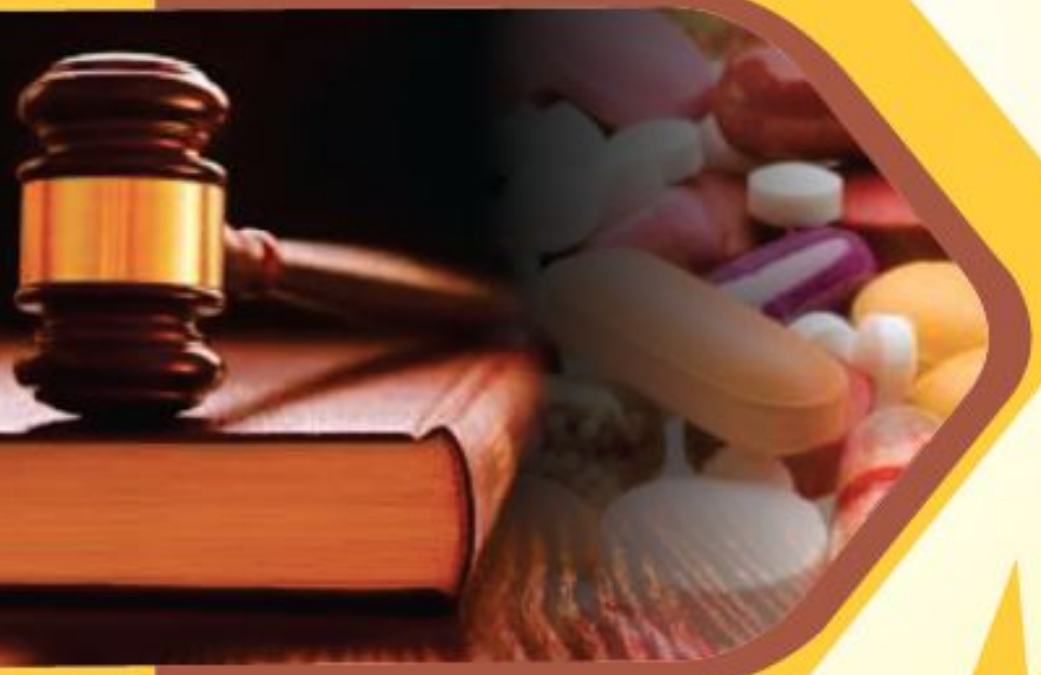
AS PER PCI REGULATIONS
THIRD YEAR B. PHARM

SEMESTER-V

PHARMACEUTICAL JURISPRUDENCE

SANDEEP D. S.
SHABANA S.
Dr. R. NARAYANA CHARYULU



NIRALI PRAKASHAN
ADVANCEMENT OF KNOWLEDGE

A Text Book of

PHARMACEUTICAL JURISPRUDENCE

As Per PCI Regulations

THIRD YEAR B. PHARM.
SEMESTER V

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Preface

Pharmaceutical Jurisprudence is the study of basic pharmaceutical laws and regulations. It is the basic subject where pharmacy students should be informed about various acts and legislative principles related to the profession of pharmacy in India and as well as the pharmaceutical industry.

A Text Book of Pharmaceutical Jurisprudence is the outcome of numerous efforts of authors to assimilate the voluminous knowledge of Jurisprudence. The present book has compiled all the topics which were included in the new revised syllabus for Semester-V of Third Year of the B. Pharm course implemented by Pharmacy Council of India regulations, New Delhi.

The book is designed to have 05 units, divided into 13 parts with simple and lucid language. The authors tried to include objectives of each topic explaining the study outcomes once the students understand the topics. Apart from the basic topics, the two new topics RTI Act and IPR concepts were also included with latest information and implementations.

The authors are delighted since it is a first attempt to write this book and hope the readers; teachers, students and the people working in pharmaceutical industries will be benefitted and may get the required information from the sources of the text book.

The Authors convey the deep sense of gratitude to their family and fellow teacher colleagues who always remained as a force behind writing this book.

The authors would like to thank the authorities of NGSM Institute of Pharmaceutical Sciences, Nitte (Deemed to be University), Deralakatte, Mangalore and East West College of Pharmacy, Bengaluru for positive and constant support.

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Any suggestions and comments for further improvements from students and teachers are welcome and will be thankfully acknowledged.

Authors

Syllabus

UNIT - I — 10 Hours

Drugs and Cosmetics Act, 1940 and Its Rules 1945

Objectives, Definitions, Legal Definitions of Schedules to the Act and Rules

Import of Drugs – Classes of Drugs and Cosmetics Prohibited from Import, Import under license or permit. Offences and Penalties.

Manufacture of Drugs – Prohibition of Manufacture and Sale of Certain Drugs,

Conditions for Grant of License and Conditions of License for Manufacture of Drugs,

Manufacture of Drugs for Test, Examination and Analysis, Manufacture of New Drug, Loan License and Repacking License.

UNIT - II — 10 Hours

Drugs and Cosmetics Act, 1940 and Its Rules 1945

Detailed Study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA).

Sale of Drugs – Wholesale, Retail Sale and Restricted License. Offences and Penalties.

Labeling and Packing of Drugs - General Labeling Requirements and Specimen Labels for Drugs and Cosmetics, List of Permitted Colours. Offences and Penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government Drug Analysts, Licensing Authorities, Controlling Authorities, Drugs Inspectors.

UNIT - III — 10 Hours

- **Pharmacy Act, 1948:** Objectives, Definitions, Pharmacy Council of India; its Constitution and Functions, Education Regulations, State and Joint State Pharmacy Councils; Constitution and Functions, Registration of Pharmacists, Offences and Penalties
- **Medicinal and Toilet Preparation Act, 1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of Alcoholic Preparations, Manufacture of Ayurvedic, Homeopathic, Patent and Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of Narcotic and Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, Opium Poppy Cultivation and Production of Poppy Straw, Manufacture, Sale and Export of Opium, Offences and Penalties.

UNIT - IV — 08 Hours

- **Study of Salient Features of Drugs and Magic Remedies Act and Its Rules:** Objectives, Definitions, Prohibition of Certain Advertisements, Classes of Exempted Advertisements, Offences and Penalties.
- **Prevention of Cruelty to Animals Act, 1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of Animals for Experiment, Records, Power to Suspend or Revoke Registration, Offences and Penalties.
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO), 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail Price and Ceiling Price of Scheduled Formulations, National List of Essential Medicines (NLEM).

UNIT - V — 07 Hours

- **Pharmaceutical Legislations:** A Brief Review, Introduction, Study of Drugs Enquiry Committee, Health Survey and Development Committee, Hathi Committee and Mudaliar Committee.
- **Code of Pharmaceutical Ethics:** Definition, Pharmacist in relation to his Job, Trade, Medical Profession and his Profession, Pharmacist's Oath.
- **Medical Termination of Pregnancy Act.**
- **Right to Information Act.**
- **Introduction to Intellectual Property Rights (IPR)**.

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UNIT I

Chapter ... 1

DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- ❖ About the compilation of Drug and Cosmetic Acts 1940 and Rules 1945.
- ❖ Regulation of import, manufacture, sale and distribution of drugs and cosmetics.
- ❖ To avoid substandard drugs and to maintain high standards of drugs and cosmetics.

1.1 INTRODUCTION

The Central Legislative Assembly passed the Drugs and Cosmetics Act 1940 and rules 1945 with an objective to regulate the import, manufacture and distribution and sale of drugs and cosmetics. It is applicable on Allopathic, Homeopathic, Unani and Siddha drugs as well on contraceptives, mosquitoe repellents, creams, lotions, cosmetics and devices used for internal and external use for diagnosis. Under this Act, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central authorities are responsible for approval of New Drugs, Clinical trials in the country, laying down standards for Drugs, control over the quality of imported drugs, co-ordination of the activities of Drug Control Organization and providing expert advice with a view of bringing about uniformity in the enforcement of Drug and Cosmetic Act.

1.2 OBJECTIVES

1. The Drugs and Cosmetics Act 1940 provides the Central legislation, which regulates import, manufacture, distribution and sale of drugs and cosmetics in the country.
2. The main objective of the Act is to ensure that the drugs available to the people are safe and efficacious and the cosmetics marketed are safe for use.

3. The D and C Act regulates the manufacture and import of drugs into India so that no substandard or spurious drugs get manufactured and imported in and into India respectively.
4. This provides the regulation of sale and distribution of drugs and cosmetics whereby only qualified and trained persons can undertake their handling, compounding and distribution.
5. This Act also provides the constitution of two boards namely, the **Drug Technical Advisory Board (DTAB)** and **Ayurvedic and Unani Drugs Technical Advisory Board** to advise the Central and State governments on technical matters arising out of the administration of this act.
6. It also provides the establishment of two **Drugs Consultative Committees (DCC)**, one for allopathic and the other for Ayurvedic, Siddha, Unani drugs to advise the various Governments and Boards on matters tending to secure uniformity throughout the country in the administration of the act.

1.3 DEFINITIONS

Drug:

(i) All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

(ii) Such substances (other than food) intend to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals.

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

(iv) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

Ayurvedic, Siddha or Unani Drug:

It includes all medicines intended for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of disease or disorder in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb system of medicine, specified in first schedule.

Misbranded Drugs:

A drug shall be deemed to be misbranded:

(i) If it is so colored, 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) If it is not labelled in the prescribed manner; or

(iii) If its 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.

Adulterated Drugs:

A drug shall be deemed to be adulterated:

(i) If it consists, in whole or in 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 contaminated with filthy or 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 coloring 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 or strength.

Spurious Drugs:

A drug shall be deemed to be spurious:

(i) If it is manufactured 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 or conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(iii) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, 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.

Drug Inspector:

A Drug Inspector appointed by the Central Government or a State Government who is an expert and qualified to monitor the safety, utility, efficacy and quality of a drug from its manufacturing till its sale at the retail shop.

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 cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

Misbranded Cosmetics:

A cosmetic shall be deemed to be misbranded:

(i) If it contains a colour which is not prescribed; or

(ii) If it is not labelled in the prescribed manner; or

(iii) If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious Cosmetics:

A cosmetic shall be deemed to be spurious:

(i) If it is imported under a name which belongs to another cosmetic; or

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

(iii) If the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(iv) If it is an imitation of, or is a substitute for, another drug or re-not truly a product.

Drug Store:

Licensed premises for the sale of drugs, a retail store which do not require the services of a qualified person and sells both prescription and non-prescription drugs.

Pharmacy:

Licensed premises for the sale of drugs, which require the services of a qualified person but where the drugs are not compounded against prescriptions.

Qualified Person:

(i) He is a person holding diploma or degree in Pharmacy or Pharmaceutical Chemistry; or

(ii) Is a registered pharmacist, (under Pharmacy Act, 1948); or

(iii) Has minimum 4 years experience of dispensing and has been approved by licensing authority as a 'Qualified Person' on or before 31st Dec 1969.

Government Analyst:

A Government Analyst appointed by the Central Government or a State Government who shall analyse or test or cause to be analysed or tested such samples of drugs as may be sent to him by Inspectors or any other persons or authority authorised by the Central Government or a State Government and shall furnish reports of the results of test or analysis in accordance with these rules.

Further, shall from time to time forward to the Government reports giving the results of analytical work and research with a view to their publication at the discretion of the Government.

Manufacture:

In relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, 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 drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

Import:

Means to bring into India.

Patent or Proprietary Medicine:

In relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha of Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books.

In relation to any other systems of medicine, a drug for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia or any other Pharmacopoeia or official books.

Homeopathic Medicines:

It includes any drug and whose therapeutic efficacy has been established through long clinical experience as recorded in authoritative Homeopathic literature, prepared according to the techniques of Homeopathic pharmacy. It does not include medicines, administered by parenteral route.

1.4 SCHEDULES TO THE ACT AND RULES

1.4.1 Schedules to the Act

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

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

1.4.2 Schedules to the Rules

Sr. No.	Schedules	Significance
1.	A	**Forms** and formats of letters for applications of **licensing** etc.
2.	B	**Fee** structure for drug analysis by **CDL** (Central Drug Laboratory) or by the Govt. Analyst.
3.	C	Biological and special products for **parenteral administration**. Examples: Antibiotics, Vitamins, Bacteriophages, Surgical dressings and Opthalmic preparations whose import, manufacture, sale and distribution are governed by special provisions.

Sr. No.	Schedules	Significance
4.	C_1	Other special products for **non-parenteral** administration. Examples: Digitalis drugs, Ergot drugs, Adrenaline, Fish liver oil, Hormonal preparations whose import, manufacture, sale and distribution are governed by special provisions.
5.	D	Drugs **exempted** from the provision of **import of drugs**.
6.	E_1	**Poisonous** substances under Ayurvedic, Siddha and Unani system of medicines.
7.	F & F_1	Special provisions applicable for the production, testing, storage, packing and labelling of biological and other special products.
8.	F_2	Standards of **surgical** dressings.
9.	F_3	Standards of sterilized **umbilical** tapes.
10.	FF	Standards for **ophthalmic** preparations.
11.	G	Various drugs/ substances to be used under the **medical supervision**.
12.	H	Various drugs to be sold on the **prescription of an RMP** (Registered Medical Practitioner).
13.	J	Various **ailments** (diseases) **that cannot be treated** by any drug currently in market.
14.	K	Various substances and drugs exempted from provisions related to manufacture of drugs.
15.	M	Regulations for manufacturing, premises, waste disposal, requirements of plant and equipments (**Good Manufacturing Practices**).
16.	M_1	Requirements for factory premises, etc. for the **manufacture of Homeopathic drugs**.
17.	M_2	Requirements for factory premises for the **manufacture of cosmetics**.
18.	M_3	Requirements for factory premises for the **manufacture of medical devices**.
19.	N	Regulations and minimum **requirements to run a pharmacy**.
20.	O	Regulations and requirements for **disinfectant fluids**.
21.	P	Regulations regarding **life period** and storage of various drugs.
22.	P_1	Regulations regarding retail package size of various drugs.
23.	Q	List of **permitted dyes** and coal tar colours in cosmetics.

Sr. No.	Schedules	Significance
24.	**R**	Standards for condoms and other mechanical **contraceptives**.
25.	**R_1**	Standards for medical devices.
25.	**S**	Various cosmetics and toiletries, and directs the manufacturers of cosmetics to confirm to the latest BSI (**Bureau of Indian Standards)** requirements.
26.	**T**	Regulations and requirements for factory premises and manufacture of Ayurvedic, Siddha and Unani products.
27.	**U**	Maintenance of manufacturing and analytical **records** of **drugs**.
28.	**U_1**	Maintenance of manufacturing and analytical **records** of **cosmetics**.
29.	**V**	Standards for **patent and proprietary** medicines.
30.	**W**	List of drugs which can be marketed under **generic names** only.
31.	**X**	List of drugs which are **habit forming**, **psychotropic** and other drugs likely to be misused for addictive purposes.
32.	**Y**	Requirement and guidelines for **clinical trials.**

1.5 IMPORT OF DRUGS

Prohibition of Import of Certain Drugs or Cosmetics:

Following Drugs and cosmetics cannot be imported:

1. Any drug or cosmetic which is not of standard quality;
2. Any misbranded or spurious or adulterated drug or cosmetics;
3. Any drug or cosmetic without import license, for the import, for which an import license is prescribed.
4. Any patent or proprietary medicine, which has not displayed the true formula or list of active ingredients with their quantities as per the label.
5. Any drug which claims to cure or prevent any disease or ailments specified in Schedule J.
6. Any cosmetic or drug containing any ingredient, which is unsafe or harmful.
7. Any drug or cosmetic whose manufacture, sale, distribution and import of which is prohibited by rule made under this act, except for the purpose of examination, test or analysis.
8. Drugs not labelled in the prescribed manner.
9. Drugs after the expiry, and those which does not meet the standards, quality and purity specified in the schedule-F.

Import of Drugs under License:

The following classes of drugs can be imported under the license 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. Minor quantities of drugs imported for the examination, test or analysis.
4. Drugs for personal use covered by a prescription of RMP.
5. Any new drug.
6. An application for an import License shall be made to the licensing authority by the manufacturer or by the manufacturer's agent in India and shall be accompanied by a License fee of ₹ 1,000 for a single drug and ₹ 1,000 for each additional drug, duly signed by or on behalf of the manufacturer.

Sr. No.	Type of Import License	Form Number	
		Application	License
1.	Drugs other than Schedule X drugs	8	10
2.	Schedule X drugs	8-A	10-A

7. Any application for import license in Form 8 or 8-A, shall be accompanied by a copy of Registration Certificate issued in Form 41; in the case of emergencies, the issue of Import License by the central government in Form 10 or 10-A without issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.
8. The License remains valid upto 31st Dec of the year following the year in which its granted unless cancelled or suspended earlier.
9. The importer should have proper storage facilities for preserving imported drugs and properties.
10. A fee of ₹ 250 shall be paid for a duplicate copy of license, if the original is defaced, damaged or lost.

Registration Certificate:

'Registartion certificate' means, certificate issued under Rule 27-A, by the licensing authority in Form-41, for the registration of premises and drugs manufactured by the manufacturer for import into and use in India.

1. A fee of ₹ 1,000 and US $ 500 dollars shall be paid through a Challan along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import and use in India.
2. A fee of US $ 300 dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged.

Suspension and Cancellation:

Both the Import License and Registration Certificate will be suspended or cancelled, if the manufacturer or licensee fails to comply with any of the conditions. The licensing authority may after giving the manufacturer or licensee, an opportunity to show cause why such an order should not be passed, by an order in writing the reasons and further take measures for the same. The reasons for the cancellation may be:

1. The drugs in the schedule C and C_1 are prohibited for import into the country after the expiry of potency of the drug product.
2. If the drug is banned in the country of origin then it is prohibited from importing into the country except for the purpose of examination, test or analysis.

Conditions of Import License:

An Import License is subject to the following conditions:

1. The licensee must observe at all the times the undertaking given by him or on his behalf in Form 9:
2. The licensee must allow any authorized Inspector to:
   (i) Enter the licensed premises where imported drugs are stored.
   (ii) Inspect the substances employed for testing.
   (iii) Take samples.
3. The licensee must furnish the adequate quantity of sample from the required batches to the licensing authority for examination along with complete protocols of the test applied.
4. If licensing authority so directs, until receipt of Certificate of Authorization, the licensee must not sell any batch products to which samples are submitted to the licensing authority.
5. The licensee must maintain the record of all sales of imported substances as prescribed under the rules, and should furnish the same during the inspection.
6. The licensee must maintain separate records for the sale or distribution of Schedule-X drugs.
7. Licensee must also comply with such further requirements, prescribed by the authority and of which he has been given not less then four months of notice.

Import of New Drugs:

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

3. An application for an import License for small quantities of a new drug, as defined in rule 122-E for the purpose of treatment of patient.
4. Every application in Form 12-AA shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.
5. The fees shall be paid through a challan in the Bank of Baroda.
6. A License for import of small quantities of a new drug, defined in rule 122-E, for the purpose may be cancelled by the licensing authority for the conditions subject to which the License was issued. If so, the licensee may appeal to the Central Government within three months of the date of the order of cancellation.

Import of Drugs for Examination, Test or Analysis:

1. The drug is imported under a license in Form-11.
2. The drug must be exclusively examined in the place specified in the license by the licensing authority.
3. An authorized inspector must be allowed to investigate the manner in which imported substances are used; thereof allowed to take the samples.
4. The record of the imported substances along with their quantities, the date of importation and the name of manufacturer should be maintained and reported to the authority.
5. The licensee must comply with any further requirements as may be specified by the authority, and of which the licensing authority has given, to him not less than notice of a month.
6. In case if the license is cancelled, the licensee may appeal to the Central Government within three months of the date of the order of cancellation.

Import of Drugs or Cosmetics for Personal use:

Import of drugs which are otherwise prohibited under section 10 of the act can be imported on following conditions:

1. Drugs or cosmetics must be a part of a passenger's bonafide baggage and must be intended for the exclusive personal use of the passenger.
2. They must be declared to the custom collector, if so directed.
3. The quantity of any single drug so imported must not exceed hundred average doses.
4. Any drug or cosmetic not forming the part of passenger's baggage, may be allowed to import to an application made to the licensing authority in form 12-A.
5. If the licensing authority is satisfied, a permit is granted in Form 12-B.

***Note: Places through which Drugs may be imported into India:**

1. Ferozpur Cantonment and Amritsar Railway Stations: by rail (across the frontier with Pakistan).
2. Ranaghat, Bangaon and Mohiassan Railway Stations: by rail (across the frontier with Bangladesh).
3. Chennai, Calcutta, Mumbai and Cochin: by sea
4. Chennai, Calcutta, Mumbai, Delhi and Ahmedabad: by air

Offences and Penalties Relating to Import of Drugs:

Sr. No.	Offence	Penalties	
		First conviction	Subsequent conviction
1.	Import of adulterated or spurious drugs or cosmetics or any cosmetic containing any ingredient which may render it unsafe or harmful for the use under directions recommended.	Imprisonment upto 3 years and fine upto ₹ 5000.	Imprisonment upto 5 years or fine upto ₹ 10,000 or both.
2.	Import of drugs or cosmetics other than referred above the import of which is prohibited.	Imprisonment upto 06 months or fine upto ₹ 500 or both.	Imprisonment upto 1 year or fine upto ₹ 1000 or both.
3.	Import of drugs or cosmetics in contravention of any notification issued under section 10-A.	Imprisonment upto 3 years or fine upto ₹ 5000 or both.	

1.6 MANUFACTURE OF DRUGS

1.6.1 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 a standard quality or is misbranded, adulterated or spurious;
2. Any patent or proprietary medicine, whose formula with the quantities, is not disclosed on the lable or container;
3. Any drug which purports or claims to prevent, cure or mitigate any such disease specified in schedule 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 made thereunder;

1.6.2 Conditions for Grant of License

The license is granted, if applicant complies with the following conditions:

1. The manufacture must be conducted under active direction and personal supervision of competent technical staff (approved manufacturing chemist), as per the rules.
2. The licensee and factory premises should comply with the conditions and requirements prescribed under Schedule M respectively.
3. The applicant must provide for various operations, adequate space, plant and equipment, as per Schedule M.
4. The applicant must provide separate testing unit or quality control section with an, independent head, with adequate facilities, for the test and standardization of drugs and raw materials.
5. The applicant should make adequate arrangements for the storage of drugs, manufactured.
6. For patent and proprietary medicines, the applicant must furnish the documents and data related to claims, safety, stability, therapeutic justifications etc., as per the rules.

After completion of inspection, Drug Inspector forwards detailed report and his recommendations to the Central Licensing Authority.

1. On receipt of application in the prescribed form along with fees for grant or renewal of license by the applicant, the authority verifies the statement, post performance of the licensee and the above requirements. Thereafter, the Licensing authority on necessary enquiries and satisfaction, grants the license to the applicant in the prescribed form.
2. If Licensing authority is of the opinion that applicant is incapable to fulfill the requirements, it may refuse to grant or renew the license.

1.6.3 Types of Licenses for Manufacture of Drugs

Sr. No.	Classes of Drugs	Form of Application	Form of License
1.	Other than Schedule C, C_1 and X	24	25
2.	Schedule X	24-F	25-F
3.	Schedule C and C_1	27	28
4.	Schedule C, C_1 and X	27-B	28-B
5.	Loan License (other than Schedule C, C_1 and X)	24-A	25-A
6.	Loan License (only Schedule C, C_1)	27-A	28-A
7.	Repacking License (other than Schedule C, C_1 and X)	24-B	25-B
8.	Large volume parenterals, sera and vaccines	27-D	28-D

1.6.4 Conditions of License for Manufacture of Drugs

Manufacture of Schedule C, C_1 and X Drugs:

Following are the general conditions of license of schedule C, C_1 and X drugs in Form 28-B and 28-D; other than schedule C and C_1 drugs in Form 25; Schedule X drugs-Form 25-F.

Sr. No.	Licensee must
1.	provide and maintain staff, premises and equipments (as per Schedule M and Schedule M_3 for medical devices).
2.	test raw materials and final products of each batch either in the laboratory approved by the licensing authority.
3.	maintain records of manufacture and testing of each batch as per schedule U.
4.	allow Drug Inspector to enter and inspect, premises, plant, process of manufacture, means of standardization and tests.
5.	allow Drug Inspector to inspect all the registers and records maintained under the rules and to take samples of manufactured drugs.
6.	provide the required information to Drug Inspector for ascertaining compliance for provisions of Act and Rules.
7.	time to time report to the licensing authority: (i) Changes in expert staff responsible for manufacture or testing. (ii) Material alterations in premises or plant. (iii) samples of desired drugs and complete protocols of tests applied.
8.	not sell any batch, sample of which is submitted to the licensing authority, until receipt of Certificate of authorization is issued.
9.	withdraw from sale remainder of any batch or recall drugs already issued, if licensing authority directs to do so.
10.	not sell any drug manufactured under the license unless due precautions, necessary for preserving its properties, are taken throughout the period after manufacturing, also must maintain such quantities of reference samples.
11.	comply with the provisions of Drugs and Cosmetics Act, 1940, rules thereunder and such further requirements time to time published in Official Gazette.
12.	maintain an "Inspection Book" in Form 35, to record impressions and defects noticed by Drug Inspectors.
13.	comply with requirements of "Good Manufacturing Practices" as per schedule M.

14.	The licensee having license to manufacture schedule C, C_1 and X drugs in Form 28-B must, (i) forward to the licensing authority every 3 months, a statement of sale to the manufacturers, wholesalers, retailers, hospitals, dispensaries, nursing homes, and registered medical practitioners. (ii) maintain as prescribed under rules, accounts of all transactions as regard to use, stock, manufacture, storage and sale of schedule X drugs. (iii) store always schedule X bulk drugs separately under custody of a responsible person.

Manufacture of Drugs for Test, Examination and Analysis:

A license is required to manufacture any drug in small quantity for the purpose of examination, test or analysis purpose.

1. If a person proposing to manufacture does not hold a license to manufacture drugs specified in Schedule C and C_1 or other than Schedule C, C_1 and X, shall obtain a license Form 29 before manufacturing such drugs.
2. The licensee shall carry the manufacture and examination of drugs at the place specified in the license.
3. In case of drugs which are unsafe for use, a license in Form 29 can be granted only on producing NOC (no objection certificate) from the licensing authority.
4. Application must be countersigned by the Head of the Institution, which proposes to undertake the manufacture.
5. License remains valid for a period of 1 year, unless cancelled or suspended.
6. Any drug for the purpose of examination, shall be placed in the containers, labelled for the purpose of manufacturing it, name and address of the manufacturer. Thereafter supplied to the any other manufacturer, when necessary.
7. The licensee shall allow Inspector to inspect the premises and satisfy himself that only examination is conducted.
8. The licensee shall keep a record the quantity of drugs supplied for analysis also mainatain 'Inspection Book'.
9. The licensee shall comply with such requirements specified and of which the authority has given him not less than 1 month's notice.

Manufacture of New Drugs:

As per the Rule 122 E of the Drug and Cosmetic Rules 1945, a New Drug can be:

1. A new substance of chemical, biological or biotechnological origin; in bulk or prepared dosage form; used for prevention, diagnosis, or treatment of disease in man or animal, which except during local clinical trials has not been used in the

country; and which, except during local clinical trials, has not been recognised in the country as effective and safe.

2. A drug already approved by the licensing authority for the proposed claims, which is now proposed to be marketed with modified or new claims; or

   A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio; or

   If the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, like:

   (i) Indications.
   (ii) Dosage form (including sustained release dosage form).
   (iii) Route of Administration.

3. All vaccines shall be new drugs unless certified otherwise by the Licensing Authority.
4. A new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

Conditions of License:

1. No 'new drug' can be manufactured, prior to the approval from the licensing authority.
2. The applicant, shall submit data as given in Appendix-1 to Schedule Y, including the results of clinical trials as per the format of Appendix-2 to Schedule Y.
3. While applying for the license, applicant shall furnish the evidence certificate that the drug has already been approved.

Note: What is a Subsequent New Drug Application?

A Subsequent New Drug application is an application for approval of an already approved new drug by the Central Drugs Standard Control Organization (CDSCO). It can be made for the following cases:

1. Bulk Drug already approved in the country (approved within 4 years).
2. New drug (Formulation) already approved in the country.
3. A drug already approved and proposed to be marketed with new indication.
4. A drug already approved and proposed to be marketed as a 'New Dosage Form / New Route of Administration'.
5. A drug already approved and proposed to be marketed as a 'Modified release dosage form'.
6. A drug already approved and proposed to be marketed with Additional Strength.

All the applications for approval of New Drug, Fixed Dose Combination and Subsequent New Drug are made under Form 44 (Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial).

1.7 LOAN LICENSE

It is issued by the licensing authority, to a person who does not own, arrangements for manufacture but intends to avail the manufacturing facilities owned by another licensee.

1. In the case of pharmacy business is operating its business in more than two states then it is required to obtain a drug license in each state where the business is carried on. A separate license shall be issued in case drugs are sold at more than one place.
2. After the license is granted to the business, the licensee must ensure that all the conditions of the drug license must be complied with during business. In the case of any changes or modification in business activity authority must be informed and all the registers, records, and forms must be maintained in a specified manner.

