Priya Consultancy (I) Pvt. Ltd.

DRUGS AND COSMETICS PROFILE

Contents of this chapter

- Definitions
- Administration of the act and rules
- Provisions related to Import
- Provisions related to Manufacture
- Provisions related to Sale
- Labeling and Packaging
- Schedules to the act and rules

Learning Objectives

- At the end of this lecture, student will be able to
  - Discuss the Provisions related manufacture drugs and pharmaceuticals
  - Explain the types of manufacturing licenses
  - Describe the prohibitions for manufacturing of drugs
  - Discuss the provisions for drugs other than those specified in Schedule C, C_1 & X
  - Discuss the provisions for drugs specified in Schedule C, C_1 but not specified in Schedule X
  - Discuss the provisions for drugs specified in Schedule C, & C_1

MANUFACTURE OF DRUGS

Manufacture in relation to any drug or cosmetic, includes any process or part of process for making, altering, ornamenting, finishing, packing, labeling, braking up or otherwise treating any drug or cosmetic with a view to its sale & distribution but does not include the compounding or dispensing of any drug or packing of any drug in ordinary course of retail business

Following licenses are provided for manufacture of drugs under D&C Act

1. Drugs other than those specified in Schedule C, C_1 & X
2. Drugs specified in Schedule C, C_1 but not specified in Schedule X
3. Drugs specified in Schedule C, & C_1
4. Drugs specific in Schedule X but not in Schedule C & C_1
5. Drugs specified in Schedule C, C_1 and X
6. Drugs for the purpose of examination, test or analysis
7. Loan Licenses
8. Repacking Licenses
9. Blood products

Repacking is also a manufacturing for the purpose of the act.

If drugs are manufactured in more than one set of premises, a separate application is to be made & separate license shall be issued in respect of each such premises.

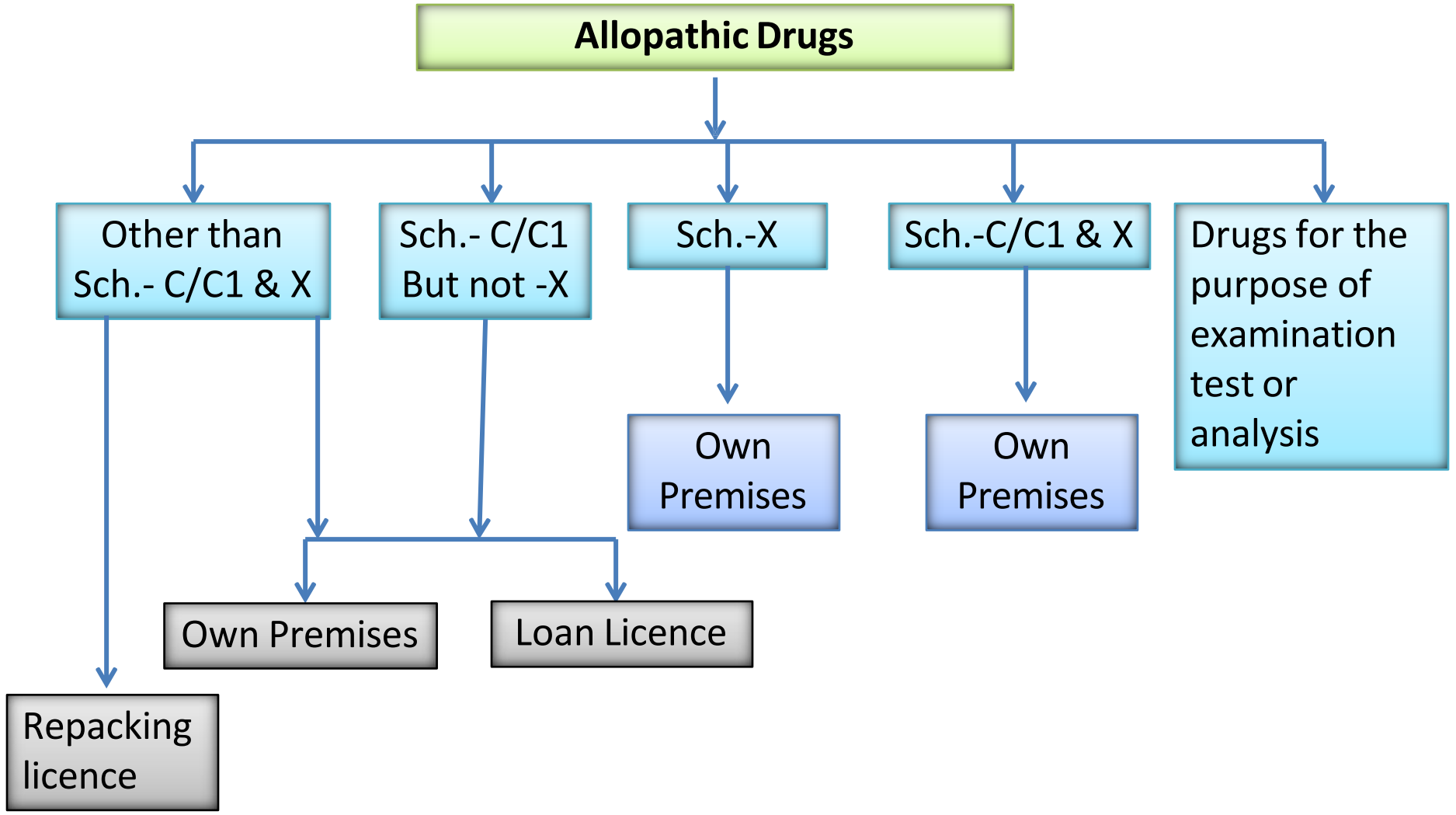
Licenses for manufacture or sale or distribution of drugs are granted or renewed by Central License Approving Authority (CLAA) appointed by the central government.

