Chapter - 3

Growth, Policies & Legislations
DRUG POLICY AND LEGISLATION

In the beginning of the current century drug industry was practically non-existent in India and pharmaceuticals were being imported from abroad the first world war changed the situation and not only were finished and cheap drugs imported in increasing volume the demand for indigenous products also was voiced from all sides. With the clamour for swadeshi goods manufacturing concerns both Indian and foreign sprang up to produce pharmaceuticals at cheaper rates to compete with imported products naturally some of these were of inferior quality and harmful for public health consider the matter of introducing legislation to control the manufacture distribution and sale of drug and medicines.

Two of the laws, The Poisons Act and the Dangerous Drugs Act were passed in 1919 and 1930 respectively. The Opium Act was quite old having been adopted as early as 1878. But to have a comprehensive legislation which the rapid expansion of the pharmaceutical production and drug market required by the end of the second decade for its control, the Indian Government appointed, in 1931, a Drugs Enquiry Committee under the chairmanship of Lt. Col. R. N. Chopra which was asked to make sifting enquiries into the whole matter of drug production, distribution and sale by inviting options and meeting concerned people. The Committee was asked to make recommendations about the ways and means of controlling the production and sale in the interest of public health. The Chopra Committee toured all over the country and after carefully examining the data placed before it, submitted a voluminous report to government suggestion creation of drug control machinery at the centre with branches in all provinces. For an
efficient and speedy working if the controlling department the Committee also recommended the establishment of a well-equipped Central Drugs Laboratory with competent staff and experts in various branches of drug standardization work. Under the guidance of the central Laboratory, it was suggested, small laboratories would work, in the provinces. For the training of young men and women, the Committee recommended the formation of Central Pharmacy Council, and the Provincial Pharmacy Councils, with registrars who would maintain the lists containing names and addresses of the licenced pharmacists.

The outbreak of the second world war in 1939 delayed the introduction of legislation on the lines suggested by the Chopra Committee which the Indian Government contemplated and considered as urgent. However, the Drug Act was passed in 1940 partly implementing the Chopra recommendations. With the achievement of Independence in 1947 the rest of the required laws were put on the Statute Book. Ten years ago in 1985, The Narcotic Drugs and Psychotropic Substances Act was enacted repealing the Dangerous Drug Act 1930 and the Opium Act of 1878.

At present there are several acts relating to manufacture and sale of drugs in India. There are also rules framed under the provisions of these laws which govern the production and sale.

The following laws operate at present in the country:

The Drugs & Cosmetics Act of 1940 as amended by the Drugs (Amendment) Act, 1955 the Drugs (amendment) Act, 1960, the Drugs
(Amendment) Act, 1962, the Drugs & Cosmetics (Amendment) Act, 1972, the

The Drugs & Cosmetics Rules of 1945.

The Drugs & Cosmetics (Amendment) Act of 1964.

The Drugs & Cosmetics (Amendment) Act of 1972.


The Pharmacy Act of 1948.

The Drugs & Magic Remedies (Objectionable Advertisement) Act of 1954.


The Poisons Act of 1919.

The Medicinal & Toilet Preparations (Excise Duties) Act of 1956.

The Medicinal & Toilet Preparations (Excise Duties) Rules of 1956

The Drugs (Prices Control) Order 1995.

SOME OTHER LAWS

There are some other laws which have a bearing on the Pharmaceutical
manufacture, distribution and sale in India. The important ones being:

The Industries (Development & Regulation) Act of 1951.


The Indian Patents & Design Act of 1970.

The Acts, the rules and the commentaries on them by various courts which
have accumulated during the past years if recorded in detail will take several
volumes. We can only give a summary of these here just to convey the important
points which should be in full knowledge of those who are dealing with drugs in any shape or form.

1. The Drugs & Cosmetics Act of 1940.

The object of the Act is to regulate the import, manufacture, distribution and sale of drugs.

Under the provisions of this Act the Central Government appoints the Drugs Technical Advisory Board to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act. The Board can constitute subcommittees for the consideration of a particular matter.

The Central Government has also to establish a Central Drugs Laboratory under the control of a Director to carry out the functions entrusted to it by this Act.

The Central Government may also constitute the Drug Consultative Committee to advise the Central Government, the State Governments and the Drug Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act.

The Drugs & Cosmetics Act prohibits import of: (a) any drug (or Cosmetic) which is not of standard quality; (b) any misbranded drug (or misbranded or spurious cosmetic); (c) any adulterated or spurious drug; (d) any drug (or cosmetic) for the import of which a licence is prescribed; (E) any patent drug if it is not labelled in prescribed manner displaying its true formula; (F) any drug which claims to cure and mitigate diseases prescribed; (G) any cosmetic
containing unsafe or harmful ingredient; any drug the import of which is banned under the act.

For contravening above mentioned provisions of the act the prescribed punishment varies from six months R. I. and fine upto Rs 5,000 to three years R. I. and fine upto Rs 5,000 those convicted a second time have been prescribed punishment varying from one year R. I. to five year fine upto Rs10,000.

The Drugs & Cosmetics Act further prohibits manufacture for sale or for distribution sale, or stock or exhibit or offer for sale; (i) any drug which is not of standard quality or is misbranded, adulterated or spurious, (ii) any cosmetic which is not of standard quality or is misbranded or spurious; (iii) any patent drug which does not bear on the label true formula or list of active ingredients together with quantities; (iv) any drug which claims to cure and making it unsafe for use; (v) any cosmetic containing any ingredient making it unsafe for use; (vi) any drug the manufacture of which is prohibited under the Act; and (vii) any drug or cosmetic manufactured in contravention of any of the provisions of the Act or rules made there under.

For any contravention of above mentioned provisions of the Act the punishments prescribed vary from one year R. I. And fine to life imprisonment and with fine depending on the nature of the offence.

The Central Government has been given powers to ban import and manufacture for sale or sale or distribution of such drugs which are therapeutically irrational or which involve risk to human beings or animals.
It shall be no defence to plead merely that the accused was ignorant of the nature, substance or quality of the drug in respect of which the offence has been committed or of the circumstances of its manufacture or import.

The Central Government and the State Governments can appoint Analysts with prescribed qualifications for specified drugs. The Government may also appoint Inspectors who possess the requisite qualifications. The Inspectors can inspect any premises wherein any drugs in being manufactured and take sample for which he will pay fair price. He can also enter and search at all reasonable times any place where he believes any offence in being committed and seize stocks of drugs. Obstruction to the work of an inspector is punishable with imprisonment up to 3 years or fine.

The Inspector on suspecting the Quality of drug will get it tested by the Government Analyst who will deliver his report which will be taken as conclusive evidence in a court. If challenged by the accused the drug will be sent to the Central Drugs Laboratory whose decision will be binding on both analysis.

The report of the Government Analyst or the Central Drugs Laboratory should not be used as an advertisement of a Drug. Anyone doing so can be punished with a fine up to Rs. 500.

When a person has been convicted under the provisions of the Drugs and Cosmetics Act the stock of the drugs in respect of which the contravention has been made shall be liable to confiscation.

