor to send to the consignee.

On arrival of the goods at the destination, the consignee should present such goods along with the triplicate application and the transport permit to the officer-in-charge. Then he shall take account of goods and complete the re-warehousing certificate on the duplicate and triplicate

and return the duplicate to the officer-in-charge of the warehouse of removal and the triplicate to the consignee for dispatch to the consignor. The consignor shall then present such triplicate copy of the application together with the warehousing certificate to the officer in-charge of his warehouse within 90 days of the issue of the transport permit to him.

G. Entry, Search and Seizure

An officer authorized by Excise Commissioner shall have free access at reasonable time to any premises, equipment, stocks and accounts of manufacturers and dealers in dutiable goods. Any excise officer authorized in this behalf by the State Government may stop and detain any person carrying or removing any dutiable goods without transport permit or other relevant document required.

Excise Officers, not below the rank of sub-inspectors has power to stop search and seize the vessel or vehicle carrying the dutiable goods. He has also power to enter and search at any time, any premises or land in which he has reason to believe that dutiable goods are stored, manufactured in contravention of the Act and Rules there under. In case of any resistance to entry or search or; seizure he has power to break open any door and remove any other obstacle and open and search into such land or premises.

Such officer may also seize and remove or detain any receptacle, packages or coverings of such goods and animals, vehicles or vessels involved in carrying the goods and the machinery used in the manufacture of such goods. All such searches, seizures etc., made under the Act are in accordance with Criminal Procedure Code.

I. Offences and Penalties

1. (a) Contravention of any of the provisions relating to the terms and conditions of a license granted under this Act; or

(b) Failure to pay any duty of excise payable under this Act; or

(c) Failure to supply required information or supplying false information; or

(d) Attempt to commit or abet any of the above offences.

Punishable with imprisonment up to six months or with fine up to Rs. 2,000/-or with both.

2. Connivance by any owner or occupier of land or by any agent of such owner occupier for any offence against the provisions of this Act, or any rules there under.

Punishable with imprisonment up to six months or with fine up to Rs. 500 or both for every offence.

3. Vexations search, seizure by any officer exercising powers under this Act or under the rules made there under.

Punishable with fine up to Rs. 2,000/-.

4. Refusal to perform or withdrawal of one-self from the duty by the Excise Officer without permission of the superior officer.

Punishable with imprisonment up to three months or with fine up to three months pay.

5. Failure to furnish proof of export, within the prescribed period to the satisfaction of Excise Commissioner, by any persons authorized to export dutiable goods in bond.

Punishable with a fine up-to Ra. 2,000/- extent to twice the amount of duty.

6. Of all the offences committed with respect to warehousing.

Punishable with a fine up to Rs. 2,000/- and the goods related to the offences are liable to confiscation.

7. Obstruction to the officers while exercising their powers regarding Entry, Search and Seizure.

Punishable with a fine up to Rs. 500/-.

8. Prosecution: Only the sub-inspector or officer above his rank can institute the prosecution under this Act.
9. Arrests: Only the sub-inspector or officer above his rank can make arrest under this Act.
10. A breach of the rules, where no punishment is provided.

Punishable with a fine up to Rs. 1,000/- and confiscation of the goods.

11. Keeping of stocks of dutiable goods in disorderly manner (not in accordance with the provisions of this Act).

Punishable with a fine up to Rs. 1,000/-

12. Maintaining false accounts of stock of goods in a manufactory or warehouse or not following the provision of this Act while maintaining such accounts.

Punishable with a fine up to Rs. 2,000/-.

13. Sale of dutiable good except in prescribed containers bearing a label.

Punishable with a fine up to Rs. 1,000/- and confiscation of the goods related with this offence.

14. Disclosure of information by Excise officers learned by him in his official capacity.

Punishable with a fine up to Rs. 1,000/-.

Reference

B. S Kuchekar. Pharmaceutical Jurisprudence. Nirali prakashan, 25th Edition, 2016.

The Narcotic Drugs and Psychotropic Substances Act, 1985, with rules, 1985

Definition:

The Narcotic Drugs and Psychotropic Substances Act, 1985, commonly referred to as the NDPS Act, is an Act of the Parliament of India that prohibits a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, and/or consume any narcotic drug or psychotropic substance.

