WELCOME

TO

This is an Education Platform

We provide Free PDF Notes and Videos Classes for Pharmacy Students

Web Site http://www.fdspharmacy.in/

You tube https://www.youtube.com/c/FDSpharmacy

What app https://chat.whatsapp.com/IzSgXtFEvhS4LN5xhUgq5z

Telegram https://t.me/Fdspharmacy

Face book https://www.facebook.com/615501075383l3/

E-mail fdspharmacyinfo@gmail.com

Diploma in Pharmacy 2nd Year
Pharmacy Law & Ethics
Chapter 3 : Drugs and cosmetic act 1940 and Rules 1945 and New Amendments

Chapter 3
Drugs and cosmetic act 1940 and Rules 1945 and New Amendments

- The main aim of The Drugs and Cosmetics Act, 1940 and Rules 1945 is to maintain the import, manufacture, distribution, and sale of drugs and cosmetics.
- Continuous use of cosmetics in luxury items prove to be harmful as they may contain harmful ingredients. Therefore, there is a need to control the cosmetics.
- This Act verifies that the drugs and cosmetics should be manufactured, distributed, and sold only by qualified persons having a licence for this purpose.
- The Central and State Drugs Control authorities are also recognised to control these actions. To this Act and Rules, timely amendments are made.
- The major amendment was made in 1982, in which Schedules E, I, and L were eliminated, Schedules G and H were revised and expanded, and Schedule X was added. Previously there were Schedule C and C, drugs, and drugs other than those specified in these schedules.
- At the present time, there are :
    1) Drugs not specified in Schedule C, C_1, and X,
    2) Schedule C and C_1 drugs, excluding Schedule X drugs, and
    3) Schedule X drugs.

Objectives

- For Preventing sub standard (Low quality) in drugs , ant for promoting high medical standards.
- For controlling the import , manufacturing , distribution and sale of drug and cosmetics by licensing.
- Ensuring that manufacturing , distribution, in sale of drugs and cosmetic is done by qualified persons only.
- For establishing Drug Technical Advisory Board(DTAB) in Drug consulting Committees (DCC) for allopathic drugs and cosmetics.

Definitions

- **Cosmetic :** Cosmetic means any articles or thing which is used for cleaning , beautifying , or promoting attractiveness.
- **Manufacture :** Any process for making, altering, ornamenting ,packaging or labeling with purpose of sale is called manufacture.
- **Import :** It means to bring any goods or services into a country from out of country for sale.

- **Drug Includes :**
  - All medicines and devices intended for internal or external use of human being or animal for treatment or for preventing disease and diagnosis.
  - All those substances intended for diagnostic purpose.
  - All those substances intended used for destruction of vermin or insects.
  - All those substances intended for use as a component of drug like empty gelatin capsule.

Legal Definition of Schedules to the Act

- **First Schedule :** In this schedule the list of the standard books of ayurveda , siddha, Unani and tibb are mentioned.
- **Second Schedule :** In this schedule those standards are mentioned which are required and requested for drugs are imported and manufactured for sale , or sold , stocked or exhibit for sale or distributed.

Legal Definition of Schedules to Rules :

A - Proforma (form) for application for the licences, issue and renewal of licences, for sending memoranda (a written message) under the Act.

B - Rates of fee for test or analysis by the Central Drugs Laboratory or the Government Analyst.

C - List of biological and special products (marine products which are obtained from sea) whose import, sale, distribution, and manufacture are governed by special provisions. (injectable)

C1 - List of other special products whose import, sale, distribution, and manufacture are governed by special provisions. (non injectable)

D - List of drugs exempted from the provisions of import of drugs.

E1 - List of poisonous substances under the Ayurvedic (including Siddha) and Unani systems of medicine.(Evil)

F

(i)- Space, equipment, and supplies required for a blood bank.

(ii)- Minimum requirement for grant of licence to procure blood components from whole human blood.

F1 –

Part I- Provisions applicable to the production of bacterial and viral vaccines.

Part II - Provisions applicable to the production of all sera from living animals.