Section 34 of the Drugs Act lays down that where an offence has been committed by a company every person who at the time of the offence held charge
and was responsible to the company shall be deemed guilty. To be exonerated, the person shall have to prove that the offence was committed without his knowledge or that he exercised all due diligence to prevent its commission.

II. The Drugs & Cosmetics Rule of 1945.

In exercise of the powers conferred by the Drugs and Cosmetics Act the Central Government has made a number Rules for the manufacture, sale and distribution of drugs in India. With the promulgation of these Rules, the Rules made by several States in India were repealed. Most of these Rules say down the procedures and details of the enforcement of the provisions of the Act. There are prescribed forms of which different applications are to be presented of reports made for different purposes. Also there are schedules framed under different Rules.

Brief summary and the purpose of the schedules is given here;

Schedule A gives the specimens of prescribed forms.

Schedule B states fees for test or analysis by the Central Drugs Laboratory or the Government Analyst.

Schedule C and C1 deals with biological and special products.

Schedule D is devoted to exemption regarding import of drugs.

Schedule E1 gives a list of poisonous substances under Ayurvedic, Siddha and Unani Systems of medicine.

Schedule F and F (I) gives details of the standards of bacterial vaccines made from any micro-organism pathogenic to man or other animals and also the vaccines made from other microorganisms which have any antigenic value.

Schedule FF gives details of the standards for ophthalmic preparations.
Schedule F (ii) gives details of standards for surgical dressings, and bandage cloth.

Schedule F (iii) gives standards for umbilical tapes.

Schedule G details of drugs to be Labeled with words "Caution - it is dangerous to take this preparation except under medical supervision".

Schedule H deals with drugs any medicines which must be sold by retail only when a prescription by registered medical practitioner is produced.

Schedule J gives the list of the ailments for which no drug should claim prevention or cure.

Schedule K lays down the condition under which certain cases are exempted from the provisions of Chapter IV of the Drugs Act.

Schedule M deals with Good Manufacturing Practices and requirements of premises, plant and equipment. Part I deals with good manufacturing practices and factory premises. Part II deals with plant and equipment.

Schedule M1 prescribes in detail requirements of factory premises for the manufacture of homeopathic drugs.

Schedule N deals with the minimum equipment of a pharmacy and gives directions regarding (a) entrance of a pharmacy, (b) premises, (c) furniture and apparatus, and (d) general provisions.

Schedule O deals with the provisions applicable to Black Disinfectant Fluids.
Schedule P deals with the life period of drugs including combinations with other drugs. It gives period in months for which the drug is expected to retain its potency under the conditions of storage notified by the licensing authority.

Schedule Q gives the list of Coal Tar Colors permitted to be used in cosmetics.

Schedule R describes the Standards for mechanical contraceptives.

Schedule T lays down the requirements of factory premises and hygienic conditions for Ayurvedic and Unani drugs.

Schedule U and U1 give the particulars to be shown in manufacturing records.

Schedule V gives details of Standards for patent and proprietary medicines.

Schedule W gives the name of the drugs, which shall be marketed under generic names only.

Schedule X gives the names of psychotropic drugs requiring special licenses for manufacture & sale.

Schedule Y specifies requirements and guidelines on clinical trials, import and manufacture of new drugs.

The main Drug rules framed by the Union Government are as follows:

It shall be the function of the Central Drugs Laboratory to analyse or test such samples of Drugs as may be sent to it and report on payment of the prescribed fee.

An import licence shall be required for the import of any biological or other special product specified in schedule C or C1.
Licence will be granted to such persons who have proper storage place for
drugs to be imported. There are other conditions attached to the licence such as
licensee shall allow an inspector to enter, with or without notice, premises where
imported drugs are stored, the licensee shall furnish samples of the drugs to the
authorities, shall maintain a record of sales, shall not offer the drugs for sale if
directed etc. The licence remains ordinarily in force for one to two years,
depending on the date when it is granted, but can be suspended or cancelled by the
Authority if the licensee fails to abide by requirements of the law.

No drug, the manufacture, sale or distribution of which is prohibited in the
country of origin, shall be imported. No Biological or other special product shall
be imported unless it complies with the standard or strength, quality or purity
specified in Schedule F. Prohibited drugs can be imported only for the purpose of
test and analysis. Under certain conditions new drugs can be allowed to be imported
for personal use.

The Drug Rules lay down in detail the qualifications, functions, powers and
responsibilities of the Government Analyst and Drugs Inspector.

One part of the rules is devoted to the sale of drugs describing how the
licensing authority will grant licence on what conditions and payment of what fee.
Licences are granted to sell, stock or exhibit for sale or distribute drugs specified
in Schedule C and C1 by retail; on restricted licence or by wholesale. Licences are
also granted to sell, stock or distribute drugs other than those specified in Schedule
C and C1. Restricted licences are granted to dealers in respect to drugs whose sale
does require the supervision of a qualified person or in exceptional cases to
itinerant vendors or travelling agents of a firm. Licences to sell drugs shall be, unless sooner suspended or cancelled valid upto 31\textsuperscript{st} December of the year following the year in which it is granted or renewed.

Application for grant of licence for sale of schedule ‘X’ drug is to be made in form 19-C. Wholesale licence for Schedule ‘X’ drugs is granted on form 20-G and for retail sale on form 20-F.

If a licence is granted certain conditions have to be satisfied; notable among these being adequate premises equipped with proper storage space for preserving the properties of drugs and competent person in charge to supervise and control the sale, distribution and preservation of drugs. Other important conditions are that the supply of any drug on a prescription shall be recorded and a register specially maintained for this purpose giving serial number of supply, name and address of prescriber, name of the patient, name of drug, name of the manufacturer, if the drug is specified in Schedule C and the signature of the qualified person under whose supervision the medicine was made up and supplied. Such records shall be maintained in case of supply of drugs, specified in Schedule C as well as purchases and sales by way of wholesale dealing of drugs in Schedule C. These records shall be preserved for three years from the date of the sale of the drug.

A drug specified in Schedule H should not be dispensed more than once unless the prescriber has given definite directions to do so.

The licensee should maintain an inspection book to enable an Inspector to record his impressions and the defects noticed by him.
If the licensee fails to comply with any of the conditions of the licence or with any provision of the Act or Rules the licence is liable to be suspended or cancelled.

For manufacture of drugs, licences can be granted either for the manufacture of drugs specified in Schedule C and C1 to the Drug Rules or for the manufacture of drugs not specified in these Schedules. In case of repacking of drugs for sale application is to be made in Form 24-B and in any other cases in Form 24. If an applicant does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by licensee, he can apply for a loan licence in Form 24-A. This system of loan Licensing is proposed to be abolished.

The conditions for the grant of manufacturing licence are that the manufacture is conducted under the active direction and personal supervision of a competent technical staff consisting of at least one person who is a whole time employee and who is either a graduate in Pharmacy or Pharmaceutical Chemistry, or a graduate in Science or a graduate in Chemical Engineering. The factory premises shall comply with the conditions prescribed in Schedule M. The applicant shall provide and maintain adequate staff, adequate premises and adequate laboratory equipment for carrying out tests.