Objectives:

- The main object of this Act is to consolidate and amend the law relating to narcotic drugs, to make stringent provision for the control and regulation of operations relating to narcotic drugs and psychotropic substances.
- It also provides licensing system for both Central and State Governments to regulate the manufacture, cultivation, import, export inter-state traffic, transportation, sale and possession etc, of the Narcotic Drugs and Psychotropic substances.

Definition:

"*Addict*": Means a person who has dependence or habitual to regular use of any narcotic drug or psychotropic substances.

"*Cannabis*": (hemp): It means

(a) *Charas*, that is, the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish;

(b) *Ganja*, that is, the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops), by whatever name they may be known or designated; and

(*c*) Any mixture, with or without any neutral material, of any of the above forms of cannabis or any drink prepared there from;

"*Cannabis plant*": means any plant of the genus cannabis.

"*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;

"*Coca leaf*": means—

(*a*) The leaf of the coca plant except 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 percentage of cocaine;

(*vii*) "Coca plant" means the plant of any species of the genus Erythroxylon;

"*Manufacture*": in relation to narcotic drugs or psychotropic substances, includes—

(1) All processes other than production by which such drugs or substances may be obtained;

(2) Refining of such drugs or substances;

(3) Transformation of such drugs or substances; and

(4) Making of preparation (otherwise than in a pharmacy on prescription) with or containing such drugs or substances;

"*Manufactured drug*": means—

(a) All coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate;

(b) Any other narcotic substance or preparation which the Central Government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the Official Gazette, declare to be a manufactured drug, but does not include any narcotic substance or preparation declared not to be manufactured drugs.

"***Narcotic drug***" means coca leaf, cannabis (hemp), opium, popy straw and includes all manufactured drugs;

"*Opium*": means—

(a) The coagulated juice of the opium poppy; and

(b) Any mixture, with or without any neutral material, of the coagulated juice of the opium poppy, but does not include any preparation containing not more than 0.2 percentage of morphine;

"*Opium derivative*": means—

(a) Medicinal opium, that is, opium which has undergone the processes necessary to adapt it for medicinal use in accordance with the requirements of the Indian Pharmacopoeia or any other pharmacopoeia notified in this behalf by the Central Government, whether in powder form or granulated or otherwise or mixed with neutral materials;

(b) 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;

(c) Phenanthrene alkaloids, namely, morphine, codeine, thebaine and their salts;

(d) Diacetylmorphine, that is, the alkaloid also known as dia-morphine or heroin and its salts; and

(e) All preparations containing more than 0.2 per cent. of morphine or containing any diacetylmorphine;

"*Opium poppy*": means—

(a) The plant of the species *Papaver somniferum* L; and

(b) The plant of any other species of *Papaver* from which opium or any phenanthrene alkaloid can be extracted and which the Central Government may, by notification in the Official Gazette, declare to be opium poppy for the purposes of this Act;

"*Poppy straw*": means all parts (except the seeds) of the opium poppy after harvesting whether in their original form or cut, crushed or powdered and whether or not juice has been extracted there from;

"*Poppy straw concentrate*": means the material arising when poppy straw has entered into a process for the concentration of its alkaloids;

"*Preparation*": in relation to a narcotic drug or psychotropic substance, means any one or more such drugs or substances in dosage form or any solution or mixture, in whatever physical state, containing one or more such drugs or substances;

"*Prescribed*": means prescribed by rules made under this Act;

'*Production*" means separation of opium, poppy straw, coca leaves or cannabis from the plants from which they are obtained;

"*Psychotropic substance*": means any substance, natural or synthetic, or any natural material or any salt or preparation of such substance or material included in the list of psychotropic substances specified in the Schedule;

"*Small quantity*": in relation to narcotic drugs and psychotropic substances, means any quantity lesser than the quantity specified by the Central Government by notification in the Official Gazette;]

"*To import inter-State*": means to bring into a State or Union territory in India from another State or Union territory in India;

"*To import into India*": with its grammatical variations and cognate expressions, means to bring into India from a place outside India and includes the bringing into any port or airport or place in India of a narcotic drug or a psychotropic substance intended to be taken out of India without being removed from the vessel, aircraft, vehicle or any other conveyance in which it is being carried.