CLAA can delegate his power of signing licenses to any other person under his control with approval of the Central Government.

Manufacture

- Prohibition of manufacture
- Manufacture of other than in Schedule-C/C_1
- Manufacture of those in Schedule-C/C_1
- Manufacture of Schedule-X drugs
- Loan license
- Repackaging license
- Offences & Penalties

Types of Manufacturing licenses



Prohibition of manufacture

- Drug not of standard quality or **misbranded, adulterated or spurious.**
- **Patent or Proprietary** medicine
- Drugs in **Schedule-J**
- **Risky** to human beings or animals
- Drugs **without therapeutic value**
- Preparation containing **cyclamates**

Prohibition for the manufacture & sale of Certain Drugs

- From the date notified by the State Government, no person shall himself manufacture for sale or distribution or sell or distribute-
  - ✓Any **drug** which is not of standard quality or is misbranded, adulterated or spurious;
  - ✓Any COSMETIC which not of standard quality or is misbranded, adulterated or spurious;
  - ✓Any **patent** or proprietary medicine whose formulae is not disclosed on ***label*** or the container;
  - ✓Any drug which purports to cure, mitigate or prevent any disease specified in Schedule J;
  - ✓Any cosmetic containing any ingredient which may render it unsafe or harmful for use;
  - ✓Any drug or cosmetic in **contravention** of this act or rules thereunder;
  - ✓Any drug or cosmetic which has been imported or manufactured in contravention of the provisions of this Act or Rules thereunder or in contravention of the conditions of a license.

- Every person not being manufacturer of a drug or cosmetic or his agent for the distribution shall if so required disclose to the inspector the name address and other particulars of the person from whom he procured the drug or cosmetic.
- **A drug or cosmetic shall not be rendered to be misbranded, adulterated or spurious or below standard quality, if-**

  -There has been added thereto some innocuous substance or ingredient required for its manufacture or preparation as an article of commerce in state fit for carriage or **consumption**, & not to increase the bulk, or weight or measure of the drug or *cosmetic or to conceal its inferior quality or other defect.*

  -In process of manufacture, preparation or conveyance some **EXTRANEOUS SUBSTANCE HAS BEEN UNAVOIDABLY BECOME INTER-MIXED WITH IT,** however this does not apply in relation to any sale or distribution of the drug or cosmetic occurring after the vendor or distributor becomes aware of such inter-mixture.
- There are two types of conditions for all manufacturing licenses

  -Conditions which are to be satisfied ***before*** a license is granted

  -Conditions which are to be satisfied ***after*** the license is granted.

Manufacture of Drugs other than those specified in Schedule C & C_1

- Application for the grand or renewal of license for the manufacture of drugs other than those specified in schedule C, c_1 & X 'd be made to LA in Form 24 & for manufacture of Schedule X drugs in Form 24F. Respective licenses are issued in form 25 & 25F
- Application for grand/renewal of such license shall be made for up to 10 items in each category in Form 24-A accompanied by fee of 6000 & an inspection fee of Rs. 1500 to LA & license shall be issued in Form 25A.
- Additional fee of Rs 300 per item is payable for each additional item
- License in form 25 or 25F remains valid for a period of 5 **years** on and from the date on which it is issued.
- If application for renewal is made before its expiry, or application made WITHIN 6 MONTHS of expiry, after payment of additional fee, the license shall continue to be valid
- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

Manufacture of drugs other than in Schedule-C/C_1

Conditions

- Premises should comply with **schedule 'M'**
- Adequate **facility for testing**, separate from manufacturing
- Adequate **storage facility**
- **RECORDS** MAINTAINED FOR AT LEAST 2 YEARS FROM DATE OF EXP.
- Should provide **sample to authority**
- Furnish **data of stability**
- Maintain the **inspection book**
- Maintain **reference samples** from each batch

Manufacture of drugs those in Schedule-C/C_1(Biological)

Conditions

- Drugs must be issued in previously **sterilized sealed glass** or suitable container
- Containers should comply with **Schedule-F**
- Some classes should be tested for **aerobic & anaerobic micro-organism**.eg. Sera ,Insulin, Pituitary hormones.
- Serum should be tested for **abnormal toxicity**
- Parenteral in doses of 10 ml or more should be tested for freedom from **Pyrogens**
- Separate lab. for **culture** & manipulation of **spore bearing Pathogens**
- **Test for sterility** should be carried out.

