Regulatory Compliance by Retail Pharmacy

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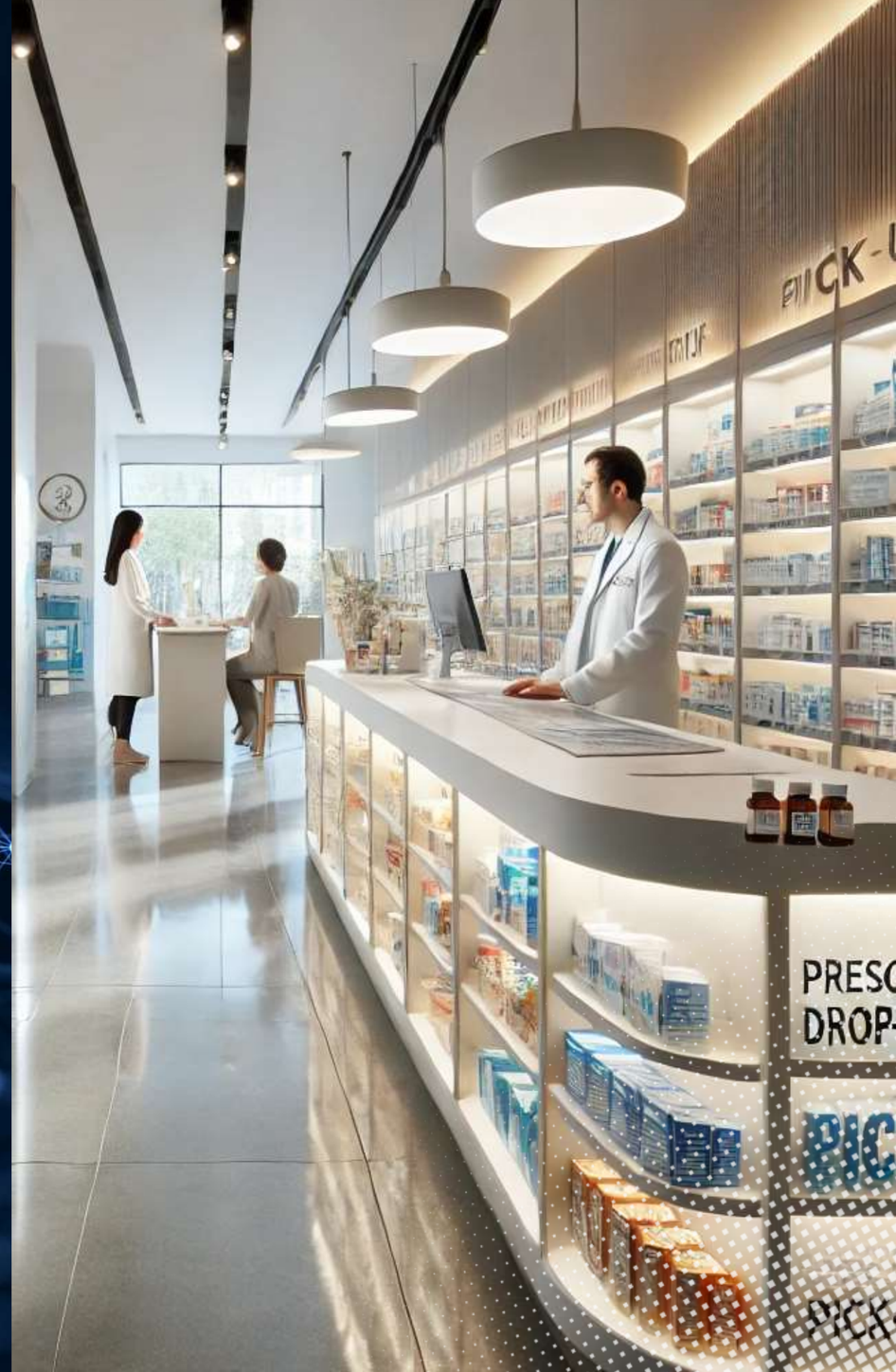
Agenda

- Retail Pharmacy
- Legality of Drug
- What is Prohibited Under Act
- About Drug License
- Conditions of License
- Liability Under the Act
- Patient Counselling
- Other Acts
- Online Pharmacies

Retail Pharmacy
(Chemists and Druggists)

- Retail pharmacy refers to the sale of medicines and other healthcare products to consumers through physical or online store.
- Retail pharmacies
  - Independently owned
  - Chain pharmacies
  - Affiliated with a hospital or healthcare system
- Pharmacy is both business and profession
- While operating as a business comprising of stringent regulations with ethical principles



Retail Sale(rule 2(f) & (g))

- Retail sale means a sale other than a sale by way of wholesale dealing (whether to hospital, or a dispensary, or a medical, educational or research institute or to any other person)

- Wholesale means a sale to a person for the purpose of selling again and include hospital, or a dispensary, or a medical, educational or research institute or to any other person.

