BHS 155

Pharmacy, Pharmacology and Toxicology

BPH, First year, Second semester

Pokhara University

Terminologies

Pharmacology

It is a branch of science that deals with the study of drugs that interacts with the living systems through chemical processes, especially by binding to regulatory molecules and activating or inhibiting normal body processes. Simply, it deals with the drugs and its effects.

OR, Pharmacology = Pharmacodynamics + Pharmacokinetics

Drug

A drug is any substance or product that is used or intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipients. The aim of the drug is to improve the quality of life.

Pharmacokinetics

It deals with absorption, distribution, metabolism and excretion. The action of drugs in the body over a period of time, including the process of absorption, distribution, localization of tissue, biotransformation and excretion. (What body does to body?)

Pharmacodynamics:

It is the study of the biochemical and physiological effects/change of drugs and the mechanism of their actions. (What drug doses to the body)

Absorption

It means the process entry of constituents from the lumen of gut to the body. Food constituents are mainly absorbed from the proximal area (duodenum) of small intestine.

Affinity

Tendency of a drug to bind with receptor.

Agonist

Drug that binds with receptor and activates them to produce a therapeutic response is called agonist.

Antagonist

Have only affinity but no efficacy. Drugs that bind to the cell receptor and thus blocks the action of other substances (neurotransmitter, hormone etc.)

Anaphylactic shock: Severe allergic reaction

Bioavailability

How much drug present in plasma level of blood or presence of drug in plasma level or measurement of active drugs reach to systemic circulation

Biological half-life: Time required to elimination of 50% drug from the body.

Biological response

The dose are taken at a time or in a fractions amount within particular time to get biological response.

Digestion

It is the breakdown of food constituents into smaller in preparation for absorption

Dose

Dose is measurement which is required to produce certain measurable biological response, either at once or sometime after administration.

Drug antagonism

It may be defined as the abolition or inhibitor of the effect of one drug by another drug. So that the combined effect of two drugs is less than that of individual drug.

Drug receptor

It is a molecule on the surface or within a cell that recognize and binds with other specific molecules, that's producing a specific effect in the cell. Drug receptor is organized cell, macromolecular in structure, protein in nature where drug interacts.

Efficacy: Ability of drug to produce its pharmacologic effects.

Medicine

It is any form which has a definite form, dose, level and is the therapeutically used for the treatment of diseases in the living subjects.

Teratogenic effects:

If a drug crosses placenta barrier it shows teratogenicity. It is harmful for infants and mother.

Side effects

Usually caused when a drugs binds to more than one type of receptor. It is therapeutically undesired and unavoidable effects that occur in association with beneficial effect at the normal therapeutic dose of a drug.

Therapeutic effect

It is the primary effect intended that is the reason the drug is prescribed such as morphine sulfate is analgesic.

Drug toxicity

It is the deleterious effect of the drug on an organism or tissue, result from overdose of external use

Drug allergy: is immunological reaction to a drug.

Drug interaction: occur when administration of one drug before or after alter effect of one or both drug.

Drug misuse: is the improper use of common medications in way that lead to acute and chronic toxicity for example laxative, antacid and vitamins.

Drug addiction: It is a state of periodic or chronic intoxication produced by the repeated consumption of certain drugs.

Drug abuse

It is an inappropriate intake of substance either continually or periodically. OR, self-administration of drug for non-therapeutic purpose, almost always for altering consciousness. Such as chronic intoxication with alcohol. Commonly abused drugs are opium, heroin, codeine, bhang, charas, LSD etc.

Drug dependence: is a person's reliance on or need to take drug or substance there are two types of dependence:

Physiological dependence

It is due to biochemical changes into the body tissue these tissue come to require substance for normal function. Examples of drugs causing this type of dependence are morphine, codeine, heroine, pethidine, cocaine, pentazocine etc.

Psychological dependence

It is emotional reliance on a drug to maintain a since of wellbeing accompanied feeling of need. Examples of drugs causing this type of dependence are cocaine, marijuana, hashish, nicotine, tea, coffee etc.

Drug habituation: denotes a mild form of psychological dependence

Illicit drug: also called street drug are those sold illegally.

Plasma half-life (t/2):

It is the time required for the plasma concentration of the drug to decrease by 50% of its original value. E.g.: $t_{1/2}$ of lignocaine is 1 hr., for aspirin it ha 4hrs.

Clinical importance: It helps;

- ✓ Determine the duration of drug action
- ✓ Determine the frequency of drug administration
- ✓ Estimate the time required to reach the steady state.

OTC drugs

- ✓ Those drug which can be used/supplied without prescription are called over the counter (OTC) drugs.
- ✓ The OTC ingredient should be safe and effective for consumer use without medical supervision. E.g., topical hydrocortisone 0.5% and 1%, paracetamol, aspirin, antacid, ORS (oral rehydration Salts) etc.

Polypharmacy:

It means prescribing many drugs to be given at one time: or excessive use of drugs or overdose of drug.

Pharmacoeconomics examines the cost-effectiveness of drug treatments

Pharmacogenetics and pharmacogenomics

Study the influence of genetic variation on pharmacodynamic and pharmacokinetic properties of drugs

Pharmacoepidemiology

- ✓ It is the study of the utilization and effect of drugs in large number of people.
- ✓ Pharmacoepidemiology is a relatively new and evolving science that attempts to quantify mainly adverse drug events and patterns of drug use in a large population.
- ✓ It is the combination of clinical pharmacology, clinical epidemiology, medical informatics and biostatics.
- ✓ WHO has operated drug surveillance program on adverse drug monitoring. Hospital and different types of patient care settings generate the large volume of data on patients.

- ✓ Such data are available in the period of time and a linked with many patients' factors and their morbidity status and clinical chemistry data.
- ✓ The pharmacoepidemiological study is easy to perform by using the tools of biostatics.

Pharmaceutical care

- ✓ Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.
- ✓ These outcomes are
    1. Cure of a disease.
    2. Elimination or reduction of a patient's symptomatology.
    3. Arresting or slowing of a disease process.
    4. Preventing a disease or symptomatology.
- ✓ Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.

Classification of Drugs (According to DDA)

- ✓ In exercise of the powers conferred by Section 40 of the Drug Act, 2035 (1978), the Government of Nepal has published "The Drug Standards Regulations, 2043 (1984) which classified the drug in rule 10 of this regulation (grouping the drugs pursuant to section 17 of the drug act 2035).
- ✓ They are divided in groups **Ka, Kha** and **Ga** and each group have sub-groups.

1) Group Ka

- ✓ This groups consist of narcotic and poisonous drugs.
- ✓ The sales and distribution of these drugs have to be made only with the prescription of a doctor; and these drugs have to be sold and distributed by the pharmacist or entrepreneur him/herself or in presence of any one of the pharmacist and the entrepreneur.
- ✓ Further classified into two subgroups; sub-group 1 and sub-group 2.

Sub-group 1

- ✓ Sub-group 1 consists of the narcotic drugs mentioned in that sub-group and drugs containing any substance related therewith.
- ✓ Examples; Apomorphine, Dihydromorphine, Dihydrocodein, Fentanyl Hydroxypethidine, Heroien, Methadone

Sub-group 2

- ✓ Sub-group 2 consist of the poisonous drugs containing any ingredients or substance related therewith mentioned in that sub-group.
- ✓ Examples; Procainamide, Chloroform, Procaine, Dhatura, 6-mercaptopurine, Heparin, Warfarin, Chloral hydrate

2) Group Kha

- ✓ This groups consists of antibiotics, hormones etc.
- ✓ The sales and distribution of these drugs have to be made only with the prescription of a doctor; and these drugs have to be sold and distributed by the pharmacist or entrepreneur him/herself or in presence of any one of the pharmacist and the entrepreneur
- ✓ Examples; Antirabies serum, Antitoxin, Antigen, Serum protein, Ampicillin, Amoxicillin, Ciprofloxacin, Neomycin, Benzocaine, carbomycin

3) Group Ga

- ✓ A seller may, based on his/her experiences, sell and distribute the drugs falling under group Ga even without prescription of a doctor; and the presence of the pharmacist or entrepreneur shall not be mandatory while selling and distributing drugs.
- ✓ Further classified into sub-group 1 and sub-group 2.

Sub-group 1

- ✓ Sub-group 1 consists of the drugs by prescribed percentage of the drugs mentioned in that sub-group.

- ✓ Examples; Amino alcohol(10%), Apomorphine (0,.20%), Cocaine (0.10%), Codeine (1%), Konin (0.10%), Dhatura (0.15%), Morphine (0.50%), Nicotine (0.20%) etc.

Sub-group 2

- ✓ Sub-group 2 consist of the drugs containing any ingredient or substance related there with mentioned in that sub-group.
- ✓ Examples; Paracetamol, Ibuprofen, Pheneramine, Niclosamide, Nicotinamide, Cynocobalamaine, Papavarine, Mebendazole etc.

Public health pharmacy

- ✓ Public health is the study and practice of how best to improve the overall health and health gain of populations rather than individuals.
- ✓ By Sir Donald Acheson, in 1988, as public health is "the science and art of preventing disease, prolonging life and promoting, protecting and improving health through the organised efforts of society".
- ✓ The pharmacist's role is expanding beyond the traditional product-oriented functions of dispensing and distributing medicines and health supplies.
- ✓ The pharmacist's services of today include more patient-oriented, administrative and public health functions. There are many functions of public health that can benefit from pharmacists' unique expertise that may include pharmacotherapy, access to care, and prevention services.
- ✓ Apart from dispensing medicine, pharmacists have proven to be an accessible resource for health and medication information. The pharmacist's centralized placement in the community and clinical expertise are invaluable.
- ✓ The re-examination and integration of public health practice into pharmacological training and pharmaceutical care is essential. The encouragement of cross-training will also maximize resources and aid in addressing the work force needs within the fields of pharmacy and public health.
- ✓ Through trans disciplinary approaches, it is envisioned that the pharmacist's contribution to the public health work force, health education, disease prevention and health promotion, public health advocacy, and health quality will aid in achieving optimal public health outcomes.

OVERVIEW OF PUBLIC HEALTH PHARMACY

Role Recognition

- ✓ The public health role of the pharmacist is yet to be clearly defined, broadly recognized and sufficiently promoted by public health agencies, pharmacy educators or other health care professionals. Pharmacists offer an accessibility that is rare among health care professionals.
- ✓ The pharmacist has health knowledge on which to build and is often uniquely situated in the community to provide public health services, in some cases 24 hours per day. No appointment is needed at most community pharmacies.
- ✓ Pharmacists work in a variety of public settings, including hospitals, drug, grocery and retail stores, and nursing homes. This convenience creates a large window of opportunity in which to provide public health services, therefore filling a void related to access to care and prevention. Further, pharmacists in the community are in an ideal position to act as information resources on lifestyle changes that can influence healthy outcomes.
- ✓ Pharmacists are involved in health screenings (e.g. diabetes, cholesterol, and osteoporosis), immunizations, pain control, participatory and clinical research, and counseling/ health education. They also provide information on self-management (e.g. hypertension, asthma, HIV), smoking cessation, alcohol, tobacco and other drug use prevention, family planning, medication indications and conditions (dyslipidemia).

- ✓ The expanding role of pharmacists emphasizes their public health roles through emphasis on outcomes like disease prevention, health maintenance/improvement and wellness.

Levels of Pharmacist Public Health Activity

- ✓ Medicine continues to evolve from a disease-oriented practice to one that is more patient-centred and focused on prevention.
- ✓ The profession of pharmacy has undergone a similar metamorphosis: from a concentration on medication dispensing to a focus on safe and effective medication use to achieve optimal patient outcomes.
- ✓ As patients move through the continuum of care, pharmacists have ample opportunity to provide population-based care. In fact, studies have shown that pharmacists with more comprehensive responsibilities have lowered total costs and improved quality of care outcomes achieved by health care systems, particularly related to chronic conditions.
- ✓ To fully utilize the pharmacist's expertise, these broad functions may be carried out by individuals, systems, and facilities in diverse sectors, encompassing both macro and micro level activities.
- ✓ At the micro level, public health activities may be one of many tasks among a pharmacist's set of responsibilities. For example, a community pharmacist who speaks to community groups about drug abuse and provides hypertension screening in his or her pharmacy is providing public health services at the micro level, while a pharmacist who is the drug program administrator of a state Medicaid program is providing services at the macro level.
- ✓ Performing public health activities on the micro level still preserves their identity as a pharmacist. Conversely, when a pharmacist works on the macro level in the capacity of health planning, evaluation and

Public Health functions

Micro level:

- ✓ Service is relatively direct as compared to the macro or planning level. For example, the director of a pharmacy is functioning at the micro level, whereas the individual who perceived the need in the population compared to other needs, determined that there should be such a clinic, and allocated resources for it, is functioning at the macro level.

Macro level:

- ✓ Formulation of health-care policy, health-care planning, and program implementation, direction, and evaluation, especially at the national level.
- ✓ These foci affect the practice arrangements of other health professionals. This work also leverages change in equity/disparity issues, quality of care, and access to health services by the population.
- ✓ Pharmacy too often ignores the macro level of public health. As a consequence relatively few pharmacists are available as role models or decision leaders

Drug Nomenclature/ Naming of Drugs

This is the system that puts drugs into classification and the three name classifications of drugs are:

1) Chemical/ Molecular/ Scientific name

2) Generic or Non-Proprietary name

3) Brand or Trade or Proprietary name

1) Chemical Name:

- ✓ It depicts the chemical/ molecular structure of the drug. It states the structure in terms of atoms and molecules accompanied by a diagram of the chemical structure.
- ✓ They are long and can be clumsy and are useful to a few technically trained personnel. For example acetyl-p-amino-phenol is for ***Paracetamol.***

2) Non-Proprietary/ Generic/ Approved Name:

- ➢ This is the abbreviated and **approved name** of the drug. It is the **official medical name** assigned by the producer in collaboration with the Food and Drugs Board and Nomenclature Committee.
- ➢ The generic name may be used by any interested party and it removes the confusion of giving several names to the same drug regardless of who manufactures them once they have the same chemical structure.
- ➢ A generic drug name is not capitalized; for example, **aluminum hydroxide.**

3) Proprietary/Trade/Brand Name:

- ✓ These are names given to the drug by the **manufacturing** and **marketing company**.
- ✓ They are **copyrighted** terms selected by a manufacturer to designate a particular product.
- ✓ Copyright laws prevent any other person from using the name.
- ✓ In most cases one drug could have so many trade/ brand names e.g. **Acetaminophen** has about 30 trade names, some are Paramol,Nico, Panadol, Capol etc.

Chemical Name	Non-Proprietary Name	Proprietary Name
1-(4-chloro benzene sulphonyl-3-propylurea)	**Chlorpropamide**	**Diabinese ®**
Chlorodihydro methyl-phenyl benzodiazepine	**Diazepam**	**Valium ®**

Methods of dispensing drugs

Two major methods of dispensing drugs:

a) **Over-The-Counter (OTC):** They do not need prescription and can be purchased at the Pharmacy shops; examples are pain relievers, blood tonics, vitamins, ORS, antacids, Anti-malarials etc.

b) **Prescription Drugs:** They must need a prescription e.g. antibiotics, anti-hypertensives, sedatives, diabetic drugs etc.

DOSAGE FORM

Limitations on the direct clinical use of the active drug substances, as they are-

- Handling – difficult or impossible (low doses)
- Accurate drug dosing – difficult or impossible
- Administration – impractical
- Environmental factors – negative impact on drug chemical instability
- Degradation at the site of administration
- Local irritations or injury
- Unpleasant organoleptic qualities (taste, smell)
- No chance for modification of PK profile

Pharmaceutical dosage forms

- Also known as **pharmaceuticals.**
- Drugs are rarely administered in their original pure state. They are converted into suitable formulations which are called dosage forms.
- Every dosage form is a combination of the drug and other non-drug components.
- The non-dug components are known as "additives". The additives are used to give a particular shape to the formulation, to increase its stability and also to increase its palatability as well as to give more elegance to the preparation.

Why the drug should be converted into dosage forms?

Ans. Transformation of drug into different dosage forms is done for the following reasons:

1. To protect the drug from oxidation (e.g. Vitamin C, Ferrous sulfate), hydrolysis (aspirin) and reduction. e.g. coated tablets, sealed ampoules.
2. To protect the drug from destructive effect of gastric juice (HCl) of the stomach after oral administration e.g. enteric coated tablets.
3. To provide a safe and convenient delivery of accurate dosage.

4. To mask the bitter (e.g. chloramphenicol), salty or obnoxious taste or odour of a drug substance e.g. capsules, coated tablets and flavoured syrups etc.
5. To provide for the optimum drug action through inhalation therapy. E.g. inhalation aerosols and inhalants.
6. To provide for the drug into one of the body-cavities e.g. rectal suppositories.
7. To provide for the maximum drug action from topical administration sites. e.g. creams, ointments, ophthalmic preparations and E.N.T. (ear, nose and throat) preparation.
8. To provide sustained release action through controlled release mechanism. e.g. sustained release tablets, capsules and suspensions.
9. To provide liquid dosage form of the drugs soluble in a suitable vehicle e.g. solutions forms?

Route of administration	Dosage forms
Oral	Powders, tablets, capsules, solutions, emulsions,syrups, elixirs, magmas, gels, cachets, pills.
Parenteral	Solutions, suspensions, emulsions.
Transdermal	Ointments, creams, powders, pastes, lotions, plaster
Rectal	Suppositories, tablets, ointments, creams, douches,foams.
Urethral	suppositories
Sublingual	Lozenges, tablets
Sublingual	Solutions, sprays, inhalations.
Conjunctival	Ointments
Intra-ocular	Solutions
Intra-respiratory	Aerosols

Classification of dosage form according to the physical properties

1) **Solid** dosage forms
2) **Semi-solid** dosage forms
3) **Liquid** dosage forms
4) **Gaseous** dosage forms

1) Solid Dosage Forms

→ Solid agents can be contained in various packages

→ Administered by almost all routes except parenterally (IV)

→ Contain inert ingredients (fillers, binders, disintegrants)

a) Powders

- For external/internal use
- Can be packaged in some forms that allow them to be sprayed, similar to liquid dosage forms

b) Granules:

- ✓ They are consisting of solid, dry aggregates of powder particles often supplied in single-dose sachets.
- ✓ Some granules are placed on the tongue and swallowed with water; others are intended to be dissolved in water before taking.
- ✓ Effervescent granules evolve carbon dioxide when added to water.

c) Tablets

i. **Compressed product** (API+ excipients – e.g., fillers, desintegrants)
ii. **Conventional** (can be divided – half/quarters)
iii. **Coated** (usually not to be divided)
iv. **Effervescent tablets** (the final dosage form is a solution) – rapid absorption (rapid onset of action)
v. **Sublingual tablets** (SL)
vi. **Chewable tablets** (if swallowing difficulty, children)
vii. **Vaginal tablets**

d) Capsules substances enclosed in the hard/soft water soluble container made of gelatin

i. **Hard gelatine capsule**
   - Consist of cap and body
   - Filled with powders, pellets, granules
   - Can be pulled apart to sprinkle the medication onto food

ii. **Soft gelatine capsule**
   - One-piece
   - Filled with paste, oil
   - Can be squeezed to dissolve medication in liquid

e) Lozenge:

- ❖ It is a solid preparation consisting of sugar and gum, the latter giving strength and cohesiveness to the lozenge and facilitating slow release of the medicament.
- ❖ It is used to medicate the mouth and throat for the slow administration of indigestion or cough remedies.

f) Suppository:

→ It is a small solid medicated mass, usually cone-shaped, that is inserted either into the rectum (rectal suppository), vagina (vaginal suppository or pessaries) where it melts at body temperature.

→ Different shape – mostly torpedo-like

2) Semi-solid dosage forms

a) Creams:

Creams are semi-solid emulsion that is mixtures of oil and water.

They are divided into two types:

A- oil-in-water (O/W) creams: which are composed of small droplets of oil dispersed in a continuous aqueous phase. Oil-in-water creams are more comfortable and cosmetically acceptable as they are less greasy and more easily washed off using water.

B- water-in-oil (W/O) creams: which are composed of small droplets of water dispersed in a continuous oily phase. These are more difficult to handle but many drugs which are incorporated into creams are hydrophobic and will be released more readily from a water-in-oil cream than an oil-in-water cream. Water-in-oil creams are also more moisturizing as they provide an oily barrier which reduces water loss from the stratum corneum, the outermost layer of the skin.

b) Pastes:

- ❖ Pastes are basically ointments into which a high percentage of insoluble solid has been added
- ❖ The extraordinary amount of particulate matter stiffens the system.
- ❖ Pastes are less penetrating and less macerating and less heating than ointment.
- ❖ Pastes make particularly good protective barrier when placed on the skin, the solid they contain can absorb and thereby neutralize certain noxious chemicals before they ever reach the skin.
- ❖ Like ointments, paste forms an unbroken relatively water – impermeable film unlike ointments the film is opaque and therefore can be used as an effective sun block accordingly.

c) Liniments:

- → Liniments are fluid, semi-fluid or, occasionally, semi-solid preparations intended for application to the skin.
- → They may be alcoholic or oily solutions or emulsions.
- → Most are massaged into the skin (e.g. counter-irritant).
- → Liniments should not be applied to broken skin.

d) Lotions:

- These are fluid preparations (aqueous) for external application without friction.
- They are either dabbed on the skin or applied on a suitable dressing and covered with a waterproof dressing to reduce evaporation.

e) Paints:

- ❖ Paints are liquids for application to the skin or mucous membranes.

- ❖ Skin paints contain volatile solvent that evaporates quickly to leave a dry resinous film of medicament.
- ❖ Throat paints are more viscous due to a high content of glycerol, designed to prolong contact of the medicament with the affected site.

3) **Liquid dosage forms:**

a. Solution:

Oral solutions are clear Liquid preparations for oral use containing one or more active ingredients dissolved in a suitable vehicle. E.g. syrup, elixir, gargles, mouth wash.

b. Emulsion:

Oral emulsions are stabilized oil-in-water dispersions, either or both phases of which may contain dissolved solids.

c. Suspension:

-Oral suspensions are Liquid preparations for oral use containing one or more active ingredients suspended in a suitable vehicle.

-Oral suspensions may show a sediment which is readily dispersed on shaking to give a uniform suspension which remains sufficiently stable to enable the correct dose to be delivered. E.g. Antacid suspension.

4) Gases

a) Pressurized dispensers (aerosol sprays):

- ❖ Several different types of pharmaceutical product may be packaged in pressurized dispensers, known as aerosols.
- ❖ Surface sprays produce droplets of 100 um diameter or greater.
- ❖ May be used as surface disinfectants, wound or burn dressing, relieve irritation of bites.
- ❖ Spray-on dusting powders are also available from pressurized containers.

b) Medicinal gases, inhalation/volatile anaesthetics (vaporised before administration by inhalation)

PHARMACEUTICAL PACKAGING

- ✓ Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use.
- ✓ Pharmaceutical packaging can be defined as the economical means of providing presentation, protection, identification, information, convenience, compliance, integrity and stability of the product.

Functions of Packaging

- ✓ Product Identification: - Packaging greatly helps in identification of products.
- ✓ Product Protection: - Packaging protects the contents of a product from spoilage, breakage, leakage, etc.
- ✓ Facilitating the use of product: - Packaging should be convenience to open, handle and use for the consumers.
- ✓ Product Promotion: - Packaging is also used for promotional and attracting the attention of the people while purchasing.

Types Of Packaging

a) **Primary packaging-** is the material that first envelops the product and hold it. This usually is the smallest unit of distribution or use. Ex. Aerosol spray can, blister packs, bottle

b) Secondary packaging -

Is outside the primary packaging perhaps used to group primary package together. Ex. Boxes, cartons

Types of Packaging Materials Used For Pharmaceutical Packaging

- ✓ Glass
- ✓ Plastics
- ✓ Rubbers
- ✓ Paper/card boards
- ✓ Metals

The Choice of Packaging Material Will Depend Upon:

- ✓ The degree of protection required
- ✓ Compatibility with the dosage form
- ✓ Customer convenience e.g. size, weight of dosage form,
- ✓ Filling method
- ✓ Sterilization method to be employed and cost

i) GLASS

Glass has been widely used as a drug packaging material

Advantages

- ✓ They are transparent.
- ✓ They have good protection power.
- ✓ They can be easily labelled.
- ✓ Economical
- ✓ Variety of sizes and shapes

Disadvantages

- ✓ Glass is fragile so easily broken.
- ✓ Release alkali to aqueous preparation

Composition of Glass

- ❖ Sand (silicon dioxide) Soda ash (sodium carbonate) Limestone (calcium carbonate) Cullet (broken glass) - aluminium, boron, potassium, magnesium, zinc, barium,
- ❖ Amber: light yellowish to deep reddish brown, carbon and sulphur or iron and manganese dioxide
- ❖ Yellow: Compounds of cadmium and sulphur
- ❖ Blue: Various shades of blue, cobalt oxide or occasionally copper (cupric) oxide
- ❖ Green: iron oxide, manganese dioxide and chromium dioxide

ii) PLASTIC

Plastics may be defined as any group of substances, of natural or synthetic origins, consisting chiefly of polymers of high molecular weight that can be moulded into a shape or form by heat and pressure.

Advantages

- ✓ Less weight than glass,
- ✓ Flexible
- ✓ Variety of sizes and shapes
- ✓ Essentially chemically inert, strong, rigid Safety use, high quality, various designs
- ✓ Extremely resistant to breakage

Disadvantages

- ✓ Permeable to moisture
- ✓ Poor printing, thermostatic charge

Types of Plastics

Thermosetting type –

When heated they may become flexible but they do not become liquid e.g. Urea formaldehyde (UF), Phenol formaldehyde, Melamine formaldehyde (MF), Epoxy resins (epoxides), Polyurethanes (PURs)

Thermoplastics type-

On heating they are soften to viscous fluid which harden again on cooling. e.g. Polyethylene{HDPE – LDPE}, Polyvinylchloride(PVC),Polystyrene Polypropylene, Nylon(PA), Polyethylene terepthalate(PET) ,Polyvinylidene chloride(PVdC), Polycarbonate Acrylonitrile butadiene styrene(ABS)

iii) Metals

Metals are used for construction of containers. The metals commonly used for this purpose are aluminium, tin plated steel, stainless steel, tin and lead

Advantages:

- ✓ They are impermeable to light, moisture and gases.
- ✓ They are light in weight compared to glass containers.
- ✓ Labels can printed directly on to their surface.