Part III - Provisions applicable to the manufacture and standardisation of diagnostic agents (bacterial origin).

F2 - Standards for surgical dressings.

F3 - Standards for sterilised umbilical tapes.

FF- Standards for ophthalmic preparations. (focus , focus)

G- List of substances to be used only under medical supervision and which are to be labelled accordingly. (Guardian)

H - List of prescription drugs.

J - Diseases or ailments which a drug may not prevent . (Jaan leva)

K- Drugs Exempted from certain provisions of the manufacture of drugs.

M- Good Manufacturing Practices (GMP) requirements of factory premises, plants, and equipment.

M_1- Requirements of factory premises, etc. for manufacture of homeopathic preparations. (HCD)

M2 - Requirements of factory premises for the manufacture of cosmetics.

M3 - Requirements of factory premises for the manufacture of medical devices.

N- List of minimum equipment for efficient running of a pharmacy. (need for pharmacy)

O- Standards for disinfectant fluids. (Dettol Lizol)

P- Life periods of drugs.

P_1- Pack sizes of drugs.

Q-

Part I - List of dyes, colours and pigments permitted in cosmetics and soaps.

Part II- List of colours permitted in soaps.

R - Standards for condoms made of Rubber latex intended for single use and other mechanical contraceptives.

R_1- Standards for medical devices. (other than Rubber)

S- Standards for cosmetics. (sundar)

T - Requirements of factory premises and hygienic conditions for Ayurvedic (including Siddha) and Unani drugs. (Tree Preparation)

U- Particulars (items) to be shown in manufacturing, raw material, and analytical records of drugs. (Utilization Record)

U1 - Particulars to be shown in manufacturing, raw material, and analytical records of cosmetics.

V- Standards for patent or proprietary medicines.

W- List of drugs to be marketed under generic names only.

X - List of drugs whose import, manufacture, sale, labelling, and packaging are governed by special provisions. (X = dangerous)

Y - Requirements and guidelines on clinical trials for import and manufacture of new drugs. (Yield)

Import of Drugs

- The Central Government exercises regulatory control over these drugs and cosmetics imported into country through (CDSCO) Central Drugs Standard Control Organisation headed by the (DCG) Drugs Controller General of India
- The manufacture, sale, and distribution of drugs are primarily regulated by the State Drug Control Authorities appointed by the State Government.
- The objective of the drug regulatory system in the country is to ensure availability of safe, effective, and quality drugs, cosmetics, and medical devices based on scientific excellence and best possible regulatory practices.
- Drug is defined in Section 3 of the Drugs and Cosmetics Act 1940. The Central Government has the power to declare any drugs, cosmetics, or medical devices as useful Drugs by giving notification in the official gazette.
- By virtue of the said power the Central Government has Notified Disposable Hypodermic Syringe, Disposable Hypodermic Needle, and Orthopedic Implant, Catheter, as drugs in 1989.

Classes of Drugs and Cosmetics Prohibited from Import

- Any drug or cosmetic of non-standard quality.
- Any misbranded or spurious or adulterated drug.
- Any misbranded or spurious cosmetic,
- Any drug or cosmetic which requires a licence for import,
- Any patent or proprietary medicine, till the true formula or list of active ingredients contained in it, along with the quantities are displayed on the label or the container.
- Any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect,as may be prescribed,
- Any cosmetic containing an ingredient which may be unsafe or harmful for use,
- Drugs which claim to prevent or cure any of the diseases or ailments specified in Schedule J,
- Drugs whose manufacture, sale and distribution are prohibited in the country of origin, except when required for the purpose of examination, test or analysis,
- Drugs not labelled and packed in the prescribed manner,
- Biological and other special products specified in Schedule C and C 1 after their expiry date or those not complying with the standards of strength, quality and purity .
- Any new drug except with express permission of the licensing authority.
- Any drug or cosmetic whose import is prohibited.