Regulations

- Drugs and Cosmetics Act 1940
- Drugs and Cosmetics Rules 1945
- Drugs and Magic Remedies (objectionable advertisements) Act 1954
- Pharmacy Act 1948
- Drugs Price Control Order 2013

What is Drug?

Section-3(b) – Drug includes

(i) **All medicines** for internal or external use of **human beings or animals** and all substances intended to be used for or in **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**.

(ii) **such substances** (other than food) intended to affect the **structure or any function** of the human body or intended to be used for **destruction of (vermin)** or insects which cause **disease in human beings** or animals as may be **specified time to time** by central government by notification in the official gazette.

Section 3(b) continued.....

(iii) all substances intended for use as **components** of a drug including empty **gelatin capsules.**

(iv) Such **devices** intended for internal or external use in the diagnosis , treatment , mitigation or prevention of disease or disorder in human beings or animals as may be **specified from time to time** by the Central Government by notification in the **official Gazette** after consultation with Board.

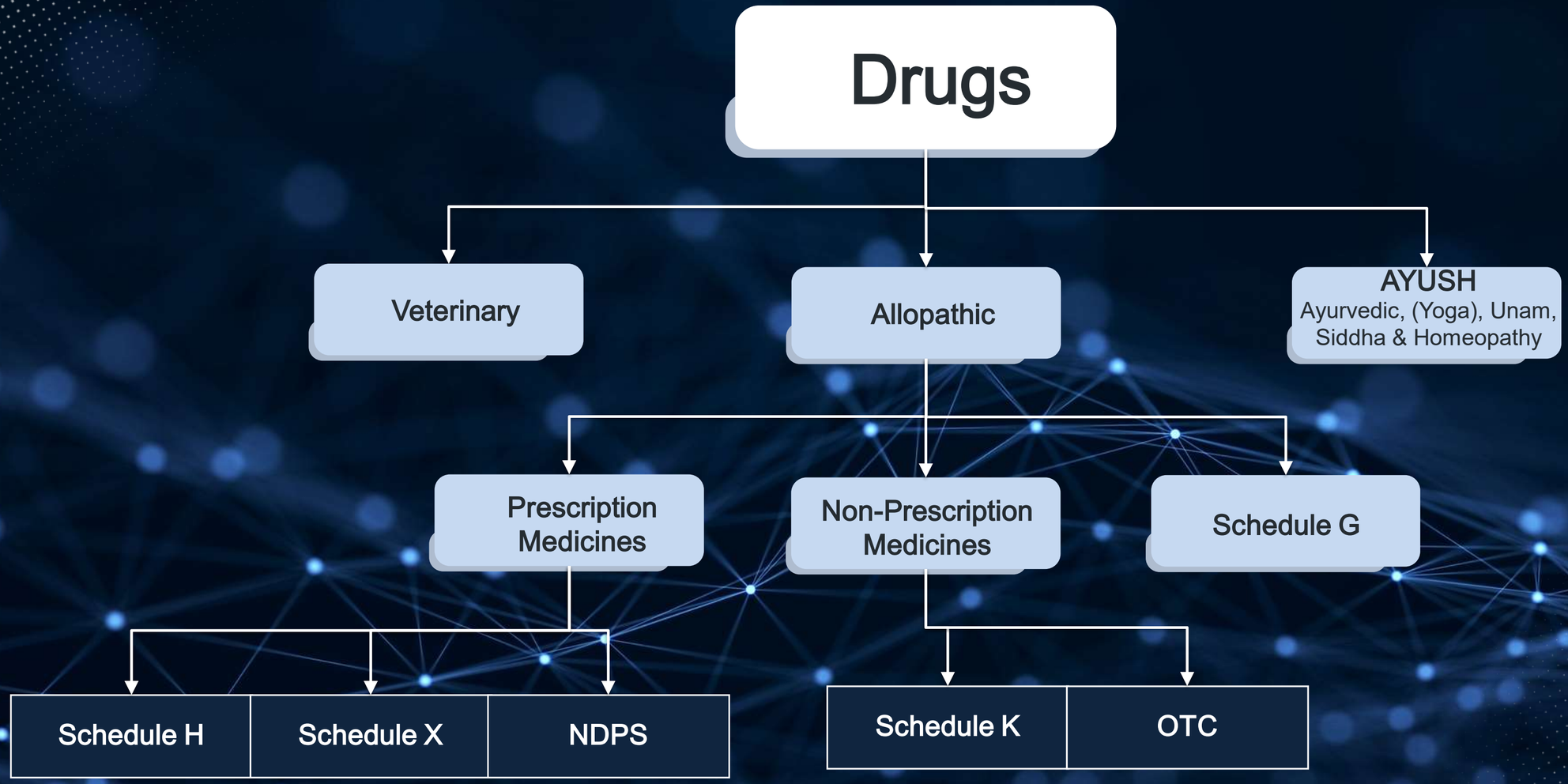
Cosmetic (section 3(aaa))

- Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on or introduced in to or otherwise applied to the human body or any part there of for cleaning , beautifying, promoting attractive ness or altering the appearance and include any article intended for use as a component of cosmetic.

