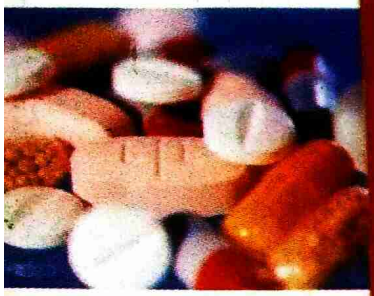

PV BOOKS

PHARMACEUTICAL JURISPRUDENCE

(FOR[illegible]ACY & ETHICS)

BINAY KUMAR JHA

Pee Vee (Regd.)

TABLE OF DEFINITIONS

1. THE PHARMACY ACT

1.	**Agreement**	It means an agreement entered into under section 20 (Interstate agreement regarding consitution of state pharmacy councils.)
2.	**Approval**	It means approval by the pharmacy council of India or Central council under section 12 (Course of study and examination in pharmacy) or section 14 (Foreign qualifications for the purpose of qualifying for registration under the Act.
3.	**Central Register**	The register of pharmacists maintained by the pharmacy council of India.
4.	**Register**	A register of pharmacists prepared and maintained under the Act.
5.	**Registered pharmacist**	It 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.
6.	**State council**	It 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.

II. THE DRUGS AND COSMETICS ACT AND RULES

7.	**Drug**	It includes:
	(a)	All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including

preparations applied on human body for the purpose of repelling insects like mosquitoes;

(b) Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of the vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Govt. by modification in the official Gazette;

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

(d) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals as may be specified from time to time by the Central Govt. by notification in the official Gazette, after consultation with the Drugs Technical Advisory Board (DTAB).

8. Cosmetic Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansings, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

9. Manufacture Any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drugs, or the packing of any drug or cosmtetics in the ordinary course of retail business.

10. Patent or properietary medicine A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals, and which is not included in the edition of the Indian pharmacopeia for the time being or any other pharmacopoeia authorised in this behalf by the central Government after consultation with the DTAB.

11. Import The carrying of the goods, across the custom frontier even in the same state.

12. Export To take out of India across any of the customs frontiers.

13. Misbranded drugs A drug is deemed to be misbranded. If

(i) It is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is ; or

(ii) It's not lebelled in the prescribed manner; or

(iii) It's label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

14. Adulterated A drug is deemed to be adulterated:

(i) If it consists in whole or part of any filthy, putrid or decomposed substance ; or

(ii) If it has been prepared, packed or stored under insanitary conditions whereby it may have been rendered injurious to health; or

(iii) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

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

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

(vi) If any substance has been mixed therewith so as to reduce its quality of strength.

15. Spurious Drugs A drug is deemed to be spurious

(i) If it is imported (manufactured in relation to manufacture sale and distribution of drugs) under a name which belongs to another drug.

or

(ii) If it is an imitation of or is a substitute for another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drugs; or

(iii) If the label or container bears the name of an individual or company purporting to the manufacture of the drugs, which individual or company is fictitious or does not exist ; or

(iv) If it has been substituted wholly or in part by another drug or substance; or

(v) If it purports to be the product of a manufacturer of whom it is not truly a product.

III. THE DRUGS AND MAGIC REMEDIES ACT

16. Advertisement Any notice, circular, label wrapper or other document, and any announcement

made orally or by means of producing or transmitting light, sound or smoke.

17. Drugs :- It includes

(objectionable advertisements)

(a) medicines for the internal or external use or human beings or animals,

(b) any substance intended to be used for or diagnosis, cure, mitigation, treatement or prevention of disease in human beings or animals,

(c) any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings,

(d) any article intended for use as a component of any medicine, substance or article referred to in (a), (b) and (c) above.

18. Magic Remedy Talisman, mantra, Kavacha and any other charm of any kind which is alleged to posess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals.

IV. THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT AND RULES

19. Addict A person addicted to any narcotic drug or psychotropic substances;

20. Cannabis (Hemp)

(a) 'Charas' that is, the separated resin, in whatever form, whether crude or purified, from the cannabis plant and also includes concentrated preparation and

resin known as hashish oil or liquid hashis;

(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 disignated; and

(c) any mixture, with or without any neutral material, of any of the above forms of cannabis or any drink prepared therefrom

21.Coca derivative It 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 it can be recovered;

(c) cocaine, that is, methyl ester of benzyl-ecgonine and its salts; and

(d) all preparations containing more than % of cocaine;

22. Coca leaf

(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 there of with or without any natural, material but does not include any preparation containing not more than 0.1% of cocaine;

23. Narcotic drug means coca leaf, cannabis (Hemp), opium, poppy straw and includes all manufactured drugs;

24. Opium It 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

preparatien containing not more than 0.2% of morphine.

25. Opium derivative It means —

(a) medicinal opium, that is, opium which has undergone the process necessary to adopt it for medicinal use in accordance with the requirements of the I.P. or any other pharmacopoeia notified in this behalf by the central Govt; whether in powder form or granulated 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 or other residue remaining after opium is smoked;

(c) phenanthrene alkaloids, namely——— morphine. codeine, the baine 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% of morphine or containing any diacetyl-morphine.

26. 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;

V. THE DRUGS (PRICES CONTROL) ORDER

27. Bulk drug means any substance including pharmacautical, chemical, biological or plant product or medicinal gas conforming to pharmacopoeial or other standard accepted under the Drugs and

cosmetics Act, 1940, which is used as such, or as an ingredient in any formulation;

28.	**Ceiling price**	means a price fixed by the Govt. for formulations specified in. category I or categrory II of the third schedule keeping in view the cost of efficiency, or both, of major manufacturers of such formulations.
29.	**Pre-tax return**	means profits before payment of income-tax and surface and includes such other expenses as do not form part of the cost of formulation.
30.	**Sale turn-over**	means the product of units of formulation sold by a manufacturer or an importer in an accounting year multiplied by retail price inclusive of sales tax, if any.
31.	**Retailer**	means a dealer carrying the retail business of sale of drugs to customers
32.	**Wholesaler**	means a dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities of drugs.
33.	**Retail price**	means the retail price of a drug arrived at or fixed in accordance with the provisions of this order and include a ceiling price.

VI. THE POISONS ACT

34.	**Poisons**	The term poison has not been defined in the Act but includes those substances specified as poisons.

VII. THE MEDICINAL AND TOILET PREPARATIONS

35.	**Medicinal preparations**	It includes all drugs which are a remedy or prescription prepared for internal or external use of human being or animals and all substances intended to be used

for or in the treatment, mitigation, or prevention of disease in human beings or animals;

36.	Toilet preparations	It means any preparation which is intended for use in the toilet of the human being or in perfumes of any description, or any substance intended to clean, improve or alter the complexion, hair, skin or teeth and includes deodorants and perfumes.
37.	Bonded manufactory	means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparation containing alcohol, opium, Indian hemp or other narcotic drug on which duty has not been paid;
38.	Non-Bonded manufactory	It means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drug or narcotics on which duty has been paid:
39.	**De natured alcohol or denatured spirit**	It means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the central Govt. or by the state-Govt with the approval of the central Govt.
40.	**Rectified spirit**	It means plain undenatured alcohol of a strength not less than 500 over proof and includes absolute alcohol.
41.	**Absolute alcohol**	It means alcohol conforming to the B.P. specifications for dehydrated alcohol.
42.	**Restricted preparation**	It means every medicinal and toilet preparation specified in the schedule and includes every preparations declared by the central Govt. as restricted preparations.
43.	**Warehouse**	It means any place or premises licensed under rule 70.

VIII. THE MEDICAL TERMINATION OF PREGNANCY ACT AND RULES

44.	**Guardian**	It means a person having the care of a minor of a lunatic.
45.	**Registered Medical practitioner**	It means a person who possesses any recognised medical qualification as defined under the Indian Medical council Act and whose name has been entered in a state Medical Register and who has such experience or training in gynaecology and obstetrics as may be prescribed by rules made under this Act.
46.	**Approved place**	It means a place approved under rule 4 of the MTP Rules, 1975.

MISCELLANEOUS

47.	**Pharmacy**	Premises licensed for the retail sale of drugs which have a qualified person and indulge in the compounding of drugs.
48.	**Qualified person**	Persons holding degree or diploma in pharmacy or pharmaceutical chemistry or registered as pharmacists under the pharmacy Act or having not less than 4 years experience of dispensing, consideres adequate by the licensing authorities or persons who were approved as qualified persons before 31.12.1969.
49.	**Chemists and Druggists**	Premises licensed for the sale of drugs which have a qualified person but wherein drugs are not compounded.
50.	**Drug Stores**	Premises licensed for the sale of drugs which do not have a qualified person;
51.	**Vendors of Drugs**	Persons who do not have fixed premises to sell drugs but are licensed to distribute them personally in specified areas.

ORIGIN AND NATURE OF PHARAMACEUTICAL LEGISLATION IN INDIA

The Drugs Act, 1940 brought a great change in the history of drug legislation in India. This Act was passed on the recommendation of Drugs Enquiry Committee. In order to control unethical practices in the pharmaceutical field, the Committee recommended the following :—

1. The central legistation to control drugs and pharmacy
2. Setting up of state drug testing laboratories in order to control the quality of production of drugs and pharmaceuticals. A central Drugs Laboratory to control the quality of imported drugs and final authority in case of disputed samples sent by the count or local Govt.
3. Appointment of an Advisory Board to advise the Govt. in making rules to carry out the objects of the Act.
4. Setting up of courses for training in pharmacy and prescribing minimum qualification for registration as a pharmacist.
5. Registration of every patent and proprietory medicine of undisclosed formula manufactured in India or imported from outside the country.
6. The crude single drugs as well as the compounded medicines used in the indigenous systems of treatment, should be brought under control.
7. The drugs industry in India should be developed.
8. The manufacturing in Medical stores Depots should be gradually reduced.
9. Steps should be taken to compile an Indian pharmacopoeia.
10. The cinchona Department should cultivate cinchona.

In response to the above recommendation in 1931 by the Drugs Enquiry Committee or Chopra committee the following development was seen:

In 1932, The first Department of pharmaceutrics was started at Banaras Hindu University.

In 1935, Pharmaceutical Association was organised, now it is known as IPA.

In 1939, Indian Journal of pharmacy was started.

In 1940, Indian pharmaceutical Association organised an All India pharmaceutical conference.

In 1943, The Govt. of India appointed a Health Survey and Development Committee to make recommendations for future developments. The committee recommended as follows:

1. The establishment of an All India pharmaceutical council and state pharmacy council representing the pharmaceutical trade, education and other pharmaceutical interests,
2. Enactment of legislation designed to protect the public from incompetance, to safeguard the interests of qualified pharmacists and to raise the professional standing of pharmacists engaged in the handling of drugs.
3. Measures for registration of pharmacists.
4. Measures for maintining disciplinary control over the practice and profession of pharmacy.
5. Revised course of study for :—

(i) Licentiate pharmacists,

(ii) Graduate pharmacists

(iii) Pharmaceutical Technologists.

6. Setting up of central Drugs Laboratory.
7. The Drugs Act 1940 should be enforced throughout the country.
8. The question of the requirements of the country in drugs and of the medical requisites should be examined by a small committee.

In 1945, The pharmacy Bill was passed to regulate the profession and practice of pharmacy.

In 1948, The Pharmacy Act was passed.

In 1954, The Drugs and Magic Remedies (objectionable Advertisements) Act was passed in order to have control over advertisements.

In 1955, The Medicinal and Toilet Preparations (Excise Duties) Act was introduced in 1955 mainly to regulate the use of alcohol in medicinal and toilet preparation.

In 1961, Health Survey and planning committee recommended that it is necessary to bring drugs prepared according to indigenous system of medicine also within the purview of the Drugs Act.

In 1985, The Narcotic Drugs and Psychotropic substances Act, was passed.

In 1994, The Drugs (Prices control) order. 1979 and 1987 was repealed, and modified.

Inspite of all the rules and regulations under the Act, even today the substandard drugs are available in the market. Drug control authorities are those persons who do not have any qualification of pharmacy. As a result of which the progress of the profession of pharmacy has been slowed down:

In a nut shell, it can be said that the concept of pharmacy is changing day by day. Under the New Education Regulation, it is expected that the pharmacist and the pharmacy will definitely develop in all aspects. As the quality of the pharmacist will be better so the enforcement of the Drugs Legislation in true sense and its progress is not questionable.

CODE OF PHARMACEUTICAL ETHICS

The conduct of any person in any society is governed by the rules and regulations of the government and the social customs. The law of the govt. has to be followed by every person compulsorily but the social customs and duties is not compulsory, that depends upon the individual. The conscience which has been developed in a person by the passage of time by living in a society is called conduct or moral. 'The science of mor.. ' or th. ode of moral principles is defined as Ethics.

The code of ethics formulate.' by the pharmacy council of India for the guidance of Indian pharmacists is as follows:

PHARMACIST IN RELATION TO H.. JOB

Scope of pharmaceutical Servic :s . In a pharmacy comprehensive pharmaceutical services sho.ld be provided. Commonly required medicines should be supplied without undue delay. Pharmacist should have willingness to furnish emergency supplies at all times.

Conduct of the pharmacy : The conditions in a pharmacy should be such that error of accidental contamination must be avoided during the compounding and dispending of medicines.

The pharmacy should reflect its professional character pharmacy.

Any notices, wordings on business or any indications should be proper in size, design and forms, Qualification of the pharmacist should be written as permissible by the law. If any scheme sponsored by the Govt. is carried out, that can be exhibited at the premises. Every pharmacy should have a qualified person i.e. a registered ..acist who shall be responsible for the conduct of pharmacy.

All dispensing and ornpounding should be done by the pharmacist only. The owner should not interfere in the working of the pharmacist.

Handling of Prescriptions : The prerscription should be received by the pharmacist without, showing any facial expression. Merits and demerits of or its therapeutic efficiency should not be discussed. As these cause anxiety in patients. Sometimes it may even shake the faith of the patient in the physician. Any question asked by the patient or the prescription holder should be answered carefully. It should neither offend the prescription holder nor disclose any information which might have been intentionally witheld from him.

A pharmacist is not allowed to add, omit or substitute any ingrediant or alter the composition of a prescription without the consent of the prescriber. He can change the ingredient if at all it is required by the techniques of the pharmacautical art, but care should be taken so that the therapeutic action of the recipe does not change. In case of any error, incompatibility or over dose the prescription should be referred back to the prescriber for the correction. It should be done in such a way so that the prescriber's reputation is not damaged.

While refilling the prescription, the pharmacist should strictly follow the instructions of the prescriber. He should advise the patient to take the medicine according to the advice given in the prescription.

Handling of Drugs: Prescription should be discussed correctly. All weighing and measuring should be accurate. No visual estimation should be practised. Drugs and medicinal preparations of standard quality should be used. Spurious, substandard and unethical preparation should never be refilled.

Poisonous drugs and drugs used for addition or schedule x should be handled very carefully. A pharmacist should be judicious in handling these types of drugs.

Apprentice pharmacist : A pharmacist should see that full facilities are provided to the trainees under him. He should always bear in mind that on completion of the training the apprentice pharmacists have acquired sufficient technique and skill to make

themselves dependable pharmacists. Certificate of the completion should not be issued till the trainee proves himself worthy of it.

PHARMACIST IN RELATION TO HIS TRADE

Price Structure: Prices, charged from customers should be fair. The purchaser should not be undully taxed.

Fair Trade Practice. In order to capture the business of the fellow pharmacist, less price or any prize should not be taken or given respectively. In case, the prescription of any other pharmacy is brought by mistake to another, the pharmacist should refuse tc accept it, and should direct the purchaser to the right place. Labels, trade marks or other signs of other pharmacist should not be imitated or copied.

Purchase of Drugs: Drugs should always be purchased from a reliable whole saler or manufacturer and obtain a receipt for the same.

Hawking of Drugs: Hawking of drugs should not be encouraged as it encourages self medication. Self-service should not be allowed in a pharmacy.

Advertising and Displays : The pharmacist shall not advetise and display, in his premises or in press or in public place, regarding the sale of medicines which claim to cure in reference to an ailment or symptoms of ill health or unethical and prohibited advertisements.

PHARMACIST IN RELATION TO MEDICAL PROFESSION

Limitation of Professional Activity: Neither Medical practitioners should practice pharmacy nor pharmacist should take to medical practice i.e. to diagnose diseases and prescribe medicine. In cases of accidents and emergencies a pharmacist may however give First aid to the Victim.

No pharmacist should recommend the name of particular medical practitioner unless asked to do so.

Clandestine Arrangements: No pharmacist should make any secret arrangement with any medical practitioner, to offer any commission or any advantage by rommending his dispensary or drug store.

Liasion with public : A pharmacist should possess upto date knowledge regarding the modern developments in pharmacy and allied sciences by regularly reading books, journals, magazines and other periodicals. So that he can be in a position to advise the medical practitioner on pharmaceutical matters. He should educate the people for maintaining healthy and sanitary conditions of living.

A pharmacist should always strive to increase his knowledge. By doing this he fulfills his quota in the advancement of learning.

A pharmacist should never disclose any information, which he has acquired during his professional activities, unless asked to do so by the law. He should never betray the confidence of his patrons, which he has won by virtue of his eminent character and conduct.

PHARMACIST IN RELATION TO HIS PROFESSION

Professional vigilance : A pharmacist should be a law- abiding citizen and he should keep himself away from doing things derogatory to the society and his profession. He should make others also fulfil the provisions of the pharmaceutical and other laws and regulations. He should not be afraid of bringing any miscreant to the notice of the law. He should help his fellow pharamacist in legitimate needs, scientific technical problems. He should be vigilant to weed the undesirable practices out of the profession in order to maintain its fair name and traditions

Law-abiding Citizens : A pharmacist engaged in the profession of pharmacy should have knowledge of the laws of the land in respect of food, drug, pharmacy, health ani sanitation and should abide by them in his life. A pharmacist is a unit whole and his life cannot be divided into compartments.

Relationship with Professional Organisation :

A pharmacist should join and advance the cause of all such organisations, the aims and objects of which are conducive to scientific, moral and cultural well-being of pharmacists. In no way it should be contrary to the code of pharmaceutical ethics.

Decorum and Propriety: A pharmacist should always refrain from doing all such acts and deeds which are not in consonance with the decorum and propriety of pharmaceutical profession and are likely to bring discredit or to upbraid the profession or himself.

PHARMACISTS OATH

"I promise to do all I can, to protect and improve the physical and moral well-being of society, holding the health and safety of my community above other considerations, I shall uphold the laws and standards governing my profession, avoilding all forms of misrepresentation and I shall safegaurd the distribution of medical and potent substances.

Knowledge gained about patients, I shall hold in confidence and never divulge unless completed to do so by law.

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and the public health better.

I furthermore promise to maintain my honour and credit in all transactions and by my conduct never to bring discredit to myself or to my profession nor to do anything to dimnish the trust reposed in my professional brethren.

May I prosper and live long in favour as I keep and hold to this, my oath, but should I violate these sacred promises, may the reverse be my lot."

CHAPTER 3

PHARMACY ACT

In order to regulate the practice of pharmacy in India the pharmacy Act was passed in 1948. The Act has been divided into 5 chapters and 46 sections. It has been amended in a major way by the pharmacy (Amendment) Act, 1976 and in a minor way in 1959 and in 1981. The Act extends to the whole of India except the state of Jammu and Kashmir. Following are the significant features of the Act:

1. The constitution of the pharmacy council of India and state pharmacy councils.
2. The prescribing of the minimum standard of education required for qualifying as a pharmacist.
3. The registration of the pharmacists by the state pharmacy councils.
4. Maintenance of disciplinary control over the profession of pharmacy.
5. Dispensing of prescriptions of registered medical practitioners only by registered pharmacists.

THE PHARMACY COUNCIL OF INDIA

The pharmacy council of India or the central council was first constituted by the central Govt in 1949. It is reconstituted every five years and consists of the following members.

Elected members:

1. Six members including at least one teacher each in pharmaceutical chemistry, Pharmacy, pharmacology and pharmacogmony 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 Grants Commission.

2. One member is elected by the medical council of India from amongst its members.
3. One member who shall be a registered pharmacist to represent each state is elected by state council from amongst its members.

Nominated members:

1. Six members including at least four persons possessing degree or diploma in pharmacy and engaged in the practice of pharmacy or pharmaceutical chemistry are nominated by the central Govt.
2. A representative each of the University Grants Commission and All India Council for Technical Education.
3. One registered pharmacist to represent each state are nominated by the State Govt/UT. Administration.

Ex-Officio members:

1. The Director General of Health Services.
2. The Director of Central Drugs Laboratory.
3. The Drugs controller of India.

The pharmacy council of India is deemed to be a corporate body having perpetual succession and a common seal. It is empowered to acquire and hold both movable and immovable property.

The members of the pharmacy council of India elects a President and a Vice president amongst themselves. They hold office for five years. They are eligible for re-election. 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 duly nominated or elected, whichever is earlier.

A nominated or elected member can resign from the membership at any time by writing to the president. A nominated or elected member is deemed to have vacated his seat, if he absents himgelf from the three consecutive meetings of the council without giving sufficient reason to the satisifaction of the council. Ex-officio members, the Director General of Health Services and the Director

of central drugs Laboratory can authorise a person each in writing to attend the meeting if he is unable to attend the meeting himself. The members nominated by the UGC or MCI or SPC shall cease to be the members of PCI, in case they are no longer members of the teaching staff in a university or college or of the MCI or have ceased to be registered pharmacists in the state, respectively. The casual vacancy is filled either by nomination or election, as the case may be. The person so nominated or elected shall hold the office for the remaining period.