"*To export from India*": with its grammatical variations and cognate expressions, means to take out of India to a place outside India;

"*To export inter-State*": means to take out of a State or Union territory in India to another State or Union territory in India;

"*To transport*": means to take from one place to another within the same State or Union territory;

"*Illicit traffic*": in relation to narcotic drugs and psychotropic substances, means—

(i) Cultivating any coca plant or gathering any portion of coca plant;

(ii) Cultivating the opium poppy or any cannabis plant;

(iii) Engaging in the production, manufacture, possession, sale, purchase, 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)Dealing in any 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*),

"*Essential narcotic drug*": means a narcotic drug notified by the Central Government for medical and scientific use;

"*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.

AUTHORITIES AND OFFICERS

Measure for preventing and combating abuse of narcotic drugs and illicit traffic therein:

Central Government under the provisions of this Act, may take the measures with respect to all or any of the following matters.

1. Co-ordination of actions by various officers, State Governments and other authorities under this Act, or under any other law for the time being in force relating to the enforcement of the provisions of this Act.

2. Obligations under the International Conventions.

3. Assistance to the concerned authorities in foreign countries and concerned international organizations regarding prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances.

4. Identification, treatment, education, aftercare, rehabilitation and social re-interaction of addicts.

5. Such other matters for effective implementation of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.

Officers of Central Government:

Under the provisions of this Act, the Central Government may appoint Narcotic Commissioner and such other officer as it thinks fit.

Narcotic Commissioner himself or with the help of other officers shall perform the functions relating to:

(i) The supervision of the cultivation of the opium poppy, and

(ii) Production of opium; and

(iii) Other functions as may be entrusted to him by the Central Government.

The State Government may appoint such officers as deemed fit for the purposes of this Acts.

The Narcotic Drugs and Psychotropic Substances Consultative Committee:

For efficient administration of this Act, the Central Government may constitute an advisory committee known as: 'The Narcotic Drugs and Psychotropic Substances Consultative Committee".

This committee consists of a Chairman and such other members not exceeding 20, as may be appointed by the Central Government. For efficient discharge of it's functions the Committee may constitute and appoint one or more sub-committees.

The committee shall advice the Central Government on the matters relating to the administration of this Act.

Prohibition, Control and Regulation:

Section 8, of this Act prohibits certain operations such as cultivation of coca plant, opium and cannabis plant, manufacture, possession, sale, purchase, transport, import, export, etc. relating to the narcotic drugs and psychotropic substances except for medical and scientific purposes. However, section 9, of this Act empowers the Central Government to permit, control und regulate by rules, certain operations relating to certain narcotic drugs and psychotropic substances.

(a) Prohibition of certain operations as per sec. 8: No person shall:

(i) Cultivate any coca plant or gather any portion of coca plant or,

(ii) Cultivate the opium poppy or any cannabis plant; or

(iii) Produce, manufacture, possess, sell, purchase, transport, ware-house, use, consume, import inter-state, export inter-state, import into India, export from India or transship any narcotic drug or psychotropic substance except for medical and scientific purposes and to the extent and in the manner provided by other provisions of this Act, or the rules or orders made there under.

(b) Power of Central Government to Permit, Control, and Regulate:

(1) Permission and Regulation of certain operations by Central Government: Central Government may, by rules permit and regulate:

(i) The cultivation, or gathering of any portion of coca plant (only on account of the Central Government), or the production, sale, purchase, transport, import inter-state, export inter-state, use or consumption of coca leaves.

(ii) The cultivation of the opium poppy; (only on account of Central Government).

(iii) The production and manufacture of opium and production of opium and production of poppy straw.

(iii) The sale of opium and opium derivatives from the Central Government factories for export from India or sale to State Government or to manufacturing chemists.

(iv)The manufacture of manufactured drugs (Other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.

(v)The manufacture, possession, transport, imports inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances.

(vi) The import into India and export from India and trans-shipment of narcotic drugs and psychotropic substances.

Control on Certain Operations by Central government: According to the rules:

(i) Government shall fix from time to time the limits within which licenses may be given for the cultivation of opium poppy.