- Note:- cosmetic requires manufacturing licence but not sale licence.

- Drug requires both manufacturing and sale licences.

Categories of Drugs



Certain Drugs and Cosmetics prohibited (Section 18)

- No person shall himself or any other person on his behalf
- Manufacture for sale (or for distribution) or sell , or stock, or exhibit (offer) for sale or distribute,

(i) Any drug not of standard quality , or misbranded or adulterated or spurious.

(ii)Any cosmetic not of standard quality or misbranded or spurious

(iii) Not displayed the true formula

(iv)Claimed for any disease or ailment which prohibited

(v) Cosmetic containing harmful ingredient.

(vi) Any drug or cosmetic in contravention of provision.

Section 18 continued...

- sell or stock or exhibit(offer) for sale or distribute any drug which has been imported or manufactured in contravention of the provisions

- manufacture for sale(or for distribution) or sell or stock or exhibit for sale or distribute **without a valid license.**

Prohibited Drugs

- **Not of Standard Quality Drug**

  Drugs not complied with the standards laid down under Indian pharmacopeia or in any other pharmacopeia or prescribed standards .

- **Misbranded drug SEC17**

  damage is concealed by coloring, coating, polishing or made to appear better therapeutic value or not labeled in prescribed manner

Prohibited Drugs Cont....

- **Adulterated** Drug SEC17A
  - (a)Filthy or putrid or decomposed substance. (b) Prepared under unsanitary conditions and rendering injurious to health. (c) Container is composed any poisonous substance rendering injurious to health. (d) Color other than prescribed. (e) Contains any harmful or toxic substance. (f) Any substance mixed to reduce its quality or strength.

- **Spurious Drug** SEC17B
  - (a) Sold under the name which belongs to another drug. (b) Imitation of another drug. (c) Labeled under the name of fictitious company. (d) Substituted wholly or part. (e) Not truly the product of the manufacturer labeled.

Ban of Drugs & Cosmetics in public interest

Section 26A:

Likely to cause risk in human beings or animals does not have therapeutic value claimed no therapeutic justification.

Types of Sales Licenses

Type of drugs	Retail	Wholesale	Wholesale and Retail	Restricted
Other than Schedule-C, C1 and X.	Form-20	Form-20B	Form-20 & 20B	Form-20A
Schedule-C, C1 excluding Sch-X.	Form-21	Form-21B	Form-21 & 21B	Form-21A
Schedule-X drugs	Form-20F	Form-20G	-	-
NDPS drugs	NDPS-2	NDPS-1	-	-

Application Fees Structure For Sales License

Application Form	Licence Form	Grant Licence Fee	Licence Retention Fee	Late fee per month	Duplicate Licence fee
19	20 (Retail)	1500	1500	2%. of the licence fee	150
19	21 (Retail)	1500	1500	2%. of the licence fee	150
19	20B (Wholesale)	1500	1500	2%. of the licence fee	150
19	21B (Wholesale)	1500	1500	2%. of the licence fee	150
19C	20F (Retail)	500	500	2%. of the licence fee	150
19C	20G (Wholesale)	500	500	2%. of the licence fee	150
19A	20A (Restricted)	500	500	2%. of the licence fee	150
19A	21A (Restricted)	500	500	2%. of the licence fee	150
Application	NDPS-2 (Retail)	50	50		
Application	NDPS-1 (Wholesale)	50	50		

Conditions to be satisfied before grant / renewal of licenses (Rule 64)

1) **Premises are adequate**
   Retail – Form 20 or Form 21 or both - not < 10 Sq. mts
   Whole Sale – Form 20 B or Form 21B or both - not < 10 Sq mts
   Both retail and whole sale - not < 15 Sq mts
2) **Equipped with proper storage accommodation**
   Cool Place – 10 ^{o}C - 25 ^{o}C
   Cold Place - Not exceeding 8 ^{o} C
3) **Person competent for sale and presentation of Drug**
   1) Registered pharmacist in case of Retail
   2) Competent person in case of Whole Sale

Additional Information (Rule 65 A)

A
1) Evidence on ownership or rental or other basis
2) Constitution of the firm
3) Any other relevant matter

B
Refusal of grant or renewal
1) Conviction
2) Previous cancellation or suspension

C.
Appeal within 30 days to the state government - Rule 64(3)

Restricted licenses in Form 20 A and 21A (Rule 62-A)

a) For sale of Drugs, does not require qualified person
b) Itinerant Vendors - exceptional circumstances
c) Travelling agents - Specific purpose

Conditions (Rule 62-B)
1) Adequate premises
2) Equipped with storage accommodations

❖ **Sale of Drugs by Whole sale from (Rule 62-C)**

Such licenses not required in case of public carrier or hired vehicle

Conditions of Licenses (Rule 65)

1) Compounding the Drug – by Registered Pharmacist

2) Supply by retail sale on prescription by or under personal supervision of registered pharmacist

3) Supply on prescription recorded in prescription register particular with (a) to (g) Or cash or credit memo book(sale bill).