Manufacture of drugs specified in Schedule C, C_1 & X

- Application for the license of manufacturing drugs specified in Schedule C, C_1 excluding those specified in Schedule X should be made to the LA in Form 27 & for manufacture of drugs specified in Schedule C, C_1 & X in for 27B. Respective licenses are issued in Form 28 & 28B.
- Application for including any additional drug in the license should be accompanied by a fee of **Rs.50 for each drug subject to a maximum of Rs.500**
- CONDITIONS FOR THE GRANT OF LICENSE: BEFORE THE GRAND OF LICENSE, THE FOLLOWING CONDITIONS MUST BE COMPLIED BY THE APPLICANT

1. The manufacture will be conducted under the active direction of a competent technical staff consisting at least one person who is a full time employee & who is

   -A graduate in pharmacy/pharmaceutical chemistry of a recognized University with at least ***18*** **months** practical experience after graduation in manufacture of drugs to which this license applies.

   -A graduate in science of a recognized University who passed in degree with **chemistry** or **microbiology** as principal subject & had al least *3 YEARS EXPERIENCE* in the manufacture of drugs to which the license applies.

C,C1 …27 C,C1,X……27B

-A graduate in **medicine** of a recognized University with at least 3 years experience in manufacture of relevant drugs; or

-A graduate in chemical engineering of a recognized University with at least 3 years experience in manufacture of relevant drugs; or

-Holding any foreign qualification comparable in quality, content and training with above qualifications & is permitted to work as competent staff by Central Government

2. The factory conditions must comply with the conditions prescribed in Schedule M and M_3

3. Applicant should provide adequate space, plant & equipment for any or all manufacturing operations as prescribed in Schedule M & M_3

4. Applicant should provide adequate **staff, premises and laboratory equipment** for carrying out such tests for strength, quality & purity of substances as required under the rules.

5. Adequate facilities for the **storage** of manufactured drugs should be provided.

6. Data on stability of drugs that may deteriorate, for fixing the date of expiry shall be furnished to LA.

7. Licensee shall comply with requirements of **GMP**.

8. For manufacture of patent or proprietary medicines, data should be provided to LA that justifies that the medicines are: stable under conditions of recommended storage.

contains such ingredients & in such quantities for which there is therapeutic justification

- License in form 28 & 28B remains valid for a period of 5 years on and from the date on which it is issued.

- If application for renewal is made before its expiry, or application made within 6 months of expiry, after payment of additional fee, the license shall continue to be valid

- License shall deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

- ***Large Volume Parenteral*** means the sterile solutions indented for parenteral administration with a volume of 100 ml or more in one container of the finished dosage form indented for single usage.

Conditions of the License

1. Licensee should provide & maintain, adequate staff & adequate premises and plant for the proper manufacture & storage of substances
2. Licensee should maintain records of the manufacture as per particulars given in schedule U.
3. Licensee should allow Inspectors to enter any premises where manufacture is carried on & to inspect the process of the manufacture.
4. Licensee should allow inspectors to inspect all registers and records maintained under these rules & to take samples of manufactured product
5. should allow the LA to inspect if any changes in expert staff & any material changes in premises or plant since date of last inspection.
6. On request by LA licensee should furnish form every batch, a sample of adequate quantity for any examination
7. If any batch has been found out by LA not to confirm with the standards, licensee should withdraw the remainder of batch from sale.
8. should maintain a Inspection book to enable inspector to record his impression.
9. should maintain reference samples of each batch of drugs manufactured by him, in a quantity twice than that sufficient for conducting all tests.
10. should forward to LA of state a statement of sales effected to manufacturers, wholesalers, retailers, hospitals, nursing homes, dispensaries every three months.

Summary

- If drugs are manufactured in more than one set of premises, a separate application is to be made & separate license shall be issued in respect of each such premises
- Licenses for manufacture or sale or distribution of drugs are granted or renewed by Central License Approving Authority (CLAA) appointed by the central government
- From the date notified by the State Government, no person shall himself manufacture for sale or distribution or sell or distribute- Any drug which is not of standard quality or is misbranded, adulterated or spurious
- Any cosmetic which not of standard quality or is misbranded, adulterated or spurious
- Any patent or proprietary medicine whose formulae is not disclosed on label or the container
- Any drug which purports to cure, mitigate or prevent any disease specified in Schedule J

ThankYou

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