Import under Licence or Permit

- The licensing authority grants a licence for the import of the following classes of drugs:
  1) Drugs specified in Schedule C and C1.
  2) Drugs specified in Schedule X.
  3) Small quantities of drugs imported for examination. test, or analysis
  4) Drugs for personal use prescribed by a Registered Medical Practitioner.
  5) Any new drug.

Manufacture of Drugs

- The manufacture of drug under this Act include the processes of making. altering, ornamenting, finishing, packing, labelling, breaking up, or adopting drugs for their sale or distribution (except compounding or dispensing or packing of drug).

Prohibition of Manufacture and sale of Certain drugs

Following type of drugs are prohibited from manufacturing and sale :

1) Any Non standard quality , or misbranded or adulterated or spurious drug or cosmetic.
2) Any patent or proprietary medicines whose formula is not disclosed on label or container.
3) Any drug which claim to prevent , cure or decrease the disease specified in schedule J.
4) any cosmetic containing any unsafe or harmful ingredient.
5) any cosmetic or drug which is in contravention of drug and cosmetic Act and Rules.
6) Any drug and cosmetic which has been imported or manufactured in contravention of Act or Rules , Or in contravention of the conditions of a license.

Conditions for grant of license and condition of license for manufacture of drugs

- Schedule C and C1 drugs are manufactured under a licence obtained from the Licensing Authority after paying the prescribed fee. A licenced person can manufacture Schedule C and C1 drugs under the following conditions:

1) The licensee should provide adequate space, plant, and equipment for manufacture of drugs
    - And the licenced premise should comply with the requirements of Good Manufacturing Practices specified in Schedule M (Schedule M III for devices).
    - Separate laboratories and utensils should be provided for culture and manipulation of spore bearing pathogenic micro-organisms which should not be used for other purpose .
2) The licensee should provide adequate arrangements for testing the strength and quality of drugs in the licenced premises
    - And the testing unit should be separate from the manufacturing unit with an independent head, who should possess a degree in Medicine or Science or Pharmaceutical Chemistry and should have experience in testing of drugs considered adequate by the Licensing Authority.
3) The drugs should be manufactured under the direction and supervision of technical staff, one of whom should be either:
    a) Graduate in pharmacy or pharmaceutical chemistry with an experience of at least 18 months' in the manufacture of drugs (6 months training is allowe d during graduation) to which this licence applies, or
    b) A graduate in medicine with an experience of at least 3 years' in the manufacture and pharmacological testing of drugs to which the licence applies, or

c) Graduate in science with chemistry or mic robiology as the principal subject or graduate in chemical engineering with an experience of at least 3 years' in the manufacture and testing of the drugs to which the licence applies, or
d) Hold any foreign qualifications which are comparable to those pr escribed under (a), (b), and (c). Further, any person who was approved by the Licensing Authority as an expert responsible for the manufacture of drugs immediately before June 29, 1957 shall also be deemed to be technical staff.

4) Schedule C and C1 drugs used for animal treatment should be manufactured by or under the supervision of graduates in veterinary science or general science or medicine or pharmacy with an experience of at least 3 years in the manufacture and testing of veterinary biological produ cts.
    - The devices specified in Schedule C should be manufactured under the supervision of a graduate in pharmacy or science with physics or chemistry or microbiology as one of the subjects or should possess a degree/diploma in mechanical, chemical, or plastic engineering.
5) The licensee should have adequate facilities for storing the drugs manufactured by him.
6) The licensee should maintain detailed records of the manufacture and testing of each batch of drugs. The records for those drugs which have date of expiry should be preserved for a period of 2 years from the date of their expiry and for other drugs for a period of 5 years from the date of their manufacture.
7) The licensee should allow an authorised inspector to inspect the premises, processes of manufacture, testing of drugs, records required to be maintained under the Act and the Rules, and to take samples of any drug manufactured by him.
8) The licensee should inform the Licensing Authority about any changes in the expert staff and also about any material changes in the plant or premise used for the manufacture.
9) The licensee should provide the Licensing Authority with samples of drugs either from each batch or from batches demanded by the Licensing Authority.
    - Along with the samples, full details of the test applied by him should also be provided.
    - The licensee should not sell or offer for sale any batch from which a sample has been supplied to the Licensing Authority, until a certificate authorising the sale has been issued by the Licensing Authority.