(a) Sl.No. (b) Date (c) Prescriber (d) Patient (e) Name of the drug, quantity

(f) Manufacturer, Batch Number & Expiry (g) Signature,PH

Conditions of Licenses (Rule 65) Cont....

4) Supply other than prescription of Schedule ‘C’ Drug

Particulars (a) to (f) – Register or cash or credit memo book

- Supply by retail shall be with cash or credit memo with particulars

  (a) Name, address, sale license number (b) SL.No.

  (c) Name & quantity of drug

- Records of purchase in a chronological order by retailer

5) Whole sale supply against cash or credit memo particulars

(a) Date (b) Name and address of licensee

(c) Drug, quantity, batch number

(d) Name of manufacturer (e) signature of competent person

- Records of purchase by wholesaler

Conditions of Licenses (Rule 65) Cont....

6) Supply of information, registers and records to drugs inspectors
7) Preservation of records for not less than 2 yrs
8) Register under any other law permitted
9) (a) Schedule H & X drugs shall be sold on prescription
   (b) Supply to Medical practitioners, hospitals, dispensaries and nursing homes against the signed order
10) Prescription is defined to possess
   (a) Writing & sign
   (b) Name and address of the patient
   (c) Total medicine and dose

Conditions of Licenses (Rule 65) Cont....

11) Compliance for supply of Sch H drug (or X)
    a) Dispense not more than once unless...
    b) Dispense stated number of times & intervals
    c) Noted on the prescription

11A) No Substitution of Sch H or X drugs

12) Manner of storing Sch X Drugs

13) . . . (Omitted)

14) . . . (Omitted)

15) Description of
    a) Drug store
    b) Chemists and Druggists
    c) Pharmacy

16) Maintenance of Inspection Book in Form 35

Conditions of Licenses (Rule 65) Cont....

17) Prohibition of sale or stock of Expiry Drug / Violation of Direction
18) Prohibition of free samples to Medical profession, ESI, CGHS, Govt MSD, AFMS or other Govt institutions - unless authorized
19) Supply of Drug in another container by pharmacist noting particulars on the wrapper etc

    Name – quantity - address
20) Medicines for treatment of animals
21) Records to be maintained for supply of Sch X Drugs
    a) Register
    b) Particulars (I) to X

Conditions of Licenses Cont....

- Displayed in a prominent place
- Comply with the provisions of drugs and cosmetics Act 1940 & Rules 1945
- Change in the qualified staff to be informed to licensing authority with in 1month.
- Drugs to be purchased under cash or credit memo from a duly licenced dealer or manufacturer
- Change in the constitution valid for 3 months – meanwhile with fresh licence with changed constitution to be obtained

Some important schedules

1) Schedule C (Biological and other special products)
2) Schedule C1(Other special products)
3) Schedule H(Prescription Drugs)
4) Schedule K(Exemptions)
5) Schedule P(Life period of drugs)
6) Schedule P1(Pack size of drugs)
7) Schedule J(Diseases that are not to be claimed for cure)
8) Schedule X(Some habit forming drugs)

Drugs supplied by registered medical practitioner exempted(Schedule K(5))

- Drug supplies by a registered Medical Practitioner to his own patients are exempted from taking License for sale of drugs under the provisions of Drugs & Cosmetics Acts & Rules, subjected to following conditions:
- Not keeping an open shop or selling across the counter or engaged in the import, manufacturing, distribution or sale of drugs in India.
- Drugs shall be purchased only from the licensed dealer or Licensed Manufacturer
- Shall Keep the record of purchases showing the name and quantity of each drug, batch no., and Name along with address of manufacturer.
- Record shall be open to inspection by inspector appointed under Drugs & Cosmetics Acts.
- Allow to take Samples for test.

Cont....

- Incase of Schedule G, H/H1 or X drugs the medicines shall be labeled with the name and address of RMP by whom it is supplied.
- Record shall be maintained regarding the name and quantity of each drug, dose, Name of Patient, Date of Supply, Serial No (Which is to be maintained on label), and preserve these records for 2 years from the date of entry in register.
- Store must be proper storage condition
- Drugs supplied by a hospital or dispensary maintained or supported by more than one RMP shall not sale any drugs without license. License is must for such units.