The council appoints a Registrar who acts as the Secretary to the PCI and if needed its treasurer also. It can appoint officers and servants necessary to crry out its functions.

It is empowered to fix, with the prior sanction of the central Govt :—

(i) The remuneration and allowances to be paid to its members and

(ii) The pay and allowances and other conditions of service of officers and servants of that council.

The PCI has to constitute an Executive committee consisting of the president (chairman of the committee) and vice president (ex-officio), and five other members elected by the PCI amongst its memebrs. The Executive committee is empowered to constitute from amongst its members other committee for such general or special purposes.

FUNCTION:

1. The PCI makes the Education Regulations prescribing the minimum standard of education required for qualification as a pharmacist.
2. It approves the courses of study and examiniations, after the enquiry and to the satisfaction of the council.
3. It maintains the central register of pharmacists in the prescribed manner.
4. The Executive Committee appoints the Inspectors

(a) To inspect any institution which provides an approved courses of study and

(b) To attend any approved examination and to report about the standard of the examination.

EDUCATION REGULATIONS

The pharmacy councils of India may make regulations called as Education Regulations with the approval of Central Govt. It prescribes the minimum standard of education required for qualification as a pharmacist. Amendments to the Education Regulations are first circulated to the state Govts. for their comments. If any comment is received within three months that is taken into account before making recommendations to the central Govt. After it is approved by the central Govt. it is published in the official Gazette.

The Education regulations prescribe as follows:

1. Minimum qualification for admission to the course.
2. The nature and period of study.and of practical training in a recognised hospital or Institution for the completion of Diploma in pharmacy course.
3. The equipment and facilities to be provided for students undertaking approved course of study.
4. The subjects of examination and the standards there in to be attained.
5. Conditions to be fulfilled by the institutions, for giving practical training to the students.
6. Conditions to be fulfilled by the authorities, holding the approved examinations.
7. Eligibility for appearing at the part I, part II and part III examinations.
8. Any other condition of admission to examination:

The Executive committee of the PCI is required to report from time to time regarding the efficacy of the Education Regulations and recommend such amendments as it may think it.

APPLICATION OF EDUCATION REGULATIONS TO STATES

After the constitution of the state pharmacy council, the state Govt. in consultation with the state pharmacy councils by notification in the official Gazette, declare that the Education Regulation shall take effect in the state. Where no such declaration is made, the

Education Regulation shall take effect on the expiry of three years from the date of the constitution of the state pharmacy council.

APPROVED COURSES OF STUDY AND EXAMINATIONS

Any authority or institution conducting a course of study for pharmacist may apply to the PCI for approval of the course and examination. The council then deputes its inspectors for preliminary inspection. The inspectors ascertain whether the institution has minimum facilities for running the course or holding examination in conformity with the Education Regulations or not. The inspectors may attend any exarnination to judge its standards. The inspectors submit their report and recommendations to the PCI ; on the basis of which a course or examination is or is not approved. This approval is essentiaal to qualify for registration as pharmacist under the Act.

When the Executive Committee reports to the PCI that an approved course of study or an approved examination is not in confirmity with Education Regulation, the PCI gives notice to the concerned institution for the withdrawal of approval. The said authority within three months from the date of such notice should complete all the deficiencis and apply to the PCI through the state Govt. If the PCI finds that the facilities are in confirmity with the Education Regulation, the course of study or examination is approved otherwise it is not.

APPROVAL OF OTHER QUALIFICATIONS:

The PCI may approve any foreign qualification for the registration under the pharmacy Act under the following circumstances:

1. If a sufficient guarantee of the skill and knowledge is afforded.
2. It may declare that any foreign qualification will be deemed to be approved only when granted after or before specified date.
3. It can approve when the country or state from which such qualification has been obtained permits the citizen of India to practice as a pharmacist.

Approval of any qualification are declared by making resolution at a meeting of the PCI. These are effective on publication in the official Gazette.

NEW EDUCATION REGULATIONS 1991

Diploma Course in Pharmacy

IMPORTANT GUIDELINES

1. Qualification for admission to Diploma in Pharmacy 1 year :— A candidate should pass in any of the following examinations with Physics, Chemistry, and Biology.

(a) Intermediate examination in Science

(b) The First year of the three year degree course in Science.

(c) 10+2 examination (academic stream) in Science.

(d) Pre degree examination or

(e) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examination.

2. Duration of the Course : Two academic years of minimum 180 working days each & 500 hours of practical training spread over a period of not less than 3 months after computing the course. (Subjects given at the end in table form)

3. Examination Scheme: Sessional : There shall be at least two periodic sessional examinations during each academic year. The highest aggregate of any two performances shall form the basis of calculating sessional marks.

A. The sessional marks in practicals (30) shall be allotted as follows :

Actual performance in the sessional examination (15 Marks)

Day to Day assessment in the practical class work (15 Marks)

B. Sessional marks in theory subjects = 20

C. **Improvement of Sessional Marks.** Candidates who wish to improve sessional marks can do so by appearing in two additional sessional examinations during the next academic year. The average score of the two examination hall be the basis for improved sessional marks in the theory. The sessional marks of practicals shall be improved by appearing in additional practical examination. Marks awarded to a candidate for day to day assessment in the practical class, cannot be improved unless he/she attends a regular course of study again.

4. Mode of examination: (Final Examination):

(i) Each theory and practical examination in the subject shall be of three hours duration. (ii) A candidate who fails in theory or practical examination of a subject (theory or practical) **shall reappear both in theory and practical of the same subject.** (iii) Practical examination shall also consist of a viva voice (Oral) Examination.

5. Minimum marks for passing the examination (Final) : A student should be declared to have passed Diploma in Pharmacy examination unless he/she secures at least 50% marks in each of the subject separately in the theory examinations, including sessional marks and atleast 50% marks in each of the practical examination including sessional marks.

6. Eligibility for promotion to Diploma in Pharmacy Second year (A.T.K.T. Rule) : All candidates who have appeared for all subjects and passed the Diploma in Pharmacy First Year exdamination are eligible for promotion to the Diploma in Pharmacy Second Year class. However, **failure in more than two subjects shall debar him/her from promotion to the Diploma in Pharmacy Second Year.**

7. Practical Training: After having appeared in Second Year examination of D. Pharm conducted by Board/University or other approved examination body or any other course accepted as being equivalent by the Pharmacy Council of India, a candidate shall be eligible to undergo practical training in one or more of the following institutions namely : (Total 500 Hours in not less than 3 month period)

(A) Hospital/Dispensaries run by Central/State Governments Municipal Corporations/Central Government. Health Scheme and Employees State Insurance Scheme

(B) A Pharmacy, Chemist and Druggist Licensed under the Drugs and Cosmetic Rules. 1945 made under the Drugs and Cosmetics Act, 1940.

(C) Drugs manufacturing Unit licensed under the Drugs and Cosmetics Act, 1940 and rules made thereunder.

8. **Equivalence of Subjects:** (i) Forensic Pharmacy and Ethics of II DCP (E.R. 81) is equivalent to Pharmaceutical Jurisprudence, of II DCP of New E.R. 1991 (ii) Pharmacognosy of II DCP of E.R. 81 is equivalent to Pharmacognosy of 1 year CDP (E.R. 1991). (iii) Pharmaceutics I of IInd DCP (E.R. 81) is equivalent to Pharmaceutics II of 2nd year DCP (E.R.1991).

(Table of Subjects)

Firt Year D. Pharm Subjects	Hours		Sess.	Mar
Subject	(Th)	Pt.	(Th)	Pt.
Pharmaceutics-1	75	100	20	30
Pharmaceutical Chemistry-1	75	75	20	30
Pharmacognosy	75	75	20	30
Bicohemistry & Clinical Pathology	50	75	20	30
Human Anatomy and Physiology	75	50	20	30
Health Education & Community Pharmacy	50	...	20	...
2nd D. Pharm Subjects				
Pharmaceutics-II	75	100	20	30
Pharmaceutical Chemisty II	100	75	20	30
Pharmacology and Toxicology	75	50	20	20
Pharmaceutical Jurisprudence	50	--	20	--
Drug Store and Business Management	75	--	20	--
Hospital and Clinical Pharmacy	75	50	20	30

THE CENRAL REGISTER OF PHARMACISTS:

The Central Register of pharmacists is maintained by the PCI as per the provisions of the pharmacy (Amendment) Act, 1976. The register contains the names of all the registered pharmacists of different states. Each state pharmacy council is required to supply

five copies of its register to the PCI as soon as after the 1st April every year. All additions and amendments are informed to the PCI from time to time. The Registrar of the PCI is required to revise the central Register from time to time and publish the same in the Gazette of India.

The central Register is a compilation of all state Registers. It is deemed to be a public document within the meaning of the Indian Evidence Act, 1872.

STATE PHARMACY COUNCILS

The state Govts. constitute a state pharmacy council under section 19 of the pharmacy Act. It consists of the following members:

Elected members:

1. Six registered pharmacists elected from amongst themselves.
2. One member elected from amongst themselves by the members of the medical council of the state.

Nominated members:

1. Five members of whom at least three shall be.possessing a degree or diploma in pharmacy or pharmaceutical chemistry or be registered pharmacists, nominated by the state Govt.

Ex-officio members:

1. Chief administrative medical officer of the state.
2. Officer-in-charge of Drugs and cosmetic Act 1940.
3. Govt. Analyst under the Drugs and cosmetics Act or where there is more than one, such as the state Govt. may appoint in this behalf.

Each state pharmacy council is deemed to be a body corporase having perpetual succession and a common seal. It has power to acquire or hold both movable and immovable property.

From five years from the first constitution, the president shall be nominated by the state Govt. He holds the office at the pleasure of the state Govt. If he is not a member, he becomes a member of the state pharmacy council in addition. After the constitution of the state pharmacy council a president and a vice-president is elected

from amongst its members who hold the office for five years. A nominated or elected member other than a nominated president holds office for five years or until his successor has been duly nominated or elected, whichever is longer.

A nominated or elected member may resign at any time by writing to the president. If any member is absent from three consecutive meetings of the council, without giving sufficient reason to the satisfaction of the council, his seat is deemed to be vacant. If a member ceases to be a registered pharmacist or a member of the medical council of the state, he also ceases to be the member of the state pharmacy council. A casual vacancy is filled accordingly, as the case may be. The person so nominated or elected shall hold the office for the remaining period. Each member is eligible for re-nomination or re-election.

The state pharmacy council may appoint a Registrar, who may act as its Secretary and also as Treasurer, It may appoint officers and servants to carry out its functions under this Act. It may fix the salaries and allowances and other conditions of service of the secretary and other officers and servants. It also fixes the rates of allowances payable to its memebrs.

Functions :

1. It prepares and maintains the state Register of pharmacists in the prescribed manner.
2. It shall supply five copies of the state Registor to the PCI after the first day of April each year as soon as possible.
3. It shall pay one fourth of the total fee collected to the PCI.
4. State pharmacy council appoints the Inspectors to inspect the premises where drugs are compounded or dispensed and to investigate any complaint given in writing.
5. It submits the necessary information to state Govt. which may be published in the desired manner.

REGISTRATION OF PHARMACISTS

In order to regulate the entry in the profession of pharmacy, all the pharmacists are required to be registered under the pharmacy Act in the state register of the state pharmacy council.

First Register:

The state Govts. are responsible for the preparation of First Register in each state before the constitution of the state pharmacy council. For the preparation of the First Register, the state Govt. constitutes a Registration Tribunal by notiflcation in the official Gazette. The Tribunal consists of three persons and a Registrar who also acts as its Secretary. The state Govt. fixes a date before which applications with the prescribed fee are to be received for the entry of names in the first Register. Person having the following qualification are registered in the first Register:

A person who has attained the age of 18 years be entitled to have his name entered in the first register on payment, if he resides or carries on the business or profession of pharmacy in the state and if he:

(a) holds a degree or diploma in phannacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or state Govt. as the case may be, or a prescribed qualification granted by an authority outside India or,

(b) holds a degree of an Indian university other than a degree or diploma in pharmacy or pharmaceutical chemistry and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners, for a total period of not less than three years, or

(c) has passed an examination recognised as adequate by the state Govt. for compounders or dispensers ; or

(d) has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical pactitioners, for a total period of not less than five years prior to the date notified by the state Govt. for receipt of applications for entry of names on the first register to the Registration Tribunal.

After the entry of names in the First Register, it is published in the manner prescribed by the state Govt. Any person aggrieved by the decision of the tribunal may appeal within 60 days from the date of such publication, to the authority appointed by the state Govt. in this behalf. A certificate of registration is issued to every registered

person. Upon the constitution of the state pharmacy councils the First Register is handed over to it. Fee collected is also credited in the account of state pharmacy council.

Subsequent Register:

After the preparation of first register and before the implementation of the Education Regulations in the state, a person who has attained the age of 18 years and resides or carries on the business or profession of pharmacy in the state is entitled to have his name entered in the register on payment of the prescribed fee if he;

(a) Satisfies the conditions prescribed and approved by the CCI, or where no qualification has been prescribed, the condition entitling a person to have his name entered on the first register and has passed a matriculation or an equivalent examination, or

(b)Is a registered pharmacist in another state,

or

(c) Possesses a qualification granted by an authority outside India, and approved by the PCI and has passed a matriculation or equivalent examination.

After the implimentation of the Education Regulations, a person can be registered-in the subsequent register if he has attained the age of 18 years, resides or carries on the business or profession of pharmacy in the state and has passed an approved examination or possesses a qualification granted by an authority outside India and approved by the PCI or a registered pharmacist in another state.

REMOVAL OF NAME FROM THE REGISTER OF PHARMACISTS

On the following grounds name of a Rgistered pharmacist can be removed from the Register of pharmacists:

1. If the name has been entered by error or on account of misrepresentation or suppression of a material fact, or

2. If the person has been convicted of any offence or has been found guitty 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

3. If the employee of the pharmacist has committed any professional offence and Executive committee of the state pharmacy council is satisfied that:

(a) the offence or infamous conduct was instigated or connived at by the registered pharmacist or

(b)Similar offence is commited by the registered pharmacist himself during the ,preceding 12 months.

or

(c) Employee again comits the same offence, and the registered pharmacist has the knowledge of all these offences or

(d)At regular interval the offence or infamous conduct is commited by one or the other person

or

(e) where the offence is offence under the Drugs and cosmetics Act

On hearing from the convict and on necessary enquiry ; if the Executive Committee comes to a conclusion that the Registered pharmacist is responsible for the offence or infamous conduct, the order for the removal of the name from the register is issued. The order is subject to confirmation by the state pharmacy councils and does not take effect until the expiry of three months from the date of such confirmation.

Three months time is given, so that the person whose name has been removed from the register can search another means of livelihood. Any person aggrieved by the order may appeal to the state Govt within 80 days from the date of such confirmation of the order. The decision of the state Govt. in this respect shall be final. It can not be called in question in any court. Person whose name has been removed shall surrender the certificate of registration to the Registrar. The name so removed is published in the official Gazette.

If the decision of the state Govt. is in favour of the person whose name has been removed from the register, the state pharmacy council may at any time, for reasons appearing sufficient to it, order that upon payment of the prescribed fee, the name of the person whose name has been removed from the register be restored thereto.

MISCELLANEOUS

Penalty for falsely claiming to be registered pharmacist:

Any person who falsely claims to be registered pharmacist by using the word such as pharmacist, chemist, Druggist, Dispensing chemist or any word which indicates that he is a registered pharmacist shall be punished on first conviction with fine extending upto Ra. 500/- and on any subsequent conviction with imprisonment upto 6 months or with fine not exceeding Rs. 1000/- or with both.

It is the responsibility of the person in question to proove that he is a registered pharmacist of another state, and he has applied for the transfer in the state in question.

Cognizance of such an offence shall be taken only upon complaint made by the order of the state Govt. or any officer authorised in this behalf by the state Govt. or by the order of the Executive Committee of the state pharmacy council.

DISPENSING BY UNREGISTERED PERSONS:

As per the pharmacy (Amendment) Act, 1976 no unregistered person is supposed to dispense the medicine on the prescription of a medical practitioner. This law is implemented from the date on which it has been announced by the state Govt. But, in the state where it has not been notified, these provisions take effect after the expiry of 8 years from the commencement of the pharmacy (Amendment) Act, 1976.

But, this rule does not prohibit medical practitioner from dispensing the medicine to his own patients. If he wants to dispense on the prescription of other medical practitioner, he will have to take permission from the state Govt.

Dispensing by unregistered person is punishable with imprisonment upto 6 months, or with fine upto Rs. 1000/- or with both.

Cognizance of such an offence shall not be taken except upon mplaint made by order of the state Govt. or by any officer appointed in this behalf or by order of the Executive committee of the state harmac council.

TRANSFER OF REGISTRATION FROM ONE STATE TO OTHER STATE

Any person who has the prescribed qualification for the subsequent Register should get registered in the state pharmacy council of the state from which the qualification has been acquired.

After being registered, if the registered pharmacist wants to migrate to another state and practice in the state in which he resides or carries on the business or profession of pharmacy, can do so in the following way :—

1. An application is made to the Registrar State Pharmacy council in the prescribed form.

2. Prescribed fee for migration and registration fee is deposited in the account of the State Pharmacy council. (Fee varies from state to state).

3. Two attested copies of each and every certificate together with the four pass port size photographs duly attested by any Gazetted officer is enclosed with the application.

4. All the original marks-card of each year and original certificates from matriculation to the qualifying examination for registration are withheld by the state pharmacy council. These original certificates are returned to the applicant together with the Registration certificate issed by the State Pharmacy council after registration.

5. The certificate of Registration of the State where the applicant was first registered is sent by the Registrar State pharmacy Council to the State Pharmacy council of which that certificate belongs.

6. That certificate of Registration is cancelled and No objection certificate is issued by the Registrar of the State Pharmacy Council from where the applicant wants to migrate. No objection certificate is sent to the Registrar of the State Pharmacy Council where the applicant has applied for migration.

7. On receipt of the No Objection Certificate the applicant is registered and a certificate of Registration is issued to the applicant by the Resistrar of the State Pharmacy Council. Original Certificates are also sent to the applicant under registered post.

CHAPTER 4

THE DRUGS AND COSMETICS ACT AND RULES

The Drugs and cosmetics Act 1940 and Rules 1945 have been passed to regulate the import, manufacture, distribution and sale of drugs and cosmetics. All the operations related drugs should be done by qualified persons. To have a check on such operations central and state Drugs control authorities are established. The major amendment of this Act was done in 1982. Schedules E, I and L have been deleted, Schedule G and H have been revised and expanded and a new schedule X has been added. Now there are following four legal categories of drug:

1. Drugs specified in Schedule C , C_1 and X.
2. Drugs not specified in schedule C , C_1 and X.
3. Drugs specified in schedule C and C_1, excluding those specified in schedule X, and
4. Drugs specified in Schedule X.

Drugs and cosmetics Rules have been divided into 18 parts each dealing with a particular subject. There are 2 schedules to the Act and 25 schedules to the Rules, which are as follows :—

SCHEDULES TO THE ACT:

First Schedule : Names of books under Ayurvedic and Sidha systems.

Second Schedule : Standard to be complied with by imported drugs and by drugs manufactured for sale, stocked, or exhibited for sale or distributed.

SCHEDULES TO THE RULES

Schedule A List of different forms that are used under the Act.

Schedule B Fees for analysis of the drugs by the central Drugs Laboratory or by the Govt. Analyst.

Schedule C List of Biological and special products.

(a) All Biological, vitamin and Antibiotic preparation for parenteral administration.

(b) Any other preparation for parenteral administration,

(c) Sterilized surgical ligature and surgical suture.

(d) Bacteriophages

(e) Ophthalmic preparations

Schedule C_1 List of other special products (not for parenteral admmistration)

(a) Digitalis group drugs

(b) Ergot preparation,

(c) Adrenaline preparations

(d) Fish liver oil,

(e) Vitamin preparations

(f) Liver extract preparations,

(g) Hormonal preparations

(h) Vaccine

(i) Antibiotic preparations which are not administered parenterally.

Schedule D List of Drugs exempted from certain provisions of the import of Drugs.

Schedule E_1 List of poisonous substances under the Ayurvedic (including Sidha) and Unani systems of Medicine.

Schedule F Provisions applicable to the production, testings, storage and packing of: Vaccines, toxins and antigens, Sera and antitoxins.

Arsphenamine and its derivatives, Insulin pituitary (Posterior lobe) extract, Adrenaline, injection, parenteral preparations, Surgical ligature and surgical suture, Backteriophages, Antibiotics and their

preparations, the special products covered under schedule C_1 and equipment and supplies required for a Blood Bank

Schedule F_1	Provision applicable to the production, testing, storage and packing of Bacterial Vaccines, Viral Vaccines, Antisera and Diagnostic agents.
Schedule FF	Standards for ophthalmic preparations.
Schedule G	List of Drugs (substances) to be used under the medical supervision.
Schedule H	List of Drugs (substances to be sold on the prescription of an RMP.
Schedule J	List of Diseases or ailments, which a drug may not purport to prevent or cure.
Schedule K	Drugs exempted from certain provisions relating to the manufacture of Drugs.
Schedule M	The requirements of Good Manufacturing practices (GMP) and factory premises and the requirments of plant and equipments.
Schedule N	List of manufacture equipments for the efficient running of a pharmacy.
Schedule O	Standards for Disinfectant Fluids.
Schedule P.	Life period of drugs.
Schedule Q	List of coal tar colours permitted to be used in cosmetics.
Schedule R	Standards for mechanical contraceptives.
Schedule S.	Standards for cosmetics.
Schedule T	Requirments of Factory premises and hygienic conditions for Ayurvedic and Unani drugs.
Schedule U	Particulars to be shown in various records of manufacture of drugs.
Schedule U_1	Particulars to be shown in various records of manufacturrng of cosmetics.
Schedule V	Standards of patent and proprietary medicines.
Schedule W	List of drugs which can be marketed under generic names only.
Schedule X	The list of drugs which are habit forming and are likely to be misused for addictive purpose.

