DRUG REGULATION

By

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WHY

Doctors prescribe the medicine and patient consumes but neither of them is sure about purity, stability, efficacy and safety of drugs.

WHY

- Thus, there is need to maintain the same. The prescriber (clinician) and the consumer (patient) should be assured and this is done by regulatory authority (government) of various countries.

PRINCIPLES OF REGULATIONS

1. Drugs should not be supplied without license

2. The license is granted on the basis of scientific evaluation that is concerned with efficacy, safety quality of drugs and supply.

PRINCIPLES OF REGULATIONS

3. License is extended after expiry as per the requirement.

4. A drug may be banned at any time if need is felt e.g. if serious adverse effect is produced. e.g. in 1982 benoxaprofen, a non-steroidal anti inflammatory agent was withdrawn due to serious adverse effects that include onycholysis and photosensitivity.

DRUG SCHEDULE

- Further to regulate the drugs various categories of drugs have been assigned a schedule and every prescriber/clinician must be aware of these schedules and should consider the schedule before the prescription and accordingly prescribe a drug.

The Drug & Cosmetics Act (1940)

- The import, manufacture, distribution and sale of drug are regulated by The Drug & Cosmetics Act (1940) of Government of India. Subsequently amendments have been made to existing drug schedule.

Schedule H

(Prescription drugs): These drugs sold only when a registered medical practitioner prescribes. The warning is mentioned on the label and it also has symbol Rx in red colour.

Schedule H1

Schedule H1: This schedule is recently created w.e.f. March, 2014: Certain drugs have been omitted from schedule H and included in schedule H1 such as CNS drugs acting on CNS e.g. alprazolam, diazepm and antimicrobials e.g. ceftazidime, cefpirome etc.

Schedule G:

- This includes the dangerous drugs and provides a list of drugs with a label that states caution. Such preparation must always be used under medical supervision.

Schedule X

- It includes drugs which have addiction or dependence liability e.g. sedative hypnotics such as barbiturates, benzodiazepines, opioids. Strict directions are mentioned with regard to labeling, prescription, storage and sale of these drugs

Schedule X

- These drugs must be kept under lock and key in safe so that only the responsible person can have access. These drugs are available on prescription by registered medical practitioner and the prescription should be in duplicate and one copy should be preserved for about 2 years by the retailer/supplier and they should maintain the record of supply of these drugs in a special register for this purpose.

Schedule X

- The symbol used for narcotic drugs is NRx in red colour and for other drugs included in schedule X is XRx in red colour.

Schedule P

- It includes regulations regarding life period and storage of various drugs (a) Schedule P-I: It has regulations regarding retail package size of various drugs.

Schedule Y:

- It includes requirement and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials.

Schedule C

It includes the various biological products and their regulation e.g. serums, adrenaline.

Schedule F

It contains regulations and standards for running a blood bank.

- Schedule F-I: It includes regulations and standards for vaccines
- Schedule F-II: It includes regulations and standards for surgical dressings
- Schedule F-III: It includes regulations and standards for umbilical tapes.
- Schedule F-F. It includes regulations and standards for ophthalmic ointments and solutions

Schedule W

- It includes such drugs which should be marketed under generic names only eg. aspirin, chlorpromazine, ferrous sulphate, piperazine, analgin.etc

Schedule J

- This is an informative schedule that includes the list of ailments for which no drugs can be claimed to be useful for prevention or cure e.g. atherosclerosis, HIV infection.

Schedule K:

- This includes the conditions under which in certain circumstances, the registered medical practitioners and hospitals are exempted from provision provided under section IV of Drugs and Cosmetics Act of India (1940).

FRADULENT DRUGS/COUNTERFEIT DRUGS

- In spite of official regulations, fraudulent drugs are in the market eg. substandard, spurious, falsified, fake and counterfeit drugs. A significant fraction 5-6% worldwide is of fraudulent drugs that cause a serious health and economic problem in countries where drug regulation law is not properly followed (implemented).

FRADULENT DRUGS/COUNTERFEIT DRUGS

- In such countries percentage of counterfeit drugs is increased to 20% or more. Few examples of fraudulent drugs or malpractices are use of low quality gradients, wrong ingredients e.g. corticosteroids mixed with herbal medicine for arthritis, no active gradients at all, false labelling and/ or false packaging. Fraud may occur at any stage from raw material to availability of drug to patient from pharmacy / medical stores.