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• Definitions
• Administration of the act and rules
• Provisions related to Import
• Provisions related to Manufacture
• Provisions related to Sale
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• Schedules to the act and rules
• Recent amendment act, 2008
HISTORY

- British misrule - Providing poor healthcare system to Indian citizens

- Observations made by - Drugs Enquiry Committee, Indian Medical Association

- Reports in - Indian Medical Gazette during 1920-30

- 1940 – Drugs and Cosmetics Act

- 1945 – Rules under the Act

Extended to whole of India......
LIST OF AMENDING ACTS AND ADAPTATION ORDERS

1. The Drugs (Amendment) Act, 1955
2. The Drugs (Amendment) Act, 1960
3. The Drugs (Amendment) Act, 1962
4. The Drugs and Cosmetics (Amendment) Act, 1964
5. The Drugs and Cosmetics (Amendment) Act, 1972
6. The Drugs and Cosmetics (Amendment) Act, 1982
7. The Drugs and Cosmetics (Amendment) Act, 1995
8. The Drugs and Cosmetics (Amendment) Act, 2008
OBJECTIVES

- To regulate the **import, manufacture, distribution and sale** of drugs & cosmetics through licensing.
- Manufacture, distribution and sale of drugs and cosmetics by **qualified persons only**.
- To prevent **substandard** in drugs, presumably for maintaining high standards of medical treatment.
- To regulate the manufacture and sale of **Ayurvedic, Siddha and Unani drugs**.
- To establish **Drugs Technical Advisory Board (DTAB)** and **Drugs Consultative Committees (DCC)** for Allopathic and allied drugs and cosmetics.
THE DRUGS AND COSMETICS ACT, 1940
DEFINITIONS

**Drugs:**

All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
Cosmetic:

Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.
**Definitions**

**Misbranded drugs:**

a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

b) if it is not labelled in the prescribed manner; or

c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.
Adulterated drug:

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

  e.g. supply of cheap cottonseed oil in place of olive oil.
Spurious drugs:

(a) if it is imported under a name which belongs to another drug; or

(b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; e.g., when methamphetamine is sold as cocaine

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.
Manufacture:

In relation to any drug or cosmetic, it includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.
Patent or Proprietary medicine:

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government.
ADMINISTRATION OF THE ACT AND RULES

A) Advisory:
   1) Drugs Technical Advisory Board-DTAB
   2) Drugs Consultative Committee-D.C.C.

B) Analytical:
   1) Central Drugs Laboratory - CDL
   2) Drug Control Laboratory in states
   3) Government Analysts

C) Executives:
   1) Licensing authorities
   2) Controlling authorities
   3) Drug Inspectors
DRUGS TECHNICAL ADVISORY BOARD (DTAB)

Ex-Officio:

(i) Director General of Health Services (Chairman)
(ii) Drugs Controller, India
(iii) Director of the Central Drugs Laboratory, Calcutta
(iv) Director of the Central Research Institute, Kasauli
(v) Director of Indian Veterinary Research Institute, Izatnagar
(vi) President of Medical Council of India
(vii) President of the Pharmacy Council of India
(viii) Director of Central Drug Research Institute, Lucknow
Nominated:

1) Two persons by the Central Government from among persons who are in charge of drugs control in the **States**

2) One person by the Central Government from the **pharmaceutical industry**

3) Two persons holding the appointment of **Government Analyst** under this Act, to be nominated by the Central Government
Elected:

1) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;

2) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

3) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

4) one person to be elected by the Central Council of the Indian Medical Association;

5) one person to be elected by the Council of the Indian Pharmaceutical Association;
Functions:

To advise the Central Government and the State Governments on technical matters arising out of the administration of this Act.

To carry out the other functions assigned to it by this Act.

(The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election)
DRUGS CONSULTATIVE COMMITTEE (DCC)

- It is also an advisory body constituted by central government.

- **Constitution:**
  
  Two representatives of the **Central Government**
  One representative of each **State Government**
DRUGS CONSULTATIVE COMMITTEE (DCC)

**Functions:**

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure *uniformity throughout India* in the administration of this Act.

- The Drugs Consultative Committee shall *meet when required*.