ADMINISTRATION OF THE ACT AND RULES

1. ADVISORY

(a) Drugs Technical Advisory Board (DTAB)

(b) Drugs consultative committee (DCC)

2. ANALYTICAL

(a) Central Drugs Laboratory (CDL).

(b) Drugs Testing Laboratory of the state SDL

(c) Government Analyst

3. EXECUTIVE

(a) Controlling Authority

(b) Licensing Authority

(c) Drug Inspector.

DRUGS TECHNICAL ADVISORY BOARD

Following are the members of Drugs Technical Advisory Board:

I. Ex-Officio Members:

1. Director General of Health services (chairman)
2. Drugs controller of India.
3. Director, central Drugs Laboratory, Calcutta.
4. Director, Central Research Institute, Kasauli.
5. Director, Indian Veterinary Research Institute, IZAT NAGAR.
6. President, pharmacy council of India.
7. President, Medical council of India.
8. Director, Central Drug Research Institute, Lucknow.

II Nominated members:

1. Two persons nominated by the central Govt from amongst persons who are in-charge of drugs control in states.
2. One person from the pharmaceutical industry nominated by the central Govt.

2. Two Govt. Analysts, nominated by the central Govt.

III. Elected Members:

1. A teacher in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University of an affiliated college, elected by the Executive Committee of the pharmacy council of India.
2. A teacher in medicine or therapeutics on the staff of an Indian University or an affiliated college, elected by the Executive Committee of the Medical Council of India.
3. One pharmacologist elected by the Governing Body of the Indian council of Medical Research.
4. One person elected by the Central council of Medical Association.
5. One person to be elected by the council of the Indian Pharmaceutical Association.

The nominated and elected members hold the office for three years. They are eligible for re-nomination or re-election. The central Govt. appoints a secretary and also provides clerical and other staff to the Board.

Function :

1. The Board advises the central Govt. and the state Govts. on the technical matters arising out of the administration of the Act.
2. It advises the central Govt; in framing and modifying the rules under the Act, related to import, manufacture, sale and distribution of drugs.

DRUGS CONSULTATIVE COMMITEE: (DCC)

It is constituted under section-7 of the Act.

CONSTITUTION:

1. Two representatives nominated by the central Govt.
2. One representative nominated by each state Govt.

The committee meets when required to do so by the central Govt. It has power to regulate its own procedure.

FUNCTION. The committee advises the central Govt., the state Govts. and the Drugs Technical Advisory Board on any matter, tending to secure uniformity throughout India in the administration of the Act.

THE CENTRAL DRUGS LABORATORY

The central Govt. established a central Drugs Laboratory (CDL) under the Act. The Director of it is appointed by the central Govt.

Different types of samples are tested in different laboratories, which are working on behalf of the CDL, Calcutta.

Types of Samples to be tested	Laboratory where tested
Sera, solutions of serum proteins for injection, vaccines, toxins, antigens, antitoxins, sterilised surgical ligature and sutures and backteriophages	Central Research Institute, Kasauli
Antisera, Vaccines, toxoids and diagnostic antigens, all for veterinary use	Veterinary Research Institute, Izatnagar and Mukeshwar.
Samples of condoms	Central pharmacopocial laboratory, Ghaziabad.
Samples of oral Poliomyelitis vaccines	National Institute of communicable Diseases;
Samples of VDRL antigen	Laboratory of Serologist and chemical Examiner to the Govt. of India, Calcutta.

The Directors of the respective laboratories exercise the functions of the Director, central Drugs Laboratory in respect of these drugs or classes of drugs and condoms.

FUNCTIONS

1. To analyse or test samples of drugs or cosmetics sent to it by the customs collectors or counts ; and
2. To carry out such other duties as entrusted to it by the central Govt. or with its permission by the state Governments, after consultation with the DTAB.

All samples for analysis or test, shall be sent under registered post in sealed packet, together with a memorandum in Form—1 addressed to the Director. The packet and the outer cover is marked with a distinguishing number. A copy. of the memorandum in Form—1 and a specimen impression of the seal, used to seal the packet shall be sent separately by registered Post to the Director. The result of the test or analysis together with full protocols of the tests applied should be sent to the sender. Certificates issued by the Laboratory under the Rules should be signed by the Director or any officer authorised by the central Govt. in this behalf by notification in the official Gazette.

In case of conflict of opinion regarding the sample, the opinion of the central Drugs Laboratory is treated as the conclusive evidence of the facts stated in its reports.

DRUGS TESTING LABORATORY

For the analysis and testing of drugs and cosmetics each state govt. has to establish a Drug Testing Laboratory (DTL)

Functions:

1. To ascertain the standards of the drugs and cosmetics.
2. To analyse or test the samples of the drugs and cosmetics, sent by the Drugs Inspector, which have been taken during his inspection.
3. To undertake the analysis and ascertain the standards of drugs and cosmetics on behalf of the private persons or concerns, on payment of prescribed fee.

GOVERNMENT ANALYST

The state Govt. by notification in the official Gazette can appoint as Govt. Analyst for such areas in the state and in respect of such drugs or classes of drugs as it may notify. The central Govt. may also appoint Govt. Analysts in respect of such drugs or classes of drugs or cosmetics, as specified.

The person to be appointed as Govt. Analyst should not have any financial interest in the import, manufacture or sale of drugs or cosmetics.

QUALIFICATIONS : For the appointment as the Govt. Analyst the person should be:

1. A graduate in medicine/science/pharmacy/pharmaceutical chemistry of a recognised university and have five years post graduate experience in the testing of drugs in a laboratory under the control of:

(i) A Govt. Analyst or (ii) head of an approved institution or testing laboratory.

2. A post graduate in medicine/science/pharmacy/ pharmaceutical chemistry of a recognised university or Associateship Diploma of the Institution of Chemists (India) obtained by passing the said examination with Analysis of Drugs and pharmaceuticals as one of the subjects with at least three years experience in the testing of drugs in a laboratory under the control of

(i) a Govt. Analyst or

(ii) Head of an approved institution or testing laboratory.

For the purpose of examination of items in Schedule C the aforesaid person should produce satisfactory evidence of training in physiology, bactereriology or serology and pathology and pharmacology or microbiology and should have experience of testing of the said items in an apprdved institution or testing laboratory for a period of not less than five years (not less than three years in case of post graduates).

For the purpose of examination of antisera, toxoid and vaccines and diagnostic antigens for veterinary use, the person appointed

should be a graduate in veterinary science/general science/ medicine/Pharmacy and should have not less than 5 years of experience in standardising of biological products or a post graduate degree in veterinary science/general chemistry with not less than 3 (three) year experience in the standardising of biological products.

Neither the central nor the state Govt. can appoint the Govt. Analyst of another state without taking no objection certificate from the Govt. under which he is working.

DUTIES OF GOVT. ANALYST:

1. To analyse or test the samples of drugs and cosmetics sent by the Drug Inspector or other persons to him. To furnish the reports of the results of test or analysis.

2. To forward to the government from time to time, reports giving the results of analysis work and research with a view to their publication at the discretion of government.

DRUGS INSPECTOR

The central or state Govts. are empowered to appoint Drugs Inspectors and to assign them definite areas. Any person having financial interest in the import, manufacture or sale of drugs or cosmetics cannot be appointed as Drugs Inspector. Drugs Inspectors are deemed to be public servants.

They are appointed under section. 21 of the Drugs and cosmetics Act.

The central Govt. can prescribe different qulifIcations for Inspectors for different purposes.

Qualifications of Inspectors : A person to be appointed as the Drugs Inspector must possess the following qualifications :—

1. A degree in pharmacy/pharmaceutical chemistry or a post graduate degree in chemistry with pharmaceutics as a special subject; of a recognised university or the Associateship Diploma of the Institution of Chemists (India) obtained by passing the examination with Analysis of Drugs and pharmaceuticals as one of the subjects ; or

2. Pharmaceutical chemists Diploma granted by the pharmaceutical Society of Great Britain, or

3. A graduate in medicine/science of a recognieed university having at least one year's graduate training in a laboratory under (i) a chemical Examiner ; or (ii) a fellow of the Royal Institute of chemists of Great Britain (Branch E); or (iii) head of an institution specially approved by the appointing authority on this behalf.

4. For inspection of the manufacture of schedule C drugs the persons appointed as Inspectors must have at least 18 months experience in the manufacture of at least one of the substances specified in schedule C in a laboratory approved by the licensing authority. Drugs Inspectors who have at least 3 years experience in the inspections of firms manufacturing any of the substances specified in Schedule C, should be authorised to inspect the manufacture of the substances mentioned in Schedule C.

For the inspection of manufacture of veterinary biological products the persons appointed as Drugs Inspector should be :

(i) a graduate in veterinary sicence/medical science/general scienc/pharmacy and have at least 18 months experience in the manufacture and testing of biological products. Provided that drugs Inspectors who have gained experience of at least 3 years in the inspection of firms manufacturing any of the drugs specified in schedule C, shall be authorised to inspect the manufacture of veterinary biological products.

POWERS OF DRUGS INSPECTORS

Under Section—22 of the Act Drugs Inspectors have been assigned with the following powers :

1. To inspect any premises where drug or cosmetic is being manufactured and means employed for standardising and testing the drug or cosmetic.

2. Inspection of premises where any drugs or cosmetic is being sold, or stocked or exhibited or offered for sale or distributed.

3. Taking samples of any drug or cosmetic which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed.
4. Taking samples of drug or cosmetic from any person conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a cosignee.
5. At all reasonable times, with necessary assistence can

(a) Search any person, who, he has reason to believe, secreted any evidence for an offence under the Act, or

(b) Enter and search anyplace, where an offence under the Act, has been or is being committed, or

(c) Stop and search any vehicle or any cqveyance in which he has reason to believe that contrabanded drug or cosmetic is being conveyed. He may order that the contraband drug not to be disposed off for a specified period not exceeding twenty days.

6. Examine any record, register, document or any other material object with any person or in any place mentioned above and size the sum if it is likely to furnish the evidence of an offence
7. Require any person to produce any record, register or other document relating to manufacture, sale or distribution of any drug or cosmetic in respect of which an offence has been ot is being committed.
8. Exercise such other powers as may be necessary for arrving a the purposes of the Act or the Rules.

DUTIES OF DRUGS INSPECTORS

(a) Inspection of premises licensed for sale:

(i) To inspect all licensed premises for the sale, not less than twice a year.

(ii) To satisfy himself that the conditions of the licences are being observed.

(iii) To procure the samples from the dealers or from the imported packages and send for test or analysis.

(iv) To institute prosecutions in respect of breaches of the Act and Rules.

(v) To investigate any complaint made to him in writing.

(vi) To make enquiries and inspection, to detect the sale of drugs in contravention of the Act.

(vii) To maintain the record of all inspections made and action taken by him. A copy of the record should be sent to the controlling authority.

(b) Inspection of premises licensed for the manufacture of Drugs:—

(i) To inspect not less than twice a year all the manufacturing units of Drugs in his alloted area.

(ii) To satisfy himself that the conditions of the license are being observed.

(iii) To take samples of the drugs manufactured and send them for analysis or test to the Govt. Analyst.

(iv) To institute prosecutions in respect of breaches of the Act and Rules.

(v) In case of manufacturing unit of schedule C and C_1, to inspect the plant and the process of manufacture, the means employed for standardising and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to effect the potency of purity of the product.

(vi) To send the detailed report of the inspection made by him and the conditions and provisions observed by the licensee, to the controlling authority of Drug.

PROCEDURE OF INSPECTORS

1. The Drugs Inspector should pay the fair price of the sample taken for analysis or test and obtain an acknowledgement of it.
2. If the price is refused or where the Inspector seizes the stock of any drug or cosmetic, he should issue a receipt for the same in the precribed form.
3. He should also inform the purpose of taking the sample to the concerned person unless he wilfully absents himself. The information is given in the prescribed form.

4. If the sample is procured from the premises for the sale of drugs, the sample should be divided into four parts in his presence (i.e. qualified person), and if it is procured from manufacturing unit it is divided into three parts. Each portion is then sealed effectively and suitably marked. The preson from whom the sample is taken should be permitted to add his own seal and mark to all or any of the portions sealed or marked.

5. One portion of the sample should be restored to the person from whom it was taken (in case of sample from manufacturing unit, it is not needed). The second portion is sent to the Govt. Analyst for test or analysis, the third one is preserved for production before the court, if required and the fourth portion is sent to the warrant or, if any.

6. An Inspector should tender a receipt in Form 16 for seizing stock of any drug or cosmetic or any record, register or any other material object.

7. The Drug Inspector should intimate the purpose to the person concerned in writing in Form 17.

8. Inspector should send the sample to the Govt. Analyst by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18. In an outer cover addressed to the Govt. Analyst. The Drug Inspector can send the sample for test or analysis directly to the Director, central Drugs Laboratory.

9. If the Drugs Inspector finds that the confiscated drug is of sub-standard quality or to contravene the provisions of the Act or the Rules, he should report to the court accordingly. The court should then order the destruction of the drug under the supervision of the Inspector in presence of such authority as thc court may prescribe.

10. If the Inspector finds that the confiscated drugs are of standard quality and do not contravene the provisions of the Act or Rules, he shall report to the court accordingly. The court may then order the sale of drugs by public auction to any party holding a requisite licence.

SEIZURE OF STOCKS

1. Any seizure or search should be done under the authority of a warrant issued under section 98 of the said Rules.
2. The Inspector should inform the judicial magistrate regarding seizure of stocks or any material object and take his orders to the costody there of, as soon as possible.
3. The incharge of the manufacturing unit or the licensed peremises for the sale or distribution of drugs or cosmetics is legally bound to disclose to the Inspector the place where the drug or cosmetic is being manufactured or kept.
4. Any person, who wilfully obstructs an Inspector in the exercise of his powers or refuses to produce any record, register or other document by any person is punishable with imprisonment upto three years or with fine, or with both.
5. After taking extract from the seized record, register or other document, the Inspector should return the same to the person from whom it was taken within 20 days from the date of seizure.

IMPORT OF DRUGS AND COSMETICS

Drugs or cosmetics can be imported into India under the Drugs and cosmetics Act and the Rules under the authority of a licence excepting those whose import is prohibited. Some drugs or cosmetics of standard quality can be imported Without any permit, provided the manufacturer or importer gives the statement to the customs collector that they comply with the provisions of import.

– PROHIBITION OF IMPORT OF CERTAIN DRUGS OR COSMETICS

Following Drugs or cosmetics cannot be imported

1. Any drug or cosmetic which is not of a standard quality;
2. Any misbranded or spurious or adulterated drug;
3. Any misbranded, spurious cosmetic;
4. Any Drug or cosmetic without import licence, for which an import licence is prescribed.

5. Any patent or proprietary medicine, which has not displayed the true formula or the list of active ingredients together with the quantities in the prescribed manner on the label.
6. Any drug which claims to curve to mitigate any disease or ailments specified in schdule J to Rules.
7. Drugs whose manufacture, sale and distributions are prohibited in the country of origin, except when required for the purpose of examination, test or analysis.
8. Drugs or cosmetics when used are harmful or unsafe.
9. Drugs not labelled in the prescribed manner:
10. Drugs after the date of expiry and those who do not meet the standards of strength, quality and purity as specified in schedule F.
11. Any new drug except with express permission of the licensing; and
12. Any drug or cosmetic the import of which is prohibited under the Rules.

NOTE : The central Govt. may after consultation with the DTAB permit subject to conditions specified in the official Gazette, the import of any drug' or class of drugs not being of standard quality.

IMPORT OF DRUGS UNDER LICENCE

The following classes of drugs can be imported under the licence or permit granted by the licensing authority :—

1. Drugs specified in schedule C and C_1 excluding those specified in schedule X;
2. Drugs specified in schedule X;
3. Small quantities of drugs imported for the purpose of examination, test or analysis;
4. Drugs for personal use covered by a prescription of Registered Medical Practitioner; and
5. Any new drug.

An application for an import licence shall be made to the proper authority in Form 8 for drugs specified in schedule C and C_1 and in form 8—A for drugs specified in schedule X, by the manufacturer's agent in India, by giving an under taking in Form 9 duly signed by or on behalf of the manufacturer.

The import licence is issued in Form 10 for the application given in Form 8 and in form 10—A for the application given in Form 8—A by the licensing authority.

The licence remains valid upto 31st December of the year following the year in which it is granted.

The importer should have proper storage facilities for preserving the properties of the imported drugs.

The licensee should inform the licensing authority about any change in the constitution of licensed form.

CONDITIONS OF IMPORT LICENCE

An import licence is subject to the following conditions

1. The manufacturer must observe at all times the under taking given by him or on his behalf in Form 9:
2. The licensee must allow an authorise l Inspector to enter the licensed premises, where the importeu substances are stocked, to inspect the means, if any, employed for testing the substances, and to take samples;
3. The licensee should furnish the adequate quantity of sample from the required batches to the licensing authority. The licensee should furnish full protocols of the t..t, if any applied.
4. If the licensing authority directs the licensee, not to sell any batch, the licensee should not sell until he is asked to do so by the licensing authority.
5. If the licensing authority confirms any batch as substandard, the licensee shall withdraw the remainder of that batch from the market as far as practicable.
6. The licensee should maintain a record of all sales of imported substances showing particulars of the substance and of person

to whom sold and such other particulars, if any specified by the licensing authority. Such records should be open for inspection.

7. The licensee must comply with such further requiremeiits as may be prescribed by the licensing authority and of which he has been given not less than four months notice.

IMPORT OF DRUGS FOR EXAMINATION, TEST OR ANALYSIS

Those drugs which are otherwise prohibited can be imported in small quantity for examination, test or analysis subject to the following conditions :—

1.The drug is imported under a licence in Form 11 only.

2. The drug should be used exclusively for examination, test or analysis in the place specified in the licence.
3. The authorised inspector should be allowed to inspect the premises, and investigate the manner in which imported substances are used: He should also be allowed to take samples there of.
4. The record of the imported substances together with their quantities, the date of importation and the name of manufacturer should be maintained and reported to the licensing authority.
5. The licensee must comply with any further requirement as may be specified and of which the licensing authority has given, to him not less than one month's notice.

In case of breach of any of the conditions, the licence may be cancelled. The licensee may appeal to the central Govt. within 3 months of the date of the order of cancellation.

IMPORT OF DRUGS FOR PERSONAL USE

Import of drugs which are .otherwise prohibited under section 10 of the Act can be imported for personal use subject to the following conditions

1. The drugs must form part of a passenger's bonafide baggage and must be intended for the exclusive personal use of the passenger;

2. The drugs must be declared to the customs collector, if so directed;
3. The quantity of any single drug so imported must not exceed hundred average doses.

The licensing authority may, in an exceptional case, sanction the import of a larger quantity.

Any drug not forming the part of the baggage of the passenger may be allowed to import on an application made to the licensing authority in form 12—A. If the licensing authority is satisfied that:

(i) The drug is for bonafide personal use,

(ii) The quantity is reasonable and covered by a prescription from a registered medical practitioner ; and

(iii) A permit is granted in respect of the said drug in Form 12—B.

Once a drug is imported without contravening any of the provisions of the Act or the Rules, the importer can dispose off the drug in any manner he likes as it becomes the personal property of the importer.

IMPORT OF NEW DRUGS

1. A written permission of the licensing authority is required for the import of new drugs.
2. For getting permission, all documentary and other evidence related to the standards of quality, purity and strength, etc. should be supplied to the licensing authority.

IMPORT OF DRUGS WITHOUT LICENCE

OR

EXEMPTED DRUGS (SCHEDULE D)

The drugs specified in schedule D are exempted from the provisions of import licence subject to the conditions specified in that schedule.

Class of drugs	Extent and conditions of exemption
Substances not intended for medicinal use	Can be imported without any restriction provided imported in bulk and the importer certifies that it is imported for non-medicinal uses. If imported otherwise then in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use.
Substances included in schedule C_1 required for manufacturing purposes but not intended for medicinal use	Exempted from all provisions regulating import except that the importer should be holding licence for manufacture of schedule C and C_1 drugs.
Substances used both as drugs as well as articles of food e.g. milk powder, spices, pre digested food, etc	Exempt from all provisions regulating import.

OFFENCES RELATING TO IMPORT OF DRUGS:

Offence	Penality	
	First conviction	**Subsequent conviction**
1. Import of adulterated or spurious drugs or cosmetics or any cosmetic containing any in gradient which may render it unsafe or harmful for use under the directions recommended.	Imprisonment upto three years and fine upto Rs. 5000 (Five thousand)	Imprisonment upto 5 years or fine upto Rs. 10,000 or both.
2. Import of any drugs or cosmetic other than referred above the import of which is prohibited.	Imprisonment upto six months or fine upto Rs. 500/- or both.	Imprisonment upto one year or fine upto Rs. 1000/- or both.
3. Import of any drug or cosmetic in contravention of any notification issued under section 10A.	Imprisonment upto 3 years or fine upto Rs. 5000/- or both.	

