

Drugs and Cosmetics Act 1940 and Rules 1945

EBC's Bare Act

DRUGS AND COSMETICS ACT, 1940

along with

DRUGS AND COSMETICS RULES, 1945

together with

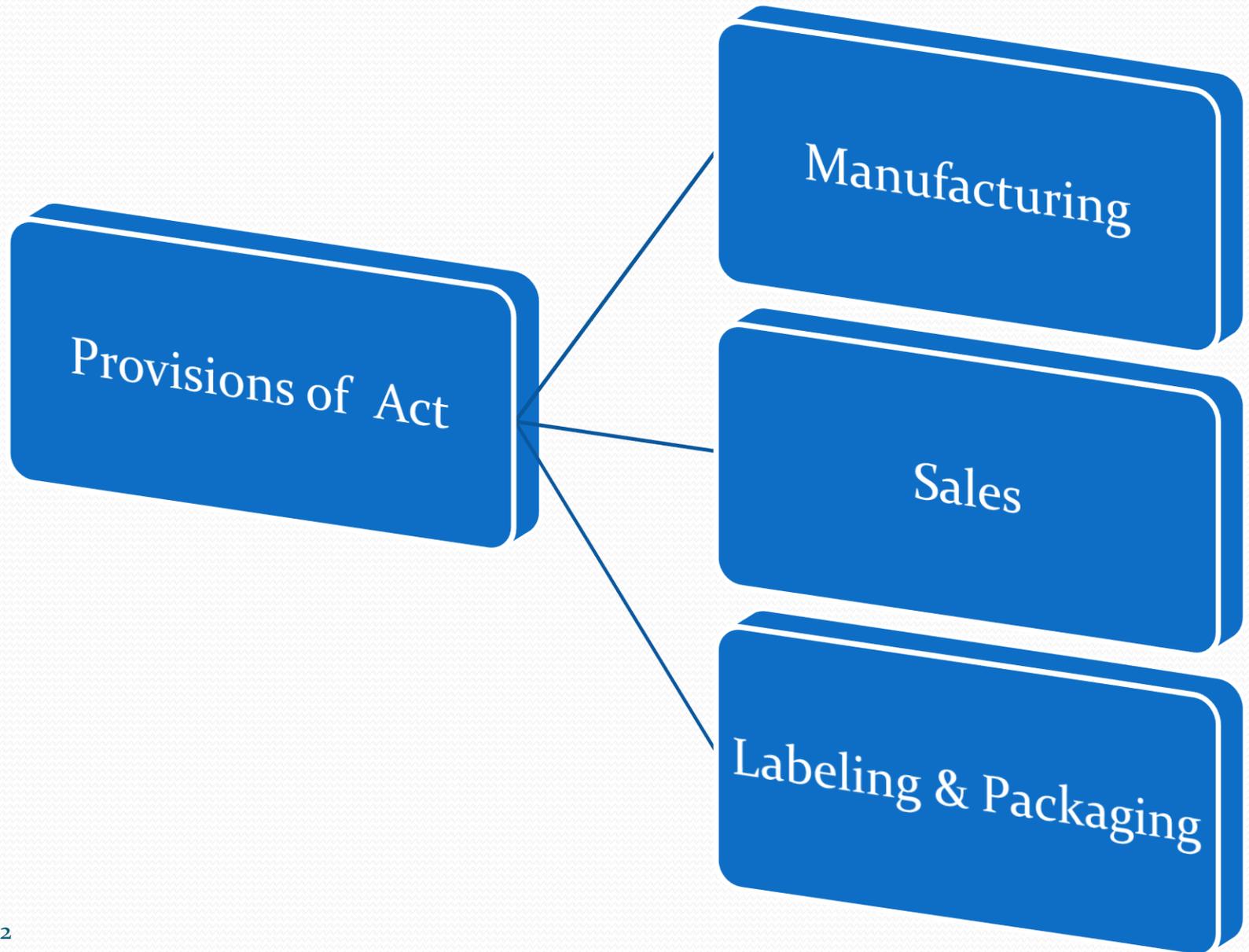
**State Amendments
Subject and Product Index**



Third Edition

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- Provisions related to Manufacture
- Provisions related to Sale
- Labeling and Packaging





