Drug and cosmetics Act 1940 and rules 1945

Introduction of Drug and cosmetics Act 1940 and rules 1945:-

The main aim of the drug and cosmetics Act 1940 and rules 1945 is to be maintained the import manufacture, distribution and sales of drugs and cosmetics.

Continuous use of cosmetics in luxury item prove to be harmful as they may be contain harmful ingredients. Therefore there is need to control the cosmetics.

This act varifies that the drug and cosmetics should be manufactured, distributed and sold only by qualified person having the licence for this purpose. The central and state drugs control authority are also recognised to control these action.

Definition of Drug and cosmetics Act 1940 and rules 1945:-

What is Drugs:-

All medicines for internal and external use of human being or animals and all substance intended to be used for in the diagnosis, treatment or prevention of any disease or disorders.

Including preparation applied on the human body for the purpose of repelling inserts like mosquitoes.

Such substance (Other than food) intended to effect the structure or any function of the human body or intended to be used for the destruction of insects which causes disease in human beings or animals as may be specified from time to time by the central government by notification in the official gazette.

Patent medicine / Brand: - Patent medicine refer to a remidies whose formula is on by the manufacturer and which is marketed usually under a name register as a trademark.

In relation to ayurvedic, sidha, Unani system of the medicine all formulation containing only such ingredients mention in the formally described in the authoritative books of Ayurvedic, Sidha, Unani

system of medicines specified in the first schedule but does not include a medicines which is administered by parenteral routes.

Mis-branded drug:-

- A drug is deemed to be Mis-branded.
- It is So coloured, coated, powdered or polished that damaged. If it is made to appear of better or therapeutic value then it is really.
- If it is not labeled in the prescribe manner.
- If it is label or container the drug bears any statement, design or device which makes any false claim for the drugs or which is false or mis-leading in any particular.

Superior cosmetics Or Mis-branded Cosmetics:-

- If it contain a colour which is not prescribed.
- If it is not labeled in the prescribed manner.
- If the label or container bears any statement which is false.

Adulterer drugs :-

- If it is consist any filthy, decompose substance.
- If it has been prepared, packed or store under insanitary condition where by it may have be injurious to health.

Spurious drug:-

- Same as adultered drugs.

Sale is the process passing of drug from the manufacturer to the consumer. The different kinds of licence issuable for wholesale and retail of drug.

There are two types of salling:-

1. Wholesale
2. Retail

Wholesale

From Shops

- License for wholesale
  Schedule of C & C1
- License for drugs
  then Schedule C & C1

From motor vehicle

- License for Schedule
  of C & C1 Drugs
- License for drugs
  then Schedule C & C1

Retail

From Shops

- Pharmacy
- Chemist
  - Separate license for C and C1 drugs
  - Separate license for X-Drug
  - Separate license for other drugs
- Drug Store
  and Druggist

Vendors

- Only specified drugs
  in specified areas

- The process of passing drugs from manufacture to consumer is termed sale. In india saling of drugs was an open trade till 1940 hence, any one can sale, compound or dispense drugs without any restriction but after implementation of the drugs and cosmetics Act 1940, selling of drugs become restricted practice and only the licence individual can involve in the wholesale, retail, compounding, dispensing of drugs.
- Licence are required for wholesale or distribution from a motar vehicle retail sale of drugs and a separate licence needed for each promise where drug are sold.

Retail distribution of drug: - Retailing of drug is done through shops or by vendors certain important and basics for Retailing selling of drugs or as follows.

Retail sale from shops :- There are following rules for the retail sale from shops.

- Facilities as per schedule N.
- Purchase only from license wholesaler.
- No sales of specified drugs (Schedule H and Schedule X) without prescription.
- Separate licence for Schedule C, C1 and X.
- Sale under qualified supervisions.
- Records
- Inspections
- Sale of specified house hold drugs from drug stores but schedule N and sale under qualified supervision not applicable.

Retail sale of drug can be done from the following shops :-

1. Chemist and druggist (Followed by registered Pharmacist but do not compound drugs)

2. Pharmacies (Followed by registered Pharmacist and engaged in compounding of drugs)

3. Drug store (Drug store which do not have a registered Pharmacist and sale drugs specified as household remedies)

Retail sale from Vendors:- Sometimes drugs are sold buy vendors who do not have a fix place of business but have been granted licence by the licensing authority to conduct business in a particular

area. Persons who distribute drugs in sparsely populated area with no others agencies for drug distribution or to travelling agents of firms dealing in drug are issues licence to sale drugs. The licence to sale drugs are issues only for drugs other than those specified in Schedule C and C1.

Wholesale distribution of drugs:-

A wholesaler with a valid trade license can approach the drug manufacturer for supplying medicines for salling to the retailers.

Followings are the conditions of granting the licence for wholesale of the drug.

1. Adequate infrastructural facilities
2. Records
3. Sale only to licensed retailers
4. Inspection

Wholesale for fix premises :-

Wholesale of drugs can be done from fix premises or by motor vehicle.

Separate licence is needed for wholesale of drugs under schedule C & C1.

Wholesale of Schedule C and C1 Drugs:- there are following conditions -

- The licence must have adequate premises not less than 10m2 in area, equipped with adequate facilities for storage of drugs in order to preserve their potency.
- The drug should be sold to person with licence to retail them.
- If the licence desired to self any other categories of drugs be should seek permission from the licensing authority.

Records of all purchases and sales of schedule C drugs by wholesale dealing should be maintained under following-

a. **The date of purchase and sale**

b. **Name and address**
c. **Name and quantities of drugs and there batch number.**
d. **Name of the manufacturer of the drugs.**

Procedure for sale, Purchase and Storage of drugs:-

In different kinds of stablisment for the sale of drug there are following:-

- Dispensing and compounding of drugs
- Sale of schedule X and Schedule H drugs
- Supply/Sale of schedule C drugs.
- Supply Sale of other drugs.
- Records of purchase of drugs
- Storage of Schedule X drugs with expiry dates.
- Storage of veterinary medicine
- Drug stores.

Labeling of the drugs

Class & Nature of Medicine in which contained	Particulars which should appear on label
Schedule C In Original form	1. Proper name of the substance along with the name of any patent. 2. License number under which manufactured or imported. 3. Batch number 4. Statement of potency in unit. 5. Name and address of the manufacture of finical products. 6. The expiry date 7. The manufacture date 8. Name and percentage of added antiseptics
Schedule – C_1 and their preparation including combination with other drug.	1. The Manufacture date 2. The expiry date 3. Import license number
Schedule F & F_1	The prescribed name

Schedule G Medicine made up ready for internal use in the treatment of human elements.	The word caution it is dangerous to take this preparation expert under medical supervisions should be Cleary printed and surrounded by a line with in which there should be no other words.
Schedule H Medicine for internal use of human beings	1. Simple should be clearly displayed on the left top corner of the label. 2. Schedule H drug warning to be sold by retain on the prescription of a registered medical practitioner only
Schedule X Medicine for internal use of human beings	1. Schedule X drugs/ Warning to be sold by retail on the prescription of the RMP. 2. Symbol X given conspicuously in red
Schedule P any drug	1. The manufactured date 2. Expiry date
Schedule W Single ingredient.	1. Proper name (No trade name)