The manufacturing unit and the testing unit should be separate under independent persons. There should be adequate arrangements for the storage of the manufactured drugs.
A licence in Form 25 shall remain valid up to 31st December of the year following the year in which it is granted or renewed unless sooner suspended or cancelled.

Those applying for manufacture of drugs for sale specified in the Schedule C and C1 shall submit their application in Form 27. In this case also loan licences are granted (when) applied for in Form 27-A. Applications for the grant of licence to manufacture Schedule ‘X’ drugs have to be made on 24-F in case of drugs other than Schedule C, C1 but specified in Schedule ‘X’ on 27-B for those specified in Schedule C, C1 and ‘X’. The conditions for obtaining these licences are those mentioned above in case of licence for manufacturing of drugs for sale other than those specified in Schedule C and C1. Besides, the licensee shall have to keep the records of the details of manufacture of each batch of the substance which is issued for sale and of the application of the tests in such form as to be available for inspection. The licensee shall allow any authorised inspector to enter with or without prior notice any premises, where the manufacture in carried on and inspect the plant and the process of manufacture or to examine all registers and records maintained under these Rules. The licensee shall notify changes in expert staff, supply samples of drugs, shall not sell any batch of drugs or will withdraw any batch of drugs from sale when called upon to do so. The licensee shall maintain an inspection book to enable the inspector to record his inspection and the defects noticed.
Before a licence is granted the Licensing Authority shall cause the establishment to be inspected in order to check that all the prescribed conditions are met with.

If the licensee fails to comply with any of the conditions the Licensing Authority may cancel the licence after it was granted.

The licence valid for one year can be granted to persons who want to manufacture drugs merely for examination, test or analysis but such drugs cannot be sold and the Inspector can inspect the premises to find that the drugs are manufactured only for the purpose mentioned. The licensee shall not only allow the inspector to enter the premises but also maintain regular record of the manufacture and comply with requirements of the law.

**Labelling of Drugs**

No drug can be sold or distributed unless it is labelled in accordance with prescribed rules. Generally, the container of a drugs should be labelled with: (a) name of the drug, (b) name and address of the manufacturer, (c) batch or lot number, and (d) date of manufacture and expiry, the latter if required.

In case of the medicine made up ready for use, the label should give name and address of the licensee by whom it is supplied. If it is for external application it shall be labelled with the word “Poison” and with the word “For external use only”.

Further if the medicine contains a substance specified in Schedule G, it be labelled with the word “Caution”. “It is dangerous to take this preparation except under medical supervision”. If it contains a substance specified in Schedule H, it
shall be labelled with the word "Schedule H drug" and a warning "to be sold by retail on the prescription of a registered medical practitioner only".

The labels of Schedule H, Schedule X and Narcotic (Schedule H) drugs should bear symbols Rx, XRx and NRx respectively.

In the case of preparations included in the British Pharmacopoeia or the British Pharmaceutical Codex, the letter "B.P." or "B.P.C." respectively should be put on.

The letter "I.P.", "B.P.", "B.P.C." and "U.S.P." shall be entered on the label of a drug only for the purpose of indicating that the drug is in accordance with the standard set out in the Indian Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex or the United States Pharmacopoeia as the case may be.

The label of the container of any preparation containing not less than 3 percent of volume of alcohol shall include a statement to this effect. Non-Sterile surgical ligature or suture should be declared on the label as such in indelible red ink. The label of a patent or proprietary medicine should carry the name and address of the manufacturer and the true formula or list of ingredients. No drug should claim to prevent or cure any or the diseases specified in Schedule J. No Drug should claim to procure or convey any idea that it may procure miscarryage in women.

**Biological or Other Special Products**

If any substance specified in Schedule C is advertise or sold as a proprietary medicine the proper name of the substance shall appear on the label of
every vial, ampoule or other container. On the label of any substances specified in Schedule C should be given: (a) the proper name of the substance; (b) the number of licence under which it is manufactured, a distinctive batch number, a statement of the potency unit and the date up to which the substance is expected to retain potency. No person shall sell, exhibit for sale any substance alter, obliterate or deface the inscription of mark recorded on the container, label or wrapper of manufactured drug.

Standards

Every substance specified in Schedules C and C1 intended for sale shall conform with the standard of strength, quality and purity specified in Schedule F and F1. The test required for determining the strength and quality of each of the substances shall be those set out in Schedule F and F1.

For the purpose of the Drugs and Cosmetics Act the Indian Pharmacopoeia, the Pharmacopoeia of the United States, the National Formulary of the United States, the International Pharmacopoeia and the State Pharmacopoeia of the Soviet Socialist Republic shall be deemed to be prescribed pharmacopoeias. For the drugs for which no standard of identity, purity and strength are specified in latest edition of pharmacopoeia but are specified in the earlier editions or in the British Pharmaceutical Codex the standards should be those given in the British Pharmacopoeia or British Pharmaceutical Codex as the case may be.
III. The Drugs & Cosmetics (Amendment) Act of 1964.

An amendment to the Drugs and Cosmetics Act, 1940 was passed by the Indian Parliament in 1964.

The object of the amendment was two-fold. First, to bring Ayurvedic and Unani drugs which were till then not covered by the law, within the scope of the Act. Secondly, to prohibit the import, manufacture, sale etc., of adelterated, misbranded, spurious or sub-standard drugs.

Under the provisions of the amendment a drug shall be deemed to be adulterated if it consists, in whole or in part filthy, putrid or decomposed substances, or if it has been prepared, packed or stored under insanitary conditions, if its container is composed of any poisonous of deleterious substances, if any substance is mixed or packed therewith so as to reduce its quality or strength.

The punishment for contravening the provisions of the law has been enhanced. Any one convicted second time of an offence under clause (a) of section 27 will be imprisoned for not less than two years, it may extend to ten years and he will also be liable to fine. In clause (b) of the same section for the words “five years” the words “ten years” have been substituted.

Furthermore, it has been provided under this act that any implements or machinery used in the manufacture of adulterated drugs and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable for confiscation.

The Drugs and Cosmetics Act was amended in 1972 and thereby it was extended to the state of Jammu and Kashmir.


The Drugs & Cosmetics (Amendment) Act of 1982 received the assent of the President in November, 1982. It came into force with effect from 1st February 1983. The main amendment made are:

(i) The definition of the term 'drug' has been enlarged. Preparations used for repelling insects like mosquitoes, all substances intended for use as components of drugs including empty gelatin capsules and devices used in diagnosis, treatment etc. of diseases (to be notified) are drugs.

(ii) Toilet soaps are cosmetics and required to be manufactured under licence.

(iii) Definitions of misbranded, adulterated drugs have been rationalised. A new term spurious Ayurvedic, Siddha or Unani drug has been provided for the first time. Similar misbranded and spurious cosmetics and misbranded and adulterated Ayurvedic, Siddha drugs have been defined.