Conditions of Licence to Manufacture of Drugs for Examination, Test or Analysis

- The manufactured of drugs for examination, test, or analysis should be manufactured under a licence obtained from the Licensing Authority.
- The person have license to manufacture this type of drugs should satisfy following conditions :
    1) The drugs should be used for the purpose for which they are manufactured.
    2) Licensee should maintain a record of the names and quantities of drugs manufactured and the names of persons to whom they have been supplied.
    3) The licensee should allow an authorised inspector to inspect the licenced premises and satisfy himself that only examination, analysis or test work is being done.
    4) The licensee should comply with other requirements for which a notice has been given to him one month before by the Licensing Authority.

Conditions of Licence for Manufacture of New Drugs

- If any one wants to may new drugs he should satisfy the conditions are mentioned in schedule Y , Some important conditions are following
    1) Application for permission.
    2) Clinical trials (4 phases)
    3) Study of new drug in special population.
    4) Post marketing surveillance.
    5) Special Study should be done Like B.A . and B.E.(Bioavailability & Bioequivalence).

Loan License and Condition

- This type of license is issued to the person who used other's Premises to manufacture the drugs . Except those drugs are specified in Schedule X can be manufactured under this license.
- The licensee and premises should comply all the conditions and requirements are necessary for manufacture of drugs.
- He Should submit the consent document of owner of the premises to the Licensing authority along with the Application for grant of Loan License.
- The licensee is required to test each batch of raw material and finished goods and should maintain the record of test for at least 5 years from the date of manufacture (2 years in the case of expiry of drug).

Repacking License

→ **Repacking :** It is a process in which someone take the products from manufacturing unit and packs on his brand name and Market the products . This type of license is required for repacking the other than drugs are specified in Schedule C and C1

Conditions are related to repacking :

1) For repacking operations sufficient space and equipment should be provided and should be carried out under hygienic conditions and under the supervision of a penon approved by the Licensing Authority as a Competent Person
    a) Who passed intermediate with chemistry. or
    b) passed diploma in pharmacy. or
    c) A registered pharmacist. or
    d) A person have 4 year experience in manufacturing , dispensing , or repacking of drugs.
2) The licensee should have sufficient arrangements for analysis and testing of each batch of raw materials and repacked drugs or should get them analysed and tested by an approved institution. He should also maintain reconds of such tests for 3 years from the date of manufacture and in case of drugs with expiry date at least for 3 months from such date.
3) The licensee should make suitable arrangements for storage of drugs and should allow an authorised Inspector to inspect the premises and take samples. The factory premises should meet the requir ements specified in Schedule M.
4) The licensee should mamtain proper records for repacking of drugs and should allow an inspector to check them.
5) The licence should be kept on the licenced premises and should be produced before an authorised Inspector on demand.
6) The drugs repacked should bear the number of the licence preceded by the words Rpg. Lic. (Repackaging Licence). No. , on their label.
7) The licensee should comply with the provisions of the Act and the Rules and other requirements, a notice for which has been given for not less than 4 months by the Licensing Authority

Study of Schedules

Schedule C and C1

→ These are Biological and special products . A license on Form 28 is required for manufacture , sale and distribution of these drugs , and a License on Form 21 is required for retail sale , and Form 21-B is required for wholesale sale.

Schedule C (they are used parenterally)

1) Sera
2) toxin
3) antigen
4) antitoxin
5) Insulin
6) Serum Protein
7) vaccine
8) Hormones
9) Antibiotics etc.

Schedule C1 (they are not used Parenterally)

1) Ergot and Ergot containing preparation.
2) Adrenaline and Adrenaline containing preparation.
3) Fish liver oil and fish liver oil containing preparation.
4) Vitamins and Vitamins containing preparation.
5) Hormones and hormone containing preparation.
6) Vaccines are not administered intravenously.

Schedule G

→ These are the drugs which are toxic in nature and a caution is labeled on drugs as " It is dangerous to take this preparation except under medical supervision ".