(ii) All Opium, the product of land cultivated with the opium poppy shall be delivered by the cultivators to the officers authorized on behalf of Central Government.

(iii)The Central Government may from time to time fix the price to be paid to the cultivators for the opium delivered.

(iv)The rules may prescribe the forms and conditions of licenses or permits for the manufacture, possession, transport, import-inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances. The rules may also prescribe the authorities granted and the fees that may be charged therefore.

(v) The rules may prescribe the forms and conditions of licenses for cultivation of the opium poppy and for the production and manufacture of opium. The rules may also prescribe the fees that may be charged therefore, the authorities by which such licenses may be granted, withheld, refused or cancelled and the authorities before which appeals against the orders of withholding, refusal or cancellation of licenses shall lie.

(vi)The rules may provide for the weighed, examined, classified according to the quality and consistence by the officers authorized in this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator.

(vii)The rules may provide for the weighment, examination and classification, according to the quality and consistence of the opium received at the factory and the deduction from or addition to the standard price to be made in accordance with the result of such examination.

(viii) The rules may prescribe the forms and conditions of licenses for the manufacture of manufactured drugs, the authorities by which such licenses may be granted and the fees that may be charged therefore.

(ix) The rules may require that opium delivered by cultivator, if found as a result of examination in the Central Government factory to be adulterated, may be confiscated by the officers authorized in this behalf.

Power of State Government to permit, control and regulate:

Permission and Regulation of certain operations by State Government: State Government may by rules permit and regulate:

(i)The possession, transport, inter-state import, inter-state export, warehousing, sale, purchase, consumption and use of poppy straw.

(ii)The possession, transport, inter-state import, inter-state export, sale, purchase, consumption and use of opium.

(iii)Cultivation of any cannabis plant production, manufacture, possession, transport, inter-state import, inter-state export, sale purchase, consumption or use of cannabis (excluding charas).

(iv)Manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.

(v)Possession, transport, purchase, sale, inter-state import, inter-state export, use or consumption of manufactured drugs other than prepared opium and of coca-leaf and any preparation containing an manufactured drug.

(vi)The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption.

Control of certain operations by State Government: The rules under this Act may

(i) Provide that the State Government shall fix from time to time the limits within which licenses may be given for the cultivation of any cannabis plant.

(ii) Make provision that, only the cultivators licensed by the prescribed authority of the State Government shall be authorized to engage in cultivation of any cannabis plant.

(iii)Require that all cannabis, the produce of land cultivated with cannabis plant, shall be delivered by the cultivators to the officers of the State Government authorized on this behalf.

(iv) Empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered.

(v)Prescribe the forms and conditions of licenses or permits licenses or permits for some or all of the followings: possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption and use of poppy straw, opium, cannabis (excluding charas).

National Fund for Control of Drug Abuse

1. The Central Government may, by notification in the Official Gazette, constitute a Fund to be called the National Fund for Control of Drug Abuse (hereafter in this Chapter referred to as the Fund) and there shall be credited thereto:
    - An amount which the Central Government may, after due appropriation made by Parliament by law in this behalf, provide.
    - The sale proceeds of any property forfeited under Chapter VA.
    - Any grants that may be made by any person or institution.
    - Any income from investment of the amounts credited to the Fund under the aforesaid provisions.
2. The Governing Body shall consist of a Chairman (not below the rank of an Additional Secretary to the Central Government) and such other members not exceeding six as the Central Government may appoint.
3. The Governing Body shall have the power to regulate its own procedure.
4. Annual report of activities financed under the Fund-
    - The Central Government shall, as soon as may be, after the end of each financial year, cause to be published in the Official Gazette, a report giving an account of the activities financed under the previous section during the financial year, together with a statement of accounts.

5. The Fund shall be applied by the Central Government to meet the expenditure incurred in connection with the measures taken for

- Combating illicite traffic of narcotic and psychotropic substances.
- Controlling abuse
- Identifying, treating, rehabilitating addicts.
- Preventing drug abuse.

- Supply of drugs to addicts.