Sr. No.	Classes of Drugs	Form of Application	Form of License
1.	Loan License (other than Schedule C, C_1 and X)	24-A	25-A
2.	Loan License (only Schedule C, C_1)	27-A	28-A
3.	Repacking License (other than Schedule C, C_1 and X)	24-B	25-B

3. The licensing authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.
4. Application for manufacture of more than ten items for each category of drug on a loan licence shall be accompanied by an additional fee of rupees three hundred per additional item specified in Schedule M and Schedule M_3.
5. The licensee shall allow Inspector to inspect the premises and satisfy himself that only examination is conducted.
6. The licensee shall mainatain 'Inspection Book' in Form 35.
7. The licensee shall comply with further requirements specified by the authority.
8. The licensee shall test each batch of raw materials used and each batch of the final product and also maintain the records of manufacture and testing of each batch as per schedule U.
9. Shall maintain the reference samples from each batch for the period of 3 years.
10. Report to the licensing authority, regarding the changes in expert staff or change in the manufacture or testing units.

11. For Schedule C and C_1 drugs, the licensee shall furnish the data of stability and date of expiry to the licensing authority.
12. If the licensing authority is satisfied that a loan licence is defaced damaged or lost or otherwise rendered useless, he may, on payment of a fee of rupees one thousand, issue a duplicate licence.

1.8 REPACKING LICENSE

1. It is granted for the purpose of breaking up any drug than those specified in Schedule C and C_1.

Sr. No.	Classes of Drugs	Form of Application	Form of License
1.	Repacking License (other than Schedule C, C_1 and X)	24-B	25-B

1. Repacking of drugs should be conducted under hygienic conditions under personal supervision of competent person, approved by the licensing authority.
2. The licensee must provide and maintain adequate arrangements for carrying out tests of drugs repacked, in the specified place by the authority.
3. The licensee shall allow Inspector to inspect the premises and to take samples of repacked drugs.
4. The licensee shall test each batch of raw materials used and each batch of the final product and also maintain the records of manufacture and testing of each batch as per schedule U. Records must be retained for 5 years from the date of repacking.
5. Licensee must allow the Inspector to inspect all the registers and records maintained.
6. The licensee shall mainatain 'Inspection Book' in Form 35.
7. Shall maintain the reference samples from each batch of repacked drugs, for the specified period.
8. Licences remain valid for a period of 5 years from the date its granted or renewed, unless suspended or cancelled.

EXERCISE

1. Define the terms 'Misbranded', Ádulterated' and 'Spurious drugs' according to the Drugs and Cosmetics act.
2. Write a note on Loan license and Repacking license.

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UNIT II

Chapter ... 2

DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- About the compilation of Drug and Cosmetic Acts 1940 and Rules 1945.
- Regulation of import, manufacture, sale and distribution of drugs and cosmetics.
- To avoid substandard drugs and to maintain high standards of drugs and cosmetics.
- Administration of the D and C Act and Rules.

2.1 DETAILED STUDY OF THE SCHEDULES

Schedule G:

Most of these drugs are hormonal preparations. The drug label must display the text. "*Caution: It is dangerous to take this preparation except under medical supervision*" prominently. Examples: Testolactone, Hydroxyurea, Carbutamide, Primidone, Mercaptopurine, Methsuximide, Thiotepa etc.

Schedule H:

The drug label must display the texts "*Rx*" on the left top corner of the label and "*Schedule H drug. Warning : To be sold by retail on the prescription of a Registered Medical practitioner only*" prominently. It can only be supplied to licensed parties. It cannot be sold without a prescription and only the amount specified in the prescription should be sold. The time and date of prescription must be noted. Examples: Androgenic, anabolic, oestrogenic and progestational substances; Alprazolam, Hepatitis B vaccine, Adrenocorticotrophic hormone, Ibuprofen, Vasopressin etc.

If a Schedule H drug also comes under the purview of Narcotic Drugs and Psychotropic Substances Act, 1985, it must carry the texts "*NRx*" in red on the left top corner of the lable and "*Schedule H drug. Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.*" on the label prominently.

Schedule M (GMP-GOOD MANUFACTURING PRACTICES):

It is defined as "the part of quality assurance which is aimed to ensure that the product are consistently manufactured to the quality appropriate to their intended use". It prescribes the requirements of premises, plant and equipment needed for setting up manufacturing unit. Also documents every stage of manufacture, packing, storage, transportation checking and testing of medicinal product, maintenance or keeping records.

Part-1: Requirements for Premises and Materials

1. Locations and Surroundings: The factory building shall be situated and constructed to avoid contamination from open sewerage, drain, disagreeable or obnoxious odour, dust and smoke etc.

2. Buildings and Premises: A building for manufacturing unit shall permit work under hygienic conditions. It should be free from any insects/rodents. Light and ventilation facility should be adequate. Walls and floor should be free from cracks and damp. Premises should also be confirmed with provisions of factory act. It shall be located so as to be:

(i) Building should be compatible of other manufacturing operations carried out in same premises.

(ii) Space should be adequate for placement of equipment and materials to avoid mix-up/contamination risk of different drugs and components.

(iii) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean.

(iv) The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.

(v) Building should have a proper drainage system. Sanitary fitting and electric fixtures shall be proper and safe.

(vi) Proper fire safety measures and proper exists should be there.

(vii) Drying space for raw material, in process medicines should be separate and measures should be done to prevent it from flies/insects/dust etc.

3. Water Supply: Water supply should be pure and of potable quality. Adequate provision of water for wasting the premises shall be made.

4. Disposable of Waste:

(i) Disposal of sewage and effluents from the factory should be as per "Environment Pollution Control Board''.

(ii) All bio-medical wastes should be destroyed as per "Biomedical Waste management rules-1996".

(iii) Hazardous, toxic and inflammable substances should be stored in suitably designed and segregated in enclosed areas, as prescribed by Central and State legislations.

5. Stores: Store should have adequate space for independently and separately store raw material, packaging material and finished products.

6. Working Space: Manufacturing area should be adequate for orderly placement of equipment, machinery and material used during manufacturing operations and quality control to facilitate easy and safe working and to minimize or eliminate any risk of mix-up between different drugs, raw materials and to prevent the cross contamination during manufacturing, storage and handling operations.

7. Sterile Products: For the manufacture of sterile products separate enclosed areas shall be provided with the air lock system for the entry and shall be essentially dust free and ventilated with an air supply for all areas where aseptic manufacturing has to be carried out. Air supply shall be filtered through bacteria proof filter (HEPA filter) and shall be at a pressure higher than in the adjacent area. The filter shall be checked for performance an installation and periodically there after, and records there of shall be maintained.

The entire surface in the manufacturing area shall be designed to facilitate cleaning and dis-infections. Routine microbial counts to facilitate cleaning and dis-infections. Routine microbial counts of all sterile area shall be carried out during manufacturing operation.

The resultant of each shall be checked against established house standards and record maintained. Access to manufacturing area shall be restricted to minimum number of authorized personal. Special procedure to be followed for entering and leaving the manufacturing area shall be written down and displayed.

8. Container's Cleaning: Washing, cleaning and drying section of containers such as bottles, vials and jars should have adequate arrangement and should be separated from manufacturing operations.

9. Machinery: To carry out manufacturing process, adequate machinery and equipment require. These machinery could be manually operated or semi-automatic or fully automatic based upon your need and investment.

10. Raw-Materials: The licensee shall keep on inventory of all raw material to be used at any stage of manufacture of drugs and maintain the record as per schedule U. All such raw material be:

(a) Identified and their container examined for damage and assigned control number.
(b) Stored at optimum temperature and relative humidity.
(c) Conspicuously labelled indicating the number of materials, control numbers, name of manufacture and be labelled 'under test' or 'approved' or 'rejected'.
(d) Systematically sampled by quality control personnel.
(e) Tested for compliance with required standard of quality.
(f) Released from quarantine by quality control personal through written instruction.
(g) The stock rotation is so organized that, it is on the basis of **first come first out**.
(h) The all rejected material are conspicuously identified and are destroyed or returned to the supplier as soon as possible and record maintained there of.

11. Equipment: Equipment used for the manufacturing of drugs shall be constructed designed, installed and maintained to

(i) Achieve operational efficiency to attain desired quality.

(ii) Prevent physical, chemical and physico-chemical change through surface contact.

(iii) Prevent contact of any substance required for operation of the equipment like lubricant etc.

(iv) Facilitate through cleaning wherever necessary.

(v) Minimize any contamination of drug and their container during manufacture.

(vi) Equipment used for critical steps in progress shall be maintained by device capable of recording the parameter or with drawn systems to indicate malfunction. These devices shall be calibrated and tested and recorded there of shall be maintained.

12. Batch Manufacturing Record: Each batch record should be maintained irrespective of product manufactured (classical preparations or patent or proprietary medicines).

(i) Manufacturing records are required to provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the Drugs and Cosmetics Act.

(ii) These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product.

(iii) Manufacturing Batch record should be signed by production chemist and analytical chemist. Stock should be transferred to finished goods store along with record of testing with date and quantity of drug.

(iv) Only after the manufactured drugs have been verified and accepted quality shall be allowed to be cleared for sale.

(v) It should be essential to maintain the record of date, manpower, machine and equipments used.

Master Formula Records:

The licensee shall maintain MFR relating to all manufacturing procedure for each product which will be prepared and endorsed by the competent technical staff that is head of production and quality control. The master formula record should have:

(a) The patent or propriatory name of the product along with generic name, if any, strength and the dosage form.

(b) A description of identification of the final container packing material label and closer to be used.

(c) The identity and quality of the raw material to be used irrespective of whether or not it appear in the finished product, the permissible averages that may be included in formulation batch, should be indicated.

(d) Description of all vessel and equipment and the size used in the progresses.

(e) Manufacturing and control instruction along with parameter for critical steps such as mixing, drying, blending, sieving and sterilizing the product etc.

(f) The theoretical yield to be expected from the formulation at different stage of manufacture and permissible yield limit.

(g) Detail instruction on precaution to be taken in manufacture and storage of drug and of semi-finished product.

The requirement of in processes quality control test and analysis to be carried out during each step of manufacture including designation of person or department responsible for execution of such test and analysis.

13. Health Clothing, Sanitation and Hygiene of Workers:

(i) All workers should be healthy and should be free from any contagious diseases.

(ii) Proper uniform should be provided to workers according to nature of work and the climates.

(iii) A uniform may include cloth or synthetic covering for hands, feet and head wherever required.

(iv) Adequate facilities for personnel use should be provided like clean towel, soap etc. Lavatories for men and women should be separate and should be away from processing and manufacturing area.

(v) Changing room facility should also be provided for changing their clothes and to keep their personal belongings.

14. Medical Services: Adequate facility for first aids should be provided by manufacturer. Medical examination of workers at the time of employment and periodical check-up should be conducted at least once in a year and proper record should be maintained.

15. Distribution Record: Distribution record (Dispatch register) should be maintained to facilitate process of prompt and complete recall of the batch. Distribution record should be maintained till expiry of batch.

16. Record of Market Complaints: A complain register should maintain to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing

authority. The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

17. Quality Control: A manufacturer can set-up own quality control section or testing could be done through government approved testing laboratory.

Part-2: Requirements for Plant and Equipments

1. **Area:**
   (i) Basic installation - Requires minimum of 30 sq. mt. (for tablets manufacturing, upto 60 sq. mt.)
   (ii) Ancillary area: 10 sq. mt. (for tablets manufacturing, upto 20 sq. mt.)
2. **Equipment:** Colloidal mill, mixing and storage tanks, stainless steel containers, Planetary mixer, Triple roller, tube filling equipments, filter proof cap sealing machine, water distillation unit, clarity testing inspection unit, disintegrator and sifter, granulator, tray or fluidized bed driers, weighing machine, tablet compression machine (single-multi-rotary punch), tablet inspection unit, dissolution test apparatus, hardness tester, friability tester, disintegration test apparatus, air conditioners, polishing pan, jacketed kettle, leakage test apparatus, capsule filling unit, hot air ovens, Laminar air flow unit, bottle washing machines, autoclave, transfer pumps, trimming machine, cutting machine etc.

Parts of Schedule M

Part 1: Describes Good Manufacturing Practices For Premises and Material.

Part 1A: Describes the specific requirement for manufacture of sterile products. Parenteral preparations (Small Volume Injections and Large Volume Parentrals) and Sterile Ophthalmic Preparations.

Part 1B: Describes the specific requirements for manufacture of oral solid forms (Capsule and Tablets)

Part 1C: Describes the specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions and suspensions).

Part 1D: Describes the specific requirements for manufacture of topical products i.e. External Preparations (Cream, Ointments, Pastes, Emulsions, Lotions, Solutions, Dusting Powders and Identical Products)

Part 1E: Describes the specific requirements for manufacture of Metered Dose Inhalers (MDI).

The other associated codes such as those of Good laboratory practice (GLP) and Good clinical practice (GCP).

Schedule N:

Describes the facilities and equipments for efficient running of a Pharmacy.

1. **Entrance:** Front of a pharmacy shall bear an inscription "Pharmacy" in front.
2. **Premises:**
   - (i) Separated from rooms, well built, dry, well lit and ventilated with sufficient dimensions for stock of medicaments.
   - (ii) Poisons to be kept in a clearly visible and appropriate manner.
   - (iii) Dispensing department shall be not less than 6 sq. m. for one pharmacist working therein with additional 2 sq. m. for each additional pharmacist.
   - (iv) Height of the premises shall be at least 2.5 metres.
   - (v) Floor of the pharmacy shall be smooth and washable.
   - (vi) Walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.
   - (vii) A pharmacy shall be provided with ample supply of good quality water.
   - (viii) The dispensing department shall be separated by a barrier to prevent the admission of the public.
3. **Furniture and Apparatus:**
   - (i) A pharmacy shall contain furniture and apparatus, drawers, containers, glasses of suitable sizes and designed to prevent dust entry.
   - (ii) Every container shall bear a labels, easily readable with names of medicaments as given in the Pharmacopoeias.
   - (iii) Shall be provided with a dispensing bench, washable top etc.
   - (iv) Separate cupboards with lock and key for Poisons, and shall be marked in red letters as ''POISON'' on a white background.
   - (v) All concentrated solutions shall be labelled as ''To be diluted''.
   - (vi) Pharmacy shall bear all the prescribed apparatus and books for official preparations and prescriptions.
     - (a) Balance
     - (b) Beakers, bottles, funnels
     - (c) Filter and litmus papers
     - (d) Mortar and pestle, other glasswares
     - (e) Spatula, scissors, stands
     - (f) Spirit lamp, thermometer
     - (g) Water bath, distillation apparatus
     - (h) Watch glasses, pill machines, suppository mould etc.

(i) Books: The Pharmacopoeia (current edition), National Formulary of India, The Drugs and Cosmetic Act 1940 and rules 1945, The Pharmacy Act, Narcotic and Psychotropic substances Act, 1985 etc.

4. General provisions: Pharamcist shall always wear a clean white overalls, records and registers shall be maintained as per the law, medicaments must bear labels when supplied as per the law.

Schedule P:

Schedule P describes the life period of drugs 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.

Sr. No.	Drug	Life period in months	Storage conditions
1.	Ampicillin	36	Cool place
2.	Bacitracin	18	Cool place
3.	Carbanicillin sodium injection	24	At temp. not exceeding 5°C.
4.	Colistin sulphate	60	Protected from light
5.	Erythromycin stearate	36	Cool place

Note: Cool place means, a temperature of 10-25°c

Schedule P_1:

Pack sizes of drugs

Sr. No.	Drug	Dosage form	Pack size
1.	Albendazole	Suspension	10 ml
2.	Atenolol	Tablets	14
3.	Piperazine	Granules	5 gm

Schedule T:

Contains various regulations and requirements for manufacture of Ayurvedic, Siddha and Unani products.

Part 1: Describes the Good Manufacturing Practice of Ayurvedic, Sidha and Unani Medicines.

A Manufacturing Premises should have adequate space for all daily activity like:

1. Receiving and Storage of Herbs, Packaging material and other raw material.
2. Production and Manufacturing Activity Area.
3. Quality Control Section.
4. Finished Goods Store.
5. Office and Administration.

6. Rejected Products/Drugs Store.
7. Minimum area required for setting up Ayurveda, Sidha and Unani Medicine manufacturing unit is 1200 sq. ft. covered with separate cabins and partitions for each activity. If unani medicines/ayurvedic medicines are manufactured along with ayurvedic medicines/unani medicines additional 400 sq. ft. area is required.

General Requirements:

1. Location and Surroundings: The factory building shall be situated and constructed to avoid contamination from open sewerage, drain, disagreeable or obnoxious odour, dust and smoke etc.

2. Buildings: A building for manufacturing unit shall permit work under hygienic conditions. It should be free from any insects/rodents. Light and ventilation facility should be adequate. Walls and floor should be free from cracks and damp. Premises should also be conformed with provisions of factory act. It shall be located so as to be:

(i) Building should be compatible of other manufacturing operations carried out in same premises.

(ii) Space should be adequate for placement of equipment and materials to avoid mix-up/contamination risk of different drugs and components.

(iii) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean.

(iv) The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.

(v) Building should have a proper drainage system. Sanitary fitting and electric fixtures shall be proper and safe.

(vi) Burner/Bhatti section could be covered with tin roof and proper ventilation, but care should be done to prevent flies and dust.

(vii) Proper fire safety measures and proper exists should be there.

(viii) Drying space for raw material, in process medicines should be separate and measures should be done to prevent it from flies/insects/dust etc.

3. Water Supply: Water supply should be pure and of potable quality. Adequate provision of water for wasting the premises shall be made.

4. Disposable of Waste: Proper waste management care should be done.

5. Container's Cleaning: Washing, cleaning and drying section of containers such as bottles, vials and jars should have adequate arrangement and should be separated from manufacturing operations.

6. Stores: Store should have adequate space for independently and separately store raw material, packaging material and finished products.

7. Working Space: Manufacturing area should be adequate for orderly placement of equipment, machinery and material used during manufacturing operations and quality control to facilitate easy and safe working and to minimize or eliminate any risk of mix-up between different drugs, raw materials and to prevent the cross-contamination during manufacturing, storage and handling operations.

8. Health Clothing, Sanitation and Hygiene of Workers:

(i) All workers should be healthy and should be free from any contagious diseases.

(ii) Proper uniform should be provided to workers according to nature of work and the climates.

(iii) A uniform may include cloth or synthetic covering for hands, feet and head wherever required.

(iv) Adequate facilities for personnel use should be provided like clean towel, soap etc. Lavatories for men and women should be separate and should be away from processing and manufacturing area.

(v) Changing room facility should also be provided for changing their clothes and to keep their personal belongings.

9. Medical Services: Adequate facility for first aids should be provided by manufacturer. Medical examination of workers at the time of employment and periodical check-up should be conducted at least once in a year and proper record should be maintained.

10. Machinery and Equipment: To carry out manufacturing process, adequate machinery and equipment require. These machinery could be manually operated or semi-automatic or fully automatic based upon your need and investment.

11. Batch Manufacturing Record: Each batch record should be maintained irrespective of product manufactured (classical preparations or patent or proprietary medicines).

(i) Manufacturing records are required to provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurveda, Siddha and Unani mentioned in the First Schedule of the Drugs and Cosmetics Act.

(ii) These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product.

(iii) Manufacturing batch record should be signed by production chemist and analytical chemist. Stock should be transferred to finished goods stored along with record of testing with date and quantity of drug.

(iv) Only after the manufactured drugs have been verified and accepted, quality shall be allowed to be cleared for sale.

(v) It should be essential to maintain the record of date, manpower, machine and equipments used and to keep in process record of various shodhana, bhavana, burning and fire and specific grindings in terms of internal use.

12. Distribution Record: Distribution record (Dispatch register) should be maintained to facilitate process of prompt and complete recall of the batch. Distribution record should be maintained till expiry of batch. For drugs who do not have expiry date like Bhasma, Rasa, Asava-arishtha etc. record should be maintained upto five years of the exhausting of stock.

13. Record of Market Complaints: A complaint register should be maintained to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints, investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

14. Quality Control: A manufacturer can set-up own quality control section or testing could be done through government approved testing laboratory read in detail about Ayurvedic, Sidha and Unani manufacturing unit quality control section.

Part 2: Describes list of recommended machinery, equipment and manufacturing premises required for the manufacture of various categories of Ayurvedic, Siddha system of medicines.

Anjana/Pisti: End runner/Ball-Mill, Sieves/Shifter.

Churna/Nasya/Manjan/Lepa: Grinder/disintegrator, Pulveriser, Powder mixer, Sieves/ shifter.

Pills/Vati/Gutika Matirai and Tablets: Ball Mill, Mass mixer/powder mixer, Granulator, Drier, Tablet compressing machine, Pill/vati cutting machine, trays/container for storage and sugar coating, Polishing pan in case of sugar-coated tablets, Mechanised chattoo (for mixing guggulu).

Kupi pakava/Ksara/Parpati/Lavana/Bhasma/Satva/Sindura Karpu/Uppu/Param: Bhatti, Karahi/Vessels/Patila Flask, Multani Matti/Plaster of Paris.

Copper rod, Earthen container, Gaj Put Bhatti, Muffle furnace (Electrically operated), End/Edge runner, Exhaust fan, Wooden/Steel spatula.

Kajal: Filling/ packing and manufacturing room should be provided with exhaust fan and ultra violet lamps, Earthern lamps for collection of Kajal, Triple roller mill, End runner, Sieves.

Capsules: Air conditioner, De-humidifier, Hygrometer, Thermometer, Capsule filling machine and chemical balance.

Ointment/Marham Pasai: Tube filling machine, Crimping Machine/Ointment Mixer, End Runner/ Mill, Storage Container.

Pak/Avaleh/Khand/Modak/Lakayam: Bhatti section fitted with exhaust fan and should be fly proof, Iron Kadahi, Storage container.

Panak, Syrup/Pravahi Kwath Manapaku: Tincture press, Exhaust fan fitted and fly proof, Bhatti section, Bottle washing machine, Filter press / Gravity filter, Liquid filling machine, Capping machine.

Asava-Aristha: Fermentation tanks, Containers and distillation plant where necessary, Filter press.

Sura: Distillation plant, Transfer pump.

Ark Tinir: Maceration tank, Distillation plant, Liquid filling tank with tap, Gravity filter/Filter press, Visual inspection box.

Tail/Ghrit Ney: Bhatti, Kadahi/Patila, Storage containers, Filtration equipment, Filling tank with tap, Liquid filling machine.

Aschyotan/Netra Malham Panir/Karn Bindu/Nasa-bindu: Hot air oven electrically heated with thermostatic control, Kettle gas or electrically heated with suitable mixing arrangements, Collation mill or ointment mill, Tube filling equipment, Mixing and storage tanks of stainless steel or of other suitable material sintered glass funnel, Seitz filter or filter candle, Liquid filling equipment, Autoclave.

Each manufacturing unit will have a separate area for Bhatti, furnace boilers, puta etc. This will have proper ventilation, removal of smoke, prevention of flies, insets, dust etc. The furnace section could have tin roof.

Schedule U:

Schedule U describes the particulars to be shown in manufacturing record, records of raw materials and analytical drugs.

Following details are included in Schedule U:

1. Manufacturing Records:
   (i) Substances other than Parenteral Preparation: Serial number, Product name, Reference of Master formula records, Batch size and number, Date-time-duration conditions of the process for manufacture, Name of all the ingredients, Specifications, Quantity required, References to analytical report number,

theoretical yield and actual production yield of finished product, specimen of label, date of release of finishes packagings etc.

(ii) Parenteral Preparations: All the above including, Sterility tests such as Leakage, Pyrogen, Clarity and Toxicity tests; records of sterilization etc.

2. Records of Raw Materials: Date of receipt, Invoice number, Name and address of the manufacturer/supplier, Batch number, Quantities received, Pack size, Dates of manufacture and expiry, Date of analysis and release/rejection by quality control, Analytical report number with special remarks, quantity and date of issue etc.

3. Particulars to be recorded in the Analytical Records.

(i) Tablet, Capsules and for other drugs: Analytical report number, Sample name, Date of receipt, Batch number, Protocols of test applied, Signature of analyst etc.

(ii) Parenteral Preparations: All the above including, sterility tests.

(iii) Raw Materials: Serial number, Number of materials, Name of manufacturer/ supplier, Quantity received, Challan/invoice number and date, Protocols for test applied.

(iv) Container and Packing Material: All the above including, Results of tests, Remarks, Signature of examiner etc.

Schedule U_I:

Schedule U_I describes the particulars to be shown in the manufacturing record for cosmetics:

1. Manufacturing Records: Serial number, Product name, Reference of Master formula records, Batch size and number, Date-time-duration conditions of the process for manufacture, Name of all the ingredients, specifications, quantity required, references to analytical report number, theoretical yield and actual production yield of finished product, specimen of label, date of release of finishes packagings, etc,.
2. Records of Raw Materials: Date of receipt, invoice number, name and address of the manufacturer/supplier, batch number, quantities received, pack size, dates of manufacture and expiry, date of analysis and release/rejection by quality control, analytical report number with special remarks, quantity and date of issue etc.

Schedule V:

Schedule V describes the standards for patent or proprietary medicines.

Patent or Proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified in single or in two divided daily doses.

Sr. No.	Drug	Unit	Adult (daily dose)
1.	Vitamin A	I.U.	NLT 5,000 and NMT 10,000
2.	Vitamin D	I.U.	NLT 400 and NMT 1,000
3.	Vitamin B_1	Mg	NLT 4.5 and NMT 10
4.	Vitamin B_6	Mg	NLT 1.5 and NMT 3

NLT - Not less than; NMT - Not more than; I.U. - International units

Schedule X:

Drugs which are habit forming, psychotropic and other drugs likely to be misused for addictive purposes. Hence import, manufacture, sale and distribution of these are regulated under special provisions.

All the regulations of Schedule H apply. The retailer must keep a copy of the prescription for two years. The drugs must be kept under lock and key. Examples: Amphetamine, Secobarbital, Glutethimide, Cyclobarbital, Phencyclidine, Phenobarbital etc.

Schedule Y:

Describes requirements and guidelines on Clinical trials for import and manufacture of new drugs.

1. Clinical Trials

(i) Permission of trials: One must apply for Form 12 for test license (TL). The application shall comprise-data for various phases, protocol for proposed trials, case report forms to be used, names of Investigators and Institutions.

(ii) Responsibility of Sponsor/ Investigator: Sponsors must submit the annual status report of each clinical trial, to the licensing authority. Any termination, unusual, unexpected or serious adverse drug reactions (ADR) detected during trial must be communicated to the authority.

(iii) In all trials, informal, written, voluntary consent must be obtained from each volunteer in the prescribed forms.

2. Data required to be submitted with the application for permission to market New Drug

(i) Clinical and Pharmaceutical Informations.

(ii) Animal toxicology: Acute, chronic, reproduction status (fertility, teratogenic and prenatal studies, local toxicology, mutagenicity, carcinogenicity).

(iii) Animal pharmacology.

(iv) Phase - 1,2,3 trials.

(v) Special studies (bioavailability and dissolution studies).

Phase 1 trials (Human/Clinical Pharmacology): Determines the maximum tolerated dose in humans; pharmacodynamics effects, adverse effects etc.

Phase 2 trials (Exploratory Trials): Determines the therapeutic doses, effective dose range, safety and pharmacokinetics.

Phase 3 trials (Confirmatory Trials): To obtain sufficient evidences about the efficacy and safety of the drugs.

The reports of the complete trials shall be submitted by the applicant duly signed by the investigator within a specified period of time. It should include description, actions, indications, dosage precautions, drug interactions, warning and adverse reactions.

Schedule F:

This contains regulations and standards for running a blood bank.

Schedule F_1:

This contains regulations and standards for bacterial vaccines, viral vaccines, antisera and diagnostic agents.

Schedule F_2:

This contains regulations and standards for surgical dressing.

Schedule F_3:

This contains regulations and standards for umbilical tapes (polyester and cotton tapes).

Schedule FF:

This contains regulations and standards for ophthalmic preparations (solutions, suspensions and ointments). The label must bear:

(i) The statement "use the solution within one month after opening the container".
(ii) Name and concentration of the preservative used.
(iii) ''Not for Injection''.
(iv) Storage instructions.
(v) Warning
  (a) If irritation persists or increases, discontinue the use and consult physician.
  (b) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate the solution.

Part XII-B:

Requirements for the premises, personnel, equipments and organizations and operation of a Blood Bank and/or for preparation of Blood components. It's a part under Schedule F.