→ some **examples :** Aminopterin , Bleomycin , Busulphan , Clorthiazide , Glibeclamide.

Schedule H

- There is a list of 551 drugs which are called prescription drugs . these drugs are labeled with " Rx " and Warning " To be sold by retail on the prescription of a registered medical practitioner Only " . If the any drug come under Narcotic drugs and Psychotropic substances it will be labeled with " NRx " and warning .
- **Examples :** acyclovir , Diclofenac , baclofen , Terazosine , verapamil , repaglinide etc.

Schedule H1

- Schedule H 1 includes sensitive antibiotics , Habit forming medications and drugs produce severe side effects . These are also labeled like Schedule H and sold by retail on prescription only .
- **Examples :** Isoniazid , Levofloxacin , zolpidem , Gemifloxacin etc

Schedule K

- These are the drugs exempted from certain provision of the manufacture of drugs .
- Following drugs are exempted :
    1) Drugs are not for medicinal use.
    2) Antimalarial drugs
    3) The substances are used for as food and medicine
    4) Mechanical and chemical contraceptive.
    5) Household medicines which are commonly used like Asprin , Paracetamol, analgesic balms, antacids, cough and cold medicine skin ointment, lozenges etc.
    6) Normal Cosmetics.

Schedule P

- Schedule P deals with life period of Drugs and the Storage conditions of drugs and serial number . These things should be mentioned on the drugs . for
- Example

SN	Drugs	Life periods	Storage
25832	Ampicilin	36 months	In a cool place

Schedule P1

- → This Schedule deals with pack size of drugs , and dosage form .
- → for example

Drugs	Dosage form	Pack Size
paracetamol	tablets	15 tabs

Schedule M

- → This Schedule deals with Good Manufacturing Practice and requirements for that . this Schedule is divided into M M1 M2 M3.
- → M (requirements of premises , factory, plant for Allopathic drugs)
- → M1 (requirements of premises , factory, plant for Homeopathic drugs)
- → M2 (requirements of premises , factory, plant for cosmetic items)
- → M3 . (requirements of premises , factory, plant for medical devices)

Requirements

1) **Location :** The factory should not be located in public and dirty place .
2) **Buildings :** The building used for manufacturing should clean and hygiene , should not be used for sleeping and other purpose . and walls should be 6 feet high and smooth and easily cleanable .
3) **Water supply :** There should be proper facility of water supply , to drain used water .
4) **Waste Disposal :** There should be proper facility of Waste disposal .
5) **Staff :** All staff should be free from transmissible disease , and their clothes should be clean .
6) **Equipments For Manufacturing Ointments , emulsions , Lotion etc** : like Mixing tank , Mixer , emulsifier etc.
7) **Equipments For Manufacturing Syrup , elixirs etc**. : like Mixer , filter equipments etc.
8) **Equipments For Manufacturing pills compressed tablets** : Like Powder mixer , Granulator , tablet machine , tablet counter etc.
9) **Equipments For Manufacturing powder** : Ball mill . hammer mill , size separators .
10) **Equipments For Manufacturing surgical dressing** : like Cutting equipment , folding pressing machine , Sterilizer etc.

Schedule N

→ This schedule deals with minimum requirement for the proper running the pharmacy.
→ A pharmacy should be under the supervision of a registered pharmacist.

1) **Entrance :** There should be written " Pharmacy " or Medical Store " in the front of a pharmacy.
2) **Premises :** The premises should be build properly , and should dry and well ventilated . the pharmacy should not be less than 6m2.
3) **Furniture and Apparatus :** The furniture and apparatus of a pharmacy should be according to need . A pharmacy should have cupboard with lock and key for storing poisons and narcotic substance.
4) **Books :**
    - IP
    - The National Formulary of India
    - The Drug and Cosmetic Act 1940 and Rules 1945.
    - The Pharmacy Act 1948
    - The narcotic drugs and Psychotropic substances Act etc

Schedule X

→ This Schedule deals with Narcotics and Psychotropic substances , these are habit forming drugs , if someone takes without the supervision of a RMP , can lead to addiction if used for a long time.
→ These drugs should be kept under lock and key.
→ These drugs are labeled with NRx and Warning " To be sold by retail on the prescription of a Registered Medical practitioner ".
→ **Examples :** Phenobarbital , secobarbital , mepromate , Diazepam , alprazolam.
→ **Dispensing :** these drugs are dispensed only on valid prescription.
→ They should be dispensed according dose size prescribed. should not be refilled without permission of physician.