MANUFACTURE



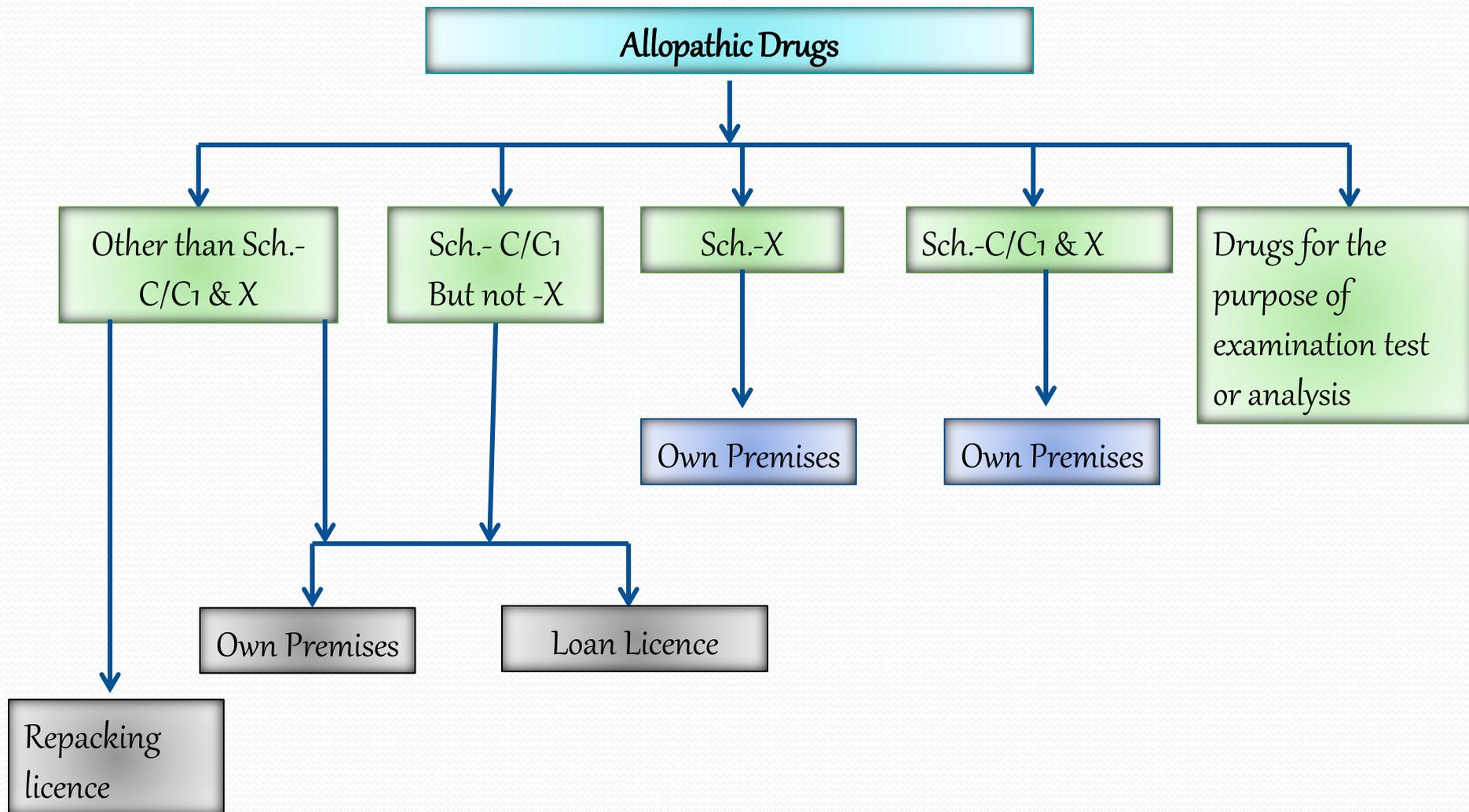
MANUFACTURE

- 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



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.
- Licence 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 ⁸⁷(or for distribution of) drugs other than those specified in ⁸⁸[Schedules C, C(1) and X]

1. I/We of hereby apply for the grant/renewal of a licence to manufacture on the premises situated at the following drugs being drugs other than those specified in ⁸⁸[Schedules C, C(1) and X] to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs categorised according to Schedule M.

3. Names, qualifications and experience of technical staff employed for manufacture and testing.

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

Date

Signature

Note.—The application should be accompanied by a plan of the premises.