Prescription

Dr. Armaan Shukla
MBBS, D.Ortho Reg.no. MMC 2314
Address: 12 Gharse Towers, M.G.Road, Mumb ai-4
Tel. no. 022-22242862

Date: 1/1/2005

For Mr L.M.Nayak Age – 17 years
Address – 2/1 Antop Hill, Mumbai - 18
Tel. No. 2842862

Rx

1. Tab. Valdecoxib 20mg .... (10)
   1 – 0 – 1 x 5 days.
   Take 1 tab after breakfast and 1tab after dinner for 5 days.

(Signature of Doctor)

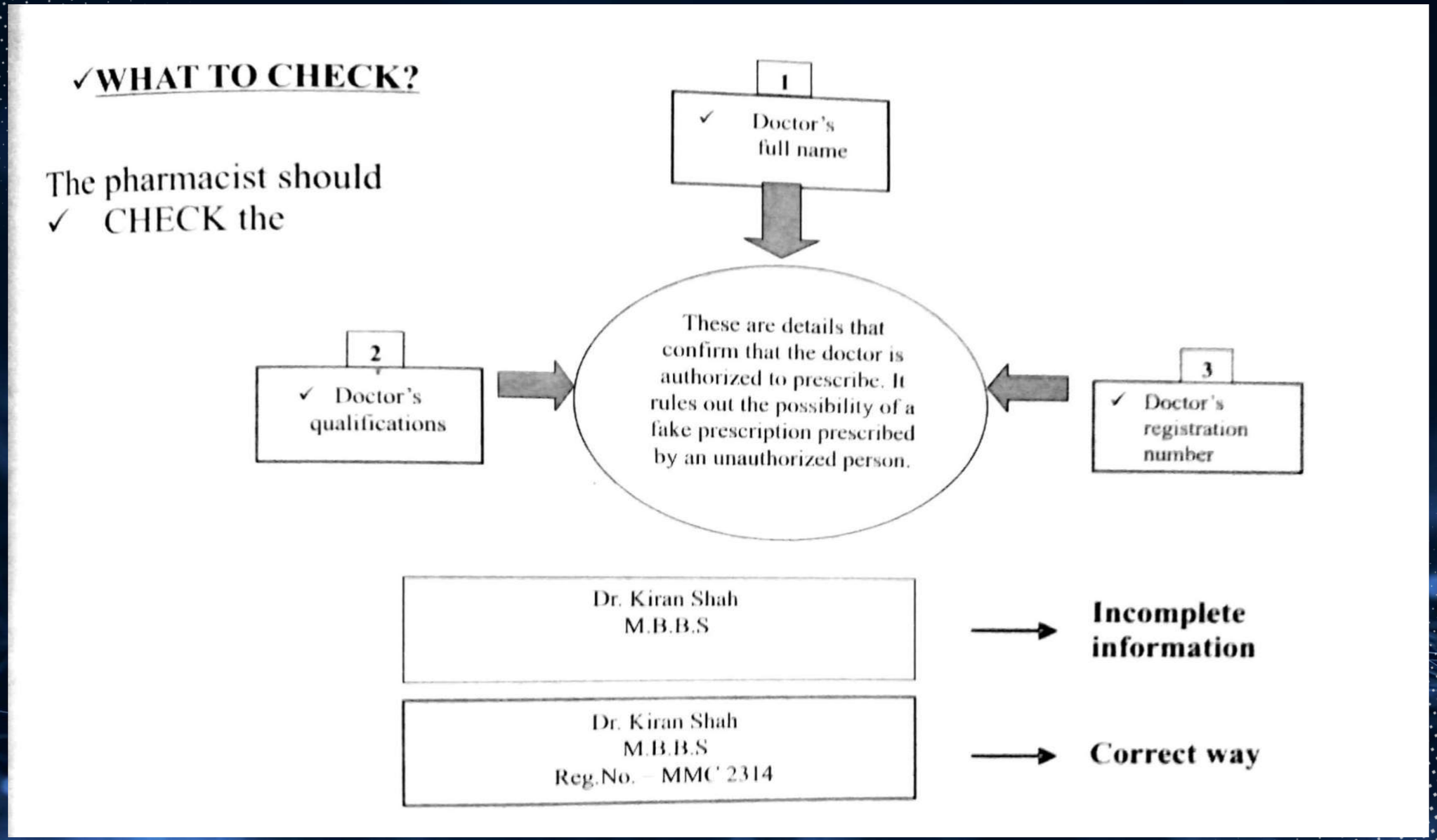
Refill info: ☐ Do not refill
No. of refills ☑ 1. ☐ 2. ☐ 3.