Disadvantages:

- ✓ They are expensive.
- ✓ They react with certain chemicals

Collapsible Tubes Metal

- ❖ The collapsible metal tube is an attractive container that permits controlled amounts to be dispensed easily, with good reclosure, and adequate protection of the product.
- ❖ It is light in weight and unbreakable.
- ❖ Most commonly used are tin, aluminium and lead.

iv) Tin

- ✓ Tin containers are preferred for food, pharmaceuticals and any product for which purity is considered.
- ✓ Tin is the most chemically inert of all collapsible metal tubes.

v) Aluminium

- ❖ Aluminium tubes offer significant savings in product shipping costs because of their light weight
- ❖ They are attractive in nature

vi) Lead

- ✓ Lead has the lowest cost of all tube metals and is widely used for non-food products such as adhesives, inks. Paints and lubricants.
- ✓ Lead should never be used alone for anything taken internally because of the risk lead poison.
- ✓ With internal linings, lead tubes are used for products such as chloride tooth paste.

vii) Rubber:

- ❖ Rubber is used mainly for the construction of closure meant for vials, transfusion fluid bottles, dropping bottles and as washers in many other types of product.

Silicon Rubbers

Advantages

- ❖ Heat resistance.
- ❖ Extremely low absorption and permeability of water.

Disadvantages

- ✓ They are very expensive.

viii) Tamper Resistant Packaging

- ❖ The requirement for tamper resistant packaging is now one of the major considerations in the development of packaging for pharmaceutical products.
- ❖ FDA approves the following configurations as tamper resistant packaging: Film wrappers, Blister package, Strip package, Bubble pack, Shrink seals, and bands Oil, paper, plastic pouches, Bottle seals, Tape seals, Breakable caps, Aerosol containers

ix) Blister package

- ✓ Blister package provides excellent environmental protection, and efficacious appearance.
- ✓ It also provides user functionality in terms of convenience, child resistance and tamper resistance
- ✓ The blister package is formed by heat softening a sheet of thermoplastic resin and vacuum drawing the soften sheet of plastic into a contoured mold.
- ✓ After cooling the sheet is released from the mold and proceeds to the filling station of the machine.
- ✓ Materials commonly used for the thermo formable blister are PVC, polyethylene combinations, polystyrene and polypropylene.

x) Strip Package

- ❖ A strip package is a form of unit dose packaging that is commonly used for the packaging of tablets and capsule.
- ❖ A strip package is formed by feeding two webs of a heat sealable flexible through heated crimping roller.
- ❖ The product is dropped into the pocket formed prior to forming the final set of seals. A continuous strip of packets is formed in general.
- ❖ The strip of packets is cut into desired number of packets.
- ❖ Different packaging materials used are: paper/polyethylene/foil/PVC.

xi) Bottle Seals

A bottle may be made tamper resistant by bonding and inner seal to the rim of the bottle in such a way that the product can only be attained by destroying the seal.

xii) Tape Seals

It involves the application of glued or pressure sensitive tape or label around or over the closure of the package which is to be destroyed to obtain the product.

Pharmaceutical Compounding

Pharmaceutical Compounding is the creation of a pharmaceutical preparation, product or a drug by a licensed compounding pharmacist done in a compounding pharmacy, combining or processing appropriate ingredients using various tools to meet the unique needs of an individual patient when a commercially available drug does not meet those needs.

What are the reasons a medication is compounded?

This may be done for medically necessary reasons and for more optional reasons such as:

- ✓ To change the form of the medication from an oral solid pill to an oral liquid dosage for patients who experience stomach upset when taking oral medication or for those who have difficulty swallowing.
- ✓ To reformulate the drug so as to avoid or exclude an unwanted or a non-essential ingredient that the patient is allergic to (such as lactose, gluten or dye).
- ✓ To customize the strength or dosage of the medication so as to obtain the exact doses(s) needed.
- ✓ To flavour the medication so as to make it more palatable for a child (altering taste or texture).

How is pharmaceutical compounding different from drug manufacturing?

- ✓ *Pharmaceutical compounding* is the process of preparation of a medication to meet the prescriber's exact specifications performed or supervised by a pharmacist licensed by a state board of pharmacy and to be dispensed directly to the patient, pursuant to a valid prescription for that patient.
- ✓ *Drug manufacturing* is the mass production of drug products that have been approved by the Food and Drug Administration (FDA). These products are sold to pharmacies, health care practitioners, or those who are authorized under state and federal law to resell them.

Does a compounding pharmacist have special training?

Compounding is considered as a central activity in the practice of pharmacy. Pharmacists are taught in pharmacy schools how to properly compound medications with utmost care. And many states conduct tests as an assessment intended to measure the pharmacists' compounding knowledge and skills before issuing them a license. Pharmacists who practice in pharmacies that specialize in compounding services have generally took advanced training in compounding after they graduated from pharmacy school.

COMMUNITY PHARMACY

"Community pharmacy includes all of those establishments that are privately owned and whose function, in varying degree, is to serve societies need for both drug products and the pharmaceutical services".

Or

"Community pharmacy is a unique hybrid of professionalism and business. In addition to dispensing pharmaceuticals, pharmacist in community (retail) pharmacies answers questions about prescription and over the counter (OTC) drugs and give advice about home health care supplies and durable medical equipment's."

Community pharmacy include a great variety of pharmacy services ranging from corporately owned chain pharmacy, to the pharmacy department in supermarket or an independently owned pharmaceutical shop that provide prescription service plus a relatively few lined of health related products.

SCOPE OF COMMUNITY PHARMACY

- ✓ As we know that there is a steep rise in the field of the medical and health services due to introduction of various latest techniques and globalization of medical profession.
- ✓ Population of whole world is rising tremendously day by day, during the last few decades it has been realized that additional medical and health services are insufficient for overall improvement of health status.
- ✓ Due to above reasons there is a requirement of an equal participation of all health professionals to obtain a common goal of disease prevention and health promotion.
- ✓ Nowadays community pharmacists are paying their attention toward the health patients, environment of the patients and the state of patients general wellness, counseling of the patients about drug related matters, health, diseased state, nutrition and drug abuse etc.

ROLES AND RESPONSIBILITIES OF COMMUNITY PHARMACIST

Following are the area where a community pharmacist can be actively involved to serve the community.

1. In all drug related problems like counseling on proper use of OTC and prescribed medicines, recording of drug and medical problem histories, immunization schedules, refer of patients toa specific health care professionals, etc.
2. A community pharmacist may involve actively into the area of "Pharacoepidemiology". Pharacoepidemiology is the post marketing phase of clinical trial of a drug, which concern with the safety or risk assessment of a new drug after coming in market.
3. A community pharmacist may involve in the control of serious communicable disease, by making

community aware through counseling. By this method a lot of diseases like tuberculosis, syphilis, gonorrhea, herpes genitals, AIDS and hepatitis can be controlled.

4 A community pharmacist can encourage, his/her patient to prevent themselves from various chronic diseases by using various proven techniques of preventions like risk of strokes of heart can be reduced by control of the high blood pressure checkup, for regulate intake of prescribed medicine, quitting smoking, controlling high blood pressure, lowering cholesterol intake and increase in physical exercise.

5. A community pharmacist may also involve in patient health education through the use of pamphlets and bulletins freely available on display racks.
6. A community pharmacist may provide counseling to pregnant ladies about material and child health, hygiene, management of pregnancy, material diet and other diseased or sub nutritional states. A community pharmacist can also play a major role by guiding the parents for the protection of child against the disease of childhood by proper immunization schedule.
7. A community pharmacist may guide patients about nutrition intake according to the requirement of the patient and their disease states.
8. A community pharmacist can make community aware about environmental health like food born disease, local hazards, carcinogens, etc.
9. A community pharmacist may provide counseling to the persons involved in alcoholism and drug abuse about the hazards and side effects or draw backs of those evils, and may refer these patients for proper treatment to an appropriate health professional.

Summary of the areas where a pharmacist can involve in public health through community pharmacy:

- ✓ Drug and nutrition counseling
- ✓ Use of OTC and prescribed medicines
- ✓ Family planning
- ✓ Pregnancy and infant care
- ✓ Immunization
- ✓ Sexually transmitted diseases
- ✓ Toxic agent control
- ✓ Health and safety
- ✓ Control of accidental injuries
- ✓ Fluoridations of community water supply
- ✓ Prevention of smoking
- ✓ Prevention of alcoholism and drug abuse

- ✓ Nutritional counseling
- ✓ Environmental protection
- ✓ Weight control program
- ✓ Poisoning and cancer detection

Pharmacy's Role in Primary Health Care

- ❖ Pharmacists add value by professional counselling in dispensing and supplying of all scheduled products; checking individual medication regimens to avoid possible drug interactions and providing special advice to patients on multiple medications; clinical interventions to ensure a medicine is appropriate to the specific needs of the consumer and liaising with GPs where a prescribed medicine is involved.
- ❖ Pharmacists are increasingly involved in testing and screening, disease management (e.g. of asthma, diabetes and hypertension), in medication reviews, in post hospital care, in continence care and falls prevention, in wound management, in illicit drug diversion programs such as methadone and buprenorphine and in public health programs such as needle and syringe supply, smoking cessation and obesity.
- ❖ They are involved also in the supply of pharmaceuticals to remote communities and in advisory services to support this supply, and in community education programs in support of government health priorities.
- ❖ There is thousand community pharmacies spread throughout urban, regional and rural areas, always staffed by a pharmacist who is able not only to dispense and give advice about medicines but who also assists in the delivery of health services in a variety of other ways.
- ❖ Pharmacists are highly trusted and immediately accessible without an appointment. Pharmacists are accustomed to keeping meticulous records and maintaining accurate audit trails of medicines. With further refinement of computer systems they can provide invaluable assistance to patients in managing their medications, monitoring their health and promoting healthy living.
- ❖ There is huge capacity for pharmacists to work with Government in providing healthcare services to the community in new as well as existing ways which are cost-effective and productive.

Hospital Pharmacy

- ✓ Provide specifications for the purchase of drugs, chemicals, biological etc.
- ✓ roper storing of drugs
- ✓ Manufacturing and distribution of medicaments such as transfusion fluids, parenteral products, tablets, capsules, ointments, and stock mixtures.
- ✓ Dispensing and sterilizing parenteral preparations which are manufactured in hospital.
- ✓ Dispensing of drugs as per the prescriptions of the medical staff of the hospital.
- ✓ Filling and labelling of all drug containers from which medicines are to be administered.
- ✓ Management of stores which includes purchase of drugs, proper storage conditions, and maintenance of records.
- ✓ Establishment and maintenance of "Drug Information Centre".
- ✓ Providing co-operation in teaching and research programmes.
- ✓ Discarding the expired drugs and containers worn and missing labels.

OBJECTIVES OF HOSPITAL PHARMACY

- ✓ To ensure the availability of right medication, at right time, in the right dose at the minimum possible cost.
- ✓ To professionalize the functioning of pharmaceutical services in a hospital.
- ✓ To act as a counseling department for medical staff, nurses and for patient.
- ✓ To act as a data bank on drug utilization.
- ✓ To participate in research projects.
- ✓ To implement decisions of the pharmacy and therapeutics committee.
- ✓ To co-ordinate and co-operate with other departments of a hospital.
- ✓ To plan, organize and implement pharmacy policy procedures in keeping with established policies of the hospitals.

Location of Hospital Pharmacy

- ✓ Located in hospital premises so that patients and staff can easily approach it.
- ✓ In multi-storeyed building of a hospital, the pharmacy should be preferably located on ground floor especially the dispensing unit.
- ✓ It should be laid in such a way that there is a continuous flow of men and materials.

Facilities Required in Hospital Pharmacy

- ✓ In smaller hospitals, with one pharmacist only, one room is required for pharmacy, having a combination of dispensing, manufacturing, administrative and all other sections of complete pharmaceutical service.
- ✓ For sterile products there should be a separate room or area.
- ✓ In large hospitals, with 200 or more beds, departmentalization of pharmacy activities is required.

Personnel Requirement in Hospital Pharmacy

- ✓ No standard rules regarding the requirement of personnel for inpatient pharmacy.
- ✓ Number of pharmacists required for a hospital are calculated on the basis of workload, and the number of bed available.
- ✓ For a small hospital minimum 3 pharmacist are required. As the number of bed increases, the number of pharmacist also increases.
- ✓ Pharmacist should possess adequate pharmacy qualification and experience.
- ✓ If manufacturing drugs is involved in pharmacy, adequate number of technicians, assistants, peons etc. required.

Clinical Pharmacy Practice

Functional Elements of Clinical Pharmacy Practice

- ✓ Clinical pharmacy have evolved and still evolving in a variety of ambulatory and institutional pharmacy settings
- ✓ Many hospitals now providing medication histories, patient drug counseling, patient drug monitoring, and drug information services
- ✓ Specialized clinical services such as clinical pharmacokinetics, nutritional support, clinical toxicology

Definitions of clinical pharmacy:

- ✓ Clinical pharmacy practice as a practice in which the pharmacist utilizes his professional judgment in the application of pharmaceutical sciences to foster the safe and appropriate use of drugs, in or by patients, while working with members of the health care team
- ✓ American Association of Colleges of Pharmacy: clinical pharmacy is that area within the pharmacy curriculum which deals with patient care with emphasis on drug therapy.
- ✓ Clinical pharmacy seeks to develop a patient oriented attitude. The gaining of new knowledge is secondary to the attainment of skills in inter-professional and patient communication

General clinical pharmacy functions and services

- ✓ Providing drug information to other health professionals
- ✓ Aimed to Defining therapeutic goals and endpoints of drug therapy
- ✓ Selecting the most appropriate therapeutic agent for drug therapy
- ✓ Prescribing the most appropriate drug regimen
- ✓ Monitoring the effect of drug therapy based upon indices of effect and
- ✓ Selecting methods for drug administration

Specialized functions and services:

- ✓ Nutritional support services
- ✓ Formal (written) drug therapy consultations
- ✓ Clinical pharmacokinetics services
- ✓ clinical toxicology services
- ✓ Clinical drug investigations
- ✓ Patient Care

What are the Actual Drug Related Problems?

- ✓ Over dosage
- ✓ Adverse drug reactions

- ✓ Drug interactions
- ✓ Drug use without indication
- ✓ Untreated indication
- ✓ Improper drug selection
- ✓ Sub therapeutic dosage
- ✓ Failure to receive drugs

What Are We Trying to Achieve through Pharmaceutical care?

- ✓ Maximizing clinical effect
- ✓ Minimizing risk of treatment
- ✓ Minimizing cost of treatment

Why Clinical Pharmacy Practice?

✓ Lack of unbiased Drug Information (DI)
✓ Physicians are overloaded with patients
✓ Too many formulations with irrational combinations
✓ Iatrogenic disorders
✓ Drug-drug interactions
✓ ADRs
✓ Lack of evidenced based medicine

Clinical Pharmacy daily activities

✓ Ward round participation
✓ Treatment chart review
✓ Drug information
✓ Patient counseling
✓ Adverse drug reaction reporting and monitoring
✓ Therapeutic Drug Monitoring

Ward Round Participation

Ward round participation is defined as, pharmacist as a member of health care team, improves the patient care by influencing the prescribing habits of the clinicians by providing unbiased drug information and assisting them to practice rational use of drugs philosophy.

Goals

- ✓ To gain an improved understanding of the patient's clinical details, planned investigations and therapeutic goals

- ✓ To provide unbiased drug information to prescribers
- ✓ To optimize drug treatment by influencing therapy selection, implementation and monitoring

Medication Chart Review

Medication Chart Review is the fundamental responsibility of the clinical pharmacist to ensure the appropriateness of the medication order.

Goals

- ✓ To optimize the patient's drug therapy.
- ✓ To ensure that the patient receives appropriate drug, in right dose and suitable dosage form.
- ✓ To optimize the timing and the duration of therapy.
- ✓ To minimize the drug related problems.

Drug Information

- ✓ Provision of accurate, unbiased, well referenced and critically evaluated up –to- date information on any aspect of drug use.

Goal

- ✓ To provide accurate relevant information contributing to patient care
  Eg: Selection of appropriate molecule meeting the clinical situation
- ✓ To optimize the drug therapy
- ✓ Eg: Drug dosing of Inj. Amikacin in a 78 year old male patient suffering from Type -2 DM, COPD and septicemic shock. Lab values suggest Se Cr is 3.6mg/dl.

Patient Counseling

- ✓ Patient counseling is defined as providing medication information orally or written form to the patient or his representative on directions of use, advice on side effects, precautions, storage, diet and life style modifications

Goal

- ✓ To improve the adherence to prescribed medications.
- ✓ To achieve the desired therapeutic outcomes.
- ✓ To improve patient's quality of life.
- ✓ To establish good professional relationships among pharmacists, prescribers and patients.

Adverse Drug Reactions

- ✓ Any response to a drug which is noxious, and unintended that occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function - World Health Organization

Goal

To detect, assess, correlate, manage, document and prevent adverse reactions to drugs

- ✓ E.g.: Ceftrioxone induced itching and rashes
- ✓ E.g.: Vomiting associated with Tramadol
- ✓ E.g.: Loose stools associated with Clindamycin
- ✓ E.g.: multiple erythema with Esomeprazole.
- ✓ E.g.: Dystonia with Ondansetran

Need for ADR monitoring & reporting

- ✓ Studies have shown that 3-7% of the hospitalized patients are likely to suffer from an ADR
- ✓ Financial burden due to ADRs is greater than the total costs of cardiovascular or diabetic care.
- ✓ Mean length of stay, cost and mortality in patients suffering from ADR are DOUBLE than the regular patients

Therapeutic Drug Monitoring

TDM is the interpretation, monitoring and communication of measured drug concentration in body fluids to optimize medicine efficiency and minimize drug toxicity.

Goals

- ✓ To optimize therapy for drugs with narrow therapeutic index
- ✓ To minimize drug toxicity
- ✓ To assess the potential drug interactions
- ✓ To assess ADRs.

Clinical Pharmacy Activities

Patient care

Education

Research

Guidelines and Protocols

Prescription

Prescription is a written order from a registered medical practitioner such as physician, dentist or any other properly licensed practitioners asking a pharmacist to compound and dispense a specific medication for the patient at a particular time.

Information required on a Prescription (Parts of prescription)

A prescription is combined document of a clinical document, a legal document and an invoice. The information and instruction that are required as a minimum are listed below:

1) Prescriber information
2) Date of prescription
3) Name, age, sex and address of the patient
4) Superscription
5) Inscription
6) Subscription
7) Signature
8) Renewal instruction
9) Prescriber's name, signature, address and registered no. of the prescriber

1. Prescriber information:

→ There should be some indication on the prescription whether the prescriber is a doctor, dentist or veterinary practitioner.

2. The date:

→ It must be written by the prescriber.

→ It helps a pharmacist to find out the date of prescribing and date of presentation for filling the prescription.

→ The prescription which prescribe narcotic or other habit forming drugs, must bear the date, so as to avoid the misuse of prescription if it is presented by the patient, a number times for dispensing.

3. Patient information:

→ The title of the patient, e.g. Mr, Mrs, Miss…

→ Full name.

→ The age of a child under 12 years old should be included, this will help the pharmacist to check for dose.

→ In some cases, weight of patient should be included.

→ The address should be clear and unambiguous.

4. **The Superscription:**

→ Which consists of the traditional Symbol R_x meaning "you take" or "recipe". It directs the pharmacist to take the drugs listed in the inscription in the quantities given to prepare the medication.

→ In olden days, the symbol was considered to be originated from the sign of Jupiter, God of healing.

5. **The Inscription (Medication prescribed):**

→ It is also called the body of the prescription. It is the most important part of the prescription.

→ It contains a list of ingredients and their quantities to be used in compounding the prescription.

→ Extensive care should be taken by the pharmacist in interpreting the abbreviations, otherwise it can lead to serious errors.

6. **The subscription (Dispensing instructions to the pharmacist):**

→ It comprises the directions to the pharmacist for preparing the prescription and number of doses to be dispensed.

→ These days, the prescribers are omitting the specific instructions to the pharmacist because the majority of the prescriptions are not compounded and dispensed.

7. **The Transcription (The signatura):**

→ Gives instructions to the patient on:

A- The quantity to be taken.

B-The frequency and timing of administration or application.

C- The route of administration or method of use.

D- Special instructions such as dilution directions.

→ These instructions are preceded by the symbol "Sig." from the Latin, meaning "write on label".

8. Renewal instruction

→ The prescriber indicate on every prescription order, whether it may be renewed and if so, how many times.

→ It is very important particularly in the prescription containing the narcotic and other habit forming drugs to prevent its misuse.

9. **Signature, address and registration number of the prescriber.**

→ The prescription must bear the signature of the prescriber along with its registration number and address.

Sources of errors in prescriptions

a) Abbreviation

- ✓ An abbreviation such as ‘g’ is written to indicate gram and ‘mg’ to indicate milligram.
- ✓ Sometimes while writing ‘gm’ for gram may be mistaken and ‘mg’ may be written due to human error which ultimately leads to error in prescriptions.

b) Name of the drugs

- ✓ There are certain drugs which are often called as SALA DRUGS (sounds alike, looks alike) which are cause of error in prescriptions. Some of them are

  Acitop- Azitop

  Diamox Dimox

- ✓ These are drugs which sounds alike.
- ✓ Similarly in market there are different brands of drugs which look alike and leads to error in dispensing.
- ✓ Cipromax (ciprofloxacin inj) and metris (metronidazole inj) are both similar in appearance.

c) Strength of preparation

- ✓ The strength of the preparation should be stated by the prescriber.
- ✓ It is most important when there is availability of drugs with different strength.
- ✓ For example, indomethacin is available in the strength ranging from 25, 50 and 75 mg strength.
- ✓ When a prescription is obtained for an indomethacin without specifying any strength, then it would be wrong to give indomethacin of any strength with guesswork.
- ✓ It should have to be review back for confirming strength.

d) Dosage form of the drug prescribed

- ✓ Many drugs are available in more than one dosage form such as tablet, capsule, liquid, injectables, topical.
- ✓ The pharmaceutical form of the drug should be written on the prescription in order to avoid confusion.

e) Dose

- ✓ Sometimes there may be confusion on the frequency of dose.
- ✓ Such types of error are generally met in case of sustained release/controlled release/delayed release formulations.
- ✓ Such formulations are generally administered once or twice daily.

- ✓ So, if prescriptions for such preparations come as four or five times a day, it should be thoroughly checked and discussed with the prescriber.
- ✓ Such error can be met in case of drugs like sodium alendronate which is taken once a week in most of the case.

f) Instructions for the patient

- ✓ The quantity of drugs to be taken, its frequency and the duration should be clearly mentioned in the prescription.
- ✓ Otherwise, it creates error in the administration of the drugs and on the overall therapy.
- ✓ Similarly, time of administration of drugs, like on empty or full stomach, should be taken in considerations.

g) Incompatibilities

- ✓ Pharmaceutical, chemical or physical incompatibilities may appear on the drugs prescribed to the patient.
- ✓ So, keen attention should be taken on it.

h) Drug-drug, drug-food interaction

- ✓ When numbers of drugs are prescribed to the patient, then it is necessary to check the possible interactions with the prescribed medicines or with the food.

DISPENSING

- ✓ Dispensing means to prepare and supply of a medicine to an individual, in accordance with the prescription of a practitioner.
- ✓ In other word the preparation, packaging, labeling, record keeping, and transfer of a prescription drug to a patient.
- ✓ The new definition of dispensing as a work of providing medicine with self-speaking label attached to the dispensed medicine in according to the physician's prescription, with required information and counselling to the patient on safe and rational use of drug and about effect and other related information about drug and therapy.
- ✓ As seen from definition of dispensing, dispending works seems to be simple and easy. But in practice it is not that level.
- ✓ A pharmacist must take reasonable steps to ensure that the dispensing of a medicine in accordance with a prescription or order is consistent with the safety of the person named in that prescription.

- ✓ In dispensing a prescription, pharmacist has to exercise an independent judgment to ensure the medicine is safe and appropriate for the patient, as well as that it conforms to the prescriber's requirements.
- ✓ If there is any doubt, the prescriber is to be contacted. In conforming to the above principle, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history, and other relevant circumstances need to be taken into account.
- ✓ According to the place of dispensing this can be categories into two groups.

  i.e. dispensing in **hospital** and other is dispensing in **community pharmacy**. Here we are dealing mostly about dispensing in community pharmacy.
- ✓ In community pharmacy normally prepared dosage form are dispensed which are manufactured by manufacturer in well controlled environment and these products are marketed only after assuring quality of product.
- ✓ In community pharmacy some time some preparation has to be prepared instantly after receiving prescription, those types of preparations are called **"extemporaneous preparation"**

As we have defined dispensing as a process starting after receiving prescription to the handing over medicines with proper counseling according to the received prescription, there are different steps exists in dispensing process.

Those **steps** can be listed below. (**General dispensing procedure**)

1) Receiving the prescription of medication order
2) Generate patient medication profile/ checking present prescription against medication profile
3) Checking prescription
4) Selection of drug
5) Consultation with consultant if necessary
6) Compounding of required drug
7) Preparation of label for prepared drug
8) Interpretation of necessary information written in prescription
9) Counselling of the patient about therapy and drug
10) Rechecking of these selected medicine with the prescription
11) Handling over medicine to the patient
12) Rechecking of labelled drug against prescription

13) Rechecking of label and information written in label with information written in prescription.

