DRUG SCHEDULES

Ms. PRIYA TIWARI
Assistant Professor
Faculty of Pharmaceutical Sciences
Rama University
Kanpur

- Therapeutic goods in the United States are regulated by the U.S. Food and Drug Administration (FDA), which makes some drugs available over the counter at retail outlets and others by prescription only.

Each of the controlled substances is identified under one of five Controlled Substances Schedules.

- Schedule I
- Schedule II
- Schedule III
- Schedule IV
- Schedule V

- **Schedule I Drugs –**
- High potential for abuse.
- No accepted medical use in the U.S. or lacks accepted safety for use in treatment in the U.S.
- –May be used for research purposes by properly registered individuals.
- Examples: heroin, methylene dioxymethamphetamine, lysergic acid diethylamide, mescaline, and all salts and isomers thereof

- **Schedule II Drugs**
- High potential for abuse.
- Has a currently accepted medical use in the U.S.
- Abuse of substance may lead to severe psychological or physical dependence.
- Examples: morphine, oxycodone, fentanyl, meperidine, dextroamphetamine, cocaine, amobarbital

- **Schedule III Drugs**
- Abuse potential less than substances in schedule I or schedule
- Has a currently accepted medical use in the U.S.
- Abuse of substance may lead to moderate to low physical dependence or high psychological dependence.
- Examples: anabolic steroids, nalorphine, ketamine, certain schedule II substances in suppositories, mixtures, or limited amounts per dosage unit

- **Schedule IV Drugs –**
- Abuse potential less than substances in schedule III.
- Has a currently accepted medical use in the U.S.
- Abuse of substance may lead to limited physical or psychological dependence relative to substances in schedule III.
- Examples: alprazolam, phenobarbital, meprobamate, modafinil

INDIAN SCHEDULES:

- Schedule A
- Gives the specimens of prescribed forms necessary for obtaining licenses, permits, certificates, intimations and so on.
- FORM 2A- Certificate of test or analysis from the Pharmacopoeial Laboratory for Indian Medicine or Government Analyst
- FORMS 3-7- (Omitted)
- FORM 8 -Application for licence to import drugs –biological and other special products (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945
- FORM 9 - Form of undertaking to accompany an application for an import license
- FORM 46- Permission / Approval for manufacture of new drug formulation
- ■There are in total upto 50 forms.

Schedule B

- This Schedule includes fees for test or analysis by the Central Drug Laboratory or the Government Analyst.

1. Fees for test and assay of Drugs requiring use of animals – Eg:- Adrenocorticotrophic hormone assay- 1000 Rs
2. Microbiological tests and assays – Eg:- Microbiological assay of vitamins - 300 Rs

Schedule B(1)

Fees for the test or analysis by the Pharmacopoeial Laboratory for Indian Medicine (PLIM) or the Government analyst

Eg:- Determination of lethal does LD 50 to 10 on mice – 2500 Rupee

- Schedule C:-
- Includes biological and special products such as Sera, Vaccines, Antigens,Toxin, Antitoxin, Insulin, Bacteriophages, solution of serum proteins intended for injection, etc.
- Schedule C1:-
- Includes Other Special products such as Digitalis Preparations, fish liver oil, ergot preparations, Liver extract, vitamins, hormones, etc.

■ Labelled with the words-- 'Caution: It is dangerous to take this preparation except under medical supervision'.

■ Prohibition of import of these products after expiry of potency

Schedule D

- Provides extent and conditions of exemption regarding import of drugs.

Eg:- Class of drugs which are substances not intended for medicinal use

- If the substance is imported in bulk, the importer should certify that the substance is imported for non-medicinal uses, and
- If imported otherwise than in bulk, each container should bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use.
- E.g. Skimmed milk, powdered milk fortified with vitamins, Lactose, cereal products, oats, ginger, pepper, cummins, etc. come under this class of drugs.
- Shedule DI- permission for manufacture and DII- permission for import.

- Schedule E

Omitted as per GOI Notification

- Schedule E (I):-

List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine : Ayurvedic System:-

- Drugs of Vegetable origin :- Bhang, Dhatura, Jaiphala, etc
- Drugs of Animal origin :- Snake Poison
- Drugs of Mineral origin :- Hartala (arsenic), Parada (mercury), etc.