I. Blood Banks/Blood Components:

(i) General
(ii) Accommodation for a Blood Bank
(iii) Personnel
(iv) Maintenance
(v) Equipments and instruments
  (a) BP apparatus
  (b) Stethoscope

(c) Blood bags (single, double, triple, quadrapole)
(d) Donor questionnaire
(e) Weighing device for donors
(f) Weighing device for blood bags
(g) Artery forceps, scissors
(h) Stripper for blood tubing
(i) Bed sheets, blankets/mattress
(j) Lancets, swab stick/tooth picks
(k) Glass slides
(l) Portable Hb meter/copper sulphate 337
(m) Test tube (big) and 12 × 100 mm (small)
(n) Test tube stand
(o) Anti-A, Anti-B and Anti-AB, Antisera and Anti-D
(p) Medicated adhesive tape
(q) Plastic waste basket
(r) Donor cards and refreshment for donors
(s) Emergency medical kit
(t) Insulated blood bag containers with provisions for storing between 2°C to 10°C.
(u) Dielectric sealer or portable tube sealer
(v) Needle destroyer (wherever necessary)

(vi) Supplies and Reagents
(vii) Good Manufacturing Practices (GMPs)/ Standard Operating Procedures (SOPs)
(viii) Criteria For Blood Donation
(ix) Special Reagents
(x) Testing of whole blood
(xi) Records
(xii) Labels

II. Blood Donation Camps:

(i) Premises, personnel etc.
(ii) Personnel for Out-door Blood Donation Camp.
  (a) One Medical Officer and two nurses or phlebotomists for managing 6-8 donor tables.
  (b) Two medico social workers.
  (c) Three blood bank technicians.

(d) Two attendants.

(e) Vehicle having a capacity to seat 8-10 persons, with provision for carriage of donation goods including facilities to conduct a blood donation camp.

(iii) Equipments.

III. Processing of Blood Components from Whole Blood by a Blood Bank:

(i) Accommodation

(ii) Equipment

(iii) Personnel

(iv) Testing Facilities

(v) Categories of Blood Components

(a) Concentrated Human Red Blood Corpuscles

(b) Platelets Concentration

(c) Granulocyte Concentration

(d) Fresh Frozen Plasma

(e) Cryoprecipitate

Drug and Magic Remedies (Objectionable Advertisements):

The act defines "magic remedy" as any talisman, mantra, kavachas or any other object which is claimed to have miraculous powers to cure, diagnose, prevent or mitigate a disease in humans or animal. It also includes such devices that are claimed to have power to influence structure or function of an organ in humans or animals.

The law prohibits advertising of drugs and remedies for –

(i) Inducing miscarriage or preventing conception in women.

(ii) Improving or maintaining the capacity for sexual pleasure.

(iii) Correction of menstrual disorders.

(iv) Curing, diagnosing or preventing any disease or condition mentioned in an included schedule.

2.2 SALE OF DRUGS

2.2.1 Wholesale, Retail and Restricted Sale Licenses

1. **Wholesale:** From stockists to shopkeepers.
2. **Retail sale:** From shopkeepers (drug store, chemists and druggists, pharmacy or dispensing chemist) to patients.

Drug control organization issues two type of license, out of which one is Retail Drug License (RDL) to run a chemist shop, and it is issued to only those persons who possess degree or diploma in pharmacy from a recognized university on the payment of the requisite fees and other is Wholesale Drug License (WDL) which is issued to a person who is engaged in the business of wholesale of drugs and medicines.

Sr. No.	Type of License	Forms		
		Other than Schedule-C, C_1 and X drugs	Schedule-C and C_1 Drugs	Schedule-X drugs
1.	Retail	20	21	20-F
2.	Restricted	20-A	21-A	--
3.	Wholesale	20-B	21-B	20-G
4.	Wholesale or distribution from motor vehicle	20-BB	21-BB	--

Conditions of Whole Sale License:

1. **Area:** Shall not be less than 10 sq. m.
2. **Storage:** It is necessary to have a refrigerator and air conditioner on the premises because certain drugs such as vaccines, insulin injections etc. are needed to be stored in the fridge.
3. **Competent Staff:** The sale can be made either by a **registered pharmacist** or another competent person who must be a graduate with one year experience in drugs or in the presence of any one who has passed S.S.L.C having experience of four years in drugs, specially approved by drug control department.
4. License shall be displayed in a prominent place.
5. The drugs shall be purchased from a duly licensed dealer or a manufacturer.
6. Supply of drugs shall be made against a cash memo. Carbon copies of the same shall be preserved for 3 years from the date of last entry.
7. Shall maintain the records of purchase, and produce all the registers and records during inspection. Records must be preserved for 2 years from the last entry.
8. An Inspection book shall be maintained in Form 35.
9. The drugs after expiry, Physician's sample and the drugs meant for Government supply, shall not be stocked or sold.
10. A separate record shall be maintained for the supply of Schedule X drugs, the copies of invoices of sale of such drugs to the retailer, shall be forwarded to the Licensing authority.
11. No sale of any drug should be made for the purpose of resale to a person not holding the license to sell or distribute the drugs.

Conditions of Restricted License:

These are issued for the retail sale of the drugs.

Restricted licences in Forms 20A and 21A.

(a) Dealers or persons in respect of drugs whose sale **does not require the supervision of a qualified person**.

(b) Licenses to itinerant vendors shall be issued only in exceptional cases for bonafide travelling agents of firms dealing in drugs.

(c) The licensing authority may issue a license in Form 21A to a travelling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers samples of biological and other special products specified in Schedule C.

(d) The licensee must have adequate premises equipped with facilities for the proper storage of which the license applies, provided that, this condition does not apply to the vendors.

(e) License should be displayed in a prominent place in a part of the premises open to the public or must be kept on the person of vendor who shall produce the same on demand by authorized government officers.

(f) Licensee must comply with the provisions of D and C act.

(g) Drugs should be purchased only from a duly licensed dealer or manufacturer.

(h) The licensee can deal only with such drugs, which can be sold without the supervision of a qualified person.

(i) Drugs must be sold in their original container.

Required Documents for Obtaining Drug License:

1. Application Form.
2. Cover letter with the name and designation of the applicant.
3. Copy of challan achieved by depositing fees for obtaining drug license.
4. Declaration in a prescribed manner.
5. Kite plan and site plan for the premises.
6. The basis of possession of premises.
7. In the case of rented property, ownership proof.
8. Document related to the constitution of business such as Incorporation certificate/ MOA (Memorandum of association)/AOA (Articles of association)/Partnership Deed.
9. Affidavit related to non-conviction of director/partner/proprietor.
10. Testimony of registered pharmacist or competent person and their appointment letter in case of an employed person.

2.2.2 Offences and Penalties

Offences and penalties relating to the Sale of drugs:

Sr. No.	Offence	Penalties	
		First conviction	**Subsequent conviction**
1.	Sale or distribution of:		
	(i) Any adulterated or spurious drugs or drug not of standard quality	Imprisonment upto 5 years and extending upto lifetime and fine of not less than ₹ 10,000.	Imprisonment upto 10 years or fine upto ₹ 20,000 or both.
	(ii) Any adulterated but not containing toxic or harmful substances injurious to health	Imprisonment from 1-3 and fine of not less than ₹ 5,000	Imprisonment for 2-4 years or fine upto ₹ 10,000.
	(iii) Without a license	Imprisonment of less than a year and a lesser fine.	Imprisonment for not less than 2 years or fine upto ₹ 10,000.
	(iv) Spurious drugs but not manufactured under the name of any other drug	Imprisonment for 3-5 years and fine of not less than ₹ 5,000.	Imprisonment for not less than 6-10 years or fine upto ₹ 10,000.
	(v) Any other	Imprisonment for 1 year.	
	(vi) Contravention of this act	Imprisonment from 1-2 years and fine.	Imprisonment for 2-4 years or fine upto ₹ 5,000 or both.
2.	Not keeping records of sale in the specified manner.	Imprisonment upto 3 years or fine upto ₹ 1000 or both.	Same as first conviction
3.	Using the report of Government analyst for advertising any drug.	Fine upto ₹ 500	Imprisonment upto 10 years or with fine or both.

2.3 LABELLING AND PACKING OF DRUGS AND COSMETICS

2.3.1 General Labelling Requirements

The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed:

1. Drug name: the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any.
2. Net content: weight, volume, in metric system or units.
3. Content of Active ingredients:
   (i) Oral liquids: Contents per single dose, i.e. 5 ml or multiple thereof. If dose is below 5 ml, then per ml.
   (ii) Liquid parenterals: Contents per ml or in percentage or per dose.
   (iii) Solid parenterals: Contents per mg or per gm or in terms of units.
   (iv) Tablets, capsules and pills: Contents per tablet, capsule, pill.
   (v) For other preparations: Contents in terms of percentage by w/w or w/v or units per gm or ml.
4. Name and address of manufacturer.
5. Manufacturing license number: Mfg. Lic. No. or ML No.
6. Batch number: Batch No. or Lot No.
7. Date of manufacturing: Mfg. Date.
8. Date of expiry: Exp. Date
9. Free samples to medical profession: "Physician's Sample - Not To Be Sold".
10. Alcoholic preparations: If alcoholic content exceeds 3% by volume, percentage of alcohol must be mentioned on the lable.
11. Information of handling, use, distribution, storage etc.
12. Maximum Retail Price: M.R.P.
13. Hair dyes containing coal tar colours: on inner and outer label both, in English and local languages: "Caution: The product contains ingredients which may cause skin irritation in certain cases and so preliminary test according to the accompanying directions shall first be made. This product shall not be used for dyeing the eyelashes or eyebrows as such if used, may cause blindness''.
14. Toothpaste containing Fluoride: Fluoride content in ppm (NMT 1000 ppm); Date of expiry.

2.3.2 Special Labelling Requirements

1. Schedule C_1 : Date of manufacture and expiry, Import license number.
2. Schedule G : "It is dangerous to take this preparation except under medical supervision''.
3. Schedule H: Symbol R_X conspicuously on the left top corner of the label; ''To be sold by retail on the prescription of a registered medical practitioner only''; For Narcotic and Psychotropic drugs, symbol NR_X conspicuously on the left top corner of the label

in red ink and ''To be sold by retail on the prescription of a registered medical practitioner only''.

4. Schedule X: Symbol XR_X in red ink, conspicuously on the left top corner of the label; ''To be sold by retail on the prescription of a registered medical practitioner only''.
5. Preparations for External use: FOR EXTERNAL USE ONLY; eg: lotion, liniment, ointment, liquid antiseptics.
6. Pharmacopoeial preparations: 'I.P.', 'B.P.', 'B.P.C', 'U.S.P', 'N.F.' etc.
7. Patents and Proprietary medicines: Quantities of active ingredients.
8. Ophthalmic preparations (solutions, suspensions and ointments): Schedule FF
   (i) The statement "use the solution within one month after opening the container".
   (ii) Name and concentration of the preservative used.
   (iii) ''Not for Injection''.
   (iv) Storage instructions.
   (v) Warning:
      (a) If irritation persists or increases, discontinue the use and consult physician.
      (b) Do not touch the dropper tip or the other dispensing tip to any surface since this may contaminate the solution.
9. Medicines for Animals: ''NOT FOR HUMAN USE, FOR ANIMAL TREATMENT ONLY"; Symbol depicting the head of a domestic animals.

2.3.3 Specimen Labels

Schedule H drug

R_x **ERYTHROMYCIN ESTOLATE TABLETS IP 500 MG**

Each uncoated tablet contains:
Erythromycin Estolate IP
equivalent to Erythromycin…….500 mg
Dosage: As directed by the Physician
Store in a cool, dark and dry place

Schedule H Drug
Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

Mfg Lic. No. 2/20 M.R.P not to exceed ₹…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

External use

15 gm

POVIDONE IODINE OINTMENT USP

Composition:
Povidone-Iodine USP……..5% w/w
(0.5% w/w available Iodine)
Water-soluble ointment base q.s.
Store in a cool place

FOR EXTERNAL USE ONLY

Mfg Lic. No. 2/20 M.R.P not to exceed ₹…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

Schedule X Drug

XR_x **PENTOBARBITONE SODIUM INJECTION USP**

Each ml contains:
Pentobarbitone Sodium USP ……50 mg

For Intramuscular Injection only

Dosage: As directed by the Physician

Schedule X Drug
Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

The Injection must be discarded if any precipitate is observed

Mfg Lic. No. 2/20 M.R.P not to exceed ₹…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

Schedule G drug

PHENIRAMINE TABLETS IP

Each uncoated tablet contains:
Pheniramine maleate IP……..25 mg
Dosage: 1 tablet 2-3 times daily or as directed by the Physician.
Store protected from light

Caution: It is dangerous to take this preparation except under medical supervision.

Mfg Lic. No. 2/20 M.R.P not to exceed ₹…….
Batch No. 2019 inclusive of all taxes
Mfg. Date
Exp. Date

Manufactured by: XYZ Pharmaceuticals, India.

2.4 LIST OF PERMITTED COLOURS

No drug shall contain a colour other than that specified below:

(1) Natural Colours: Annatto, Carotene, Chlorophyll, Cochineal, Curcumin, Red oxide of iron, Yellow oxide of iron, Titanium dioxide, Black oxide of iron.

(2) Artificial Colours: Caramel, Riboflavin.

(3) Coal Tar Colours: Quinazarine Green SS, Alizarin Cyanine Green F, Fast Green FCF, Tartrazine, RED (Erythrosine), Eosin YS or Eosine G, Toney Red or Sudan III, Indigo Carmine, Brilliant Blue FCF, Orange G, Resorcin Brown, Naphthol Blue-Black.

(4) Lakes the aluminium or calcium salts (lakes) of any of the water-soluble colours listed above.

(5) The label on the container of a drug containing a permitted colour shall indicate the common name of the colour.

2.5 OFFENCES AND PENALTIES

Same as offences and penalties under sale of drugs.

2.6 ADMINISTRATION OF THE ACT AND RULES

2.6.1 The Drugs Technical Advisory Board (DTAB)

The Central Government constituted this Board, so as to advise the Central Government and the State Governments on technical matters arising out the administration of this Act and to carry out the other functions assigned to it by this Act.

The Board shall consist of the following members, namely:

1. Ex-Officio memebers:
   (i) The Director General of Health Services, who shall be Chairman.
   (ii) The Drugs Controller, India.

(iii) The Director of the Central Drugs Laboratory, Calcutta.
(iv) The Director of the Central Research Institute, Kasauli.
(v) The Director of the Indian Veterinary Research Institute, Izatnagar.
(vi) The President of the Medical Council of India.
(vii) The President of the Pharmacy Council of India.
(viii) The Director of the Central Drug Research Institute, Lucknow.

2. Nominated members:
   (i) Two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States.
   (ii) One person nominated by the Central Government from the Pharmaceutical Industry.
   (iii) Two persons holding the appointment of Government analyst, nominated by the Central Government.
3. Elected members:
   (i) One person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto.
   (ii) One person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto.
   (iii) One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research.
   (iv) One person to be elected by the Central Council of the Indian Medical Association.
   (v) One person to be elected by the Council of the Indian Pharmaceutical Association.

The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election.

The Central government shall appoint persons to be secretary of the board and other staffs, if necessary.

Provided that, the person nominated or elected, shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years. As it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

2.6.2 The Central Drugs Laboratory (CDL)

The Central Government established a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules. This was established in Calcutta to carry out the following functions:

1. To analyse or test, samples of drugs as may be sent to it by the Custom Collectors or Courts.

2. Since, CDL is not equipped for testing of all types of products, some other Government labs and Institutes shall also perform the functions of CDL :
   (i) Central Research Institute, Kasauli; carries out the assigned functions in respect of: Sera, vaccines, toxins, antigens, sterilized surgical sutures and ligatures, Bacteriophage.
   (ii) Pasteur Institute of India, Conoor and Enterovirus Research Centre, Mumbai in respect of Polio vaccine.
   (iii) Indian Veterinary Research Institute, Izatnagar or Mukteshwar in respect of: antisera, toxoids, vaccines, diagnostic agents for veterinary use.
   (iv) Central Indian Pharmacopoeia Laboratory, Ghaziabad in respect of Condoms.
   (v) Laboratory of the Serologist and Chemist examiner to the Government of India, Calcutta in respect of VDRL antigen.
   (vi) Department of Biomedical engineering of the Indian Institute of Technology, New Delhi in respect of Intra Uterine Devices.
   (vii) Homeopathic Pharmacopoeia Laboratory, Ghaziabad in respect of Homeopathic medicines.
3. All samples sent to the laboratories are required to be sent by registered post in a sealed packet enclosed together with a memorandum in the prescribed form, addressed to the Director.
4. On receipt of the packet, it must be opened by an authorized officer, in this behalf by the Director.
5. After test, the results with complete protocols of the tests applied, should be sent to the sender.
6. Certificates issued by the Laboratory under the rules should be signed by the Director or any other Central Government authorized officer.

2.6.3 The Drugs Consultative Committee (DCC)

This is also an advisory body constituted by the Central government for the purpose of advising the Central government the State government and the DTAB, on any matter tending to secure uniformity throughout India in the administration of this Act.

1. The Drugs Consultative Committee shall consist of two representatives nominated by the Central Government and one representative nominated by each State Government.
2. The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

2.6.4 Government Drug Analysts

1. The Central and State Government both, by notification in the Official Gazette, appoint such persons, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.
2. A person to be appointed as Government analyst should not have any financial interest in the import, manufacture or sale of drugs or cosmetics.

Qualifications of Government Analyst

1. A graduate in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 5 years post graduate experience in the testing of drugs; or
2. A post graduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a recognized university, with not less than 3 years experience; or
3. Associateship Diploma of the institution of chemists with 'Analysis of Drugs and Pharmaceuticals' as one of the subjects with not less than 3 years experience in the testing of drugs in the laboratory under the control of: A government analyst; or Head of the institution or testing laboratories approved by the government authorities.

Duties of Government Analysts:

1. On receipt of a package of a sample from Drug Inspector, the analyst compares the seals on packages with the specimen impression of the seal received separately and notes the condition of seals.
2. Thereafter, analyse or test the samples of drugs and cosmetics sent to him by Drug Inspectors or other persons and to furnish the reports.
3. On completion of analysis, he furnishes the reports of analytical and research work to the Inspector in Form 13, along with test protocols applied.

Note: If purchaser want to analyse the drug or cosmetic, he has to make an application for analysis in Form 14-A, with a prescribed fee. The reports of such drugs will be furnished in Form 14-B, by Government analyst.

2.7 LICENSING AUTHORITIES

1. These are appointed by the Central and State governments for the grant and the renewal of a licence for the import, manufacture, sale, distribution etc. of any drug or cosmetic.
2. The licenses once issued, shall remain valid forever, unless suspended or cancelled by the licensing authority.
3. The licensing authorities are mostly designated as Drug Controller.
4. The Drug Controller, India has recently been notified as the Central License Approving Authority.

Qualification of a Licensing Authority:

1. He must be a graduate in Pharmacy or Pharmaceutical chemistry or medicine with specialization in Clinical Pharmacology or Microbiology, from a recognized university.
2. He must be experienced in manufacture or testing of drugs for a minimum period of 5 years.

2.8 CONTROLLING AUTHORITIES

All Drug Inspectors appointed by the Central Government or the State Government act are under the control of an officer appointed by respective governments referred to as Controlling authority.

Qualification of a Controlling Authority:

1. He must be a graduate in Pharmacy or Pharmaceutical chemistry or medicine with specialization in Clinical Pharmacology or Microbiology, from a recognized university.

2. He must be experienced in manufacture or testing of drugs for a minimum period of 5 years.

The Drug Control Department (DCD): The department is vested with the licenseing of manufacturing and sales premises of drugs and cosmetics in the state. It primarily strives to ensure the supply of quality drugs. It comprises 3 wings: Enforcement wing, Educational wing and Drugs Testing Laboratory (DTL).

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.

The Drugs and Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central and state regulators for regulation of drugs and cosmetics.

1. It envisages uniform implementation of the provisions of the Act and Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics.
2. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.
3. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and co-ordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
4. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

2.9 DRUG INSPECTORS

The Central Government or a State Government appoints such persons, having the prescribed qualifications, to be Inspectors.

1. Who have not less than 18 months experience in the manufacture of atleast one of the substances specified in Schedule C; or
2. Who have not less than 18 months experience in testing of atleast one of the substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority; or
3. Who have gained experience of not less than 3 years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as Drug Inspectors.

Duties of Drug Inspector:

1. To inspect:

(i) Any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizing and testing the drug or cosmetic;

(ii) Any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale or distributed;

2. **Take samples of any drug or cosmetic:**
   (i) Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;
   (ii) From any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;
3. **For entering and searching any place, person or vehicle etc.** in which he has reason to believe that an offence has been, or is being, committed; or Stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of an offence been or being committed;
4. **For seizure of stocks:**
   (i) Not to dispose off any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been or being committed.
   (ii) Examine any record, register, document or any other material object found with any person, or in any place, vehicle, vessel or other conveyance, and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;
   (iii) Require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;

The provisions of the Code of Criminal Procedure, 1973, shall, so far may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code.

If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter or refuses to produce any record, register or other document when so required, shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

EXERCISE

1. Give qualifications, duties and functions of Drug Inspectors.
2. Discuss the general requirements of GMP as per schedule M of the Drugs and Cosmetics Rules, 1945.
3. Write the qualifications and functions of Government Analyst.
4. Explain in detail, classes of drugs prohibited and permitted to be imported under license or permission under D and C act.
5. Describe the constitution and functions of DTAB and DCC.
6. Explain in detail about Schedule N.

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UNIT III

Chapter ... 3

PHARMACY ACT, 1948

♦ **LEARNING OBJECTIVES** ♦

After completing this chapter, the reader should be able to understand:

- The objectives of the Act.
- The constitution and functions of Pharmacy council of India.
- The constitution and functions of State and Joint state pharmacy councils.
- The qualifications for Pharmacist required for first and subsequent registers.
- The offences and penalties of the Act.

3.1 INTRODUCTION

Pharmacy Act regulates the profession of pharmacy in India. Since there was no legislative law and stringent regulations to control the profession of pharmacy in India before the pre-independence, which was mishandled by persons with no pharmacy knowledge to compound and prescribe the medicines which were leading to cause great harm to public health, pharmacy act was framed in the year 1948 to resolve all these issues.

This act also provides regulations for the good conduct of pharmaceutical education, revising the curriculum to gain academic and practical training for the pharmacists by framing standard guidelines. This act extends to the whole part of India except Jammu and Kashmir.

3.2 OBJECTIVES OF THE ACT

The main of objectives of Pharmacy Act, 1948 are:

I. To provide uniform education and training to those persons willing to enter the pharmacy profession.

II. To maintain control over the persons of the pharmacy profession by registering them as registered pharmacists in every state and union territories.

3.3 DEFINITIONS

Central Council means the Pharmacy Council of India.

State Council means the State Council of Pharmacy constituted under the Act and includes the joint state pharmacy councils.

Central Register means the register of Pharmacists maintained by the Central Council (Pharmacy council of India).

Medical Practitioner means a person holding-medical qualification as provided in the Indian Medical Degree's Act or Indian Medical Council Act or a person registered or eligible for registration in the medical Register of the State or a Dentist or a Veterinarian.

Registered Pharmacist means a person whose name, for the time being, is entered in the Register of Pharmacists of the state in which he is for time being residing or carrying on his profession or business of Pharmacy.

3.4 CONSTITUTION OF PHARMACY COUNCIL OF INDIA

The Pharmacy Council of India (PCI) is constituted by the Central Government every five years.

The first Pharmacy Council of India was constituted in the year, 1949.

The PCI is composed of the following members:

A. Elected members:

(i) Six members, at least one teacher each of Pharmacy, Pharmaceutical Chemistry and Pharmacognosy elected by UGC from the teaching staff of an Indian University or an affiliated college granting a degree or diploma in Pharmacy.

(ii) One member, elected by the Medical Council of India from amongst its members.

(iii) One member elected by each State Pharmacy Council who shall be a Registered Pharmacist.

B. Nominated members:

(i) Six members, nominated by the Central Government, including at least four persons possessing degree or diploma in Pharmacy and engaged in the practice of Pharmacy or Pharmaceutical Chemistry.

(ii) One representative each of University Grants Commission and the All India Council for Technical Education.

(iii) One Registered Pharmacist to represent each State nominated by the State Government/Union Territory Administration.

C. Ex-officio Members:

(i) The Director General of Health Services.

(ii) The Director of Central Drugs Laboratory.

(iii) The Drugs Controller of India.

The President and Vice-President of the Pharmacy Council are elected by its members from amongst themselves. They have a term of office of five years. Any member absenting without sufficient excuse is deemed to have vacated his seat from the Council. A casual vacancy in the PCI is filled by fresh nomination or election and the person so nominated or elected holds the office only for the remaining term.

All members of the Council are eligible for re-election or re-nomination. The Council also appoints:

(i) A Registrar who acts as its Secretary and, if necessary, its treasurer as well,

(ii) Other officers and servants for carrying out its statutory functions.

(iii) The Executive Committee of the PCI consisting of the President (Chairman of the Committee) and the Vice-President and five other members elected by the Central Council from amongst its members.

3.4.1 Functions of Pharmacy Council of India

1. To prescribe the minimum standards of education required for qualification as a Registered Pharmacist.
2. To regulate the minimum educational standards by inspecting the institutions.
3. To recognise the qualification granted outside the territory to which the Pharmacy Act, 1948 extends, for the purpose of qualifying for registration.
4. To compile and maintain a Central Register for Pharmacist, containing names of all Registered persons.
5. Any other function required for the furtherance of objectives of the Pharmacy Act, 1948.

3.4.2 Education Regulations for Pharmacy

The Pharmacy Council of India has laid down certain minimum standards of education required as Pharmacist. These standards are known as Education Regulations and prescribe:

(i) Minimum educational qualification required for admission to the course of Pharmacy.
(ii) Duration of course of study and training.
(iii) Nature and period of practical training to be undertaken after the completion of regular course.
(iv) Subjects of examination and the standards to be attained therein for qualification.
(v) Minimum facilities required to be provided by an institution for the conduct of course of examination and practical training.
(vi) Conditions to be fulfilled by the authorities holding approved examinations.

Main Features of Education Regulations – 91:

According to ER-91, a candidate has to undergo practical training after having appeared in Diploma in Pharmacy Part II examination in one or more of the following institutions:

(i) Government hospitals/dispensaries.
(ii) Other hospitals dispensaries recognised by the PCI.
(iii) Licensed pharmacy, chemists and druggists shops.
(iv) Licensed drug manufacturing units.

Practical training should be for a minimum of 500 hours spread over a period of not less than three months out of which not less than 250 hours must be devoted to actual dispensing of preparations. In the course of practical training, the trainee should have exposure to:

(i) Working knowledge of records required by various acts covering the profession of Pharmacy.
(ii) Practical experience in:
    (a) The manipulation of pharmaceutical apparatus in common use.
    (b) The reading, translation, and copying of prescriptions including checking of dose.
    (c) The dispensing of prescriptions illustrating the commoner methods of administering medications.
    (d) The storage of drugs and medical preparations.

These Education Regulations are approved by the central government. However, before submitting ER or any amendment to the central government for approval, the Pharmacy Council of India sends copies to all State Governments and takes into consideration the comments of any state government received within 3 months from the date of furnishing draft ER. The ER is notified in the official gazette by the central government.

Approval of Institution Providing a Course of Study and Examination for the Pharmacy Profession:

Any institute or organization providing a course of study and examination in Pharmacy has to follow the below procedure for the PCI approval.

1. **Application by the institute:** The institute proposing to conduct the pharmacy course has to apply to the PCI.
2. **Inspection:** After receiving the application, PCI deputes its inspectors to visit the institution and inspect weather the institution has the prescribed facilities for imparting training or holding examinations in accordance with the ER or not. The inspectors may also attend an examination without interfering their conduct to inspect the standards. After the inspection, inspectors report to the PCI about the facilities available in the institute for the course of study and examination.
3. **Approval:** If the PCI is satisfied with the report of inspectors, it may accord approval and the said course or examination will be claimed to be approved for qualifying registration as Pharmacist.
4. **Declaration:** Once the institute has been approved by PCI, such approval will be published in Gazette.

Withdrawal of Approval:

If the executive committee reports to the PCI that an approved course of study or an approved examination does not continue to be in conformity with the Education Regulations, the PCI gives notice of its intention to withdraw its approval. The said institution should make a representation within the 3 months to PCI through state government and PCI then decides to either to continue the approval or to withdraw.

Approval of Qualification Granted Outside India:

The PCI may approve any qualification in Pharmacy granted by an authority outside India, to be approved qualification for the purpose of qualifying for registration as a pharmacist under this act, if a sufficient guarantee of the requisite skill and knowledge affords. This is applicable to Indian citizens.

Other countries' citizens holding qualification granted there, shall be eligible for registration in this country when an Indian national holding the same qualification by law allowed to enter and practice the profession of pharmacy in this country.

Registration of Pharmacists:

The PCI is required to maintain a Central Register of pharmacists which contains the names of all persons for time being entered in the registers of different State councils of India. Each state pharmacy council has to supply five copies of its register to the PCI as soon as after 1st April every year. After receiving the registration details of the person in the register for a State, Registrar of PCI enters the name of such persons in the central register. The central register is published in Gazette from time to time.

3.5 STATE AND JOINT STATE PHARMACY COUNCILS

Each state of India can constitute state pharmacy council under the provision of Pharmacy Act by their respective State Governments. Joint state pharmacy councils can also be constituted where two or more states agree to serve the needs of the other participating states.