First step of dispensing is receiving of prescription from the patient these received prescription are coded and registered in the register as per the documentation policy of the pharmacy. Sometime some pharmacy keeps the Xerox copy of the received prescription according to their own policy, but most of the dispensary keep the record in patient profile in computerized data base. But in context on Nepal record keeping of the patient prescription is not employed.

After receiving, registering the prescription and profile updating the prescription is checked for dose and the medication error, contraindication and drug interactions. If any error or chance of drug interaction is observed then the corresponding pharmacist has to contact the prescriber for rectification of the error.

After this select the drug according to the prescription. If the medicine is prescribed generically ad there is more than one brand available, check the selected brand which is listed in the interchangeable multi-source medicines list. Check the expiry date of medicine.

After selecting the medicine proper label should be prepared. In the label following things should be present.

a) Name of the product
b) Name of patient
c) Way of administration
d) Frequency of administration
e) Duration of therapy
f) Dispensed date
g) Dispensing pharmacy
h) Expiry date of the product.

Then the patients are suggested to get cancelling, and before leaving the pharmacy the patient should understand

a) Why the medicine has been prescribed for them
b) How to take it
c) When to take it
d) How long to take it for
e) How to recognize side effects
f) What to do if side effect occur
g) What special precautions to take
h) Foods or medicines to avoid
i) Correct strength of the medicine
j) What to do if they think the medicine is not working
k) When to contact doctor
l) Appropriate disposal of any unused medicine.

Labelling of dispensed product

Pharmacists are to label dispensed medicines in accordance with any statutory provisions and these with a view to:

• Maximizing the benefits of the therapy

• Improving the patient's understanding of the treatment

• Enhancing compliance

• Minimizing adverse effects.

The label is to include the following:

- The brand and generic names of the medicine
- The strength, the dose form and the quantity supplied; for extemporaneously prepared medicines and medicines not dispensed by counter
- The name and strength of each active ingredient, and the name and strength of any added preservatives or the name of the formula as described in a standard reference book
- Specific directions for use, including frequency and dose the patient's name
- The date of dispensing or supply
- The dispenser's (and if different, the checking pharmacist's) initials
- A unique identifying code
- The name, address and telephone number of the pharmacy or pharmacy department at which the prescription was dispensed
- Storage directions (where important) and expiry date (where applicable)
- The words 'Keep out of reach of children

Preparation of labels for dispensed medicines

The label on the dispensed medicines should provide the following information:

1. Name and address of the patient
2. Name and address of the supplier and date of supply
3. Precise details regarding contents of the container when dispensed
    a) The name of the medicine
    b) The strength of the medicine
    c) The quantity in the container
4. Storage conditions and shelf life of the product
    a) Temperature
    b) Humidity
    c) Light
5. Instruction to the patient
    a) Directions

b) Shake the bottle

c) Take with water

Cautionary and Advisory labelling

The problem of poor compliance and adverse effects from medicine can be minimized when the pharmacist takes the time to ensure the patient understands the dosage instructions. The following wording may be given on the label:-

1 **Do not drink alcohol while being treated with this medicine.**

2 Not to be taken

3 **Take each dose on an empty stomach**-
One hour before or two hour after food

4 **Do not take milk, iron preparation with this medicine**

Do not take aspirin while taking this medicine.

5 **To be sucked of chewed** other medicines

To be dissolved under the tongue

6 **Dissolve or mix with water before taking**

To be taken with plenty of water

To be swallowed whole, not to be chewed

Avoid exposure of skin to direct sunlight.

The preparation may colour the urine or stool

7 **Keep away from naked flame**

Do not use ……days after opening
(Date of opened…. /……../……..)

Do not stop taking medicine without consulting your doctor.

This medicine may make you sleepy and make it dangerous to drive of operate machinery.
'Avoid alcohol intake'

Patient counseling

- ✓ Patient counseling refers to the process of providing information, advice and assistance to help patients use their medications appropriately.
- ✓ The information and advice is given by the pharmacist directly to the patient or the patient's representatives, and may also include information about the patient's illness or recommended lifestyle changes.
- ✓ Patient counseling is defined as providing medication information orally or in written form to the patients or their representatives on directions of use, advice on side effects, precautions, storage, and diet and lifestyle modifications.

Objectives of Patient Counseling

- ❖ Good communication skills are needed to get patient confidence and to help motivate the patient to adhere the recommended regimen
- ❖ Better patient understanding to their illness and role of medication
- ❖ Improve medication adherence

Functions

- ✓ Better patient understanding of their illness and the role of medication in its treatment.
- ✓ Improved medication adherence.
- ✓ More effective drug treatment
- ✓ Reduced incidence of adverse effects and unnecessary healthcare costs.
- ✓ Improved quality of life for the patient
- ✓ Better coping strategies to deal with medication related adverse effects.
- ✓ Improved professional rapport between the patient and pharmacist.

Qualities of a Good Counselor

a. <u>Be a good listener:</u>

- ✓ Counseling is an interactive process.
- ✓ The pharmacist must listen attentively to the patient and observe both verbal and non-verbal behavior.
- ✓ This gives the pharmacist an opportunity to assess the patient's knowledge about their disease and medications.

b. <u>Be flexible:</u>

- ✓ The pharmacist should be flexible and provide advice and information which is tailored to the individual patient's needs and capabilities.

c. Be empathetic:
   - ✓ The pharmacist should try to understand the patient's personal suffering and situation as if the problem is his or her own.

d. Be non-judgmental:
   - ✓ The pharmacist should not judge the behavior of patient based on their illness or the group s/he belongs to.

e. Be tolerant:
   - ✓ During the course of counseling, patients may become agitated, unreasonable or hostile.
   - ✓ The pharmacist should acknowledge patient's feelings and and be tolerant of these.

f. Communicate confidently:

✓ The pharmacist should speak confidently as this will improve the patient's acceptance of the pharmacist's advice.

Communication Skills for Effective Patient Counseling

i. Language:
- ✓ When speaking to patients, use simple language and avoid unnecessary medical words.
- ✓ If possible, speak the patient's own language.

ii. Tone:
- ✓ While counseling, the tone of one's voice is important.
- ✓ Changes in the level and range of pitch convey information about feelings and attitude of the person speaking; the tone of the voice should be caring and reassuring.

iii. Volume:
- ✓ Ideally, counseling should be conducted in a quiet, private setting where it is unnecessary to raise one's voice.
- ✓ Although, it may be necessary to speak more loudly to patients with hearing problem, most deal patients gain more benefit if the speaker moves closer, and directs their voice towards the patient's ear.

iv. Speed:
- ✓ The clarity of our communication depends on our rate of speech.
- ✓ Patients may have difficulties to interact with a pharmacist who speaks quickly because they may feel the pharmacist is too busy.
- ✓ This may happen if the pharmacist is nervous or is uncertain about the information being given

v. Proximity:
- ✓ This refers to the distance that people maintain between themselves during the counseling process.

- ✓ This space has been classified as: intimate(45 cm or less), personal (45 cm to 1.2 m), social (1.2 m to 3.6 m)
- ✓ Generally, counselors or healthcare professionals use intimate or personal proximities.

vi. **Eye contact:**

- ✓ The duration of time that people look at one another during a conversation varies depending upon whether they are speaking or listening.
- ✓ Listeners look at the speaker more often and for longer period of time.
- ✓ For cultural or personal reasons such as timidity, sadness or depression some people may avoid looking into the counselor's eyes.

vii. Facial expression:

- ✓ These can be used during counseling to demonstrate empathy towards the patient.
- ✓ Head movements such as nodding, hand gestures, and body postures also can be used to advantage.

Steps during Patient Counseling

- ❖ Counseling is a two way communication process, and interaction between the patient and the pharmacist is essential for counseling to be effective.
- ❖ The following steps can be considered during patient counseling:
- ✓ Preparing for the session
- ✓ Opening the session
- ✓ Counseling content
- ✓ Closing the session
- ✓ Getting started

a) Preparing for the Session

- ✓ The success of counseling depends upon the knowledge and skills of the counselor.
- ✓ The pharmacist should know as much as possible about the patient and his/her treatment details.
- ✓ In the hospital setting this may be possible through reference to the patient's case notes.
- ✓ In the community pharmacy setting, sources of information include the patient and their prescription, and in some cases a record of previous dispensing for the patient.
- ✓ If the patient is receiving a medication which is unfamiliar to the pharmacist, then a drug information reference should be consulted before the counseling has been commenced.
- ✓ The next issue to be considered is the mental and physical state of the patient.

- ✓ If the patient is in hurry, in pain, or is non-communicative, it is very difficult to counsel the patient effectively.
- ✓ In situations like these, the aim of counseling may need to be changed.

b) Opening the Session

- ✓ The most initial phase of counseling is used for gathering of information.
- ✓ The pharmacist should introduce himself to the patient and greet by their name.
- ✓ If any help is required in pronouncing the name, ask colleagues or the patient directly.
- ✓ It is best to use titles like Mr., Mrs., Ms. and then say the first name.
- ✓ The pharmacist should identify the purpose of the session very clearly.
- ✓ For example: *"Hello, Mr. Hari! My name is ABC and I am a pharmacist. I would like to tell you about your medications. Do you have few minutes to spend with me?"*
- ✓ Patients who visit community pharmacies are often in a hurry to go home with the medication, and this type of introduction mentally prepares the patient to spend time with the pharmacist.
- ✓ The pharmacist gathers the information from the patient about their understanding of their disease, drug treatment and use of alternative medications such as ayurvedic or home remedies.
- ✓ Other information which may be relevant includes, previous drug allergies, past medical history and personal habits such as chewing of pan masala, cigarette smoking and alcohol consumption.
- ✓ Using open ended question is useful technique for gaining the confidence of the patient, and the answers allow the pharmacist to assess the patient's information needs.
- ✓ For example: "*What did your doctor tell you about your illness?", "What do you know about your disease?"*
- ✓ *This allows the pharmacist to assess the patient's understanding of their medication and helps the pharmacist to avoid giving information which may contradict advice given by the patient's doctor.*

c) Counseling Content

- ✓ The counseling content is considered to be the heart of the counseling session.
- ✓ During this step, the pharmacist explains to the patient about his or her medications and treatment regimen.
- ✓ Lifestyle changes such as diet or exercise may also be discussed.
- ✓ Topics commonly covered include:
  - Name and strength of medication

- Reason why it has been prescribed (if known), or how it works
- How to take the medication (how much and how often)
- Expected duration of treatment
- Expected benefits of treatment
- Possible adverse effects
- Possible medication or dietary interactions
- Advice on correct storage
- Minimum time duration required to show therapeutic benefit
- What to do if a dose is missed
- Special monitoring requirements, e.g..: blood tests
- Arrangements for obtaining further supplies

✓ Because of time constraints, it is often necessary to prioritize these points.

d) Closing the Session

✓ Before closing the session, it is essential to check the patient's understanding.

✓ This can be assessed by feedback questioning, such as 'Can you remember what this medication is for?' or 'How long should you take this medication for?'

✓ During the discussion some of the patient's information needs may have new questions or doubts.

✓ It is therefore advisable to finish the session by asking the patient 'Do you have any questions?'

✓ Before final closure and if time permits, summarize the main points in a logical order.

✓ If appropriate, the pharmacist can give their telephone number to encourage the patient to make contact if they need further advice or information.

e) Getting Started

✓ In both hospital and community pharmacies, time and the availability of staff often determine who one can counsel.

✓ High patient numbers mean that pharmacists may need to identify and give priority to those patients who are most in need of counseling services.

These may include:

- Patients receiving specific medications, such as antibiotics or drugs with a narrow therapeutic window such as warfarin, theophylline or methotrexate
- Patients receiving complex medication regimens, e.g. antitubercular drugs
- Patients receiving medications via a specialized delivery system e.g. rotohalers
- Patients with a history of poor medication adherence

- Elderly patients taking many medications
- Patients being discharged from hospital
- Patients referred by physicians

Counseling Aids

- ✓ When information is provided to the patient verbally, there are many chances of the patient forgetting the information over a period of time.
- ✓ A variety of teaching or educational aids have been developed to assist the patient counseling.
- ✓ If information is provided in printed format, the patient can go through the information at leisure as and when the information is required.
- ✓ Medication cards can be a useful aid particularly for those patients who are taking many medications on a long-term basis.
- ✓ A medication card is a written summary of a patient's medications, presented in a way which is easy for the patient to understand
- ✓ Cards may be hand written or computer generated.
- ✓ Once a card is given to a patient, it can be used to assist the patient to organize medication routines at home, and is also useful to show other healthcare providers.
- ✓ It is important that the card is updated when changes to the medication regimen are made.

Reference: *A Textbook of Clinical Pharmacy Practice, G.Parthasarathi, Karin Nyfort-Hansen, Milap C Nahata*

Manufacturing and Expiry date of Drug

- The manufacturing date is a date on which a product is placed in the container or package in which it will be sold to the customers.
- The expiry date is the point in time when a pharmaceutical product is no longer within an acceptable condition to be considered effective. The medication reaches the end of its 'shelf life'. Depending on the product, the expiry date may be set as a fixed time

  After manufacture

  After dispensing

  After opening of the manufacturer's container
- The expiry date is that point in time when a pharmaceutical product is no longer within acceptable specifications for **potency** and **stability.**
- In determining an expiry date, a range of characteristics of the product are studied over time. One important characteristic is the chemical stability of the active ingredient.
- Temperature has a pronounced effect on the rate of degradation of the active ingredient. As the rate of decomposition usually doubles for every 100˚C rise in temperature, it is important to comply with the storage conditions specified on the container.
- The expiry date may be set as a fixed time after manufacture, dispensing or opening of the manufacturer's container. It is good practice not to use drugs past their expiry date.
- The date after which a consumable product such as food or medicine should not be used because it may be spoiled, damaged or ineffective.
- Expiration dates are especially important in the case of medications, since the expiration date provides the only indication about whether the product can still be safely used, unlike food items where there is often visible indication that its "best by" date has passed.
- As using expired medical products is risky and may be harmful to health, the FDA mandated specifying expiration dates on all prescription and over-the-counter medicines in the late 1970s. Also called "expiry date."
- Expiration dates for medicines are often marked "EXP" and can be found printed on the label or stamped on to the medicine bottle or carton.
- The manufacturer's expiry on a container is the unopened expiry date. Certain oral preparations have a shorter shelf life once they have been opened. This should be highlighted on the medicine label or container.
- Expired medicines can be rendered less effective or made more risky due to a change in chemical composition. Since chemical compounds may have decreased potency over a period of time, it is important to adhere to expiry dates. Taking an expired medication

that is less effective may have serious consequences because it may not be able to control the underlying condition as well as an unexpired medication would.

- ❖ In some cases, the USFDA may extend the expiry date of a medication if there is a shortage of it. The extended expiration date is based on stability data for the medication that has been reviewed by the FDA.
- ❖ Expired medication should be disposed of in a proper manner, rather than being dumped straight in the trash. If no disposal instructions are provided for an expired drug, consumer should check for drug take-back programs in their state or municipality.
- ❖ In the absence of specific instructions or take-back programs, U.S. federal guidelines recommend disposing of expired or unwanted medicines by putting them in a bag or container and mixing up with coffee grounds or kitty litter. A small number of medicines that can be fatal to children or pets with even one dose are permitted to be flushed down the sink or toilet if they expire or are no longer needed.

EXPIRED DRUGS:

- ❖ Expired drugs are those pharmaceutical products, which are no longer within acceptable specification for potency and stability .they have decreased or limited potency of active ingredient, altered physiochemical characteristics (such as ph ,dissolution rate of tablet and capsules)and are changed to toxic degradation products. They are unacceptable because they altered bioavailability, safety hazard and discomfort for use.
- ❖ Expired date on a product is set as a fixed time after manufacturing, dispensing or opening of the container. So it is good practice not to use expired drugs.
- ❖ The shelf life of a drug is time up to which it stay within pharmacopoeial parameter .but the expired drug reaches the end of self-life limit. For some drugs like eye drops self is determined not only by decomposition of the active drug but also by the risk of microbial contamination.

Reasons for discarding expired drugs

Except in case of emergency when there is no alternate solution and there is feasibility for estimating percentage purity of the only compound available is possible, all the expired medicines must not be used. The reasons behind this are as follows:

1) **Change in concentration:** due to loss of active ingredients, the expired drugs have less than the claim percentage and for some products containing alcohol, loss of vehicle can result in an increase in the concentration of active ingredient. The situation endangers the therapy.
2) **Alteration in bioavailability:** bio-availability and bioequivalence are parameter to judge the quality of the product. Expired drugs have alteration in this parameter and using them may not maintain desired therapeutic concentration**.**
3) **Loss of content uniformity:** Expired drug show a loss of content uniformity as a function of time. Particularly in case of suspension problem in re-dispersion or alteration in sedimentation volume is noted.
4) **Decreased microbiological status:** on passing expiry date, there may increase in the number of viable micro organism. if the package is damaged during distribution and storage micro-organism may increase easily.
5) **Toxic product**: the degraded product may become toxic for use, e.g. tetracycline may change to epihydrotetracycline which is very toxic.
6) **Damage in packaging:** damage in package integrity during distribution or storage creates a stability problem. For e.g. if a plastic screw cap loses back of torque, the chemical and microbiological hazard significantly increases**.**
7) **Loss of pharmaceutical elegance:** expired medicine may lose color, e.g. loss of color from colored solution and tablet.

Environmental factors affecting quality of drugs:

Environmental factors affect the stability of pharmaceutical products. The instability may be either due to effect on active constituents or and excipients. Decomposition or degradation of the product can be minimized if the case is known.

<u>According to Rhodes, there are six causes of product instability which are:</u>-

A) Loss of active drug due to hydrolysis or oxidation e.g. hydrolysis of aspirin.
B) Loss of vehicle e.g. evaporation of water from oil in water cream.
C) Loss of colours and flavours e.g. fading from tablets.
D) Reduction of bio-availability.
E) Loss of content uniformity e.g. creaming of emulsion.
F) Formation of toxic product from any degradation.

Environmental factors causing deterioration of drug products are as follows.

1) Physical factors.

a) Effect of light.

b) Moisture.

2) Chemical factors.

a) Oxidation.

3) Biological factors.

1) PHYSICAL FACTORS.

A) Effect of light:

- ✓ Degradation due to light is known as photolysis. The light having shorter wavelength is more damaging e.g. ultra –violet light is more harmful than visible light.
- ✓ When light Energy is absorbed, it is either re-emitted or transformed into physical or chemical energy which is usually lost as heat. Chemical energy may cause cleavage or rearrangement of the molecular bonds.
- ✓ Drugs which are light sensitive are packed in amber coloured glass bottles and stored in dark places, Eg. Hydrolysis of amyl nitrate, Oxidation of volatile oils, Colour change of morphine and codeine.

B) Temperature:

The entire drug undergo chemical degradation i.e. reaction continues. And all the chemical reacting depends on temperature. The rate of degradation reaction doubles for every 10°C rise in temperature.

C) Moisture or humidity:-

Atmospheric moisture decreases the stability of dosage from like tablet and capsules. In presence of moisture gelatin of capsules undergo surface hydrolysis and becomes sticky.

Moisture or humidity refers to water molecules which enhance hydrolysis, oxidation and microbial growth.

2) CHEMIAL FACTORS:

A) Oxidation:-

- ✓ Addition of oxygen to drug molecule is oxidation. Oxidation due to atmospheric oxygen is known as auto-oxidation and if involves a chain reaction.
- ✓ First oxygen free radicals are formed resulting to formation of peroxyradicals. Free radicals than react with drug molecules and forms hydroperoxide and more free radicals. This process propagates until all the drugs molecules have been consumed. Finally peroxyradical combine with hydroperoxide to form inactive product.

3) BIOLOGICAL FACORS:-

Microbial decomposition of drug product may occur due to poor packaging and bad storage condition that provides the entry and ultimately growth of the microbes makes the product useless. For eg microbial contamination may destroy emulsifying agent resulting to cracking of emulsion.

Other factors affecting product quality are.

i) Property of each active and inactive ingredient of product.

ii) Particle size, ph, properties of solvent used.

iii) The nature of packaging.

Shelf life

- The term "shelf life" of a drug slightly differs from a drug's "expiration date". The shelf life generally relates to a drug's quality over a specified period of time, whereas the expiration date relates to both quality and safety of a medication at a specific point in time.
- A drug that has passed its shelf life might still be safe for consumption, but its quality is no longer guaranteed. Shelf life is variably influenced by storage conditions, such as exposure to heat, light and moisture.
- A drug's shelf life is usually shortened if it is not stored in its original container. In manufacturing terms, shelf life can also mean the time that elapses between when the drug is made and the expiration date assigned by the manufacturer.

DRUG STORAGE:

Definition;-

Storage of the drugs is the process of keeping the medicines and medicinal items in a safe and good condition.

AIM:

- To preserve their potency, physical and chemical properties.
- To protect from sunlight, moisture, incorrect handling.
- For proper use, to be kept away from children as many drugs are poisonous.
- To protect the medicament from degradation.

IMPORTANCE:

1) Incorrect handling and storage leads to degradation and retards self life of the drug.

2) A numbers of medication poisoning on children have occurred due to unsafe storage as children are notoriously curious, so drug be stored away from reach of children's.
3) Many medicines are sensitive to light, heat and humidity, they are to be placed in a cool dark and dry place.
4) Drugs have limited self life and they cannot be used after expiry date so can't be stored for ever.

While designing drug store, following basic point should be considered.

a) Rooms selected should be dry, cool, well-ventilated, and be located away from direct sunlight.
b) Room should be well equipped with facilities such as refrigerators safe cabinets and racks.
c) Drugs should be placed in their appropriate place following some system like alphabetically or therapeutic categorically so that their selection should be easy.

Storage requirements

1) Warm place: temperature ranges between 30ºC and 40ºC
2) Room temperature: temperature ranges between 20ºC- 25ºC
3) Cool place: temperature ranges between 8ºC- 25ºC
4) Cold place: temperature ranges between 2ºC- 8ºC

Storage condition	Examples of drugs
Cold place	Anti-venoms, certain blood products, diagnostic reagents, hormones, sera, vaccines
Cool place	Antibiotics, vitamins, certain hormones
Under lock and key	Narcotic & psychotropic substances, schedule Ka drugs
Separate rack with lock & key	Poisons

The following categories of drugs require special storage facilities;

✓ Products that must be kept frozen (vaccines and sera)
✓ Products sensitive to heat that require refrigeration.
✓ Products that have a reduced shelf life at uncontrolled room temperature and need mechanical ventilation or air-conditioning.
✓ Flammable products that require separate, fireproof area.
✓ Products prone to theft or misuse.

Items needing storage at controlled environment

- ✓ The shelf life of the following products may be reduced if stored at uncontrolled humidity or at room temperature in hot climates. So controlled condition is necessary. For example, injectables like adrenaline. These products must be protected from heat and light.
- ✓ **Intravenous fluid, pessaries, suppositories, creams and ointments-**These products may melt at temperature greater than 30° C. If the temperature exceed the active ingredient in the formula may become unevenly distributed. So, it is better not to use if temperature exceeds the limit.
- ✓ **Products containing rubber, latex, cellulose and plastics-** Condoms, sterile disposable needles, syringe and catheters require protection from excessive humidity, cold and strong light. Any of these conditions make products brittle, stained and unusable.
- ✓ In hot climate, these products should be stored at air-conditioned room.

Items needing freezing or refrigeration

- ✓ Vaccines and blood products lose potency if kept even for short time outside the recommended range of temperature. For these products **cold chain** should be maintained at every stage.
- ✓ Freezing is a damaging as high temperature for some products like injectables, contraceptives, insulin, adrenaline, DPT, DT, TT, and hepatitis B vaccine. These require the **pre-mentioned condition**.
- ✓ Short periods at room temperature are acceptable for products like insulin and ergotamine.
- ✓ Other items such as vaccines should always be transported in cold boxes.

Controlled drugs

- ✓ **Narcotics drugs** for example morphine, pethidine and other specified drugs that may be abused are governed by special drugs legislation and regulation that control import, export , production, supply, possession, prescribing, record keeping and retention of documents. The following security measures are applied
- ✓ A safe double locked cabinet fitted with a light (generally red) that glow when the door is open.
- ✓ A special register recording details of each receipt or issues with two signatures, physical counting after each entry, and signatures at 'handover-takeover'.
- ✓ Independent audit.

Attractive items

- ✓ The items prone to theft, abuse or misuse like expensive drugs, equipments such as scissors, safety razors, and rolls of cotton are stored at separate locked area or cupboard where they can be supervised.
- ✓ These items require strict record keeping and more frequent stock taking than other items.
- ✓ Periodic record of consumption (issue) against actual recorded use (outpatient use, prescription records or ward stock record) should be made to detect any theft or misuse.

Flammables and corrosives

- ✓ Acetone, anesthetic ether, alcohols and kerosene require a separate outdoor store located away from the main building.
- ✓ Fire extinguishers should be readily available.
- ✓ A small working amount of flammables may be kept in a steel cabinet in well-ventilated premises, away from open flames and electrical appliances.
- ✓ The cabinet should be marked 'highly flammable liquid'.
- ✓ Corrosives and oxidant substances like glacial acetic acid, silver nitrate, sodium nitrate, sodium hydroxide pellets should be stored away from flammables, ideally in a separate steel cabinet.
- ✓ Appropriate protective gloves should be used when handling them.

