UNIT–II

Drug and Cosmetic Act, 1940 and its rules 1945

xxx

Schedule G:— List of drugs for which Caution should be written on the lable that it is dangerous to take preparation except under medical supervision.

⇒ List of substances that are required to be used only medical supervision and which are to be labelled accordingly.

Schedule H:— List of prescription drugs.

Schedule M:— Good Manufacturing Practices (GMP) requirements of factory premises, plant and equipment for Pharmaceutical products.

M_1 — Requirements of factory premises etc for manufacture of homeopathic preparations

M_2 — Requirements of factory premises for the manufacture of Cosmetics.

M_3 – Requirements of factory premises for manufacture of medical shop devices.

Schedule N :— List of minimum equipment for efficient running of a pharmacy.

—xxx—

Schedule P :— Life periods of drugs.

Schedule P_1 :— Pack sizes of drugs.

Schedule T – GMP for Ayurvedic, Siddha and Unani Medicines

Part I – Good manufacturing Practices

Part II - A - List of machinery, equipment and minimum manufacturing premises for manufacture of various Categories of Ayurvedic, Siddha system of medicines.

Part II - B. List of machinery, equipment and minimum manufacturing premises for manufacture of various Categories of Unani system of medicines.

Part II - C. List of equipment recommended for in-house quality Control section.

Schedule U – Particulars to be shown in manufacturing, raw material and analytical records of drugs.

Schedule U_1 – Particulars to be shown in manufacturing, raw materials and analytical records of Cosmetics.

Schedule V- Standards for patent or proprietary medicine.

Schedule X- List of drugs whose import, manufacture and sale, labelling and packing are governed by special provisions.

Schedule Y — Requirement and guidelines on clinical trials for import and manufacture of new drugs.

Schedule F Part XII B- Requirement for the functioning and operation of the blood bank and/or for preparation of blood components.

DMR (OA) - Drug and Magic Remedies (objectionable Advertisement) Act 1954

SALE OF DRUGS

xxx

The drug reach the consumers from the manufacturers by retail through shopkeepers.

Manufacturers generally sell their goods to the wholesaler (Stockists) who in turn, sell the same to the retailers.

manufacturer → trade → wholesaler → retailer → consumer

~~Wholesale — Whole~~

Wholesale of Drugs

xxx

Wholesaler means a dealer or his agent or stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency.

1] Drugs other than those specified in schedule C, C_1 and X :— Licence issued in Form 20B.

⇒ Drug should be purchased only from a duly licensed dealer or manufacturer.

2] Schedule X drugs — Licence issued in Form 20G

3] Drug specified in Schedule C & C_1 but not included in Schedule X :— ~~HOG — QAE 1806~~ Licence issued in the Form 21B.

H] Drugs specified in Schedule C & C1 from motor Vehicle:— Licence issued in the Form 21 BB

Retail Sale

—xxx—

For retail sale two types of licences are issued,

i) General
2) Restricted

General licences are granted to persons who have premises for the business and who engage the services of a qualified person to supervise the sale of drugs and do the Compounding and dispensing.

Conditions:—

⇒ Licence should be displayed in a prominent place in a part of the premises open to public.

⇒ Licensee should comply with provisions of Drugs and Cosmetics Act and Rules in force.

⇒ Any change in the qualified staff in charge should be reported by licensee to licensing authority with in 1 month.

⇒ Any change in Constitution of licensed firm should be informed to licensing authority with in 3 months and in the meantime a fresh licence should be obtained in the name of the firm with changed Constitution.

Restricted Licenses

xxx

Licences for restricted sale of drugs other than those specified in Schedule C, C_1 and X and those specified in Schedule C, and C_1 but not in Schedule X are issued in the form 20A and 21A respectively.

Condition for ~~Restrict~~ Restricted Licence:—

⇒ Licensee must have adequate premises equipped with facilities for proper storage of drugs to which licence applies provided that this condition does not apply to vendors.

⇒ Licensee should comply with provisions of Drugs and Cosmetics Act and rules in force.

⇒ Drugs should be purchased only from a duly licensed dealer or manufacturer.

⇒ If licensee is a vendor having no fixed place of business, he should buy drugs from dealers specified in his licence.

⇒ Drugs should be sold in their original Containers.

Labeling & Packing of Drugs.

xxx

The Containers of all the drugs including patent or proprietary medicine are to be labelled in accordance with the drugs and Cosmetics Rules 1945.

Following particulars should be either printed on written in indelible ink and should appear in a conspicuous manner on the label of the inner most container of any drug and every other covering in which the container is packed:-

⇒ Proper name of the drug should be printed in a more conspicuous manner than the trade name, if any.

⇒ A correct statement of the net contents in term of weight, measure, volume, number of units of activity as the case may be are expressed in matrix system.