NOTE: Consignment of the drugs or cosmetic in respect of which the offence has been committed are liable to confiscation.

MANUFACTURE OF DRUGS FOR SALE

Drugs have been classified as follows for the issue of licence for the manufacture of Drugs for sale:

1. Drugs other than those specified in schedule C , C_1 and X
2. Drugs specified in Schedule C, C_1 but not specified in schedule X;
3. Drugs specifled in schedule C and C_1;
4. Drugs specified in schedule X but not in schedule C and
5. Drugs specified in schedule C, C_1 and X;
6. Drugs for the purpose of examination, test or analysis;
7. Loan Licences and
8. Repacking Licences.

-PROHIBITION OF MANUFACTURE AND SALE OF CERTAIN DRUGS

The following drugs are prohibited to manufacture for sale under section 18 of the Act :—

1. Any drug or cosmetic which is not of standard quality or is misbranded, adulterated or spurious;
2. Any patent or proprietory medicine whose formula is not disclosed on the label or container;
3. Any drug which purports or claims to prevent, cure or mitigate any disease specified in Sch. J;
4. Any cosmetic containing any ingredient which may render it unsafe or harmful for use;
5. Any drug or cosmetic in contravention of this Act or Rules there under;
6. Any drug or cosmetic which has been improved or manufactured in contravention provisions of this Act or rules there under or in contravention of the condition of a licence;

The central Govt. may permit the manufacture for sale or for distribution, of any drugs or class of drugs, not being of standard quality.

The central Govt. is empowered to prohibit the manufacture and sale ete. of drugs and cosmetics, if their use is likely to involve any risk to human beings or animals.

LICENCES TO MANUFACTURE FOR SALE OF DRUGS

An application is given in the prescribed form together with the prescribed fee for different classes of drugs separately and the licence is issued accordingly by the licencirig authority.

Different Licences To Manufacture of Drugs For Sale And Different Forms Used For The Same

Sr No.	Classes of Drugs for which Licence is required	Applied in Application Form No.	Licence issued in Form No.	Certificate of Re-newal of Licence Form No.
1.	Drugs other than those specified in Sch C, C_1 and X.	24	25	26
2.	Drugs specified in schedule X	24 F	25 F	26 F
3.	Drugs specified in schedules C and C_1	27	28	26
4.	Drugs specified in schedules C, C_1 and X	27 B	28 B	26 F
5.	Loan Licence to manufacture for sale of drugs other than those specified in schedules C, C—1 & X	24 A	25 A	26 A
6.	Loan Licence to manufacture for the sale of drugs specified in schedules C & C_1 excluding those specified in schedule X.	27 A	28 A	26 A
7.	Repacking Licence for sale of Drugs other than those specified in schedules C, C—1 and X	24 B	25 B	26 B

CONDITIONS OF LICENCE FOR TIIE MANUFAC TURE

OF: Drugs other than those specified in schedules C, C_1 & X, Drugs specified in schedules-C & C_1; Drugs specified in schedule-X and Drugs specified in Schedule-C, C_1 & X.

1. The manufacture shall be conducted under the active direction and personal supervision of a competent technical staff; i.e. approved manufacturing chemist.
2. The premises shall comply with the conditions and with the requirements, specified in schedule M.
3. Provide a separate testing unit or quality control section with an independent head, with the adequate facilities, for the test and standardisation of drugs and raw materials.
4. The licensee shall make adequate arrangements for the storage of drugs manufactured.
5. The licensee shall furnish the required, datas or evidences to manufacture patent or proprietary medicine.
6. The licensee shall test each batch of raw materials used and each batch of the final product. Maintain the records of tests, as specified in schedule-U. Retain the records for a period of five years from the date of manufacture.
7. The licensee shall test each batch of raw materials used and each batch of the final product. Maintain the records of tests, as specified in schedule-U. Retain the records for a period of five years from the date of manufacture.
8. The licensee shall keep the records of details of manufacture as specified in schedule-U. The records should be kept for 5 years.
9. The licensee shall allow the Drug inspector to enter any premises, to inspect the plant, the process and the means of manufacture and standardisations and the records.
10. The licensee shall allow the Drug Inspector to take samples. Furnish any informations required by him.
11. The licensee, if directed, shall furnish, specified quantity of sample, and protocols of test, to the licensing authority or the controlling authority. In such cases, if authority so directs, the licensee shall not sell such batches, till he permits to sell.
12. If any batch is found, that it does not comply with the standards by the licensing authority or the controlling authority, the licensee must withdraw such batches from sale, on being directed to do so.
13. The licensee must maintain an Inspection Book, in Form 35.
14. The licensee shall maintain reference sample from each batch. Those samples shuld be retained for five years.
15. For schedule C & C_1 drugs (Biological and other special products) only :—

(a) The applicant shall furnish to the licening authority if required to do so, the datas of the stability and the conditions on which it may deteriorate for fixing the date of expiry.

(b) No drug n manufactured, shall be sold, unless the necessary precautions are taken to preserve its properties throughout the period after manufacture.

In case of schedule X drugs, in addition to the above conditions, the licensee shall have to follow the following conditions:

(1) The licensee shall forward a statement of manufacture of schedule-X drug and the details of sales and supply, to the licensing authority, for every three months.

(2) The licensee shall maintain all the accounts of transaction of schedule-X drugs in the specified columns. Such records shall be preserved for 5 years.

(3) The licensee shall store the schedule-X drugs in bulk form. It should be kept under the direct custody of a responsible person during manfacturing.

(4) Schedule-X drug shall not be supplied as "physician's sample.

LOAN LICENCES

A loan licence is issued by the following authority to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee.

An application for the grant of Loan Licence for the manufacture of drugs is made to the licensing authority in Form 24—A, for other than those specified in schedule—C, C_1 and X and in Form 27—A, for those specified in schedules C and C_1. The licence for these are

issued in Form 25—A . nd 28—A respectively subject to the following conditions :-

1. The licensee shall furnish to the licensing authority, the evidee and the data to justify the (a) useful (b) Safety (c) Stability and (d) the prescribed quantities of the ingredients and the additives used
2. The manufacturing unit of which the facilities will be availed should have adequate staff and facilities for the manufacture of drugs on Loan Licence.
3. If the licence of the manufacturing unit whose facilities are availed is cancelled or suspended, the Loan Licence is deemed to be cancelled or suspended.
4. The licensee shall allow the Drug Inspector to inspect all records and furnish any required information to him.
5. The licensee shall comply with the provisions of the Act and with such further requirements, if any.
6. The licensee shall maintain an Inspection Book in Form 35.
7. The lincensee shall test each batch of raw materials used and each batch of the final product. Maintain the records of such tests as specified in schedule-U. The records are retained for the period of five years.
8. The licensee shall either provide and maintain the adequate staff and laboratory facilities or make arrangement with an approved institution for test and analysis.
9. The licence shall maintain the reference samples from each batch of the drug manufactures. These samples shall be maintained for a period of three years.
10. Any change in the constitution of the manufacturing unit or in the expert staff should be reported to the licensing authority.
11. For schedule C & C_1 drugs, the licensee shall furnish to the licencing authority, the data of the stability which is likely to deteriorate for fixing the date of expiry.

REPACKING LICENCES

Repacking licences are granted for the purpose of breaking up any drug other than those specified in schedule C and C_1. The application for it is made in Form 24 B and the licence is issued in Form 25 B subject to the following conditions:

1. The repacking operation should be carried out under hygienic conditions and under the supervision of a competent person ; namely

(a) A person who holds an approved Diploma in Pharmacy or is a Registered pharmacist ; or

(b) A person who has passed the intermediate examination with chemistry as one of the principal subjects or an equivalent recognised examination ; or

(c) A person who has passed the matriculation or equivalent recognised examination and has at least four years practical experience in the manufacture, dispensing or repacking of drugs.

2. The factory premises must comply with the conditions prescribed in schedule M;
3. The applicant should have adequate arrangements in his own premises for the testing of drugs at a testing unit which should be separate from the repacking unit. Provided that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods the licensing authority may permit such tests to be conducted at approved institutions.
4. The licence should be kept at the licened premises and produced at the request of Drugs Inspector.
5. Any change in the competent staff should be reported to the licensing authority.
6. For repacking any additional items, application should be made to the licensing authority.
7. Apart from the other particulars, the label on the repacked drugs should mention the name and address of the licensee and his licence number preceded by the word "Rpg. Lic. No.'
8. The licence remains valid upto 31st December, of the year following the year in which it is granted.
9. The licensee shall maintain an Inspection Book in Form 35.
10. The licensee shall make adequate arrangements for the sotrage of drugs.

SALE OF DRUGS

Sale in defined as 'a contract for sale of goods is a contract whereby the seller transfers or agrees to transfer the property in goods to the buyer for a price.'

Wholesaler means a dealer or his agent, or a stockist appointed by a manufactrurer or an importer for the sale of his drugs to a retailer, and a retailer means a dealer canying on the retail business of sale of drugs of customers.

For the sale of drugs a licence is required. If drugs are sold or stocked for sale at different places, a separate licence is required for each place.

For issuing the sale licences the drugs are divided to the following categories :—

1. Drugs other than those specified in Sch. C, C_1 and X;
2. Drugs specified in Sch. C and C_1 but excluding X ; and
3. Drugs specified in Schedule-X.

CONDITIONS OF LICENCE FOR RETAIL SALE OF DRUGS

1. An application in made together with the prescribed fee to the licencing authority for the retail sale of drugs in Form 19 for drugs other than those specified in schedule-X and in Form 19-C, for those specified in schedule-X.

2. The licencing authority issues the licence for the retail sale of drugs in Form 20 for the application made in Form 19 i.e. for drugs other than those specified in schedules-C, C_1 & X; in Form 21, for the application made in Form 19—C.

i.e. for those specified in schedules-C & C_1 and in Form 20. F, for the application made in 19—C. i.e. for those specified in schedule X ; subject to the following conditions :—

(a) The licensed premises are adequate and equipped with the facilities of proper storage of drugs.

(b) The pharmacy shall comply the requirements of Schedule N.

(c) The licence shall be displayed in a prominent place.

(d) All the compounding and dispensing of drugs shall be made under the direct and personal supervision of a qualified person i.e. Registered pharmacist.

(e) The supply of a drug other than schedule-X drugs on a prescription shall be recorded either in prescription register or in a cash or credit memo book.

(f) The supply of schedule C drug, shall be recorded either in a register or in a cash or credit memo book.

(g) The drugs shall be purchased from a duly licensed dealer or a duly licensed manufacturer. Purchase bills shall be serially numbered and maintained in an order.

(h) All registers and records shall be produced for inspection by an Inspector. Any information required by the Inspector, shall be supplied to him.

(i) All registers and records shall be preserved for a period of two years from the date of last entry.

(k) Schedules-H and X drugs shall be sold on and in accordance with the prescription of a Registered Medical practitioner. For schedule-X drugs the prescription shall be in duplicate. One shall be retained by the licensee for a period of two years.

(l) The supply of schedule H and X drugs to the Registered Medical practisioners. Hospitals and Nursing Homes, shall be made only again the signed order in writing. Such orders shall be preserved for a period of two years.

(m) The schedule H and X drugs shall not be supplied more than once, unless the number of times stated by the prescriber. The name and address of the seller shall be noted on the prescription after dispensing.

(n) Only the prescribed schedule-H and X drugs shall be dispensed, but not the substitutes.

(o) Schedule-X drugs shall be stored in a cupboard under lock and key separately, under the control of a responsible person.

(p) The description "chemist and Druggist" or 'pharmacy' shall be displayed.

(q) An Inspection Book in Form-35 shall be maintained.

(r) The Drugs after the date of expiry shall not be sold or stocked.

(s) The physician's sample drugs and the drugs meant for the Government supply with a distinguishing mark, shall not be sold or stocked.

(t) The drugs for animal treatment shall be stored in separate cupboard, with the words "Not for human use for animal treatment only" on the cupboard.

(u) The supply of schedule-X drugs shall be recorded in a separate register separate pages shall be alloted for each drug.

(u) Any change in the constitution of the firm and in the qualified person shall be reported to the licensing authority. However, in case of change of the firm from one place to other, the previous licence remains valid upto three months form the date of the change. A new licence should be issued for new shop.

(w) The licence remains valid upto 31st December of the year following the year in which it is granted or unless suspended or cancelled.

(x) For the sale of additional categories of drugs listed in schedule C and C_1 excluding X, the licensee must take prior permission of the licensing authority.

RESTRICTED LICENCES

Restricted Licences are issued for the retail sale of drugs

1. Dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.
2. Itinerant vendors in exceptional cases for bonafide travelling agents of firms dealing in drugs or
3. A vendor who purchases drugs from a licensed dealer for distribution in sparsely populated areas where other channels of distribution of drugs are not available.

Restricted licences may also be issued to a travelling agent of a firm for the special purpose of distribution to the medical practitioners or dealers for supply of biological and other special products specified in schedule C.

This licence is issued for drugs other than those specified in schedules-C, C_1 and X in Form 20-A on application made in Form-19 A. and For drugs specified in schedules C and C_1 in Form 21 A on application made in 19 A subject to the following conditions:—

CONDITIONS OF LICENCE

1. The licensee must have adequate premises equipped with facilities for the proper storage of which the licence applies provided that this condition does not apply to vendors.
2. The licence should be displayed in a prominent place in a part of the premises open to the public or should be kept on the person of vendor who shall produce the same on demand by an Inspector or other officer authorised by the state Govt. in this behalf.
3. The licensee should comply with the provisions of the Drugs and cosmetics Act and Rules thereunder in force.
4. Drugs should be purchased only from a duly licensed dealer or manufacturer.
5. The licensee can deal only in such drugs as can be sold without the supervision of a 'qualified person.'
6. If the licensee be a vendor having no fixed place of business, he should buy drugs only from such dealers as may be specified in his licence.
7. Drugs should be sold in their original container.

Before Issuing the licence, the licensing authority shall keep in mind the number of licences issued in that area during last three years.

SCHEDULE-N [(Rule (64(I))]

LIST OF MINIMUM EQUIPMENT FOR THE EFFICIENT RUNNING OF A PHARMACY

I Entrance: The front of Pharmacy shall bear ah inscription "Pharmacy".

II Premises : The premises shall be separated from the private rooms. The premises shall be well built, well ventilated and dry. Adequate space shall be provided to stock the drugs in a clear and appropriate manner.

The area of the dispensing department, for one pharmacist shall be minimum 6 square meters and two square meter for each additional Pharmacist. The height shall be minimum 25 meters.

The floor and walls of the Pharmacy shall be smooth, durable and washable. They shall be devoid of holes and cracks.

III A. Minimum apparatus:

1. Dispensing Balance.
2. counter Balance (3 Kg)
3. Beakers-assorted sizes
4. Prescription bottles-assorted sizes.
5. Cork-assorted sizes
6. Cork extractors.
7. Porcelain evaporating dish.
8. Filter paper.
9. Glass funnels.
10. Litmus paper.
11. Glass measuring cylinders
12. Glass pestles & Mortars.
13. Wedge wood pestles & Mortars.
14. Ointment pot & slab.
15. Graduated pipettes.
16. Iron retort, ring stand.
17. Rubber stamps and pad.
18. Scissors.
19. Stirring glass rods.
20. Stainless and rubber spatulas
21. Spirit lamp.
22. Thermometer.
23. Tripod stand.
24. Watch glass.
25. Water bath
26. Water distillation still.
27. Weights-1 mg to 100 G
28. Wire guaze.
29. Pill machine, finisher and Box.
30. Suppository mould.

B. BOOKS (Current editions)

1. The Indian Pharmacopoeia.
2. The National Formulary of India.
3. The Drugs and Cosmetic Act- 1940.
4. The Drugs and Cosmetic Rules 1945.
5. The Pharmacy Act-1948
6. The Narcotic Drugs and Psychotropic Substances Act-1985.

IV General Provision

1. The Pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist. His name shall be displayed in a prominent place.
2. The Pharmacist shall always put on clean white appron.

3. The premises and fittings of the Pharmacy shall be in good order, clean and properly kept.
4. All registers and records shall be maintained in accordance with the laws.
5. All containers taken from the locked cupboards shall be replaced, immediately after use. The key shall be kept under the custody of the responsible person.
6. Medicaments shall have the specified labels.

The above requirements are subjected to modification at the discretion of the licensing authority. The decision of the licensing authority shall be the final.

WHOLE SALE OF DRUGS

Application for the grant of whole sale of drug Licence is made in Form-19 for drugs other than those specified in schedule-X and in Form 19-C, for drugs specified in schedule

On being satisfied with the conditions fulfilled by the applicant, the licensing authority issues the licence in Form 20- B for drugs other than those specified in schedules—C_1 C_1 & X and in Form 21-B, for those specified in schedules-C & C_1 and in Form 20 G, for those specified in schedule X.

CONDITIONS OF WHOLE SALE LICENCE

1. The area of the proposed premises shall not be less than 10 sq. meters.
2. It shall be in the charge of a compe ent erson, who is a registered pharmacist or who has ssed the matriculation examination or its equivalent wit . 4 years experience in dispensing of drugs.
3. The premises should have adequate facilities for the storage of drugs.
4. The licence shall be displayed in a prominent place.
5. The drugs shall be purchased from a duly licensed dealer or a duly licensed manufacturer.

6. The supply of drug by wholesale shall be made against a cash memo. Carbon copies of the cash or credit memos shall be preserved for a period of three years from the date of last entry.
7. Records of purchase of drugs shall be maintained. Purchase bills shall be serially numbered and maintained in an order.
8. All registers and records shall be produced for inspection by an Inspector. Any information required by the Inspector, shall be supplied to him.
9. All registers and records shall be preserved for 'period of two years from the date of last entry.
10. An Inspection Book shall be maintained in Form 35.
11. The drugs after the date of expiry shall not be sold or stocked.
12. The 'physician's sample' drugs and the drugs meant for the Govt. supply with a distinguishing mark, shall not be sold or stocked.
13. The supply of schedule-X drugs shall be recorded in a separate register. Separate pages shall be alloted for each drug.
14. The copies of invoices of sale of schedule-X drug, to the retailer shall be forwarded to the licensing authority.
15. Any changes in the constitution of the firm and in the competent person shall be reported to the licensing authority.
16. No sale of any drug should be made for the purpose of resale to a person not holding the requisite licence to sell or distribute the drugs. Provided that this shall not apply to the sale of any drug to

(a) an officer or authority purchasing on behalf of Govt.; or

(b) a hospital, medical, educational or research institution or a RMP for the purpose of supply to his patients ; or

(c) a manufacturer of hydorgenated vegatable oils, beverages, confectionary and other non-medicinal products, where such drugs are required for processing their products.

DISTRIBUTION OF DRUGS FROM MOTOR VEHICLES

Now a days licences are issued for the distribution of drugs from motor vehicles. Separate licences are issued for schedule C & C_1 drugs and drugs other than those inculded in schedule C & C_1.

Condition for this licence is similar to whole sale licence of the drugs.

1. Drugs can be distributed to only such persons who hold valid licences for retail sale of drugs. But this rule shall not apply to the sale of any drug to an officer purchasing this drug on behalf of the Govt; hospital, medical, educational or re search institution or an RMP, manufacturer of hydrogenated vegetable oils, beverages, confectionary and other non- medicinal pducts,where such drugs are required for processing their products.
2. The license should be displayed in a prominent place in the vehicle.
3. Any change in the ownership of the vehicle or constitution of the firm should be informed to the licensing authority within a week of the change.
4. In case of change in the constitution of the firm, fresh licence should be requested to be issued within three months of the change.
5. For the distribution of schedule C & C_1 drugs the licensee should provide proper facilities for storage of the drugs.

CANCELLATION AND SUSPENSION OF LICENCES

The licensing authority may cancel or suspend the licence either wholly or in respect of some of the substances to which it relates, if the licensee fails to comply with the conditions of licence or with any provisions of the Act or Rules thereunder.

If the contravention has been done by the employee and the licensee prooves to the satisfaction of the licensing authority that

1. The offence or contravening of the Act was not instigated or connived at by him.
2. He or his employee had not been guilty of any similar act or omission with in twelve months before the date on which the act or ommission in question took place, or if the offence was

committed and the licencse had not or could not reasonably have had, knowledge of that previous offence or contravention.

3. If the act or omission was a continuing one, he had not or could not reasonably have had knowledge of that previous act or omission, or
4. He had used due diligence to observe the provisions of Drugs and cosmetic Act & Rules.

A licensee whose licence has been cancelled or suspended may appeal within three months from the date of cancellation or suspension of the licence to the state Govt. procedure for Disposal of Drugs if the Licence in cancelled:

1. The licensee should apply to the licensing authority giving the following particulars:

(a) Name and address of the person to whom the drugs are proposed to be sold and his licence number.

(b) Names of drugs together with their quantities, batch numbers, the names and address of the manufacturers and the dates of their expiry, if any, proposed to be sold to the person mentioned above.

2. The licensing authority may, after examination of the particulars furnished and if necessary, after inspection by an inspector of the premises, where the drugs are stoked, grant the necessary permission for their disposal.