Sale of drugs

- → The process of passing drugs from manufacturers to consumers is termed "sale".
- → Before 1940 , there was no restriction / prohibition for selling , compounding , and dispensing of drugs.
- → but after implementation of D& C Act 1940 , selling , compounding , dispending of drugs became a prohibited work , and only licensed persons can involve in these works.

Types of Sale

1) Wholesale of Drugs
2) Retail Sale of drugs

Wholesale of Drugs :

- → A wholesale licensee can directly contact to manufactures for supplying of drugs to retailers .

Conditions for wholesale of drugs :

- ◈ Separate licenses are required for the drugs of Schedule C and C1 and the drugs are other than Schedule C and C1.
- ◈ The Licensee must have adequate premises , and premises should not be less than 10 square meters.
- ◈ There should be facilities for storage of drugs that can preserve the potency of drugs.
- ◈ these drugs should not be sold to whom , who don't have preservation facilities.
- ◈ The wholesale Licensee sell the drugs to persons who have a license to retail them , and drugs also can be sold to hospital , educational and research institutes , but the records of the drugs should be maintained for 3 years with their names , quantity , batch no. ,date manufacturer name and cash memo (bill)
- ◈ The license should be displayed in premises.

Retail Sale of drugs

Conditions For retail sale of drugs :

1) Facility according to Schedule N.
2) Purchase only from Licensed wholesalers.
3) Separate license for Schedule C and C 1 drugs , Schedule X and for the drugs other than schedule C and C 1 and X.
4) Schedule H and X drugs will not be sold without valid prescription.
5) All the registers and records should be maintained for at least 2 years from the date of the last entry.
6) The licensee should allow the inspectors for inspection of premises , registers and records.

Restricted License

→ This is a type of license , and issued to sale the drugs other than specified in schedule C , C 1 and X , . and the drugs are sold under this license don't require the supervision of a Qualified person. This license is issued under Forms 20A and 21 A.

Conditions :

a) Well- equipped premises.
b) Display license in premises.
c) Purchase from a licensed dealer.
d) Drugs should be sold in their original container.

Some Examples of drugs permitted to be sold under this license :

- Aspirin Tab. , Paracetamol Tab . , Analgesic Balms , Antacids , Antiseptic cream etc.

Records to be Kept in Pharmacy

All the sale of drugs on prescription should be recorded in a register with :

- Serial no. of Entry.
- Date of supply.
- prescriber's name and address.
- patient 's name and address.
- name and quantity of drugs.
- Manufacturer name , batch no.
- Credit Bill

Records of Purchases of Drugs

Records should be maintained by Retailer and wholesaler :

- Purchase date
- Name and address of Licensee from whom drugs are purchased.
- Drugs name , Batch no. and quantity.
- manufacturer 's name.
- Purchase bill (cash credit).