(iv) The Central Government has now acquired powers to ban, by notification, import and manufacture of such drugs which involve risk to human beings or animals or are therapeutically unsound.
(v) Punishment for various contraventions of the provision of the Act have also been rationalised. For a drug, which is adulterated and is likely to cause death or grievous hurt imprisonment of not less than 5 years which may extend to a term of life has been provided. For adulterated and spurious drugs the punishment are upto three and five years respectively.

(vi) Powers of Inspectors have been enhanced. They can now stop and search any vehicle or vessel or any other conveyance.

(vii) Provision has been made for summary trial of offences under this Act.

(viii) Central Government can constitute an Advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee.


Sections 26& 32 have been amended and this empowers any person or a consumer association to take samples of drugs for test/analysis and they can also prosecute firms for manufacture/sale of sub-standard drugs.

VII. The Pharmacy Act of 1948.

The Pharmacy Act was passed in 1948 and was amended in 1959, 1976 and 1984. The aim of this law is to regulate the profession of Pharmacy in India. Under the provisions of this act the Central Government constitutes a Central Council of India consisting of following members:
(a) Six members from the teachers of Pharmacy.

(b) Six members from practising Pharmacists or Pharmaceutical Chemists holding degree or diploma.

(c) One member elected by the Medical Council of India.

(d) The Director-General of Health Services.

(e) The Director of the Central Drugs Laboratory.

(f) The Chief Chemist, Central Revenues.

(g) One member to represent each State elected by members of State Councils who shall be a registered Pharmacist.

One member to represent each State Government who shall be either registered medical or a registered pharmacist.

The President and Vice-President of the Central Council of Pharmacy are elected by the members of the Council among themselves, hold office for five years and are eligible for re-election.

All disputes arising out of elections have to be referred to the Central Government whose decisions are final. The elected or nominated member holds office for a term of five years can resign or cease to be member if he remains absent for three consecutive meetings of the council.

The Central Council appoints a paid Secretary and can also appointed other Officers and servants with the sanction of the Government.

To carry on its work the Council constitutes an executive committee consisting of the President, the Vice-President and five other members elected by the Council from amongst its members.
With the approval of the Central Government, Central Council makes regulations prescribing the minimum standard of education required for qualification as a pharmacist. The regulations prescribe the nature and period of study and the practical training to be undertaken before admission to an examination, equipment and facilities to be provided for students, the subjects of examination and any other conditions for admission to examination.

The Education Regulations shall take effect if a state so notifies in the official Gazette or on the expiry of three years from the date of the constitution of the State Council.

The conducting of courses of study for pharmacists and the examinations in pharmacy in the states are subject to the approval of the Central Council.

Besides the Council has the responsibility to supervise the Education of Pharmacy in the States. Where it is found that the course of study is not in conformity with the Education Regulations, the Council may withdraw approval accorded to the course or the examination. The Central Council can approve qualifications granted by an outside authority for qualifying for registration under this Act.

The Executive committee appoints Inspectors to inspect any institution which provides an approved course of study, to attend at any approved examination and to inspect any institution whose authorities have applied for the approval of its course of study or examination. The inspectors report to the Executive Committee about their findings on the sufficiency of every examination and other matters.
State Pharmacy Council

The Act makes it incumbent upon the State Governments to constitute State Pharmacy Councils with the following members:

(a) Six members elected from amongst themselves by registered Pharmacists of the State.

(b) Five members of whom at least two shall be persons possessing a prescribed degree or diploma in Pharmacy or Pharmaceutical Chemistry or members of the Pharmaceutical Profession nominated by the State Government.

(c) One member elected by the State Medical Council.

(d) The Chief Administrative Medical Officer of the State.

(e) The State Drug Controller.

(f) The Government Analyst.

Two or more State Governments can enter into an agreement for constitution of joint state councils or the council of one state can serve the needs of the other. The President and Vice-President of the State Councils are elected by the members from amongst themselves except in the first instance where they are nominated by the State Government. The President and the Vice-President hold office for five years and are eligible for re-election. Any disputes regarding the elections are referred to State Government whose decisions are final. The members of the Councils hold office for five years and are eligible for re-election.

With the approval of the State Government, State Pharmacy Council appoints a Register who also acts as Secretary and Treasure. The Council also
appoints such other paid officers and servants as may be required to carry out the work. The first Registrar who holds office for four years is a nominee of the State Government.

The State Council constitutes an Executive Committee consisting of the President, Vice-President and such member or other members as may be prescribed. Report of the meeting of the council and the Executive Committee are furnished to the State Government as well as the Central Pharmacy Council.

Registration of Pharmacists.

The state government has under the provisions of the Pharmacy Act to get a register of state pharmacists prepared and it is the state pharmacy council which has to maintain the register. The register shall contain the name and residential address of pharmacist, the date of his first admission to the register, qualifications for registration, his profession address, the name of his employer and prescribed particulars.

For preparing the first register a Registration Tribunal consisting of three persons with a Registrar-Cum-Secretary will be appointed by the State Government.

Applications will be invited and examined by the tribunal. Those possessing requisite qualifications will be registered. Anyone who is 18 years or more of age and resides or carries on his business of pharmacy in the state is, on payment of prescribed fee entitled to be registered. Other qualifications for registration are that the applicant: (a) holds degree or diploma in Pharmacy of Pharmaceutical Chemistry, (b) holds any degree of an Indian University and had been engaged in
compounding of drugs for a period of not less that three years, (c) has passed a recognised examination of compounders or dressers course, and (d) has been engaged in compounding of drugs for a total period of not less than five years.

After the Education Regulations have taken effect in the State a person shall on payment of the prescribed fee be entitled to have his name entered in the register if he has attained the age of 18 years, resides or carries on business or profession of pharmacy in the state and if he has passed an approved examination or possess the approved qualification or is a registered pharmacist in another state.

Upon entry of a name, in the register, the Registrar shall issue a certificate of registration in the prescribed form. The State Government can direct that for the retention of a name on the register after the expiry of one year the registered pharmacist shall have to pay a renewal fee before the first day of April of the year to which it relates. Where renewal fee is not paid by the due date the Registrar shall remove the name of the defaulter from the register. Any additional qualifications of a pharmacist can be entered in the register on payment of fee.

The name of pharmacist can be removed from the register if the Registrar is satisfied that: (a) the name has been entered by error or on account of misrepresentation or suppression of a material fact, or (b) the pharmacist has been convicted of any offence or is guilty of any infamous conduct, or (c) the pharmacist employed a person for the purpose of his business of a pharmacy who has been convicted of an offence or has been guilty of any infamous conduct.

The State Council can restore the name of a person to the register whose name has been removed from it.
The registrar can issue a duplicate of the certificate when it is destroyed or lost on payment of a fee. The Registrar shall get the register to be printed soon after 1\textsuperscript{st} April.

No order refusing to enter a name on the register or removing a name from it shall be called in question in a court.