OFFENCES AND PENALTIES

Offences	Penalties	
	First conviction	Subsequent conviction
1. Manufacture, sale, distribution, stocking etc. of:		
(a) any adulterated or spurious drug or drug not of standard and quality.	Imprisonment for a minimum of 5 years extending upto life imprisonment and fine of not less than Rs. 10,000.	Imprisonment upto 10 year or fine upto Re. 20,000 or both.
(b) adulterated drug but not containing any toxic or harmful substances which may render injurious to health; Or	Imprisonment from 1 to 3 years and fine of not less than Rs. 5000.	Imprisonment from 2 to 4 years and fine of not less than Rs. 10,000 however.
(c) Without a licence	The court may however for any adequate and special reason to be recorded in judgement impose a term of imprisonment of less than a year and a lesser fine.	The court may for adequate and special reason to be recorded in judgement award imprisonment for less than 2 yeras and fine of less than Rs. 10,000.
(d) Spurious drugs but not manufactured under the name of any other drug. (e) Any other	Imprisonment for not less than 3 to 5 yeras and fine of not less than Rs. 5000/-. However the court may award	Imprisonment for not less than 6 years to 10 years and fine of not less than Rs. 10,000.

	imprisonment for lesser time but not less than 1 year.	
contravention fo this chapter of the Act and the rule there under.	Imprisonment from 1 to 2 years and fine. The court may however, for any adequate and special reason to be recorded in judgement, award imprisonment for less than 1 year.	Imprisonment for 2 to 4 years or fine of not less than Rs. 5000 or both.
2. Not disclosing the name of a manufacturer or the place where the manufactured drugs are kept.	Imprisonment upto 3 years or fine upto Rs. 1000 or with both	Same as first conviction.
3. Not keeping records of manufacturer or, sale of drugs in the specified manner.	Imprisonment upto 3 years or fine upto Rs. 1000 or with both.	Same as first conviction.
4. Using the report of a Government Analyst for advertising any drug.	Fine upto Rs. 500/-.	Imprisonment upto 10 years or with fine or both.

LABELLING AND PACKING OF DRUGS

The containers of all the drugs and medicines are to be labelled in accordance with the Drugs & cosmetics Rule 1945. Following particulars should appear on the label of the inner most container of any drug and on every other covering in which the container is packed.

Manner of Labelling

I Labelling of Drugs manufactured for sale:

1. The name of the drug

(a) Proper name or

(b) For official products the name or synonym specified in the pharmacopocia, followed by the recognised abbreviation of the respective official pharmacopocia, e.g., Analgin Tablets I.P.

(c) For a new drug, containing a single active ingredient or a preparation containing a single active ingredient specified in schedule W-the generic name, not the trade name e.g. Ferrous sulphate Tablets.

2. The net content:

   Weight in grams (Solids, Semi-solids)

   Volume in ml. (liquids)

   Unit in number (Unit dosage forms-Tablets, Capsules, etc.)

3. The content of active ingredients in a single dose or in 5 ml or in 1 ml. or in one unit or in percentage.
4. The name and address of the manufacturer.
5. Batch No. or Lot No.
6. Manufacturing Licence number-Mfg. Lic. No. or M.L
7. Date of manufacuring Mfg. Date.
8. Date of expiry-for the preparations containing schedule P or schedule-C_1 drugs.
9. Import Licence number for the imported preparation containing schedule-C_1 drugs.

10. 'Physician's sample' not to be be sold' for the free sample to distribute to the medical professional.
11. The quantity of alcohol as average percentage by volume of absolute alcohol, if the preparation contains more than 3 percent of alcohol.
12. The words "For single use only" for mechanical contraceptive.
13. Retail price not to exceed Rs. ..... + Local taxes extra.

In addition to the above particulars (which ever applicable), the following particulars are also labelled accordingly.

14. The drug for internal use, containing schedule-G sub stance-labelled with the words.

"CAUTION: It is dangerous to take this preparation except under medical Supervision:"

15. The drug for internal use, containing schedule-H substance-labelled with the symbol R on the left top corner of the label and with the following words.

"SCHEDULE-H DRUGS"

WARNING: To be sold by retail on the prescriptions of a Registered Medical Practitioner only:

16. The drug for internal use, containing schedule-H substnace which comes under the purview of the Dangerous Drugs). The Narcotic Drugs & Psychotropic substances Act, 1985) Act, labelled with the symbol NRx in red on the left top corner of the label and with the following words.

"SCHEDULE-H DRUGS"

WARNING: To be sold by retail on the prescription of a Registered Medical Practitioner only".

17. The drug for internal use, containing a schedule-X substance labelled with the symbol XRx red, on the left top corner of the label and with the following words:

"SCHEDULE-X DRUGS"

WARNING: To be sold by retail, on the prescription of a Registered Medical Practitioner only."

18. The preparation used as liniment, lotion, liquid antiseptic or other liquid medicine for external use, shall be labelled with the words in capital. "FOR EXTERNAL USE ONLY".
19. The drug for animal treatment shall be labelled with words "Not for human use" ; For animal treatment only" and with a symbol of the head of an animal.
20. The drug containing industrial methylated spirit for human treatment shall be labelled with the words "FOR EXTERNAL USE ONLY"
21. Non sterile surgical Ligature and suture should be labelled with the words in red "Non-sterile surgical Ligature & Suture not to be used for operation upon the human body unless efficiently sterilized."

II Labelling of Drugs Meant For Export:

Label shall meet the requirements of law of the country to which the drug is to be exported. The following particulars shall also appear on the label:

1. Name of the drug.
2. The name and address of the manufacturer.
3. The manufacturing licence number.
4. Batch or Lot number.
5. Date of expiry, if any.
6. The word 'FOR EXPORT ONLY" shall also appear on label.

SCHEDULE J

Appendicits, Arterioscierosis, Blindness, Blood poisoning, Brights disease Cancel, Cataract, Deafness, Diabetes, Diseases and discorders of the optical system, disorders of brain, diseases and disorders of uterus, disorders of menstrual flow, disorders of nervous system, disorders of prostatic glands, Dropsy, Epilepsy, Female disease (in general), Fevers (in general), Fits, Gall stones, kidney stones and bladder stones, Gangrene, Glaucoma, Goitre Heart diseases, High or low blood pressure, Hydrocele, Infantile paralysis, Insanity, Leprosy, Leucoderma, Lockjaw, Locomotor ataxia, Lupus, Nervous debility, Obesity, Paralysis, Plague, Pleurisy, Pneumonia, Rheumatism, Sexual impotence, small pox, sterility in women, Trachoma, Tuberculosis, Tumours, Typhoid fevers, ulcers of gastrointestinal tract, venereal diseases, including syphilis, Gonorrhoea, Soft chancre, Veneral granuloma, Lymphogranuloma.

III Labelling of Drugs, Dispensed By Compounding On the Prescription of a Registered Medical Practitioner only:

1. The name and address of the supplier.
2. The name of the patient.
3. The quantity of the patient.
4. Registeration number of the prescription.
5. The dose, if the drug is for internal use.
6. The words "For External use only" for external applications.

APPENDIX

SCHEDULE B

Fees for test, analysis by the Central Drugs Laboratory or the Government Analysts

1. Fees for drugs including hormones etc requiring biological assay.

	Rs.
Adrenocorticotrophic Hormone	200
Digitalis	200
Strophanthus	200
Pituitary (Posterior lobe) Extract	100
Adrenaline preparations	100
Thyroid	200
Sex gland preparations	200
Ovarian	200
Luteal	200
Orchis	200
Insulin and insulin combinations (prolonged action)	400 to 1000
Heparin	150
Organic arsenicals, neoarsphenamine etc.	75 to 100
Protamine sulphate	150
Test for sterility	50
Abnormal toxicity or undue toxicity or safety test	75
Determination of lethal dose LD 50 to LD 100 on Mice	250
Pyrogen test	60
Antibiotic (bio-assay)	50
Chemical test for each ingredient	
Disinfectants	100
Surgical sutures	50 to 100
(depending on the number of tests to be carried out)	
Depressor or Histamine like substance test	75
Hyaluronidase	100

Any other test requiring animal experimentation	50
Microscopic examination	25
Chemical tests and Assays:	
Identification test	25
Disintegration of tablets and capsules:	
(a) Ordinary	10
(b) Sugar Coated	20
(c) Enteric coated	40
Physicochemical Assays	30
Tests other than assay (limit tests for impurities, ash content, total solids, acid value, iodine value.	
Saponification value, loss on drying etc.) for each test	10
Optical rotation	25
Refractive index	25
Physical tests (solubility, pH, uniformity of weight, physical constants etc.) for each test	5
Water (Karl Fisher)	30
Heavy metals	25
Arsenic test	25
Paper chromatography	25
Thin layer chromatography	25
Column chromatography	30
Gas liquid chromatography	100
Infra Red Identification	50
Polymorphtest (content of Polyhmorph-A in Chioroamphenicol Palmitate)	200
Other miscellaneous tests	25 to 100
II. Fees for sera and vaccines : Sera	
(a) Examination according to specifications in pharmacopoeia	850
(b) Determination that sample is up to titre specified	100
Vaccines	

(a) Examination in which animal test is employed	100 to 300
(b) Examination in which animal test is not employed	50
Diagnostic toxins:	
(a) Identification test	50
(b) Potency test	200
Diagnostic Sera, Potency and Acidity tests	
Diphtheria, Pertussis and Tetanus products	100
(a) Potency of Pertussis fraction of the Vaccine	500
(b) Potency of tetanus fraction aoo	300
(c) Potency of diphtheria fraction	200
III. Cosmetics	100 to 300
IV. Rubber Condoms	**250**
V. Homeoopathic medicines	**50**
(i.) Identification test for raw material of botanical origin (other than assay of constituents)	
(ii) Identification test for raw material of chemical origin (other than assay)	25
(iii) Limit test for drugs of chemical origin	
(iv) Assay of total alkaloids or of drugs of chemical origin	30
(v) Identification test for drugs of animal origin or macro-biological	25
(vi) Fee for testing of mother tinctures, lower potencies upto 3X or equivalent.	50

* The exact amount of fee shall be determined by the Director or the Govt. Analyst, as the case may be.

SCHEDULE C:

1. Sera ; 2. Solutions of serum proteins intended for injection ; 3. Vaccines for parenteral injections; 4. Toxins ; 5. Antigens ; 6. Antitoxins ; 7. Neo-arsphenamine and analogous substances used for the specific treatement of infective diseases. 8. Insulin ; 9. Pituitary (Posterior Lobe) Extract 10. Adrenaline and Solutions of Salts of Adrenaline; 11. Drugs and Preparations thereof in a form to be administered parenterally (i) Penicilline ; (ii) Streptomycin; (iii) Chlortetracycline; (iv) Oxytetracycline ; (v) Chloramphenicol; (vi) Viomycin ; (vii) Neomycin : (viii) Bacitracin' (ix) Tetracycline; (x) Carbomycin ; (xi) Erythromycin; (xii) Vancomycin ; (xiii) Polymyxin B. 12. Any other preparation which is meant for parenteral administration as such or after being made up with a suitable solvent or medium or any other sterile product which either requires to be stored in a refrigerator or does not require to be stored in a refrigerator. 13. Sterile Ligature; 14. Bacteriophages.

SCHEDULE CL

1. Drugs belonging to the Digitalis group and the preparations containing drugs belonging to the Digitalis group not in a form to be administered parenterally.
2. Ergot and its preparations containing Ergot not in a form to be administered parenterally.
3. Adrenaline and preaparations contain ing adrenaline not in a form to be administred parenterally.
4. Fish Liver Oil and preparations containing Fish liver oil.
5. Vitamins and preparations containing any Vitamin not in a form to be administered parenterally.
6. Liver extract and preparations containing liver extract not in a form to be administered parenterally.
7. Hormones and preparations containing hormones not in a form to be administered parenterafly.
8. Vaccines not in a form to be administered parenterally.
9. Following drugs and preparations containing them not in a form to be administered parenterally.

(i) Penicillin ; (ii) Streptomycin ; (iii) Chiorotetracycine (iv) Oxytetracycline ; (v) Chioramphenicol ; (vi) Neomycin (vii)

Carbomycin ; (viii) Erythromycin ; (ix),Bacitracin (x) Tetracycline ; (xi) Gramicidin ; (xii) Tyrothricin ; (xiii) Viomycin ; (xiv) Framycetin ; (xv) Griseofulvin ; (xvi) Novobiocin (xvii) Nystatin ; (xviii) Oleandomycin; (xix) Polymycin B, (xx) Spiramycin, (xxi) Vancomycin.

SCHEDULE F

Schedule-F has been divided into 'thirteen prts. At present part I top XII A has been omitted.

Part XII B: Space, Equipment and Supply required for a Blood Bank.

C : (a) Minimum requirements for grant of Licence to process blood components from whole human blood.

(b) Plasmapheresis

Part XIII : General

SCHEDULE F (I)

Part I : Vaccines

(A) : Provisions applicable to the production of Bacterial Vaccines

(B) : Provisions applicable to the production of Viral Vaccines.

Part II: Antisera

Provisions applicable to the production of All sera from Living Animals

Part III : Diagnostic Antigens

Provisions applicable to the manufacture and standardisation of Diagnostic Agents (Bacterial Origin)

Part IV : General

SCHEDULE F (II)

Standards for Surgical Dressings

SCHEDULE F (III)

Standards for Umbilical Tapes

(A): Standards for Sterilised Umbilical Polyester Tapes

(B) : Standards for Sterilised Umbilical Cotton Tapes

SCHEDULE FF

Standards for Opthalmic Preparations (Solutions, Suspensions and Ointments)

SCHEDULE P

Life Period of Drugs

(1) Name of the drug	(2) Period in months (unless otherwise specified) between date of manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specified in column No. 3	(3) Conditions of Storage
ANTIBIOTICS		
Adramycin	30	In a cool place
Ampicillin	36	In a cool place
Ampicihin Dry Syrup	24	
Ampicillin Injection	24	
Ampicillin Sodium	36	In a cool place

(1)	(2)	(3)
Ampicillin Trihydrate	30	In a cool place
Amoxycillin Trihydrate	36	In a Cool place
Amoxycillin Trihydrate Capsules	24	
Amoxycillin Trthydrate Dry Syrup	18	
Bacitracin	18	In a cool place
Bacitracin or Zinc Bacitracin tablets	12	
Bacitracin Lozenges	12	
Carbanicillin Sodium Injection	24	At temperature not exceeding 5°C
Carbanicillin sodium Powder	24	At temperature not exceeding 5°C
Cephalexin	24	In a cool place
Chloramphenicol	60	In a cool place
Chloramphenicol Capsules and Tablets	48	
Chloramphenicol palminte	48	
Chlorampbemcol Palitate Oral Suspension	36	
Chloramphenicol Eye drops	24	
Chloramphenicol Sodium Succinate powder	48	In a cool place
Chloromphenicol Sodium Succinate Injection	36	In a cool place
Chlorteracycline Hydrochloride	60	In a cool place
Chiortetracycline Hydrochloride Capsules	60	In a cool place
Chlortetracydline Hydrochloride tablets	24	
Chlortetracycline Hydrochloride	24	

(1)	(2)	(3)
Ointment		
Cloxacillin (Oral)	36	In a cool place
Cloxacillin Sodium (Injection Grade)	36	In a cool place
Colistin Sulphate	60	Proected from light
D-Cycloserine	48	In a cool place
Dimethyl chlorteracycline Hydrochloride	48	
Dimethyl Chortetracycline Hydrochloride Capsules	36	
Daunobiastin Injection	36	
Doxycycline Hydrochloride	48	In a cool place
Doxycycline Monohydrate	36	In a cool place
Doxycycline Monohydrate for Oral Suspension	24	
Doxycycline Monohydrate capsules	36	
Erythromycjn Estolate	36	In a cool place
Erythromycjn Ethylsuccinate	60	In a cool place
In a cool place In a cool place		
Erythromycin Oral Suspension	36	
Erythrornycin Estolate for Oral Suspension	36	
Erythromycin Ethyl Succinate tablet	24	
Erythromycin Estolate tablet	24	
Erythromycin Estolate tablet		
Erythromycin Stearate	36	In a cool place
Framycetin Sulphate	48	In a well closed container with temperature not exceeding30°C

(1)	(2)	(3)
Framycetin Sulphate Eye drops	24	In a well closed container with temperature not exceeding 30°C
Franiycetin Sulphate ointment	24	In a well closed container with temperature not exceeding 30°C
Gentamycin Sulphate	60	In a cool place
Gentamycin Sulphate Injection	36	
Gramicidin	60	In a cool place
Griseofulvin	48	In a cool place
Griseofulvin Tablets	36	
Kanamycin sulphate Injection	24	
Kanamycin Acid Sulphate Powde	r 48	In a cool place
Mitomycin C	48	In a cool place
Neomycin Sulphate	48	In a cool place
Nystatin	36	At temperature not exceeding 5°C
Oleandomycin Phosphate sterile	24	In a cool place
Oleandomycin Phosphate non sterile	36	In a cool place
Oxytetracycline Hydrochloride	36	In a cool place
Oxytetacycline Hydrochloride	36	Capsule
Oxytetracycline Hydrochloride tablets	24	
Oxytetracycline Hydrochloride Injection	24	
Oxytetracycline Hydroxchloride Ointment	36	
Penicillin Crystalline	36	In a cool place
Penicillin Tablets	18	In a cool place
Procaine Penicilline G	36	In a cool place
Benzathin Penicilline G	48	In a cool place
Potassium Phenoxy Methyl	48	In a cool place

(1)	(2)	(3)
Penicillin Potassium Phenoxy Methyl Penicillin tables	24	
Polymixin B sulphate	48	In a cool place
Polymixin B Sulphate Ointment or Powder	24	In a cool place
Rifampicin	36	In a cool place
Rifamycin Capsules	24	
Spiramycin Base	24	In a cool place
Streptomycin Injection	36	
Streptomycin Ointment	24	
Streptomycin tablets	24	
Streptomycin Sulphate	48	At temperature not exceeding 20°C
Tetracycline Base	24	In a cool place
Teetracycline Hydrochloride Capsules	36	In a cool place
Tetracycline Tablets	36	
Tyrothricin	24	
VITAMINS	36	In a cool place
Vitamin A Injection	24	
Vitamin B Injection	24	
Thiamine Mononitrate tablets	36	
Thiamine hydrochloride	48	In a well closed container, protected from light, in a cool place.
Thiamine Mononitrate	48	In a well closed container protected from light, in a cool place.

(1)	(2)	(3)
Riboflavin	60	In a well closed container, protected from light, in a cool place.
Riboflavin 5 Phosphate	24	In a well closed container, protected from light, in a cool place
Riboflavin Tablets	36	
Vitamin B2 Injection	24	
Vitamin B6	60	In a well closed container, protected from light, in a cool place.
Vitamin B 6 tablets	36	
Cyanacobalamin	48	In a well closed container, protected from light, in a cool place.
Hydroxycobalamin	48	In a well closed container, protected from light, in a cool place
Vitamine B 12 Injection	36	
Calcium Panothenate	36	In a well closed container, protected from light, in a cool place.
Vitamin C Injection	24	
Calcium Pantothenate tablets	36	
Vitamin C	48	In a well closed container, protected from light in a cool place

(1)	(2)	(3)
Vitamin D2	36	In a well closed container, protected from light, in a cool place.
Vitamin E or E Acetate	60	In a well closed container, protected from light, in a cool place.
Folic acid	60	In a well closed container, protected from ligft, in a cool place
Folic Acid tablets	36	
Vitamin K	60	In a well closed container, protected from light, in a cool place.
Vitamin K Injection	36	
Niacinamide	60	In a well closed container, protected from light, in a cool place.
Niaeinamide tablets	36	
D-Panthenol	60	In a well closed container, protected from light, in a cool place.
INSULIN		
Preparations		
Globuline Zinc Insulin Injection	24	At temperature between 2°C and 8°C must not be allowed to freeze.
Insulin Injection	24	At temperature between 2°C and 8°C must not be allowed to freeze.