Schedule F

- It includes requirements for the Functioning and operation of a blood bank and / or for preparation of blood components.
- General :- Blood bank location, infrastructure requirements, Staff and equipments required, etc.
- Minimum requirement for grant of license to procure blood components from whole human blood.

- F (I) :- Give details of the standards of bacterial vaccines, antisera and diagnostic antigens.
- F (II):- Standards for Surgical Dressings that include bandage cloth, absorbent gauze, rolled bandage,etc.
- F (III):- Standards For Umbilical Tapes like umbilical polyester tape, cotton tape, etc.

- Schedule FF

It lays down Standards for Ophthalmic preparations. Ophthalmic Solutions and suspensions.

1. sterile when dispensed
2. contain suitable substances to prevent the growth of micro-organisms
3. free from foreign matter & in bottles made of either neutral glass or soda glass.
4. Label Contains:- 'Use the solution within one month after opening the container'.

The words 'NOT FOR INJECTION'.

WARNING:- " Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solutions".

- Schedule G
- Medicines listed as schedule G medicines carry on the label a caution
- Caution – “it is dangerous to take this preparation except under medical supervision”
- The Caution is conspicuously printed and surrounded by a line within which there should be no other words.
- It is necessary to make proper bill of sale.
- Records of purchase and sale of these medicines must be maintained for a period of 2 years.
- Eg: Aminopterin, L-Asparaginase, Bleomycin, Busulphan, Chlorambucil, Chlorthiazide, Glibenclamide, Hydantoin, Hydroxyurea, Insulin, Metformin, etc.

- Schedule H
- This Schedule includes PRESCRIPTION DRUGS i.e. Drugs and Medicines which must be sold by retail only when a prescription by RMP is produced.
- The time and date of prescription must be noted.
- The drug label must display the texts "Rx" and "Schedule H drug.
- Warning : To be sold by retail on the prescription of a Registered Medical practitioner only" prominently.
- Drugs specified in Schedule H, and comes within {Narcotic Drugs and Psychotropic Substances Act, 1985} labelled with the symbol "NRx" & Schedule H drug Warning prominently.
- Eg:-Abxicimab, Acyclovir, Diclofenac, Baclofen, Carbidopa, Terazosin, etc.

- Schedule H1
- Introduced under the Drugs and Cosmetics (4th amendment) rules 2013, to regulate sale of antibiotics.
- To have separate regulation to check unauthorized sale of antibiotics, thus monitoring use and abuse of these antibiotics.
- Here, the drug has to be labelled with symbol “Rx” in red and conspicuously displayed on left corner of the label with the following words in box with red border
- Warning 1. It is dangerous to take this preparation except in accordance with the medical advice.
- 2 Not to be sold by retail without the prescription of a RMP.
- Eg:-Gemifloxacin, Cefixime, Levofloxacin, Cefpodoxime, Clofazimine, Zolpidem, etc

- Schedule I
- Particulars as to proportion of poison in certain cases.
- Omitted by GOI Notification .

Schedule J

- Contains a list of various diseases and conditions which a drug may not purport to prevent or cure or make claims to prevent or cure.
- No drug may legally claim to treat these diseases.

Eg :-AIDS, Blindness, Deafness, Encephalitis, Diabetes, Leukemia, Paralysis, etc.

Schedule- K

- Drugs exempted from certain provisions relating to the manufacture and sale of drugs
- Currently, non drug-licensed stores (e.g. non-pharmacists) can sell a few medicines classified as 'Household Remedies' listed in Schedule K.
- Eg- Paracetamol tablets, Analgesic Balms, Antacid Preparations, Calcium preparations with or without Vitamin D, Gripe Water for use of infants, Inhalers (containing drugs for treatment of cold and nasal congestion), Syrups lozenges, pills and tablets for cough, cold or sore throat.

- Schedule L :-
- Omitted Schedule L
- Good Laboratory Practices and requirements of premises and equipments, Chemicals & Reagents, etc.

Schedule M

This Schedule includes Good Manufacturing Practices and requirements of premises, plant and equipment for manufacture of pharmaceutical products.

