Drugs and Cosmetics Act 1940

Chapter-3

Part-2

PHARMACY LAW AND ETHICS

One Shot Complete Video

We learn in this Topic:

Chapter-3 | Part-2

- **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.** Complete PDF Notes and online Class

According to New Syllabus D.Pharma

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Syllabus

Part-1:

- Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments 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.

Part-2:

- 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.

Part-3:

- Study of schedule C and C1, G, H, H1, K, P, M, N, X and Y. Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India.
- Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.

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

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.

Manufacture of Drugs

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

- A person who is interested in starting manufacturing of drugs is required to fulfill several conditions laid down in DCA and Rules.
- The conditions to be fulfilled before license is granted are collectively called as "Conditions Precedent" and conditions that are required to be fulfilled after the license is obtained for manufacturing are called "Conditions Subsequent".
- The Licensing Authority is both in States and at Central Government. The Central Government is empowered to prohibit manufacturing and sale of any drug formulation in public interest.

1. Manufacturing of drugs for examination, test or analysis

- If the manufacturer does not hold separate licence for test, analysis or examination, the licence is obtained in Form 29. The provisions relating prohibition of manufacturing of certain drugs do not apply for such manufacturing meant for test or analysis. The validity of the licence is for I year.

Conditions:

1. The manufactured drugs should be kept in containers bearing appropriate label indicating the purpose of test or analysis.
2. The drugs should be used for the purpose for which they are manufactured.
3. When the material is supplied to other manufacturer, the label stating the name and address of manufacturer, scientific name of the drug, licence number, date of manufacture etc., should be provided.
4. The manufacturer should allow the Inspector to inspect the premises, manufacturing, and analytical records and withdraw the samples if required for analysis. The manufacturer should comply with the provisions of the Act and Rules.
5. The manufacturer should maintain an Inspection Book and the same be shown to the Inspector.
6. The licensee should comply with other requirements for which a notice has been given to him one month before by the Licensing Authority.

2. Manufacture of new drug

- In addition to provisions for manufacture of drugs, there should be documentary evidence for quality, purity, therapeutic trials of new drugs and evidence for approval under schedule 'Y' (Clinical trials).

3. Manufacturing under Loan licences

- Loan license is given to a person who does not have his own arrangements for manufacturing but wishes to avail the manufacturing facilities owned by another licensee. For drugs other than Schedules C, C(I) and X, loan licences can be given. Drugs specified in Schedules C/C(I),

Procedure:

- A licence is obtained from licensing authority on application in prescribed form No. 24 A, 27 A with prescribed fees.
- Application for grant or renewal of loan licence is made in Form 24- A.
- The licence is issued by Licensing Authority in Form 25-A, which is valid for 1 year.

3. Manufacturing under Loan licences

Conditions:

- The general conditions applicable to other than Schedules C, C(I) and X.

Additional conditions:

1. Application must be supported by the parent firm.
2. Drug inspector inspects the premises of parent firm and checks and assesses the spare capacity.
3. Loan license is required to test each batch of raw materials and finished products.
4. Records of testing should be maintained for 5 years or 2 years in case of expiry drugs from such data.
5. Patent medicines must be safe for use in the context of vehicle and additives.
6. The production must be supervised by competent person of loan licensee.

4. Licence for Repacking:

- Process of breaking up any drug from its bulk container [8] into small packages and labeling with a view to their sale and distribution is done under repacking licence. It is issued for drugs other than Schedules C, C1 and X, subject to fulfillment of conditions.

Procedure:

- The application is made for grant or renewal of licence in Form 24-B. The licence is issued by Licensing Authority after inspection in Form 25-B.

Conditions:

1. Adequate space and equipment should be provided. Hygienic conditions of working should always be maintained.
2. Repacking should be supervised by competent person.
3. There should be adequate arrangement for testing of samples.
4. The licence should always be displaced at premises of repacking.
5. The factory primises for repacking should comply with provisions of Schedule M.
6. Adequate staff should be appointed and any change in staff structure should be immediately informed to Controlling Authority.
7. The container or package of repacked drug should bear on its label the words - "Rpg.Lic.No".
8. The licence is valid till31Ist December every year and required to be renewed. There should be separate application for separate licence.

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