\textit{Penalty for False Claims}

If any person falsely claims to be a registered pharmacist and uses such words with his name as to suggest that his name is so entered he makes himself liable to conviction and fine upto 500 rupees and on any subsequent conviction for such offence he may be imprisoned upto six months and also fined.

For this purpose it is immaterial whether or not any person is deceived by such pretence. The use of the description “pharmacist”, “chemist”, “druggist”, “Pharmaceutist”, ”dispensing chemist”, or any combination of such words will be deemed to suggest that the person’s name is entered in the register.

After the State Government has fixed a date no person other than registered pharmacist shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner. A medical practitioner can, however, dispense medicines for his own patients, or with the sanction of the Government for the patients of another medical practitioner. Contravention of this will be punished with imprisonment for a term which may extend to six months with or without fine. In 1984 this has been amended. Every state has now to enforce Section 42.
If any person whose name has been removed from the register fails to surrender his certificate of registration he shall be punishable with fine upto 500 rupees.

If it appears to the Central Government that the Central Pharmacy Council is not complying with the provisions of the Pharmacy Act, it can appoint a commission to enquire into the affairs. Similarly the State Government can also appoint an enquiry commission regarding the affairs of the State Pharmacy Council.

VIII. The Drugs & Magic Remedies (Objectionable Advertisement) Act of 1954.

This Act is meant to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities and to provide for matters connected therewith.

The Drugs & Magic Remedies Act prohibits a person from taking part in the publication of any advertisement referring to any drug which suggests the use of the drug for: (a) the procurement of miscarriage in women or prevention of conception in women; and (b) the maintenance or improvement of the capacity of the human being for sexual pleasure; (c) the correction of menstrual disorder in women; (d) the diagnosis, cure, mitigation, treatment or prevention of any venereal disease. It is prohibited to directly or indirectly gives a false impression regarding the true character of a drug or make false claim for it or to convey any false or misleading information in any material particular about it. No person shall import into or export from India any document containing an advertisement of this nature.
Whoever contravenes the provisions of this Act shall, on conviction, be punishable with imprisonment which may extend to six months, with or without fine. In case of subsequent convictions the imprisonment can be extended to one year. The document, article or thing which contains the offending advertisement can be seized and confiscated.

If the person contravening any of the provisions of the Act is a company, every person who at the time the offence was committed was in charge of the business of the company shall be deemed guilty.

The prohibition under this Act does not apply to: (a) any signboard or notice displayed by a registered medical practitioner including the treatment for any of the disease, (b) any treaties or book dealing with any of the matters from a bonafide scientific standpoint, (c) any advertisement relating to any drug sent confidentially only to a registered medical practitioners or to chemists for distribution among registered medical practitioners or to a hospital or laboratory, and (d) Government advertisements.

IX. **The Narcotic Drugs & Psychotropic Substances Act, 1985.**

This is an Act to consolidate and amend the law relating to Narcotic Drugs, to make stringent provisions for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances and for matters connected therewith.
In this Act:

(1) "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 from 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 diamorphine or heroin and its salts; and

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

(2) "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;
(3) "Poppy Straw" means-all parts (excepts the seeds) of the opium poppy after harvesting whether in their original form or cut, crushed or powered and whether or not juice has been extracted therefrom;

(4) "Poppy straw concentrate" means-the material arising when poppy straw has entered into a process for the concentration of its alkaloids;

(5) "Preparation" in relation to a narcotic drug of psychotropic substance means any one or more such drugs or substances in dosage from or any solution or mixture, in whatever physical state containing one or more such drugs or substances;

(6) "Prescribed" means-prescribed by rules made under this Act;

(7) "Production" means-the separation of opium, poppy straw, coca leaves or cannabis from the plants from which they are obtained.

(8) "Psychotropic substance" means-any substance, natural or synthetic, or any natural material or any salt or preparation or such substance or material included in the list or psychotropic substances specified in the Scheduled.

(9) "to import inter-state" means-to bring into a State or Union territory in India from another State or Union Territory in India.

(10) "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 or a narcotic drug or a psychotropic substances 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.
Explanation - For the purposes of this clause and clause (xxvi), “India includes the territorial waters of India.

(11) “to export from India” with its grammatical variations and cognate expressions means to take out of India to a place outside India:

(12) “to export inter-state” means to take out of a State of Union territory in India to another State or Union Territory in India.

(13) “to transport” means to take from one place to another within the same State or Union territory;

(14) words and expressions used therein and not defined but defined in the Code of Criminal Procedure, 1973 have the meanings respectively assigned to them in that Code.

The Narcotic Drugs & Psychotropic Substances Act, 1985 provides deterrent punishment for those who contravene the provisions of the Act by engaging themselves in manufacture, sale, purchase, transport etc. of narcotic drugs and psychotropic substances like Coca, Opium, Cannabis and psychotropic substances. The punishment provided is rigorous imprisonment for a term which shall not be less than 10 years but which may extend to 20 years and shall also be liable to fine which shall not be less than 1 lack rupees but which may extend to 2 lack rupees. Where a contravention relates to ‘ganja’ or the cultivation of cannabis plant, the punishment prescribed is rigorous imprisonment for a term which may extend to five years and shall also be liable to fine which may extend to fifty thousand rupees, where contravention relates to Cannabis other than ganja, the punishment is rigorous imprisonment for ten years, but which may extend to
twenty years and fine up to 1 lac rupees which may extend 2 lac rupees. In case of repeat offences, the Act provides for every subsequent offence, rigorous imprisonment for a term which shall not be less than 15 years but which may extend to 30 years and shall also be may extend to fine which shall not be less than 1 lac 50 thousand Rupees but which may extend to 3 lac rupees. Under the Rules farmed under this Act, officers of the Central and State Government have powers to search, seize and arrest offenders and to investigate offences under the act.

X. The Poisons Act of 1919.

The object of this Act is to consolidate the laws regulating the importation, Possession, and sale of poisons.

The State Government can regulate within its territory the sale and possession or sale of any specific poison and can grant licence to posses any specified poison for sale, wholesale or retail.

The State Government can also fix fees for such licence and decide about the class of person to whom the licences may be granted, the class of persons to whom alone the poison may be sold, the maximum quantity which may be sold, the registers that vendor should maintain, the way the poisons are to be kept in custody and the method of inspection of the poison.

Importation of poison without a permit is prohibited.

The following substances are deemed to be poisonous:

List “A” Aconite, Aconine, Alkaloids, Arsenic, Atropine, Belladonna, Cantharidis, Chloral Hydrate, Coca, Corrosive, Sublimate, Cyanide of Potassium, Diamorphine (also known as Heroin) Diethyle Barbituric Acid. Digitalis. Digitalin, Ecgonine,
Ergot of Rye, Lead, Nux Vomica, Strychnine, Morphine, Picrotoxin, Prussic Acid
Savin and its Oils, Stramonium, Strophanthus, Strophanthin, Tartar Emetic,
Tetraethyl lead.