⇒ The name and address of manufacturer. In case of the drug contained in an ampoule or a similar small container it is enough if only the name of the manufacturer and his principal place of business is shown.

⇒ manufacturing licence Number as Mfg. Lic No. or M.L.

⇒ A distinctive batch number, the figure representing the batch number being preceded by the words 'Batch No. or B. No, as Lot No, or Lot.

⇒ Expiry particulars,

⇒ Precautionary information related to care in handling, use, distribution etc.

⇒ Information related to storage or manner of use.

⇒ General information such as "physician's sample, not for sale etc.

Packing of Drugs

xxx

The pack size of drugs meant for retail sale shall be as prescribed in Schedule P1 to the rules and for other drugs given bellow.

i) Less than 10 Tablets/capsules: Packing by integral number
• More than 10 Tablets/capsules: multiples of 5

ii) Liquid oral preparation:- 30 ml (paediatric only)
60 ml / 100 ml / 200 ml / 450 ml

iii) Paediatric oral drops: 5 ml / 10 ml / 15 ml

iv) Eye / ear / nasal drops: 3 ml / 5 ml / 10 ml

v) Eye ointment: 3 gm / 5 gm / 10 gm.

However these provisions shall not apply to:—

i] imported formulations in finished form

ii] Preparations for veterinary use

iii] Preparations for export

iv] Vitamins / tonics / cough preparations/ antacids / laxatives in liquid oral forms/ unit dose forms.

v] Physician's samples, pack sizes of dosage forms for retail sale to hospitals

vi] Pack sizes of large volume IV fluids.

The Schedule x drugs shall be marketed in packing not exceeding:—

i) 100 unit doses in the case of tablets/ capsules

ii) 300ml in the case of oral liquid preparations.

iii) 5ml in case of injections.

Administration of the Act and Rules

For the efficient administration of the Act and the Rules, the following agencies have been provided.

- Advisory
  - Drug Technical Advisory Board (DTAB)
  - Drug Consultative Committee
- Analytical
  - Central Drug Laboratory
  - Drug Control Laboratories in States
  - Government Analysts.
- Executive (कार्यपालक)
  - Licensing Authorities
  - Controlling Authorities
  - Drug Inspectors
  - Customs Collectors.

Drug Technical Advisory Board (DTAB)

xxx

DTAB is constituted by 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:—

a) Director ~~Central~~ General of Health Services (Chairman)
b) Drug Controller of India.
c) Director, Central Drug laboratory, Kolkata
d) Director, Central Research Institute, Kasauli
e) Director, Indian Veterinary Research Institute, Izatnagar
f) President, Pharmacy Council of India
g) President, Medical Council of India
h) Director, Central Drug Research Institute, Lucknow

III] Nominated members:—

a) Two persons nominated by the Central Government from amongst persons who are incharge of drugs Control in states.
b) one person from the Pharmaceutical industry, nominated by the Central Government.
c) Two Government analyst, nominated by the Central Government.

III] Elected members:—

a) 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.

b) 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

c) one Pharmacologist elected by the Governing body of the Indian Council of medical Research.

d) One Person elected by the Council of the central medical ~~Ass~~ Association.

e) One Person to be elected by the ~~central~~ Council of the Indian Pharmaceutical Association.

Drug Consultative Committee (DCC)

xxx

The drugs Consultative Committee is consituted 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

xxx

The Act provides for the establishment of a Central Drug laboratory under the Control of a director appointed by Central Goverment. 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, and.

⇒ To Carry out such other duties as entrusted to it by the Central Government or with its permission, by the State Governments after Consultation with the DTAB.

The functions of the laboratory in respect of sera, solutions of serum proteins for injection, vaccines, toxins antigens, ~~antio~~ antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out at the Central Research Institute Kasauli.

Government Analysts

Government Analysts are appointed by the Central Government or a State Government U/s 33-F in relation to Ayurvedic, Siddha or Unani drugs and U/s 20 in relation to any other drug or Cosmetic.

The Central Government may also similarly appoint Government Analysts, in respect of such drugs, classes of drugs, Cosmetic, classes of Cosmetics, as specified.

Qualification of Government Analysts:—

⇒ A graduate in medicine / science / Pharmacy / Pharmaceutical Chemistry of a recognised university and have five years post graduate experience in the testing of drugs in a laboratory under the control of

i) A Government Analyst

ii] Head of an approved institution or testing laboratory or has completed two years' training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory.

2] A post graduate in medicine / science / Pharmacy / Pharmaceutical Chemistry of a recognised University or Associateship Diploma of the Institution of Chemists (India) obtained by passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years experience in the testing of drugs in a laboratory under the control of i] a Government Analyst

ii] Head of an approved institution or testing laboratory or has completed two years training on testing of drugs including items stated in Schedule C, in Central Drug Laboratory.