(1)	(2)	(3)
Insulin Zinc suspension	24	At temperature between 2°C and 8°C must not be allowed to freeze.
Isophane Insulin Injection	24	At temperature between 2°C and 8°C must not be allowed to freeze.
Normal Human Plasma		
Anti Haemophillic Human Globulin	12	In a cool place.
Dried Plasma	60	At temperature not exceeding 25°C.
Dried Normal Human Serum Albumin	60	At temperature not exceeding 25°C.
Frozen Plasma	60	In deep freeze
Liquid Plasma	24	In cold place
Liquid Normal Human Serum Albumin	60	In cold place
Whole Human Blood	21	At tempertaure days between 4°C and 6°C
Sera Toxin and Toxoid		
Alum Precipitated Dipheriatoxoid	24	In cool place
Alum precipitated Diphtheria and Tetanus toxoid and Pertusis vaccine combined	18	In cool place
Alum Precipitated Tetanus Toxid	24	In cold place
Aluminium Hydroxide Absorbed Diphtheria Toxoid	24	In cold place
Aluminium hydloxide Absorbed Diphtheria Tetanus Toxoid and Pertussis Vaccine combined	18	In cold place
Aluminium Phosphate Absorbed Diphtheria Toxoid	24	

(1)	(2)	(3)
Aluminium phosphate absorbed Diphtheria and Tetanus Toxoid and Pertussis vaccine combined Diphtheria and Tetanus Toxoid	24	In cold place
Aluminium phosphate absorbed	18	In cold place
Diagnostic Diphtheria Toxin (Schick Test)	12	In cold place
Cobra venom in solution	3	Between 2°C and 5°C protected form light
Diphtheria Toxoid In activated	24	In cold place
Diagnostic Diphtheria Toxin Liquid serum	12	Between 2°C and 1°C preeferable at the lower limits.
Lyophilised anti-snake venom serum	60	
Lyophilised Schick test Toxin and control	60	
Old Tuberculin	60	In cold place
Thrombin (Bovin Origin)	36	In cold place
Tetanus Toxoid	24	In cold place
Tuberculin PPD	60	In cold place
OTHER VACCINES		
Alum precipitated pertussis vaccine	18	In cold place
BOG Vaccine	14 days	In cold place
Cholera Vaccine	18	In cold place
DHL Vaccine (for dog)	12	In cold place
Measles Vaccine	24	In cold place
Plague Vaccine	36	In cold place
Polio Vaccine	24	When stored at minus 20°C
	6	When stored at 0°C
Rabies vaccine	3	When stored at 4°C

(1)	(2)	(3)
Thyphoid vaccine	6	In cold place
Rabies vaccine	18	In cold place
Typhoid and Para Typhoid vaccine	18	In cold place
Typhoid Para Typhoid A and B vaccine	18	In cold place
Typhoid Para Typhoid A, B and vaccine	18	In cold place
Typhoid Para Typhoid A, B and C and Tetanus Vaccine	18	In cold place
Typhus vaccine	12	In cold place
Yellow Fever Vaccine	12	In cold place
Antitoxin (For serum extracted preparations)		
20% Excess potency	12	In cold place
30% Excess potency	24	In cold place
40% Excess potency	36	In cold place
50% Excess potency	48	In cold place
(For enzyme preparations)		
5% Excess potency	12	In cold place
10% excess potency	24	In cold place
15% Excess potency vaccine	36	In cold place
20% Excess potency Miscellaneous Drugs	12	In cold place
Adrenaline for Injection	12	In cold place
Chorionic Gonadotraphin for injection (Lyophilised)	46	At temperature not exceeding 20°C
Corticotrophin	24	In cold place
Corticotrophin Lyophilised	36	In cold place
Heparin Injection	36	In cool place
Liquid Extract of Ergot	12	In cool place
Liver Extract Crude Injection	24	In cool place

Oxytonic Injection	24	In cold place
Paraldehyde Injection	6	In cold place protected from light
Pituitary Injection	24	In cold place
Vasopression Injection	24	In cold place

Storage conditions:

Cold : Temperature between 2° and 8°C.

Cool : Temperature between 8° and 25°C. If not specified it can be kept in a refrigerator (at 2° to 8°C)

Room Temperature: If not specified, it means the drugs can be stored in a temperature prevailing in a working area.

Warm: Any temperature between 30° and 40°C.

Where no specific directions are indicated, storage conditions include protection from moisture, freezing and excessive heat.

SCHEDULE P (I)

PACK SIZES OF DRUGS

Name of the Drug	Dosage Form	Pack Size
Albendazole	Suspension	10 ml
Atenolol	Tablets	14
Anti-Haemmorhoidal	Rectal	20
	Capsules	
Topicals		
Aspirin (Low-dose)	Tablets	14
Cholecalciferol or Ergocalciferol	Granules	1 gm sachet
Ergocalciferol		
Ciclopiroxolamine	Vaginal Cream	30 gms
Catalin	Ophthalmic drops	15 ml.
Famotidine	Tablets	14
Glyceryl Trinitrate	Spansules (Log Acting)	25
Isosorbide Dinitrate	Spansules (Long	25

	Acting)	
Isomazide	Syrup	200 ml.
Ipecacuanha	Syrup	10 ml.
Oral Rehydration Salt (OHS)	Powder	Pouches to be reconstituted to one litre in one pack or in 5 unit dose sachets in one pack.
Piperazine	Granules	5 gm
	Syrup	30 ml.
	Pyrantel Pamoate Syrup	8 ml. or 10 ml.
Potassium Chloride	Syrup	60 ml. and 200 ml.
Progestogen Qestrogen (Combinations for Oral Contraception	Tablets	21 or 22 with or without 7 placebo
Roxatidine Acetate or Hydrochloride	Tablets	14
Vitamin A Oral Drops	Drops	7.5 ml

SCHEDULE G

Aminopterin, L-Asparaginase, Bleomycin, Busuiphan; and its salts, Carbutamide, Chlorambucil ; and it salts, Chlorothiazide and other derivatives of 1, 2, 4, benzothiadiazine, Chloropropamide; its salts, Chlorthalidone and other derivatives of Chlorobenzene compound, Cyclophosphamide; ard its salts, Daunorubicin, Di- hopropyl Fluorophosphate, Disodium stilboestrol Di-phosphate, Doxorubicin

Hydrochloride, Ethacrynic Acid, and its salts, Ethouximide, Glibenclamide, Hydantoin, its salts; its derivatives, and their salts, Hydroxyurea, Insulin, all types, Mannomustine; its salts, Mercaptopurine, its Salts, metforniin: its salts, Methsuximide, Mustine ; its salts, paramethadione Phenacemide, Phenformin: its salts, 5.Phenylhydantoin its alkyl and arylderivatives; its salts, Primidone, Quinthazone, Sarcolysine, Testolactone, Thiotepa, Tolbutamide, Tretamine; its salts, Troxidone, Antihistaminic substances, the following are their salts, their derivatives, salts of their derivatives., Antazoline, Bromodiphenhydramifle, Buclizine, Chlorcyclizine, Chiorpheniramine, Clemizole, Cyproheptadine Diphenhydramine, Diphenylpyraline, Doxylamine succinate. Isothipendyl, Mebhydroline Napadisylate, Meclozine, Phenindamine, Pheniramine, Promethazine, Thenalidine, Triprolidine, Substnace being, te'ra-N- substituted derivatives of Ethylene Diamine or propylenediamine.

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

SCHEDULE H

Prescription Drugs

Adrenocorticotrophic Hormone (ACTH), Amyloride Hydrochloride, Analgin, Androgenic Anabolic, Oestrogenic and Progestational substances, the following :

Benzestrol, Derivative of stilbene, dibenzyl or nepthalene with oestrogenic activity, their esters, Steroid Compounds with ancirogenic or progestational activity, their esters, Allopurinol, Alphachmotrypsin, Arnantadine Hydrochloride, Amitriptyline, its salts, ammidinammoidin, Antibiotics, Apiol, Aprotinin, Arsenic, organic compounds of, for Injection, Azathioprine, Barbituric acid, its salts, derivatives barbituric acid, their salts compounds of barbituric acid, its salts, its derivatives, their salts with any other substance excluding those inicouded in Schedule X, Beclomethasone Dipropionate Benactyzine, its salts, Betahistine Dihydrochioride, Betamethasone 17-Benzoate, Bethanidine Sulphate, Biperiden Hydrochloride, Bioscanate, Bretylium Tosylate, Bromhexine Hydro-

chloride, Bupivacaine Hydrochloride, Carbenoxlone Sodium, Cansoprodol, Chloral Hydrate, Chiord azepoxide; its salts, Chiorprothixene, Citrated Calcium Carbamide, Clidinium Bromide, Clofazimine, Clofibrate, Clonidine— HC1, Clopamide, Cloximazole Clorexolone, Corticosteroids, their esters, their derivatives and esters, on their derivatives Cyclandelate, Dapsone its salts and derivatives, Deoxyribonuclease, Diazepam, Diazoxide, Dilazep Hydrochloride, Dimethothi azine Mesylate, Disopyramide, Disulfiram, Dopamine Hydrochloride Dothiepin Hydrochloride, Doxapram Hydrochloride, Doxepian Hydrochloride,, Drugs coming within the purview of the Dangerous Drugs Act, Epinephrine; its salts, Epsilon Aminocaproic Acid, Ergot, alkaloids of, whether hydrogenated or not; their homologues any salt of any substance falling within this item, Ethacridine Lactate, Ethambutol Hydrochloride, Ethinyloestradiol, Ethionamide Fenfluraniine Hydrochloride, Flufenamic acid; its salts; its esters their salts, Flupenthixol, Fluphenazide Enanthate and Decanoate, Flurbiprofen, Galanthamine Hydrobromide, Gallamine, its salts its quarternary compound, Glucagon, Glycopyrrolate, Glydiazinemide, Guanethidine, Halogenated Hydroxyquinoline, derivatives of Haloperidol, Heparin, Hyaluronidase, Hydroxyzine; its salts Ibuprofen, Imipramine, its salts, Indapàmide, Indomethacin its salts Iron preparations for parenteral use, Isonicotinic acid hydrazine and other hydrazine derivative of Isonicotinic acid; their derivatives their salts, Isoptin Hydrochloride, Isosorbide Dinitrate, Isoxsuprine Ketainine Hydrochloride, L-DihydroxypbeflY1a1anme Levarterene its salts, Lidoflazine, Lithium Carbonate, Loperamide, Lorazepam Mebendazole, Mebeverifle Hydrochloride, Medigoxin, Mefenamic acid, its salts, its esters, their salts, .Megestrol Acetate, Meglumine Locarmate, Mephenesin its esters, Mesterolone, Methixene; its salts, Methocarbainol, Methoxsalefl, Methylpenthynol; its esters and other derivatives, 1-Methyl 1-4-Phenylpiperidine 4-Carboxylic acid, esters of their salts, Metoclopranhide, Metronidazole, Miconazole, Morphazinamide Hydrochloride, Nalidixic Acid, Naproxen, Natamycin, Nicofuranose, Niflumic Acid, Nimorazole, Nitrazepam, Orphenadrine its salts, Oxazepam, Oxazolidine; its salts, Oxethazaine Hydrochloride, Oxolinic Acid, Oxprenolol Hydrochloride, Oxyfedrine, Oxymetazoline, Oxyphenbutanzofle, Oxytocin, Para- amino benzene

sulphonamide, its salts, derivatives of para-amino benzene suiphonamide having any of hydrogen atoms of the para-amino group of the sulphonamide group substituted by another radical excluding carbutamide; their salts, Paraamino salicylic Acid; its salts; its derivatives; their salts, Pancuronium Bromide, Pempidine; its salts, Penamecillin, D-Penicillamine, Pent,azocine, Pentoxifyllin, Pheneizine, its salts, Phenothiazine, derivatives of and salts of its derivatives not otherwise specified in the schedule, Phenybutazone; its salts, Phenyipropanolamifle Hydrochloride, Pimozide, Pindolol, Piracetam, Pivazide, Pituitary gland, the active principles of, not otherwise specified in this schedule and their salts, Prednisolone Stearoylgiycolate, Promazine, is salts, Propanidid Propranolol Hydrochloride, Protriptyline Hydrochloride, Pyrantel Pamoate. Pyrazinamide, Pyrvinium, its salts, Rauwolfia alkaloids of their salts; derivativçs of the alkaloids of rauwolfia; their salt, Salbutarnol Sulphate, Salicyclazosulphapyridine Sodium Cromoglycate,. Sodium and Meglumine Lothalamates, Sotalol, Sulfonal; alkyl sulfonals, Sulfamethoxine, Suiphamethoxy- pyridazine, Sulphaphenazole, Sulthiame, Terbutaline Sulphate, Tetramisole Hydrochloride. Thiabendazole, Thiacetazone, Theithylperazine, Thiopropazate; its salts, Thiothixene, Tinidozole, Tranylcypromine ; its salts. Tretinoin, Tribromoethyl propanol (alcohol), Trichloromethiazide, Trifluopera.zine, Thfluperidol Hydrochloride, Trimeprazine; its salts, Trimethoprim, 'Trimiprarnine, Vasopressin.

SCHEDULE X

Amobarbital, Amphetamine, Barbital, Cyclobarbital, Dexamphetamine, Ethehiorvynol, Glutethimide, Meprobainate, Methamphetamine, Methaqualone, Methylpheriidate, Methyipheno-barbital, Pentobarbital, Phencylidine, Phenmetrazine, Phenobarbital, Secobarbital.

NOTE

Preparations containing Meprobamate or Phenobarbital in combination with other drugs may be exempted from this schedule by the Licensing Authority.

CHAPTER 5
THE DRUGS AND MAGIC REMEDIES

(Objectionable Advertisernent). Act, 1954 & RULES, 1955.

INTRODUCTION

The modern age is known as the advertising era' as advertising has become a part of our life. Everyday newer methods of advertisement are in progress. Drugs are essential commodities which one has to take without option, even then, to exist in the market, the manufacturers of Drugs & cosmetics are bound to advertise their product. Ethical advertising is never objectionable but exaggerated advertisement of the drug is not at all acceptable as it leads to false hopes to the patient. Advertisements for drugs are not for the public directly but are for the persons related to medical profession only.

In India Magic Rernidies are in practice since times immemorial. Under this remedy, innocent people are deceived by unsocial elements. Sometimes patients sacrifice their life due to the prolonged and ineffective treatment given by the man. They claim to cure even those diseases, for which no drug or no treatment is available yet.

In recent years, objectionable advertisements related to cures for veneral diseases, sexual stimulants and about disease related to women are found in the newspapers on streets and public places. In the public interest, these advertisements should be stopped: as innocent people become the prey for the quacks or such advertiser.

In order to control such objectionable and misleading advertisements, the Drugs and Magic Remidies Act, 1954 was passed. The object of passing this Act and Rule was to prohibit the advertisement fcr certain purposes for remedies alleged to possess magic qualities. This Act & Rules cover all advertisements which are objection ble or unethical and are used to promise self-medication or self treatment.

The Act was passed on 1st April, 1955 and ammended in 1963. This Act extends to whole of India except the state of Jammu and Kashmir.

PROHIBITED ADVERTISEMENTS

1. No person can take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for:

(a) The Procurement of miscarriage in women, or prevention of conception in women ; or

(b) The maintenance or improvement of the capacity of human beings for sexual pleasures ; or

(c) The correction of menstrual disorder in women ; or

(d) The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, or condition specified in the schedule J or any other disease, disorder of condition which may be specified in the rules made under this Act.

2. No person shall take part in the publication of any advertisement to a drug if the advertisement contains any matter which —

(a) directly or indirectly gives a false impression regarding the true character of the drug ; or

(b) makes a false claim for the drug , or

(c) is otherwise false or misleading in any material particular.

3. No person carrying on or purporting to carry on the profession of advertising magic remedies should take part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in (1) above.

4. Import and export of all the above mentioned advertisements is prohibited. Any documents containing any such advertisements are deemed to be goods of which import or export has been prohibited under the sea customs Act, 1878.

Subject to the provisions of any rules made in this behalf, any Gazetted officer autborised by the state Govt. may within the local limits of the area for which he is so authorised —

(a) enter and search at all reasonable times, with such assistants, as necessary, any place in whichh has reason to believe that an offence under this Act has been or is being committed.

(b) Seize any advertisement which he has reason to believe contravenes any of the provisions of the Act.

Power of seizure under this clause may be exercised in respect of any document, article or thing which contains any record, register, document or any other material object found in any place mentioned under (a) above and seize the same if it is likely to furnish the evidence of the commission of an offence punishable under this Act.

Search and seizure should be made under the authority of a warrant as provided in the code of criminal procedure, 1898. An offence punishable under this Act shall be cognizable. A magistrate should be informed of any seizure and his order should be taken as to the custody thereof.

EXEMPTED ADVERTISEMENTS

Following advertisements can be made without any prohibition:

(a) Any sign board or notice displayed by a registered medical practitioner on his premises indicating that treatment for any disease, disorder or condition is undertaken relating to which advertisements othrwise are prohibited ; or

(b) Any treatise or book dealing with any of the matters relating to the diseases or conditions which are otherwise prohibited to be advertised, provided published from a bonaflde scientific or social standing ; or

(c) Any advertisement relating to any drug sent confidentially in the piescribed manner only to a registered medical practitioner. Advertisements can be sent confidentially by posting to a registered medical practitioner or to a whole saler or retail chemist and bearing at the top, printed in indeliable ink in a conspicuous manner, the words 'For the use only of registered medical practitioner or a hospital or a laboratory; or

(d) Any advertisement relating to a drug printed or published

by the Govt. or by any person with the previous sanction of the Government granted prior to the commencement of the Drugs and Magic Remedies (Amendment) Act, 1963. Such sanction could be obtained by making an application to the officer authorised in this behalf by the central or the state Govt. mentioning the registered name and the trade mark of the drug, its detailed composition and any special reasons justifying the sanction of the Govt.

Such sanction can be withdrawn by the Govt. after giving the person an opprtunity of showing cause against such withdrawal.

The central Govt. may, in the public interest, permit the advertisement of any specified, drug or classes of drugs which is otherwise prohibited under the Act, by notification in the official Gazette.

(e) Any advertisement, labels or sets of instruments which are permitted under the Drugs and cosmetics Act or Rules there under.

The central Govt. through a notification issued in 1967 has further exempted from the provisions of the Act the following classes of advertisements with the conditions mentioned against them.

CLASS OF ADVERTISEMENT	CONDITIONS
1. Leaflets or literature accompanying packings of drugs	1. The advertisement contains only such information as is required for the guidence of registered medical practitioner in respect of matters relating to— (a) therapeutic indications of the drug (b) its administration (c) its side effects and (d) its dosage and (e) the precautions to be observed in the treatment with the drug.

2. Advertisements of drugs in medical, pharmaceutical scientific and technical journals.	2. The responsibility to prove that any claim made in the advertisement in respect of the drug is not false, exaggerated or misleading lies on the advertiser.
3. Price lists or therapeutic indexes published by manufacturers, importers or distributors of drugs duly licensed under the Drugs & Cosmetics Act 1940 and the Rules there under, and	3. The advertisement contains only such technical information as is required for the guidance of RMP in regard to therapeutic indications of drugs the manner of their administration, their dosage, side affects and the precuations to be observed in the treatment.
4. Medical literature distributed by medical detailers appointed by manufacturers, importers, or distributors of drugs, duly licensed under the Drugs & cosmetics Act, 1940 and the Rules there under.	4. The distribution of such literature is confined only to the RMP's, hospitals, dispensaries, medical and research institutions, and chemists and druggists or pharmacies duly licensed under the provisions of the Drugs and cosmetics Rules. 5. The responsility to prove that any claim made in the advertisement in respect of the drug is not false, exaggerated or misleading, lies on the advertiser.

OFFENCES AND PENALTIES

	Penalities	
	First conviction	Subsequent conviction
On contravention of any of the provisions of Act and Rules.	Imprisonment upto 6 months or with fine or both	Imprisonment upto one year or fine or both.

CHAPTER 6

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT AND RULES, 1985

INTRODUCTION

The Act was passed in 1985 and extends to whole of India. The Act repeals the opium Act 1857, the opium Act 1878 and the Dangerous Drugs Act 1930. The Rules repeal the Central Opium Rules 1934, the Dangerous Drugs Rules 1957 and the central manufactured Drugs Rules, 1962.

Due to increase in the number of drug abuse the central Govt. passed the Narcotic Drugs and Psychotropic substances Act and Rules in order to curb the menace and threat to the physical and moral health of the human race, particularly the youth. The Act was passed 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 concerned matters.' Most significant feature of the Act is the exemplary punishment provided for most of- the offences ; in some cases rigorous imprisonment upto 30 years in addition to a fine of more than 3 lacs of rupees. For most of the offences a minimum term of imprisonment and minimum amount of fine are provided and as '. consequence once an offence is proved, the court has no option but to award at least the minimum penalty.

Even the possession of a small quantity of any narcotic drug or psychotropic substance for personal use, or consumption of such drug are cognizable offencés under the Act.

MEASURES BY CENTRAL GOVERNMENT

To prevent and combat abuse of narcotic and pychtropic substances and the illicit traffic therein, the central Govt. may take measures with respect to the following matters:

1. Co-ordination of action by various officers, state Governments and other authorities under this Act or under any other law for the time being in force in connection with enforcement of the provisions of this Act;
2. Obligation under the International conventions;
3. Assistance to the concerned authorities in foreign countries and international organizations to facilitate co-ordination and universal action for prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances.
4. Identification, treatment, education, after care rehabilitation and social re-integration of addicts ; and
5. Such other matters as the central Govt. deems necessary or expedient for the purpose of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES CONSULTATIVE COMMITTEE

This committee is constituted by the central Govt. to advise the central Govt. on such matter relating to the administration of this Act as are referred to it by the Govt. from time to time.

PROHIBITION OF CERTAIN OPERATIONS:

Under Section-8 of the Act following operations are prohibited:

No person shall (a) Cultivate any coca plant or gather any portion of the coca plant ; or

(b) Cultivate the opium or any Cannabis plant ; or

(c) Produce, manufacture, possess, Sell, purchase, transport, warehouse, use, consume, import and export interstate, or tran ship any narcotic drug or psychotropic substance except for medical or scientific purpose and in the manner and to the extent prescribed or in accordance with the terms and conditions of a licence, permit or authorisation, if provided.

POWER OF CENTRAL GOVT. TO PERMIT CONTROL AND REGULATE

The central Govt. may

(a) Permit and regulate —

(i) the cultivation and gathering of any portion (only on behalf of the central Govt.) of coca plant, or the production, possession, sale, purchase, transport, inter-state import and export, use of consumption of coca leaves,

(ii) the cultivation (only on bahalf of the central Govt.) of the opium poppy:

(iii) the production and manufacture of opium and production of poppy straw:

(iv) the sale of opium and opium derivatives from the central Govt. factories for export from India or sale to state Govt. or to manufacturing chemists;

(v) 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 legally entitled to possess,

(vi) the manufacture, poession, transport, interstate import and export, sale, purchase, consumption or use of psychotropic substance;

(b) prescribe any other requirsite to render effective the control of the central Govt. over any of the matters specified above.