List “B”: Essential Oil of Almonds (unless deprived of prussic acid),
Antimonial Wine, all salts of Barium except Sulphate of Barium, Tincture
Cantharidis, Carbolic Acid, Chloroform, Mercuric Sulphocyanide, Oxalic Acid,
Poppies (Papaver theoes), Precipitate White and Red and all Oxides of Mercury,
Sulphonal, Zinc Chloride.

The poisons classified under list “B” are exempted from certain provisions.

The State Government may direct that any breach of the rule framed to
regulate possession or sale of poison shall be punished with imprisonment upto one
year with or without fine together with confiscation of the person in respect of
which the breach has been committed.

Any substance which has been declared by the State Government as poison
under this Act is to be deemed as poison for the purposes of this Act.

Having reason to believe or suspect any poison is possessed or sold in
contravention of the Act the District Magistrate, the Sub-divisional Magistrate or
the Commissioners of Police may issue a warrant for the search of any place. The
person to whom the warrant is directed can then enter and search the place.

XI. The Medicinal and Toilet Preparations (Excise Duties) Act of 1956:

This is a law to provide 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.
Duties of excise are levied and collected by the Central Government at the rates specified in the schedule on all dutiable goods manufactured in India.

These duties are leviable:

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

(b) Where the dutiable goods are not manufactured in bond, in the state in which such goods are manufactured.

Where alcohol, opium, Indian Hemp or other narcotic drug or narcotic had been supplied to a manufacturer for use as an ingredient and a duty or excise on them had already been recovered a rebate to such manufacturer of the excess shall be granted by the Government.

The Central Government may order under this Act that from a specified date no person shall engage in the production or manufacture of any dutiable goods or of any specified component parts or ingredients of such goods or containers of such good except under authority and in accordance with the terms and conditions of licence granted under this act.

Contravention of the provisions of this Act or evasion to pay excise duty or failure to supply required information or attempt to commit any offence under the Act is punishable with imprisonment for a term which may extend to six months with or without fine.
The court trying an offence under the act may order forfeiture to the collecting government of any dutiable goods in respect of which the court is satisfied that the offence has been committed.

Any authorised excise officer may arrest any person whom he has reason to believe to be liable to punishment under this Act.

If any person accused or reasonably suspected of an offence refuses to give his name and address or gives false name and address the officer can arrest him to ascertain his name and address.

An empowered excise officer can summon any person whose attendance he considers necessary either to give evidence or produce a document or any other thing in an enquiry which such officer is making.

If dutiable goods are manufactured at any place in contravention of the provisions of the Act the owner or occupier of the land is bound to give notice of such manufacture to a Magistrate or to an officer of Excise, Customs, Police or Land Revenue Department. If he connives at the offence he can be punished with imprisonment up to six months with or without fine.

Any officer who exercises his powers under this Act without reasonable ground for suspicion searches any place, vessel or conveyance or vaxatiously or unnecessarily detains or arrests any person shall for every such offence be punished with fine up to Rupees 2,000.

Any excise officer who refuses to perform the duties unless he has obtained a permission to withdraw shall be punishable with imprisonment up to three months with or without fine.
The schedule to the Act gives a description of dutiable goods and rate of excise duty on them.

XII. The Medicinal & Toilet Preparations (Excise Duty) Rules of 1956

The Central Government has framed certain rules under the provisions of the Medicinal and Toilet Preparations (Excise Duties) Act. The important ones among these are:

Any person expressly impliedly authorised by the owner of dutiable goods to be his agent will be deemed as owner of such goods for all purposes of Act.

The following are exempted from duty on medicinal preparations containing alcohol:

Hospitals and dispensaries, under the Government or subsidised by the Government.

Charitable hospitals and dispensaries under local bodies.

Medical Stores of Government.

Any institution certified by District Medical Officer.

The Government may also exempt any dutiable goods from the levy of the duty in the interest of the trade or in public interest.

Duties short-levied or erroneously refunded can be recovered. Erroneously paid duties will be refunded if claimed within six months from the date of payment.

For the purpose of excise duty manufactured medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics, have been divided into those manufactured outside bond. Detailed rules have been laid down for such matters as supply of rectified spirit, entry into and
exit from bond manufactory, arrangement of receptacles, indent for opium, Indian hemp and narcotic drugs, storage or finished products, disposal of substandard preparations emission of duty in case of loss due to accident, opening and closing hours, building arrangements, sample to be taken by the Excise Officer for analysis, Accounts in prescribed printed registers.

In these rules there is a special provisions applicable to medicinal preparations containing alcohol.

Allopathic preparations fall under two categories, namely: (i) those preparations which are made strictly in accordance with the formula given in recognised pharmacopoeias, and (ii) those preparations which are prepared according to allopathic system of medicines and conform strictly to the formula displayed on the label.

At the end of the rules a schedule is attached which gives a list of medicinal and toilet preparations containing alcohol.

Allopathic preparations fall under two categories, namely: (i) those preparations which are made strictly in accordance with the formula given in recognised pharmacopoeias, and (ii) those preparations which are prepared according to allopathic system of medicines and conform strictly to the formula displayed on the label.

At the end of the rules a schedule is attached which gives a list of medicinal and toilet preparations containing alcohol which are capable of being consumed as ordinary alcoholic beverages. These are called restricted preparations, preparations of a proprietary nature are presumed to be the restricted preparations unless
declared to the contrary by the Central Government. In case of Homoeopathic preparations, American, British and general pharmacopoeias that are in vogue at present in various states shall be recognized as standard pharmacopoeias for the purposes of these rules.

All homoeopathic preparations containing alcohol shall be classified as capable of being consumed as ordinary alcoholic beverages and shall fall under the category of restricted preparation.

Regarding Ayurvedic preparations, Asawas and Aristas are the principal types of preparations in which alcoholic content is self-generated and not added as such. Until standard Ayurvedic pharmacopoeia has been evolved by the Central Government, the pharmacopoeias that are in vogue in the various States shall be recognised as Standard Ayurvedic pharmacopoeias. Ayurvedic preparations contains self-generated alcohol in which alcohol content does not exceed two percent proof spirit shall be deemed to be non-alcoholic and no duty shall be levied on such preparations. Where the percentage of proof spirit is in excess of two percent duty will be leviable.

One chapter of the rules gives instructions about “warehousing” while another lays down the procedure for obtaining licence for manufacture under bond and outside bond for payment of duty. Chapter III of the rules deals with the interstate movement of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics.

Any Officer authorised by the Excise Commissioner shall have free access at all reasonable times to any licenced premises and to any place where dutiable
goods are manufactured, stored or kept for sale and may without notice to the owner inspect the building, the plant, the machinery, the stocks and the accounts. If he is wilfully obstructed in this or misinformed by some one, the latter shall be liable to a penalty which may extend to Rs. 500. An excise officer can detain a person found carrying or removing any dutiable goods for transport of which a permit or the other transport document is required if duty has not been paid on dutiable goods these can be seized.

Anything liable to confiscation or any person liable to penalty under these rules shall be adjudged by the Excise Commissioner or any other Excise Officer empowered by the State Government.