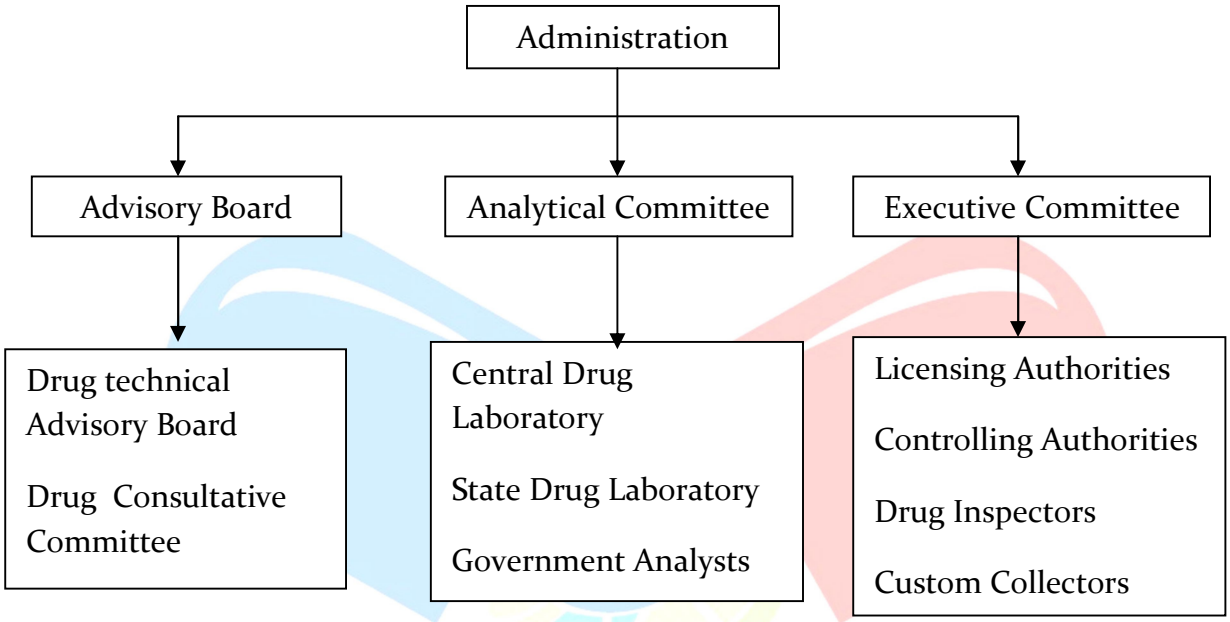
Drugs Prohibited For manufacture and Sale

1) Misbranded , spurious , adulterated and non- standard quality drugs.
2) Patent drugs with unclosed Formulation.
3) Drugs Claiming by any way to cure any disease are mentioned in schedule J.
4) Expired Drugs.
5) Drugs are provided by government freely.
6) "Physician 's sample , not to be sold " is written on container.
7) The drugs manufactured or imported in contravention of D and C Act.

Offenses and penalties regarding Sale of Drugs

Offences	Penalties
Sale , stocking , exhibition , or offer for sale of drugs which may cause death or serious hurt.	Imprisonment from 5 years to life and fine of not less than 10,000 rupees
Sale , stocking , exhibition , or offer for sale of spurious drugs	Imprisonment of 1-3 years and fine of up to 5,000 rupees on first conviction , and for 2-6 years Imprisonment and fine 10,000 rupees on next conviction.
Sale , stocking , exhibition , or offer for sale in Contravention of any other provisions.	Imprisonment of 1-2 years and for subsequent offence 2-4 years , or 5000 fine.
Failure to keep records or disclose required Information	Imprisonment for 1 year or fine up to 1000
False warranty to purchase	Imprisonment for 1 year or fine up to 5,000 on first conviction , and imprisonment for up to 2 years or fine or both on subsequent convictions

Administration of The Drug and Cosmetic Act and Rules



Drug Technical Advisory Board (DTAB)

- → DTAB is constituted the Central Government to advise the Central and State Governments on technical matters arising out of the administration of this Act.
- → It consists of 18 members, of whom are ex-officio, 5 nominated and 5 elected members, as follows:

I. Ex- officio members :

1. Director General of Health Services (chairman)
2. Drug Controller of India.
3. Director, Central Drug laboratory, Kolkata
4. Director, Central Research Institute, Kasauli
5. Director, Indian Veterinary Research Institute, Izatnagar
6. President, Pharmacy Council of India g. President, medical Council of India
7. Director, Central Drug Research Institute, Lucknow

II. Nominated members

- Two Persons nominated by the Central Government from amongst persons who are incharge of drugs Control in states.
- One person from the Pharmaceutical industry, nominated by the Central Government
- Two Government analyst, nominated by the Central Government.