- Has power to regulate its own procedure.
SCHEDULES TO THE ACT

1. Names of books under Ayurvedic, Siddha and Unani Tibb systems
2. Standard to be complied with by imported drugs and by drugs manufactured for sale, stocked or exhibited for sale, sold or distributed.

Appendix I, II, III, IV, V, VI.
CENTRAL DRUG LABORATORY (CDL)

- Established in Calcutta, under the control of a director appointed by the Central Government.

**Functions:**

- Analysis or test of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical Q.C. of the imported samples.
- Collection, storage and distribution of internal standards.
- Preparation of reference standards and their maintenance.
- Maintenance of microbial cultures.
- Any other duties entrusted by Central Government.
- Acting as an appellate authority in matter of disputes.
IMPORT
IMPORT OF DRUGS & COSMETICS

- Classes of drugs prohibited to import
- Import of drug under license
  1) Specified in Schedule-C/C₁
  2) Specified in Schedule-X
  3) Imported for Test/Analysis
  4) Imported for personal use
  5) Any new drugs
- Drugs exempted from provisions of import
- Offences and Penalties
CLASSES OF DRUGS PROHIBITED TO IMPORT

- Misbranded drugs
- Drugs of substandard quality
- Drugs claiming to cure diseases specified in Sch-J
- Adulterated drugs
- Spurious drugs
- Drugs whose manufacture, sale/distribution are prohibited in original country, except for the purpose of test, examination and analysis.
- Patent/Proprietary medicines whose true formula is not disclosed.
CLASSES OF DRUGS PROHIBITED TO IMPORT

- Drugs not labelled/packed in prescribed manner.

- Drugs of biological products (C/C₁) after the date of expiry

- Drugs not claiming therapeutic values.

- Drugs which is risky to human beings or animals.

- Any new drug except with express permission of Lic. authority.
IMPORT OF THE BIOLOGICAL DRUGS(C/C₁)

Conditions to be fulfilled:

- Licensee must have adequate facility for the storage.

- Licensee must maintain a record of the sale, showing the particulars of the names of drugs and of the persons to whom they have been sold.

- Licensee must allow an inspector to inspect premises and to check the records.

- Licensee must furnish the sample to the authority.

- Licensee must not sell drugs from which sample is withdrawn and he is advised not to sale, and recall the batch from the market.
IMPORT OF THE **SCHEDULE-X DRUGS (NARCOTIC & PSYCHOTROPIC DRUGS)**

**Conditions to be fulfilled:**

- Licensee must have adequate *storage facility*.
- Applicant must be *reputable* in the occupation, trade or business.
- The license *granted ever before* should not be *suspended or cancelled*.
- The licensee has *not been convicted any offence* under the Drugs and Cosmetics Act or Narcotic and Psychotropic Substances Act.
Conditions to be fulfilled:

- License is necessary under form-11
- Must use imported drugs **only for said purpose** and at the place specified in the license.
- Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
- Must **allow an inspector** to inspect the premises and check the records.
DRUGS IMPORTED FOR PERSONAL USE

Conditions to be fulfilled:

- **Up to 100 average doses** may be imported **without any permit**, provided it is part of passenger’s luggage.

- More than 100 doses imported with license. Apply on form no.-12-A,12-B

- Drugs must be **bonafide personal use**.

- Drugs must be **declared** to the custom collectors if so directed.
<table>
<thead>
<tr>
<th>OFFENCES</th>
<th>PENALTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Import of spurious OR adulterated drug OR drug which involves risk to</td>
<td>a) 3 years imprisonment and 5000 Rs. fine on first conviction</td>
</tr>
<tr>
<td>human beings or animals OR drug not having therapeutic values</td>
<td>b) 5 years imprisonment OR 1000 Rs. fine OR both for subsequent conviction</td>
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</tr>
<tr>
<td>Contravention of the provision</td>
<td>a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction</td>
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<td></td>
<td>b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence</td>
</tr>
</tbody>
</table>
IMPORT OF COSMETICS

Cosmetics prohibited to import:

- Misbranded cosmetics
- Spurious cosmetics
- Cosmetic containing harmful ingredients
- Cosmetics not of standard quality
- which contains more than 2 ppm Arsenic, 20 ppm lead, 100 ppm heavy metals
CONT....