Duties of Government Analysts:—

xxx

⇒ To cause to be analysed or tested samples of ~~drugs~~ drugs or Cosmetics sent to him 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.

BP- 505 T

Licensing Authorities

Any Application for the grant or renewal of a licence for the import, manufacture, sale, distribution etc. of any drug or Cosmetic is to be made to LA.

The Qualification of a licensing authority has been prescribed under "Rule 49 A" by the Drugs and Cosmetics Rules 1989.

Qualification :— No person shall be qualified to be a licensing authority under the Act unless-

i) He is graduate in Pharmacy / pharmaceutical chemistry / medicine with specialization in clinical Pharmacology / microbiology, from a recognised university.

ii) He has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.

Controlling Authorities

Drug Inspectors appointed under the Act are under the control of a Controlling authority.
The qualification of a Controlling authority has been prescribed under "Rule 50 A" by the Drugs and Cosmetics Rules, 1989.

Qualification:— No Person shall be qualified to be a Controlling authority under the Act unless.

i] He is a graduate in Pharmacy / Pharmaceutical Chemistry / medicine with specialization in clinical Pharmacology / microbiology, from a recognised University.

ii] He has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.

Drug Inspectors

xxx

In relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government U/s 33-G

⇒ In relation to any other drug or Cosmetic, an Inspector appointed by the Central Government or a State Government U/s 21.

The Central and State Governments are empowered to appoint Drug Inspectors and to assign them definite areas. Any person having financial interest in the import, manufacture or sale of drugs or Cosmetics can not be appointed as Drugs Inspector. Drug Inspectors are deemed to be public servants and are officially subordinate to the Controlling Authority.

Qualification of Drug Inspectors:— For appointment as Drug Inspectors a person must have a degree in Pharmacy or pharmaceutical Science or Medicine with specialization in Clinical Pharmacology or microbiology from an Indian University.

xxx

For Inspection of the manufacture of Substances in Schedule C the persons appointed as Drug Inspectors

must have

⇒ at least 18 month's experience in the manufacture of at least one of the substances specified in Schedule C

⇒ at least 18 month's experience in testing of at least one of the substances in Schedule C in an approved testing laboratory.

⇒ gained experience of not less than three years in the inspection of firms manufacturing any of the substances in Schedule C during the tenure of their service as Drug Inspectors.

Powers of Inspectors

xxx

A] Inspection of premises where any drug or Cosmetic is being manufactured and the means employed for standardising and testing the drug or Cosmetic

⇒ Inspection of premises where any drug or Cosmetic is being sold, or stocked or exhibited or offered for sale or distributed.

B] Taking samples of any drug or Cosmetic which is being manufactured or being sold/ stocked/ exhibited / offered for sale being distributed

⇒ ~~Taking samples of drug or~~

⇒ Taking samples of drug or Cosmetic from any person Conveying delivering or preparing to deliver such drug or Cosmetic to a purchaser or a Consignee.

⇒ Examine any record, register, document or any other material object with any person or in any place mentioned above and seize the same if it is likely to furnish the evidence of an offence.

⇒ Require any person to produce any record, register or other document relating to manufacture, sale or distribution of any drug or Cosmetic in respect of which an offence has been or is being Committed.

Duties of Drug Inspectors

xxx

A] Inspection of premises licenced for sale:—

⇒ Inspect not less than once a year all establishments licenced for the sale of drugs with in the area assigned to him and to satisfy himself that the conditions of the licence are being observed.

⇒ Procure and send for test or analysis, if necessary imported packages which he has reason to ~~suspect~~ Suspect Contain drugs being sold in Contravention of the provisions of the Act or the Rules thereunder.

⇒ Investigate any complaint made to him in writing and to institute prosecutions in respect of breaches of the Act or Rules thereunder.

⇒ Maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks and to submit copies of such records to the Controlling authority

⇒ make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act.

⇒ When so authorised by the State Government to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

B] Inspection of manufacture of drugs or Cosmetics:—

⇒ To inspect not less than once a year, all premises licenced for the manufacture of drugs with in the area allotted to him and to satisfy himself that the conditions of the licence and the provisions of the Act and Rules thereunder are being observed.

⇒ In the case of establishments licenced to manufacture products specified in Schedules C and C_1 to inspect the plant and the process of manufacture, the means employed for standardising and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to effect the potency or purity of the product.

⇒ To send to the Controlling Authority after each inspection a detailed report indicating the condition of the licence and provisions of the Act and rules.

⇒ To take the samples of the drugs manufactured on the premises and send them for test or Analysis.

⇒ To Institute prosecution in respect of breaches of the Act and Rules.