Handling of drugs

a) Handling of solid dosage forms
b) Handling of liquid dosage forms
c) Handling of injectabales
d) Handling of poisonous drugs

Describe the importance of manufacturing and expiry date of drugs with examples

IMMUNIZING AGENT

Immunity:

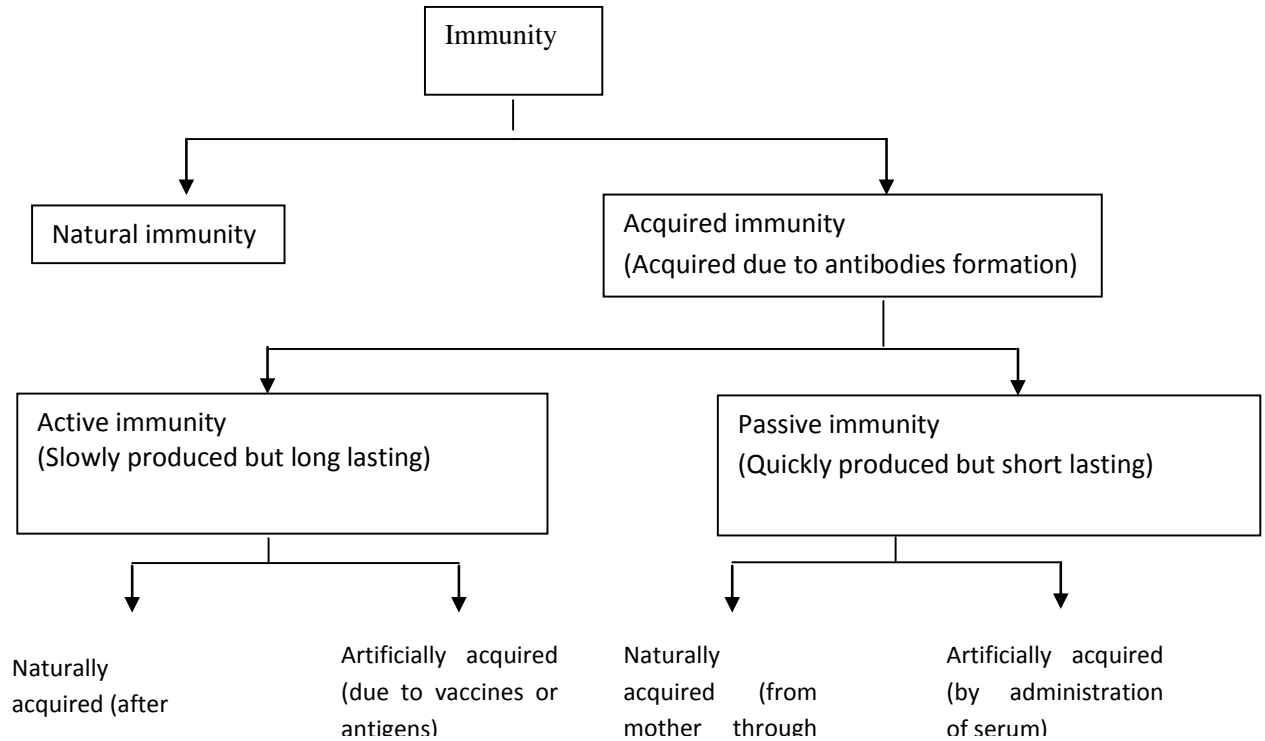
The power of the body to resist the effects of invasion of pathogenic micro-organisms is known as immunity.

The lack of power of the body to resist infection is called susceptibility.

The factors responsible for immunity are:

- Phagocytosis
- Anti-body formation

TYPES OF IMMUNITY



Acquired immunity:

Resistance against disease acquired by an individual during life is called as acquired specific immunity. This is of two types.

1. Active acquired immunity:

The resistance induced in an individual after effective contact with an antigen is called active acquired immunity. It follows either by natural infection or by vaccination.

In this immune system actively participates in producing antibody often through cell mediated immunity.

2.Passive acquired immunity:

This results in immediate protection from disease of short duration by the administration of readymade antibodies e.g. diphtheria anti-toxins.

Immune system:-

The immune system is a network of defense mechanism of living body against various disease classified as humoral and cellular immunity. It provides immunity by two ways. That is by:

1.Humoral immunity:-(anti-body mediated immunity)

This is provided by β-lymphocytes which produces antibodies therefore called as antibody mediated immunity.

2.Cellular immunity:(cell mediated immunity)

This is provided by T-lymphocytes which produces CD4 T-cells and CD8 T-cells etc.

Antigens:

These are the foreign substances which when introduced into the body stimulates anti-body formation.

Antibody:

These are serum glycoprotein produced by the living body as a result of antigenic stimulation that can react specifically with antigen to neutralize it.

Immunizing agent:

Immunizing agents may be classified as

1.Vaccines

2.Immunoglobulin(antibody)

3.Anti-sera

1.vaccines

- ✓ **Vaccination** is the administration of antigenic material (a vaccine) to stimulate an individual's immune system to develop adaptive immunity to a pathogen. Vaccines can prevent or ameliorate morbidity from infection.
- ✓ Vaccines are the antigenic preparation which produces active immunity to the body when administered.
- ✓ Vaccines when administered, stimulates the body to produce antibodies, which provides active immunity as a prophylactic measures, used to protect individual against a particular infection or disease.
- ✓ The term 'vaccine' was originally derived from the Latin word "vacca" meaning cow.
- ✓ Vaccine may be defined as-
- ✓ 'Pharmaceutical suspension or solution of an immunogenic substances and compounds that is intended to induce active immunity'.
- ✓ According to British Pharmacopoeia, 1998 vaccines defined as- 'Preparation containing antigenic substances that have been shown to be capable of inducing a specific and active immunity in man.'

- ✓ Another school of thought defines vaccines as- 'Any preparation that is normally used to confer active immunity, and active immunization involves the use of antigenic preparations which, when administered, stimulate the body to produce antibodies specific to the antigen administered'.
- ✓ Vaccine is an antigen, which causes production of antibodies in the biological system. It can be prophylactic or therapeutic.
- ✓ Vaccines confer immunity against infectious agent or toxin produced by organisms. They may contain living or killed microorganisms, bacterial toxoids or antigenic material from particular part of the bacterium, rickettsia or virus.
- ✓ In the rapidly involving field of new vaccine technologies one can discern
  (1) The improvement of existing vaccines
  (2) The development of vaccines for diseases against which there are no vaccines currently available.

Types of vaccines:

a) live attenuated vaccines:

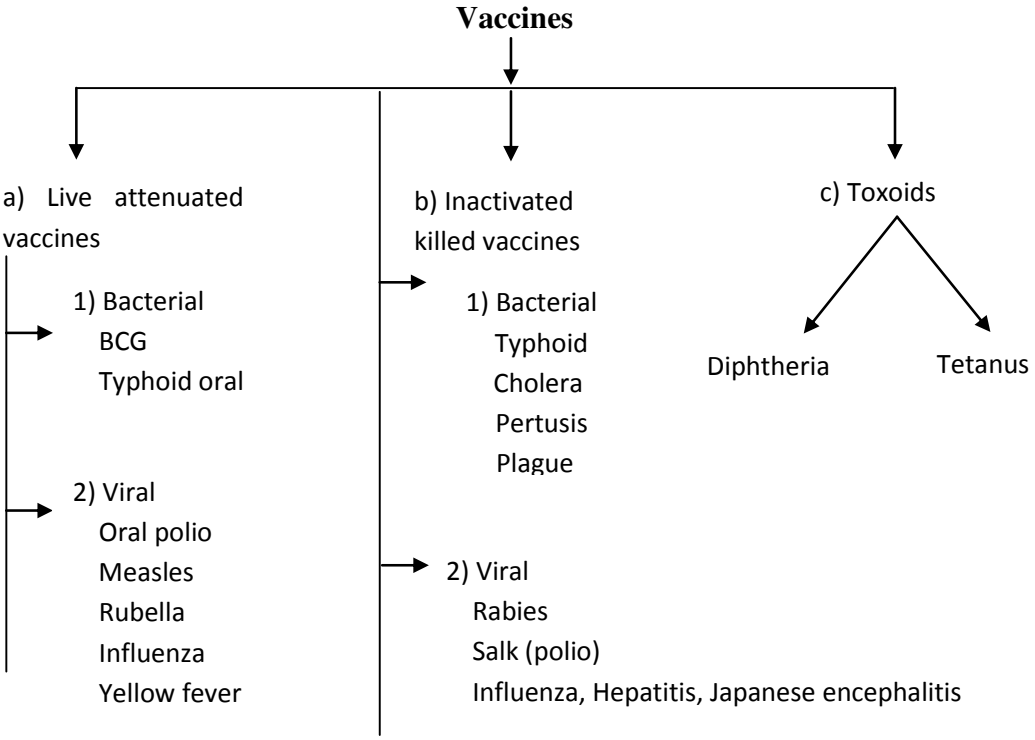
Consist of live bacteria or viruses which have been rendered a virulent.

b) Killed (inactivated) vaccines:

Consist of micro-organisms killed by heat or chemicals.

c) Toxoids:

Toxoids are modified exotoxins so that toxicity is lost but antigenicity is retained.



Characteristics of an Ideal Vaccine

- Is 100% efficient in all individuals of any age
- Provides lifelong protection after single administration
- Does not evoke an adverse reaction
- It is stable under various conditions (temperature, light, transportation)
- Is easy to administer, preferably orally
- Is available in unlimited quantities
- Is cheap

2. Immunoglobulin (antibody):

- ✓ Immunoglobulins are separated human gamma-globulin which carries the antibodies. These may be non-specific (normal) or specific (hyper-immune) against a particular antigen.
- ✓ These are used in the prophylaxis of viral and bacterial infections and are replacement of antibodies in immune-deficient.
- ✓ The different types of immunoglobulin are IgG=80%, IgA=20%, IgM=3-8%, IgE, IgD.

3. Anti-sera:

Anti-sera are purified and concentrated preparation of serum of horses actively immunized against a specific antigen e.g.

- Tetanus anti-toxin
- Diphtheria anti-toxin
- Anti-rabies serum
- Anti-snake venom polyvalent.

Vaccine	Dose(s)	Age of administration	Route of administration
BCG (Bacillus-Calmette-Guérin) i.e. Copenhagen strain	1 (0.05 ml)	At birth	Intradermal (I.D)
Pentavalent Vaccine i.e. DPT-HepB-HiB (Diphtheria, Pertussis, Tetanus, Hepatitis B and Hemophilus Influenza B)	3 (0.5 ml)	6,10,14 weeks	Intramuscular (I.M)
OPV (Oral Polio Vaccine)	3 (0.5 ml)	6,10,14 weeks	Oral
PCV (Pneumococcal Conjugate Vaccine)	3 (0.5 ml)	6,10 weeks and 9 months	Intramuscular (I.M)
IPV (Injectable Polio Vaccine)	1 (0.5 ml)	14 weeks (Addon to OPV)	Intramuscular (I.M)
MR (Measles-Rubella)	2 (0.5 ml)	9 and 15 months	Subcutaneous (S.C)
JE (Japanese Encephalitis) i.e. SA-14-14-2 strain	1 (0.5 ml)	12 months	Subcutaneous (S.C)
Td (Tetanus diphtheria)	2 (0.5 ml)	As soon as pregnancy is known (2 doses 1 month apart)	Intramuscular (I.M)

COLD CHAIN METHODS

- ✓ The "cold chain" is a system of transporting and storing vaccines within a recommended temperature range of 2 to 8 degrees Celsius (°C). From the place of manufacture to the point of administration ensuring people receive an effective vaccine / medicine consumable that have retained their viability and have not had exposure to temperature excursions (i.e. affected by heat or cold).
- ✓ This temperature range has been selected by the World Health Organization (WHO) for the National Immunization Program (NIP), as a guide to protect vaccines against loss of vaccine potency due to excessive cold or heat.
- ✓ The cold chain system requires that processes be in place to ensure that potent vaccines and viable medicines consumables reach the recipients. Maintenance of a satisfactory temperature range will not only assure this occurs but will prevent potential costly wastage. This dual rationale warrants commitment of staff to the relevant processes.
- ✓ The process of maintaining the temperature of a vaccine and other related substances from manufacturer to target person or population until it is being used is called cold chain.
- ✓ A system of distributing vaccine in potent state from the manufacture to the actual vaccination site.
- ✓ Combination of skilled man power and properly working equipment both active and passive units.
- ✓ If there is sophisticated equipment available then there will be no more man power requirement.

Logistic Management System at all Level (Top to Bottom)

- In the cold chain system 5M plays a vital role at all level.
  M=Man power
  M= Machine (active units)
  M=Materials (passive units)
  M= Money
  M = Management
- Correct management of all these five M will helps the correct maintaining of vaccines at all level (top to bottom)

Responsibility of District Health Officer in maintaining of cold chain

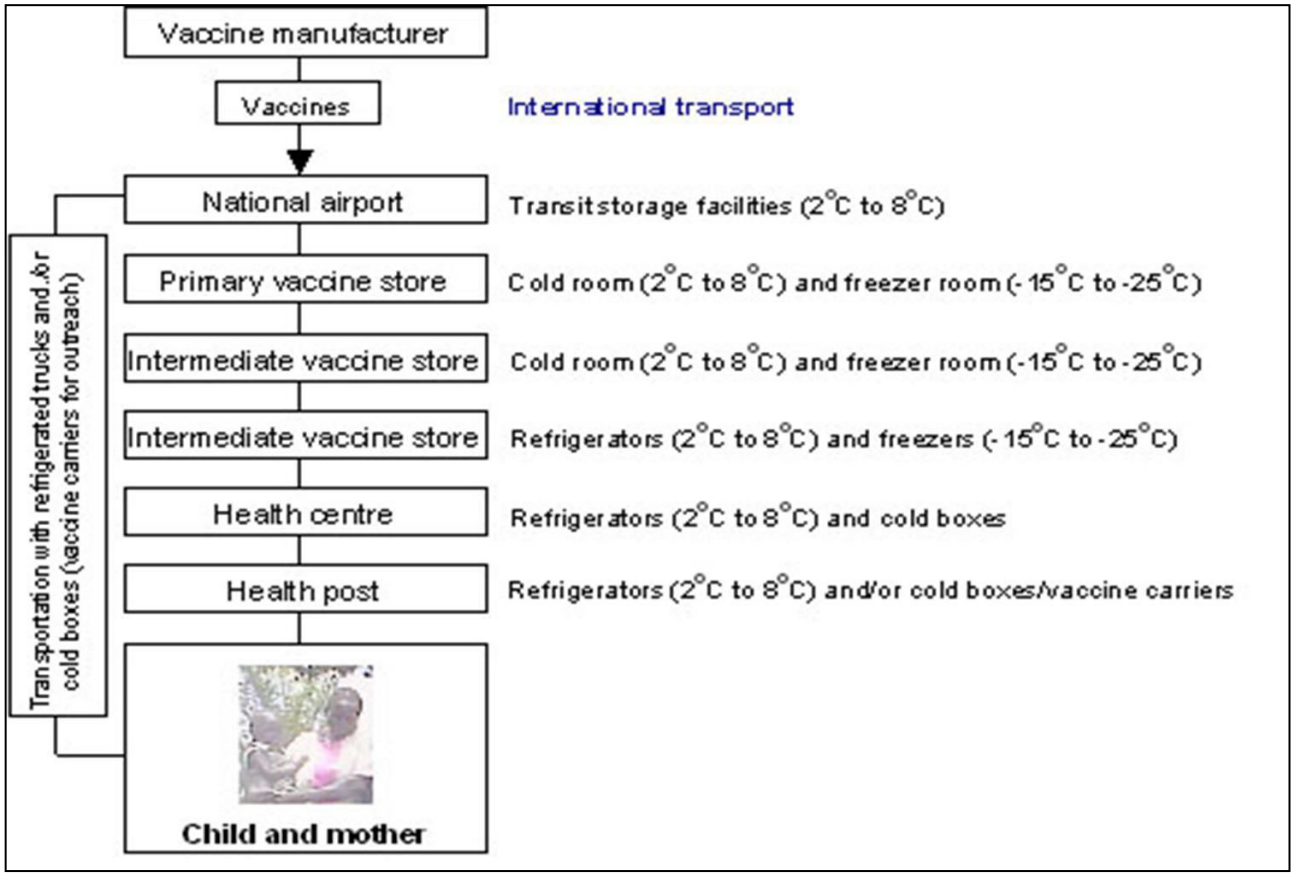
- ✓ Follow up on cold chain issues with PHCMs as appropriate
- ✓ Ensure staff have undertaken relevant training to provide vaccines testing
- ✓ Approve requests for refrigerator repairs
- ✓ Consider and approve the purchase of new Purpose Built Temperature Controlled Refrigerators as per Standard Clinical Equipment List

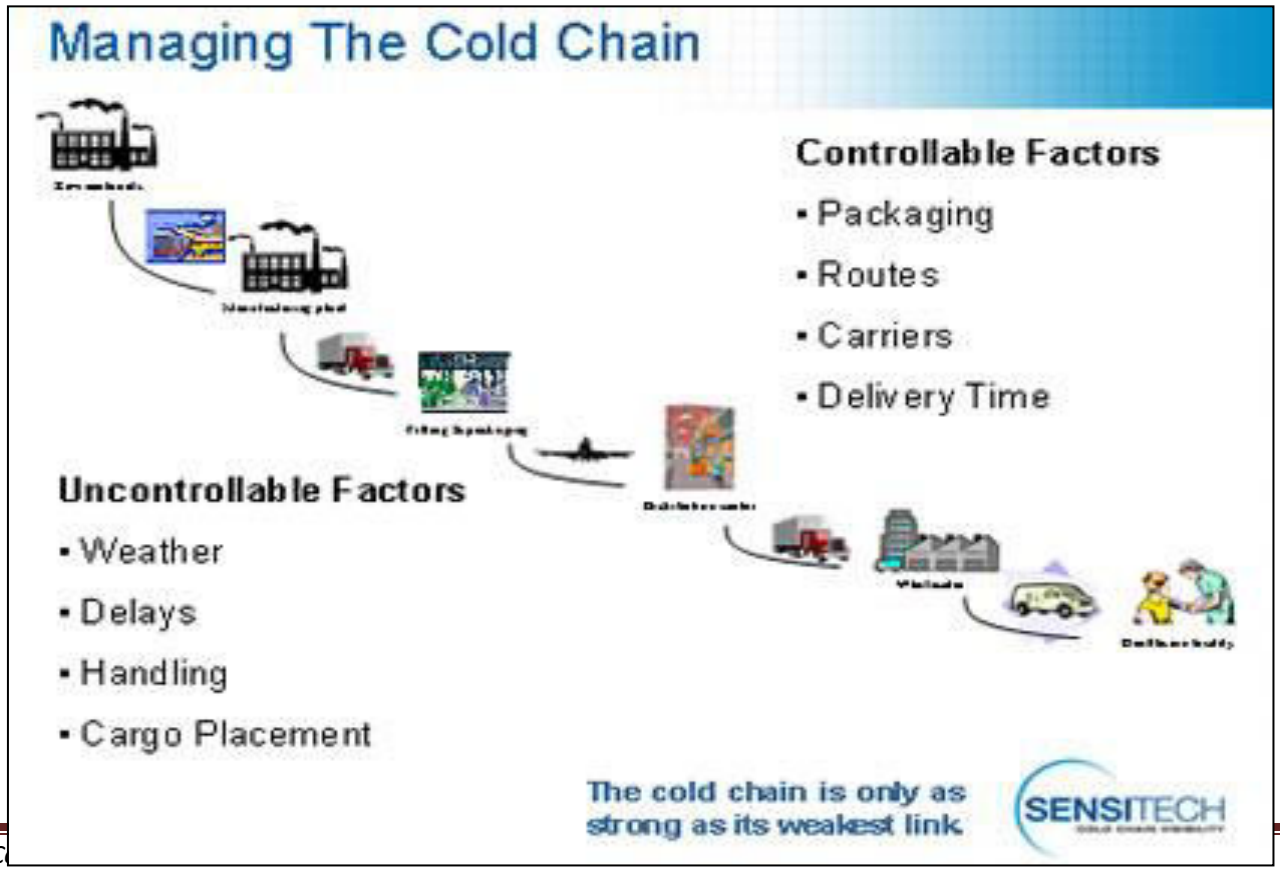
The cold chain system comprises three major elements:

- ➢ **Personnel**, who use and maintain the equipment and provide the health service;
- ➢ **Equipment** for safe storage and transportation of vaccines; and
- ➢ **Procedures** to manage the programme and control distribution and use of the vaccines.

PROCEDURE:

- The vaccines are supplied in special container to the airport.
- They must be collected at the correct cold temperature in refrigeration at the central store, regional store and district hospital.
- They must be kept in cold during transport from one store to another.
- If it is needed to take the vaccines to immunization camp, they should be carried in ice.
- During immunization session, the vaccines should be in ice bottle.





Importance of maintaining cold chain

- Vaccines are sensitive biological products which may become less effective, or even destroyed, when exposed to temperature outside the recommended range.
- Cold sensitive vaccines an immediate loss of potency following freezing.
- Vaccines exposed to temperatures above the recommended temperature range experience some loss of potency with each episode of exposure.
- Repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible.

Maintaining the potency of vaccines is important for several reasons.

- There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine preventable disease.
- Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccines may result in the cancellation of immunization clinics resulting in lost opportunities to immunize.
- Revaccination of people who have received an ineffective vaccine is professionally uncomfortable and may cause a loss of public confidence in vaccines and/or the health care system.
- An estimated 17% to 37% of healthcare providers expose vaccines to improper storage temperatures.
- Refrigerator temperatures are more commonly kept too cold rather than too warm.
- One study involving site visits showed that 15% of refrigeration units had temperatures of +1°C or lower.

Temperatures falling outside the recommended range require immediate action to avoid loss of product.

- When a cold chain break is identified after a vaccine has been administered, consult your local public health office or immunization program for advice.
- The type of vaccine, duration and temperature of the exposure will be taken into account when assessing the situation. Serological testing or revaccination may be suggested.
- Vaccines are sensitive biological products that may become less effective, or even destroyed, when exposed to temperatures outside the recommended range and/or on exposure to direct sunlight or fluorescent light.

The effective cold chain

Three main elements combine to ensure proper vaccine transport, storage and handling.

- Trained personnel
- Transport and storage equipment
- Efficient management procedures

Basic concept of rational drug use

- ✓ The rational drug use is the practice in which patients receive medication appropriate to their clinical need in dose that meet their own individual requirements for adequate period of time and at the lowest cost at them and their community.
- ✓ In simple word rational drug use is practice of taking correct drug at right dose at right time and for right duration of time to achieve a therapeutic goal.
- ✓ The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community. *(WHO conference of experts Nairobi 1985)*
- ✓ Rational drug use attained more significance nowadays in terms of medical, socio economical and legal aspect.

Concept of rational drug use

a) ***Sound diagnosis***: Rational drug follows after sound diagnosis. There should be a flow loss diagnosis to define the problem.
b) ***Appropriate drug or non-drug***: In rational drug use there should be a firm reason of prescribe. The reason should be strongly based on sound medical considerations.
c) ***Appropriate drugs***: The correct drug should be selected taking consideration of the efficacy and safety of the drug therapy diagnosis of the disease health condition of the patient and the cost of the drug therapy**.**
d) ***Appropriate dosage***: Administration and duration of treatment.
e) ***Minimal unwanted effects***: The likelihood of adverse drug reaction drug interaction and drug food interaction should be zero if not than minimal.
f) ***Correct dispensing***: There should be correct dispensing including appropriate information for patients about the prescribed medicines.
g) ***Patient adherence to treatment***: Patient compliance should be maintained various methods to ensure patient the patient compliance should be carried out such as therapeutic drug monitoring.

Promote rational drug use ??????

Rational drug use attained more significance nowadays in terms of medical, socio economical and legal aspect.

Factors that have led sudden realization for rational drug use are;

1. ***Drug explosion***: Increase in the number of drugs available has increadibly complicated the choice of appropriate drug for particular indication.

2. ***Efforts to prevent the development of resistance:*** Irrational use of drugs may lead to the premature demise of highly efficacious and lifesaving new antimicrobial drug due to development of resistance.

3. ***Growing awareness***: Today, the information about drug development, its uses and adverse effects travel from one end of the planet to the other end with amazing speed through various media.

4. ***Increased cost of the treatment***: Increase in cost of the drug increases economic burden on the public as well as on the government. This can be reduced by rational drug use.

5. ***Consumer protection Act***: Extension of consumer protection act in medical profession may restrict the irrational use of drugs.

Rational Prescribing

- ✓ Many countries are witnessing steady increase in drug consumption and irrational use of drugs by both the prescriber and the consumer with great possible economic and social consequences.
  - ❖ Correct diagnosis
  - ❖ Appropriate drug, dose, route and duration
  - ❖ Simple regimen
  - ❖ Avoid drugs if therapeutic advantage not supported by independent evidence
  - ❖ Avoid drugs with poor risk/benefit ratios
  - ❖ Review regularly and terminate if no longer needed.

Steps to increase the rational prescribing

- ✓ Step I: Identify the patient's problem based on symptoms and recognize the need for action.
- ✓ Step II: Diagnosis of the disease. Identify underlying cause and motivating factors. This may be specific as in infectious disease or nonspecific.
- ✓ Step III: List possible intervention or treatment. This may be non-drug treatment or drug treatment. Drug must be chosen from different alternatives based on efficacy, convenience and safety of drugs including, drug interaction s and high risk group of patients.
- ✓ Step IV: Start the treatment by writing an accurate and complete prescription e.g name of drugs with dosage forms, dosage schedule and total duration of the treatment.
- ✓ Step V: Give proper information instruction and warning regarding the treatment given e.g. side effects (ADR), dosage schedule and dangers/risk of stopping the therapy suddenly.
- ✓ Step VI: Monitor the treatment to check, if the particular treatment has solved the patient's problem.

Irrational Prescribing

Common patterns of irrational prescribing may be manifested in the following forms:

- ✓ The use of drugs, when no drug therapy is indicated: antibiotics for viral URI infections
- ✓ The use of a wrong drug for a specific condition requiring drug therapy: Tetracyclines in childhood diarrhea requiring ORS
- ✓ The use of drugs with doubtful/unproven efficacy: the use of antimotility agents in acute diarrhea.