The composition of State and Joint State Pharmacy Councils is as follows:

State Pharmacy Council	Joint State Pharmacy Council
Elected Members: 1. Six members elected amongst themselves by Registered Pharmacists of the State. 2. One member elected by the Medical Council of the State from amongst its members.	**Elected Members:** 1. Six members elected amongst themselves by Registered Pharmacists of each participating State. 2. One member elected by the Medical Council of the State from amongst its members.
Nominated Members: 1. Five members nominated by the State Government, of whom, at least three should possess a degree or diploma in pharmacy or half should possess a degree or diploma in pharmacy, pharmaceutical chemistry or be Registered pharmacists.	**Nominated Members:** 1. Two to four members nominated by each participating State Government, of whom, more than half should possess a degree or diploma in pharmacy, pharmaceutical chemistry or be Registered pharmacists.
Ex-officio Members: 1. Chief administrative medical officer of the state. 2. Officer-in-charge of Drugs Control Administration of the State. 3. Government Analyst of the State or where there is more than one Analyst, such one may be appointed by the State Government.	**Ex-officio Members:** 1. Chief administrative medical officer of each of the participating State. 2. Officer-in-charge of Drugs Control Administration of each participating State. 3. Government Analyst of each participating State.

The President and Vice-President of the State Councils are elected by the members from amongst themselves. Both the nominated and elected members of the Council can hold office for a term of five years. Any member absenting without sufficient excuse is deemed to have vacated his seat from the council. A casual vacancy in the Council is usually filled by fresh nomination or election. All members of the Council are eligible for re-election or re-nomination. Like the PCI, State and Joint State Pharmacy Councils also usually appoint a Registrar (who may also act as its Secretary and Treasurer) and other necessary officers and staff as may be required to carry out its functions under the Pharmacy Act. An Executive Committee is also constituted in similar way to that of PCI and its function is to furnish necessary information and annual report to the PCI.

3.5.1 Functions of State Pharmacy Councils and Joint State Pharmacy Councils

I. Inspection by State Councils:

The State and Joint State Pharmacy Councils with permission from the respective State Governments may appoint a sufficient number of Inspectors having prescribed qualification:

(i) To inspect any premises where drugs are compounded or dispensed.
(ii) To enquire whether the dispensing or compounding of drugs is done by registered pharmacists or not.
(iii) To investigate any complaint made in writing regarding contravention of the Act.
(iv) To institute prosecution under the direction of the Executive Committee of the State.
(v) To exercise such other powers as may be necessary for certain provisions of the Act.

II. Registration of Pharmacists in the First and Subsequent Registers:

The Pharmacy Act, 1948 provides for the registration of Pharmacists in all the states of India.

The first Register of Pharmacists in a State is required to be prepared by the State government. State Pharmacy Councils are responsible for the maintenance of the first and subsequent Registers where pharmacists' names are to be entered. Every year, before the end of June, State councils are required to pay Central council, a sum equivalent to one fourth of fees prescribed by the PCI during the period of 12 months before the end of 31st March. The Register of Pharmacists includes the following particulars:

(i) Full name and residential address of the registered person.
(ii) The Date of his first entry in the Register.
(ii) Qualification of the person required for registration.
(iv) Professional address of the person and in the case of employed persons, the details of the employer.
(v) Such other particulars as may be prescribed.

First Register:

For preparing the first Register, the State Government constitutes a Registration Tribunal comprising of three persons and a Registrar who also acts as its secretary. The State Government then appoints a date before which all applications for registration, accompanied by the prescribed fee should reach the Registration Tribunal. On receipt of the applications, the tribunal then examines all the applications upto the appointed date and when satisfied that an applicant is duly qualified, directs his or her name to be entered into the Register.

The first Register is published by the State Government. Any person who is dissatisfied with the decision of the Tribunal can appeal to the authority appointed by the Government within 60 days of such publication in this behalf. The decision of the State Government is considered to be final and the Tribunal has to amend the Register in accordance with the directions of the Government. Upon the constitution of the State Council, the Register is handed over into its custody.

Qualifications for Entry of a Person into the First Register:

A person whose name has to be entered into the First Register should have the following qualifications:

(i) Should have attained the age of 18 years.
(ii) Should pay the prescribed fee to the state council.
(iii) Should be a resident of the State or should carry out his business or profession of pharmacy in the State.
(iv) Should have the following qualifications.
  (a) A degree or diploma in Pharmacy or Pharmaceutical Chemistry or a Chemist and Druggist Diploma of an Indian University or a State Government or possess any other qualification granted outside the India which is recognised as adequate for registration, or
  (b) A degree of an Indian university other than a degree or diploma in Pharmacy or Pharmaceutical chemistry and engaged in dispensing and compounding of drugs in a hospital or dispensary or any other place where drugs are regularly dispensed on the prescription of a Registered Medical Practitioner for a time period of not less than 3 years, or
  (c) Have passed an examination recognized as adequate by the State Government for compounders and dispensers, or
  (d) Have an experience of not less than five years in dispensing and compounding of drugs in a hospital or dispensary or any other place where drugs are regularly dispensed on the prescription of a Registered Medical Practitioner, prior to the date notified by the State Government for receipt of applications for entry of names on the first Register.

Subsequent Registers:

After the preparation of the first Register and before the Education Regulations have taken effect in a state, a person desirous of having his name registered in the Subsequent Register has to qualify for the following particulars:

(i) Should be at least 18 years of age.
(ii) Should have paid the prescribed fee.
(ii) Should be a resident of the State or should carry out his business or profession of pharmacy in the State.
(iv) Should fulfill the following requirements:
  (a) Requirements as prescribed for registration and where no such requirements have been prescribed, possess the qualifications which would have entitled him to have his name registered on the first Register and is at least matriculate, or
  (b) Is a Registered Pharmacist in another State, or
  (c) Possess a qualification granted outside India which is recognized as adequate for registration and is at least matriculate qualification required after Education Regulations have taken effect.

Special Provisions for Registration of Certain Persons:

The Pharmacy (Amendment) Act of 1959 made some special provisions for certain classes of persons affected by the partition of the country in 1947. These provisons are applicable to those who migrated to India or resisted in a place which became Indian territory. These provisons became effective after years of commencement of Pharmacy (Amendement) Act, 1959 which made special provisons for the following persons:

1. Persons holding a degree or diploma in pharmacy, pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or a State government or have passed an examination recognised by the state government as adequate for componders and dispensers and who were eligible for registration between closing of the First Register and the date when Education Regulation came into effect.
2. Persons approved as **Qualified Persons** before 31st December 1969 for compounding and dispensing of medicines under the Drugs and Cosmetics Act, 1940 and Rules.
3. **Displaced persons** from Bangladesh who left Bangladesh after 14th April, 1957 but before 25th March, 1971 and **Repatriates** from Burma, Srilanka, Uganda or any other country who left or were displaced from such country between 14th April, 1957 and 25th March, 1971 and were carrying out the business or profession of pharmacy as the principle means of their livelihood for a total period of five years prior to the date of application.
4. Citizens of India who had been engaged in the business or profession of pharmacy abroad and satisfied the conditions for registration in the first register of the respective Indian State Councils.
5. Persons who have been engaged in the dispensing of drugs in a hospital or dispensary or another place where the drugs are dispensed regularly on prescriptions of Registered Medical Practioners for a period of five years prior to the date appointed.

Removal of Names from the Register:

The names of the registered persons may be removed from the register on the following reasons:

1. If his name has been entered into the Register by error, misrepresentation or suppression of facts.
2. If he has been convicted of an offence in any professional respect which in the opinion of Executive Committee renders him unfit to be on the Register of Pharmacists.
3. If a person employed under him in connection with any business of pharmacy has been convicted of any offence or has been found guilty of any infamous conduct, such that if he himself was a Registered Pharmacist, his name would have been removed from the Register.

However, under this section, action against the Pharmacist can only be taken if it is proved that:

(a) The offence or infamous conduct was instigated or connived at by the Registered Pharmacist, or

(b) The Registered Pharmacist himself has been guilty of such an offence during the period of 12 months preceding the offence.

(c) Any person employed by the Pharmacist for purpose of the business of pharmacy has been guilty of similar offence during the preceding 12 months and the

Registered Pharmacist had, or reasonably ought to have had, knowledge of such previous offence.

(d) The offence or infamous conduct continued over a period, the registered pharmacist had or reasonably ought to have, knowledge of continuing the offence or infamous conduct.

(e) The act is an offence under the Drugs and Cosmetics Act, 1940 and the Pharmacist had not used his intelligence to ensure that the provisions of the Act were being complied at his place of business and by persons employed by him or by persons under his control.

An order of removal of names of persons from the register may direct that the person whose name is removed shall not be eligible for registration either permanently or for time being under this act. The order of Executive Committee is subject to confirmation by the State Pharmacy Council and does not take effect until after three months from the date of such confirmation.

Any person aggrieved by the order for removal of his name from the register may appeal within 30 days from the communication to him of confirmation of the order by the State Council and the State Government decision is final. A person whose name has been removed from the register has to surrender his registration certificate to State Pharmacy Council Registrar and the name so removed is published in the Gazette.

Printing of Registers:

Subsequent to the commencement of the Pharmacy (Amendment) Act, 1959, as soon as may be after the 1st April, every year, the registrars of the State Council were required to print the registers as they stood on that date. They are also required to print as soon as may after the 1st April in each year, copies of the annual supplement to register, showing all additions to, and other amendments, in the said register. The registrar should bring up-to-date the respective registers, three months before ordinary elections of the State Council are held and print copies of the register. Such copies should be made available to persons applying for the same, on payment of the prescribed charge. Such copies are the evidence that on the date referred to in the register of annual supplement, the persons, whose names are entered therein, were registered pharmacists.

3.5.2 Offences and Penalties

The offences and penalties of the Pharmacy Act are as follows;

Falsely claiming to be registered pharmacist: Any person who falsely claims to be a registered pharmacists and/or uses in connection with his name or title any words or letters to show that his name has been entered in the register of Pharmacist, such person is punishable on first conviction with a fine extending up to ₹ 500 and a fine up to ₹ 1000 and imprisonment for up to 6 months on second or subsequent conviction. The use of words, Pharmacist, Chemist, Druggist, Pharmacist, Dispenser, Dispensing Chemist or any combination of such words shall be deemed to suggest that a person is a Registered Person.

If a person is a Registered Pharmacist in another state and at the time of making such acclaim, has filed an application for registration in the state, he shall not be deemed to be guilty of the offence.

Dispensing by Unregistered Persons:

After the date notified in this behalf, by the State Government, no person other than a Registered Pharmacist can dispense, mix or compound drugs on the prescription of a medical practitioner. This, however, does not apply to dispense of medicines by a Medical Practitioner to his own patients, or with the permission of the State Government to the patients of other medical practitioner.

Dispensing by unregistered persons is punishable with imprisonment of upto six months or a fine of up to ₹ 1000 or both. Cognizance of this offence can be taken only on the complaints by the state government or by an officer authorized in this behalf or by the order of the Executive Committee of the State Pharmacy Council.

Failing to Surrender Certificate of Registration:

If any person, whose name has been removed for the time being from the Regtister, fails to surrender his certificate of registration without sufficient reason is punishable with a fine up to ₹ 50. Cognizance of this offence shall not be taken except by an order of the Executive Committee of the State Pharmacy Council.

Penalty for Obstructing Inspectors:

Any person willfully obstructing Inspector of State Pharmacy Council shall be liable to imprisonment of up to 6 months or a fine of up to ₹ 1000 or both.

EXERCISE

1. Discuss the constitution and functions of pharmacy council of India. Add a note on educational regulations.
2. Write the objectives of the Pharmacy Act.
3. Explain the constitution and functions of state and joint state pharmacy councils.
4. What is first register? Give the qualifications required for the entry in to the first register.
5. Enlist the qualifications required for the entry of persons in subsequent register.
6. Describe the procedure notified in the Pharmacy Act, 1948 for the removal of names from the register of pharmacists.
7. What are the special provisions applicable to the certain persons as per the Pharmacy Act, 1948.
8. Discuss the offences and penalties of the Pharmacy Act, 1948.

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Chapter ... 4

MEDICINAL AND TOILET PREPARATIONS (EXCISE DUTIES) ACT, 1955

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- The objectives of the Act.
- The procedure of getting license for manufacturing medicinal and toilet preparations.
- The bonded and non-bonded manufacturing process of alcoholic preparations.
- The export process of alcoholic preparations.
- The offences and penalties of the Act.

4.1 INTRODUCTION

Alcohol has excellent solvent properties apart from its preservative mechanism and hence it has found a very important role in the manufacturing of drugs and medicines. Drinking alcohol is an abuse whereas its usage in toilet preparations may be considered as a luxury. For this reason, alcohol, which is used either for drinking or for the manufacture of toilet preparations such as perfumes, is subject to a much higher rate of excise duty than that used for the manufacture of medicinal preparations which cannot be used as ordinary alcoholic beverages. Prior to the enactment of this act, each state in India had an Excise manual and a set of rules of its own. Thus, differences existed in the rates of excise duty for the same item in different states, leading to large scale inter-state smuggling of such preparations. The Act was passed mainly to curb this evil and repealed the laws in force in any state prior to the commencement of this Act. However, any state rules not inconsistent with this Act are still valid and have the same force as if they have been made by an authority in this behalf under this Act.

The Medicinal and Toilet preparations Act was passed in the year 1955 and the Rules were passed in 1956. The Act extends to the whole of India and came into force on 1st April 1957.

4.2 OBJECTIVES OF THE ACT

This Act was passed with the following objectives:

(i) To provide the collection of levy and duties of excise on medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics.

(ii) To provide for uniformity in the rules and rates of Excise duties leviable on such preparations throughout the country.

4.3 DEFINITIONS

Alcohol means ethyl alcohol of any strength and purity having the chemical composition C_2H_5OH.

Absolute alcohol means alcohol conforming to the British Pharmacopoeial specifications for dehydrated alcohol.

Dutiable goods means the medicinal and toilet preparations specified in the Schedule as being subject to the duties of excise levied under the Act.

Medicinal preparation 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.

Toilet preparation means any preparation which is intended for use in the toilet of the human or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter complexion, hair, skin or teeth, and includes deodorants and perfumes.

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

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

Patent or Proprietary medicines means any medicinal preparation which bears either on itself or on its container or both, a name which is not specified in a monograph in a Pharmacopoeia, formulary or other publications notified in this behalf by the Central Government in the Official Gazette, or which is a brand name or any other mark such as a symbol, monogram, label, signature or invented words or any writing which is used in relation to that medicinal preparation for the purpose of indicating or so as to indicate a connection in the course of trade between the preparation and some person having the right either as proprietor or otherwise to use the name or mark with or without any indication of the identity of that person.

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

Rectified spirit means plain denatured alcohol of strength not less than 50.0° over proof and includes absolute alcohol.

London proof spirit means that mixture of ethyl alcohol and distilled water which at the temperature of 51°F weighs exactly $12/13^{th}$ parts of an equal measure of distilled water at the same temperature.

Restricted preparation means every medicinal and toilet preparation specified in the Schedules and includes every preparation declared by the Central Government as restricted preparation.

Unrestricted preparation means any medicinal or toilet preparation containing alcohol but other than restricted preparation or a spurious preparation.

4.4 LICENSING PROCEDURE

Manufacturing of alcoholic and narcotic preparations can only be undertaken under the authority of a license granted for the purpose and such a license is issued only if the requisite license for manufacture of drugs under the Drugs and Cosmetics Act and Rules has been first obtained. Application for the license or for its renewal is to be made to Licensing authority who is the excise in the case of a bonded manufactory or ware house and in other cases, such officer as the State government may authorize in this behalf. A separate application is to be made if more than one kind of license is desired. Where the applicant has more than one place of business, he should obtain a separate license in respect of each such place of business. The application for the license should be submitted in the prescribed form accompanied by the prescribed fee, at least two months before the proposed date of commencement of the manufacture.

The following particulars are required to be submitted in the application for obtaining a license to manufacture dutiable goods in or outside bond:

1. Name and address of the applicant and place and site on which the manufactory is situated or to be constructed. If the applicant is a firm, the name, and address of every partner of the firm, and if it is a company, its registered name, and address, and the names and addresses of its directors, managers, and managing agents.
2. The amount of capital proposed to be invested in the venture.
3. Approximate date from which the applicant desires to commence the manufactory and the statement whether the bonded laboratory will require the services of a whole-time or part time excise officer and whether quarters for the excise staff will be provided within the manufactory.
4. The number and full description of vatts, still and other permanent apparatus and the machinery which the applicant wishes to get up together with the maximum quantity of alcohol and alcohol content in the finished preparations and the maximum quantities by weight of opium, Indian hemp or other narcotic drugs or narcotic and their contents in finished and unfinished preparations.
5. The site and elevation plans of the manufactory/building and also similar plans for the quarter of the Excise Officer together with relevant records.
6. The amount in cash or Government Promissory Notes which the applicant is prepared to furnish for the due performance of the conditions on which the license may be granted.
7. The kind and number of each license under the Drugs and Cosmetics Act held by applicant.
8. A list of all preparations which the applicant proposes to manufacture and/or those manufactured during the preceding year showing the percentage or proportion of alcohol in alcoholic preparations or opium, Indian hemp or another narcotic drug in terms of weight in proportion containing those substances, quoting the pharmacopoeia under which such preparations were proposed to be manufactured.

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

(i) The qualifications and previous experience of technical personnel engaged in the manufacturing operations.
(ii) The equipment of the bonded and non-bonded laboratory.
(iii) The soundness of the applicant's financial position.
(iv) Suitability of the proposed building for the establishment of the manufacturing unit.

The license cannot be sold or transferred. It should be exhibited in a conspicuous part of the licensed premises. Where a licensee sells or transfers his business to another person, the purchaser or the transferee has to obtain a fresh license but for the residue of the period covered by the license, it is issued free of cost. A licensee can enter into partnership after obtaining the prior sanction of the licensing authority and his license is then suitably amended. If a partnership is dissolved, every partner is required to send a report of dissolution to the licensing authority within ten days. If a licensee desires to transfer his business to new premises he can do so by informing the licensing authority at least fifteen days in advance, specifying the address of the premises, and getting his license suitably amended.

A license can be revoked, or suspended by the licensing authority if the licensee or any other in his employment is found to have committed a breach of the prescribed conditions or any of provisions of the act or rules, or has been convicted of an offence; after giving him a reasonable opportunity of showing cause against the action proposed to be taken. The license remains valid for a period of one year and should be renewed thereafter. The application for renewal should be submitted at least one month before the commencement of the year to which it relates. The licensee also provides 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 licensed premises. On termination of the period of the license, the licensee has to deliver the Visit Book, the account and the license to such officer as directed by the licensing authority. All invoices, cash memoranda, permits and other documents relating to the consignments received and dealt with licensee are to be preserved for a year after the year to which they relate.

4.5 MANUFACTURE

Manufacture of alcoholic and other narcotic drugs can be undertaken only under the authority a license granted for the purpose. Such license is issued only when the requisite license for the manufacture of drugs under the Drugs and Cosmetics Act has been first obtained. The license cannot be transferred or sold and has to be exhibited in a conspicuous part of the licensed premises. Manufacture of medicinal and toilet preparations containing alcohol is permitted both 'in bond' as well as 'outside bond.

4.5.1 Manufacture in Bond

Preparations are deemed to be manufactured in the bond when they are manufactured in the premises, that are licensed or approved for this purpose and on which excise duty is not paid until the finished products are removed from the licensed premises. Rectified spirit is issued for the purpose only if manufacturer enters into a bond with sufficient security towards due payment of the duty.

Bonded Laboratory:

A bonded laboratory should have the following provisions:

1. A spirit store unless the laboratory is attached to a distillery or a spirit warehouse.
2. A large room for the manufacture of medicinal preparations and separate arrangement for the manufacture of toilet preparations.
3. There should be one or more separate rooms for the storage of finished medicinal or toilet preparations.
4. Accommodation with necessary furniture for the officer-in-charge of the bonded laboratory near its entrance.
5. Malleable iron rods not less than 1.9 cm in thickness, set not more than 10 cm apart, embodied in brick work to a depth of at least 5 cm and covered on the inside with strong wire netting or expanded metal of a mesh not more than 2.5 cm in diameter or length, in every window of the bonded laboratory.
6. A board outside every room bearing the name and a serial number of the room.
7. All pipes from sinks inside the laboratory, connected with the general drainage system of the premises.
8. Provisions for cutting off the gas and electric supply to the laboratory at the end of the day's work.

There should be only one entrance to the laboratory and only one door for each of its compartments. The laboratory can be opened only in the presence of the Excise officer-in-charge and during his absence, all the doors should be secured with excise ticket locks. Addition or alteration to the permanent fixture in the premises can be made only with the previous permission of the Excise Commissioner. The permanent vessels for the storage of alcohol, narcotic drugs and narcotics received under bond and all the finished products on which duty has not been paid should be secured with excise ticket locks. All vessels intended to hold alcohol and liquid preparations should bear a distinctive serial number and their full capacity distinctly and indelibly marked on them.

Manufacture of Alcoholic Preparations in Bond:

1. Procurement of Spirit from a Distillery or Spirit Warehouse:

Rectified spirit required for the manufacture of medicinal and toilet preparations can be obtained on an indent counter signed by the officer-in-charge of the laboratory, from any approved distillery or spirit warehouse either situated in the same State or in another Stare. The officer of the distillery warehouse, on receipt of the duplicate copy of the indent, shall issue the spirit in duly sealed containers and send advice of the consignment to the Excise officer-in-charge of the bonded laboratory.

2. Verification and Storage of Spirit Received:

Consignments of spirit received at the laboratory have to be verified in volume and strength by the Excise officer and then stored in the Spirit Store from where it can be issued from time to time to the manufacturer, according to his requisition.

3. Issue of Spirit from the Spirit Store for Manufacture:

Calculated quantities of spirit can be obtained by the manufacturer on a requisition to the officer in-charge who shall then issue the same from the Spirit Store. The spirit so issued

has to be immediately mixed with other ingredients of the preparation in the presence of the officer-in-charge. The percolators or other vessels charged with the spirit should be labeled with the following particulars:

(a) Name and Batch number of preparation.
(b) Description and quantity of alcohol put in it.
(c) Date of removal of preparation and the quantity of such preparation removed.

As soon as the manufacture of preparation has been completed, it should be removed to the finished goods store, measured and stored in the vessels provided for the purpose. Details of the preparation should also be entered in a register and it should be given a Batch number. The Excise officer-in-charge may permit the manufacturer to take a sample of not more than 250 ml for analysis purpose, free of duty. A separate account must be maintained by the manufacturer regarding the number of samples used by him for analysis and any amount left over after analysis should be mixed with the main bulk of the batch.

4. Storage of Finished Product:

All finished preparations should be stored in bulk in jars or bottles, each containing not less than 2.25 litres of the preparation. Every container should be labeled with the name of the preparation of its batch number, strength, date of storage and the actual content in bulk litres. The containers should be so arranged in suitable racks so as to allow ready identification of each batch. A record of all deficiencies in bulk content of finished preparations should be kept by the officer-in-charge and Excise Commissioner quarterly. If the Excise Commissioner is satisfied that the deficiency reported was due to some unavoidable reasons, he may remit the duty payable. Otherwise, such loss is subject to levy of duty at a penal rate which shall not be more than double the prescribed rates.

5. Issue of Alcoholic Preparations from Bonded Laboratories:

Alcoholic preparations from a bonded laboratory can be taken out by the manufacturer by making an application to the officer-in-charge and after payment of the excise duty. Duty is payable even on Physician's free samples. However, preparations issued to a bonded warehouse or for export to a place outside India or to institutions authorized to receive duty free preparations may be issued without the payment of duty.

Disposal of Substandard Preparations:

A finished medicinal or toilet preparation if suspected to have deteriorated in quality may be destroyed by the manufacturer with the permission of the Excise Commissioner. The Excise Commissioner may also allow the manufacturer to reprocess a sub-standard preparation. The Excise Commissioner shall waive the duty on the alcoholic content of the preparation so destroyed, if he is satisfied that the deterioration of the preparation or its improper manufacture was due to reasons beyond the control of the manufacturer.

Disposal of Recovered Alcohol:

Alcohol recovered in the course of production of a medicinal or toilet preparation may be for subsequent production of the same preparation, provided, such alcohol is collected and accounted separately. Where the alcohol recovered from a preparation liable to duty at the lower rate is sought to be used in the manufacture of a preparation subject to a higher rate of duty, the duty on the preparation so manufactured shall be collected after determining the

spirit strength of the preparation. An account of recovered alcohol shall be maintained by the officer-in-charge in the prescribed form. Recovered alcohol unfit for the consumption shall be destroyed by the manufacturer in the presence of officer-in-charge. No rebate of duty shall however, be allowed on recovered alcohol so destroyed.

Wastage of Spirit during Manufacture:

The permissible percentage of wastage of alcohol during the manufacture of a particular medicinal or toilet preparation is fixed by the State Government from time to time. Any wastage exceeding the permissible limit and not properly accounted for shall be charged with the duty together with such penalty not exceeding the duty leviable thereon as the Excise Commissioner may deem fit.

Remission of Duty In Case of Loss Due to Accident:

In case of any accidental loss of alcohol in bonded manufactory (except on account of theft), the Excise commissioner may remit the duty on the alcohol so lost, if he is advised by the Excise Officer in-charge of the laboratory that the loss was beyond the control of the manufacturer.

4.5.2 Manufacture Outside Bond

Preparations are deemed to be manufactured outside bond when they are manufactured in a premise, licensed or approved for this purpose and where duty paid spirit is used for the preparation. The manufacture and sale in a non-bonded laboratory have to be conducted between sunrise and sunset on days and hours fixed for this purpose by the Excise Commissioner.

1. Receiving Duty Paid Spirit:

Rectified spirit can be obtained from any distillery or spirit warehouse on an indent prepared in triplicate. The original copy is sent to the distiller or spirit warehouse keeper, the duplicate is sent to the officer in-charge of the distillery or spirit warehouse and triplicate is retained by the licensee. The duty should be paid to the Government Treasury and a challan in token of such payment should be enclosed along with the duplicate copy of the indent being sent to the officer-in charge of the distillery or spirit warehouse. The treasury officer sends advice to the officer-in-charge of the distillery or the spirit warehouse who shall issue the spirit together with a permit covering the issue. The spirit so brought into the non-bonded manufactory has to be immediately transferred to the spirit store and the necessary accounts written up in the prescribed register. The manufacturer cannot sell or transfer the rectified spirit obtained by him. In any case, the quantity of rectified spirit in the possession of the manufacturer should not exceed the limit fixed by the licensing authority.

2. Manufacture, Storage, and Sale:

The manufacture, storage, and sale should be carried out in the licensed premises only. Each preparation should be registered and bear a distinctive batch number. All finished preparations should be transferred from the laboratory to the 'finished store' and be so arranged that the checking of stock of every batch of preparation from the register is facilitated. Preparations stored in bulk should be measured into the storage vessel to the nearest fluid ounce and sealed. The quantities taken out from time to time should be entered in the stock card maintained for the purpose.

3. Sampling:

Without previous notice to the manufacturer, the excise Sam officer shall take samples of not less than 10% and not more than 15% of the total number of preparations from the finished stocks at least once every month. These samples are forwarded to the chemical examiner for the verification of alcohol contents thereof. If the report of the chemic examiner differs by more than 3° proof strength as declared by the manufacturer, the manufacturer is liable to a penalty at the rate of 10 times the difference in duty on the quantity so manufactured but not exceeding ₹ 2000. The frequent occurrence of such offence shall be ground for the cancelation of the license held by the manufacturer. All samples are to be taken by the excise officer personally and in the presence of the manufacturer or his authorized agent. Every sample (8 fluid ounces or as fixed by the Excise Commissioner) should be taken in duplicate and the cork of each bottle should be fixed with an officer's personal seal. The label of the bottle should be signed by the officer taking the sample.

The manufacturer can also affix his seal and sign the labels. Duplicate samples are to be preserved carefully under lock and key and returned promptly to the manufacturer when needed no more. The manufacturer is not entitled to any compensation for the samples taken for analysis.

4. Returns:

The manufacturer should maintain up-to-date and proper accounts of the transactions of a business in his manufactory and deliver them to the proper officer by the 5^{th} of each month. The manufacturer is also required to furnish a list of all his employees who are required to enter non-bonded manufactory, to the Excise Commissioner and only such persons should be allowed to enter the laboratory.

5. Inspection:

The non-bonded laboratory can be inspected by the Excise Commissioner and other having jurisdiction over the area in which the manufactory is situated. It shall be inspected at once every month by the proper Excise officer. The State Government may authorize inspection of the non-bonded establishment by any officer of Prohibition, Land Revenue or Medical and Public Health Departments.

4.6 EXPORT OF ALCOHOLIC PREPARATIONS

No duty is required to be paid on alcoholic preparations which are exported from India.

Such preparations can be exported in either of the following two ways:

(i) Under bond (directly from a bonded laboratory without payment of duty), or

(ii) Under claim for rebate of duty.