MANUF. OF DRUGS THOSE IN SCHEDULE-C/C₁(BIOLOGICAL)

Conditions:

- Drugs must be issued in previously **sterilized sealed glass** or suitable **container**
- Containers should comply with req. of **Sch-F/F₁**
- Drug must comply with std. (quality, purity, strength) specified **in sch.-F**
- Serum tested for freedom from **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 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 **XR_x**
- 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:

Licence is obtained from licensing authority (FDA) on application in prescribed **forms (24-A, 27-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.

Repackaging of drugs is granted of drugs other than Schedule-C/C₁ and X.

Procedure:

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



PENALTIES RELATED TO MANUFACTURE

OFFENCES	PENALTIES
Manufacture of any spurious drugs	a) 1-3 years imprisonment and Rs.5000 fine b) 2-6 years imprisonment & Rs.10000 fine on subsequent conviction
Manufacture of adulterated drugs	a) 1 year imprisonment & Rs.2000 fine b) 2 years imprisonment & Rs.2000 fine for subsequent conviction
Manuf. of drugs in contravention of the provisions	a) Imprisonment up to 3 months & Rs.500 fine b) Imprisonment up to 6 months & Rs.1000 fine on subsequent conviction

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**

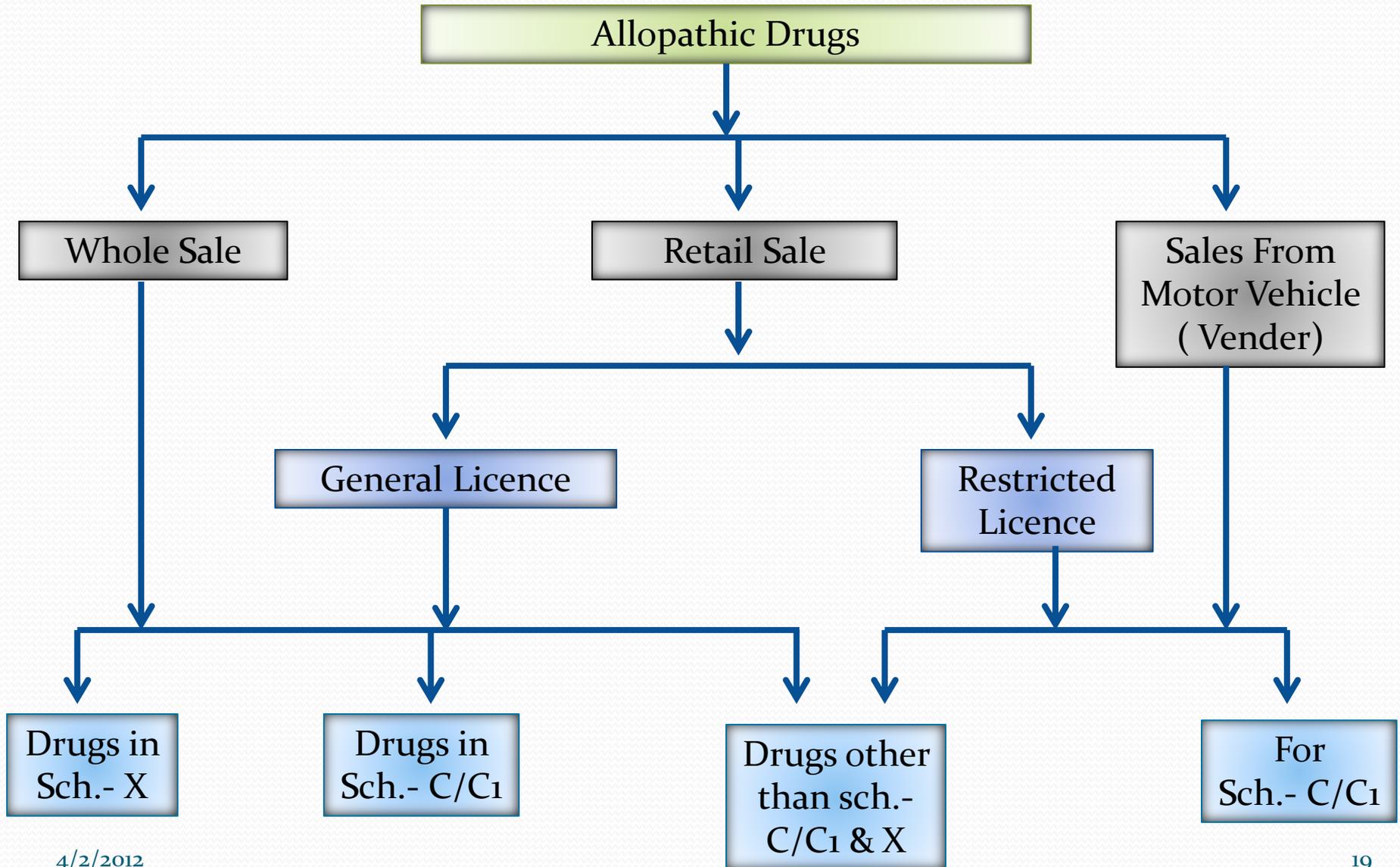
SALE



SALE OF DRUGS

- *Classes of drugs prohibited to be sold*
- *Wholesale of biological (C/C₁)*
- *Wholesale of other than those specified in C/C₁ and X*
- *Wholesale of Sch-X drugs*
- *Retail sale*

TYPES OF SALES LICENCES



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*

FORMS

S.No.	Category	Type Sale	Application Form	Licence Form	Fees for Grant/Renewal	Renewal Certificate Form No.	Fee+ Penalty after expiry but within six months	Fees for duplicate copy of Org. Lic.
1	Drugs other than those specified in Schedule C&C (1)&X	Whole Sale	19	20-B	Rs.1500	21 -C	Rs.1500+Rs.500 p.m. or part there of	Rs.150