XIII. The Drugs (Prices Control) Order 1995.

The Drugs (Prices Control) Order (DPCO) 1995 has been notified by the Government on 6-1-1995. This order has now come into force in place of the DPCO 1987. The new DPCO has taken into account the modifications in the Drug Policy 1986 announced by the Government in September, 1994 in regard to the price control on drugs and has been issued in exercise of the powers conferred on the Central Government by section 3 of the Essential Commodities Act, 1955.

In the modifications in the Drug Policy, 1986 government had announced the criteria for identifying drugs to be kept under price control, namely: (i) annual turnover of Rs. 400 lakhs, (ii) exclusion of drugs in which there is sufficient market competition determined by the existence of at least 5 bulk drug producers and at least 10 formulators with none having more than 40% market share in the retail trade, and (iii) inclusion of drugs in which there is a monopoly situation to be
determined on the basis of an annual turnover of the bulk drug of over Rs. 100 lakhs or more and existence of a single formulator having 90% or more market share in the retail trade. It had also been decided that for determining the turnover, the data as on 31-3-1990 complied by the expert Group set up for this purpose, and for the purpose of determining the market share in the retail trade, the ORG or March, 1990, would be adopted. On the basis of this approach, 76 drugs have been identified for being kept in the First Schedule of the DPCO which lists the drugs to be kept under price control. The First Schedule is given below:

Unlike the DPCO 1987 in which there were two categories of drugs under price control namely Category-I for the National Health Programme comprising 21 drugs and Category-II comprising other essential drugs numbering 124 (three drugs being common to both lists), with different Maximum Allowable Post Manufacturing Expenses (MAPE) of 75% and 100% for each of the categories, now there is a single list of drugs under price control with a MAPE of 100%.

22 Drugs, so far outside price control have been brought in the price controlled category. Some of these were having a heavy annual turnover exceeding Rs. 10 crores, 83 drugs have been decontrolled. Many of these were having an insignificant annual turnover with a declining usage of negligible growth. With price control on the 76 drugs mentioned in Schedule-I of the DPCO, almost 50% of the retail pharmaceutical market would be under price control. The Associations of Drugs Manufacturers have been cautioned to advise all their members to exercise restraint and self discipline in regard to medicines going out of price control and to ensure that their prices are not raised unreasonably, so that
Government is not constrained to exercise its powers to bring back these medicines under price control.

It is envisaged that the list of drugs to be kept under price control will be reviewed periodically, based on the data to be collected in this regard.

Substantial changes have been brought about so as to make the reporting system by way of forms and information required to be submitted periodically by the Industry to the government, less cumbersome. The forms have been not only reduced form the existing number of 9 to 6, but they have also been substantially simplified. A significant simplification is in regard to the submission of information of formulations that are being decontrolled. In this sector the industry would be required to submit only the price list of medicines on a periodical basis.

An important provision introduced is the stipulation of time limits of two months for deciding applications for price revision of formulation and four months for price fixation/revision of applications regarding bulk drugs. There is also a stipulation in the DPCO enjoining the Government to notify on an annual basis the norms relating to conversion costs, packing material costs and packing charges.

The new DPCO also provides for fixing of ceiling prices for commonly used packs of formulations based on price controlled drugs and these prices would be applicable to all manufacturers and also the single ingredient formulations sold under generic name. The small scale sector will not be required to come for price fixation for these packs and they will be required to only adhere to the discipline of observing the ceiling prices. In regard to other packs they would continue to enjoy, as before, exemption from price control on formulations.
A provision has also been added in the DPCO to allow for exemption from price control to a new bulk drug, which has not been produced elsewhere if developed through indigenous R & D.

Further a provision has also been built to allow the use of funds collected in the Drug Equalisation Account for the purpose of promoting higher education and research in pharmaceutical sciences and technology and purposes incidental thereto.

The DPCO 1995 lays down a more transparent procedure for the working of the price control mechanism which would be in the ultimate interest of the consumers as well as the manufacturers.
CONSTITUTION OF INDIA

Duty of the state to raise the level of nutrition and the standard of living and to improve public health

The state shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and in particular. The state shall endeavour to bring about prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health.

The Drugs and Cosmetics Act

The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Act amendment 1982 are the main drug legislations that are supposed to provide some form of control over the manufacture and sales of drugs. The drugs controller of India has the power to prohibit manufacture of drugs which are not in public interest.

Power of Central Government to prohibit manufacture etc. of Drug and cosmetic in Public interest.

Without prejudice to any other provision contained in this chapter if the central government is satisfied, that the use of any drug or cosmetics is likely to involve any risk to human beings on animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contained ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then the government may, by notification in the official gazette prohibit the manufacture, sale or distribution of such drug or cosmetic.
PENALTY FOR MANUFACTURE ETC. OF DRUGS OR COSMETICS IN CONTRAVENION OF SECTION 26 A.

Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetics in contravention of the provisions of any notification issued under section 26 A. shall be punishable with imprisonment for a term which may extend to 3 years and shall also be liable to fine which may extent to Rs. 5,000.

PENALTY FOR SUBSEQUENT OFFENCES

Whoever having been convicted of an offence:

Under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 6 years with fine which shall not be less than Rs. 10,000 provided that the court, may for any judgement impose a sentence of imprisonment for a term of less than 2 years and of less than Rs. 10,000. (b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 6 years but which may extend to 10 yrs and with fine which shall be less than Rs. 10,000.

(c) Under clause (d) of section 27 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 4 years or with fine which shall not be less than Rs. 5000 or with both.

(d) Under clause (b) of section 27 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which may extend to 10 years or with fine or with both.

CONFISCATION
COGNIZANCE OF OFFENCES

No prosecution under this chapter shall be instituted except by an inspector.

POWER OF CENTRAL GOVERNMENT TO MAKE RULES

POWER TO GIVE DIRECTION

The central government may give such direction to any state government as may appear to the central government to be necessary for carrying into execution in the state any of the provision of this act or of any rule made there under.

1. The central government may after consultation with or on the recommendation of the board and after previous publication by notification in the official gazette make rule for the purpose of giving effect to the provision of the chapter.

COMMENTS ON THE SECTION 33 E

The Act of possessing a contraband or a prohibited article constitutes a continuing offence. A dealer could not process such drugs during any period following the date of the issue of Notification and there after (Subhash Chander VS State of Punjab and others AIR 1979 P and H 238)

COMMENT ON SECTION 339

If a dealer is found selling, stocking or exhibiting for sale the prohibited drugs, an Inspector appointed under this Section can prosecute him by filing a complaint to the court who may in turn punish him. (Subhash Chander VS State of Punjab and others, AIR 1979 Pand H 238)
THE CONSUMER PROTECTION ACT, 1986

Objectives of the Act:

The consumer protection Act, 1986 (68 of 1986) is a milestone in the history of socioeconomic legislation in the country. It is one of the most progressive and comprehensive pieces of legislation enacted for the protection of consumers. The new law has been enacted after in-depth study of consumer protection laws and arrangements in the U.K., U.S.A., Australia and New Zealand. Before its formulation, consultations with representatives of consumers, trade and industry were held. Various ideas and suggestions were also considered in a number of inter-ministerial meetings within the Government.