- Cosmetics meant for eye and containing coal tar dyes
- Cosmetics coloured with lead OR arsenic compounds
- Cosmetics containing Hexachlorophene OR Mercury
- Risky to user
CHAPTER IV

MANUFACTURE, SALE & DISTRIBUTION OF DRUGS AND COSMETICS
MANUFACTURE

- Prohibition of manufacture
- Manufacture of other than in Sch-C/C₁
- Manufacture of those in Sch-C/C₁
- Manufacture of Sch-X drugs
- Loan license
- Repackaging license
- Offences & Penalties
PROHIBITION OF MANUFACTURE

- Drug not of standard quality or misbranded, adulterated or spurious.

- Patent or Proprietary medicine

- Drugs which claims to cure diseases specified in Sch-J

- Drugs which Risky to human beings or animals

- Drugs without therapeutic value

- Preparation containing cyclamates
TYPES OF MANUFACTURING LICENCES

Allopathic Drugs

- Other than Sch.- C/C1 & X
  - Own Premises
  - Repacking licence

- Sch.- C/C1 But not -X
  - Own Premises
  - Loan Licence

- Sch.-X
  - Own Premises

- Sch.-C/C1 & X
  - Own Premises

- Drugs for the purpose of examination test or analysis
MANUF. OF DRUGS OTHER THAN IN SCH-C/C₁

**Conditions:**

- Premises should comply with *schedule ‘M’*
- Adequate *facility for testing*, separate from manufacturing
- Adequate *storage facility*
- *Records* of mfg. & testing-maintained for at least 2 years from date of Exp.
- Licensee should provide *sample to authority*
- Furnish *data of stability*
- Maintain the *inspection book*
- Maintain *reference samples* from each batch
- *Accounts of production* recorded & maintained for 5 years or 1 year after Expiry.
FORM 24

[See Rule 69]

Application for the grant of or renewal of a licence to manufacture for sale \textsuperscript{87}[or for distribution of] drugs other than those specified in \textsuperscript{88}[Schedules C, C(I) and X]

1. I/We \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \dot \d
MANUF. OF DRUGS THOSE IN SCHEDULE-C/C₁(BIOLOGICAL)

**Conditions:**

- Drugs must be issued in previously sterilized sealed glass or suitable container.
- Drug must comply with std. (quality, purity, strength).
- Serum tested for freedom from abnormal toxicity.
- Parenterals 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 SCH-X DRUGS

**Conditions:**

- **Accounts of all transactions** regarding manuf. should be maintained in serially bound & paged register. (Preserved for 5 years)
- Have to sent **invoice of sale** to licensing authority every 3 months
- Store drugs in **direct custody of responsible person**.
- Preparation must be labeled with **XRx**
- Marketed in packings **not exceeding**
  - 100 unit dose – Tablets/Capsules
  - 300 ml - Oral liquid
  - 5 ml - Injection
**LOAN LICENSE**

**Definition:**
A person (applicant) who does not have his own arrangements (factory) for manufacture but who wish to avail the manufacturing facilities owned by another licensee. Such licenses are called Loan licenses.

**Procedure:**
License forms (25-A) is obtained from licensing authority (FDA) on application in prescribed forms (24-A) with prescribed fees (Rs. 6000, 1500).

**Loan licenses are issued for:**
1) Drugs other than specified in C/C₁ & X.
2) Drugs specified in Schedule-C/C₁,
FORM 27-A

(See Rule 75-A)

Application for grant or renewal of a loan license to manufacture for sale 8a(or for distribution of) drugs specified in Schedules C and C(1)8b(excluding those specified in 8c(Part XB and) Sch. X)

1. I/We *.......................... of.......................... hereby apply for the grant/renewal of loan license to manufacture on the premises situated at...........C/o.............. the under mentioned drugs, being drugs specified in Schedules C and C(1) 8b(excluding those specified in 8c(Part XB and) Sch .X) to the Drugs and Cosmetics Rules, 1945.

Names of drugs (each substance to be separately specified).

1. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

   a) Name(s) of expert staff responsible for manufacture..................

   b) Name(s) of expert staff responsible for testing..................

1. I/We enclose:-

   a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

   b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their
REPACKAGING LICENSE

**Definition:**

Process of breaking up any drug from a bulk container into small packages and labeling with a view to their sale and distribution.