Refilled once

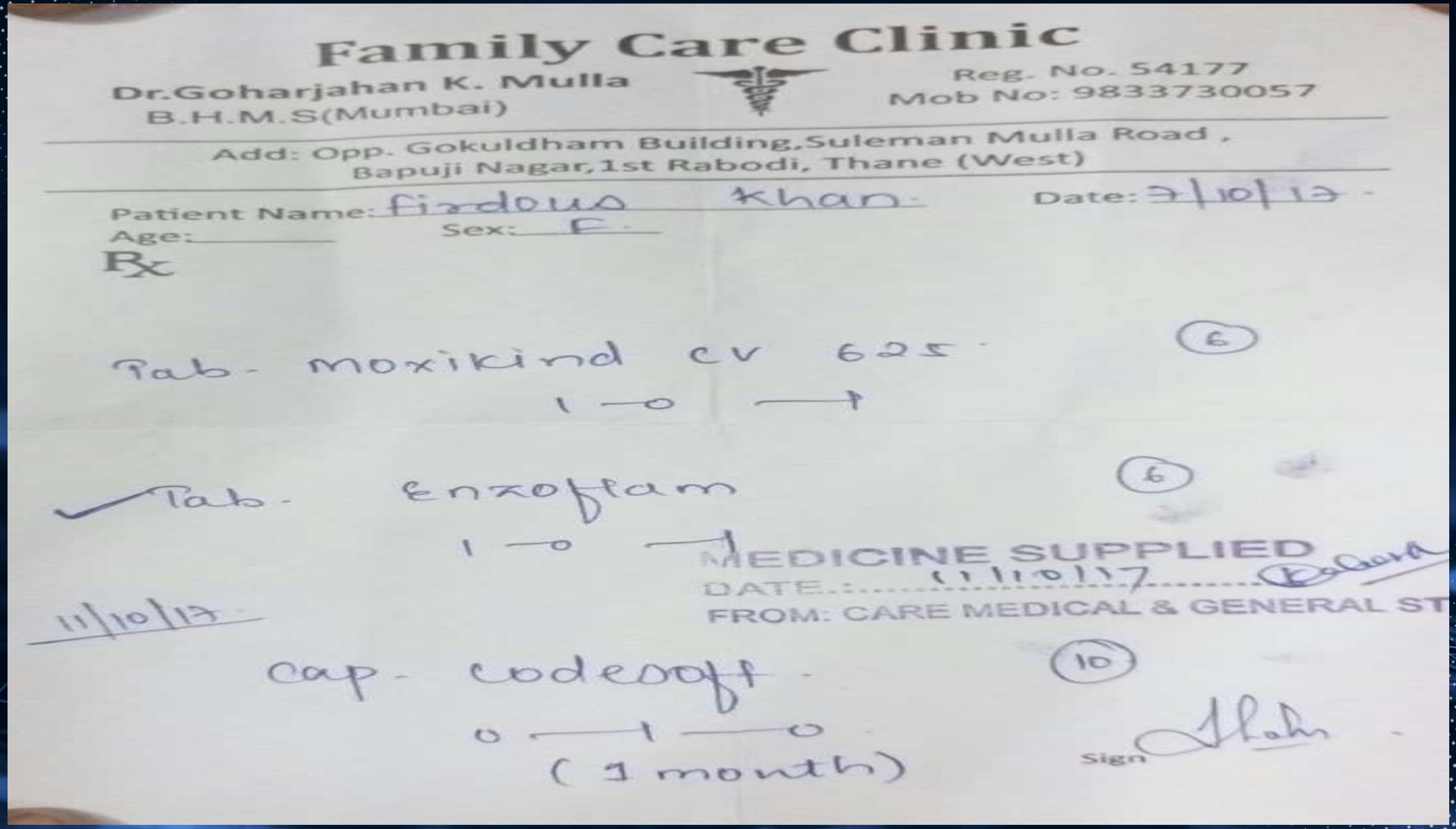
(Sign of Pharmacist) Date of refill
sd/- 8/1/05

DISPENSED
ABC Pharmacy
Date 2/1/05
Sign of pharmacist
sd/-

Contents Of Prescription



Sample Prescription With Supplied Stamp



Family Care Clinic

Dr.Goharjahan K. Mulla
B.H.M.S(Mumbai)

Reg. No. 54177
Mob No: 9833730057

Add: Opp. Gokuldham Building,Suleman Mulla Road ,
Bapuji Nagar,1st Rabodi, Thane (West)

Patient Name: firdous khan. Date: 7/10/17.
Age: Sex: F.

℞

Tab. Moxikind CV 625 (6)
1 — 0 — 1

Tab. Enzoflam (6)
1 — 0 — 1

MEDICINE SUPPLIED
DATE: 11/10/17
FROM: CARE MEDICAL & GENERAL ST

11/10/17

Cap. Codesoft (10)
0 — 1 — 0
(1 month)

Sign

Concept of Absolute Liability

- **Section 19(i) :** Save as herein after provided in this section, it shall not be a defense in prosecution under this chapter to prove merrily that the accused was ignorant of the nature , substance or quality of drug(cosmetic) in respect of which the offence has been committed.
  - This section imposes absolute liability.
  - Mensrea is not available as defense.
- **Section 19(3):** A person not being manufacturer has to prove three ingredients as defense.
  (1) Acquired from duly licensed manufacturer.
  (2) Reasonable diligence used .
  (3) Properly stored.

Offences by companies

- **Section 34 :**

1) Every person in charge of and responsible for business and as well as company deemed to be guilty.