POWER OF STATE GOVT TO PERMIT, CONTROL AND REGULATE

Subject to the provisions of the Act, the state Govt. may by rules:

(a) Permit and regulate

1. The possession, transport, import, inter-state, export inter- state, warehousing, sale, purchases, consumption and use of poppy straw.
2. The possession, transport, import inter-state, export inter- state, sale, purchase, consumption and use of opium.

3. The cultivation of any cannabis plant, production, manufacture, possession, transport, import inter-state, export inter-state, sale, purchases consumption or use of cannabis (excluding charas).
4. The manufacture of medicinal opium or preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.
5. The possession, transport, purchase, sales, import interstate, export inter-state, use or consumption of manufactured drugs other than prepared opium and of coca leaf and any preparation containing any manufactured drugs.
6. The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the state Govt. on medical advice for his personal consumption.

(b) Prescribe any other matter requisite to render effective the control of the state Govt. over any of the matters specified above.

Special provisions relating to coca plant and coca leaves for use in the preparation of flavouring agent:

The central Govt. may permit with or without conditions, and on behalf of Govt., the cultivation of any coca plant or gathering of any portion there of or the production, possession. sale, purchase, transport, import inter-state, export interstate or import into India of coca leaves for use in the, preparation of any flavouring agent which shall not contain any alkaloid and to the extent necessary for such use.

Special provision relating to cannabis:

The government, by general or special order may allow cultivation of any cannabis plant for industrial purposes or for horticultural purposes.

OPIUM POPPY CULTIVATION AND PRODUCTION OF OPIUM POPPLY STRAW

Opium poppy cultivation for the production of opium poppy straw can be done only on behalf of the central Govt. in the notified tracts in states of M.P; U.P. and Rajasthan.

The application is made to the District opium officer for the grant of such licence in Form 2 accompanied by a fee of Rs. 5/. On fulfilment of the conditions the licenceis issued to the applicant in Form 1.

CONDITIONS OF LICENCE

1. The licensee shall not transfer his licence and cultivate poppy only for production of opium or poppy straw over the area of land and the plots specified in the licence.
2. The land for poppy cultivation shall be free from litigation.
3. The licensee shall get his daily collections of opium obtained from the crop weighed by the Lambardar and affix his signature/ thumb impression against each entry made by the Lambarder in token of the correctness of such entry and shall submit preliminary weighments carried out by the staff of the Narcotics Department in the village during which he shall produce the entire quantity collected by him.
4. The licensee shall bring to and deliver at, the place fixed for weighment all opium collected by him from the crop and shall accept for opium so brought by him the price fixed by the central Government for the crop year.
5. The licensee shall deliver the opium for weighment and it shall be weighed under the supervision of the District Opium officer or any other officer auth orised by the Narcotics Commissioner.
6. If the licensee does not . rrender his entire product of opium to Govt. or retains, embezzles or otherwise, illegally disposes of any part of the same, he shall be liable to be prosecuted.
7. The licensee shall extract as much opium as is reasonably possible.
8. The final payment of opium delivered by the licensee shall be made at the appropriate time and accordingly the final adjustment of account be made.
9. The licensee shall comply with the provisions of the Narcotic Drugs and psychotropic substances Act and Rules and orders issued by the competent authorities. The licence may be cancelled or with held at any time for any reason making him ineligible for the grant of a licence. Breach of any of the conditions of the licence is punishable.

The licence shall specify the area and plots to be cultivated with opium poppy. The District opium officer shall designate any such cultivator as Lambardar in each village where opium poppy is cultivated. Lambardar shall perform such functions and on such terms and conditions as may be prescribed by the Narcotics commissioner.

SALE OF NARCOTIC DRUGS

Sale by Dealer under Licence in Form D.D. 10:

1. A licenced dealer in manufactured drugs may sell otherwise than on prescription manufactured drugs or preparations to:

(a) an approved practitioner who is either known to the licensee or is introduced by some one known to him

(b) a chemsit or dealer licensed under these rules.

(c) an approved practitioner or a Govt. Medical officer, holding authorisation.

(d) a person holding appropriate licence in any other state/Union Territory of India.

(e) an approved practitioner engaged in veterinary practice.

2. The licensee shall maintain, a register in Form D.D. 13, of all transaction of manufactured drugs.
3. Such accounts/record shall be preserved for a period of not less than two years from the date of last entry.
4. The licensee shall, on the first day of every quarter, submit a correct quarterly statement to the collector and the Drugs controller.
5. The containers of the preparations. containing manufactured drugs, shall show on the label, the actual quantity of the drugs present in each container.
6. A preparation, mixture, extract or any other substance containing any manufactured drugs, shall be sold only in package or bottle plainly marked.

SALE OF NARCOTICS BY A CHEMIST UNDER LICENCE IN FORM D.D. 11.

The collector may grant a chemist, licence in Form D.D. 11 to a person, who is holding licence in Forms for the sale of drugs in Form 20 and 21 under Drugs & cosmetics Act and Rules.

The licensed chemist shall possess manufacured drugs or preparations containing any manufactured drug in such quantities specified in his licence.

The licensing authority may authorise a licensed chemist to possess the following manufactured drugs or the preparations c

ing the manufactured drugs:

(i) Medicinal opium (excluding the extract or tincture of medicinial opium) or preparation containing medicinal opium.

(ii) Opium alkaloidal derivatives of:

(a) Morphine and their salts,

(b) Codine and shair salts,

(c) The baine and their salts,

(d) All preparations containing more than 0.2% of morphine.

(iii) Pethidine.

The Excise Commissioner may, by speial order, authorise, a licensed chemist to possess, extracts or tinctures of medicinal opium or any preparation containing more than 0.1% of cocaine

CONDITIONS OF LICENCE

1. The licensee shall observe all the provisions of Narcotic drugs & Psychotropic substances Act and any other Act passed by the Govt. from time to time.
2. The liceneee shall be responsible for the acts and ommissions of every person employed by him in carrying on his business.
3. The licensee shall not permit to dispense any drug by any person other than a medical practitioner of a dispenser registered under the Pharmacy Act.
4. Cocaine or extracts and tinctures of the medicinal opium and medicinal cannabis shall be possessed and sold with the previous permission of the Excise Commissioner.
5. The licensee shall be authorised to sell the drugs only against a prescription issued by an approved RMP.
6. The licensee shall keep or sell the drugs at all times in the premises specified in the licence.
7. The licensee shall obtain his supplies either by direct importation from any other state /U.T. or from any other licensed dealer after obtaining the permit under this Act.
8. The licensee shall not possess the drugs in greater quantities than the prescribed quantities in the licencee.

9. The licensee is authorised to compound any preparations containing any manufactured drugs from the materials which is lawful entitled to possess.
10. The name of person or firm dispensing the drug, the address and the date must be entered in prescription.
11. The drugs are dispensed on the prescription written in Form D.D. 12 by the approved RMP.
12. The licensee shall sell the drugs to such persons only. Specified in the prescription. If the prescription does not bear a subscription for repeating the same prescription, the drugs should be sold once only. If, it bears the subscription, it should be refilled as many times as it is written to be repeated.
13. The licensee shall maintain correct account of transaction in the prescribed form.
14. The containers should contain the actual quantity of drugs shown on the label.
15. All the stocks of drugs and accounts and records of transaction shall be open to inspection by an officer of the excise department and any officer of the drug control department.
16. The licensee shall submit correct quarterly statement of transaction to the District Excise officer and Drugs Inspector on the first day of every quarter. Statement of transaction of Tincture/Extracts of opium and cannabis shall be submitted every month.
17. The licensee shall deliver his licence, on request by the excise commisssioneror to the duly authorised officer.
18. If any quantity of or the drug remain in the possession of the licensee either on expiry or on cancellation of the licence, the licensee shall surrender the stock to the collector. Licensee shall not be entitled to claim any compensation for loss.
19. The licensee shall sell or dispense any manufactured drugs or the preparations containing these drugs for the medicinal purpose only.

OFFENCES AND PENALTIES

Offence	Penalty	
	First conviction	Second or subsequent conviction
(1)	(2)	(3)
1. In relation to poppy straw :		
To produce, possess, transport, inter state import or export, sell, purchase, use or omit to ware house poppy straw or to remove or to do any act in respect of ware-housed poppy straw, in contravention of any provision of this Act or Rules etc.	rigorous imprisonment for not less than 10 to 25 year and fine not less than Rs. one lakh. The court may, for reasons to be recorded in judgement, impose a fine exceeding Rs. two lakh.	regorous imprisonment for not less than 15 to 30 years and fine not less than Rs. 1.5 to 3 lacs.
2. In relation to coca plant and coca leaves		
To cultivate any coca plant or to gather any portion of a coca plant or to produce, possess, sell, purchase, transport into State import, or export or to use coca leaves in contravention of any provision of this Act or any rule etc.	Do	Do

(1)	(2)	(3)
3. In relation to prepared opium		
To manufacture, possess, sell, purchase, transport, inter State import or export or to use prepared opium in contravention of any provision of this Act or any rule etc.	Do	Do
4. In relation to opium poppy and Opium.		
To cultivate the opium poppy, or to produce, manufacture, possess, sell, purchase, transport, interstate import or export, or to use opium in contravention of any provision of this Art or any rule etc.	Do	Do
5. Embesslement of opium by cultivators.		
Embezzlement or otherwise illegally disposing of the opium produced on any part thereof by cultivator licensed to cultivate the opium poppy on account of the Central Govt.	Do	Do

(1)	(2)	(3)
6. In relation to cannabis plant and cannabis :		
(a) To cultivate any cannabis plant, or	Do	Do
(b) To produce, manufacture, possess, sell, purchase, transport, inter-state import or export, or to use cannabis, in contravention of any provision of this Act or any rules etc.		
(i) Where such contravention relates to cannabis other than ganja.	Do	Do
(ii) Where such contravention relates to ganja or the cultivation of cannabis plant.		
7. In relation to manufactured drugs and preparations :		
To manufacture, possess, sell purchase, transport, inter-state import or export, or to use any manufactured drug of any preparation containing any manufactured drugs in contavention of any provision of this Act or any rule etc.	rigourous imprisonment not less than 10 to 20 years and fine not less than 1 to 2 lakh rupees. The court may for reasons to be recorded in writing, impose a fine exceeding 2 lakh rupees.	rigorous imprisonment for not less than 15 to 30 years and fine not less than 1.5 to 3 lakh rupees.

(1)	(2)	(3)
8. In relation to psychotropic substances :		
To manufacture, possess, sell purchase, transport, inter-state import or export, or to use psychotropic substance in contravention of any provision of this Act or any rule etc.	Do	Do
9. Illegal import, export or transhipment of narcotic drugs and psychotropic substances :	Do	Do
To import into India or to export from India or to tranship any narcotic drug or psychotropic substance in contravention of any provision of this Act or any rule etc.		
10. External dealings in narcotic drugs and psychotropic substances :		
To engage in or to control any trade whereby a narcotic drug or psychotropic substance is obtained outside India and supplied to any person outside India without the Prior authorisation of the Central Govt. or otherwise than in accordance with the conditions of such authorisation.	Do	Do

(1)	(2)	(3)
11. Allowing premises etc. to be used for commission of an offence.		
Anybody being the owner or occupier having the control or use of any house, room, enclosure, space, animal or conveyance knowingly permitting to use for the commission by any other person of an offence punishable under any, provision of this Act.	Do	Do
12. Certain acts by licensee or his servents :		
If the holder of any licence, permit or authorisatoin or any person in his employment and acting on his behalf		
(a) omits without any reasonable cause to maintain accounts or to submit any return as per the provisions of this Act or any rule.		
(b) fails to produce without reasonable cause such licence, permit or authorisation or State Govt. in this behalf.	imprisonment upto fine or both	3 years or
(c) Keeps any accounts or makes any statement which is false or which he knows or has reason to		

(1)	(2)	(3)
believe to be incorrect; or		
(d) wilfully and knowingly does any Act in breach of any of the conditions of licence, permit or authorisation for which a penalty is not prescribed elsewhere in this Act.		
13. Illegal possession in small quantity authorisation for personal consumption or consumption of any narcotic durg or psychotropic substances:		
To possess in a small quantity any narcotic drug psychtropic substance intended for personal consumption and not for sale or distribution to consume any narcotic drug or psychotropic substance in contravention of any provision of this Act or any rule etc.		
(a) In case of cocaine, morphine, diacetyl morphin, of any other narcotic drug or psychotropic substance specified by	Imprisonment upto 1 year or fine or both	

(1)	(2)	(3)
Other than those specified under (a) above.	Imprisonment for 6 months or fine or both	
14. Attempts to commit offences : Any body attempting to commit any offence or causing such offence to be committed and in such attempt doing any act towards the commission of the offence, punishable under this Chapter.	same punishment as provided for the offence	
15.Abetment and criminal conspiracy: For abeting, or being a party to a criminal conspiracy to commit an offence punishable under this Chapter (even though the offence is not actually committed)	same punishment as provided for the offence	
16.Preparation Anybody who makes preparation to do anything which constitutes an offence under any of the provisions of Sec. 25, but is prevented by circumstances indpendent of his will.	rigourous imprisonment and fine both from one hail of the maximum penalty provided for the respective offence. The court may, for reasons to be recorded in the judgement, impose a higher fine.	

(1)	(2)	(3)
17. Offence for which no penalty is provided: For contravention of any provision of this Act or any rule etc. for which no punishment is separately provided	Imprisonment for 6 months or fine or both	

18. **Security for abstaining from commission of an offence:** whenever any person is convicted of an offence punishable under the Act, the convicting court may, if it deems fit, while passing the sentence, order such person to execute a bond for a sum proportionate to his means, with or without sureties, for abstaining from commission of any offence under the Act, during such period not exceeding 3 years. Such an order nay also be made by an appellate court or by the High Court or Sessions Judge when exercising the powers of revision. The bond becomes void if the conviction is set aside.

19. **Presumption of culpable mental state :** Culpable mental state include intention, motive, knowledge of a fact and belief in or reason to believe, a fact. The court shall pressure the existence of such mental state and the accused can prove otherwise in his defence.

20. **Offence by companies :** Where an offence has been committed by a company, every person, who, at the time of commission of offence was in charge of, and was responsible for the conduct of the business as well as the company, shall be deemed to be guilty of the offence and shall be liable to any punishment accordingly. However, such person shall not be liable to any punishment if he proves that the offence was committed without the knowledge or inspite of his exercising due diligence to prevent the commission of such offence. If it is provided that the offence has been committed with the consent or connivance of in-charge of the company. The in-charge shall be liable to be punished.

Chapter 7(a)

THE DRUGS PRICE CONTROL ORDER, 1987

(as modified in september 1994)

Drugs are the essential commodity for [redacted] to the Drugs price control order, the manufacturers of Drugs used to sell the drugs at exhorbitant prices. Which, in the interest of the public was unethical as well as not economial. The central Govt. is empowered to control the production, supply, distribution, etc. under section 3 of the Essential commoidities Act, 1955. In order to ensure equitable distribution of essential bulk drugs and to fix the maximum retail prices of drug formulations, the Central Govt. passed the Drugs price control order in 1987 : It replaced the Drugs (prices control) order, 1979.

On September 15, 1994 a modified drug policy was announced by the central Govt. Following are the salient features of the modified drug policy:

1. Abolition of industrial licensing for all bulk drugs and their formulations except for five identified bulk drugs reserved for the public sector, drugs involving use of recombinent DNA technology and specific cell or tissue targetted formulations.
2. Reduction in the number of drugs under price control from the existing 142 drugs to 73 drugs.
3. Higher rate of returns in fixation of prices for drugs under price control.
4. Companies with foreign equity upto 51 percent to be on a par with wholly Indian Companies.
5. Automatic approval for foreign technology to be given.
6. A uniform maximum allowable post-manufacturing expenses of 100 to be allowed in all cases of drugs under price control.
7. National drug authority (NDA) to be set up by a separate Act of parliament to monitor standard practices in drug promotion and to clearly identify acceptable one's and prohibit those found against consumer interest.

8. A national pharmaceutical pricing authority (NPPA) to be set up to excute price fixation.
9. At levy of cess of one percent on production of drugs and pharmaceuticals proposed for encouraging research and development in the drug sector.
10. Ayurvedic, Unani, Sidha, homoeopathic and other traditional system of medicines to be promoted through the creation of a separate department.
11. Inter-ministerial co-ordination committee under the chairmanship of Secretary, Department of chemicals proposed for monitoring areas of key concern.
12. In case of manufacture of drugs from basic state, a rate of return higher by four per cent over the existing rates which are 14 per cent on net worth of 22per cent on capital employed to be allowed in fixation of prices for drugs under price control.
13. The government to keep a close watch on the prices of medicines taken out of the price control list.
14. The government to take appropriate measures, including reclamping of price control, if medicine prices rise unreasonably.

SCHEDULES

The DPCO has he following schedules :—

The First Schedule: List of bulk drugs (including salts, esters and derivatives, if any) required for National Health Progammes (T.B. eradication, leprosy eradication, trachoma control, control of blindness, prevention of dehydration under ORT, malaria eradication and filaria eradication), used in Category I formulations under third schedule.

The Second Schedule : List of bulk drugs (including salts, esters and derivatives, if any) used in category II formulations, appearing in Third Schedule.

The Third Schedule : Category I formulations — All formulations based on the bulk drugs specified under the First schedule individually or in combination with other bulk drugs.

Category II formulations: All formulations based on the bulk drugs specified in the second schedule either individually or in combination with other bulk drugs except the following :—

(i) Single ingredient formulations based on the bulk drugs specified in the second schedule and sold under generic names.

(ii) All single ingredient vitamin formulations containing individual vitamins specified in the Third Schedule sold either under brand name or under generic name.

The Fourth Schedule: Various Forms

The Fifth Schedule : Statement showing maximum pre-tax return on sales turnover of manufacturers or importers of formulations.

POWER TO FIX THE SALE PRICE OF INDIGENOUSLY MANUFACTURED BULK DRUGS SPECIFIED IN THE FIRST OR SECOND SCHEDULE.

1. The Central Govt. may regulate a maximum sale price of bulk drug.

2. While Fixing the price of a bulk drug, the Govt. may take into consideration, a post-tax return higher by 4 percent over the existing rates which are 14 per cent on net worth of 22 percent on capital employed to be allowed in fixation of prices for drugs under price control.

3. No person shall sell a bulk drug at a price exceeding the sale price fixed.

PRICES OF NON-SCHEDULED BULK DRUGS

1. Every manufacturer of non.scheduled bulk drugs shall submit within 30 days of the commencement of DPCO, list of all such bulk drugs manufactured by him to the Govt. and indicate the details of Govt. of such bulk drugs in the prescribed Form-I.

2. Any manufacturer commencing the production of nonscheduled bulk drugs after passing of DPCO shall submit within 14 days of commencement of production the details and indicate the price at which he proposes to sell the drug.

3. The manufacturer may revise the price after submitting the details of cost to the Govt.

4. The Govt. may fix or revise the price of any nonscheduled bulk drug and thç manfacturer or importer of such bulk drug shall implement the price so fixed or revised, within 15 days of the receipt of the Drug Price control order.

CALCULATION OF RETAIL PRICE OF FORMULATION

The retail price of the formulation is calculated in accordance with the following formula :—

$$R.P. = (M.C. + C.C. + P.M. + P.C) \times (1 + \frac{MAPE}{100}) + E.D.$$

where,

R.P. means retail price.

M.C. means material cost and includes the cost of drug and other pharmaceutical aids used including overages, if any, plus process loss specified as a norm.

C.C. means conversion cost worked out in accordance with established procedures of costing and may be fixed as a norm.

P.M. means cost of the packing materials used in the packing of ccncerned formulation and includes process loss specified as a norm.

P.C. means packing charges worked out in accordance with established procedures of costing and may be fixed as a norm,

MAPE means maximum allowable post-manufacturing expenses including trade margin and shall not exceed —

100% in the case of formulations in category I and category II of the third schedule. MAPE means all cost incurred by a manufacturer from the stage of Ex-factory cost to retailing including trade margin.

E.D. means Excise Duty.

In the case of an imported formulation, the landed cost (The cost of import of drug inclusive of customs duty and clearing charges) shall form the basis for fixing its price along with such margin to cover selling and distributing expenses including interest and importer's profit which shall not exceed of the landed cost.

GENERAL PROVISIONS REGARDING PRICES OF FORMULATION

1. No manufacturer or importer shall market a new formulation or a new pack or a new dosage form of his existing formulation without obtaining the prior apprval of its price from the Govt.

2. For getting the approval of the price from the Govt. for any formulation, an applcation is made to the Govt. in Form 2 or Form 3 as the case may be. The Govt. may within a period of four months

of the receipt of an application, accord its approval, subject to such modification, if any.

If approval is not given within four months, the manufacturer or new importer, may market the new formulation or new pack or new dosage form, at a price not exceeding the price claimed by him in his application after intimating the Govt. accordingly.

FURNISHING OF PRICE LIST BY MANUFACTURER OR IMPORTER TO GOVT

1. Every manufacturer or importer of a bulk drug intended for sale shall submit a price list in Form-5 to the Government, every year.

2. Every manufacturer, importer or distributor of a formulation intended for sale, shall furnish a price list to the dealers, State Drugs controller and the Govt. in Form-5.