Export under Bond:

Only those persons who have a bonded laboratory or a bonded warehouse can export alcoholic preparations under bond. The exporter should present an application in triplicate to the officer-in-charge of the laboratory or warehouse, stating whether the goods are to be exported by land, sea, air or by post parcel. A separate application is required in respect of each consignment. The officer-in-charge sends the original copy of the application to the customs officer or the border examiner or the post master, as the case may be, at the place

of export. The duplicate is delivered to the consigner and the triplicate is retained as the office copy. Goods for export should be packed in cases or packages and should be legibly marked in ink or oil color with the following particulars:

1. Serial number commencing with 1 for each year.
2. Owner's name and special mark, if any.
3. The total quantity of dutiable goods with their alcohol content in L.P. litres.

After verifying the particulars entered in the application, the officer note particulars on the body of each package:

(i) Name and address of the consignee.
(ii) Description of the goods.
(iii) The total quantity of goods packed.
(iv) The gross weight of the package.

The said officer shall then seal each package with his official seal in such a manner that the package cannot be tempered with, without breaking the seal. The officer shall also endorse all the copies of the application and specify the period within which the goods should be actually exported and return the duplicate copy to the consigner. After dispatching the goods, the consigner should enter the number and date of Railway Receipt or bill of lading on the duplicate copy and communicate these particulars to the proper officer for entry in the other copies.

If the goods are being sent by post, the exporter should present the duplicate copy of his application, duly endorsed by the Excise officer, to the Post master at the office of booking together with relevant packets or packages. Post master of the destination Post office should certify on the duplicate application that the goods have been duly exported out of India and return the same through the Post master at the Post office of booking, to the exporter who shall present it to the officer-in-charge of his laboratory or warehouse.

Export of Duty Paid Goods:

Goods on which duty has already been paid can be exported under claim for rebate of duty. The owner of a non-bonded manufactory or a warehouse dealer, who wants to export duty paid goods should give at least 48 hours notice to the proper Excise officer for supervising the packing of goods to be exported. The consigner should present the entire consignment before the proper officer who shall take samples of the goods and send to the Chemical examiner for analysis. On receipt of a report from the Chemical Examiner, he shall enter the alcoholic content of the goods, in the duplicate copy of the application. This copy of the application should be presented by the exporter to the Excise Commissioner for claiming a rebate of excise duty.

After verifying the particulars entered in the application, the officer-in-charge may get the following particulars entered on the body of each package:

(i) Name and address of the consignee.
(ii) Description of the goods.
(iii) The total quantity of goods packed and their alcoholic content in L.P. litres.
(iv) The gross weight of the package.

The officer-in-charge should then seal each package with his official seal so as to make them temper proof. The packages can then be exported in the same manner as in the case of the bonded goods. Claim for a rebate of duty has to be made within one month of the issue of export certificate presenting the duplicate certified application to the Excise Commissioner. The rebate is sanctioned by the Excise Commissioner if he is satisfied that the claim is in order. The Excise Commissioner may extend the period within which such claim for rebate shall be made.

4.7 MANUFACTURE OF AYURVEDIC, HOMEOPATHIC AND PATENT AND PROPRIETARY PREPARATIONS

4.7.1 Ayurvedic Preparations

'Asavas' and 'Aristas' are the principal types of Ayurvedic preparations which contain self-generated alcohol. The pharmacopoeias that are used in various States are presently recognised as Ayurvedic pharmacopeias. Ayurvedic preparations containing self-generated alcohol in which the alcohol content does not exceed 2% proof spirit are deemed to be non-alcoholic and hence are exempted from the payment of the excise duty.

Preparations containing more than 2% alcohol but not capable of consumption as an ordinary alcoholic beverage are also exempted from excise duty. The preparations which can be consumed as alcoholic beverages are liable to a duty of ₹ 1 per L.P. litre. Registered Ayurvedic Practitioners of good standing may be allowed to manufacture and dispense such preparations free of duty, provided, they take license and use preparations only for their patients. The practitioner should allow excise officer to take samples to ensure that the preparations contain only self-generated alcohol and also maintain a daily account of all the preparations manufactured and dispensed giving particulars of names and addresses of the patients. Ayurvedic preparations made by distillation or to which alcohol is added at any stage of manufacture are treated as preparations capable of being used as ordinary alcoholic beverages and hence are liable to a duty of ₹ 30 per L.P. litre.

4.7.2 Homeopathic Preparations

All homoeopathic preparations containing alcohol are classified as being consumed as ordinary alcoholic beverages and attract duties prescribed for such class of preparations falling under the category of restricted preparations.

Patent and Proprietary Preparations:

All Allopathic preparations containing alcohol can be categorized into the following two types:

1. Official preparations made strictly according to the formulae given in the current editions of B.P., B.P.C., I.P., U.S.P., N.F.(U.S.), any other pharmacopoeia recognised under the Drugs and Cosmetics Act, 1940 by the Government of India, and Veterinary Codex recognised by the Government of India.
2. Non-official allopathic preparations referred to as proprietary preparations which are prepared according to the allopathic system of medicine and conform strictly to the formula displayed on the label.

Medicinal and toilet preparations capable of being consumed as ordinary alcoholic beverages are referred to as 'restricted preparations' and are enlisted in the Schedule.

All other standard preparations and proprietary preparations not being capable of being consumed as alcoholic beverages are referred to as 'unrestricted preparations.

Any of the unrestricted preparations, if misused widely, may be declared to be restricted preparations by the Central Government either on the request of the State Government or on its own; and on the advice of the Standing Committee. Any new proprietary preparation is presumed to be a restricted preparation unless declared to the contrary by the Central Government on the advice of the Standing Committee. Any manufacturer wanting to manufacture a proprietary preparation should submit two samples of the preparation together with its formula to the State Government. The State Government shall then forward the samples to the Central Government which seeking the advice of the Standing Committee, will declare whether the sample is to be categorized as a restricted or an unrestricted preparation.

The Standing Committee consists of the following members;

1. Drugs Controller of India.
2. Chief Chemist, Central Revenues Laboratory.
3. One pharmacologist nominated by the Central Government.
4. The adviser on Indigenous System of Medicine, Ministry of Heath, Family Planning and Urban Development.

The Committee advises the Central Government on all matters connected with the technical aspects of administration of the Act and the Rules and particularly whether (i) a particular preparation is to be treated as a genuine medicinal or toilet preparation for the purposes of the Act; and if so (ii) whether it should be treated or continue to be treated as a restricted or unrestricted preparation.

4.8 OFFENCES AND PENALTIES

Sr. No.	Offences	Penalties
1.	Non-compliance with conditions of the license and failure to pay duty; or	Imprisonment up to 6 months or fine upto ₹ 200 or both.
2.	Failure to supply information asked or giving false information; or	Imprisonment up to 6 months or fine upto ₹ 200 or both.
3.	Attempting or committing or abetting commission of any offence.	Imprisonment up to 6 months or fine upto ₹ 200 or both.
4.	The connivance of offences by owners or occupiers of land.	Imprisonment up to 6 months or fine up to ₹ 500 or both.
5.	Vexatious search, seizure etc. by Excise Officer.	Fine upto ₹ 2000 for every offence.
6.	Failure of Excise Officer on duty.	Imprisonment up to 3 months or fine up to 3 months pay or both.
7.	Improper maintenance of stocks or accounts.	Fine upto ₹ 100.
8.	Making false entries or tearing pages from stock book.	Fine upto ₹ 2000 and goods liable to confiscation.
9.	Sale of dutiable goods otherwise than in prescribed containers bearing the labels.	Fine upto ₹ 1000 and goods liable to confiscation.
10.	Failure to furnish proof of export within specified period.	Fine upto ₹ 2000.

Sr. No.	Offences	Penalties
	Offences with respect to Warehousing:	
1.	Opening any locks or door of the warehouse without prior consent; or	Fine upto ₹ 2000 and goods liable to confiscation.
2.	Making any alteration in the warehouse without prior consent; or	Fine upto ₹ 2000 and goods liable to confiscation.
3.	Warehousing or removing goods in contravention of the rules; or	Fine upto ₹ 2000 and goods liable to confiscation.
4.	Privately removing or concealing any goods either before or after being warehoused;	Fine upto ₹ 2000 and goods liable to confiscation.
5.	Obstructing officers and giving false information.	Fine upto ₹ 500.
6.	Willfully and maliciously giving information.	Imprisonment up to 2 years or fine up to ₹ 2000 or both.

EXERCISE

1. Define the following terms in relation to Medicinal and Toilet preparations Act
   (a) Absolute alcohol
   (b) Denatured alcohol
   (c) Rectified spirit
   (d) Restricted preparation
2. Define Bonded laboratory. Enlist the requirements of a bonded laboratory.
3. Describe the manufacturing process of alcoholic preparations in Bonded laboratory.
4. Define non-bonded laboratory. Explain the steps involved in the manufacturing of alcoholic preparations in Non-bonded laboratory.
5. Discuss the rules and provisions for getting license for manufacture of alcoholic preparations as per MTP Act.
6. Describe the manufacturing of ayurvedic, homoeopathic, patent and proprietary preparations containing alcohol as per MTP Act.
7. Discuss briefly the export of alcoholic preparations under medicinal and toilet preparations Act.
8. Discuss the offences and penalties of Medicinal and Toilet preparations Act.

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Chapter ... 5

NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, 1985 AND RULES

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- The objectives of NDPS Act.
- The composition and roles of Narcotic drugs and Psychotropic sbstances consultative cmmittee.
- The prohibition, control and regulations by central and state governments.
- The rules for the cultivation, production, manufacture, sale and export of opium as per NDPS Act.
- The purpose and function of National fund for drug abuse.
- Offences and penalties of the Act.

5.1 INTRODUCTION

Coca, hemp, and opium are considered to be medicinal drugs but because of their habit forming and degenerating effect, their use has been restricted from the social point of view. Opium was brought under legislative control in 1857 after framing Opium Act with the main objective to protect public welfare by preserving the health and eliminating undesirable social and moral effects commonly associated with indiscriminate use of the drugs.

In the present day, drugs like heroin, brown sugar, charas and many more have been added to the list of habit forming drugs. The unfortunate fact was that, these narcotic drugs and psychotropic substances are creating an increasing number of addicts in all the corners of the world. Smuggling and sale of narcotic drugs and psychotropic substances is still a lucrative business amongst anti-social elements.

With the passage of time and the developments in the field of illicit drug traffic and drug abuse at the national and international level, the statutory control [particularly the Opium Act, 1857, the Opium Act, 1858 and the dangerous Drugs Act, 1930] was found to be inadequate and required fresh legislation. This resulted in the enactment of the Narcotic Drugs and Psychotropic Substances Act and Rules, 1985.

The Act came in force on 14 November 1985 and extends to the whole of India and it also applies (a) to all citizens of India outside India; (b) to all persons on ships and aircrafts registered in India, wherever they may be.

5.2 OBJECTIVES OF THE NDPS ACT

1. To consolidate and amend the existing laws relating to Narcotic Drug.
2. To make stringent provisions for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.
3. To considerably enhance the penalties particularly for trafficking offences.
4. To make provisions for the implementations of International Conventions relating to Drugs and Psychotropic Substances to which India is a party.

5.3 DEFINITIONS OF THE ACT

Cannabis (hemp) means

(i) Charas, i.e., the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish.

(ii) Ganja, i.e, 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 as designated.

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

Cannabis Plant means any plant of the genus cannabis.

Coca Derivative means

(i) Crude cocaine, i.e., any extract of coca leaf which can be used, directly or indirectly, for the manufacture of cocaine.

(ii) Ecgonine and all the derivatives of ecgonine from which it can be recovered.

(iii) Cocaine, i.e., methyl ester of benzoyl-ecgonine and its salts.

(iv) All preparations containing more than 0.1% of cocaine.

Coca Leaf means

(i) The leaf of the coca plant except a leaf from which all ecgonine and any other ecgonine alkaloids have been removed.

(ii) Any mixture thereof with or without any neutral material.

(iii) But does not include any preparation containing not more than 0.1 percent of cocaine.

Coca Plant means the plant of any species of the genus Erythroxylon.

Controlled substance means any substance which the Central Government may, having regard to the available information as to its possible use in the production or manufacture of narcotic drugs or Psychotropic substances or to the provisions of any International Convention, by notification in the official gazette, declare to be a controlled substance.

Illicit traffic in relation to Narcotic Drugs and Psychotropic Substances means

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

(ii) Cultivating the opium poppy of any cannabis plant.

(iii) Engaging in the production, manufacture, possession, sale, purchase, transportation warehousing, concealment, use or consumption, import inter-state, export inter-State, import into India, export from India or transhipment of narcotic drugs or Psychotropic substances.
(iv) Dealing in any activities in narcotic drugs or Psychotropic substances other than those referred to above.
(v) Handling or letting out any premises for carrying on of any of the activities referred to above.

Manufacture in relation to narcotic or psychotropic substances includes
(i) All processes other than production by which such drugs or substances may be obtained.
(ii) Refining of such drugs or substances.
(iii) Making of preparation (otherwise than in a pharmacy on prescription) with or without containing drugs or substances.

Manufactured Drug means
(i) All coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate.
(ii) Any other substance or preparation which the Central Government may, by notification in the official Gazette, declare to be a manufactured drug.

Medicinal Cannabis or Medicinal Hemp means any extract or tincture of cannabis (hemp).

Narcotic Drug means coca leaf, cannabis (hemp), opium straw and includes all manufactured goods.

Opium means:
(i) The coagulated juice of the opium poppy.
(ii) Any mixture, with or without any neutral material, of the coagulated juice of the opium poppy, but does not include any preparation containing not more than 0.2 per cent of morphine.

Opium Derivative means
(i) Medicinal opium, i.e., opium which has undergone the processes necessary to adopt it for medicinal use in accordance with the requirements of the Indian Pharmacopoeia or any other pharmacopoeia notified in this behalf by the Central Government, whether in powder form or granulated or otherwise or mixed with neutral materials.
(ii) Prepared opium, that is any product of opium by any series of operations designed to transform opium into an extract suitable for smoking and the dross or other residue remaining after opium is smoked
(iii) Phenanthrene alkaloids, namely morphine, codeine, thebaine and their salts.
(iv) Diacetylmorphine, that is, the alkaloid also known as dia-morphine or heroine and its salts.
(v) All preparations containing more than 0.2 per cent of morphine or containing any diacetyl morphine.

Opium Poppy means

(i) The plant of the species *Papaver somniferum* L.

(ii) The plant of any other species of Papaver from which opium or any phenanthrene alkaloid be extracted and which the Central Government may, by notification in the official Gazette declare, to be opium poppy for the purposes of this act.

Poppy Straw means all parts (except the seeds) of the opium poppy after harvesting whether in their original or cut, crushed or powdered and whether or not juice has been extracted there from.

Poppy Straw Concentrate means the material arising when poppy straw has entered into a process for the concentration of its alkaloids.

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.

5.4 AUTHORITIES AND OFFICERS

1. Measures by Central Government:

To prevent and combat abuse of narcotic and psychotropic substances and the illicit traffic therein, the Central Government may take measure with respect to the following matters;

(a) Co-ordination of actions by various officers, State Government, and other authorities under this Act or under any other law for the time being in force in connection with the enforcement of the provisions of this Act;

(b) Obligations under the International Conventions;

(c) 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.

(d) Identification, treatment, education, after care, rehabilitation and social re-integration of addicts; and

(e) Such other matters as the Central Government deems necessary expedient for the purpose of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.

The Central Government is also empowered to constitute an authority for the purpose of exercising such powers and for taking measures with respect to the matters mentioned above or specified in an order.

Such authority or authorities may exercise the powers and functions and take measures, subject to the supervision and control of the Central Government and the provisions of such order as if empowered by this Act to exercise those powers and take such measures.

2. Officers of Government:

In addition to the above authorities, the Central Government shall appoint a Narcotics Commissioner and such other officers as it thinks fit for the purpose of this Act. The Narcotics Commissioner shall exercise all powers and perform all functions relating to the superintendence of the cultivation of the opium poppy and production of opium and shall

exercise and perform such other powers and functions as may be entrusted to him by the Central Government. The officers shall be subject to the general control and direction of the Central Government, or if so directed by the Government, also of the Board or any other authority or officer. The Narcotics Commissioner may authorise any officer subordinate to him, to exercise all or any of his powers under the Rules. The Narcotics Commissioners and such other officers as may be appointed by the Central Government, may perform all or any of the functions, or exercise any of the powers assigned under the rules to the officers subordinate to them.

3. Officers of State Government:

The State Government may appoint officers with such designations as it thinks fit for the purpose of this Act. These officers shall be subjected to general control and direction of the State Government, or if so directed by that Government, also of any other authority or officer.

5.5 NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES CONSULTATIVE COMMITTEE

The Central Government may constitute an advisory committee to be called The Narcotic Drugs and Psychotropic Substances Consultative Committee in order to advise it on such matters relating to the administration of this Act as may be referred to it by that Government from time to time.

The Committee shall consist of a Chairman and such other members, not exceeding twenty, as may be appointed by the Central Government. It shall meet when required to do so by the Central Government and shall have the power to regulate its own procedure.

The Committee may, for the efficient discharge of its functions, constitute one or more sub-committees and may appoint to such sub-committee any person who is a not member of the Committee. The term of office, the manner of filling casual vacancies in the offices, the allowances payable to the Chairman and other members of the Committee and other procedures shall be such as may be prescribed by rules made by the Central Government.

5.6 NATIONAL FUND FOR CONTROL OF DRUG ABUSE

The Central Government may, by notification in the Official Gazette, constitute a Fund to be called the National Fund for Control of Drug Abuse (hereafter in this Chapter referred to as the Fund) and there shall be credited thereto—

(a) An amount which the Central Government may, after due appropriation made by Parliament by law in this behalf, provide;
(b) The sale proceeds of any property forfeited under Chapter VA;
(c) Any grants that may be made by any person or institution;
(d) Any income from investment of the amounts credited to the Fund under the aforesaid provisions.

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

(a) Combating illicit traffic in narcotic drugs, psychotropic substances or controlled substances;

(b) Controlling the abuse of narcotic drugs and psychotropic substances;
(c) Identifying, treating, rehabilitating addicts;
(d) Preventing drug abuse;
(e) Educating the public against drug abuse;
(f) Supplying drugs to addicts where such supply is a medical necessity.

The Central Government may constitute a Governing Body as it thinks fit to advise that Government and to sanction money out of the said Fund subject to the limit notified by the Central Government in the Official Gazette.

The Governing Body shall consist of a Chairman (not below the rank of an Additional Secretary to the Central Government) and such other members not exceeding six as the Central Government may appoint. The Governing Body shall have the power to regulate its own procedure. The Central Government shall, as soon as may be, after the end of each financial year, cause to be published in the Official Gazette, a report giving an account of the activities financed under section 7A during the financial year, together with a statement of accounts.

5.7 PROHIBITION, CONTROL AND REGULATION

The following operations are totally prohibited under the Narcotic Drugs and Psychotropic Substances Act:

(i) Cultivation of any coca plant or gathering of any portion of the coca plant.
(ii) Cultivation of opium poppy or any cannabis plant.
(iii) Production, manufacture, possession, sale, purchase, transportation, warehousing consumption, import, export etc. of any Narcotic drug or Psychotropic substance, except for medical or scientific purposes and in the manner and to the extent provided or in accordance with the terms and conditions of a license, permit or authorization, if provided.

The prohibition shall take effect only from the date which the Central Government, may, by notification in the Official Gazette specify in this behalf.

Power of Central Government to Permit, Control and Regulate:

The Central Government may, by rules:

1. Permit and regulate:
   (a) The cultivation, or gathering of any portion (only on account of the Central Government) of coca plant, or the production, possession, sale, purchase, transport, import inter-state, export inter-state, use or consumption of coca leaves.
   (b) The cultivation (only on account of the Central Government) of the opium poppy.
   (c) The production and manufacture of the opium and production of poppy straw.
   (d) The sale of opium and opium derivatives from the Central Government factories for the export from India or sale to State Government or to the manufacturing chemists.
   (e) The manufacture of manufactured drugs (other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.
   (f) The manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of Psychotropic substances.

(g) The import into India and export from India and transhipment of Narcotic drugs and Psychotropic substances.

2. Prescribe any other matter required to render effective the control of the Central Government over any of the matters specified above.

The Central Government may permit, with or without conditions, and on its behalf, the cultivation of any coca plant or gathering of any portion thereof or the production, possession, sale, purchase import inter-State, export inter-state, or import into India of coca leaves for use in preparation of any flavouring agent which shall not contain any alkaloid for such use. The Central Government may also allow cultivation of any cannabis plant for industrial purposes only or obtaining fibre or seed or for horticultural purposes.

The Central Government may also, if it deems necessary, provide for the regulation of the production, manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption, use, storage, distribution, disposal or acquisition of any controlled substance.

Power of State Government to Permit, Control and Regulate:

The State Government may, by rules

1. Permit or regulate:
   (i) The possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption, and use of a poppy straw.
   (ii) The possession, transport, import inter-state, export inter-state, sale, purchase, consumption and use of opium.
   (iii) The cultivation of any cannabis plant, production, manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of cannabis (excluding charas).
   (iv) The manufacture of medicinal opium or any preparation containing drug from materials which the maker is lawfully entitled to possess.
   (v) The possession, transport, purchase, sale, import inter-state, export inter-state, use. Consumption of manufactured drugs other than prepared opium and of coca leaf, any preparations containing any manufactured drug.
   (vi) The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption.
2. Prescribe any other matter requisite to render effective the control of the State Government over any of the matters specified above.

5.8 CULTIVATION OF OPIUM POPPY AND PRODUCTION OF OPIUM OR POPPY STRAW CULTIVATION

According to NDPS Act, no person can cultivate or engage production of opium or poppy straw except on behalf of the Central Government and under a license granted for the purpose in such parts of the country as may be specified. For the cultivation of opium in specified area and plots licenses are issued by the District Opium Officers.

The District Opium Officer may also designate one of the licensed cultivators as Lambardar in each village who shall perform such functions and on such terms as may be specified by the Narcotic Commissioner. The licenses granted by District Opium Officers may be withheld or cancelled by higher officers after giving a chance to the cultivator for being heard. If any opium is cultivated under a license which is subsequently cancelled, the standing crop may be destroyed under the supervision of an authorised officer in such manner as may be specified by the Narcotic Commissioner.

Production of Opium:

During harvesting, cultivators shall daily take their day's collection of Opium to Lambardar for weighment of quantity produced on the day and entry in records which should be jointly attested, every day by the Lambardar and the cultivator. These records shall be checked by authorised officers. In case of any discrepancies between quantity produced and quantity entered in the records, an enquiry shall be made by an authorised officer to determine the liability of the cultivator for punishment.

All opium produced has to be delivered to District Opium Officers who shall weigh, examine and classify the same according to its quality and consistence and forward it to the Government Opium Factory in such manner as may be specified by the Narcotic Commissioner. A cultivator who is dissatisfied with the classification done by the officer may have the opium forwarded to Government Opium Factory. All opium forwarded to Government factory has to be classified under the supervision of the General Manager in such manner as may be specified by the Narcotic Commissioner. If the District Opium Officer suspects any opium delivered to him to be adulterated, he may send it separately to Government Opium Factory after sealing in the presence of the lambardar and cultivator. Adulterated opium is liable to confiscation after giving a hearing to the cultivator.

Fixation of Price of Opium:

The Central Government shall, from time to time, fix the price of opium, to be paid to the cultivators. Such price shall be fixed per kilogram of the opium of a standard consistence.

5.9 MANUFACTURE, SALE, AND EXPORT OF OPIUM

5.9.1 Manufacture of Opium

Manufacture of Opium can be made only by the Central Government at its two factories situated at Ghazipur and Neemuch. However, opium mixtures may be manufactured from lawfully possessed opium by a person authorised under the rules made by the State Government for the said purpose.

5.9.2 Sale of Opium

Sale of opium to State Governments or manufacturing chemists can be made only from the Government Opium Factory, Ghazipur. The sale to manufacturing chemists is possible only under permit it from the concerned State Government within whose jurisdiction; the chemist resides or has his place of business. The permit by the State Government shall be issued in quadruplicate. One copy shall be retained by the issuing authority and the remaining copies forwarded to the Government Opium Factory, Ghazipur. The factory shall retain the duplicate copy for the record, send the original copy with the consignment of

opium and return the triplicate copy to the issuing authority after endorsing thereon the quantity actually supplied and the date of dispatch.

The price to be charged for opium sold by the Government Factory shall be fixed, from time to time by the Central Government.

5.9.3 Export of Opium

The export of opium is prohibited except when it is on the behalf of the Central Government.

5.10 OFFENCES AND PENALTIES

Sr. No.	Offence	Penalty
1.	Contraventions of provisons in the Act or Rules in relation to poppy straw, opium poppy, coca leaves, prepared opium, manufactured drugs and psychotropic substances.	Rigorous imprisonment upto 10 to 20 years and fine of not less than ₹ 1 lakh on first conviction and with Rigorous imprisonment upto 15 to 30 years and a fine of ₹ 2 lakh on second and subsequent conviction.
2.	Illegal import or export or external dealings in narcotic drugs or psychotropic substances.	Rigorous imprisonment upto 10 to 20 years and fine of not less than ₹ 1 lakh rupees on first conviction and with Rigorous imprisonment upto 15 to 30 years and a fine of ₹ 2 lakh on second and subsequent conviction.
3.	Embezzlement of opium by the cultivator.	Rigorous imprisonment upto 10 to 20 years and fine of not less than ₹ 1 lakh rupees on first conviction and with Rigorous imprisonment upto 15 to 30 years and a fine of ₹ 2 lakh on second and subsequent conviction.
4.	Allowing use of premises, conveyance, for commison of an offence under the Act.	Rigorous imprisonment upto 10 to 20 years and fine of not less than ₹ 1 lakh rupees on first conviction and with Rigorous imprisonment upto 15 to 30 years and a fine of ₹ 2 lakh on second and subsequent conviction.
5.	Contravention in relation to the cannabis plant and cannabis other than ganja.	Rigorous imprisonment upto 10 to 20 years and fine of not less than ₹ 1 lakh rupees on first conviction and with Rigorous imprisonment upto 15 to 30 years and a fine of ₹ 2 lakh on second and subsequent conviction.
6.	Contravention of the provisions in the Act or Rules in respect of cannabis plant and	Rigorous imprisonment for 5 years and fine upto ₹ 50,000 on first

Sr. No.	Offence	Penalty
	cannabis related to ganja.	conviction and rigorous imprisonment for 10 years and fine upto ₹ 1 lakh on second and subsquent conviction.
7.	Illegal possession in small quantities for personal consumption or consumption of cocaine, morphine, diacetylmorphine or any other narcotic drug or psychotropic substances specified in this behalf.	Imprisonment upto 1 year or fine or both.
8.	Keeping false accounts or making false statements.	Imprisonment upto 5 years or fine or both.
9.	Failure to produce a license, permit or authorization on demand by an authorized person.	Imprisonment upto 5 years or fine or both.
10.	Failure to maintain accounts or submit any return without any reasonable cause in accordance with the provisions of this Act.	Imprisonment upto 5 years or fine or both.

EXERCISE

1. Enlist the objectives of NDPS Act.
2. Define the following terms in relation to NDPS Act.
   (i) Cannabis
   (ii) Coca derivative
   (iii) Illicit traffic
   (iv) Opium derivative
   (v) Opium poppy
3. Discuss the role of Narcotic Drugs and Psychotropic Substances Consultative Committee.
4. Explain the prohibition, control and regulation for opium by central and state government of India under NDPS Act.
5. Describe the rules for the cultivation, production, manufacture, sale and export of opium as per NDPS Act.
6. Discuss about the National Fund for controlling the Drug Abuse under NDPS Act.
7. Discuss the offences and penalties of Narcotic Drugs and Psychotropic Substances Act (NDPS).

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UNIT IV

Chapter ... 6

THE DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT AND ITS RULES

♦ **LEARNING OBJECTIVES** ♦

After completing this chapter, the reader should be able to understand:

- The objectives of Drugs and Magic remedies Act.
- The types of Prohibited and Exempted advertisements.
- The offences and penalties of the Act.

6.1 INTRODUCTION

In today's modern life, advertisements have significant role to provide information regarding the usage of products like cosmetics, electronic gadgets and many more. Modern methods of advertising like TV, internet, cell phones etc. have proved to be very effective. Advertising drugs including medicinal products to the normal people may lead to self medication which may be resulted in serious complications. To overcome such demerits an implementation was made that drugs should be advertised only to qualified persons like doctors, nurses, pharmacists and other health professionals.

One of the commonly faced problems in India is advertisement of magic remedies like kavachas, mantras, talismans which are believed to be curative remedies for diseases for which no cure or treatment is available. Because of this, innocent persons fall in the trap of such unsocial elements and waste their money and time. To control and inhibit all these issues, the Drugs and Magic Remedies Act was passed in the year 1954 with a view to control and prohibit certain advertisements of drugs and magic remedies which were likely to mislead the general public.

The Act came into effect from April 1st 1955 and was implemented in 1963. The Act extends to whole of India except the state of Jammu and Kashmir. The Act was also referred as Objectionable Advertisements Act.