- ✓ Failure to provide available, safe and effective drugs: Failure the vaccinate against measles, tetanus etc., Failure to prescribe ORS for acute diarrhea
- ✓ The use of correct drug with incorrect administration, dosage and duration: IV use of Metronidazole when oral or suppository would be appropriate.
- ✓ The use of unnecessary expensive drugs: the use of 3rd generation of broad spectrum of antimicrobial, when a 1st line agent narrow spectrum is indicated.
- ✓ Over use of antibiotics and antidiarrheal for specific diarrhea
- ✓ Indiscriminate use of injections.
- ✓ Multiple drug prescription(polypharmacy)
- ✓ Excessive use of antibiotics for treating minor ARI
- ✓ Minerals and tonics for malnutrition

Reasons

- ✓ Patients: drug misinformation, misleading beliefs, patient's demands and expectations
- ✓ Prescribers: lack of education and training, inappropriate role models, lack of objective drug information, generalization of limited experiences, misleading beliefs about drugs efficacy.
- ✓ Workplace: heavy patient load, pressure to prescribe, lack of adequate lab capacity, insufficient staffing,
- ✓ Drug supply: unreliable suppliers, shortage and expired dugs supplied.
- ✓ Drug regulation: non-essential drug available, lack of regulation enforcement, non-formal prescribers.
- ✓ Industry: promotional activities, misleading claims

Impacts

- ✓ Reduction in the quality of drug therapy leading to increased morbidity and mortality
- ✓ Waste of resources leading to reduced availability of other vital drugs and increased costs
- ✓ Increased risk of unwanted effects such as ADRs and the emergence of drug resistance.
- ✓ Psychological impact, such as when patients come to believe that there is "a **pill for every ill**", which may cause an apparent increased demand for drugs.

Causes of Irrational Drug Use

1. **Diagnosis** :(aspects that lead to irrational drug use)
   - ✓ Inadequate examination of patient
   - ✓ Incomplete communication between patient and doctor
   - ✓ Lack of documented medical history

- ✓ Inadequate laboratory resources

2. **Prescription**: Types of Irrational Drug Use

- ✓ Under prescribing
- ✓ Incorrect prescribing
- ✓ Extravagant prescribing
- ✓ Over prescribing
- ✓ Multiple prescribing

Under-prescribing:

There are cases where the needed medication is not prescribed; when the given dose is inadequate; the interval between the doses are too long; or duration of treatment is insufficient.

When expensive drugs are used, this may result from inability of the patient to meet the cost of treatment.

Incorrect Prescribing:

- ✓ This is seen when drugs selected and prescribed are of doubtful efficacy or of low efficacy for the illness concerned; or if adjustments are not made for co-existing medical, genetic and environmental and other factors.
- ✓ Prescribers are often unaware of the economic effects of their prescribing on the patients and community.
- ✓ There is also no continuing education of practitioners to give them the information on new drugs or recent advance in the treatment.
- ✓ Most of the time they have to rely on the promotional literature or efforts of the pharmaceutical industry, which in itself may be biased.

Extravagant prescribing

- ✓ Using sophisticated and expensive drugs, when comparable drugs that are less expensive will do.
- ✓ While use of expensive medication may be justified in the life threatening conditions, most illnesses respond to simple inexpensive drug and may even improve with no therapy, some studies have found that 60% of hospitalized patient are wrongly prescribed antibiotics.
- ✓ Use of potent and expensive medication of these cases may deprive seriously ill patients of the needed drugs.
- ✓ Prescribers' are prone to have a preference for brand names but this will not only add to the cost but may add to the confusion regarding treatment.

Over-prescribing and multiple-prescribing:

- ✓ These are cases where drugs are prescribed where they are not indicated or are ineffective;

- ✓ when too many ingredients are used where one or two would have achieved the same effect;
- ✓ When the dose prescribed is either too large or the duration of treatment too long; or when treatment is given for several related conditions when treatment of the primary condition would have sufficed.

3**. Dispensing**: Types of Irrational Drug Use

- ✓ Incorrect interpretation of the prescription
- ✓ Retrieval of wrong ingredients
- ✓ Inaccurate counting, compounding, or pouring
- ✓ Inadequate labeling
- ✓ Unsanitary procedures
- ✓ Packaging; (poor quality packaging materials, odd packaging size, which may require repackaging, unappealing package)

Hazards of Irrational Use of Drugs

- ✓ Ineffective and unsafe treatment
- ✓ Prolongation of illness
- ✓ Distress and harm to patient
- ✓ Increase the cost of treatment

Measures to Promote Rational Drug Use

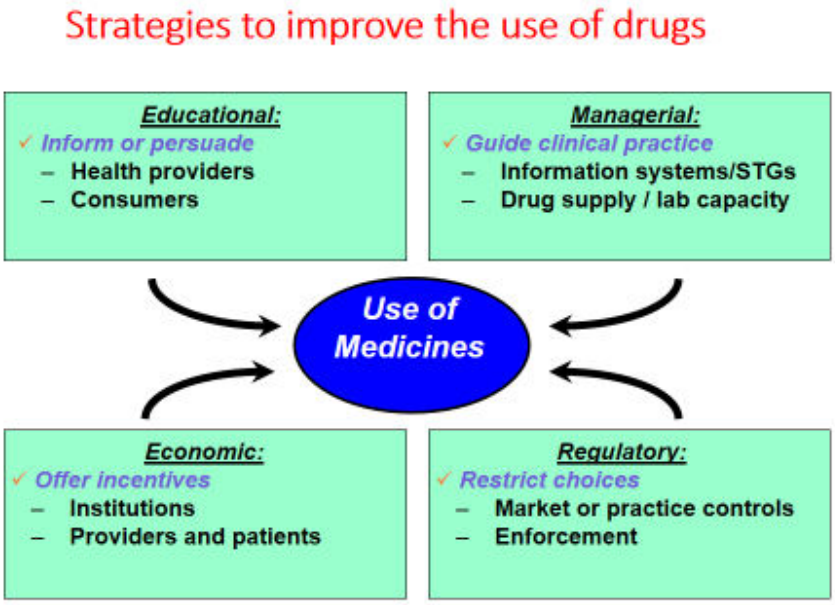
- ✓ Medicines cannot be used rationally unless everyone involved in the pharmaceutical supply chain has access TO objective information about the drug they buy and use.
- ✓ Knowledge and ideas about drugs are constantly changing and clinician is expected to know about the new development in drug therapy.
- ✓ The pre-requisities of rational drug use are;

a. critical assessment and evaluation of benefits and risk of drug used.

b. Compare the advantages, disadvantages, safety and cost of the rug with existing drug for some indication.

Obstacles exist in Rational Drug Use

- ✓ Lack of objective information and of continuing education and training in pharmacology.
- ✓ Lack of well-organized drug regulatory authority and supply of drugs.
- ✓ Presence of large number of drugs in the market and the lucrative methods of promotion of drugs employed by pharmaceutical industries.
- ✓ The prevalent belief that " every ill has a pill"



a) Educational Strategies

Goal: to inform or persuade

Training for Providers

- ✓ Undergraduate education
- ✓ Continuing in-service medical education (seminars, workshops)
- ✓ Face-to-face persuasive outreach e.g. academic detailing
- ✓ Clinical supervision or consultation

Printed Materials

- ✓ Clinical literature and newsletters
- ✓ Formularies or therapeutics manuals
- ✓ Persuasive print materials

Media-Based Approaches

- ✓ Posters
- ✓ Audio tapes, plays
- ✓ Radio, television

b) Managerial strategies

Goal: to structure or guide decisions

Changes in selection, procurement, distribution to ensure availability of essential drugs

Essential Drug Lists, morbidity-based quantification, kit systems

Strategies aimed at prescribers

Targeted face-to-face supervision with audit, peer group monitoring, structured order forms, evidence-based standard treatment guidelines

Dispensing strategies

Course of treatment packaging, labelling, generic substitution

C) Economic strategies

Goal: to offer incentives to providers a consumers

Avoid perverse financial incentives

- ✓ prescribers' salaries from drug sales
- ✓ insurance policies that reimburse non-essential drugs or incorrect doses
- ✓ flat prescription fees that encourage polypharmacy by charging the same amount irrespective of number of drug items or quantity of each item
- ✓ (reverse – Quebec, dispensing fee is given even if pharmacist does not dispense for good reason)
- ✓ Reimburse without treatment guidelines (ceftriaxone as an OPD medicine)

d) Regulatory strategies

Goal: to restrict or limit decisions

Drug registration

Banning unsafe drugs - but beware unexpected results

Substitution of a second inappropriate drug after banning a first inappropriate or unsafe drug

Regulating the use of different drugs to different levels of the health sector e.g.

Licensing prescribers and drug outlets

Scheduling drugs into prescription-only & over-the-counter

Regulating pharmaceutical promotional activities

Only work if the regulations are enforced

Self-medication practice

- ✓ Self medication is a human behaviour in which an individual use drugs or medicine for self treatment for physical or psychological ailment. Or, Simply taking any medicine especially OTC drugs against minor illness.
- ✓ The most used drugs for self medication are Over-The-Counter drugs due to its easy availability.

OTC drugs

- ✓ Over the Counter drugs is also known as the nonprescription medicine, which means this drugs can be bought without any prescription. They are safe and effective when you follow directions on the label or as directed by physicians.

Effective use of OTC drugs

- ✓ Always know what you are taking.
- ✓ Know the effects and read warnings and cautions
- ✓ Avoid the use of OTC drugs more than 1-2 weeks
- ✓ Use as Directed in Label

Hazard of Self medications

- ✓ Practice of self medication is extremely dangerous. It can cause serious problems so a medical supervision is needed before the administration of any drugs for prevention of any medical causalities .
- ✓ It is because a medical professional is trained to accurately diagnose the aliment and provide an appropriate medication to treat a condition or diagnosis.

Risk of Self medication

- ✓ Over dose
- ✓ Drugs interactions
- ✓ Inaccurate Diagnosis
- ✓ Risk of misuse or abuse
- ✓ Inaccurate dose leading to severe side effects and Adverse reactions.
- ✓ Masking signs of severe diseases.
- ✓ Chances of resistance by microbes.
- ✓ Chronic and acute toxicity

Prevalence

- ✓ In Nepal ,access to health care is difficult and much expensive making Self medication much easier and cost-effective option
- ✓ Furthermore even prescription only medicines are dispensed by non medical persons without any valid prescription, which makes easy availability and miss-use of OTC drugs
- ✓ The public may prefer to get drugs from pharmacy rather than visiting doctors as thje overall process is much more expensive.
- ✓ Also, the availability of the medicinal herbs increases incidence of self –medication with the common perception that they hold minimal side efffects.

- ✓ Prevalence of self medication was found to be 11.9%.Males ages >40 years and involving in moderate level activity of occupation were found to be significantly associated with higher self-medication usage .
- ✓ Fever(31%) and Headache (19%) and abdominal-pain (16.7%) are most common illness where self-medication are used. Majority of self – medication is harmless (66.6%) . Also prevalence rate of advising others is (73.8%)

Management

- ✓ Strict dispensing of OTC drugs only by a trained professionals
- ✓ Prescription only medicines must be dispensed only by valid prescription.
- ✓ Clear and bold indication of dose upon OTC drugs
- ✓ Awareness program against Self medication

Conclusion

- ✓ Self medication is the important concern for health authorities at global level. This study was aimed to find the prevalence of self medication for the allopathic drugs and associated factors among households of the urban community.
- ✓ This study was also aimed at assessing the attitude of respondents who had experienced self-medication. Health education of the public and regulation of pharmacies may help in limiting chances of self medication.

Pharmacopoeia

- ✓ Derived from Greek word **'Pharmakon'** means **drug** and **'Poiea'** means **to make**.
- ✓ It is a legal and official book issued by recognized authorities usually appointed by **Government of each country**. It comprises list of pharmaceutical substances, formulae along with their description and standards.
- ✓ The books containing the standards for drugs and other related substances are known as pharmacopoeias and formularies. Collectively these books are known as Drug Compendia.
- ✓ The pharmacopoeias contain a list of drugs and other related substance regarding their source, descriptions, tests, formulas for preparing the same, action and uses, doses, storage conditions etc.
- ✓ Pharmacopoeias however, do not cover the entire field of therapeutics and some countries have found it necessary to supplement the pharmacopoeia with a more comprehensive formulary or codex. These books are prepared under the authority of the government of the respective countries.
- ✓ These books are revised from time to time as to introduce the latest information available as early as possible after they become established.

Classification: The drug compendia are classified as: 1) Official compendia 2) Non-official compendia

1) Official compendia: Official compendia are the compilation of drugs and other related substances which are recognized as legal standards of purity, quality and strength by government agency of respective countries of their origin. Official compendia include

a) British Pharmacopoeia
b) British Pharmaceutical Codex
c) Indian Pharmacopoeia
d) United State Pharmacopoeia
e) National Formulary
f) The State Pharmacopoeia of USSR
g) Pharmacopoeia of other countries

2) Non-official compendia: The books other than official drug compendia which are used as secondary reference sources for drugs and other related substances are known as non-official drug compendia. These include

a) Merck Index

b) Extra Pharmacopoeia (Martindale)

c) The United States Dispensary

1) Indian Pharmacopoeia

- ✓ First official Pharmacopeia of India appeared in **1868** which was edited by **Edward John Waring.**
- ✓ In pre-independence days, British Pharmacopeia was used in India.
- ✓ The colonial addendum of **BP 1898** was published in **1900** appeared as Government of India edition in **1901.**
- ✓ In **1946** Government of India issued one list known as **'The Indian Pharmacopeial list'**
- ✓ Committee under chairmanship of **Sir R. N. Chopra** alongwith other nine members prepared **'The Indian Pharmacopeial list'**
- ✓ It was prepared by **Dept. of Health, Govt. of India, Delhi** in **1946.**
- ✓ In **1948** Government of India appointed an Indian Pharmacopeia committee for preparing **'Pharmacopeia of India'**
- ✓ Tenure of this committee was **five years.**
- ✓ Indian Pharmacopeia committee under chairmanship of **Dr. B. N. Ghosh** Published **first edition of IP** in **1955.**
- ✓ It is written in **English** & official titles of monographs given in **Latin**.
- ✓ It covers **986** monographs.
- ✓ Supplement to this edition was published in **1960**.
- ✓ Second edition of IP was published in **1966** under the chairmanship of **Dr. B. Mukkerji**.
- ✓ Official titles of monographs given in **English**.
- ✓ Dose were expressed in **Metric system**.
- ✓ For **Tablets and Injections "USUAL STRENGTH"** have been given.
- ✓ Formulations of the drugs were given immediately after the monograph of drugs.
- ✓ **274** monographs from IP 55 & their supplement were deleted.
- ✓ **93** new monographs were added.
- ✓ Supplement to this edition was published in **1975.**
- ✓ **126** new monographs have been included & **250** monographs have been amended.
- ✓ **Cholera vaccine** has been deleted.
- ✓ Third edition of **IP** was published in **1985** with two volumes & nine appendices.
- ✓ **261** new monographs have been added.
- ✓ **450** monographs were deleted.

- ✓ Addendum I to IP was published in **1989** were **46** new monographs added and **126** amended.
- ✓ Addendum II was published in **1991** were **62** new monographs added and **110** amended.
- ✓ Fourth edition of **IP** was published in **1996** under the chairmanship of **Dr. Nityanand**.
- ✓ It has been made effective from **1st December 1996.**
- ✓ It covered **1149** monographs and **123** appendices.
- ✓ It includes **294** new monographs & **110** monographs have been deleted.
- ✓ Addendum I has been made effective from **31st December 2000** were **42** new monographs have been added.
- ✓ Addendum II has been made effective from **30th June 2003** were **19** new monographs have been added.
- ✓ The veterinary supplement to **IP 1996** contains **208** monographs & **four** appendices.
- ✓ Fifth edition of **IP** was published in **2007** & addendum to this edition was published in **2008.**
- ✓ **IP 2007** is presented in **Three Volumes**.
- ✓ Volume **One** contains general notices & general chapters.
- ✓ Volume **Two & Three** contains general monographs on drug substances, dosage forms & Pharmaceutical aids.

Seventh Edition of Indian Pharmacopoeia

- ✓ The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- ✓ The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
- ✓ The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.
- ✓ A list of 577 New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing 313 New Monographs on drug substances, Dosage forms & Pharmaceutical aids (A to Z), 43 New Drugs Substances Monographs, 10 Antibiotic Monographs, 31 Herbal Monographs, 05 Vaccines & immunosera for human use, 06 Insulin Products, 07 Biotechnology Products etc. along with the 19 new General Chapters.
- ✓ 19 New Radiopharmaceutical Monographs & 1 General chapter is first time being included in this edition.
- ✓ This edition of Indian Pharmacopoeia-2014 is now under printing and will be available to stakeholders probably in Sept.2013, before three months of its effective date, i.e. 1st Jan. 2014.

2) BRITISH Pharmacopoeia

- ✓ First edition of **BP** was published in **1864**.
- ✓ It consist of two sections

Part I:- **Materia Medica** &

Part II:- **Preparation & compounds.**

- ✓ Second edition of **BP** was published in **1867**.
- ✓ Fourth edition of **BP** was published in **1898**.
- ✓ Fifth edition of **BP** was published in **1914**.
- ✓ Eighth edition of **BP** was published in **1953**.
- ✓ In this edition titles of drugs & preparations were in **English** instead of **Latin** and **metric system**.
- ✓ It has been published annually**.**
- ✓ In **BP 2007** monographs has been introduced for material specifically used in preparation of Traditional Chinese medicines.
- ✓ Term **'Prolonged release'** has been replaced the term **'Slow'** and the term **'Gastro-resistant'** has been replaced with **'Enteric coated'** in number of monographs.
- ✓ BP **2008** contains approximately **3100** monographs for substances, preparations and articles used in practice.
- ✓ It has been made effective from **1st January 2008**.
- ✓ **BP 2007 -2009** were given in Six Volumes i.e. **Volume I to Volume VI.**

Volume I & II contains medicinal substances.

Volume III contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homoeopathic preparations.

Volume IV contains supplementary chapters, IR spectra etc.

Volume V contains veterinary.

Volume VI contains CD ROM version.

Current edition of **BP 2010** is in process.

3) UNITED STATE Pharmacopoeia

- ✓ **First edition** of United state Pharmacopeia was published on 15th **December 1820** in both ***Latin & English***.
- ✓ From 1820 to 1942 it was published at **Ten years** intervals.
- ✓ From 1942 to 2000 it was published at **Five years** intervals.
- ✓ From 2002 it was published **annually**.
- ✓ First ***National Formulary*** of the United States appeared in **1888**.

Supplement to Book……

- ✓ **USP21-NF16** have eight supplements.
- ✓ First appeared in **January 1985** & last in **November 1988**.
- ✓ **USP22-NF17**, **1990** is the third revision that consolidates USP & NF into a single volume.
- ✓ Electronic version of USP-***NF*** on floppy disks was introduced in **1992**.
- ✓ **USP23-NF18**, was published in Mumbai as an Asian edition at the end of **1994**.
- ✓ ***USP23*** has ten supplements.
- ✓ First supplement was published in **January 1995** & Last in **May 1999**.
- ✓ ***USP24-NF19***, appeared from first **January 2000**.
- ✓ ***USP30-NF25***, appeared from **May 2007**.
- ✓ It contains Scientific standards for drugs, dietary substances, biological products & Excipients used in dosage forms.
- ✓ It contains **4,100** monographs and **200** general chapters.
- ✓ It has been printed in **three volume** set.
- ✓ **Volume I** contains general chapters & **Volume II & III** contains monographs.
- ✓ First supplement to ***USP30-NF25***, appeared from **August 2007** & second supplement from **November 2007 which** will be considered official from **May 2008**.
- ✓ From 2006, Spanish edition of USP is also being published.
- ✓ Current edition of **USP 2014** is in process.

United States Pharmacopoeia 30 – National Formulary 25

- ✓ New heavier paper stock
- ✓ Complete table of contents and index in each volume
- ✓ Special 'Using the New USP-NF Print' tutorial CD
- ✓ Convenient slipcase for easy access and storage (English edition only).

United States Pharmacopoeia 31 - National Formulary 26

The USP-NF is a single-volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP. Excipient monographs are included in the NF.

United States Pharmacopoeia 32 - National Formulary 27

- ✓ More than 4,200 monographs
- ✓ Includes over 200 general chapters, covering general tests and assays
- ✓ Displays helpful guides and charts that make it easy to find focus-specific information

- ✓ Includes information on emerging areas of science and medicine
- ✓ Helps ensure compliance with official standards
- ✓ Enables validation of test results against proven benchmarks
- ✓ Creates in-house standards for operating procedures and specifications
- ✓ Expedites new product development and approvals.

United States Pharmacopoeia 33 - National Formulary 28:

- ✓ More than 4,400 monographs
- ✓ Over 200 general chapters covering general tests and assays
- ✓ A new, easy-to-read format and monograph layout
- ✓ Helpful guides and charts that make it easy to find focus-specific information
- ✓ Ensures compliance with official standards
- ✓ Establishes in-house standard operating procedures and specifications
- ✓ Facilitates new product development and approval.

United States Pharmacopeia 34 - National Formulary 29:

USP 34-NF 29 features more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics. USP 34-NF 29 also offers harmonized material and more than 230 General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.

United States Pharmacopeia 35 - National Formulary 30:

The 'United States Pharmacopeia 35 - National Formulary 30' (USP-NF) is a combination of two official compendia: the 'United States Pharmacopeia (USP)' and the 'National Formulary (NF)' and is officially applicable from **1 May, 2012 to 30 April, 2013.**

Nepalese National Formulary (NNF)

- ✓ Nepalese National Formulary (NNF) is meant to provide information on medicines and their dosage forms available in the country.
- ✓ It has wide use and application in various levels of health institutions, as well as for individual practitioners.
- ✓ The concept of publishing NNF was conceived long before the adoption of National List of Essentail Drugs, Nepal (EDL).

- ✓ The Drug Advisory Committee recommended for the preparation of the manuscript for NNF in August 1982.
- ✓ A Committee comprising of Mr. A.D. Shrestha, Dr. H. Dixit, Dr. I.L. Acharya and Dr. K.K.Kafle was constituted for drafting the manuscript.
- ✓ The idea of NNF publication was to identify the products needed for the country according to diseases prevalence.
- ✓ The manuscript of NNF was completed in 1996, after which editing was done to bring NNF **1997 (First edition).**
- ✓ NNF is meant to provide information on medicines and their dosage forms available in the country.
- ✓ It has wide use and application in various levels of health institutions as well as for individual health care providers.
- ✓ The **2nd edition** of NNF was published in **2010**

Information included in NNF

a) Guidance on rational prescribing

This section includes information on rational prescribing, prescription writing, adverse reaction to drugs, prescribing in elderly, terminal care, liver diseases, and renal diseases and during pregnancy and breast-feeding. Most of the information included in the tables in this section is based on the WHO Model Formulary, 2008.

b) **Classified notes on drugs**

- ✓ This is the main part of the formulary.
- ✓ General discussion on the group of drugs is provided. Indication, adverse reactions, cautions and dose of the drug is described. The dosage forms and strength is also included. However, some of the dosage forms or some medicines may not be available in the market.
- ✓ When a drug is included in more than one chapter, a detailed description is given in one chapter and cross-reference is made in other places. However, for the convenience of users, effort has been made to minimise the cross-references. To identify the drugs included in
- ✓ National List of Essential Medicines (EML), the heading is printed in ***BOLD ITALIC***, whereas other drugs are only in **BOLD**.
- ✓ National List of Essential Medicines is included in appendix II.
- ✓ The drugs are classified according to the systems for which they are used.

c) Formulary

- ✓ Effort has been made to provide information of the dosage forms available in the market.

- ✓ Fixed-dose combinations of drugs that have proven benefit are included, for example, co-trimoxazole, co-careldopa etc. A list of such combination, except antiretroviral, is also included in the chapter of rational prescribing.

d) **Appendices-**

- ✓ Three appendices are included.
- ✓ Appendix I contains detailed list of drug interactions. This section is also mainly based on the information from WHO Model Formulary, 2008.
- ✓ Appendix II contains National List of Essential Medicines (fourth revision, 2010). This list has been approved by Drug Advisory Committee. It has to be approved by Government of Nepal to make it official.
- ✓ Information on Adverse Drug Reaction reporting is included in Appendix III. Adverse Drug Reaction reporting system has been initiated in Nepal.

Nepal is the member of International Drug Monitoring Programme of WHO, which is coordinated by Uppsala Monitoring Centre. DDA is the national centre for Nepal.

Appendix III includes ADR reporting form currently being used in Nepal, and the address of DDA, its branch offices as well as the hospitals functioning as regional centres. Other hospitals are encouraged to join this programme and report the adverse reaction of drugs.

Good Pharmacy practice

- ✓ All practicing pharmacists are obliged to ensure that the service they provide to every patient is of appropriate quality.
- ✓ Good Pharmacy Practice is a means of clarifying and meeting that obligation.
- ✓ The conditions of practice vary widely from country to country and the national pharmaceutical organizations in individual countries are best able to decide what can be achieved and within what timescale.
- ✓ In developing these standards, important differences amongst countries have to be recognized.
- ✓ Affluent countries usually have effective legally based drug regulatory systems which assure and monitor the quality of industrially produced pharmaceutical products.
- ✓ Quality may be assured through the issuance of product licenses or marketing authorizations for pharmaceutical products.
- ✓ Quality could be kept maintained through licensing and inspection of pharmaceutical manufacturers, wholesale and other distributors, community and hospital pharmacies and other drug outlets. Similarly, it can be done through quality control in a governmental quality control laboratory.
- ✓ Many developing countries lack an effective drug regulatory system, puts the main responsibility for the quality of pharmaceutical products on the pharmacists. They then have to rely on their own, or the pharmacists association's quality assessment and make sure that they only procure medicines from reliable sources.
- ✓ There are numerous reports about an unacceptable prevalence of substandard and counterfeit pharmaceutical in international trade.
- ✓ Developing countries are the ones most frequently exposed to such products which may be inefficacious or toxic products, and which threaten to erode confidence in the healthcare system.