OFFENCES AND PENALTIES

1. **Punishment for contravention in relation to poppy straw:**
2. **Punishment for contravention in relation to coca plant and leaves:**
3. **Punishment for contravention in relation to prepared opium:**
4. **Punishment for contravention in relation to opium poppy and opium:**
5. **Punishment for embezzlement (illegal disposal) of opium by cultivator:**
6. **Punishment for contravention in relation to cannabis plant and cannabis:**
   (a) Where such contravention relates to ganja or the cultivation of cannabis plant: Rigorous imprisonment upto five years with a fine upto fifty thousand rupees.
   (b) Where such contravention relates to cannabis other than ganja: Rigorous imprisonment for not less than ten years which may extend to twenty years with fine not less than one lakh rupees which may extend to two lakh rupees.
7. **Punishment for contravention in relation to manufactured drugs and preparations:**
8. **Punishment for contravention in relation to psychotropic substances:**
9. **Punishment for illegal import into India, export from India or transhipment of narcotic drugs and psychotropic substances:**
10. **Punishment for external dealings in narcotic drugs and psychotropic substances in contravention of the provisions of this Act:** Rigorous imprisonment for not less than ten years which may extend to twenty years with a fine not less than one lakh rupees which may extend to two lakh rupees.
11. **Punishment for allowing premises, etc. to be used for commencement of an offence:** Rigorous imprisonment for not less than ten years which may extend to twenty years with fine not less than one lakh rupees which may extend to two lakh rupees.
12. **Punishment for certain acts by licensee or his servants:** The acts are:

(a) Omitting to maintain accounts in accordance with the provisions of this Act.

(b) Failure of producing license, permit or authorization on demand of any authorized officer.

(c) Keeping any false account or making false statement.

(d) Knowingly doing any act in breach of any of the conditions of license, permit or authorization for which a penalty is not prescribed elsewhere in this Act: Imprisonment up-to three years or fine or both.

13. **Punishment for illegal possession in small quantity for personal consumption of any narcotic drug or psychotropic substance or consumption such drug or substance:**

(a) Where the narcotic drug or psychotropie substance possessed or consumed is cocaine, morphine, diacetyl-morphine or any other narcotic drug or any psychotropic substance. Imprisonment up-to one year or fine or both.

(b) Where the narcotic drug or psychotropic substance possessed or consumed is other than those mentioned in (a) above: Imprisonment up-to six months or fine or both.

14. **Punishment for abetment and criminal conspiracy:** Punishment provided for the offences.
15. **Enhanced punishment for certain offences after previous conviction: On second and every subsequent conviction of offences:**
16. **Punishment for offence for which no punishment is provided under this act:** Imprisonment up-to six months or fine or both.

Opium Poppy Cultivation and Production of Poppy Straw

The NDPS Act empowers the Central Government to permit and regulate cultivation of opium poppy for medical and scientific purposes. The Government of India notifies the tracts where opium cultivation can be licensed as well as the General Conditions for issuance of license every year.

Opium and poppy straw are the raw materials obtained from the opium poppy plant (Papaver somniferum), from which alkaloids such as morphine, thebaine and codeine are extracted. Concentrate of poppy straw is a product obtained in the process of extracting alkaloids from poppy straw.

Production and supply of the opium

- Opium (also called "raw opium") is the latex obtained by making incisions on the green capsules of opium poppy plants.
- Cultivation can be done only in those areas, notified by the govt.
- Licences are granted by district opium officers for cultivation. He appoints one licenced cultivator who performs duties as specified by narcotic commissioner with help of small cultivators under him.
- Harvest of each day's collection is weighed and entered in records which is signed by cultivator. The records are checked by the dist opium officer.
- The whole opium collected by the dist. Officer is then delivered to opium factory.

- The cultivators are paid and they should not dispose off any part of the procedure and adulteration is liable for confiscation.
- Cultivator should cultivate full area of land for which he may have received advance amount from the govt.
- Opium shall not be cultivated in any part of the India except UP and MP (as per central opium rules, 1934).