The main objective of the new law is to provide for the better protection of the consumers. Unlike existing laws which are punitive or preventive in nature, the provisions of this Act are compensatory in nature. The Act intends to provide simple, speedy and inexpensive redressal to the consumer's grievances. For this purpose, the Act envisages a three-tier quasi-judicial machinery at the national, State and district levels, the Act enshrines certain rights of the consumers and provides for the setting up of Consumer Protection Councils in the centre and the States. The objective of these Consumer Protection Councils will be to promote and protect the rights of the consumers.

Extent and coverage of the Act:

The salient features of the Act are summed up as under:

- The Act applies to all goods and services unless specifically exempted by the Central Government.
- It covers all the sectors whether private, public or cooperative.
The provisions of the Act are compensatory in nature.

It enshrines the following rights of the consumers:

1. The right to be protected against the marketing of goods which are hazardous to life and property;

2. The right to be informed about the quality, quantity, potency, purity, standard and price of goods so as to protect the consumer against unfair trade practices;

3. The right to be assured, wherever possible, access to a variety of goods at competitive prices;

4. The right to be heard and to be assured that consumers’ interests will receive due consideration at appropriate forums;

5. The right to seek redressal against unfair trade practices or unscrupulous exploitation of consumers; and

6. The right to consumer education.

The Act envisages establishment of consumer protection councils at the central and state levels whose main object will be to promote and protect the rights of the consumers.

To provide simple, speedy and inexpensive redressal of consumer grievances, the Act envisages a three-tier quasi-judicial machinery at the national, State and district levels. At the national level, there will be a National consumer disputes redressal commission (to be known as the ‘National commission’). At the state level, there will be consumer disputes redressal commissions (to be known as ‘State commission’) and at the district level there will be consumer disputes redressal forums (to be known as ‘district forums’).

The provisions of this Act are in addition to and not in derogation of the provision of any other law for the time being in force.
Who is a Consumer?

All of us are consumers of goods and services. The producers of some goods and services also consume various other goods and services produced by others. In the consumer protection Act, the word ‘consumer’ has been defined separately for the purpose of goods and services.

➢ For the purpose of goods, a consumer means a person belonging to the following categories:

1. One who buys any goods for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment;

2. It includes any user of such goods other than the person who actually buys goods and such use is made with the approval of the purchaser.

For the purpose of services, a consumer means a person belonging to the following categories:

1. One who hires any service or services for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment;

2. It includes any beneficiary of such service other than the one who actually hires the service for consideration and such services are availed with the approval of such person.

Who Can file a complaint?

Following categories of persons may file a complaint under the Act:

➢ A consumer.

➢ Any voluntary consumer organisation. Registered under the societies registration Act 1860 or the companies Act, 1956 or under any other law for the time being in force.
➢ The central government.

➢ The State Governments or Union Territory Administrations.

What constitutes a complaint?

Under the Act, a complaint any allegation in writing made by a complainant in regard to one or more of the following:

➢ That he has suffered loss or damage as a result of any unfair trade practices adopted by any trader.

➢ That the goods mentioned in the complaint suffer from one or more defects.

➢ That services mentioned in the complaint suffer from deficiencies in any respect.

➢ That a trader has charged for the goods mentioned in the complaint, a price in excess of the price.

i Fixed by or under any law for the time being in force; or

ii Displayed on goods; or

iii Displayed on any packet containing such goods.

➢ The definition of ‘goods’, ‘services’ and ‘unfair trade practices’, ‘defect’ and ‘deficiencies’ are given in the Annesure-1.

Where to file a complaint?

➢ If the cost of the goods or services and compensation asked for, is less than rupees one lakh, then the complaint can be filed in the District Forum which has been notified by State Government for the district where the cause of action has arisen or where the opposite party resides.

➢ If the cost of the goods or services and compensation asked for is more than rupees one lakh but less than rupees ten lakhs, the complaint can be filed before the State commission notified by the State Government or the Union Territory concerned.
The National Commission and state Commission are required to decide the appeal, as far as possible, within 90 days from the first date of hearing.

Definitions


2. “Service” means service of any description which is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, entertainment, amusement or the purveying of yews or other information, but does not include the rendering of any service free of charge or under a contract of personal service;

3. the expression “unfair trade practice” shall have the same meaning as in section 36A of the Monopolies and Restrictive Trade Practices Act, 1969, but shall not include an unfair trade practice adopted by the owner of an undertaking to which part A of Chapter III of that Act applies or by any person acting on behalf of, or for the benefit of, such owner.

4. “defect” means any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force or as is claimed by the trader in any manner whatsoever in relation to any goods.

5. “deficiency” means any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to be maintained by or under any law for the time being in force or has been the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service.
Procedure for filling the appeal

- Appeal against the decision of a District Forum can be filed before the State Commission within a period of thirty days. Appeal against the decision of a State Commission can be filed before the National Commission within thirty days. Appeal against the orders of the National commission can be filed before the Supreme Court within a period of thirty days.

- There is no fee for filing appeal before the State commission or the National commission.

- Procedure for filing the appeal is the same as that of complaint, except that the application should be accompanied by the orders of the District Forum/State commission as the case may be and reasons for filing the appeal should be specified.

Time limit for deciding complaint/appeal

The thrust of the Act is to provide simple, speedy and inexpensive redressal to consumer grievances. To ensure speedy disposal of consumer grievances, the following provisions have been incorporated in the Act and the rules framed thereunder:

- It is obligatory on the complainant or appellant or their authorised agents and the opposite parties to appear before the Forum/Commission on the date of hearing or any other date to which hearing could be adjourned.

- The National commission, State commission and District Forums are required to decide complaints, as far as possible, within a period of three months from the date of notice received by the opposite party where complaint does not require analysis of testing of the commodities and within five months if it requires analysis or testing of commodities.
If the cost of goods or services and compensation asked for, exceeds rupees ten lakhs, the complaint can be filed before the National commission at New Delhi.

**How to file a complaint?**

Procedures for filing complaints and seeking redressal are simple and speedy.

- There is no fee filling a complaint before the District Forum, the State commission or the National Commission.
- The complainant or his authorised agent can present the complaint in person.
- The complaint can be sent by post to the appropriate Forum/commission.
- A complaint should contain the following information:

  (a) the name, description and the address of the complainant;
  (b) the name, description and address of the opposite party or parties, as the case may be, as far as they can be ascertained;
  (c) the facts relating to complaint and when and where it arose;
  (d) documents, if any, in support of the allegations contained in the complaint;
  (e) the relief which the complainant is seeking.

The complaint should be signed by the complainant or his authorised agent.

**Relief available to consumers:**

Depending on the nature of relief sought by the consumer and facts, the redressal Forums may give orders for one or more of the followings relief;

(a) removal of defects from the goods;
(b) replacement of the goods;
(c) refund of the price paid; or
(d) award of compensation for the loss or injury suffered.