III. Elected members

- A teacher in Pharmacy or Pharmaceutical Chemistry or Pharmacognosy on the staff of an Indian University or an affiliated - College, elected by the Executive Committee of the Pharmacy Council of India.
- A teacher in medicine or therapeutic on the staff of an Indian University or an affiliated college, elected by the Executive Committee of the medical Council of India.
- One Pharmacologist elected by the Governing body of the Indian Council of medical Research.
- One Person elected by the Council of the central medical Association.
- One Person to be elected the Council of the Indian Pharmaceutical Association.

Drug Consultative Committee (DCC)

- → The drugs Consultative Committee is constituted by the Central Government. It is an advisory committee for the Central and State governments and the DTAB
- → It Consists of two representatives nominated by the central Government and one nominee of each of state Governments.
- → The Committee meets when required by Central Government to do so and is empowered to regulate its own procedure.

Central Drug Laboratory

- The Act provides for the establishment of a Central Drug Laboratory under the Control of a director appointed by Central Government. This laboratory established in Kolkata has been entrusted with the following functions.
- To analyse or test samples of drugs or Cosmetics send to it by the Customs Collectors or Courts.
- To carry out such other duties as entrusted to it by the Central Government or with its permission by the State Government after Consultation with the DTAB.
- The functions of the laboratory in respect of sera, Solutions of serum proteins for injection, vaccines, toxins antigens, antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out at the Central Research Institute Kasauli.

Government Analysts

- → The Analysts analyse and test the drugs and cosmetics samples sent by the drug Inspectors or other persons , and prepares reports . they do other works given by the government.

Qualification of Government Analysts

- A graduate in medicine/ science / Pharmacy / Pharmaceutical Chemistry of a recognized university and have five years past graduate experience in the testing of drugs in a laboratory under the Control of

a) A Government Analyst:
b) Head of an approved institution or testing laboratory or has completed two years training testing of drugs, including items stated in Schedule C in Central Drugs Laboratory.
c) A post graduate in medicine | science / Pharmacy / Pharmaceutical Chemistry of a recognised University or Associate ship Diploma of the Institution of Chemists (India) obtained by Passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years' experience in the testing of drugs in a laboratory under the Control

Duties of Government Analysts

- To cause to be analysed or tested sample of drugs or cosmetics sent to under the act and to furnish reports of the results of test or analysis.
- Forward to the Government from time to time, reports giving the results of analysis work and research with a view to their publication at the discretion of Government

Licensing Authorities

- The Central Government appoints the licensing authorities to issue license for Import of Drugs.
- The state Government appoints the licensing authorities to issue licenses for manufacture and sale of drugs and cosmetics.
- The Licensing authority has choice to issue the license or refuse.
- If licensee does not follow the conditions , the licensing authority can cancel the license.
- The decision of Licensing authority can be challenged in court.

Controlling Authorities

→ These are persons who control the Drug Inspectors . They send them for inspection of premises for manufacture of drugs or sale of drugs .

Qualification

- Graduation in Pharmacy , Pharmaceutical Chemistry or medicine with specialization in clinical Pharmacology or microbiology . and has 5 years experience in manufacturing of drugs or enforcement of provisions of the Act .

Drugs Inspectors

→ Drug Inspectors are appointed by Central government or by State government as much required,

Functions

- Inspection Of Premises licensed for the Sale of Drugs.
- Inspection Of Premises licensed for the Manufacture of drugs.

Qualification

- Degree in Pharmacy , Pharmaceutical science or medicine with specialization in clinical Pharmacology or microbiology.
- He should have Associated ship diploma of the Institution of Chemists (India) after passing examination with analysis of drugs and pharmaceuticals.

Hello

Friends

If you Get Any Help From This Notes / Videos

Next You Turn To Help Us

Please Contribute Some Amount

To Our

FDSPharmacy Team

Phone pe 6398439940

Paytm 6398439940

Google Pay 6398439940

Amir Khan

Thank You

Keep Supporting