(person not liable if he proves offence committed without his knowledge or exercised diligence to prevent it)

2) Offence committed with the consent of Director, Manager, Secretary or other Officer such persons also liable

Common Mistakes

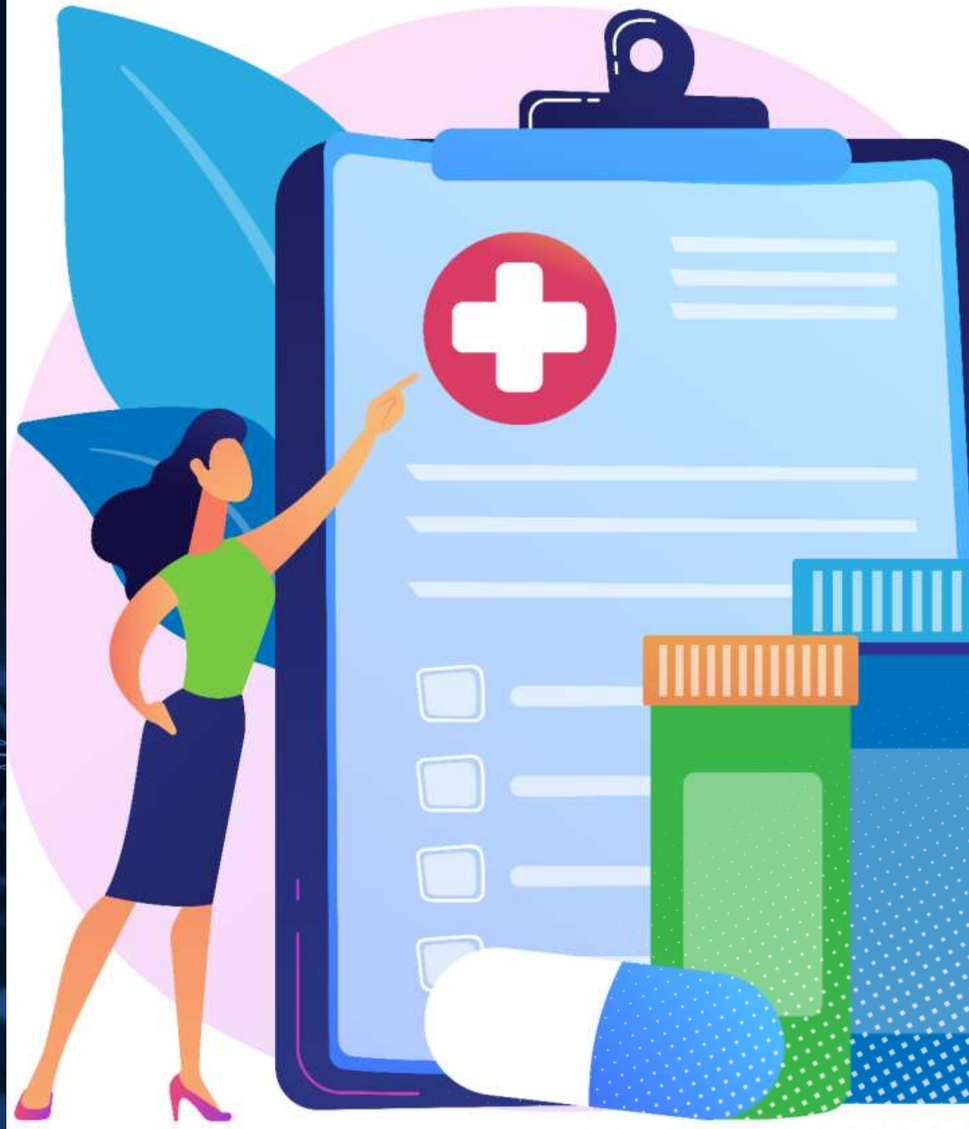
- Sale in absence of a Pharmacist.
- Wrong entries in the sales bill.
- Not verifying the details in the purchase bills.
- Sale with improper/without prescriptions.
- Stamping on the prescriptions.
- Segregation of veterinary drugs.
- Overall Cleanliness.

Common Offence

- Issue of bills without purchases and sale.
- Bills issued only for reimbursement.
- Purchase without purchase bills.
- Obligation of labels e.g. change in expiry date, removing words ‘Physicians sample’, ‘Hospital supply’ goods, govt, supply etc.
- Proper name not written on bills.