6.2 OBJECTIVES

1. To control some of the drug related advertisements which can mislead the public.
2. To prohibit certain kind of advertisements related to magic remedies which make false claims and are likely to mislead the public.

6.3 DEFINITIONS

Advertisement: It includes all the notices, labels, circulars, wrappers or other documents and all the announcements made orally or by means of producing or transmitting light, sound or smoke.

Drug: It includes the following definitions:

(i) A medicine for the internal or external use of human beings or animals.
(ii) Any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of diseases in human beings or animals.
(iii) Any article, other than food, intended to affect the body of human beings.
(iv) Any article intended for use as a component of any medicine, substance or article referred to above.

Magic Remedy: It includes talismans, mantras, kavachas and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any diseases in human beings or animals or for affecting in any way the structure or any organic function of the body of human beings or animals.

6.4 PROHIBITED ADVERTISEMENTS

The following are the classes of advertisements that are prohibited under the Act:

1. Advertisements, relating to drugs, which are likely to lead to their use in the following ailments or conditions:
   (a) For the procurement of miscarriage or prevention of conception in women.
   (b) For the correction of menstrual disorders in women.
   (c) For the maintenance or improvement of the capacity of human beings for sexual pleasure.
   (d) The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in Schedule J of the Drugs and Cosmetics Rules, 1945.
2. Advertisements which:
   (a) Directly or indirectly gives a false impression regarding the true character of the drug.
   (b) Make a false claim for the drug.
   (c) Are otherwise false or misleading in any material particular.
3. Advertisements relating to magic remedies claiming their efficacy for any of the conditions outlined in (1) by persons, who purport to carry on the profession of administering magic remedies.

Advertisements Whose Import and Export are Prohibited:

Import and export of all documents containing an advertisement of nature referred to above 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.

6.5 EXEMPTED ADVERTISEMENTS

The following classes of advertisements and displays are exempted from the purview of the Act and hence can be made without any prohibition:

1. Any sign boards or notices displayed by Registered Medical Practitioner (RMP) indicating that treatment is undertaken for the disease or disorder, advertisements relating to which are otherwise prohibited.
2. Any books or treaties relating to the diseases or ailments which are otherwise advertised, provided published from bonafide scientific or social standing.
3. Any drug related advertisements sent confidentially, in the prescribed manner, to RMP's. However, such advertisements should bear the following words on top, in a conspicuous manner: For the use only of RMP or a Hospital or a Laboratory.
4. Any advertisement relating to a drug printed or published by the Government or by any person with the prior permission of the Government.
5. Advertisements, labels or set of instructions which are permitted under the Drugs and Cosmetics Act or Rules made there under.

The Central Government may also permit the advertisement of any drug which it feels shall be in the interest of the public.

Advertisements Exempted Conditionally:

The following classes of advertisements have been exempted conditionally:

Class of Advertisement:

1. Leaflets or literature accompanying packing of drugs.
2. Advertisements of drugs in medical, pharmaceutical, scientific and technical journals.

Conditions:

(i) The advertisement contains only such information as it is required for the guidance of a registered medical practitioner in respect of matters relating to:
   (a) Therapeutic indications of the drug.
   (b) Administration and dosage of the drug.
   (c) Side effects of the drug.
   (d) The precautions to be observed in the treatment with the drug.

(ii) The responsibility to prove that any claim made in the advertisement is not false, exaggerated or misleading shall lie on the advertiser.

Class of Advertisement:

1. Price lists or therapeutic indexes published by manufacturers, importers or distributors of drugs duly licensed under the Drugs and Cosmetics Act 1940 and the Rules there under.
2. Medical literature distributed by medical or distributors of drugs, duly licensed under the Drugs and Cosmetics Act, 1940 and the Rules there under.

Conditions:

(i) Conditions (i) and (ii) above.

(ii) The distribution of such literature is confined only to the registered medical practitioners, hospitals, dispensaries, medical and research institutions, chemists and druggists or pharmacies duly licensed under the provisions of the Drugs and Cosmetic Rules.

Procedure for Sending Advertisements Confidentially:

All the documents containing advertisements relating to drugs to be sent confidentially shall be sent by post to an RMP by name, or to a wholesaler or retail chemist, the address of such RMP or wholesaler or retail chemist at the given address. Such documents shall bear at the top, printed in indelible ink in a conspicuous manner, the words "For the use of registered medical practitioner or a hospital or a laboratory".

Scrutiny of Misleading Advertisements Relating to Drugs:

Any person authorised by the State Government in this behalf, if satisfied that, a particular advertisement has been made in contravention of the provisions of the Act, may require the manufacturer, packer, distributor or seller in question to furnish, within the specified time, information regarding the composition of the drug or its ingredients or any other information he deems necessary for scrutinizing the advertisement. Such a manufacturer, packer, distributor or seller shall be duty bound to comply with this order.

Provided that no publisher or advertising agency taking part in the publication of a prohibited advertisement shall be deemed guilty, unless he has failed to comply with any direction made by the authorised person in this behalf calling upon him to furnish the name and address of the manufacturer, packer, distributor or seller of advertising agency, who/which caused the publication of such advertisement.

6.6 OFFENCES AND PENALTIES

Whoever contravenes any of the provision of this Act or Rules made there under shall be punishable with imprisonment upto six months or with fine or both on a first conviction, and imprisonment upto one year or fine or both on any subsequent conviction.

If the person contravening any of the provisions of this Act is a company, every person who, at the time the offence was committed, was in charge of, and was responsible for the conduct of its business, as well as the company, shall be deemed to be guilty and punished

accordingly, unless it is proved that the offence was committed without his knowledge or that he had exercised due diligence to prevent the commission of that offence. If it is proved that, the offence by a company was committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary etc. of the company, such person shall also be deemed to be guilty of that offence and shall be punished accordingly.

Where a person has been convicted under this Act, the court may direct the forfeiture of any document, article or thing, in respect of which the contravention is made including the contents thereof.

An offence punishable under this Act shall be cognizable and cannot be tried by any court inferior to that of a presidency magistrate or a magistrate of the first class.

No suit, prosecution or another legal proceeding shall lie against any person for anything done in good faith or intended to be done under this Act.

Schedule J: Diseases which cannot be claimed to be cured (Drugs and Cosmetics Rules, 1945).

Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders like AIDS, Appendicitis, Arteriosclerosis, Asthma, Blindness, Blood poisoning, Bright's disease, Cancer, Cataract, Deafness, Diabetes, Diseases and disorders of brain, optical system and uterus; Disorders of menstrual flow, nervous system and prostatic gland; Dropsy, Epilepsy, Female diseases (in general), Fits, Form and structure of female bust; Gall stones, kidney stones and bladder stones; Gangrene, Glaucoma, Goitre Heart diseases, High or low blood pressure, Hydrocele, Hysteria, Infantil paralysis, Insanity, Leprosy, Leucoderma, Lockjaw, Locomotor ataxia, Lupus, Nervous debility, Obesity, Paralysis, Plague, Pleurisy, Pneumonia, Rheumatism, Ruptures, Sexual impotence, Smallpox, Stature of persons, Sterility in women, Trachoma, Tuberculosis, Typhoid fever, Ulcers of gastrointestinal tract, Venereal diseases including syphilis, gonorrhea, soft chancre, venereal granuloma and lympho granuloma.

EXERCISE

1. Discuss about the provisions under which the Drugs and Magic Remedies Act.
2. Define the following terms in relation to Drugs and Magic Remedies Act:
   (a) Advertisement
   (b) Drug
   (c) Magic remedy
3. Discuss the advertisements which are prohibited under Objectionable Advertisements Act.
4. Enlist the classes of advertisements that are exempted conditionally under the Drugs and Magic Remedies Act.
5. Discuss the offences and penalties of the Drugs and Magic Remedies Act.

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Chapter ... 7

THE PREVENTION OF CRUELTY TO ANIMALS ACT, 1960

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- ❖ The composition and functions of Institutional animal ethics committee.
- ❖ The CPSCEA guidelines for animal handling and experimentation.
- ❖ The conditions to suspend or revoke the CPSCEA registration for the approved animal house.
- ❖ The offences and penalties of the Act.

7.1 INTRODUCTION

For the scientific drug research studies, animals have been used as experimental subjects because of their physiological similarity to human beings. In order to establish the therapeutic efficiency and the safety of drugs, usage of laboratory animals for experimentation is unavoidable. During the pre-clinical study, animals may be subjected to injury, pain and even they may die. But causing unnecessary pain is considered to cruelty and unethical. The Prevention of cruelty to animals Act was enacted with the main objective to prevent the infliction of unnecessary pain or suffering on animals. This act provides information on the provisions of pharmaceutical interest which are related to Animal Experimentations.

This Act extends to the whole of India except the state of Jammu and Kashmir.

7.2 DEFINITIONS

"Animal" is defined as any living creature other than a human being.

"Board" means the Animal Welfare Board established under section 4 of the Act.

"Breeder" means a person including an institution, which breeds animals for the purpose of transfer to the authorised institution for performing experiments.

"Committee" means the committee constituted under section 15 of the Act for control and supervision on animals.

Establishment means any individual, company, firm, corporation other than schools up to higher secondary level, which performs experiments on animals.

Experiment means any programme or project involving use of animal for the acquisition of knowledge of a biological, psychological, ethological, physical or chemical nature; and includes the use of animal(s) in the production of reagents and products such as antigens and antibodies, diagnostics, testing activity and establishment of transgenic stocks for the purpose of saving or prolonging life or alleviating suffering or significant gains in well being for people of the country or for combating any disease whether on human beings or animals.

Institutional Animals Ethics Committee means a body comprising of a group of persons recognised and registered by the Committee for the purpose of control and supervision on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee.

Contract research means any research undertaken by an individual, company, firm, corporation or institution on behalf of a foreign individual, company, corporation or institution for any consideration.

Cruelty to Animals Under the Act, "treating animals cruelly" means-

(a) Subjecting any animal to unnecessary pain or suffering or treatment, or
(b) Usage of any unfit animal for work or labour, or
(c) Willfully and unreasonably administering any injurious drug or substance to any domestic or captive animal, or
(d) Keeping or confining any animal in any cage of insufficient size not permitting it reasonable movement, or
(e) Failure to provide any animal with sufficient food, drink or shelter by its owner, or
(f) Unnecessarily torturing any animal or killing any animal in a cruel manner etc.

7.3 INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)

The primary duty of IAEC is to work for the achievement of the objectives as mentioned below.

(a) Experiments shall be performed under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;
(b) Experiments are performed with care and humanity and that as far as possible experiments involving operations are performed under the influence of some anesthetic of sufficient power to prevent the animals feeling pain;
(c) Animals which, in the course of experiments under the influence of anesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;
(d) Experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;
(e) Experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, mice, rats, etc;

(f) As far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
(g) Animals intended for the performance of experiments are properly looked after both before and after experiments;
(h) suitable records are maintained with respect to experiments performed on animals.

IAEC will review and approve all types of research proposals involving small animal experimentation before the start of the study. For experimentation on large animals, the case is required to be forwarded to CPCSEA in prescribed manner with the recommendation of IAEC.

IAEC is required to monitor the research throughout the study and after completion of study through periodic reports and visit to animal house and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

Composition of IAEC:

Institutional Animals Ethics Committee shall include eight members as follows.

1. A biological scientist,
2. Two scientists from different biological disciplines,
3. A veterinarian involved in the care of the animal,
4. Scientist in-charge of animals facility of the establishment concerned,
5. A scientist from, outside the institute,
6. A non-scientific socially aware member and
7. A nominee of CPCSEA.

The specialist may be co-opted while reviewing the special project using hazardous agents such as radio-active substance and deadly micro-organisms.

The Chairperson of the Committee and Member Secretary would be nominated by the Institution from amongst the eight members. Members against Serial number 5,6 and 7 will be nominated by CPCSEA, with a provision of a Link nominee for CPCSEA nominee.

7.4 BREEDING AND STOCKING OF ANIMALS

Only registered establishments can carry on the business of breeding of animals or trade of animals for the purpose of experiments. Every breeder carrying on the business of breeding animals or trade animals for the purpose of experiments shall apply for registration within sixty days from the date of commencement of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 and stop the breeding of animals if the Committee subsequently refuses registration. The application for registration by a breeder shall be made in the specified format to the Member-Secretary or any other person authorised by Committee in this regard.

For registration of breeders (including universities and colleges), the Government of India has set up the "Committee for the Purpose of Control and Supervision of Experiments on Animals" (CPCSEA) under the Ministry of Social Justice and Empowerment, Shastri Bhavan, New Delhi.

The Secretary or the authorised officer of the Committee may ask for information relating to premises where the experiments are to be conducted, animal housing facilities, details of breeding of animals and its trade, infrastructure including availability of manpower trained in handling animals and for verification of facts mentioned in the application for registration; and if satisfied, shall register such breeder. Every registered breeder shall maintain a day-to-day register of particulars about the animals used for conducting experiments, with the number of animals, the species, the age, gender, and other particulars. The Committee or any other authorized officer may examine the register so maintained and if the Committee is not satisfied even after opportunities given for improvement, it may take appropriate action.

The animals shall be stocked by the breeder and the establishment in a prescribed manner. Animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises kept tidy, hygienic and the animals protected from drought and extremes of weather. Animal cages and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided. There shall be satisfactory arrangements for looking after the animals during off-hours and on holidays. The registered breeder shall adhere to the detailed specifications notified by the Committee for housing, feeding, and maintenance of various species to be used in animal experimentation. Where standards have been laid down by the Indian Standards Institution (ISI), the cages or the stable shall conform to those standards. Animal's attendants must be suitably trained and experienced in the duties allotted to them.

7.5 PERFORMANCE OF EXPERIMENTS

Performing experiments on animals for the purpose of advancement by the new discovery of knowledge, which will be useful for saving or prolonging life, or alleviating suffering, or for combating any disease in human beings animals or plants; is lawful. The experiment shall neither be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognized training institutions; nor by way of an illustration or as a public demonstration. Where experiments are performed in any institution, the responsibility is placed on the head of the institution and in cases where experiments are performed outside the institution by an individual qualified in that behalf; the experiments are performed on his responsibility. All experiments shall be performed by or under the supervision of a duly qualified person from a an institution recognized under the Rules. Experiments shall be performed with due care and humanity. For any experimental procedure, the experiment should be designed using a minimum number of animals to give statistically valid results at a 95% degree of confidence and animals which may give scientifically valid results should be first preferred.

It must be ensured that, animals are not subjected to unnecessary suffering before, during or after the performance of experiments on them. Experimental animals should be properly looked both before and after experiments. Experiments involving severe operative procedure shall be performed under the influence of anaesthetic administered by a trained person to make animals free of pain throughout the experiment. In the course of experiments under the influence of the anaesthetic, if animals are injured that recovery would involve pain or suffering, they shall be destroyed humanely while still under the influence of

anaesthesia. If there is a reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage discontinuing the experiment.

7.6 TRANSFER AND ACQUISITION OF ANIMALS FOR EXPERIMENT

Transfer of any animal by way of sale or otherwise by a breeder to an unregistered establishment is not permitted. An establishment shall acquire animals for experiments from registered breeders only and shall maintain a record in this regard and shall produce the same before the Committee, whenever required. However, In case of non-availability of the animal from registered breeders, the animal may be procured from alternate legal sources with prior written permission from the competent authority.

A breeder/establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment. Similarly, every establishment after the acquisition of animal/animals shall not transfer such animal/animals by sale or otherwise to any other person or establishment except to a registered breeder/establishment. However, the animals used for experimentation in a production/breed improvement programme may be given out by the breeder institution for domestic use. For the acquisition of laboratory bred experimental rats and mice species of genetically defined strains not available in India, the registered breeder/establishments shall take the permission of the Institutional Animal Ethics Committee. A breeder or an establishment shall comply with the directions given by the Committee for the Purpose of Controlling and Supervising Experiments on Animals (CPCSEA).

7.7 RECORDS

Every establishment/Institutional Animals Ethics Committee maintain a record of the animals under its control and custody and furnish such information, as the Committee may, from time to time require in the specified format. All laboratories shall inform the exact number/species of animals to the Secretary or any other officer authorised in this regard by the Committee as per the specified format.

7.8 POWER TO SUSPEND OR REVOKE THE REGISTRATION

If the Committee is satisfied that the rules made by it are not being complied with by any establishment/breeder/Institutional Animals Ethics Committee or its directions are being violated the Committee may, after giving a reasonable opportunity of being heard in the matter, suspend or revoke the registration either for a specified period or indefinitely, or may allow the establishment/breeder/Institutional Animals Ethics Committee to carry on subject to such special conditions as the Committee may impose.

7.9 OFFENCES AND PENALTIES

Offence	Penalty
1. Treating animals cruelly.	1. Fine up to ₹ 50 in the first instance. In case of repeat offence within three years, fine may extend to ₹ 100 or with imprisonment up to three months or both.

Offence	Penalty
2. Contravention of any order made by or committing a breach of any condition imposed by the Committee.	2. Fine extending to ₹ 200.
3. Contravention or breach of condition in any institution.	3. The person in charge of the institution shall be guilty of the offence and shall be punishable accordingly.

EXERCISE

1. Discuss about the Prevention of Cruelty to Animals Act, 1960.
2. Write the constitution of IAEC.
3. Describe the CPSCEA guidelines as per the Prevention of Cruelty to Animals Act, 1960.
4. Define the following terms under the Prevention of Cruelty to Animals Act, 1960.
   (a) Experiment
   (b) Institutional Animal Ethics Committee (IAEC)
   (c) Cruelty
5. Write the offences and penalties of the Prevention of Cruelty to Animals Act, 1960.

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Chapter ... 8

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- The objectives and definitions of DPCO Act.
- The calculation of retail price of drug formulations of the Act.
- Fixation of ceiling and retail prices for Scheduled and Non-scheduled drug formulations.
- The National List of Essential Medicines with examples.

8.1 INTRODUCTION

Drugs are considered as essential commodities and they should be made available always at a reasonable cost of price. Drug Price Control Orders (DPCO) are issued by the Government, in exercise of the powers conferred under Section 3 of the Essential Commodities Act, 1955, for enabling the Government to declare a ceiling price for essential and life saving medicines (as per a prescribed formula) so as to ensure that these medicines are available at a reasonable price to the general public. The latest Drug Price Control Order (DPCO-2013) was issued on 15th May 2013.

8.2 HISTORY OF PRICE CONTROL POLICY

The Drug Policy of 1994, as implemented through the Drugs Prices (Control) Order, 1995, was introduced in the context of the liberalization of the economy and the abolishment of industrial licensing, as well as allowing of foreign investment in the country, including in the drug industry. The principle for price control broadly adopted in this policy represented a radical departure from the earlier policies. This envisaged control over prices on the basis of drugs on the basis of economic criteria as represented in the market share of different companies in the context of total market sales turnover of various drugs. Thus, those drugs were brought under the ambit of price control, where the company turnover was of a particular level and where the market share of leading producers was beyond a particular level. The control over prices was to be on the basis of the cost of production with allowance being given for post production expenses. As per the criteria of 1994 Policy, a list of 74 bulk drugs was identified and these drugs, as well as the formulations based on these drugs (around 1577 in number), were brought under the price control regime. Certain exceptions

such as for small scale units, drugs produced through indigenous research and development, etc. were envisaged for exemption under the Policy.

In the year 2000, further liberalization in the economy was effected, in light of which, Foreign Direct Investment (FDI) in the pharmaceutical sector was brought in the automatic route and the limit raised upto 100%. Following this, a new pharmaceutical pricing policy was introduced in the year 2002 which further liberalized the span of control over pricing. The turnover limit for purposes of price control was raised from ₹ 4 crores to ₹ 25 crores and the parameters of market share were also relaxed further. All drugs where unit price did not exceed ₹ 2.00 were also excluded from the ambit of price control. There were also exemptions given for drugs developed through indigenous R&D, New Delivery Systems etc.

The 2002 Drug Policy was, however, challenged in the Karnataka High Court, which by order dated 12.11.2002 issued stay on the implementation of this Policy. This order was challenged by the Government in the Supreme Court which vacated the stay vide its order dated 10.03.2002 but observed that Government shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May 2003".

In the light of the order of the Supreme Court, it was decided that a fresh Pharmaceutical Pricing Policy be formulated and accordingly, the 2002 Drug Policy was never implemented and the 1994 Drug Policy continued to be applicable.

Meanwhile, in accordance with the guidelines of the Supreme Court, the Ministry of Health revised the List of medicines in the National List of Essential Medicines (NLEM) earlier notified in 1996. The revised list was notified as NLEM, 2003. In November 2004, the Government also set up a Task Force under the Chairmanship of Principal Advisor, Planning Commission, Dr. Pronab Sen to look into the issue of price control, options other than price control, and other issues and to make recommendations for making available life saving drugs at reasonable prices. The basis of drugs to be considered was the NLEM, 2003, which is the latest list at that time. The Pronab Sen Committee submitted its recommendations in September, 2005. In 2011, the Ministry of Health revised the NLEM and notified the new NLEM, 2011.

A need was felt to revise the Drug Policy, 1994 to meet the challenges brought about by the competitive international pharmaceutical industry in a globalised economic environment, as much as meeting the country's requirements for safe and quality medicines at reasonable prices. Therefore, the Government enunciated the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which replaced the Drug Policy enunciated in September 1994.

8.3 OBJECTIVES OF THE DPCO ACT

1. To regulate the equitable distribution of essential bulk drugs.
2. To fix the maximum retail prices of essential bulk drugs and drug formulations.

The DPCO has the following classes of schedules of drugs:

Schedule I: It contains the list of essential bulk drugs that are included in 27 different sections of National list of Essential Medicines (NLEM), 2011 rule.

Schedule II: It contains various forms for the approval, fixation or revision of prices of Scheduled formulations.

Schedule III: It specifies the maximum pre-tax return on the sales turnover of manufacturers or importers of formulations.

8.4 DEFINITIONS

Bulk Drug means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940, and which is used as such or as an ingredient in any formulation.

Ceiling Price means a price fixed by the Government for Scheduled formulations.

Dealer means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjuction with any other business, and includes his agent.

Distributor means a distributor or his agent or a stockist appointed by a manufacturer or an importer for stocking his drugs for sale to a dealer.

Free Reserve means a reserve created by appropriation of profits, but does not include reserves provided for contingent liability, disputed claims, goodwill, regulation and other similar reserves.

Drug includes:

(i) All medicines for internal or external use of human beings or animals and all substances intended to be used for, or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

(ii) Such substances, intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by notification in the Official Gazette.

(iii) Bulk drugs and formulations.

Formulation means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis treatment, mitigation and prevention of disease in human beings or animals, but shall not include:

(i) Any medicine included in any bonafide Ayurvedic (including Siddha) or Unani (Tibb) system of medicines.

(ii) Any medicine included in the Homoeopathic system of medicine; and

(iii) Any substance to which the provisions of the Drugs and Cosmetics Act, 1940 does not apply.

Import means bringing into India from a place outside India, and importer in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer.

Manufacture includes any process or part of a process for making altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business.

Manufacturer means any person who manufactures a drug.

Net-worth means the paid-up share capital of a company plus free reserve, if any, and surpluses excluding outside investments which are not readily available for operational activity.

Non-scheduled Bulk Drug means a bulk drug not specified in the First Schedule.

Non-Scheduled Formulation means a formulation not containing any bulk drug specified in the First Schedule.

Pre-tax Return means profit before payment of income tax and surtax includes such other expenses as do not form of the cost of formulation.

Retail Price means the retail price of a drug arrived at or fixed in accordance with the provisions of this order and includes a ceiling price.

Retailer means a dealer carrying on the retail business of sale of drugs to customers.

Sale Turn-over means the product or units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied by retail price inclusive of sales tax, if any, paid on direct sales by the manufacturer or importer, but does not include excise duty and local taxes, if any.

Scheduled Bulk Drug means a bulk drug specified in the First Schedule.

Scheduled Formulation means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First schedule and sold under the generic name.

Wholesaler means a dealer or his agent or a stockiest 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.

8.5 SALE PRICES OF BULK DRUGS

The Government may fix from time to time, by notification in the Official Gazette, the maximum sale price at which any bulk drug specified in the First Schedule can be sold. No person can sell a bulk drug at a price exceeding the fixed price plus local taxes if any.

Any manufacturer who commences the production of any bulk drug specified in the First Schedule, after the commencement of this order, is required to furnish the necessary details in Form I within fifteen days of the commencement of the production of such bulk drug to the Government. The Government may then, after making the necessary inquiries, fix the maximum sale price of the bulk drug by notification in the Official Gazette.

Any manufacturer, who desires revision of the maximum sale price of a bulk drug, should make application to the Government in Form I. The Government shall then, within four months from date of receipt of the complete information, fix a revised price for such bulk drug or reject application for reasons to be recorded in writing.

Every manufacturer of a Scheduled bulk drug or a non-Scheduled bulk drug has to submit to the Government a list of all bulk drugs produced by him indicating the details of the cost of each bulk drug within thirty days of the commencement of this Order and by 30th September thereafter every year.

The government may, in public interest, fix or revise the price of any non-Scheduled bulk drug and the manufacturer or importer of such bulk drug shall not sell the same at a price exceeding the price so fixed or revised, within fifteen days of receipt of the order.

8.5.1 Calculation of Retail Price of Formulations

The retail price of a formulation can be calculated in accordance with the following formula,

$$\textbf{R.P. = (M.C. + C.C. + P.M. + P.C.) × (1 + MAPE/100) + E.D.}$$

where R.P. means retail price;

M.C. means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf;

C.C. means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

P.M. means the cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

P.C. means packing charges worked out in accordance with the established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

MAPE (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by the manufacturer from the stage of ex-factory cost to retailing and includes trade margin for the manufacturer and it shall not exceed 100 per cent for indigenously manufactured Scheduled formulations;

E.D. means Excise duty.

Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed 50 per cent of the landed cost. For the purpose of this provision, Landed Cost means the cost of import of formulation inclusive of customs duty and clearing charges.

8.5.2 Pricing of the Scheduled Formulations Covered under Drugs (Prices Control) Order, 1995

The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31st May 2012, shall remain effective up to 30th May, 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy.

The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this Order, fixed and notified under the provisions of the said order, up to 31st May 2012, shall remain effective for further one year i.e. 30th May, 2013 and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.

8.5.3 Ceiling Price or Retail Price of a Pack

The average price to retailer shall be calculated on the dosage basis, (per tablet, per capsule or injection in volume as listed in First Schedule) and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack, as the case may be.

In the event of the unit of the dosage for a scheduled formulation not available in the First Schedule, the lowest pack size for that category of medicine, as specified in the Drugs and Cosmetics Act, 1940 and the rules there under, shall be taken as unit dosage for calculating the ceiling price or retail price as the case may be, for that scheduled formulation and this shall be applicable while calculating the per unit price of even non-scheduled medicines for arriving at the retail price.

8.6 PRICE OF FORMULATIONS (BRANDED OR GENERIC) LISTED IN THE NLEM LAUNCHED BY A MANUFACTURER

A manufacturer, launching a scheduled formulation, shall be free to fix the price of the scheduled formulation equal to or below the ceiling price fixed for that scheduled formulation by the Government. Where an existing brand is re-launched by another manufacturer, the provisions of paragraph 13 shall be applicable.

Price of Scheduled Formulations for the Existing Manufactures:

All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price (plus local taxes as applicable).

Provided that, in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of 45 days of the date of such notification that the MRP of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing MRP.

Fixation of Ceiling Price of Scheduled Formulations:

The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of paragraphs 4 and 6, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.

Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

Fixation of the Retail Price of a New Drug for Existing Manufacturers of Scheduled Formulations:

The Government shall form a Committee of Experts to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".

Where an existing manufacturer of a drug with dosages and strengths as specified in NLEM launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I under Schedule-II of this Order.

On receipt of application, in the event of the new drug not available in domestic market, the Government shall fix the retail price of the new drug in accordance while in the event of new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within 30 days of the receipt of application.

The Government shall, on receipt of the recommendation of the Standing Committee of Experts fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.

Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

8.7 NATIONAL LIST OF ESSENTIAL MEDICINES, 2011

Section 1: Anesthesia.

1.1 General Anesthetics and Oxygen - Ether, Halothane with vaporizer, Isoflurane, Ketamine Hydrochloride, Nitrous Oxide, Oxygen, Thiopentone Sodium, Sevoflurane, Propofol

1.2 Local Anesthetics - Bupivacaine Hydrochloride, Lignocaine Hydrochloride, Lignocaine Hydrochloride + Adrenaline, EMLA cream

1.3 Preoperative Medication and Sedation for Short Term Procedures- Atropine Sulphate, Diazepam, Midazolam, Morphine Sulphate, Promethazine

Section 2: Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders.