**Procedure:**

Licence forms (25-B) is obtained from licensing authority (FDA) on application in prescribed forms (24-B) with prescribed fees (Rs. 500, 200).
**PENALTIES RELATED TO MANUFACTURE**

<table>
<thead>
<tr>
<th>OFFENCES</th>
<th>PENALTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacture of any spurious drugs</td>
<td>a) 1-3 years imprisonment and Rs.5000 fine</td>
</tr>
<tr>
<td></td>
<td>b) 2-6 years imprisonment &amp; Rs.10000 fine on subsequent conviction</td>
</tr>
<tr>
<td>Manufacture of adulterated drugs</td>
<td>a) 1 year imprisonment &amp; Rs.2000 fine</td>
</tr>
<tr>
<td></td>
<td>b) 2 years imprisonment &amp; Rs.2000 fine for subsequent conviction</td>
</tr>
<tr>
<td>Manuf. of drugs in contravention of the provisions</td>
<td>a) Imprisonment up to 3 months &amp; Rs.500 fine</td>
</tr>
<tr>
<td></td>
<td>b) Imprisonment up to 6 months &amp; Rs.1000 fine on subsequent conviction</td>
</tr>
</tbody>
</table>
MANUFACTURE OF COSMETICS

Prohibited for the following classes of drug:

- **Misbranded or spurious** cosmetics and of substandard quality
- Cosmetics containing **hexachlorophene or mercury** compounds
- Cosmetics containing color which contain more than-
  - 2 ppm of **arsenic**
  - 20 ppm of **lead**
  - 100 ppm of **heavy metals**
- **Eye preparations** containing **coal-tar color**
SALE
SALE OF DRUGS

- Classes of drugs prohibited to be sold
- Wholesale of biological (C/C_1)
- Wholesale of other than those specified in C/C_1 and X
- Wholesale of Sch-X drugs
- Retail sale
TYPES OF SALES LICENCES

Allopathic Drugs

Whole Sale
- Drugs in Sch. - X
- Drugs in Sch. - C/C1

Retail Sale
- General Licence
  - Drugs in Sch. - C/C1
- Restricted Licence
  - Drugs other than sch. - C/C1 & X
  - For Sch. - C/C1

Sales From Motor Vehicle (Vender)
CLASSES OF DRUGS PROHIBITED TO BE SOLD

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/Proprietary drugs with undisclosed formula
- Sch-J drugs
- Expired drugs.
- Drugs used for consumption by government schemes such as E.S.I.S., Armed force.
- Physician’s samples
<table>
<thead>
<tr>
<th>S.No.</th>
<th>Category</th>
<th>Type Sale</th>
<th>Application Form</th>
<th>Licence Form</th>
<th>Fees for Grant/Renewal</th>
<th>Renewal Certificate Form No.</th>
<th>Fee+ Penalty after expiry but within six months</th>
<th>Fees for duplicate copy of Org. Lic.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drugs other than those specified in Schedule C&amp;C (1)&amp;X</td>
<td>Whole Sale</td>
<td>19</td>
<td>20-B</td>
<td>Rs.1500</td>
<td>21-C</td>
<td>Rs.1500+Rs.500 p.m. or part thereof</td>
<td>Rs.150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retail Sale</td>
<td>19</td>
<td>20</td>
<td>Rs.1500</td>
<td>21-C</td>
<td></td>
<td>Rs.150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restricted(Gen.Store)</td>
<td>19-A</td>
<td>20-A R-61 (1)</td>
<td>Rs.500 R-59 (2)</td>
<td>21-C</td>
<td></td>
<td>Rs.150 R-59 (3)</td>
</tr>
<tr>
<td>2</td>
<td>Drugs specified in Schedule C&amp;C (1) but excluding those specified in Schedule ‘X’</td>
<td>Whole Sale</td>
<td>19</td>
<td>21B</td>
<td>Rs.1500</td>
<td>21-C</td>
<td>Rs.1500+Rs.500 p.m. or part thereof</td>
<td>Rs.150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retail Sale</td>
<td>19</td>
<td>21</td>
<td>Rs.1500</td>
<td>21-C</td>
<td></td>
<td>Rs.150</td>
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<tr>
<td></td>
<td></td>
<td>Restricted(Gen.Store)</td>
<td>19-A</td>
<td>21-A R-61 (1)</td>
<td>Rs.500 R-59 (2)</td>
<td>21-C</td>
<td></td>
<td>Rs.150 R-59 (3)</td>
</tr>
<tr>
<td>3</td>
<td>Drugs specified in Schedule ‘X’</td>
<td>Whole Sale</td>
<td>19-C</td>
<td>20-G</td>
<td>Rs.500</td>
<td>21-C</td>
<td>Rs.500+Rs.250 p.m. or part thereof</td>
<td>Rs.150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retail Sale</td>
<td>19-C</td>
<td>20-F R-61(1)</td>
<td>Rs.500 R-59(2)</td>
<td>21-C</td>
<td></td>
<td>Rs.150 R-59 (3)</td>
</tr>
<tr>
<td>4</td>
<td>Sale of Drugs from motor vehicles (1) Drugs other than those specified in Schedule C&amp;C (1) (2) Drugs specified in Schedule C&amp;C (1)</td>
<td>Whole Sale</td>
<td>19-AA</td>
<td>20-BB</td>
<td>Rs.500</td>
<td>21-CC</td>
<td>Rs.500+Rs.250 p.m. or part thereof</td>
<td>Rs.150</td>
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<tr>
<td>5</td>
<td>Homoeopathic Medicines</td>
<td>Whole Sale</td>
<td>19-B</td>
<td>20-D</td>
<td>Rs.250</td>
<td>20-E</td>
<td>Rs.250+Rs.50p.m. or part thereof</td>
<td>Rs. 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retail Sale</td>
<td>19-B</td>
<td>20-C R-67-C</td>
<td>Rs. 250 R-67-A(2)</td>
<td>20-E</td>
<td></td>
<td>Rs.250+Rs.50p.m. or part thereof of R-67-A(2)</td>
</tr>
</tbody>
</table>
FORM 19-C
{See Rule 59(2)}