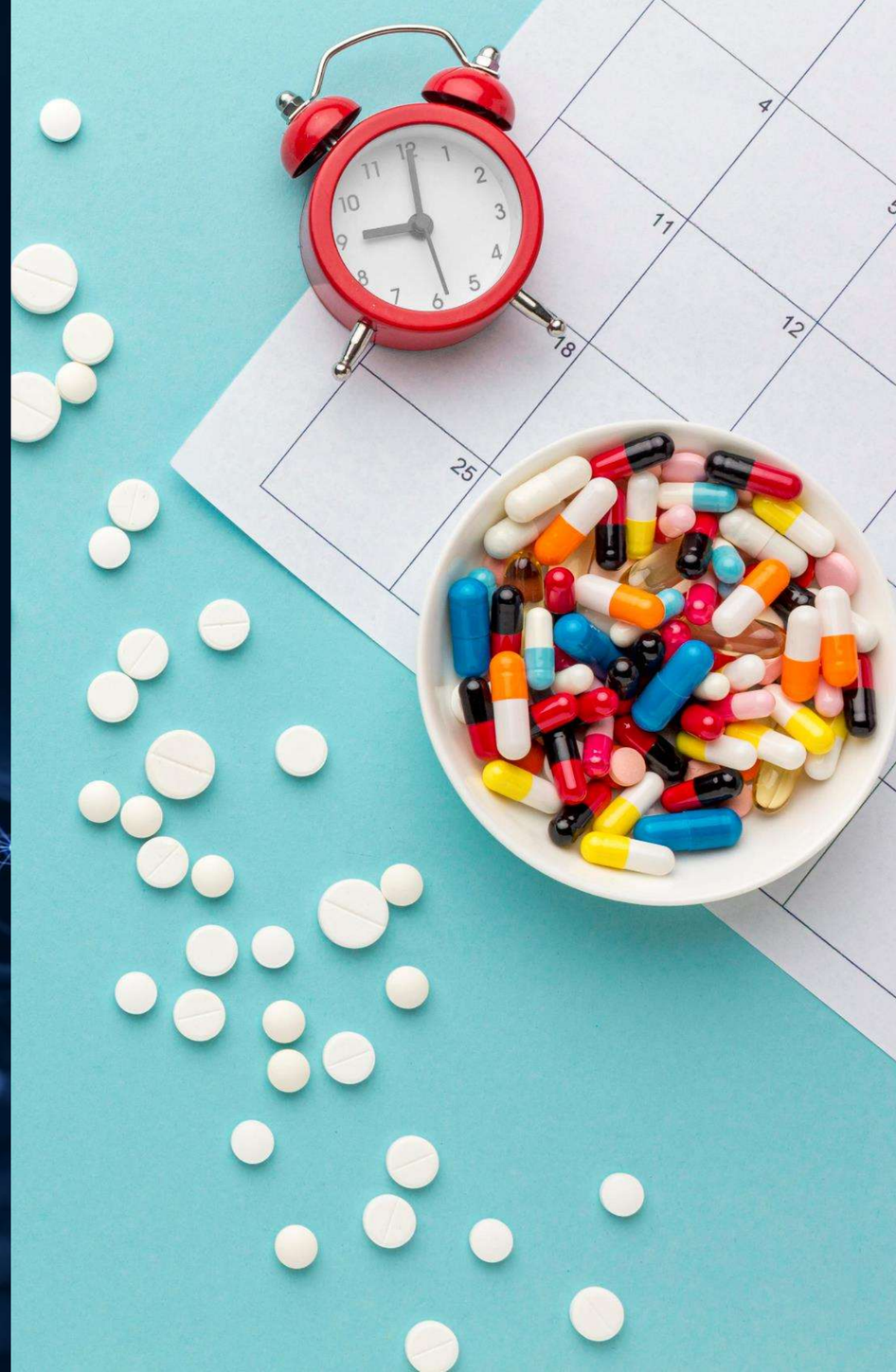
Patient Counselling- Why?

- Intake of Drugs with food and drinks
- Drugs to be avoided in pregnancy and lactation
- Drugs Alcohol interactions
- Drugs Nicotine interaction
- Drugs to be avoided in Children
- Discoloration of Feces /urine
- Alertness.
- To be discarded within 30 days of opening the bottle. (ask patient to write the date of opening of bottle on label at the time of opening)



General Instructions - Prescription

- Time of Administration
- Take the medicine at the same time each day.
- Skipped dose, what to do?
- Potential common and severe adverse effects.



Object of the DMR(OA) Act 1954

- To control drug advertisements in certain cases.
- Prohibit advertisements for remedies that claim to have magical powers.
- Prevent the advertisements of drugs for certain diseases and disorders that are listed in the Schedule.
- To prevent people from self medication

Advertisement

- **Section 2 (a)** – ‘advertisement’ includes
  - any notice, circular, label, wrapper, or other document
  - any announcement made orally or
  - by any means of producing or transmitting light, sound or smoke;

- Advertisement relates to commerce or trade and not to propagating ideas

- **Section 2 (c)** – ‘magic remedy’ includes a talisman, mantra, kavacha, and any other charm of any kind

- alleged to possess miraculous powers for or in diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals;

Other Acts

- **Pharmacy Act 1948**
  - Registration as a pharmacist with state pharmacy counsel to obtain RP certificate.
  - Requires regular training certificate for renewal.

- **Drugs price control order 2013**
  - Retail pharmacy should sell drugs as per MRP on the label, suffered taxes can be added.
  - Refusal to sell drugs is offense.

Online Pharmacies

- Currently there are no specific laws.
- They are being regulated under Drugs and Cosmetics Act 1940 and Rules 1945.
- E-pharmacy should sell schedule H drugs after obtaining a valid prescription from a registered medical practitioner.
- Draft rules are proposed – Drugs , Medical Devices and Cosmetics Bill 2022, includes regulations on E-pharmacies, it is yet to be approved.


Thank you!