2.1 Non-Opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Medicines- Acetyl Salicylic Acid, Diclofenac, Ibuprofen, Paracetamol

2.2 Opioid Analgesics - Morphine Sulphate, Tramadol, Fentanyl

2.3 Medicines used to treat Gout - Allopurinol, Colchicine

2.4 Disease modifying agents used in Rhcumatoid disorders - Azathioprine, Methotrexate, Sulfasalazine, Hydroxychloroquine phosphate, Leflunomide

Section 3: Antiallergics and Medicines used in Anaphylaxis - Adrenaline Bitartrate, Chlorpheniramine Maleate, Dexchlorpheniramine Maleate, Dexamethasone, Hydrocortisone Sodium Succinate, Pheniramine Maleate, Prednisolone, Promethazine, Cetrizine

Section 4: Antidotes and Other Substances used in Poisoning

4.1 Non-specific - Activated Charcoal

4.2 Specific - Atropine Sulphate, Specific Antisnake venom, Calcium gluconate, Desferrioxamine mesylate, Methylthioninium chloride (Methylene blue), Penicillamine, Dimercaprol, Flumazenil, Sodium Nitrite, Sodium Thiosulphate, Naloxone, Pralidoxime Chloride (2-PAM), N acetylcysteine

Section 5: Anticonvulsants/Antiepileptics

Carbamazepine, Diazepam, Magnesium sulphate, Phenobarbitone, Phenytoin Sodium, Sodium Valproate, Lorazepam

Section 6: Anti-infective Medicines

6.1 Anthelminthics

6.1.1 Intestinal Anthelminthics - Albendazole, Piperazine

6.1.2 Antifilarials - Iethylcarbamazine citrate

6.1.3 Antischistosomals and Antitrematode Medicines - Praziquantel

6.2 Antibacterials

6.2.1 β lactam medicines - Amoxicillin, Ampicillin, Bezathine, Benzylpenicillin, Cefotaxime, Cefriaxone, Cephalexin, Cloxacillin, Amoxicillin + Clavulinic acid

6.2.2 Other antibacterials - Amikacin, Azitromycin, Ciprofloxacin chloride, Co-Trimoxazole, (Doxycycline, Eryihromycin Estolate, Gentamicin, Metronidazole, Nitrofurantoin, Sulphadiazine, Vancomycin Hydochloride

6.2.3 Antileprosy medicines - Clofazimine, Dapsone, Rifampicin

6.2.4 Antitubercular medicines - Ethambutol, Isoniazid, Ofloxacin, Pyrazinamide, Rifampicin, Streptomycin Sulphate

6.3 Antifungal medicines - Griseofulvin, Nystatin, Amphotericin B, Clotrimaxole, Fluconazole

6.4 Antiviral medicines

6.4.1 Antiherpes medicines - Acyclovir

6.4.2 Antiretroviral medicince -

6.4.2.1 Nucleoside reverse transcriptase inhibitors - Didanosine, Lamivudine, Lamivudine + Nevirapine + Stavudine Lamivudine + Zidovudine, Stavudine, Zidovudine, Stavudine + Lamivudine, Zidovudine + Lamivudine + Nevirapine

6.4.2.2 Non-nucleoside reverse transcriptase inhibitors - Efavirenz, Nevirapine

6.4.2.3 Protease inhibitors - Indinavir, Nelfinavir, Ritonavir, Saquinavir

6.5 Antiprotozoal Medicines

6.5.1 Antiamoebic and Antigiardiasis medicines - Diloxanide Furoate, Metronidazole

6.5.2 Antileishmaniasis medicines - Amphotericin B, Pentamidine Isothionate, Sodium Stibogluconate

6.5.3 Antimalarial Medicines

6.5.3.1 For curative treatment - Artesunate (To be used only in combination with Sulfadoxine + Pyrimethamine), Chloroquine phosphate, Primaquine, Pyrimethamine, Quinine sulphate, Clindamycin

6.5.3.2 For prophylaxis - Mefloquine

6.5.4 Anti Pneumo Cystosis and Anti Toxoplasmosis medicines - Co-Trimoxazole (Trimethoprim + Sulphamethoxazole), Pentamidine Isothionate

Section 7: Anti migraine medicines

7.1 For treatment of acute attack - Paracetamol, Acetyl Salicylic Acid, Dihydroergotamine,

7.2 For Prophylaxis - Propranolol hydrochloride

Section 8: Antineoplastic, immunosuppressives and medicines used in palliative cure

8.1 Immunosuppressive medicines - Azathioprine, Cyclosporine

8.2 Cytotoxic medicines - Actinomycin D, Alpha Interferon, Bleomycin, Busulphan, Cisplatin, Cyclophosphamide, Cytosine arabinoside, Danazol, Doxorubicin, Etoposide, Flutamide, 5-Fluorouracil, Folinic Acid, Gemcitabine hydrochloride, L-Asparaginase, Melphalan, Mercaptopurine, Methotrexate, Mitomycin-C

8.3 Hormones and antihormones - Prednisolone, Raloxifene, Tamoxifen Citrate

8.4 Medicines used in palliative care - Morphine Sulphate, Ondansetron, Filgrastim, Allopurinol

Section 9: Antiparkinsonism medicines

Bromocriptine, Mesylate, Levodopa + Carbidopa, Trihexyphenidyl Hydrochloride

Section 10: Medicines affecting the blood

10.1 Antianaemia medicines - Cyanocobalamin, Ferrous Sulphate/Fumrate, Folic Acid, Iron Dextran, Pyridoxine

10.2 Medicines affecting coagulation - Heparin Sodium, Protamine sulphate, Phytomenadione, Warfarin sodium, Enoxaparin

Section 11: Blood products and Plasma substitutes

11.1 Plasma Substitutes - Dextran-40, Dextran-70, Fresh frozen plasma, Hydroxyethyl Starch (Hetastarch), Polygeline

11.2 Plasma fractions for specific use - Albumin, Cryoprecipitate, Factor VIII, Concentrate Factor IX Complex (Coagulation Factors II, VII, IX, X), Platelet Rich Plasma

Section 12: Cardiovascular medicines

12.1 Antianginal medicines - Acetyl salicylic acid, Diltiazem, Glyceryl Trinitrate, Isosorbide 5 Mononitrate/Dinitrate, Metoprolol, Clopidogrel

12.2 Antiarrhythmic medicines - Adenosine, Amiodarone, Diltiazem, Esmolol, Lignocaine Hydrochloride, Procainamide Hydrochloride, Verapamil

12.3 Antihypertensive medicines - Losartan Potassium, Methyldopa, Nifedipine, Sodium Nitroprusside, Hydrochlorthiazide Amlodipine, Atenolol, Enalapril Maleate

12.4 Medicines used in heart failure - Digoxin, Dobutamine, Dopamine Hydrochloride
12.5 Antithrombotic medicines - Acetyl Salicylic Acid, Heparin Sodium, Streptokinase, Urokinase
12.6 Hypolipidemic Medicines - Atorvastatin

Section 13: Dermatological medicines (Topical)
13.1 Antifungal medicines - Miconazole
13.2 Antiinfective medicines - Framycetin Sulphate, Methylrosanilinium Chloride (Gentian Violet), Neomycin + Bacitracin, Povidone Iodine, Silver Sulphadiazine, Acyclovir
13.3 Antiinflammatory and antipruritic medicines - β-methasone, Dipropionate, Calamine
13.4 Astringent Medicines - Zinc Oxide
13.5 Medicines affecting skin differentiation and proliferation - Dithranol, Glycerin, Salicylic Acid, Coal Tar
13.6 Scabicides and Pediculicides - Benzyl Benzoate, Permethrin

Section 14: Diagnostic agents
14.1 Ophthalmic medicines - Fluorescein, Lignocaine, Tropicamide
14.2 Radiocontrast media - Barium Sulphate, Iopanoic Acid, Meglumine Iothalamate, Meglumine Iotroxate, Propyliodone, Sodium Iothalamate, Sodium Meglumine, Diatrizoate

Section 15: Disinfectants and antiseptics
15.1 Antiseptics - Acriflavin + Glycerin, Benzoin Compound, Cetrimide, Chlorhexidine, Ethyl Alcohol 70%
15.2 Disinfectants - Bleaching Powder, Formaldehyde Solution, Glutaraldehyde, Potassium Permanganate

Section 16: Diuretics - Furosemide, Hydrochlorothiazide, Mannitol, Spironolactone

Section 17: Gastrointestinal medicines
17.1 Antacids and other Antiulcer medicines- Aluminium Hydroxide + Magnesium Hydroxide, Omeprazole, Ranitidine, Pantoprazole, Famotidine
17.2 Antiemetics - Omperidone, Metoclopramide, Promethazine, Ondansetron
17.3 Antiinflammatory medicines - 5-Amino Salicylic Acid (5-ASA)
17.4 Antispasmodic medicines - Dicyclomine Hydrochloride, Hyoscine Butyl Bromide
17.5 Laxatives - Bisacodyl, Ispaghula
17.6 Medicines used in Diarrhorea
17.6.1 Oral dehydration salts - Oral Rehydration Salts
17.6.2 Antidiarrhoeal medicines - Zinc Sulfate

Section 18: Hormones, other endocrine medicines and contraceptives
18.1 Adrenal hormones and synthetic substitutes - Dexamethasone, Hydro-cortisone, Sodium Succinate, Methyl Prednisolone, Prednisolone
18.2 Androgens - Testosterone
18.3 Contraceptives

18.3.1 Hormonal Contraceptives - Ethinyl Estradiol + Levonorgesterol, Ethinylestradiol + Norethisterone, Hormone Releasing IUD
18.3.2 Intrauterine devices - IUD containing Copper
18.3.3 Barrier methods - Condoms
18.4 Estrogens Ethinylestradiol
18.5 Medicines used in diabetes mellitus
18.5.1 Insulins and other Antidiabetic agents - Glibenclamide, Insulin Injection (Soluble), Intermediate Acting (Lente/NPH Insulin), Metformin, Premix Insulin 30:70 Injection
18.5.2 Medicines used to treat hypoglycemia - glucagon, 25% Dextrose
18.6 Ovulation Inducers - Clomiphene Citrate
18.7 Progestogens - Medroxy Progesterone Acetate, Norethisterone
18.8 Thyroid and antithyroid medicines - Carbimazole, Levothyroxine, Iodine

Section 19: Immunologicals
19.1 Diagnostic agents - Tuberculin, Purified Protein derivative
19.2 Sera and immunoglobins - Anti-D immunoglobin (human), Polyvalent Antisnake Venom, Antitetanus Human immunoglobin, Diphtheria Antitoxin, Rabies immunoglobin
19.3 Vaccines
19.3.1 For Universal Immunization - C.G. Vaccine, D.P.T. Vaccine, Hepatitis B Vaccine, Measles Vaccine, Oral Poliomyelitis vaccine (LA)
19.3.2 For Specific Group of Individuals - Rabies Vaccine, Tetanus Toxoid

Section 20: Muscle Relaxants (Peripherally acting) and Cholinesterase Inhibitors Atracurium besylate, Neostigmine, Pyridostigmine, Succinyl Choline Chloride, Vecuronium

Section 21: Ophthalmological Preparations
21.1 Anti-infective agents - Chloramphenicol, Ciprofloxacin Hydrochloride, Gentamicin, Miconazole, Povidone Iodine, Sulphacetamide Sodium
21.2 Antiinflammaory agents - Prednisolone Acetate, Prednisolone Sodium Phosphate
21.3 Local Anaesthetics - Tetracaine Hydrochloride
21.4 Miotics and Antiglucoma medicines- Acetazolamide, β-xolol Hydrochloride, Pilocarpine, Timolol Maleate
21.5 Mydriatics - Atropine Sulphate, Homatropine, Phenylephrine
21.6 Ophthalmic Surgical Aids - Methyl Cellulose

Section 22: Oxytocics and Antioxytocics
22.1 Oxytocics - Methyl Ergometrine, Mifepristone, Oxytocin, Misoprosd
22.2 Antioxytocics - Terbutaline Sulphate, Nifedipine, β-methasone

Section 23: Peritoneal Dialysis Solution - Intraperitoneal Dialysis Solution

Section 24: Psychotherapeutic Medicines
24.1 Medicines used in Psychotic Disorders - Chlorpromazine hydrochloride, Haloperidol, Olanzapinenn
24.2 Medicines used in mood disorders

24.2.1 Medicines used in Depressive disorders - Amitriptyline, Fluozetine hydrochloride, Imipramine

24.2.2 Medicines used in Bipolar disorders - Lithium Carbonate, Sodium Valproate

24.3 Medicines used for Generalized Anxiety and Sleep Disorders - Alprazolam, Diazepam

24.4 Medicines used for obsessive compulsive disorders and panic attacks - Fluoxetine hydrochloride

Section 25: Medicines acting on the respiratory tract

25.1 Antiasthmatic medicines - Beclomethasone Dipropionate, Hydrocortisone sodium succinate, Salbutamol sulphate, Ipratropium bromide

25.2 Antitussives - Codeine phosphate, Dextromethorphan

Section 26: Solutions correcting water, electrolyte and acid-base disturbances

26.1 Oral - Oral Rehydration Salts

26.2 Parenteral - Glucose, Glucose with sodium chloride, Normal Saline, N/2 Saline, N/5 Saline, Potassium Chloride, Ringer Lactate, Sodium Bicarbonate

26.3 Miscellaneous - Water for Injection

Section 27: Vitamins and Minerals

Ascorbic Acid, Calcium Carbonate, Multivitamins (As per Schedule V of Drugs and Cosmetics Rules), Nicotinamide, Pyridoxine, Riboflavin, Thiamine, Vitamin A, Vitamin D (Ergocalciferol), Calcium gluconate.

EXERCISE

1. Discuss about the regulations of Drug Price Control Order (DPCO) Act.
2. Explain how the sale prices of bulk drugs can be fixed under DPCO Act.
3. Explain how the retail price of formulation can be fixed and calculated as per DPCO Act.
4. Write about the fixation of ceiling and retail prices of Scheduled formulations under DPCO Act.
5. Write the National List of Essential Medicines under DPCO Act.

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UNIT V

Chapter ... 9

PHARMACEUTICAL LEGISLATIONS IN INDIA

♦ **LEARNING OBJECTIVES** ♦

After completing this chapter, the reader should be able to understand:

- The history of pharmaceutical legislation in India.
- The recommendations of chopra committee and action taken by the government on the recommendations.
- Evolution of Bhore, Mudaliar and Hathi committees and their recommendations.

9.1 HISTORY OF PHARMACEUTICAL LEGISLATION IN INDIA

The Genesis of Modern Medicine and Pharmacy:

In ancient years, Ayurveda system of medicines was popular in India. Indians were depending on the indigenous source of medicines. Allopathic system of medicine was introduced to India due to the invasion of the British.

In Calcutta, the first chemist shop was introduced by Mr. Bathgate in the year 1811. It took about 100 years to this firm to develop the first tinctures and spirits. In the year 1821, Smith Stanistreet and Co. started a new shop and in the year 1918, the manufacturing process was adopted by this firm. Acharya Prafulla Chandra Roy started a new company called Bengal Chemical and Pharmaceutical works, in Calcutta in the year 1901. In 1903, the initiative was taken by Prof. T. K. Gajjar, who established the Alembic Chemical Works Ltd. at Baroda. All the above establishments could not satisfy the need of the population and hence many medicines were imported to India.

After the First World War, there was a drastic change in the import of medicines. Many cheap drugs were imported to India. The competition developed between the foreign company drugs and indigenous drugs, as a result, many filthy practices came into picture which resulted in the development of inferior misbranded and spurious drugs. This led to a harmful impact on the public.

Due to the ill effects of the drug, the government of India was bound to implement legislation pertaining to import, export, manufacture, distribution and sale of the drug. As a result, acts like Opium Act 1878, Poison Act 1919 and Dangerous Drugs Act 1930 came into force. These acts were insufficient for the safety of the rampant growing population and the flourishing pharma industries. Therefore, Drug Enquiry Committee was established.

9.2 DRUGS ENQUIRY COMMITTEE

On 11th August 1930, the Government of India, appointed The Drug Enquiry Committee under the chairmanship of Late Col. R. N. Chopra also known as Chopra Committee to explore the scope of the problem and to make recommendations regarding the measures.
Some of the recommendations of the Chopra committee are as follows:

- This committee developed Central and State Pharmacy council whose function was to look after the training and education of pharmacy professionals and also maintain the register containing the name and the address of the registered pharmacist.
- The drug control machinery departments were established at the centre in all states due to the recommendation of this committee.
- The committee also proposed the need of well-equipped Central Drug laboratory (CDL) with well-qualified staff and experts.
- The committee suggested appointing an advisory board to advise the government in making rules to carry out the objectives of the Act.
- Framing the academic curculium for educating pharmacy students and also providing training for them to become registered pharmacists.
- The committee provided a basis for registration of patent and proprietary medicines manufactured in India or imported from outside the country.
- Inclusion of drug products used in indigenous systems and crude drugs of plant and animal origin.
- Pharmaceutical industry development plans in India.
- The committee also suggested compiling Indian Pharmacopoeia.

Actions are taken by Government on the Chopra Committee Recommendations:

The following pharmaceutical legislation and actions of the central government can be traced to the above said recommendations:

1. Passing Drugs Act in 1940 for regulating the import, manufacture, distribution, and sale of drugs. The Drugs Rules were framed in 1945 to give effect to the provisons of the Act.
2. In 1948, Pharmacy Act framed regulations for prescribing minimum educational qualifications for the profession and practice of pharmacy.
3. Government drug testing laboratories were setup both in State and Central level.
4. Establishment of Government advisory boards such as the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).
5. Drugs and Medicines of Indigenous system of medicines have been brought under the control of Drugs and Cosmetics Act, 1940.
6. Registration of all the drugs and formulations that are sold in India.
7. Official Indian Pharmacopoeia was developed.
8. The Drugs and Magic remedies Act in 1954, Medicinal and Toilet preparations Act in 1955 and Narcotic Drugs and Psychotropic Substances (NDPS) Act in the year 1985 were implemented.

9.3 HEALTH SURVEY AND DEVELOPMENT COMMITTEE

This committee was set up by Indian Government on October 1943, under the chairmanship of Sir Joseph Bhore to make a survey of the existing position in respect of health care delivery organization in India and to make recommendations for future developments.

The following recommendations were made:

1. An All India Pharmaceutical Council and Provisonal Pharmaceutical Council was established in order to represent the pharmaceutical trade, education, and other paharmaceutical interests.
2. Enactment of legislation designed to protect the public from incompetence, to safeguard the interests of qualified pharmacists and to raise the professional standard of pharmacists engaged in the handling of drugs.
3. Stringnent rules were framed to control the profession and practice of pharmacy.
4. Starting of revised courses of study for:
   (a) Licentiate Pharmacists,
   (b) Graduate Pharmacists,
   (c) Pharmaceutical Technologists,
5. Setting up of Central Drugs Laboratory.
6. Rigid enforcement of the Drugs and Cosmetics Act, 1940 thoughout the country.

9.4 MUDLIAR COMMITTEE

This committee was appointed in June 1959 under the chairmanship of Dr. A. Lakshmanswamy Mudliar and this committee was also known as Health Survey and Planning Committee which recommended the inclusion of indigenous systems of medicine under the supervision of the Drugs Act. Based on its recommendations, drugs prepared according to indigenous systems of medicine were brought within the purview of Drugs and Cosmetics Act, 1940. The committee submitted its report of recommendations in 1961.

9.5 HATHI COMMITTEE

This committee was set up under the Chairmanship of Jaisukh Lal Hathi to implement special provisons for the development of pharmaceutical industry in India. The report of this committee covered all aspects ranging from licensing, price control, imports, the role of the foreign sector, quality control etc.

EXERCISE

1. Write about the History of Pharmaceutical Legislation in India.
2. Discuss the recommendations and actions taken by Drugs enquiry committee.
3. Write about the Mudliar and Hathi Committee.

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Chapter ... 10

CODE OF PHARMACEUTICAL ETHICS

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- ❖ The meaning of Professional and Pharmaceutical Ethics.
- ❖ The code of ethics of Pharmacist in relation to his job and trade,
- ❖ The code of ethics of Pharmacist in relation to his and medical profession,
- ❖ The Pharmacist's Oath.

10.1 INTRODUCTION

The meaning of ethics is moral principles. It is also a science of moral duty. The code of ethics is a carefully formulated system of principles or rules of practice for the guidance of a particular group of individuals like the members of a profession. The development of this code of ethics is the indication of the evolution and the growth of moral consciousness. Ethics are different from laws. Law is defined as 'Rules of human conduct binding on all persons in a state or nation'. Ethics is defined as 'Rules by which a profession regulates actions and sets standards for all its members'. The major difference involving both of it is in the method of enforcing compliance with the rules. When a law is broken, the violator may be subjected to punishment, a fine or imprisonment or both or the violator may be subjected to considerable monetary penalties in civic action. But when rules are broken, the professional body may subject the violator to loss of professional privileges. Law may prevent one from causing injury to another, but it cannot force him to help his neighbour in the hours of need. Helping the neighbour is the function of ethics.

10.2 PHARMACEUTICAL CODE OF ETHICS

The profession of pharmacy is noble in its ideals and pious in its character. In handling, selling, distribution, compounding and dispensing medical substances, including poisons and potent drug, a pharmacist, in collaboration with medical men and others, is charged with the onerous responsibility of safeguarding the health of people. It is the duty of all those involved in the pharmacy field to be sure that the pharmacist in training knows the standards of professional conduct and understands that, deviation from those standards cannot maintain the status of the pharmacy profession.

The Government restricts the practice of pharmacy to those, who qualify under regulatory requirements and grants them privileges necessarily denied to others. In return, the Government expects the pharmacists to recognize their responsibilities and fulfil their professional obligations honourably and with due regards for the well-being of the society. Every pharmacist should, not only be willing to play his part in giving service but should also

avoid any act or omission which would prejudice the giving of the services or impart confidence for the pharmacist as a body. A pharmacist must, above all, be a good citizen and must uphold and defend the laws of the state and the nation.

Ethics of Pharmacist in Relation to his Job:

A. Scope of Pharmaceutical Services:

- When the premises are registered under statutory requirements and opened as a pharmacy, reasonably comprehensive pharmaceutical services should be provided.
- This involves a willingness to furnish emergency supplies at all times.

B. Conduct of the Pharmacy:

- The conditions in a pharmacy should be such that it should preclude avoidable risk or error of accidental contamination in the preparation, dispensing and supply of medicines.
- The appearance of the pharmacy should reflect the professional character of the pharmacy.
- It should clear to the public that, the practice of pharmacy is being carried out in the establishment.
- Signs, notices, description, wordings on business, stationary and related indications, should be restrained in size, design and terms.
- A notice, stating that dispensing under E.S.I.S (Employees State Insurance Scheme) or any such other scheme sponsored by the government is carried out, may be exhibited at the premises.
- In every pharmacy, there should be a pharmacist, in personal control of the pharmacy who will be regarded as primarily responsible for the observance of proper standards of conduct in connection to it.
- Any obstruction of the pharmacist in the execution of his duty by the owner will be regarded as a failure on the part of the owner to observe the standards in question.

C. Handling of Prescriptions:

- When a prescription is presented for dispensing, it should be received by a pharmacist without any discussion or comment over it, regarding the merits and demerits of its therapeutic efficacy.
- The pharmacist should not even show any physiognomic expression of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may even shake faith in their physician.
- Any questions that are raised related to the prescription should be answered with every caution and care, it should neither offend a patron nor should it disclose any information which might have been intentionally withheld from him.
- A pharmacist is not given the privilege to add, omit or substitute any ingredient or alter the composition of a prescription, without the consent of the prescriber, unless the change is emergent or is demanded purely by the technique of the pharmaceutical art and does not cause any alteration in the therapeutic action of the recipe.

- In case of any obvious error in it, due to any omission, incompatibility or over dosage, the prescription should be referred back to the prescriber for correction or approval of the change suggested.
- In matters related to the refilling of prescription, a pharmacist should solely be guided by the instructions of the prescriber and he should advise patients to use medicines or remedies, strictly in accordance with the intention of the physician, as noted on the prescription.

D. Handling of Drugs:

- All possible care should be taken to dispense a prescription correctly, by weighing and measuring all ingredients, in correct proportions, by the help of scales and measures; visual estimations must be avoided.
- A pharmacist should always use drugs and medicinal preparations of standard quality. He should never fill his prescription with spurious, substandard and unethical preparations.
- A pharmacist should be judicious in dealing with drugs and medicinal preparations known to be poisonous or to be used for addiction or another abusive purpose.
- Such drugs and preparations should not be supplied to any one, if there is a reason to suppose that, it is required for such purpose.

E. Apprentice Pharmacist:

- While in charge of a dispensary, drug store or hospital pharmacy, where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training they acquired sufficient technique and skill to make themselves dependable pharmacists.
- No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

10.3 PHARMACIST IN RELATION TO HIS TRADE

A. Price Structure:

- Price charged from the customers, should be fair and in keeping with the quality and quantity of commodity supplied, and the labour and the skill that is required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist, taking into consideration his knowledge, skill, time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

B. Fair Trade Practice:

- No attempts should be made to capture the business of a contemporary by cut-throat competitions, i.e., by offering any sort of prizes or gifts or any kind of allurement to patronisers or by knowingly charging lower prices for medical commodities than those charged by a fellow pharmacist, if they are reasonable.
- In case, if any order or prescription, genuinely intended to be served by some dispensary, is brought by mistake to another, then the latter must refuse to accept it and must direct the customer to the right place.
- Labels, trademarks and other signs and symbols of the contemporary should not be imitated or copied.

C. Purchase of Drugs:

- Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly, the manufacture, possession, distribution, and sale of spurious or substituted drugs.

D. Hawking of Drugs:

- Hawking of drugs and medicinals should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
- 'Self-service' method of operating pharmacies and drug-stores should not be used as this practice may lead to the distribution of therapeutic substances without expert supervision and thus would encourage self-medication, which is highly undesirable.

E. Advertising and Displays:

No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public of medicines or medical appliances which is undignified in style or which contains: –

(a) Any wording design or illustration reflecting unfavourably on pharmacist collectively or upon any group or individual.
(b) A disparaging reference, direct of by implication to other suppliers, products, remedies or treatments.
(c) Misleading, or exaggerated statements or claims.
(d) The word "Cure" in reference to an ailment or symptoms of ill-health.
(e) A guarantee of therapeutic efficacy.
(f) An appeal to fear,
(g) An offer to refund the money paid.
(h) A prize, competition or similar scheme.
(i) Any reference to a medical practitioner or a hospital or the use of the terms "Doctor" or "Dr." or "Nurse" in connection with the name of preparation not already established.
(j) A reference to sexual weakness, premature ageing or loss of virility.
(k) A reference to complaints of sexual nature in terms which lack the reticence proper to the subject.

No article or preparation, advertised to the public by means of display material of a kind mentioned above should be exhibited in a pharmacy if it is known or could reasonably be known that the article or preparation is so advertised.

10.4 PHARMACIST IN RELATION TO MEDICAL PROFESSION

A. Limitation of Professional Activity:

- Whereas it is expected that medical practitioners, in general, would not take to the practice of pharmacy by owning drug stores, as this ultimately leads to coded prescriptions and monopolistic practices detrimental to the pharmaceutical profession and also to the interest of patients.
- It should be made a general rule that pharmacists under no circumstances take to medical practice that is to diagnosing diseases and prescribing remedies therefore even if requested by patrons to do so.
- In cases of accidents and emergencies, a pharmacist may, however, render First Aid to the victim.
- No pharmacist should recommend particular medical practitioner unless specifically asked to do so.

B. Clandestine Arrangements:

- No pharmacist should enter into any secret arrangements or contract with a physician to offer him any commission or any advantage of any description in return for his favour of patronage by recommending his dispensary or drug store or even his self to patients.

C. Liaison with the Public:

- Being a liaison between medical profession and people, a pharmacist should always keep himself abreast with the modern developments in pharmacy and other allied sciences by regularly reading books, journals, magazines and other periodicals, so that on the one hand he may be in a position to advise the physician on pharmaceutical matters like those of colours, flavours, vehicles and newer forms of administration of medicines, on the other hand he may be able to educate the people for maintaining healthy and sanitary conditions of living.
- Thus, a pharmacist can contribute his share in the nation-building activities of the country.
- A pharmacist should at all times endeavour to promote knowledge and contribute his quota in the advancement of learning. A pharmacist should never disclose any information which he has acquired during his professional activities to any third party or person unless required by law to do so.
- He should never betray the confidence which his patrons repose in him or which he has won by virtue of his eminent character and conduct.

10.5 PHARMACIST IN RELATION TO HIS PROFESSION

A. Professional Vigilance:

- It is not only sufficient for a pharmacist to be law-abiding and to deter from doing things derogatory to Society and his profession, but it should be his bounden duty to make others also fulfil the provisions of the pharmaceutical and other laws and regulations.
- He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession.
- Whereas it is obligatory for a pharmacist to extend help and co-operation to a fellow member in his legitimate needs, scientific, technical or otherwise, he is to be, at the same time, vigilant to weed the undesirable out of the profession and thus help to maintain its fair name and traditions.

B. Law-abiding Citizens:

- A pharmacist engaged in the profession has to be an enlightened citizen endowed with a fair knowledge of the land and he should strive to countenance and defend them. He should be particularly conversant with the enactments pertaining to food, drug, pharmacy, health, sanitation and the like and endeavour to abide by them in every phase of his life.
- A pharmacist is a unit whole and his life cannot be divided into compartments.