Manufacture-

Poppy straw is first pulverized, then washed as many as six to ten or more times in water which may have an acid added to increase solubility, to produce **poppy straw concentrate** (**PSC**, also known as **concentrate of poppy straw**, **CPS**). Dried, the concentrate is a beige to brown powder. It contains salts of various alkaloids, and can range from nine to 30 times the morphine concentration of poppy straw. Opium concentrates using solvents other than acidifed or plain water are often but not necessarily called PSC.

Fee for grant of licence.

The licence of cultivation of opium poppy may be granted by the District Opium Officer on payment of a fee of [rupees twenty-five].

Form of licence for cultivation of the opium poppy-

The licence for cultivation of opium poppy for the production of opium or poppy straw shall be issued in Form No. 1 appended to these rules.

Issue of licence-Subject to the general conditions relating to grant of licence notified by the Central Government*, the District Opium Officer may issue licence to any person for a crop year for cultivation of the opium poppy for production of opium or poppy straw on receipt of an application made by that person in Form No.2 appended to these rules.

Licence to specify the area, etc.-The licence for cultivation of opium poppy issued under rule 8 shall specify the area aid designate the Plots to be cultivated with opium poppy.

Procedure with regard to measurement of land cultivated with opium poppy.-

1. All plots of land cultivated with opium poppy in accordance with the licence issued under these rules, shall be measured in metres by the proper officer in the presence of the cultivator.

2. The measurement conducted by the proper officer shall be subject to such further checks bv such officers as may be specified by the Narcotics Commissioner in this behalf.

Delivery of opium produced-

All opium, the produce of land cultivated opium poppy, shall be delivered by the cultivators to the district Opium Officer or any other officer duly authorised in this behalf, by the Narcotics Commissioner at a place as may be specified by such officer.

Manufacture Sale and Export of Opium

Manufacture of opium- Opium shall not be manufactured save by the Central Government Opium Factories at Ghazipur and Neemuch: Provided that opium mixtures may be manufactured from opium lawfully possessed by a person authorised under the rules made by the State Government for the said purpose.

Export of opium-The export of opium is prohibited save when the export is on behalf of the Central Government.

Sale to State Governments or manufacturing chemist.-

1) The sale of opium to the State Governments or manufacturing chemists or the person or entity who has been granted licence under sub-section (2A) of rule 36, as the case may be, shall be only from the Government Opium Factories, located at Neemuch and Ghazipur
2) The sale of opium from the Government Opium Factory at Neemuch and Ghazipur to manufacturing chemists or the person or entity who has been granted licence under sub-rule (2A) of rule 35, as the case may be, shall be only under a permit granted by or under the orders of the State Government within whose jurisdiction the chemist or the person or entity resides or has his place of business in the forms prescribed by that Government.

Manufacture of Manufactured drugs

- Morphine, thebaine, dihydro-morphine, codeine, dihydro codeine and salts are manufactured at govt factory, Ghazipur.
- Manufacture of crude cocaine, cocaine salts, ecgonine, diacetylmorphine and its salt is prohibited.
- Manufacturing of cocaine and its salt is prohibited, except cocaine hydrochloride which can be prepared from confiscated cocaine only.
- Medicinal hemp manufacture shall be under licence issued by chief excise authority of the state govt.
- Manufacture of synthetic drugs is prohibited, except it is under the authorized license granted by narcotic commissioner on govt behalf.
- Licensee

- Should have drug manufacturing license granted to him under drugs and cosmetics act 1940.
- Should deposit 5000 as security and shouldn't manufacture excess than requirements of the country for a year according to international narcotics board.
- Notice of commencement of drug manufacture must be given 15 days prior to licensing authority and also one month's notice before he ceases to manufacture.
- Security arrangements are made around manufacturing premises.

Offences and penalties

- For contravening any provisions of the act or rules imprisonment for 10 to 20 yrs and fine from one lakh to two lakh rupees can be imposed. In certain cases rigorous imprisonment will be 15 to 30 yrs and fine from 1.5 lakh to 3 lakh.
- ▪ Illegal possession of cocaine, morphine punishable with imprisonment upto one yr or fine or both.
- ▪ Failure to keep accounts or submit returns as required by law, punishable law imprisonment for 6 months and fine.
- ▪ Failure to produce records, license, permit, authorization etc., on demand by the authorized persons, punishable with imprisonment upto 5 yrs or fine or both.

Reference

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