Underlying philosophy

- ✓ The **mission of pharmacy** practice is to provide medications and other health care products and services and to help people and society to make the best use of them.
- ✓ Comprehensive pharmacy service encompasses involvement in activities to secure good health and the avoidance of ill health in the population.
- ✓ When the treatment of ill health is necessary the quality of each person's medicine use process should be assured to achieve maximum therapeutic benefit and to avoid untoward side effects.
- ✓ This presupposes the acceptance by pharmacists of shared responsibility with other professionals and with patients for the outcome of therapy.

- ✓ In recent years the term Pharmaceutical Care has established itself as a philosophy of practice with the patient and the community, as the primary beneficiary of the pharmacist's actions.
- ✓ The concept becomes particularly relevant to special groups of populations such as the elderly, mothers and children, and chronically ill patients, and to the community as a whole, e.g. in terms of cost containment.
- ✓ While the basic concepts of ***Pharmaceutical Care*** **and** ***Good Pharmacy Practice*** are largely identical; it could be said that Good Pharmacy Practice is the way to implement Pharmaceutical Care.

Good pharmacy practice requirements

A. ***Good Pharmacy Practice*** requires that a pharmacist's first concern must be the welfare of the patients in all settings.

B. ***Good Pharmacy Practice*** requires that the core of the pharmacy activity is the supply of medication and other health care products, of assured quality, appropriate information and advice for the patient, and monitoring the effects of their use.

C. ***Good Pharmacy Practice*** requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and appropriate medicine use.

D. ***Good Pharmacy Practice*** requires that the objective of each element of pharmacy service is relevant to the individual, is clearly defined and is effectively communicated to all those involved.

E. **In satisfying these requirements**

- ✓ Professional factors should be the main philosophy underlying practice, although it is accepted that economic factors are important.
- ✓ There must be pharmacist input to decisions on medicine use.
- ✓ The ongoing relationship with other health professionals, particularly physicians, should be seen as a therapeutic partnership involving mutual trust and confidence in all matters relating to pharmacotherapeutics.
- ✓ The relationship with other pharmacists should be as colleagues, each seeking to improve pharmacy service, rather than as competitors.
- ✓ In practice organizations and group practices, pharmacy managers should accept a share of responsibility for the definition, evaluation and improvement of quality.
- ✓ The pharmacist should be aware of the essential medical and pharmaceutical information about each patient. Obtaining such information is simplified if the patient chooses to use only one pharmacy or if the patient's medication profile is available.

- ✓ The pharmacist needs independent, comprehensive, objective and current information about therapeutics and medicines in use.
- ✓ Pharmacists in each field of practice should accept personal responsibility for maintenance and assessment of competence throughout their professional working lives.
- ✓ Educational programmes for entry to the profession should appropriately address contemporary and foreseeable future changes in the practice of pharmacy.
- ✓ It is necessary to specify national standards of good pharmacy practice that should be adhered to by practitioners.

Requirements in practice

There are four main elements of Good Pharmacy Practice to be addressed:

1. Activities associated with promotion of good health, avoidance of ill health and the achievement of health objectives.

2. Activities associated with the supply and use of medicines and items for the administration of medicines or otherwise related to treatment. These activities may be undertaken in the pharmacy or in an institution or home care setting.

3. Activities associated with self-care, including advice about and, where appropriate, the supply of a medicine or other treatment for the symptoms of ailments that can properly be self-treated.

4. Activities associated with influencing prescribing and medicine use.

In addition to the four main elements Good Pharmacy Practice also encompasses:

- ✓ Establishment of arrangements with other health professional communities for health promotion activities at a population level, including the minimization of the abuse and misuse of medicines
- ✓ Professional assessment of promotional materials for medicines and other products associated with health
- ✓ Dissemination of evaluated information about medicines and aspects of health care
- ✓ Involvement in all stages of clinical trials.

Main Elements of GPP

For each of the four main elements of GPP, national standards covering processes and necessary facilities should be established and promoted to the profession.

1. Health Promotion and Ill-health Prevention

National standards are needed for:

(i) Facilities for confidential conversation that cannot be overheard by others.

(ii) Provision of general advice on health matters.

(iii) Involvement of personnel in briefings for specific campaigns to ensure coordination of effort and consistency of advice.

(iv) Quality assurance of equipment used and advice given in diagnostic testing

2. Supply and the use of prescribed medicines and other health care products

(a) Reception of the prescription and confirmation of the integrity of the communication

National standards are needed for:

(i) Facilities

(ii) Procedure

(iii) Personnel

(b) Assessment of the prescription by the pharmacist

(1)Therapeutic aspects (Pharmaceutical & Pharmacological)

(2) Appropriateness for the individual

(3) Social, legal, economic aspects.

National standards are needed for:

(i) Information sources

(ii) Competence of pharmacist

(iii) Medication records

(c) Assembly of the prescribed items

National standards are needed for:

(i) Sources of supply of medicines and other items; manufacture of medicines

(ii) Storage

(iii) Condition at time of supply to the patient

(iv) Personnel involved

(v) Equipment required

(vi) Facilities and workplace required

(vii) Preparation and quality assurance of extemporaneous preparations.

(viii) Disposal of unused pharmaceutical products and pharmaceutical waste

(d) Advice to ensure that the patient or carer receives and understands sufficient written and oral information to derive maximum benefit from the treatment

National standards are needed for:

(i) Facilities for confidential conversation that cannot be overheard by others.

(ii) Information sources

(iii) Procedure to be followed and the appropriate documentation of these procedures.

(iv) Competence of personnel involved.

(e) Following up the effect of prescribed treatments

National standards are needed for:

(i) Procedure to be followed in regular, systematic evaluation of progress or outcomes of treatment for individual patients or groups of patients.

(ii) Access to necessary monitoring equipment and facilities.

(iii) Quality assurance of monitoring facilities.

(f) Documentation of professional activities

National standards are needed for:

(i) Recording professional activities and pertinent data in a manner that allows access to comprehensive information.

(ii) Procedures for self-assessment of professional activities and quality assurance.

3. **Self-care**

National standards are needed for:

(i) Facilities for confidential conversation that cannot be overheard by others.

(ii) Qualifications of personnel to be involved.

(iii) How proper assessment of need is to be made, e.g.

a) Who has the problem?

b) What are the symptoms?

c) How long has the condition existed?

d) Action already taken?

e) Medicines already being taken?

(iv) Efficacy and safety of products recommended?

(v) When reference to medical practitioner is appropriate and how to follow up?

4. **Influencing prescribing and medicine use**

General rational prescribing policies

National standards are needed for:

(i) Quality of prescribing data provided to the pharmacist.

(ii) The preparation of formularies on medicines.

(iii) Contacts with physicians on individual prescribing.

(iv) Evaluation of data on the use of medicines in medical and pharmaceutical practices.

(v) Assessment of promotional materials

(vi) Dissemination of evaluated information within a formal network.

(vii) Educational programmes for health professionals

(viii) Reference sources available to the pharmacist

(ix) Confidentiality of data relating to individual patients.

Research & Practice Documentation

- ✓ Pharmacists have a professional responsibility to document professional practice experience and activities and to conduct and /or participate in pharmacy practice research and therapy research.

Achieving GPP in Practice

- ✓ Specific standards of Good Pharmacy Practice can be developed only within a national organization framework.
- ✓ These guidelines are recommended as a set of professional goals in the interest of the patients or customers in the pharmacy.
- ✓ Responsibility for moving the project forward will rest upon each national pharmaceutical organization.
- ✓ Achieving specific standards of ***Good Pharmacy Practice*** for each nation within these guidelines may require considerable time and effort.
- ✓ As health professionals, pharmacists have a duty to begin the process without delay.

Standard treatment guideline

- A systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances
- Standard treatment guidelines (STGs) list the preferred pharmaceutical and non-pharmaceutical treatments for common health problems experienced by people in a specific health system.
- As such, they represent one approach to promoting therapeutic effective and economically efficient prescribing.
- When implemented effectively, an STG offers advantages to
- patients (e.g., it provides more consistency and treatment efficacy),
- providers (e.g., it gives an expert consensus, quality of care standard, and basis for monitoring),
- supply managers (e.g., it makes demand more predictable and allows for prepackaging),
- health policy makers (e.g., it provides focus for therapeutic integration of special programs and promotes efficient use of funds).
- Effective implementation, however, is perhaps the greatest challenge in introducing STGs.
- Guidelines are a valuable resource in the management of pharmaceutical therapy because—
- Treatment of diseases may have many different approaches.
- Many practitioners will not remember the best method of treatment.
- Applying the most effective treatment benefits both the patient and the health care system.
- Formulary management will have only limited impact if medicines are used incorrectly. **Advantages**
- The use of STGs can benefit health care providers, health care officials, supply management personnel, and patients in the following ways.

❖ Health care providers

- Provides standardized guidance to practitioners
- Encourages high quality care by directing practitioners to the most appropriate medicines for specific conditions
- Encourages the best quality of care since patients are receiving optimal therapy
- Utilizes only formulary or essential medicines, so the health care system needs to provide only the medicines in the STGs
- Provides valuable assistance to all practitioners, especially to those with lower level skills

- Enables providers to concentrate on making the correct diagnosis because treatment options will be provided for them

❖ Health care officials

- Provides a basis for evaluating quality of care provided by the health care professionals
- Provides the most effective therapy in terms of quality
- Provides a system for controlling cost by using funds more efficiently
- Provides information for practitioners to give to patients concerning the institution's standards of care
- Can be a vehicle for integrating special programs (e.g., diarrhea disease control, acute respiratory infection (ARI), tuberculosis control, malaria) at the primary health care facilities using a single set of guidelines

❖ Supply management

- Utilizes only formulary or essential medicines, therefore the health care system needs to provide only medicines in the STGs
- Provides information for forecasting and ordering (because medicines and quantities for common diseases will be known)
- Provides information for purchase of prepackaged medicines

❖ Patients

- Patients receive optimal pharmaceutical therapy
- Enables consistent and predictable treatment from all levels of providers and at all locations within the health care system
- Allows for improved availability of medicines because of more consistent use and ordering
- Helps provide improved outcomes because patients are receiving the best treatment
- regimens available
- Lowers cost

Disadvantages

• Inaccurate or incomplete guidelines will provide the wrong information for providers and therefore do more harm than good. Guidelines may not be based on the most reliable information.

• Developing and updating guidelines is difficult and time-consuming and must be done on a regular schedule or they will become obsolete very quickly.

Guidelines provide a false sense of security; that is, many providers will limit their evaluation of a particular patient as soon as it fits into a particular standard treatment

GMP- GOOD MANUFACTURING PRACTICE

GMP are the practices required to follow the guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products and active pharmaceutical products.

GMP is that part of quality assurance which ensures that the products are consistently manufactured and controlled for the purpose of their intended use.

Basic principles of GMP

1.Write instructions correctly before starting any job.
2.Always follow the instructions exactly.
3.Ensure that right material and equipment is being used.
4.Ensure that equipment used for manufacturing is clean.
5.Prevent mix-up and contamination.
6.Be conscious with labeling errors.
7.Always work accurately and precisely.
8.Keep things (including operator) clean and tidy.
9.Always look out for non conformances and report then immediately.
10. Document accurately and check/ recheck the operations carried out.

GMP GUIDELINES:

- GMP guidelines are the guidelines which provides guidance for manufacturing, testing and quality assurance in order to ensure that a drug product is safe for human consumption.
- However, gmp guidelines are not prescriptive instruction on how to manufacture products.
- There are certain guidelines of GMP which are discussed below.

1) GENERAL REQUIREMENTS:

a) Location and surroundings:

Manufacturing building should be far from open sewage, drain, public lavatory or any other factory which produces dust, smoke, fumes etc. in order to avoid the risk of contamination to the product from external environment.

b) Building and premises:

Building should be designed and constructed in such a way that the production of drug under hygienic condition.

Some requirements for building and premises are :

- Working area should have adequate space inorder to avoid contamination and cross contamination.
- Facilities like air conditioning, light, ventilation, humidity should be provided in the working area.
- Proper drainage system should be provided.
- The wall and floor of manufacturing room should be smooth (no cracks) washable and disinfected.

c) Water system:

- Treatment of water should be done with validated system.
- Water should store in clean tank and ensure freedom from microbial growth.

d) Disposal of waste:

- Sewage and affluents (solid, liquid and gas) from manufacturing area should dispose according to the requirements of environment pollution control board.
- Bio-medical waste should dispose according to provision of bio medical waste rules.
- Provision should be made for the storage and disposal of rejected drugs and record should maintain all disposal of waste.

2) Warehousing area:

- Adequate area should be designed for sufficient warehousing starting and packaging materials, intermediates, bulk and finished products, equipment spare parts etc.
- Warehousing area should be clean, dry, temperature and humidity controlled so as to ensure good storage conditions.
- Sampling area in warehousing should be separate in order to prevent cross-contamination.
- Rejected, recalled and returned material should be stored separately.

- Highly hazardous materials (like narcotics, psychotropic drug etc) should be stored in safe and secure areas.
- Printed packaging material should be stored in secure area.
- Dispensing areas to b-lactum, sex hormones and cytotoxic substances should be separate and pressure controlled.
- Dispensing of sterile materials should be conducted under aseptic conditions.
- Regular check should carry out to ensure any breakage and leakage of containers.

3) Production area:

- Production area should be clean.
- Separate dedicated facilities should be provided for manufacturing of potent products.
- Working space should be adequate to permit orderly and logical positioning of equipment and material.
- Frequent movement of personnel should be avoided.
- Electrical fittings, pipeline and ventilation should be fixed to avoid creation of recesses.

4) Ancillary area:

- Rest and refreshment rooms should be separate from other areas.
- There should be written instruction for cleaning and disinfection of such areas.
- Maintenance area should be away from production area.

5) Quality control area:

QC laboratories shall be independent of the production area. Separated area should be provided each for physicochemical biological, microbiological or radioisotopes analysis. Separated instrument room with adequate area shall be provided.

6) Personal:

The manufacture shall be conducted under the direct supervision of complete technical staff with prescribed qualification and practical experience in the relevant or active pharmaceutical production.

7) Health, clothing, and sanitation of worker:

The personnel handling Beta -lactum antibiotics shall be tested for Penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall he periodically examined for adverse effects. These personnel should be moved out of these sections (except in dedicated facilities) by rotation, as a health safeguard.

Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof. The licensee shall provide the services of a qualified physician for assessing the health status of personnel involved in different activities

8) Manufacturing operations and control:

All manufacturing operation shall be carried out under supervision of technical staff approved by licensing authority.

9) Sanitation in the manufacturing premises:

The manufacturing premises shall be cleaned and maintained in an orderly manner so that it is free from accumulated waste.

10) Raw material

All incoming material shall be quantified immediately after receipt of processing . all the material shall store under appropriate conditions and should be checked.

11) Equipments:

Equipment shall be located designed constructed adopted and maintained to suit the operation to be carried out. The layout and sesign of the equipment shall minimized the risk of error and avoid the cross-contamination.

12) Documentation and record:

Documentation is an essential part of QA system shall be related to all aspect of GMP . its aim is to define the specification for all material method of manufacturing and control to

ensure that all personal concern with manufacture information necessary to decide whether or not to release a batch of drug for sale and-to provide an audit trail that shall permit investigation of the history of any suspected defective batch.

13) **Labels and other printed materials.**

Labels are absolutely necessary for identification of the drugs and their use. "The printing shall be done in bright colours and in a legible manner. The label shall carry all the prescribed details about the product.

14) Quality assurance:

This is a wide ranging concept concerning all matters that individually or collectively influence the equality of a product. It is the totality of the arrangements made with the object of ensuring that products arc of the quality required for their intended use.

14.1 The system of quality assurance appropriate to the manufacture of pharmaceutical products shall ensure that

(a) the pharmaceutical products are designed and developed in a way, that takes account of the requirements of Good Manufacturing Practices (hereinafter referred as GMP) and other associated codes such as those of Good Laboratory Practices (hereinafter referred as GLP) and Good Clinical Practices (herein after, referred as GCP):

(b) adequate arrangements arc made for manufacture, supply, and use of the correct starting and packaging materials;

(c) adequate controls on starting materials, intermediate products, and hulk products and other in process controls, calibrations and validations arc carried out;

(d) the finished product is correctly processed and checked in accordance with established procedures;

(e) the pharmaceutical products arc not released for sale or supplied before authorised

persons have certified that each production batch has been produced and controlled in accordance with the requirements of the label claim and any other provisions relevant to production, control and release of pharmaceutical products.

15) Self inspection and quality audit:

It may be useful to constitute a self inspection team supplemented with a quality audit procedure for assessment of all or part of a system with the specific purpose of improving it.

15.1 To evaluate the manufacturer's compliance with GMP in all aspects of production and quality control, concept of self-inspection shall he followed. The manufacturer shall constitute a team of independent, experienced, qualified persons from within or outside the company, who can audit objectively the implementation of methodology and procedures evolved. The procedure for self-inspection shall be documented indicating self-inspection results, evaluation, conclusions and recommended corrective actions with effective follow up program. Therecommendations for corrective action shall be adopted

15.2 The program shall he designed to detect "shortcomings in the implementation of Good Manufacturing Practice and to recommend the necessary corrective actions. Self-inspections shall be performed routinely and on specific, occasions, like when product recalls or repeated rejections occur or when an inspection by the licensing authorities is announced. The team responsible for self-inspection shall consist of personnel who can evaluate the implementation of Good Manufacturing Practice objectively, all recommendations for corrective action shall be implemented.

15.3 Written instructions for self-inspection shall be drawn up which shall include the following:

a) Personnel.
b) Premises including personnel facilities
c) Maintenance of buildings and equipment.
d) Storage of starting materials and finished products.
e) Equipment.
f) Production and in-process controls.

g) Quality control.

h) Documentation.

i) Sanitation and hygiene.

j) Validation and revalidation programmes.

k) Calibration of instruments or measurement systems.

l) Recall procedures.

m)Complaints managem ent.

n) Labels control.

o) Results of previous self-inspections and any corrective steps taken.

16) Quality control system:

Quality control shall be concerned with sampling specifications, testing, documentation, release procedures which ensure that the necessary and relevant tests are actually carried and that the materials are not released for use, nor products released for sale or supply until their quality has been judged to be satisfactory. It is not confined to laboratory operations but shall be involved in all decisions concerning the quality of the product. It shall be ensured that all quality control arrangements are effectively and reliably carried out. The department as a whole shall have other duties such as to establish evaluate. validate and implement all Quality Control Procedures and methods.

16.1 Every manufacturing establishment shall establish its own quality control laboratory manned by qualified and experienced staff.

16.2 The area of the quality control laboratory may be divided into Chemical, Instrumentation Microbiological and Biological testing.

16.3 Adequate area having the required storage conditions shall be provided for keeping reference samples. The quality control department shall evaluate, maintain and store reference samples.

16.4 Standard operating procedures shall be available for sampling, inspecting, and testing of raw materials, intermediate, bulk finished products and packing materials and wherever

necessary, for monitoring environmental conditions.

16.5 There shall be authorized and dated specifications for all materials, products, reagents and solvents including test of identity, content, purity and quality. These shall include specifications for water, solvents and reagents used in analysis.

16.6 No batch of the product shall be released `or sale or supply until it has been certified by the authorised person(s) that it is in accordance with the requirements of the standards laid down.

16.7 Reference/retained samples from each batch of the products manufactured shall be maintained in a quantity which is at least twice the quantity of the drug required to conduct all the tests, except sterility and pyrogen/Bacterial Endotoxin Test performed on the active material and the product manufactured. The retained product shall be kept in its final pack or a simulated pack for a period of three months after the date of expiry.

16.8 Assessment of records pertaining to finished products shall include all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack. Assessment records should be signed by the in-charge of production and countersigned by the authorised quality control personnel before a product is released for sale or distribution.

16.9 Quality control personnel shall have access to production areas for sampling and investigation, as appropriate.

16.10 The quality control department shall conduct stability studies of the products to ensure and assign shelf life at the prescribed conditions of storage. All records of such studies shall be maintained.

16.11 The in-charge of Quality Assurance shall investigate all product complaints and records

thereof shall be maintained.

16.12 All instruments shall be calibrated and testing procedures validated before these are adopted for routine testing Periodical calibration of instrument and validation of procedures shall be carried out.

16.13 Each specifications for raw materials, intermediates, final products, and packing materials shall be approved and maintained by the Quality Control Department Periodic revisions of the specifications shall be carried out whenever changes are necessary.

16.14 pharmacopoeia, reference standards. working standards, reference spectra, other references materials and technical books, as required shall be available in the Quality Control Laboratory of the licensee.

GOOD LABORATORY PRACTICE-GLP

Good Laboratory Practice is defined in the OECD Principles as *"a quality system concerned with the organisational process and the conditions under which non-clinical health and environ-mental safety studies are planned, performed, monitored, recorded, archived and reported."*

The purpose of the Principles of Good Laboratory Practice is to promote the developmentof quality test data and provide a tool to ensure a sound approach to the management of labo-ratory studies, including conduct, reporting and archiving. The Principles may be consid-ered as a set of standards for ensuring the quality, reliability and integrity of studies, the reporting of verifiable conclusions and the traceability of data. The Principles require institu-tions to assign roles and responsibilities to staff in order to ensure good operational manage-ment of each study and to focus on those aspects of study execution (planning, monitoring, recording, reporting, archiving) that are of special importance for the reconstruction of the whole study. Since all these aspects are of equal importance for compliance with GLP Prin-ciples, it is not permissible to partially implement GLP requirements and still claim GLP compliance. No test facility may rightfully claim GLP compliance if it has not implemented, and does not comply with, the full array of the GLP rules.

As far as pharmaceutical development is concerned, the GLP Principles, in their regula-tory sense, apply only to studies which

- are non-clinical, i.e. mostly studies on animals or in vitro, including the analytical aspects of such studies;
- are designed to obtain data on the properties and/or the safety of items with respect to human health and/or the environment;
- Are intended to be submitted to a national registration authority with the purpose of registering or licensing the tested substance or any product derived from it.

Depending on national legal situations, the GLP requirements for non-clinical labora-tory studies conducted to evaluate drug safety cover the following classes of studies

- Single dose toxicity
- Repeated dose toxicity (sub-acute and chronic)
- Reproductive toxicity (fertility, embryo-foetal toxicity and teratogenicity, peri-/post natal toxicity)
    - ✓ Mutagenic potential
    - ✓ potential
    - ✓ Toxicokinetics (pharmacokinetic studies which provide systemic exposure data for the above studies)
    - ✓ Pharmacodynamic studies designed to test the potential for adverse effects (Safety pharmacology)
    - ✓ Local tolerance studies, including phototoxicity, irritation and sensitisation studies, or testing for suspected addictive and/or withdrawal effects of drugs.

GLP Principles are independent of the site where studies are performed. They apply to studies planned and conducted in a manufacturer's laboratory, at a contract or subcontract Facility, or in a university or public sector laboratory.

GLP is not directly concerned with the scientific design of studies. The scientific design may be based on test guidelines and its scientific value is judged by the (Drug) Regulatory Authority that provides marketing authorisation. However, adherence to GLP will remove many sources of error and uncertainty, adding to the overall credibility of the study. Through the application of technically valid and approved Standard Operating Procedures many sources of systematic error and artefacts may be avoided. The requirement to for-mulate a study plan with a defined scientific purpose for the study will prevent false starts and diminish the incidence of incomplete or inconclusive studies. Respecting the GLP Principles will thus indirectly optimise the scientific yield of studies.

When implementing GLP in a test facility, and particularly during training, it is impor-tant to clearly differentiate between the formal, regulatory use of the term Good Labora-tory Practice and the general application of "good practices" in scientific investigations. Since the term "Good Laboratory Practice" is not a trade-mark protected

term, any labora-tory may consider that it is following good practices in its daily work. This does not com-prise GLP compliance.

It must be clearly understood that only adherence to, and compliance with, all the requirements of the OECD GLP Principles constitutes real compliance with GLP. Therefore, the use of similar terminology to describe quality practices outside the scope of GLP proper should be strongly discouraged.

Good Clinical Practice (GCP)

- ✓ Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human subjects.
- ✓ Compliance with this standard provides assurances that the rights, safety and well-being of the trial subjects are protected and the data and reported results are credible and accurate.
- ✓ GCP is also defined as a standard for the design, conduct, performance, and monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.
- ✓ GCP assures that the rights, safety and well-being of clinical trial subjects are protected, and that clinical trials are credible.

International conference on harmonization (ICH)

- ✓ An international body, formed in 1990, which regulates clinical trials involving human subjects.
- ✓ Developed to internationalize and standaridized clinical trials.
- ✓ Representatives from industry, government and regulatory agencies and academia combined to discuss international, minimal standards of conduct and testing of products.
- ✓ Guidance developed within the expert working group of the ICH of technical requirements for registration of pharmaceuticals for human use.
- ✓ The ICH GCP document was compled using the good clinical practice of Japan, the U.S, the European Union, Australia, Canada, the Nordic countries and the WHO.
- ✓ It has been subject to recommendations of the regulatory agencies of multiple countries.
- ✓ Endorsed by the ICH steering committee in April 1996 for adoption by the regulatory agencies.
- ✓ Published in the Federal Register of the U.S on May 9, 1997 *62FR 25692) and is applicable to drug and biologic products.

Principal of GCP

- ❖ Clinical trials should be conducted in accordance with the ethical principles that have their origin in the declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirements.

- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety and well-being of the trial subjects are the most important consideration and should prevail over interests of science and society.
- The available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
- A trial should be conducted in compliance with the protocols that have received prior Institutional Review Board (IRB)/Independent ethics committee (IEC) approval/favorable opinion.
- The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
- Each individual involved in conducting a trial should be qualified by education, training and experience to conduct or perform the respective task.
- Freely given informed consent should be obtained form every subject prior to clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements.
- Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice. They should be used in accordance with the approved protocol.
- Systems with procedures that assure the quality of every aspect of the trial should be implemented.

National Drug Policy -1995

1. Introduction

1.1 Preamble

In accordance with the objectives of the National Health Policy 1991, to fulfill the commitment of Government of Nepal (GoN), to provide “health for all” and to improve and manage by establishing co-ordination among the governmental , non-governmental and private organizations involved in the activities related to drug production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow, the National Drug Policy 1995 has been promulgated for implementation.

1.2 Definition

For the purpose of this policy, a "drug" means any substance which is intended to be used in human beings or animals for diagnosis, treatment, cure, mitigation and prevention of diseases or for promotion of health or for the destruction of micro-organisms which have caused disease or to affect the physical structure or function of a body.

2. Main Policy

To maintain, safeguard and promote the health of people by making the country self-reliant in drug production; ensuring the availability of safe, effective, standard, and quality drugs at affordable price in quantities sufficient to cover the need of every corner of the country; and to manage effectively all the drugs-related activities including production, import, export, storage, sale, supply and distribution.

3. Objectives

a) To evolve a suitable mechanism to ensure the availability of safe, effective and quality medicines at reasonable price throughout the country.
b) To adopt a well-defined and effective mechanism for procurement, transportation, sale-distribution, storage and dispensing of drugs at various levels of governmental and non governmental health institutions.
c) To supply adequate quantity of essential drugs at each level of government health institutions.
d) To include drug industries as priority sector by all concerned ministries of GoN in order to make the nation self-reliant in production of essential drugs.
e) To develop pharmacy manpower for the effective implementation of the drug policy.
f) To promote rational use of drugs and to establish a drug information system.
g) To set up a well equipped quality control laboratory with trained staff under the Ministry of Health and Population to carry out the testing, analysis and standardization of drugs.
h) To develop an appropriate system to administer and monitor uniformity in drug prices.
i) To define, promote, and regulate the quality and standards of Ayurvedic, Homeopathic, Traditional and other systems of medicine by adopting scientific approach.

j) To improve the existing infrastructure of the Department of Drug Administration (DDA) and provide sufficient qualified and trained personnel for strengthening the drug administration mechanism and effective enforcement of the Drug Act.
k) To consolidate and amend the existing Drugs Act, Rules and Regulations to facilitate effective implementation of the Drug Policy.

4. Policy Strategies

4.1 Drug Management

4.1.1 Selection of Essential Drugs.

The Policy aims at preparing National Lists of Essential Drugs for use in central, regional, primary health centers, and referral hospitals as well as other lists for district hospitals, health posts, sub-health posts and primary health care in accordance with WHO`s concept of essential drugs.

4.1.2 Procurement, storage and distributions of drugs at different health institutions.

a) The policy aims at procuring necessary drugs by accepting tenders from a list of standard manufacturers or their authorized agents and identified by GoN using a pre-qualifying process
b) Procurement of essential drugs by GoN will be made under generic names.
c) Drug related activities such as procurement, distribution, storage and dispensing at governmental as well as non-governmental institutions will be carried out by qualified pharmacy personnel.
d) In order to ensure sufficient volume of the required drugs at different health institutions, the schemes related to partial or full cost-sharing will be implemented phase-wise.
e) To apply scientific methods for maintaining quality and minimizing all possible changes of deterioration of drugs during transport and storage.
f) The mechanism of procurement and distribution of drug will be modernized to assure timely supply of drug to all health institutions.
g) The regional offices of the DDA will be established phase-wise at all five regions in the country.

4.2 Quality assurance and regulatory control measures

a) National Medicines Laboratory will be developed as an independent National Quality Control Laboratory and under this organizational structure Regional Drug Testing Laboratory will be set up in a phase-wise manner.
b) Drug registration will be based on scientific facts. The manufacture, import, sale and distribution of ineffective, harmful, toxic as well as irrationally combined formulations will be banned.
c) Submission of a certificate of “Good Manufacturing Practices (GMP)” issued as per WHO guideline will be made compulsory for registration of manufacturers of imported drugs.
d) The quality and standard of locally manufactured drugs will meet the standards prescribed in National Code of Drug Manufacturing Conduct similar to WHO specifications.
e) The mechanism of registration and evaluation of drug will be updated to ensure the quality of marketed products.

f) A definite custom point will be identified for entrance of imported pharmaceuticals into the country.

4.3 Rational drug use and its information

4.3.1 Education and Training

a) To promote rational use of drugs, the health workers at all levels who are eligible to prescribe drugs, available at the health institutions will be trained regularly in "Standard Drug Treatment Schedule". The prescribers will have to adhere to the schedule allocated for the level of health care they are involved in.
b) Rational use of drugs will be promoted by involving the qualified pharmacists in the pharmacy services at all levels hospitals services and other relevant institutions.
c) Curricula for training on different aspects of drugs will be developed and training will be conducted for pharmacists and other health personnel.
d) Training modules on production technologists, quality assurance and good manufacturing practices will be developed for pharmacists involved in the production of drugs.

4.3.2 Drug Information

a) GoN will effectively develop an efficient "Drug Information System" to disseminate the relevant information about proper use of drug, adverse reaction, pharmacology, toxicity, standard and efficacy etc. to all concerned through different media including publication of National Drug Formulary.
b) Nepalese Pharmacopoeia consisting of individual monographs, standards of drug materials and accessory raw materials to be used in a formulation will be brought out.
c) Non-governmental organizations will also be encouraged to participate in providing information about rational use of drugs to the public.

4.3.3 Prudent Use of Antibiotics (added by amendment in 2001)

a) Prevailing antibiotics used in food products, animal feeds and agriculture substances will be managed properly.
b) Supervision and monitoring on use of antibiotics will be carried out. Misuse will be controlled and proper recording system will be developed.
c) Antibiotic will be classified into different groups for prescribing purposes by medical Doctors, veterinary doctors and other health personnel.
d) GoN will constitute a national antibiotic control committee comprising of experts from human and animal health, agriculture and representation from professional organizations/councils and organizations involved in consumers right and other sectors for prudent use of antibiotic.
e) GoN will constitute a national antibiotics therapeutics advisory committee (NATAC) comprising of experts from relevant sectors to advice a prudent use of antibiotics.

4.4 Manpower Development

a) A Pharmaceutical Affairs Unit will be set up in the Ministry of Health and Population for effective coordination of activities pertaining to pharmaceutical development.
b) Academic institutions will be encouraged to develop pharmaceutical education both in governmental as well as in non-governmental sectors for the production of qualified pharmacy manpower required for the country.
c) Regulatory measures will be adopted to bring registration to pharmacy manpower involved in the various activities under the pharmaceutical profession.

4.5 National Drug Industry

a) The domestic pharmaceuticals industries will be accorded a status among national priority sectors.
b) In order to achieve self-reliance in the production of essential drugs the entrepreneurs will be encouraged to promote and establish pharmaceutical industries both in public and private sectors. The aim is to be able to produce 80% of the essential drug formulations in the coming 10 years.
c) Production of active ingredients, excipient and packaging materials will be encouraged.
d) While purchasing drugs for the public sector, first priority will be given to domestic products in accordance with the financial regulations.
e) The government will provide facilities in the importation of machineries, equipments, raw materials, excipients and packing materials required for the domestic pharmaceutical production.
f) Private sectors will also be encouraged to set up quality control laboratories for drugs to be used within the country.

4.6 Traditional Medicines

a) In order, to promote the drugs under Ayurvedic, Homeopathic and other systems, the production of drugs for which the formula is well documented under their recognized literature will be facilitated both at governmental and private sectors.
b) The drugs based on these formulas as well as other ingredients will be modernized into dosage form and be subjected to scientific evaluation for their safety, efficacy and quality.
c) Activities related to drugs under Ayurvedic, Homeopathic, and other systems will be developed suitably by involving qualified personnel and related technologies.
d) The Ayurvedic Department will conduct and coordinate all technical activities related to Ayurvedic drugs.

5. Research and Development

a) Research on the novel areas such as improved pharmaceutical technology for production of bulk drugs as well as development of the new drug delivery system will be encouraged.
b) Clinical trials of drugs will be carried out through Nepal Health Research Council at the institutions recognized by GoN.

6. Technical Cooperation

GoN will encourage involvement of national and international agencies for technical cooperation in areas of pharmaceutical manpower training and technology exchange.

7. Monitoring and Evaluation

a) GoN will constitute a committee responsible for successful and effective implementation of the Drug Policy as well as for monitoring and supervision of its implementation.
b) GoN will identify responsible sector for successful implementation of the national Drug Policy as well as develop criteria for its evaluation.

Drugs Act, 2035, (1978)

Date of Authentication and Publication

2035.7.8 (25 October 1978)

Amending Acts:

1. **The Drugs (First Amendment) Act, 2045 (1988)** **2045.7.10 (26 November 1988)**
2. **The Drugs (Second Amendment) Act, 2057 (2000)** **2057.8.14 (29 November 2000)**

Act number 21 of the year 2053 (1978)

An Act Made to Make Provisions relating to Drugs

Preamble: Whereas, it is expedient to prevent the misuse or abuse of drugs and allied pharmaceutical substances and false or misleading information relating to the efficacy and use of drugs and to control the production, sale, distribution, export, import, storage and consumption of those drugs which are not safe for public consumption, efficacious and of standard quality;

Now, therefore, His Majesty King Birendra Bir Bikram Shah Dev has, with the aid and advice of the National Panchayat, enacted this Act.

Chapter- 1

Preliminary

1. Short title, extent and commencement: (1) This Act may be called as the "Drugs Act, 2035 (1978)".

(2) This Act shall extend to the whole of Nepal.

(3) Section 1 of this Act shall come into force immediately, and other sections shall come into force in such area and on such date as Government of Nepal may, by notification in the Nepal Gazette, appoint from time to time.[†]

[†] Notifications on the commencement of the Act:

(a) Sections 3 and 4 of this Act have been appointed to commence forthwith to the whole of Nepal (the Nepal Gazette dated 2037.3.5 (18 June 1980).

(b) Sections 2, 25, Sub-section (1) of section 34, sections 38 and 39 of this Act have been appointed to commence forthwith to the whole of the Nepal (the Nepal Gazette dated 2040.3.13 (27 June 1983).

(c) Sections 7, 8, 9, 10, 11 and 37 of this Act have been appointed to commence to the whole of the Nepal on 2040.12.6 (19 March 1984) (the Nepal Gazette dated 2040.12.6 (19 March 1984).

(d) Sections 20, 21, 22, 23, 24, 28, 29, 30, 33 and Sub-sections (2) and (3) of Section 34 of this Act have been appointed to commence to the whole of the Nepal on 2043.4.1 (16 July 1986) (the Nepal Gazette dated 2043.2.12 (26 May 1986).

(e) Sections 12, 13, 14, 15, 16, 17, 18, 19, 32, 35 and 36 o f this Act have been appointed to commence to the whole of the Kingdom of Nepal on 2046.5.26 (11 September 1989) (the Nepal Gazette dated 2046.5.26 (11 September 1989).

(f) Section 26 of this Act has been appointed to commence on 2049.8.1 (16 November 1992) (the Nepal Gazette dated 2049.8.1(16 November 1992).

2. **Definitions:** In this Act, Unless the subject or the context otherwise requires,-

(a) "Drug" means any substance to be used for the diagnosis, cure, mitigation, treatment or prevention of a disease in a human being, animal or bird or to be used to destruct vermin or insects which cause diseases in the human being, animal or bird or any substance used to affect the structure or any organic function of the body of a human being, animal or bird or allied ingredients or components to be used for the preparation of such substance.

(b) "Manufacture" means the process of making, preparing, refining, altering, packing, repacking or labeling a drug or any or all of the processes followed in this respect.

Provided that, this term does not include the process of dispensing, packing or repacking a drug prior to its consumption or sale.

(c) "Dispensing" means the issuing of a drug in a suitable container, appropriately labeled and compounded for its subsequent consumption by a patient.

Explanation: For purposes of this Clause, "compound" means the process of mixing two or more specific ingredients to fabricate them into a single drug.

(d) "Label" means the name and other related description of a drug written on the container of that drug.

(e) "Doctor" means a (doctor) registered pursuant to the Nepal Medical Council Act, 2020 (1964).

(f) "Consumption" means the giving or administering of a drug either by a (doctor) or by a person authorized by the (doctor) to a patient with intention to bring about improvement in his/her physical or mental condition at that time or the taking or administering of such drug by the patient him/herself according to the prescription written by such doctor.

(g) "Department" means the Department of Drugs Administration constituted pursuant to Section 5.

(h) "Administrator" means the Head of Department.

(i) "Inspector" means a person deputed by the Department for purposes of Chapter-6[♣]

(j) "Prescribed" or "as prescribed" means prescribed or as prescribed in the Rules framed under this Act.

Chapter- 2

Drugs Advisory Council and Drugs Advisory Committee

3. Drugs Advisory Council: (1) A Drugs Advisory Council shall be constituted as prescribed to advise Government of Nepal on theoretical and administrative matters relating to drugs.

(2) The functions, duties and powers of the Drugs Advisory Council shall be as prescribed.

4. Drugs Advisory Committee: (1) A Drugs Advisory Committee shall be constituted as prescribed to advise the Department on technical matters related with the research, development and control of drugs.

(2) The functions, duties and powers of the Drugs Advisory Committee shall be as prescribed.

Chapter- 3

Research and Control of Drugs

5. Department of Drug Administration: (1) Government of Nepal shall establish a Department of Drug Administration for the implementation of the objectives of this Act.

(2) The Department established pursuant to Sub-section (1) shall carry out all the functions related with the control of drugs under this Act and the Rules framed there under.

[♣] Amended by the First Amendment.

6. **Drug Research Laboratory and Other Laboratories:** (1) The Drug Research Laboratory established by Government of Nepal shall be the principal body of Government of Nepal to perform scientific research, testing and analysis of drugs.

♦(1a)The procedures to be followed by the Royal Drug Research Laboratory established pursuant to Sub-section (1) in performing scientific research, testing and analysis of drugs shall be as prescribed.

(2) Any native or foreign person or institution may, with the approval of Government of Nepal , establish any other research centre or laboratory for the scientific research and development of any drugs.

Chapter- 4

Manufacture, Sale, Distribution, Export and Import of Drugs

7. **Recommendation letter to be obtained to establish drug industry:** Any person who intends to establish an industry to manufacture any drugs shall obtain a recommendation letter from the Department as prescribed, prior to the obtaining of approval of the Government of Nepal pursuant to the prevailing law.

8. **Product license to be obtained:** (1) After the establishment of a drug industry by obtaining recommendation of the Department pursuant to section 7 and before the manufacturing of that drug, the drug manufacturer shall obtain the product license from the Department as prescribed⌘, by paying the prescribed fees.

(2) Any drug industry which has already been established prior to the commencement of this Act shall also obtain the product license pursuant to Sub-section (1), --------✂ by paying the prescribed fees.

♦**8A.** **Registration of drug:** (1) Any drug manufacturing industry shall, prior to the

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♦ Inserted by the Second Amendment.
⌘ Amended by the Second Amendment.
✂ Deleted by the Second Amendment.
♦ Inserted by the Second Amendment.

sale and distribution of each drug manufactured by it, register the drug with the Department, as prescribed, and obtain the drug registration certificate, by paying the prescribed fees.

(2) Any person who intends to import a drug shall, prior to its importation, get each drug of a licensed company which it intends to import registered with the Department, as prescribed, and obtain the registration license, by paying the prescribed fees[↘].

9. Recommendation letter to be obtained for exportation or importation of drug: Any person who intends to export or import a drug shall, prior to obtaining the export or import license pursuant to the prevailing law, obtain a recommendation letter from the Department, as prescribed, on payment of the prescribed fees.

10. Registration of name for sale and distribution of drug: Any person who sells and distributes a drug shall get his/her name and shop or firm registered with the Department, as prescribed, and obtain a certificate, on payment of the prescribed fees[↘].

[♦]**10A. Sale and distribution of registered drugs only:** Any person who has obtained the certificate pursuant to Section 10 shall sell and distribute only the drugs registered pursuant to Section 8A.

[♣]**11. Validity period and renewal of product license, recommendation letter and certificate:** (1) The license as referred to in Section 8, the certificate as referred to in section 8A[♦], the recommendation letter as referred to in Section 9 and the certificate as referred to in section 10 shall remain valid for two years from the date of its issue.

(2) Each license, recommendation letter and certificate shall be got

[↘] Inserted by the First Amendmend .
[↘] Inserted by the First Amendmend .
[♦] Inserted by the Second Amendment.
[♣] Amended by the First Amendment.

renewed for each year within thirty five days of the expiry of its validity period[⌘].

[♦](3) If the renewal is not made within the specified time limit pursuant to Sub-section (1), and an application is made, setting out the reasons for the failure to have renewal, within thee months after the date of expiry of the time limit, the Department shall make renewal by charging an additional fee of twenty five percent of the renewal fee. The license, recommendation letter or certificate not renewed even within that time limit shall ipso facto be invalid.

Chapter- 5

Quality Standard of Drugs

12. Drugs to be safe for public consumption, efficacious and of quality standard: Each drug shall be safe for public consumption, efficacious and of quality standard in such a manner as to keep on maintaining its prescribed quality standard.

13. **Prohibition on manufacture, sale, distribution, export, import, storage or consumption of drug not conforming to prescribed standard**: No person shall manufacture, sell, distribute, export, import, store, or cause to do same or cause the consumption of, a drug which is not safe for public consumption, efficacious and of quality standard.

14. Return of drug which is not safe for public consumption, efficacious and of quality standard: (1) If a drug which has already been marketed for sale and distribution is not safe for public consumption, efficacious and of quality standard pursuant to Section 12, the manufacturer or his/her agent shall get back such drug from the seller or distributor.

(2) If it comes to the knowledge of the Administrator in any manner that a drug which is not safe for public consumption, efficacious and of quality standard has been marketed for sale and distribution, he/she may cause the seller or distributor of the drug to return the drug to its manufacturer.

♦ Inserted by the Second Amendment.
⌘ Amended by the Second Amendment.
♦ Inserted by the Second Amendment.

15. **Provision of compensation:** If a drug manufactured in such a manner that it is not safe for public consumption, efficacious and of quality standard results in the death of, or causes injury to the health of any person, the drug manufacturer shall be responsible for it and provide compensation, as prescribed, to the successor to the deceased for such death and to that person in the event of such injury.

⌘**16.** **Submission of letter of guarantee to Department:** A drug manufacturer him/herself or his/her authorized agent or exporter or importer shall submit to the Department a certified copy of the document issued by the manufacturer guaranteeing that the drug registered pursuant to Section 8A is safe for public consumption, efficacious and of quality standard.

17. **Categorization of drugs:** (1) The drugs may be classified into categories or sub-categories, as prescribed.

(2) No person shall sell or distribute such drugs without prescription of a doctor as categorized not to be sold or distributed without such prescription pursuant to Sub-section (1). The pharmacist or pharmacy assistant♦ or professional person himself shall sell or distribute such drugs on prescription of a doctor; and the presence of a pharmacist or pharmacy assistant♦ or professional person shall be compulsory where a person other than the doctor, pharmacy assistant♦ or professional person sells or distributes such drugs.

(3) The drugs categorized as to be sold or distributed only in presence of a pharmacist or pharmacy assistant♦ or professional person or any of them while making categorization pursuant to Sub-section (2) may be sold or distributed only by them or in their presence.

(4) Any seller may, based on the experience, sell in a reasonable quantity

⌘ Amended by the Second Amendment.
♦ Inserted by the Second Amendment.
♦ Inserted by the Second Amendment.
♦ Inserted by the Second Amendment.
♦ Inserted by the Second Amendment.

the drugs other than those categorized pursuant to subsections (2) and (3). **Explanation:** "Pharmacist" means a person who has done graduation in pharmacy[⌘] or graduation in pharmaceutics or and been recognized by the Drugs Advisory Committee, "pharmacy assistant" means a person who has passed certificate level or equivalent in pharmacy[♦] and "professional person" means a person who has possessed the prescribed qualifications and been recognized by the Drugs Advisory Committee.

18. Prohibition on misuse or abuse of drugs: (1) No person shall misuse or abuse drugs.

(2) Sale and distribution of any drug in contravention of the provisions contained in Sub-sections (2) and (3) of Section 17 shall be deemed to have misused or abused such drug.

19. Prohibition on false or misleading advertisement of drugs: (1) No person shall make a false or misleading publicity or advertisement about the use, utility or efficacy of any drug.

(2) Any person who intends to make publicity or advertisement of any drug shall obtain the license, as prescribed, from the Department, by paying the fees prescribed for the same.

Chapter- 6

Inquiry and Inspection

20. Powers of Inspector to make inquiry and inspection: (1) The Inspector may inspect, enquire and search any place where a drug is being manufactured, stored[♦] sold, distributed or transported.

(2) If, in making inspection, inquiry or search pursuant to Sub-section (1), the Inspector suspects that any drug is not safe for public consumption, efficacious or of quality standard or has a reasonable ground to believe that any

[⌘] Amended by the Second Amendment.
[♦] Inserted by the Second Amendment.
[♦] Inserted by the Second Amendment.

activity is being carried out in contravention of this Act or the Rules framed under this Act, the Inspector may seal the drug which he/she has found, hand over its custody to its owner, receive a receipt from that owner, withhold such drug and give order to immediately stop such activity[⌘].

(3) If the Inspector makes inspection, inquiry or search pursuant to this Section or stops a drug or sends sample of that drug for testing, he/she shall submit a report thereon to the Administrator within three days.

(4) If the drug, which has been withhold by the Inspector pursuant to Sub-section (2), is proved, from the analysis or test by a research center, laboratory, hospital, pharmacy or clinic, that it is not safe for public consumption, efficacious or of quality standard, such drug may be seized or destroyed by order of the Administrator; and the Administrator may, while issuing such order, order to cancel the recommendation letter, product license, certificate or license issued under this Act.

[♦](4a) If, in carrying out analysis or test pursuant to Sub-section (4), any drug is found to be safe for public consumption, efficacious and of quality standard but the person manufacturing, selling, distributing, storing, transporting, exporting or importing such drug is held to have committed any activity in violation of this Act or the Rules framed under this Act, the Administrator may seize such drug and control the manufacturing, sale, distribution, storage, transportation, export or import of such drug or suspend the license or certificate or recommendation letter of such person for a period not exceeding six months.

(5) The manufacturer shall bear the expenditures incurred in destroying the drug pursuant to Sub-section (4) If the drug seized from the seller and stopped is to be destroyed, the value of such drug received by the manufacture from the seller shall also be got reimbursed by the manufacturer to the seller.

[♦](6) The Department may, as per necessity, depute any expert in the concerned subject to assist in the inquiry and inspection as referred to in this section.

[⌘] Amended by the Second Amendment.
[♦] Inserted by the Second Amendment.
[♦] Inserted by the Second Amendment.

⌘**21.** **Filing complaint against order of Administrator:** (1) A person who is not satisfied with an order issued by the Administrator to cancel or suspend the product license, recommendation letter, certificate or license pursuant to Sub-section (4) and (4a) of section 20 may file a complaint before the Secretary at the Ministry of Health within thirty five days after the date of receipt of such order.

(2) The complaint filed pursuant to Sub-section (1) shall be decided within three months.

22. **Procedures to be followed while making inspection or inquiry:** The methods and procedures, as prescribed, shall be followed while making inspection, inquiry and search under this Act.

♣**23.** **Qualifications of Inspector and Analyst:** (1) The Inspector shall possess the following qualifications:

(a) Graduation in pharmacy⌘, or

(b) -----✂

(c) -----✂

⌘ (d) Having passed certificate level or equivalent in pharmacy and gained at least five years of experience in pharmacy related works.

(2) The Analyst shall possess the following qualifications:

(a) Graduation in pharmacy, or⌘

♦(a1) Master's degree in chemistry, or

(b) Graduation in chemistry and gained at least three years of experiences in drug analysis⌘.

⌘ Amended by the Second Amendment.
♣ Amended by the First Amendment.
⌘ Amended by the Second Amendment.
✂ Deleted by the Second Amendment.
✂ Deleted by the Second Amendment.
⌘ Amended by the Second Amendment.
⌘ Amended by the Second Amendment.
♦ Inserted by the Second Amendment.
⌘ Amended by the Second Amendment.

24. **Sending sample of drug for test:** The Inspector shall send the sample of a drug, which has been withheld or seized in the course of inspection or inquiry, to the research center, laboratory, hospital, dispensary or clinic, as prescribed, for test or analysis; and the Analyst shall also carry out necessary test or analysis and send a report thereof to the Administrator, as prescribed.

Chapter- 7

Miscellaneous

⌘25. **Powers of Government of Nepal to prohibit manufacture, sale, distribution, storage, transportation, export, import or consumption of drugs:** If Government of Nepal thinks it necessary to prohibit the manufacture, sale, distribution, storage, transportation, export, import or consumption of any drug, it may, by a notification in the Nepal Gazette, issue order to prohibit the manufacture, sale, distribution, storage, transportation, export, import or consumption of such drugs.

26. **Powers to fix price of drug:** The Department may, if it deems necessary, fix the price of any drug, by obtaining approval of the Government of Nepal. If the Department so fixes the price of any drug, a notice thereof shall be published in the Nepal Gazette♦.

⌘ 27. **Provisions relating to prescription:** The provisions relating to the issuance of prescription by the prescribed doctor or recognized (integrated) doctor or health worker about the drugs categorized pursuant to Section 17 shall be as prescribed.