Application for grant or renewal of a {licence to sell, stock, exhibit or offer for sale, or distribute} drugs specified in Schedule X

1. I/We ........................................ of ................ hereby apply for a licence to sell by Wholesale/retail drugs specified in Schedule-X to the Drugs and Cosmetics Rules, 1945. We operate a pharmacy on the premises, situated at ............

2. The sale and dispensing of drugs will be made under the personal supervision of the qualified persons mentioned below:-

   Name..................................(Qualification)
   Name..................................(Qualification)

1. Name of drugs to be sold.
2. Particulars of storage accommodation.
3. A fee of rupees.............................. has been credited to Government account under the head of account..................................................

Date........................................

Signature..............................
WHOLESALE OF BIOLOGICAL (C/C₁)

- Adequate premises, with greater than 10 M² area, with proper storage facility
- Drugs sold only to retailer having license
- Premises should be in charge of competent person who is Reg. Pharmacist.
- Records of purchase & sale
- Records preserved for 3 years from date of sale
- License should displayed on premises
WHOLESALE OF OTHER THAN THOSE SPECIFIED IN C/C₁ AND X

- All the conditions as discussed in for biological.
- Compounding is made by or under the direct and personal *supervision of a qualified person.*
For retail sale, two types of licenses are issued:

i) General licenses

ii) Restricted licenses

**Restricted license:**

Granted to those dealers who do not engage the services of a qualified person and only deal with such classes of drugs whose sales can be effected without qualified person and vendors who do not have fixed premises.
FORM 19-A
{(See Rule 59(2)}
Application for the grant or renewal of a restricted licence to sell, stock or exhibit (or offer) for sale or distribute drugs by retail by dealers who do not engage the service of a qualified person.

1. I/We .............................................................................. of
............................................................................................. hereby apply for a licence to sell by retail (i) {Drugs other than those specified in Schedule C, C(1) and X on the premises situated at
............................................................................................. or (ii) Drugs specified in {Schedule C(1) on the premises situated drugs specified in {Schedule C(1) as vendor in the at..........................
 are.................................................................

2. Sales shall be restricted to such drugs as can be sold without the supervision of a qualified person under the Drugs and Cosmetics Rules.

3. Names or classes of drugs proposed to be sold.................................................................

4. Particulars of the storage accommodation for the storage of {Schedule C(1) drugs on the premises referred to above.

5. The drugs for sale will be purchased from the following dealers and such other dealers as may be endorsed on the licence by the licensing authority from time to time.