3. Every dealer shall display the price list on a place open to public in the licensed premises. It shall be easily accessible to any person wishing to consult the same.

RETAIL PRICE TO BE DISPLAYED ON THE LABEL OF THE CONTAINER

The maximum retaiL price of formulation intended for sale shall be displayed in indelible print mark, on the label of the container of the formulatidn and the minimum pack there of with the word 'retail price not to exceed' preceding it, and local taxes extra' succeeding it.

PRICE TO THE WHOLESALER AND RETAILER

1. The manufacturer, importer or distributor shall sell a formulation to a wholesaler at a price not higher than

(a) the retail price minus 20% there of in the case of ethical drugs (schedule C, C_1, (3 & H) and

(b) the retail price minus 18%, thereof, in the case a non- ethical drugs, (other than the ethical drugs).

2. The manufacturer, importer distributor or wholesaler shall sell a formulation to a retailer at a price not higher than

(a) the retail price minus 17% thereof, in the case of ethical drugs (schedule C, C, G& H)

(b) the retail price minus 15% thereof, in the case of non- ethical drugs (all drugs other than ethical drugs).

MANUFACTURER, DISTRIBUTOR AND DEALER NOT TO REFUSE SALE OF DRUGS

Subject to the provision of the Drugs and cosmetics Act and Rules:—

(a) no manufacturer or distributor shall withhold from sale or refuse to sell a dealer any drug without good and sufficient reasons,

(b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer wanting to purchase such drug'

PENALTIES : Any contravention of this order shall be punished in accordance with the provisions of the Essential commodities Act, 1955.

THE FIRST SCHEDULE

BULK DRUGS

List of Bulk Drugs (including salts, esters and derivatives, if any) required for the following National Health Programmes, used in Category H Formulations appearing in Third Schedule.

I. National TB. Eradication Programme

Streptomycin, Isoniazid, Thiacetazone, Ethambutol, Sodium PAS, Pyrazinamide, Rifampicin

II. National Leprosy Eradication Programme

Dapsone, Clofazaniine, Rifampicin.

III. National Trachoma Control Programme and National Programme for Control of Blindness.

Tetraycline Hydrochloride, Sodium Suiphacetarnide, Pilocarpine, Hydrocortisone, lodoxouridine, Timolol, Acetazolmidê, Atropine, Homatropine

IV. Programme for Prevention of Dehydration under ORT

Oral Rehydration Salt

V. National Malaria Eradication Programme

Chloroquine, Amodiaquine, Quiinine, Primetheamine, Sul phamethopyrezine, Paracetamol

IV. National Filaria Eradicaion Programme

Diethyl Carbamazine

THE SECOND SCHEDULE

BULK DRUGS

List of Bulk Drugs (including salts, esters and derivatives, if any) used in Category II Formulations appearing in Third Schedule.

Aspirin, Amoxycillin, Ampicihin, Amiloride, Aluminium Hydroxide, Amitryptihine, Aminophylline, Baralgan Ketone, Bephenium, Benzathine Benzylpenicillin, Betamethasone, Chiorpheniramine, Cyproheptadine, Carbamazepine, Chioroquine, Cephalexin, Chloramphenicol, Cloxacillin, Cetrimide, Cemetidine, Carbimazole, Chiorpromazine, Calcium Pantothe nate, Chiorhexidne, Dextropropoxyphene, Dexamethasone, Diazepam, Dehydroemetine, Diloxanide, Doxycycline, Digoxin, Dihydralazine, Dipyridamole, Dopamine, Dichioro Meta Xylenol, Diphenoxylate, Epinephrine, Ethosuximide, Erythromycin, Ethionainide, Ergotamine, Ergometrine, Ephedrine, Framycetin, Folic Acid, Frusemide, Furazolidone, Flurazepam, Gentamycin, Griseofulvin, Glyceryl Trinitrate, Glibenclamide, Hydroxycobalamine/Cyanocobalamine, Heparin, H ydralazine, Hydrochlorothiazide, Hydrocortisone, Hepatitis-B Vaccine, Ibuprofen, lodochiorohydroxyquinoline, Eron Dextran, Isoprenaline, Isosorbide Dinitrate, Insulin, Imipramine, Ketoprofen, Lidocaine/Xylocaine, Levamisole, Loperamide, Lorazepam, Metamizol (Analgin), Mebhydroline, Metron idazole, Methyl Dopa, Metaclopramide, Menthol, Methyl Salicylate, Nalidixic Acid, Nitrofurantoin, nitrazepa Oxytetracycline, Oxethazine, Oxytocin, Oazepam, Pentazocine, Piroxicam, Probenecid, Pheniramine, Prednisolone, Prochlorperazine, Phenobarbitone, Phenytoin, Piperazine, Pyrental, Penicihins, Phenoxymethylpenicillin, Procaine senzylpenicillin, Protionamide, Pentainidine, Primaquine, Procainamide, Parachioro Meta Xylenol, Promethazine, Quinidine, Reserpine, Ranitidine, Salazosulfapyridine, Sulfadimidine, Sulfacetamide, Sulfadiazine, Sulfamethizole, Sulfamethoxazole, S ulfaphenazole, Sodium Stibogluconate, Sulfadoxine, Sodium Nitropruside, Spironolactone, Silver Nitrate, Salbutamol, Tetramisole, Thiabendazole, Tetracycline, Trimethoprim, Triametrene, Trifluperazine, Triflupromazine, Terbutaline, Theophylline, Valporic Acid, Verapainil, Vitamin A, Vitamin Bi, Vitamine B2, Vitamin B6, Vitamin C, Vitamin D, Vitamin E. Warfarin, Xanthinol.

Note:

All vitamins as bulk drugs are exempt from price control.

CHAPTER 7(b)

POISONS ACT, 1919

Poison Act was passed in 1919. The object of it is to consolidate and amend laws regulating the import, possession for sale and sale of poisons.

According to the provisions of the Act, the central Govt. has been empowered to regulate the importation of poisons into India. State Govts. have been empowered to make rules regarding the possession and sale of poisons within their respective territories.

Any substance specified as a poison in a rule made or notification issued under this Act is deemed to be a poison for the purpose of this Act.

IMPORT OF POISONS: The Central Govt. is empowered to prohibit any poison for importation except under and in accordance with the conditions of a licence. It may make rules to grant such licences.

Possession for sale and sale of Poisons : The rules for the whole sale or retail sale of poison provides for :—

1. The grant of licences to posses any specified poison for wholesale or retail sale and fixing of the fee to be paid for such licences.
2. The classes of persons to whom such poisons may be sold.
3. The maximum quantity of any such poison which may be sold to ny one person.
4. The classes of persons to whom alone such licences may be granted.
5. Sales registers to be maintained by the vendor of such poison. The particulars to be entered in such registers and inspection of the same.
6. The safe custody of such poisons and the labelling of vessels, packages or covering in which any such poison is sold or possessed for sale ; and

7. The inspection and examination of any such poison when possessed for sale by any such vender. The sale is not said to be completed until the registered pharmacist accepts the offer of the customers. The pharmacist can say "this drug ought not to be sold to the customer."

In the area where 'particular poison is misused for the sale of murder, mischief or suicide, the state Govt. make rules to regulate the possession of any specified poison in that particular area. Any person who contravenes that rule shall be punishable with imprisonment upto one year or with fine which may extend to Rs. 1000/- or with both. The poison and vessel, packages or covering concerning it will also be confused.

Penalties: Anyone who either imports or possesses or sells any poison by contravening the Act shall be punishable with imprisonment which may extend to three months or a fine upto Ra. 500/- or both on first conviction : and with imprisonment upto 6 months or a fine upto Rs. 1000/- or both on any subsequent conviction.

CHAPTER 7(c)

THE MEDICINAL AND TOILET PREPARATIONS (Excise Duties) Act and Rules

Introduction The medicinal and Toilet preparations Act was passed in 1955 and the Rules were passed in 1956 to provide for the collection of levy and collection of duties of excise on medicinal and toilet preparations containing alcohols, narcotic drugs or narcotics, The Act extends to whole of India. It came into force on 1st April, 1957. Before the enactment of this Act, difference in the rates of excise duty for the same item was different in different states. As a result of which smuggling of such preparations on which excise duty varied was done on the large scale. In order to stop all these unwnated activities this Act was passed. Laws of the state related to excise duties was repealed.

LICENSING PROCEDURE:

1. Licence for the alcoholic preparation and narcotics or narcrotic drugs can be issued only to those applicants, who have licence to manufacture Drugs under the Drugs & Cosmetics Act and Rules.

2 An application is made to the Excise comissior in the case of a bonded manufactory or ware-house in other cases it is made to the officer authorised by the state Govt. in this behalf.

3. A separate application is to be made if more than one kind of licence is required. In case of more than one place of business, separate licence is to be obtained for each place.

4. The application should be made in the prescribed form accompanied with the prescribed fee at least two months ahead of the commencement of the manufacture.

LICENCE FEE

Purpose of licence	Licence fee In- bond	for manufacture Outside bond
1. Allopathic medicinal preparations and toilet preparations containing alcohols consumption of alcohol is		
(i) 125 LP. litres of less per annum		Rs. 10/-
(ii) more than 125 LP. litres but less than 500 LP. litres per annum		Rs. 25/-
(iii) 500 LP. litres or more per annum		Rs. 200/-
(iv) Less than 4000 L.P. litres per annum,	Rs. 100/-	
(v) more than 4000 L.P. litres per annum	Rs. 200/-	
2. Non alcoholic medicinal and toilet preparation containing opium, Indian hamp, or other narcotic drug narcotic.	Rs. 10/-	Rs. 10/-
3. Medicinal preparations in Ayurrvedic, Unani or other indigenous systems of medicines containing alcohol and which are prepared by distillation or so which alcohol has been added.	Rs. 25/-	Rs. 25/-

4. Bonded warehouse	Rs. 25/-	
5. Manufacture of medicinal preparations combining alcohol by hospitals, dispensaries and other charitable institutions eligible for exemption from duty.	NIL	

On receipt of the application, the Licensing authority may enquire into the following :—

1. The qualifications and previous experience of technical personel engaged in the manufacturing operations:
2. The equipment of the bonded and non-bonded laboratory.
3. Soundness of the applicant's financial position ; and
4. Suitability of the proposed building for the establishment of manufactory.

On being satisfied, the Licensing authority may issue the licence for the mfr. in band or mfr. outside bond.

Cotiditions of Licence:

1. The licence can not be sold or transferred.
2. It should be exhibited at the prominent place in the licenced premises.
3. If a licensee sells or transfers his business, the purchaser or the transferee has to obtain a fresh licence. For the remaining period covered by the licence, no fee in charged.
4. If a licensee desires to transfer his business to new place, he should inform the Licensing authority at least 15 days in advance, and get his licence suitably amended.
5. Any correction in the licence is valid only if ordered and atterted by the licensing authority.
6. A licence can be revoked or suspended by the licensing authority if the licensee or any other person in his employment is found to have committed a breach of the prescribed conditions or of any of the provisions of the Act or Rules.

7. The licence remains valid for a period of one year and should be renewed. There after. The application should be given for the renewal at least one month before the commecement of the year to which it relates.
8. The licensee is also required to provide a visit book paged and stamped by any officer empowered by the Excise Commissioner in this behalf in which the visiting officers may record any remarks when inspecting the premises.
9. On termination of the period of the licence, the licensee has to deliver the visit book, the account and the licence to such officer as directed by the licensing authority.
10. All invoices, cash memos, perm t and other documents relating to the oonsignments received and dealt with by the licensee are to be preserved for a year after the year to which they relate.

MANUFACTURE

Manufacture of medicinal and Toilet preparations are either done under manufacture in Bond or Manufacture outside Bond. In the case of manufacture In-Boad, alcohol (on which duty has not been paid), is to be used under excise supervision and in the case of, manufacture outside bond, only alcohol on which duty has been paid, has to be used.

Manufacture In Bond or Bonded Manufactory:

The manufacturer enters into a bond with sufficient sucurity towards due payment of excise duty and observance of the rules.

Following provisions should be provided in a Bonded manufactory:

1. One plain spirit store unless the manufactory is attached to a distillary or a spirit warehouse:
2. One large room for the preparation of medicinal preparations, and one large room for toilet preparations.
3. There should be separate store room for storing the finished products of medicinal preparations and Toilet preparations.
4. Accomodation, with necessary furniture, near the entrance is provided for the excise officer-in-charge.

5. Every window is provided with, three quarter inch thick maleable iron rods, embodied in brick. From insides it is covered with. Strong metal mesh.
6. Each room is provided with a name board and a serial number.
7. All pipes from the sinks and basins shall be directly connected to the general drainage system.
8. The gas and electric connections are arranged in such a way that the supply can be cut off at the end of the day's work. The regulators and switches are securely locked.
9. The permanent vessels are provided for the storage of alcohol, Naroctics and finished products.
10. No addition or alteration shall be made in the licensed premises without the previous order of the Excise Commissioner.
11. The bonded premises shall be opened only, in the presence of th excise officer-in-charge.

Procurement of Rectified Spirit :

1. The licensee of the bonded manufactory shall make indent in Form I.D. 1 in triplicate, for the rectified spirit, to the approved distillery or spirit warehouse.
2. The indents shall be countersigned by the officer-in-charge.
3. The original shall be sent by the licensee to the distillary.
4. The duplicate shall be sent through the officer-incharge to the distillary or spirt warehous officer.
5. The triplicate is retained with the licensee.
6. Officer of the distillary or spirit warehouse, on receiving the duplicate copy of the indent, shall issue the spirit in duly sealed containers and send on advice of the consignment to the officer-in-charge.
7. Consignments of spirt received under bond have to be verified in volume and strength at the bonded laboratory and the amount entered in a register maintained for the purpose. The spirit should than be stored in the spirit store.

ISSUE OF RECTIFIED SPIRIT FROM THE SPIRIT STORE

1. The licensee shall keep ready all the ingredients of the preparation to be mixed with spirit.
2. The licensee shall calculate the required quantity of spirit. He shall make the requisition for spirit in Form R.Q. 1. to the officer-in-charge.
3. The officer-in-charge issues the spirit.
4. The issued spirit shall be mixed in the preparation as soon as possible in the presence of the officer-in-charge.
5. After the completion of the manufacture, the preparations shall be stored in the permanent vessels and in the finished product store.
6. A separate account of spirit used, shall be maintained. The entries shall be signed by the officer-in-charge.

MANUFACTURE OUTSIDE BOND

The manufacture and sale in a non-bonded manufactory has to be conducted between sunrise and sunset and on such days and hours as fixed by the Excise Commissioner.

PROVISIONS OF NON-BONDED MANUFACTORY

1. There should be a spirit store, a laboratory and a finished store each having one door and only one enterance to the non- bonded laboratory.
2. Construction of the windows and other provisions are same as mfr. in-bonds or Bonded manufactory.
3. Spirit store and finished store should be separate for the rectified spirit purchased at different rates and preparation made from such spirits.
4. Any alteration in the arrangement of licensed premises, plant can be made only with the previous sanction of the Excise commissioner.
5. The state Govt. may relax all or any of these provisions in the case of small manufacturers whose annual consumption of alcohol does not exceed 100 galloons and also in the case of

those who prepare medicinal preparations for dispensing to their patients only and not for sale.

6. Suitable vessels should be provided for the storage of alcohols and finished preparations.
7. Permanent vessel, macerators and percolators and filled bottles should be labelled adequately.

PROCURING DUTY PAID SPIRIT

1. An indent is prepared in triplicate. The original is sent to the distiller or spirit warehouse keeper from where the spirit is to be procured. The duplicate copy accompanied with the Treasury challan of the duty paid in the Govt. Treasury is sent to the officer-in-charge of the distillery or spirit warehouse and the triplicate is retained by the licensee.
2. The treasury officer sends an advice to the officer-in- charge of the distillary or the spirit warehouse who shall issue the spirit together with a permit covering the issue.
3. The spirit brought in the non-bonded manufactory should be immediately transferred to the spirit store and account is maintained in the prescribed register.
4. The manufacturer can not sell or transfer the rectified spirit obtained by him. In any case the quantity of the rectified spirit should not exceed the limit fixed by the licensing authority.

MANUFACTURE, STORAGE AND SALE

1. The manufacture, storage and sale should be carried out at licensed premises only.
2. Each preparation should be registered and bear a Batch No.
3. All finished preparations should be transferred from the 'laboratory' to the 'finished stose' and be so arranged that the checking of stock of every batch of preparation from the register is facilitated.
4. Preparations stored in bulk should be measured into the storage vessel to the nearest fluidounce and sealed.
5. The quantities, taken out from time to time, should be entered in the stock card maintained for the purpose.

CHAPTER 7(d)

MEDICAL TERMINATION OF PREGNANCY ACT AND RULES

The MTP Act was passed in 1971 and the Rules in 1975. It provides for the termination of certain pregnancies by RMP and related matters. The Act extends to whole of India except the state of Jammu & Kashmir.

Termination of Pregnancies: When the length of pregnancy does not exceed 12 weeks and the RMP is of the opinion that:

(i) the continuance of the pregnancy would involve a serious risk to the life of the pregnant women or of grave injury to physical or mental health ; or

(ii) there is a substential risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.

When the length of pregnancy exceeds 12 weeks but does not exceed 20 weeks and if not less than two RMPS are of the opinion that as stated in point no. (i) & (iii) above.

But this provision shall not apply to the termination on of pregnancy by an RMP in cases where he is of the opinium that the termination of such pregnancy is immiediately necessary to save the life of the pregnant woman.

Where pregnancy is causd by rape, the mental tension due to the pregnancy may constitute grave injuiry to the mental health of the pregnant woman.

In case of failure of any device used by the married couple for limiting the size of the family, may constitute a grave injury to the mental health of the pregnant woman.

For determining whether the continuance of the regnancy will lead to grave injury to her physical or mental health, the pregnant womans environment should be taken into account.

No pregnancy shall be terminated without the consent of pregnant woman except when;

(a) the pregnant woman is less than 18 yrs. in age or

(b) the pregnant woman in a lunetic although she has attained the age of 18 yrs.

Termination of the pregnancy shall be made only at the following places:

(a) a hospital established or maintained by Govt.

(b) an approved place for this purpose by the Govt.

No suit can lie againt any RMP for any damage caused or likely to be caused by anything which is done in good faith under this Act.

Admission Register: Every head of the hospital or owner of the approved place shall maintain an admission register. It is maintained serially year wise e.g. 6/1994. It is a secret document. it's matter can be disclosed, only when asked by the law.

The RMP can issue a certificate of employed woman whose pregnancy has been terminated for obtaining leave from the employer. The employer should also not disclose the same to any other person.

Penalties. Any person who wilfully contravens or wilfully fails to comply with the requirements of any regulation shall be liable to be punished with fine which may extend to Re. 1000/- only.

IMPORTANT QUESTIONS AND THEIR ANSWERS

1. Define Ethics. Explain in detail the code of pharmaceutical ethics as has been given by pharmacy council of India.

Ans. See Page No. 14-18.

2. Discuss the constitution and functions of pharmacy council of India.

Ans. See Page No. 19-23.

3. Give an account of Education Regulation. What are the duties of an Inspector appointed for the inspection of an Institution for its approval.

Ans. See Page No. 22-26.

4. Write short notes on:

(a) The pharmacy Act

(b) The central Register of Pharmacists.

Ans. (a) See Page No. 19.

(b) See Page No. 26-27.

5. In what manner the state pharmacy council is constituted under the pharmacy Act? What are the functions of it?

Ans. See Page No. 27-30.

6. What do you understand by the Resistered pharmacist ? What qualifications will entitle a person to have his name registered as pharmacist on FIRST and SUBSEQUENT REGISTER?

Ans. See Page No. 28-31.

7. Under which circumstances and In what manner can the name of a pharmacist be removed from the register of pharmacists ? Describe, the rights and method of reappeal

Ans. See Page No. 30—33.

8. Write short notes on:

(a) Penalties for Dispening by unregistered person

(b) Approval of qualification granted outside India for registration as Pharmacist.

(c) Penalties for falsely claiming to be a Registered pharmacist.

Ans. (a) See Page No. 32.

(b) See Page No. 23.

(c) See Page No. 32.

9. Write short notes on:

(a) Drugs Technical Advisory Board

(b) Drugs consultative committee

(c) Central Drugs Laboratory.

Ans. (a) See Page No. 37.

(b) See Page No. 38.

(c) See Page No. 39.

10. What are the qualifications and duties of Govt. Analyst ? What are the penalties for advertising the report of Govt. Analyst?

Ans. See Page No. 40-42.

11. What are the qualifications and duties of Drugs Inspector? Discuss the power and procedure of Inspection of Drugs Inspector.

Ans. See Page No. 42-46.

12. Write short notes on:

(a) Import of Drugs for personal use (page no. 50-51).

(b) Import of Drugs for Examination, Test or Analysis (50)

(c) Import of Schedule D drugs (page no. 52).

13. Outline the procedure that is followed for obtaining a licence for the maufacture of Biological products (Schedule C & C_1). Discuss the conditions of the licence.

Ans. See Page No. 55-60.

14. Write short notes on

(a) Loan Licence

(b) Repacking Licence

(c) Restricted Licence

Ans. (a)See page No. (a) 57-58.

(b) See page No. (a) 59.

(c) See page No. (a) 62.

15. Discuss the manner of Labelling under the provisions of Drugs and cosmetics Act & Rules.

Ans. See Page No. 71-73.