C. Relationship with Professional Organisations:

- In order to inculcate a corporate life in his own professional colleagues, a pharmacist should join and advance the cause of all such organisations, the aims and objects of which are conducive to the scientific moral and cultural well-being of pharmacists and at the same time are in no way contrary to the code of pharmaceutical ethics.

D. 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 or which are likely to bring discredit or upgrade to the profession or to himself.

10.6 PHARMACIST'S OATH

A young prospective pharmacist should feel no hesitation in assuming the following Pharmacist's Oath:

"I swear by the Code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of the health care team. I shall uphold the laws and standards governing my profession. I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.

I shall follow the system, which I consider best for pharmaceutical care and counselling of the patient. I shall endeavor to discover and manufacture drugs if quality to alleviate the sufferings of humanity. I shall hold in confidence, the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.

I shall associate with organizations having their objectives for the betterment of the profession of Pharmacy and make a contribution to carry out the work of these organizations.

While I continue to keep this oath inviolate, may it be granted to me to enjoy life and practice of pharmacy respected by all, at all times. Should I trespass and violate the oath, the reverse be my lot."

EXERCISE

1. What do you mean by professional ethics? Give its significance.
2. Describe the ethics that a pharmacist should have in relation to his job.
3. Explain the code of ethics of pharmacist in relation to his and the medical profession.
4. Write the code of ethics of pharmacist in relation to his trade.
5. Describe the Pharmacist's Oath.

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Chapter ... 11

MEDICAL TERMINATION OF PREGNANCY ACT

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- ❖ The purpose and objectives of the Act.
- ❖ The procedure of pregnancy termination by Medical Practitioner.
- ❖ The offences and penalties of the Act.

11.1 INTRODUCTION

The Medical Termination of Pregnancy Act was passed by the parliament in 1971 with a view to provide for termination of pregnancy by Registered Medical Practitioners for bonafide medical reasons.

The Act extends to the whole of India except the state of Jammu and Kashmir. The Act was framed mainly due to the following reasons:

1. Legal abortions were difficult at that time and many were being carried out illegally under unhygienic or unsafe conditions resulting in harm to health or life of women.
2. As a population control measure since it provided for termination of unwanted pregnancy resulting from a failure of any device or method used by the married woman or her husband for limiting the number of children.

11.2 DEFINITIONS

(a) **Guardian** means a person having the care of the person of a minor or a lunatic.

(b) **Lunatic** has the meaning assigned to it in Section 3 of the Indian Lunacy Act, 1912.

(c) **Minor** means a person who, under the provisions of the Indian Majority Act, 1875 (9 of 1875), is to be deemed not to have attained his majority.

(d) **Registered medical practitioner** means a person who possesses any recognised medical qualification as defined under the Indian Medical Council Act whose name

has been entered in a state Medical Register and who has such experience or training in gynecology and obstetrics as may be prescribed by rules made under this Act.

11.3 PROVISIONS OF THE ACT

The Medical Termination of Pregnancy Act provides that, pregnancies of women may be terminated by Registered Medical Practitioners under the following circumstances:

1. Pregnancies of women, 18 years of age or more, with their consent or in case of women who are less than 18 years of age or are lunatics, with the written consent of their guardian.
2. A pregnancy which is not more than 12 weeks old and the medical practitioner is of the opinion (formed in good faith) that its continuance is a grave danger to the life of the woman or to her physical and mental health or the child to be born would be seriously handicapped due to physical or mental abnormalities.
3. A pregnancy which is more than 12 weeks but not more than 20 weeks old, provided that not less than two registered medical practitioners are of such an opinion.
4. A pregnancy of any duration provided that the medical practitioner is of the opinion that such termination is immediately necessary to save the life of the pregnant woman.
5. A pregnancy which is alleged to have been caused due to rape or due to failure of a contraceptive device used by a woman or her husband for family planning purposes.

11.4 REQUIREMENT OF EXPERIENCE OR TRAINING FOR AN RMP TO TERMINATE PREGNANCY

Any RMP having the following experience/training in the practice of gynecology and obstetrics can terminate a pregnancy under the Act –

(i) If the RMP was registered in a State Medical Register before the commencement of this Act:
   (a) Experience in the practice of gynecology and obstetrics for not less than three years.

(ii) If the RMP was registered on or after the commencement of this Act:
   (a) Six months of house surgery in gynecology and obstetrics.
   (b) In case, he has not done any such house surgery, experience gynecology, and obstetrics in any hospital for not less than one year.
   (c) An experience by way of assistance given by the person to an RMP in the performance of twenty five cases of medical termination of pregnancy in a hospital established or maintained, or a training institute approved for this purpose, by the Government.

11.5 MAINTENANCE OF RECORDS

Records pertaining to the admissions of women for termination of pregnancy shall be maintained by the head of the hospital or the owner of the approved place, in special registers kept for the purpose. The entries in the register shall be made serially yearwise. The admission register shall be a secret document and the information contained therein shall not be disclosed to any person except as provided under the Act.

However, in case of an employed woman whose pregnancy has been terminated, the RMP shall grant a certificate on demand in order to enable her to obtain leave from her employer. The employer shall however not disclose this information to any other person.

No entry regarding the name or identity of the woman shall be made in any case sheet, operation theatre register, follow-up card or any other document or register (except the admission register). Any reference to the pregnant woman shall be made on the basis of the serial number assigned to the woman in the admission register.

Every admission register shall be destroyed on the lapse of five years from the date of last entry in the register. Other papers shall be destroyed on the lapse of three years from the date of termination of the pregnancy concerned unless otherwise directed. The consent given by the pregnant women regarding the termination of her pregnancy together with the certified opinion of the RMP shall be sealed in an envelope by the RMP. The envelope shall bear the serial number assigned to the pregnant woman, the name of the RMP by whom the pregnancy was terminated and shall be marked **SECRET**. The envelope shall be kept in safe custody by the head of the hospital or the owner of the approved place.

11.6 OFFENCES AND PENALTIES

The termination of a pregnancy by a person who is not a Registered Medical Practitioner is a punishable offence under the Indian Penal Code. Any one who fails to comply with rules made under the Act or contravenes them may be fined upto ₹ 1,000.

EXERCISE

1. Discuss the provisions of the Medical Termination of Pregnancy for the termination of pregnancy.
2. Write in brief about the Medical Termination of Pregnancy Act.
3. Discuss the requirement of experience for pregnancy termination and procedure for maintenance of records related to pregnancy termination of a woman.
4. Enlist the objectives of Medical Termination of Pregnancy Act.

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Chapter ... 12

RIGHT TO INFORMATION (RTI) ACT

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- The objective of RTI Act.
- The composition of State and Central information commission.
- The powers and functions of the State and Central information commission.

12.1 INTRODUCTION

In a democratic Republic, it is expedient to provide for furnishing certain information to citizens who desire to have it. Democracy requires an informed citizenry and transparency of information which are vital to its functioning and also to contain corruption and to hold Governments and their instrumentalities. The revelation of information in actual practice is likely to conflict with other public interests including efficient operations of the Governments, optimum use of limited fiscal resources and the preservation of confidentiality of sensitive information. It is necessary to harmonize these conflicting interests while preserving the paramountey of the democratic ideal.

Right to information is guaranteed to every citizen of India under section 3 of the Right To Information Act, 2005.

The main objective of this act is to provide for setting out the practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, the constitution of a Central Information Commission and State Information Commissions and for matters connected therewith or incidental thereto.

12.2 DEFINITIONS

(a) "Appropriate Government" means in relation to a public authority which is established, constituted, owned, controlled or substantially financed by funds provided directly or indirectly (i) by the Central Government or the Union territory administration, (ii) by the State Government;

(b) "Central Information Commission" means the Central Information Commission constituted under sub-section (1) of Section 12;

(c) "Central Public Information Officer" means the Central Public Information Officer designated under sub-section (1) and includes a Central Assistant Public Information Officer designated as such under sub-section (2) of Section 5;

(d) "Chief Information Commissioner" and "Information Commissioner" means the Chief Information Commissioner and Information Commissioner appointed under sub-section (3) of Section 12;

(e) "Competent Authority" means: (i) the Speaker in the case of the House of the People or the Legislative Assembly of a State or a Union territory having such Assembly and the Chairman in the case of the Council of States or Legislative Council of a State; (ii) the Chief Justice of India in the case of the Supreme Court; (iii) the Chief Justice of the High Court in the case of a High Court; (iv) the President or the Governor, as the case may be, in the case of other authorities established or constituted by or under the Constitution; (v) the administrator appointed under article 239 of the Constitution;

(f) "Information" means any material in any form, including records, documents, memos, e-mails, opinions, advices, press releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material held in any electronic form and information relating to any private body which can be accessed by a public authority under any other law for the time being in force;

(g) "Prescribed" means prescribed by rules made under this Act by the appropriate Government or the competent authority, as the case may be;

(h) "Public authority" means any authority or body or institution of self government established or constituted— (a) by or under the Constitution; (b) by any other law made by Parliament; (c) by any other law made by State Legislature; (d) by notification issued or order made by the appropriate Government, and includes any (i) body owned, controlled or substantially financed; (ii) non-Government organization substantially financed, directly or indirectly by funds provided by the appropriate Government;

(i) "Record" includes: (a) any document, manuscript, and file; (b) any microfilm, microfiche and facsimile copy of a document; (c) any reproduction of image or images embodied in such microfilm (whether enlarged or not); and (d) any other material produced by a computer or any other device;

(j) "Right to information" means the right to information accessible under this Act which is held by or under the control of any public authority and includes the right to: (i) inspection of work, documents, records; (ii) taking notes, extracts or certified copies of documents or records; (iii) taking certified samples of material; (iv) obtaining information in the form of diskettes, floppies, tapes, video cassettes or in any other electronic mode or through printouts where such information is stored in a computer or in any other device;

(k) "State Information Commission" means the State Information Commission constituted under sub-section (1) of Section 15;

(*l*) "State Chief Information Commissioner" and "State Information Commissioner" means the State Chief Information Commissioner and the State Information Commissioner appointed under sub-section (3) of Section 15;

(m) "State Public Information Officer" means the State Public Information Officer designated under sub-section (1) and includes a State Assistant Public Information Officer designated as such under sub-section (2) of section 5;

(n) "Third party" means a person other than the citizen making a request for information and includes a public authority.

12.3 RIGHT TO INFORMATION AND OBLIGATIONS OF PUBLIC AUTHORITIES

Every public authority shall maintain all its records duly catalogued and indexed in a manner and the form which facilitates the right to information under this Act and ensure that all records that are computerized are, within a reasonable time and subject to availability of resources, computerized and connected through a network all over the country on different systems so that access to such records is facilitated.

Every public authority shall, within one hundred days of the enactment of this Act, designate as many officers as the Central Public Information Officers or State Public Information Officers, as the case may be, in all administrative units or offices under it as may be necessary to provide information to persons requesting for the information under this Act.

In sub-section 3 of section 8, a duty is cast on the public authority to provide information regarding any occurrence, event or matter that has happened 20 years before the date of the request for supply of information. This implies that, authorities are under obligation to maintain the information or records of last and for the next 20 years in such a manner so as to facilitate the enforcement of the RTI Act.

A person, who desires to obtain any information under this Act, shall make a request in writing or through electronic means in English or Hindi or in the official language of the area in which the application is being made, accompanying such fee as may be prescribed, to (a) the Central Public Information Officer or State Public Information Officer, as the case may be, of the concerned public authority; (b) the Central Assistant Public Information Officer or State Assistant Public Information Officer, as the case may be; specifying the particulars of the information sought by him or her.

An applicant making request for information shall not be required to give any reason for requesting the information or any other personal details except those that may be necessary for contacting him. Information shall ordinarily be provided in the form in which it is sought unless it would disproportionately divert the resources of the public authority or would be detrimental to the safety or preservation of the record in question.

Information that may be Refused:

There shall be no obligation to give any citizen,

(a) Information, disclosure of which would prejudicially affect the sovereignty and integrity of India, the security, strategic, scientific or economic interests of the State, relation with foreign State or lead to incitement of an offence;

(b) The information which has been expressly forbidden to be published by any court of law constitute contempt of court; or tribunal or the disclosure of which may constitute contempt of court;

(c) Information, the disclosure of which would cause a breach of privilege of Parliament or the State Legislature;

(d) Information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;

(e) The information available to a person in his fiduciary relationship, unless the competent authority is satisfied that the larger public interest warrants the disclosure of such information;
(f) Information received in confidence from foreign Government;
(g) Information, the disclosure of which would endanger the life or physical safety of any person or identify the source of information or assistance given in confidence for law enforcement or security purposes;
(h) The information which would impede the process of investigation or apprehension prosecution of offenders;
(i) Cabinet papers including records of deliberations of the Council of Ministers, Secretaries and other officers;
(j) Information which relates to personal information, the disclosure of which has no relationship to any public activity or interest, or which would cause unwarranted invasion of the privacy of the individual unless the Central Public Information Officer or the State Public Information Officer or the appellate authority, as the case may be, is satisfied that the larger public interest justifies the disclosure of such information.

12.4 THE CENTRAL INFORMATION COMMISSION

The Central Government shall, by notification in the Official Gazette, constitute a body to be known as the Central Information Commission to exercise the powers conferred on, and to perform the functions assigned to, it under this Act.

The Central Information Commission shall consist of:

(a) The Chief Information Commissioner; and
(b) Such number of Central Information Commissioners, not exceeding ten, as may be deemed necessary.

The Chief Information Commissioner and Information Commissioners shall be appointed by the President on the recommendation of a committee consisting of:

(i) The Prime Minister, who shall be the Chairperson of the committee;
(ii) The Leader of Opposition in the Lok Sabha; and
(iii) A Union Cabinet Minister to be nominated by the Prime Minister.

The general superintendence, direction and management of the affairs of the Central Information Commission shall vest in the Chief Information Commissioner who shall be assisted by the Information Commissioners and may exercise all such powers and do all such acts and things which may be exercised or done by the Central Information Commission autonomously without being subjected to directions by any other authority under this Act. The Chief Information Commissioner shall hold office for a term of five years from the date on which he enters upon his office and shall not be eligible for reappointment:

Provided that, no Chief Information Commissioner shall hold office as such after he has attained the age of sixty-five years.

12.5 THE STATE INFORMATION COMMISSION

Every State Government shall, by notification in the Official Gazette, constitute a body to be known as the (name of the State) Information Commission to exercise the powers conferred on, and to perform the functions assigned to, it under this Act.

The State Information Commission shall consist of:

(a) the State Chief Information Commissioner, and

(b) such number of State Information Commissioners, not exceeding ten, as may be deemed necessary.

The State Chief Information Commissioner and the State Information Commissioners shall be appointed by the Governor on the recommendation of a committee consisting of:

(i) the Chief Minister, who shall be the Chairperson of the committee;
(ii) the Leader of Opposition in the Legislative Assembly; and
(iii) a Cabinet Minister to be nominated by the Chief Minister

The general superintendence, direction and management of the affairs of the State Information Commission shall vest in the State Chief Information Commissioner who shall be assisted by the State Information Commissioners and may exercise all such powers and do all such acts and things which may be exercised or done by the State Information Commission autonomously without being subjected to directions by any other authority under this Act.

The State Chief Information Commissioner and the State Information Commissioners shall be persons of eminence in public life with wide knowledge and experience in law, science, and technology, social service, management, journalism, mass media or administration and governance. The State Chief Information Commissioner or a State Information Commissioner shall not be a Member of Parliament or Member of the Legislature of any State or Union territory, as the case may be, or hold any other office of profit or connected with any political party or carrying on any business or pursuing any profession.

The headquarters of the State Information Commission shall be at such place in the State as the State Government may, by notification in the Official Gazette, specify and the State Information Commission may, with the previous approval of the State Government, establish offices at other places in the State.

The State Chief Information Commissioner shall hold office for a term of five years from the date on which he enters upon his office and shall not be eligible for reappointment: Provided that, no State Chief Information Commissioner shall hold office as such after he has attained the age of sixty-five years.

12.6 POWERS AND FUNCTIONS OF THE INFORMATION COMMISSIONS

Subject to the provisions of this Act, it shall be the duty of the Central Information Commission or State Information Commission, as the case may be, to receive and inquire into a complaint from any person;

(a) Who has been unable to submit a request to a Central Public Information Officer or State Public Information Officer, as the case may be, either by reason that no such officer has been appointed under this Act, or because the Central Assistant Public Information Officer or State Assistant Public Information Officer, as the case may be, has refused to accept his or her application for information or appeal under this Act for forwarding the same to the Central Public Information Officer or State Public Information Officer or Senior Officer specified in subsection (1) of section 19 or the Central Information Commission or the State Information Commission, as the case may be;
(b) Who has been refused access to any information requested under this Act;

(c) Who has not been given a response to a request for information or access to the information within the time limit specified under this Act;
(d) Who has been required to pay an amount of fee which he or she considers unreasonable;
(e) Who believes that he or she has been given incomplete, misleading or false information under this Act; and
(f) In respect of any other matter relating to requesting or obtaining access to records under this Act. (2) Where the Central Information Commission or State Information Commission, as the case may be, is satisfied that there are reasonable grounds to inquire into the matter, it may initiate an inquiry in respect thereof.

The Central Information Commission or State Information Commission, as the 5 of 1908 case may be, shall, while inquiring into any matter under this section, have the same powers as are vested in a civil court while trying a suit under the Code of Civil Procedure, 1908, in respect of the following matters, namely:

(a) Summoning and enforcing the attendance of persons and compel them to give oral or written evidence on oath and to produce the documents or things;
(b) Requiring the discovery and inspection of documents;
(c) Receiving evidence on affidavit;
(d) Requisitioning any public record or copies thereof from any court or office;
(e) Issuing a summons for examination of withesses or documents; and
(f) Any other matter which may be prescribed.

EXERCISE

1. Discuss the RTI Act, 2005.
2. Write about the Right to information and obligations of public authorities under the RTI Act.
3. Discuss the constitution and functions of The Central Information Commission enacted under the RTI Act.
4. Enlist the Powers and functions of the Information Commissions as per the RTI Act.

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Chapter ... 13

INTELLECTUAL PROPERTY RIGHTS

♦ LEARNING OBJECTIVES ♦

After completing this chapter, the reader should be able to understand:

- The importance of Patent and Patent Act.
- The procedure of getting Patent.
- The concept of Intellectual Property Rights.
- The importance of Trademarks, Copyright and Designs.

13.1 INTRODUCTION

Intellectual property refers to creations of the mind: inventions; literary and artistic works; and symbols, names, and images used in commerce. Intellectual property has increasingly assumed a vital role with the rapid pace of technological, scientific and medical innovation that we are witnessing today. Moreover, changes in the global economic environment have influenced the development of business models where intellectual property is a central element establishing value and potential growth. In India, several new legislations for the protection of intellectual property rights (IPRs) have been passed to meet the international obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

13.2 PATENTS AND PATENT ACT

A patent in relation to inventions is an exclusive right granted by the Government to the patentee, in exchange of full disclosure of his invention, for excluding others from making, using, selling, importing the patented product or process producing that product for those purposes.

13.2.1 Indian Patent Act

The Patent Act in India was implemented in 1970 which came into force on 20th April 1972 and extended to the whole of India. This Act was amended in March 1999 and June 2002 to meet India's obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which forms part of the agreement establishing the World Trade Organization (WTO).

13.2.2 Definitions of Indian Patent Act

According to the Patents Act,

Assignee includes the legal representative of a deceased assignee, and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person.

Controller means the Controller General of Patents, Designs and Trademarks.

Exclusive license means a license from a patentee which confers on the licensee, or on the licensee and the persons authorised by him, to the exclusion of other persons (including the patentee), any right in respect of the patented invention, and "exclusive license" shall be constructed accordingly.

Food means any article of nourishment and includes any substance intended for the use of babies, invalids or convalescents as an article of food or drink.

Invention means any new and useful:

(i) Art, process, method or manner of manufacture.

(ii) Machine, apparatus or another article.

(iii) A substance produced by the manufacturer and includes any new and useful improvement of any of them and an alleged invention.

Medicine or Drug includes

(i) All medicines for internal or external use of human beings or animals.

(ii) All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals.

(iii) All substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals.

(iv) Insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants.

(v) All chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to.

Patent means a patent granted under this Act.

Patent agent means a person for the time being registered under this Act as a patent agent.

Patented article and **Patented process** means respectively an article or process in respect of which patent is in force.

Patentee means the person for the time being entered on the register as the grantee or the proprietor of the patent.

Inventions which are Patentable: An invention to be patentable should be technical in nature and should meet the following criteria:

(a) Novelty: The matter disclosed in the specification is not published in India or elsewhere before the date of filing of the patent application in India.

(b) Inventive step: The invention is not obvious to a person skilled in the light of the prior publication/knowledge/document.

(c) Industrially applicable: Invention should possess utility so that it can be made or used in the industry.

Inventions not patentable: The following are not inventions within the meaning of this Act and hence are not patentable.

(a) An invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) An invention, the primary or intended use or commercial exploitation of which would be contrary to which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) The mere discovery of a scientific principle or formulation of or discovery of any living thing or non-living substance occurring in nature;

(d) The mere discovery of a new form of a known substance which does not result in the enhancement of any known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

(e) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) The mere arrangement, rearrangement or duplication of known devices each functioning independently of one another in a known way;

(g) A method of agriculture or horticulture;

(h) Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or increase their production or propagation of plants and animals;

(i) Plants or animals in whole or any part thereof other than microorganisms but including seeds, varieties, and species and essentially biological processes for production or propagation of plants and animals;

(j) A mathematical or business method or a computer programme;

(k) A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(*l*) A mere scheme or rule or method of performing mental act or method of playing the game;

(m) A presentation of information;

(n) The topography of integrated circuits;

(o) An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components.

13.2.3 Types of Patent

Following types of patents are granted under the Act:

(i) An ordinary patent.

(ii) A patent of addition for improvement in or modification of an invention for which a patent has already been applied for or granted.

(iii) A patent granted in respect of a convention application filled under section 135 of the Act.

(iv) A product patent for a medicine or drug as provided by the Patents (Amendment) Act, 1999.

13.2.4 Procedure for Getting a Patent

An application for an ordinary patent including that for a product patent may be made by the person claiming to be the first or true inventor, his legal representative, or his assignee, either alone or jointly with any other person. An application for a patent of addition may be made only by the applicant for original patent to which it is an addition if the application for the original patent is pending or by the registered proprietor of such original patent if the patent has already been granted. A convention application may be made by any person who has made the application for patent in respect of that invention in a convention country, or by this assignee or his legal representative.

Every application for a patent should be for one invention only and should be made in the prescribed form and filed in the Patent Office (Head Office at Calcutta and Branch Offices at Chennai, Mumbai, and Delhi). If the application is made by virtue of an assignment, then the proof of the right to make an application should be furnished. It must be stated in the application that, the applicant is in possession of the invention and the name of the owner claiming to be the true and first inventor must also be stated.

Every application must be accompanied by a provisional or a complete specification. A provisional specification is a document in a prescribed form containing a description of the essential features of the invention. A complete specification is a document drawn in a prescribed form and contains the following:

(i) A full description of the invention and its operation or use and the method of performance.

(ii) Disclosure of the best method of performing the invention known to the applicant and for which he is entitled to claim protection.

(iii) A statement of claim or claims defining the scope of the invention for which protection is sought.

Every specification, whether provisional or complete shall describe the invention and begin with a title sufficiently indicating the subject-matter to which the invention relates. Where an application is accompanied by a provisional specification, a complete specification must be filed within 12 months from the date of filing of the application.

On receiving the application for a patent along with complete specification, the Controller shall refer it to an examiner for making a report to him in respect of:

(i) Whether the application and specification are in accordance with the requirements of this Act and of any rules made there under.

(ii) Whether there is any lawful ground of objection to the grant of a patent under the Act in pursuance of the application.

(iii) The result of the investigation made by him regarding anticipation of the invention by virtue of a previous publication or prior claim.

(iv) Any other matter which may be prescribed.

The examiner to whom the application and specification relating thereto have been referred to should ordinarily make the report to the Controller within a period of 18 months from the date of such reference. If the report is adverse to the applicant or requires any amendment of application, the Controller shall communicate the gist of the objections to the applicant and give him an opportunity of being heard. The Controller is also empowered to refuse to proceed with the application or require the application, specification or drawings to be amended to his satisfaction.

On the acceptance of the complete specification, the Controller shall notify the applicant and advertise in the Official Gazette the fact that the specification has been accepted and thereupon the application and specification with the drawings if any shall be open to public inspection.

On and from the date of advertisement of the acceptance of a complete specification till the date of sealing of a patent, the applicant shall have the like privileges and rights as if the patent for the invention had been sealed on the date of advertisement of acceptance of the complete specification. However, the applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.

13.3 DIFFERENT IPR APPROACHES

Trade Mark:

Trade Marks Act, 1940 was the first statute law on trade marks in India, which was replaced by the Trade and Merchandise Marks Act, 1958. Certain minor amendments were carried out by the repealing and amending Act, 1960 and the Patents Act, 1970. The current law of trademarks contained in the Trade Marks Act, 1999 is in harmony with two major international treaties on the subject, namely

1. Paris Convention for protection of Industrial Property and
2. TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement.

A Trade mark is a mark capable of being represented graphically and which is capable of distinguishing the goods and services of one person from those of others goods and services

of one person from those of others as defined by the TMA 1999. It includes shapes of goods, their packaging, and combination of colours. "Marks" means any device, brand, heading, label, ticket, name, signature, words, letter, numerals, the shape of goods, their packaging or any combination thereof.

Functions of Trade Marks:

- It distinguishes the product from similar ones in the market place. If a mark cannot be relied upon to differentiate, it cannot fulfill any other role.
- Eliminates confusion and reduces product searching costs.
- It identifies the product. Products are recognized on the basis of TMs.
- It indicates the source and origin of the producer-primary function and establishes a connection between goods and people.
- It advertises the product – investment function not merely the symbol of goodwill but often the most effective agent for the creation of goodwill. Mark actually sells goods.
- It guarantees and assures of a certain quality. TM is standard of quality-customer expects that goods bearing the same mark will be of the same quality.

Different Types of Trademarks:

1. A name (including personal or surname of the applicant or predecessor in business or the signature of the person).
2. Alphanumeric or Letters or numerals or any combination thereof.
3. Image, symbol, monograms, letters etc.
4. Sound marks in audio format.

Designs and Designs Act of 2000:

Considerable progress has been made in the field of science and technology after the enactment of Designs Act, 1919 by the British Government in India. The Designs Act, 2000 is meant to consolidate and amend the law related to the protection of designs and resemble the Designs Act 1911. This act was in force since 11th may 2001 and extends to the whole of India.

"**Design**" means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction or anything which is in substance a mere mechanical device, and does not include any trade mark as defined in clause (v) of sub-section (1) of section 2 of the Trade and Merchandise Marks Act, 1958 or property mark as defined in section 479 of the Indian Penal Code or any artistic work as defined in clause (c) of section 2 of the Copyright Act, 1957.

An industrial design refers to the ornamental or aesthetic aspects of an article. A design may consist of three dimensional features, such as the shape or surface of an article, two dimensional features such as patterns, lines or colors.

Industrial designs are applied to a wide variety of industrial products and handicrafts; from technical and medical instruments to watches, jewelry and other luxury items; from house wares and electrical appliances to vehicles and architectural structures from textile design to leisure goods.

13.4 COPYRIGHT

Copyright is a legal concept, enacted by most governments. A copyright is a law that gives the owner of a written document, musical composition, book, picture, or other creative work, the right to decide what other people can do with it. Copyright laws make it easier for authors to make money by selling their works. Because of copyright, a work can only be copied if the owner of the copyright gives permission.

According to Harrods Librarians Glossary, copyright is, "A procedure whereby the originator of a piece of intellectual Property (book, article, piece of music etc.) acquires a series of rights over the work created, including copying, publishing, performing, broadcasting and adaptation. According to Eric Miller, "Copyright refers to laws that regulate the use of the work of a creator, such as an artist or author. This includes copying, distributing, altering and displaying creative, literary and other types of work. Unless otherwise stated in a contract, the author or creator of a work retains the copyright."

Indian Copyright Act:

Indian government passed the copyright Act in the year 1957. Subsquently this act was amended many times due to the influence of many international treaties for which India was a signatory.

Copyright has its origin in the 20^{th} century. It is a form of Intellectual property, which deals with protecting the rights of a copyright holder.

Objectives:

1. To stop the copyright misuse.
2. To help in protecting the rights of a person who holds the copyright.
3. To encourage the authors, music composers, singers to create their original piece of works by granting them exclusive rights.

EXERCISE

1. Define the following terms under Patents Act:
   (a) Patent
   (b) Invention
   (c) Exclusive license

2. Enlist the types of inventions which are not patentable as per Patents Act.
3. Describe the procedure for getting a patent.
4. Write about the purpose of Intellectual Property Rights.
5. Discuss the Trademarks and Designs.
6. Write a short note on Copyright and its benefits.

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