- Part 1 :-Good Manufacturing Practices for premises and materials.
- Part 2 :- Requirements of Plant and equipments

- M- I:- Prescribes in detail requirements of factory premises for the manufacture of Homeopathic drugs.
- M- II:- Prescribes requirements of factory premises for manufacture of cosmetics.
- M- III:- Prescribes requirements of factory premises for manufacture of medical devices.

- Schedule N

List of minimum equipment for the efficient running of a pharmacy

Gives directions to Pharmacies regarding:-

a) Entrance of Pharmacy
b) b) Premises
c) c) Furniture & Apparatus
d) d) General Provisions.

Schedule O

Deals with the provisions applicable to disinfectant fluids.

- Part 1:- Provisions applicable to black and white fluids
  Part 2:- Provisions applicable to Other Disinfectants.

Schedule P

- It deals with life period of drug and the conditions of the storage of drugs.
- Period in months (unless otherwise specified) between date of manufacture and date of expiry
- ampicillin- stable for 36 month and store in cool place
- Schedule P1
- specifies the pack size of certain drugs
- Aspirin (Low Dose) Tablets 14 Tabs per pack.

- Schedule Q
- Gives the list of dyes, colors and pigments permitted to be used in cosmetics and soaps.
- No drug should contain a colors other than specified by the Bureau of Indian Standards below :

(1) Natural Colors:- Carotene, Chlorophyll, Red Oxide of Iron, Yellow Oxide of Iron, Titanium Di-oxide, Black Oxide of iron

(2) Artificial Colors:-Caramel

(3) Coal Tar Colors

- Schedule R
- Standards for mechanical contraceptives.
- Eg. Cu-T, etc
- Label contain:- – The date of manufacture.
- – The date up to which the contraceptive is expected to retain its properties.

Schedule R1

- Standards for medical devices.

The following medical device shall conform to the Indian Standards specification laid down from time to time by the Bureau of Indian Standards: -

1. Sterile Disposable Perfusion sets for single use only
2. Sterile Disposable Hypodermic Syringes for single use only
3. Sterile Disposable Hypodermic Needles for single use only

Schedule S

- Prescribes Standard for Cosmetics
- The following cosmetics in finished form should conform to the specifications laid down from time to time by the Bureau of Indian Standards (BIS).

Skin Powders , Tooth Powder, Toothpaste ,Shaving Creams, Hair Creams.

Schedule T

- Lays down the Good Manufacturing Practices for Ayurvedic, Siddha and Unani Medicines
- PART I:- Good manufacturing practices.
- PART II:- List of recommended machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of ayurvedic, siddha system of medicines.

Schedule U & U1

- Gives the particulars to be shown in manufacturing records.
- Gives the particulars to be recorded of raw materials.
- Gives the particulars to be recorded in analytical records.
- The records or registers shall be retained for a period of 5 years for Drugs & 3 years for Cosmetics from the date of manufacture

Schedule V

- Give details of standards for patent and proprietary medicines.

Schedule W

- Inserted as per G.O.I in 1981 and deleted IN 2000.
- Gives the name of the drugs which shall be marketed under generic names only.
- Its label contain the Names and quantities of active ingredients.

- Schedule X
- Contains list of narcotic drugs and psychotropic substance.
- Have a warning mentioned on a label 'Schedule X drug' - Warning : to be sold on retail on prescription of a RMP only.
- The label will also have a symbol 'NRx' in red & conspicuously displayed on the top left corner.
- After dispending the drug the pharmacist must Stamp & retain the prescription for 2 years.
- Maintain & record purchase & sale of the drug and preserve it for a period of 2 years from the date of transactions.
- All the regulations of Schedule H apply. The drugs must be kept under lock and key.
- Examples of few drugs under schedule X :- Phencyclidine, Secobarbital, Amobarbital, Amphetamines, Glutethimide, Methylphenidate, etc.

Schedule Y

- This Schedule includes requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials It include:
- Application for permission
- Clinical trial:-

✓ Approval for trial

✓ Responsibilities of sponsor, investigator, Ethics Committee

✓ Phases I, II, III, IV

✓ Studies in special population like Geriatric, Pediatric and Pregnant/ Nursing women

✓ Post Marketing Surveillance