6. A fee of rupees __________ has been credited to Government under the head of account
.............................................................................................

Date.............................

Signature.............................
All the general and specific labeling and packaging specified to all classes of drugs and cosmetics should be as per the provisions made under the act.
SCHEDULES TO THE ACT

- **First schedule** – Names of **books** under **Ayurvedic** and **Siddha** systems

- **Second schedule** – **Standard to be complied** with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution
<table>
<thead>
<tr>
<th>TYPE</th>
<th>CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>“A”</td>
<td>Performa for <strong>forms no. 1 to 50</strong> (Application, issue, renewal, etc.)</td>
</tr>
<tr>
<td>“B”</td>
<td><strong>Rates of fee</strong> for test or analysis by CDL or Govt. analysts</td>
</tr>
<tr>
<td>“C”</td>
<td>List of <strong>Biological and special products (Injectable)</strong> applicable to special provisions. Ex. Sera, Vaccines, Penicillin.....etc</td>
</tr>
<tr>
<td>“C₁”</td>
<td>List of Biological and special products (<strong>nonparenteral</strong>) applicable to special provisions. Ex. Digitalis, Hormones , Ergot</td>
</tr>
<tr>
<td>“D”</td>
<td>List of drugs that are <strong>exempted</strong> from provisions of <strong>import</strong></td>
</tr>
<tr>
<td>“E₁”</td>
<td>List of poisonous substances under the <strong>Ayurvedic, Siddha and Unani systems</strong></td>
</tr>
<tr>
<td>“F”</td>
<td>Provisions applicable to <strong>blood bank</strong></td>
</tr>
</tbody>
</table>
# Schedules to the Rules

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<thead>
<tr>
<th>Type</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>“F₁”</td>
<td>Special provision applicable to biological and special products, e.g. Bacterial and viral vaccines, sera from living animals, bacterial origin diagnostic agents</td>
</tr>
<tr>
<td>“F₂”</td>
<td>Standards for <em>surgical dressings</em></td>
</tr>
<tr>
<td>“F₃”</td>
<td>Standards for <em>umbilical tapes</em></td>
</tr>
<tr>
<td>“FF”</td>
<td>Standards for <em>ophthalmic preparations</em></td>
</tr>
<tr>
<td>“G”</td>
<td>List of substances required to be used under medical supervision and labelled accordingly Ex. Metformin, Anti Histaminic, ...etc</td>
</tr>
<tr>
<td>“H”</td>
<td>List of substances (prescription) that should be sold by retail only on prescriptions of <em>R.M.P.</em> Ex. Atenolol, Lorazepam, Dapson ...etc</td>
</tr>
<tr>
<td>TYPE</td>
<td>CONTENT</td>
</tr>
<tr>
<td>------</td>
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</tbody>
</table>
| “J”  | List of diseases and ailments that drug should not claim to cure  
      Ex. Cancer, AIDS, Cataract, Diabetes…etc |
| “K”  | List of drugs that are exempted from certain provisions regarding manufacture |
| “M”  | Requirements of manufacturing premises, GMP requirements of factory premises, plants and equipments |
| “M”  | Requirements of factory premises for manufacture of Homeopathic medicines |
| “M”  | Requirements of factory premises for manufacture of cosmetics |
| “M”  | Requirements of factory premises for manufacture of medical devices |
| “N”  | List of minimum equipment for efficient running of a Pharmacy |
| “O”  | Standards for disinfectant fluids Ex... Phenol, H₂O₂, alcohol….
## Schedules to the Rules

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>“P”</td>
<td>Life period (expiry) of drugs Ex. Insuline Inj. – 24 months</td>
</tr>
<tr>
<td>“Q”</td>
<td>Coal tar colors permitted to be used in cosmetics Ex. Caramel, TiO2, Toney red…..</td>
</tr>
<tr>
<td>“R”</td>
<td>Standards for mechanical contraceptives</td>
</tr>
<tr>
<td>“R₁”</td>
<td>Standards for medical devices</td>
</tr>
<tr>
<td>“S”</td>
<td>Standards for cosmetics</td>
</tr>
<tr>
<td>“T”</td>
<td>Requirements (GMP) of factory premises for Ayurvedic, Siddha, Unani drugs</td>
</tr>
<tr>
<td>“U”</td>
<td>Manufacturing and analytical records of drugs</td>
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## Schedules to the Rules