		Retail Sale	19	20	Rs.1500	21 -C	Rs.1500+Rs.500 p.m. or part there of	Rs.150
		Restricted(Gen.Store)	19-A	20-A R-61 (1)	Rs.500 R-59 (2)	21 -C	Rs.500+Rs.250 p.m. or part thereof R-59 (4)	Rs.150 R- 59 (3)
2	Drugs specified in Schedule C&C (1) but excluding those specified in Schedule 'X'	Whole Sale	19	21B	Rs.1500	21 -C	Rs.1500+Rs.500 p.m. or part there of	Rs.150
		Retail Sale	19	21	Rs.1500	21 -C	Rs.1500+Rs.500 p.m. or part there of	Rs.150
		Restricted(Gen.Store)	19-A	21-A R-61 (1)	Rs.500 R-59 (2)	21 -C	Rs.500+Rs.250 p.m. or part thereof R-59 (4)	Rs.150 R- 59 (3)
3	Drugs specified in Schedule 'X'	Whole Sale	19-C	20-G	Rs.500	21-C	Rs.500+Rs.250 p.m. or part there of	Rs.150
		Retail Sale	19-C	20-F R-61(1)	Rs.500 R-59(2)	21-C	Rs.500+Rs.250 p.m. or part there of R-59(4)	Rs.150 R- 59 (3)
4	Sale of Drugs from motor vehicles (1)	Whole Sale	19-AA	20-BB	Rs.500	21-CC	Rs.500+Rs.250 p.m. or part there of	Rs.150
	Drugs other than those specified in Schedule C&C (1)							
	(2) Drugs specified in Schedule C&C (1)	Whole Sale	19-AA	21-BB R-62-D	Rs.500	21-CC	Rs.500+Rs.250 p.m. or part there of	Rs.150
5	Homoeopathic Medicines	Whole Sale	19-B	20-D	Rs.250	20-E	Rs.250+Rs.50p.m. or part there of	Rs. 50
		Retail Sale	19-B	20-C R-67-C	Rs. 250 R-67-A(2)	20-E	Rs.250+Rs.50p.m. or part there of R-67-A(2)	Rs. 50 R-67-A(2) *GSR No. 421 dated 24/08/2001

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 ofhereby 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.**

RETAIL SALE

- 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 ator (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.....



LABELING & PACKAGING



- 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.

References

- Available on www.cdsco.nic.in
- “Pharmaceutical Jurisprudence” by Dr.G.K.Jani; Atul prakashan; Fifth edition(2005-06); 28-133.
- Forensic Pharmacy by C.K. Kokate and S.B. Gokhle; Published by Pharma Book Syndicate; 152.

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