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<td>“U,”</td>
<td>Manufacturing and analytical records of cosmetics</td>
</tr>
<tr>
<td>“V”</td>
<td>Standards for <strong>patent or proprietary medicines</strong></td>
</tr>
<tr>
<td>“W”</td>
<td>List of drugs marketed under generic names- <strong>Omitted</strong></td>
</tr>
</tbody>
</table>
| “Χ”  | List of **narcotic drugs and psychotropic** substances  
EX. Opium, Morphine, Barbital...... |
| “Γ”  | Requirement and guidelines on **clinical trials** for import and manufacture of new drugs |
Salient features of the Act:-

- Substantial enhancement in punishment
- Life imprisonment for offenders involved in manufacture, sale and distribution of spurious and adulterated drug likely to cause grievous hurt
- Minimum punishment of seven years which may extend to life imprisonment
- Provision for compensation to affected person
Salient features of the Act:-

- Corresponding enhancement in punishment for repeated offenders

- Cognizance can be taken on the complaint of any gazetted officer authorized by Central or State Government

- Cases to be tried by Sessions Court
DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

Salient features of the Act:-

- Designation of **special courts** for trial of offences in respect of adulterated and spurious drugs

- All offences relating to adulterated and spurious drugs made **cognizable** and **non bailable**

- Restrictions on bail – **Bail cannot be granted** unless public prosecutor is heard

- Certain offences made **compoundable**
• SCHEDULE M
SCHEDULE M

GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR PHARMACEUTICAL PRODUCTS.

1. GENERAL REQUIREMENTS
   - Location and surroundings
   - Building and premises
   - Water System
   - Disposal of waste

2. WAREHOUSING AREA

3. PRODUCTION AREA

4. ANCILLARY AREAS
5. Quality Control Area
6. Personnel
7. Health, clothing and sanitation of workers
8. Manufacturing Operations and Controls
9. Sanitation in the Manufacturing Premises
10. Raw Materials
11. Equipment
12. Documentation and Records
13. Labels and other Printed Materials
14. Quality Assurance
15. Self Inspection and Quality audit
16. Quality Control System
17. Specification
18. Master Formula Records
19. Packaging records
20. batch packaging records
21. Batch Processing records
22. SOPs and Records
Schedule Y
Schedule Y

Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to Undertake Clinical Trials

Schedule Y for India is a law and not a mere guideline. The enforcement that came into existence in 1988 was an essential provision for providing support to the upscale of generic pharma scenic present in those days.

1. Application for permission
2. Clinical Trial
3. Studies in special populations
4. Post Marketing Surveillance
5. Special studies: Bioavailability / Bioequivalence Studies.
• **APPENDIX I** - DATA TO BE SUBMITTED ALONG WITH THE APPLICATION TO CONDUCT CLINICAL TRIALS / IMPORT / MANUFACTURE OF NEW DRUGS FOR MARKETING IN THE COUNTRY.

• **APPENDIX I-A** - DATA REQUIRED TO BE SUBMITTED BY AN APPLICANT FOR GRANT OF PERMISSION TO IMPORT AND / OR MANUFACTURE A NEW DRUG ALREADY APPROVED IN THE COUNTRY.

• Appendix II - STRUCTURE, CONTENTS AND FORMAT FOR CLINICAL STUDY REPORTS

• Appendix III - ANIMAL TOXICOLOGY (NON-CLINICAL TOXICITY STUDIES)

• Appendix IV - ANIMAL PHARMACOLOGY

• **APPENDIX V** – INFORMED CONSENT

• **APPENDIX VII** – UNDERTAKING BY THE INVESTIGATOR

• **APPENDIX VIII** – ETHICS COMMITTEE

• **APPENDIX X** – CONTENTS OF PROTOCOL

• **APPENDIX XI** – DATA ELEMENTS FOR REPORTING SAE
1. **Application for permission.** - Application for permission to import or manufacture new drugs for sale or to undertake clinical trials shall be made in Form 44 accompanied with following data in accordance with the appendices, namely:

- Chemical and pharmaceutical information
- Animal toxicology data
- Human Clinical Pharmacology Data
- For new drug substances discovered in India, clinical trials are required to be carried out in India right from Phase I
- For new drug substances discovered in countries other than India, Phase I data as required should be submitted along with the application. After submission of Phase I data generated outside India to the Licensing Authority, permission may be granted to repeat Phase I trials and/or to conduct Phase II trials and subsequently Phase III trials concurrently with other global trials for that drug.
- Regulatory status in other countries
2. CLINICAL TRIAL

• (1) Approval for clinical trial
  Clinical trial on a new drug shall be initiated only after the permission has been granted by the Licensing Authority under rule 21 (b), and the approval obtained from the respective ethics committee(s).

• (2) Responsibilities of Sponsor

• (3) Responsibilities of the Investigator(s)

• (4) Informed Consent

• (5) Responsibilities of the Ethics Committee
(6) Human Pharmacology (Phase I)

The objective of studies in this Phase is the estimation of safety and tolerability with the initial administration of an investigational new drug into human(s). Studies in this Phase of development usually have non-therapeutic objectives and may be conducted in healthy volunteers subjects or certain types of patients.

(7) Therapeutic exploratory trials (Phase II)

The primary objective of Phase II trials is to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side-effects and risks associated with the drug. Studies in Phase II should be conducted in a group of patients who are selected by relatively narrow criteria leading to a relatively homogeneous population.
• (8) Therapeutic confirmatory trials (Phase III)
  Phase III studies have primary objective of demonstration or confirmation of therapeutic benefit(s). Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. These studies should be intended to provide an adequate basis for marketing approval. Studies in Phase III may also further explore the dose-response relationships (relationships among dose, drug concentration in blood and clinical response), use of the drug in wider populations, in different stages of disease, or the safety and efficacy of the drug in combination with other drug(s).

• (9) Post Marketing Trials (Phase IV)
3. Studies in special populations

- Information supporting the use of the drug in children, pregnant women, nursing women, elderly patients, patients with renal or other organ systems failure, and those on specific concomitant medication is required to be submitted if relevant to the clinical profile of the drug and its anticipated usage pattern.

- **(1) Geriatrics.**- Geriatric patients should be included in Phase III clinical trials (and in Phase II trials, at the Sponsor's option) in meaningful numbers, if-
  - (a) the disease intended to be treated is characteristically a disease of aging; or
  - (b) the population to be treated is known to include substantial numbers of geriatric patients; or
  - (c) when there is specific reason to expect that conditions common in the elderly are likely to be encountered; or
  - (d) when the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric patient.
2) Pediatrics.

(i) The timing of pediatric studies in the new drug development program will depend on the medicinal product, the type of disease being treated, safety considerations, and the efficacy and safety of available treatments. For a drug expected to be used in children, evaluations should be made in the appropriate age group. When clinical development is to include studies in children, it is usually appropriate to begin with older children before extending the trial to younger children and then infants.

3) Pregnant or nursing women.

(i) Pregnant or nursing women should be included in clinical trials only when the drug is intended for use by pregnant/nursing women or fetuses/nursing infants and where the data generated from women who are not pregnant or nursing, is not suitable.
Post Marketing Surveillance.-

- Subsequent to approval of the product, new drugs should be closely monitored for their clinical safety once they are marketed. The applicants shall furnish Periodic Safety Update Reports (PSURs) in order to-
  - (a) report all the relevant new information from appropriate sources;
  - (b) relate these data to patient exposure;
  - (c) summarize the market authorization status in different countries and any significant variations related to safety; and
  - (d) indicate whether changes should be made to product information in
  - order to optimize the use of the product.
Special studies: Bioavailability / Bioequivalence Studies

- (i) For drugs approved elsewhere in the world and absorbed systemically, bioequivalence with the reference formulation should be carried out wherever applicable. These studies should be conducted under the labeled conditions of administration. Data on the extent of systemic absorption may be required for formulations other than those designed for systemic absorption.

- (ii) Evaluation of the effect of food on absorption following oral administration should be carried out. Data from dissolution studies should also be submitted for all solid oral dosage forms.

- (iii) Dissolution and bioavailability data submitted with the new drug application must provide information that assures bioequivalence or establishes bioavailability and dosage correlations between the formulation(s) sought to be marketed and those used.
THANKS