28. **Prohibition on manufacture, sale, distribution, dispensing or storage without making arrangement of required human resource♦ or resources:** No person shall manufacture, sell, distribute, dispensing, store, export or import✍ any drug without adequately arranging such human resource and

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⌘ Amended by the Second Amendment.
♦ Inserted by the Second Amendment.
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✍ Inserted by the First Amendmend .

other[♦] necessary materials related with such activity as prescribed for the manufacture, sale, distribution, dispensing, storage, export or import[↘] of such drug.

29. Prohibition on adulteration in drugs and sale of adulterated drugs: (1) No person shall adulterate any drug so as to root out or lessen or change its effect or be injurious or sell or offer to sell such drug or dispense it to any one for treatment with knowledge of such adulteration.

(2) No person shall sell any other substance representing it to be a drug.

30. Prohibition on sale or distribution of date expired drugs: No person shall sell or distribute any drug which is date expired.

31. License to be obtained from Department for clinical trial of new drug: Any person who intends to carry out a clinical trial of any new drug shall obtain license from the Department, as prescribed, for such trial.

Explanation: For purposes of this section "clinical trial" means the testing of a new drug by administering it to any patient or other person with his/her consent in a hospital or similar other clinic as prescribed in the license in order to ascertain whether it is appropriate to bring that drug into use.

32. Disclosure of system of drug and other particulars while manufacturing drug: (1) While manufacturing any drug, its label shall set out the matter which of the Allopathic, *Ayurvedic*, Homeopathic or *Unani* systems that drug belongs to.

(2) While manufacturing any drug, the possible side effects from the consumption of that drug shall be mentioned as prescribed.

33. Narcotic and poisonous drug to be kept safely: (1) A clear label shall be put on the prescribed narcotic and poisonous drug, and such drug shall be kept safely.

(2) Any person who sells and distributes the narcotic and poisonous drugs as referred to in Sub-section (1) shall maintain records of the narcotic and

[♦] Inserted by the Second Amendment.
[↘] Inserted by the First Amendment .

poisonous drug sold or distributed by him/her in the prescribed format; and a prescription relating to such narcotic and poisonous drug written by a doctor shall be attached with such records.

34. **Penalties:** (1) Any person who violates Chapter 4 or an order as referred to in section 25 shall be punished with imprisonment for a term not exceeding three years or a fine not exceeding Twenty Five Thousand Rupees⌘ or with both.

(2) Any person who makes an improper use of or misuses a drug contrary to Section 18♦ or adulterates a drug or sells an adulterated drug or sells any other substance representing it to be a drug contrary to section 29 or sells or distributes a date-expired drug contrary to section 30 or does any act contrary to section 33⌘ shall be punished as follows:

(a) in the event of the possibilit y of a risk of claiming life, life imprisonment or imprisonment for a term not exceeding ten years and a fine;

(b) in the event of the possibility of disempowerment or deprival of capacity of any organ of the body, imprisonment for a term not exceeding ten years and a fine; and

(c) in other conditions, imprisonment for a term not exceeding five years or a fine or both.

(3) Except as mentioned in Sub-sections (1) and (2), a person who commits any act contrary to this Act or the Rules framed under this Act shall be punished with imprisonment for a term not exceeding one year or a fine not exceeding Five Thousand Rupees⌘ or both.

35. **Ceiling of fine and imprisonment in lieu of fine:** (1) For the purpose of imposing a fine pursuant to Sub-section (2) of Section 34, such fine shall not exceed the

⌘ Amended by the Second Amendment.
♦ Inserted by the Second Amendment.
⌘ Amended by the Second Amendment.
⌘ Amended by the Second Amendment.

amount in controversy (*Bigo*) or One Hundred Thousand Rupees[⌘] whichever is higher.

Provided, however, that such excessive fine shall not be set as is not suitable to the condition of an offender or the circumstance of the offence.

(2) While setting the punishment of fine pursuant to Sub-section (1), the judicial authority shall also specify in his/her decision the term of imprisonment, in lieu of the fine, which the offender has to serve for his/her failure to pay that fine.

(3) Where the punishment of fine is imposed for an offence and there is also a provision of punishment of imprisonment for such offense, punishment of imprisonment shall not be set for a term exceeding five years for the failure to pay the fine under Sub-section (2). If punishment of life imprisonment is imposed, no additional imprisonment shall be imposed.

36. Right to register patent of drug: The right related with the registration of patent of a drug shall be as per the prevailing law.

37. Delegation of authority: Government of Nepal may delegate to any official all or any of the powers conferred to the Administrator pursuant to this Act.

38. Government to be the plaintiff : Government of Nepal shall be plaintiff in the cases of under this Act.

39. Investigation and filing of case: (1) The Inspector shall investigate any case related with an offense punishable under this Act and file the case with the Judicial Authority after completion of such investigation.

[♦](1a) In investigating a case pursuant to Sub-section (1), the Inspector shall have the powers to arrest a person involved in the offense, search any place whatever related with the offense, take custody of a document or other goods related with the offense and execute a deed of public inquiry (*sarjamin*).

[♦](1b) In making investigation pursuant to Sub-sections (1a) and (1b), the Inspector may get the accused to make deposition and, on reasonable grounds,

[⌘] Amended by the Second Amendment.
[♦] Inserted by the Second Amendment.
[♦] Inserted by the Second Amendment.

release him/her on personal bail, security or guarantee or detain him/her for a period not exceeding twenty five days, by obtaining prior permission of the Judicial Authority.

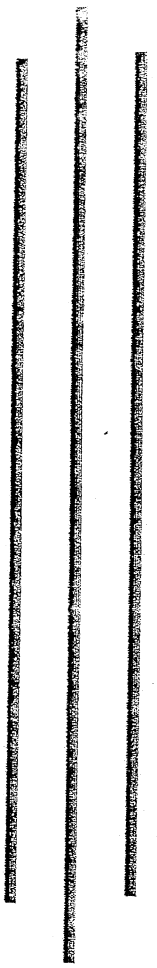
♦(1c) In doing any activity as referred to in Sub-sections (1a) and (1b), the Inspector may, as per necessity, seek assistance of the police personnel. If such assistance is sought, the police personnel shall render necessary assistance.

(2) In investigating and filing a case pursuant to Sub-section (1) the Inspector may seek opinion of the Government Attorney. After the filing of a case, the Government Attorney shall plead and appeal the case.

40. **Power to frame Rules:** Government of Nepal may frame Rules in order to implement the objectives of this Act.

♦ Inserted by the Second Amendment.

अस्पताल फार्मेसी सेवा निर्देशिका, २०७२



नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

रामशाहपथ, काठमाडौं

अस्पताल फार्मेसी सेवा निर्देशिका, २०७२

प्रस्तावना:

स्वास्थ्य सेवामा प्रभावकारी रुपमा सबैको पहुँच सुनिश्चित गर्नका लागि फार्मेसी विषयका दक्ष जनशक्तिमार्फत् अस्पतालहरुबाट आफ्नै फार्मेसी सेवा सञ्चालन गरी विरामी एवं सेवाग्राहीहरुलाई सुलभ एवं गुणस्तरीय सेवा पुऱ्याउन (सुशासन व्यवस्थापन तथा सञ्चालन) ऐन, २०६४ को दफा ४५ ले दिएको अधिकार प्रयोग गरी नेपाल सरकारले देहायको निर्देशिका बनाएको छ ।

१. संक्षिप्त नाम र प्रारम्भः (१) यस निर्देशिकाको नाम "अस्पताल फार्मेसी सेवा निर्देशिका, २०७२" रहने छ ।

(२) यो निर्देशिका नेपाल सरकारबाट स्वीकृत भएको मिति देखि लागू हुनेछ ।

२. परिभाषाः बिषय वा प्रसंगले अर्को अर्थ नलागेमा यस निर्देशिकामा,

(१) **"मन्त्रालय"** भन्नाले स्वास्थ्य तथा जनसंख्या मन्त्रालय सम्झनु पर्दछ ।

(२) **"अस्पताल"** भन्नाले नेपाल सरकारको पुर्ण वा आंशिक स्वामित्व वा नियन्त्रणमा रहेको वा विकास समिति ऐन, २०१३ अनुसार सञ्चालनमा रहेको सरकारी अस्पताल एवं स्वास्थ्य संस्थाहरु सम्झनु पर्दछ ।

(३) **"फार्मेसी सेवा"** भन्नाले अस्पतालहरुमा सञ्चालनमा रहेका र सञ्चालन गरिने औषधि तथा औषधिजन्य पदार्थ वा सामग्रीबाट दिइने सेवा सम्झनु पर्दछ ।

(४) **"समिति"** भन्नाले दफा ३ बमोजिम गठित अस्पताल फार्मेसी तथा थेराप्युटिक समिति सम्झनु पर्दछ ।

(५) **"अस्पताल फर्मुलरी"** भन्नाले अस्पतालमा प्रयोग हुने औषधि तथा औषधिजन्य पदार्थ वा सामग्रीहरुको विवरण पुस्तिका सम्झनु पर्दछ ।

३. अस्पताल फार्मेसी तथा थेराप्युटिक समितिः अस्पतालमा औषधी तथा औषधीजन्य पदार्थ वा सामग्रीहरुबाट दिइने सेवा व्यवस्थित एवं प्रभावकारी रुपमा सञ्चालन गर्न गराउन देहाय बमोजिमको अस्पताल फार्मेसी तथा थेराप्युटिक समिति गठन हुनेछ ।

(क) अस्पताल प्रमुख वा निजले तोकेको वरिष्ठ चिकित्सक - अध्यक्ष

(ख) चिकित्सकीय विभाग वा इकाईका प्रमुखहरु - सदस्य

(ग) नर्सिङ विषय हेर्ने प्रमुख - सदस्य

(घ) प्रशासन शाखा प्रमुख - सदस्य

(ङ) आर्थिक प्रशासन शाखा प्रमुख - सदस्य

(च) अस्पताल फार्मेसी प्रमुख - सदस्य-सचिव

४. समितिको काम, कर्तव्य र अधिकार: समितिको काम, कर्तव्य र अधिकार देहाय बमोजिम हुनेछ ।

(क) अस्पताल फार्मेसीमा राखिने औषधी र औषधीजन्य पदार्थ वा सामग्रीको सूची निर्धारण गर्ने ।

(ख) आवश्यकता अनुसार औषधी वा औषधीजन्य पदार्थ वा सामग्रीका उत्पादक एवं आपुर्तिकर्ताहरुको पुर्वयोग्यता निर्धारण गर्ने ।

(ग) गुणस्तरको विश्वसनियताको आधारमा कुनै खास ब्राण्ड स्वीकृत वा अस्वीकृत गर्ने ।

(घ) अस्पताल फर्मुलरीको स्वीकृति दिने वा थपघट गर्ने ।

(ङ) औषधीको प्रतिकुल प्रभाव (Adverse Drug Reaction) को अनुगमन गर्ने ।

(च) अस्पतालबाट प्रदान गरिने उपचार सेवा सम्बन्धी निर्देशिका बनाउने ।

(छ) अस्पताल फर्मुलरीमा आधारित औषधीको सूची सहितको प्रेस्क्रिप्सनको ढाँचा तयार गर्ने ।

(ज) अस्पताल फार्मेसीको समय समयमा निरीक्षण, अनुगमन गर्ने ।

(झ) अस्पताल फार्मेसी सेवा सञ्चालन सम्बन्धी विषयमा मन्त्रालयको निर्देशन कार्यान्वयन गर्ने गराउने ।

५. समितिको बैठक सम्बन्धी व्यवस्था: (१) समितिको बैठक कम्तीमा प्रत्येक दुई महिनामा बस्नेछ ।

(२) समितिको बैठक बस्नुभन्दा कम्तीमा अढ्चालीस घण्टा अगावै सदस्य सचिवले सबै सदस्यहरुलाई बैठकको कार्यसुची उपलब्ध गराउनु पर्नेछ ।

(३) समितिको कुल सदस्य संख्याको पचास प्रतिशत भन्दा बढी सदस्यहरु उपस्थित भएमा समितिको बैठकको लागि गणपुरक संख्या पुगेको मानिनेछ ।

(४) बैठकको अध्यक्षता समितिको अध्यक्षले गर्नेछ ।

(५) समितिको बैठकको निर्णय उपस्थित सदस्यको बहुमतबाट हुनेछ । मत बराबर भएमा अध्यक्षले निर्णयक मत दिनेछ ।

(६) समितिको बैठकको निर्णय समितिको सदस्य-सचिवले प्रमाणित गर्नेछ ।

(७) समितिको बैठक सम्बन्धी अन्य कार्यविधि समिति आफैंले निर्धारण गरे बमोजिम हुनेछ ।

६. अस्पताल फार्मेसी सञ्चालन समिति: (१) अस्पताल फार्मेसी व्यवस्थित रुपमा सञ्चालन गर्न गराउन देहाय बमोजिमको फार्मेसी सञ्चालन समिति गठन हुनेछ ।

(क) अस्पताल फार्मेसी प्रमुख - संयोजक

(ख) आर्थिक प्रशासन प्रमुख वा निजको प्रतिनिधि - सदस्य

(ग) खरिद शाखाका प्रमुख वा निजको प्रतिनिधि - सदस्य

(घ) अस्पताल फार्मेसी प्रमुखले तोकेको कर्मचारी - सदस्य-सचिव

(२) उपदफा (१) बमोजिमको समितिका अन्य काम, कर्तव्य र अधिकार अस्पताल फार्मेसी तथा थेराप्युटिक समितिले निर्धारण गरे बमोजिम हुनेछ ।

(३) उपदफा (१) बमोजिमको समितिको बैठक सञ्चालन सम्बन्धी कार्यविधि अस्पताल फार्मेसी सञ्चालक समिति आफैंले निर्धारण गरे बमोजिम हुनेछ ।

७. फार्मेसी प्रमुखको काम, कर्तव्य र अधिकार: फार्मेसी प्रमुखको काम, कर्तव्य र अधिकार देहाय बमोजिम हुनेछ ।

(क) समितिका निर्णयहरु कार्यान्वयन गर्ने गराउने ।

(ख) समितिको बैठकका लागि प्रस्ताव तयार गरी पेश गर्ने ।

(ग) अस्पतालमा प्रयोग गर्ने औषधीको सूची तयार गर्ने गराउने ।

(घ) क्लिनिकल फार्मेसी सेवा प्रदान गर्न आवश्यक मिलाउने ।

(ङ) मातहतका कर्मचारीको सुपेरिवेक्षण गर्ने ।

(च) नियमित मौज्दात तथा म्याद गुज्रने मिति नजिक भएका औषधीहरुको रुजु गरी विक्रि व्यवस्थापन गर्ने गराउने ।

(छ) समितिले तोकेका अन्य कार्यहरु गर्ने ।

८. औषधी तथा औषधीजन्य सामग्री र पदार्थको खरिद प्रक्रिया: औषधी तथा औषधीजन्य सामग्री र पदार्थ खरिद गर्दा सार्वजनिक खरिद ऐन, २०६३ तथा सार्वजनिक खरिद नियमावली, २०६४ बमोजिमको प्रकृया अवलम्बन गरी गर्नु पर्नेछ ।

९. औषधी र औषधीजन्य पदार्थको विक्री मुल्य: औषधी र औषधीजन्य पदार्थको विक्री मुल्य निर्धारण गर्दा यसको खरिद मुल्यमा बीस प्रतिशतमा नबढाई निर्धारण गरिनेछ ।

तर, यसरी बिक्री मुल्य निर्धारण गर्दा अधिकतम खुद्रा मुल्य (Maximum Retail Price, MRP) भन्दा बढी हुनुहुँदैन ।

१०. अस्पताल फार्मेसीको लागि जनशक्ति: (१) अस्पतालले फार्मेसी सञ्चालनका लागि स्थायी जनशक्तिको व्यवस्था गर्नुपर्नेछ ।

(२) उपदफा (१) मा जुनसुकै कुरा लेखिएको भएता पनि स्थायी जनशक्ति उपलब्ध नहुञ्जेल सम्मका लागि वैकल्पिक व्यवस्थाबाट फार्मेसी सेवा सञ्चालन गर्न बाधा पर्ने छैन् ।

(३) स्थायी जनशक्ति नेपाल स्वास्थ्य सेवाबाट र अन्य आवश्यक जनशक्ति अस्पतालले प्रचलित नियमानुसार पूर्ति गर्न सकिनेछ ।

(४) फार्मेसी सञ्चालनका लागि कम्तीमा देहाय बमोजिमको जनशक्ति रहनेछ:

क्र.	अस्पताल/स्वास्थ्य संस्था	क्लिनिकल* फर्मासिष्ट	फर्मासिष्ट	फार्मेसी सहायक	सहयोगी
१.	१०० शैया भन्दा माथिका अस्पताल	१	३	६	२
२.	५१ देखि १०० शैया सम्मका अस्पताल	१	२	४	२
३.	२६ देखि ५० शैया सम्मका अस्पताल	–	१	२	१
४.	१५ देखि २५ शैया सम्मका अस्पताल	–	–	२	१

स्पष्टिकरण: यस दफाको प्रयोजनको लागि क्लिनिकल फर्मासिष्ट भन्नाले क्लिनिकल फार्मेसी वा फर्मासिउटिकल केयरमा स्नातकोत्तर वा वि.फार्मेसीपछीको फार्म डी गरेकालाई सम्झनुपर्दछ ।

(५) उपदफा (४) मा जुनसुकै कुरा लेखिएको भएता पनि अस्पताल फार्मेसीले अस्पतालको शैया, कार्यबोझ र दैनिक कारोबारका आधारमा जनशक्तिमा थपघट गर्न सक्नेछ ।

तर, यसरी दरबन्दी थप गर्दा प्रति दश हजार रुपैंया प्रतिदिनको कारोबारमा एकजनाभन्दा बढी थप गर्न सकिने छैन् । मासिक कारोबार घटेको अवस्थामा थप दरबन्दी स्वत: खारेज हुनेछ ।

११. अस्पताल फार्मेसीको भौतिक पूर्वाधार: (१) अस्पतालले फार्मेसी सञ्चालनका लागि औषधी विक्रि वितरण संहिता, २०७१ पालना हुने गरी आवश्यक औषधी वितरण कक्ष र भण्डारणको लागि पर्याप्त ठाउँको व्यवस्था गर्नुपर्नेछ ।

(२) औषधी वितरण कक्ष ओस नलाग्ने, सूर्यको प्रत्यक्ष प्रकाश नपर्ने र पर्याप्त भेण्टिलेसन भएको हुनुपर्नेछ । औषधी/औषधीजन्य पदार्थको लेवलमा तोकिएको सञ्चय तापक्रम अनुकूल भण्डारण गर्नुपर्नेछ ।

(३) फार्मेसी संचालन गर्ने ठाउँ सर्वसाधारणले सजिलै देख्ने हुनुपर्दछ र सम्भव

भएसम्म अस्पतालको अगाडिको भागमा हुनुपर्छ । आवश्यकता अनुसार अस्पतालमा एकभन्दा बढी फार्मेसी सञ्चालन गर्न सकिनेछ ।

(४) बिरामीलाई परामर्श दिने उपयुक्त व्यवस्था सहितको ठाउँ रहनुपर्नेछ ।

(५) बिक्री वितरणका लागि अनुपयुक्त वा फर्काउनु पर्ने वा म्याद गुज्रेका वा नष्ट गर्नुपर्ने औषधि तथा औषधिजन्य सामग्री, असम्बन्धित व्यक्तिको पहुँच नहुने गरी सुरक्षित राख्ने छुट्टै भण्डारणको व्यवस्था मिलाउनु पर्नेछ ।

(६) औषधि पूर्जा लिने, डिस्पेन्स गर्ने र भुक्तानी लिने व्यक्ति र ठाउँको उपयुक्त व्यवस्था हुनुपर्नेछ ।

(७) औषधि तथा औषधिजन्य सामग्रीको मौज्दात तथा खपत अभिलेख, विजकीकरण, औषधिको सूचना, लेवल औषधि सम्बन्धी समस्याहरुको जानकारी आदि संलग्न भएको उपयुक्त सफ्टवेयर सहितको कम्प्युटरको माध्यमबाट गर्नुपर्नेछ ।

(८) नेपाल सरकारबाट प्रदान गरिने निःशुल्क औषधीहरु र औषधीजन्य सामग्रीहरुको सूची सबैले देख्न सक्ने गरी राख्नु पर्नेछ ।

(९) अस्पताल फार्मेसी सञ्चालनका अन्य पक्ष औषधी विक्रि वितरण संहिता, २०७१ र स्वास्थ्य संस्था स्थापना, सञ्चालन र स्तरोन्नती सम्बन्धी मापदण्ड निर्देशिका, २०७० बमोजिम हुनेछ ।

(१०) अस्पतालहरुबाट निःशुल्क प्रदान गर्ने औषधीहरु र सो बाहेकका औषधीहरु स्पष्ट छुट्टिने गरी फार्मेसीमा राख्नुपर्नेछ ।

(११) अस्पताल परिसरमा औषधीको व्यापारिक प्रवर्द्धन सम्बन्धी कुनैपनि क्रियाकलाप गर्न पाइनेछैन् ।

तर, औषधीको वैज्ञानिक प्रस्तुति गर्नुपर्दा सामुहिक सहभागिता हुने गरी सभा सम्मेलनको रुपमा समितिको स्वीकृतिमा सञ्चालन गर्न बाधा पुग्ने छैन् ।

१२.विउ रकम (Seed Money) उपलब्ध गराउने: (१) मन्त्रालयले अस्पताल फार्मेसी सञ्चालनका लागि विउ रकम (Seed Money) उपलब्ध गराउन सक्नेछ ।

(२) मन्त्रालयले आवश्यक देखेमा उपदफा (१) बमोजिमको रकम अनुदानको रुपमा परिणत गर्न सक्नेछ ।

१३. निःशुल्क बितरण गरिने औषधी सम्बन्धमा: (१) नेपाल सरकारबाट निशुल्क बितरण गर्ने भनी तोकिएका औषधि अस्पताल फार्मेसीले निःशुल्क उपलब्ध गराउनुपर्नेछ ।

(२) निःशुल्क बितरणका लागि तोकिएका औषधी र औषधीजन्य सामग्री तथा

पदार्थको आवश्यकता अनुसार मन्त्रालयबाट प्रदान गर्ने अनुदान रकम वा औषधी खरिदका लागि प्राप्त रकमबाट खरिद गर्नुपर्नेछ । स्वास्थ्य सेवा विभाग मातहतका अन्य अस्पतालको हकमा विभाग, क्षेत्रीय स्वास्थ्य निर्देशनालय र जिल्ला स्वास्थ्य/जनस्वास्थ्य कार्यालयहरुबाट खरिद गरी उपलब्ध गराइनेछ ।

(३) कारणवश निःशुल्क वितरण गरिने औषधीको मौज्दात नभएको अवस्थामा त्यस्तो औषधी निःशुल्क उपलब्ध गराउन फार्मेसी बाध्य हुने छैन ।

तर, निशुल्क वितरण हुने औषधी र औषधीजन्य सामग्री मौज्दात नभएको जानकारी सम्बन्धीत विरामीको प्रेस्क्रिप्सनमा फार्मेसीले जनाइदिनु पर्नेछ ।

(४) सरकारी अस्पतालहरुले निःशुल्क औषधीहरु मौज्दातमा नभएमा पनि अतिगरिब र असहाय विरामीलाई औषधी निःशुल्क दिने व्यवस्था गर्नुपर्नेछ र यो सेवा प्राप्त गर्ने विरामीहरुको विस्तृत विवरण सहितको अभिलेख मासिक रुपमा सार्वजनिक गर्नुपर्नेछ ।

१४. निःशुल्क प्राप्त औषधीको वितरणः (१) सबै अस्पतालहरुले कुनैपनि श्रोतबाट निःशुल्क रुपमा प्राप्त भएका वा कुनै कम्पनीबाट बोनस स्वरुप प्राप्त भएका औषधी र औषधीजन्य सामग्रीहरु निःशुल्क रुपमा प्रदान गर्नुपर्नेछ ।

(२) औषधी तथा औषधीजन्य सामग्रीहरु निःशुल्क प्राप्त गर्दा अस्पताल फर्मुलरीमा सूचीकृत औषधीहरुमा आधारित भई औषधी दान वा उपहार प्राप्त गर्न सकिनेछ । यसका अतिरिक्त औषधी व्यवस्था विभागले तोकेकोवा विश्व स्वास्थ्य संगठनको औषधी दान वा उपहार प्राप्त गर्ने सम्बन्धी निर्धारित मापदण्ड अनुरुप गर्नुपर्नेछ ।

१५. आर्थिक व्यवस्थापनः (१) अस्पताल फार्मेसीको अलग्गै खाता हुनेछ ।

(२) उपदफा (१) बमोजिमको खाताको सञ्चालन अस्पताल प्रमुख वा निजले तोकेको व्यक्ति र लेखा प्रमुखको संयुक्त दस्तखतमा सञ्चालन हुनेछ ।

(३) उपदफा (१) बमोजिमको खातामा देहायका रकम जम्मा हुनेछन्:

(क) मन्त्रालयबाट प्राप्त रकम,

(ख) दैनिक विक्रीबाट प्राप्त रकम,

(ग) स्थानीय निकायबाट प्राप्त रकम,

(४) फार्मेसी सञ्चालन समितिको सिफारिश र समितिको निर्णय विना उपदफा (१) बमोजिमको खातामा रहेको रकम अन्य प्रयोजनमा खर्च गरिनेछैन् ।

(५) प्रत्येक दिनको कारोबार रकम सोही दिन अथवा भोलीपल्टको मध्यान्ह सम्ममा बैंक दाखिला गरिसक्नुपर्नेछ ।

(६) फार्मेसीमा काम गर्ने करारका कर्मचारीको तलबभत्ता लगायतका खर्च उपदफा (१) बमोजिमको खाताबाट मात्र व्यहोरिनेछ।

(७) औषधी बिक्रीको कूल रकमबाट मासिक रुपमा कम्तीमा दश प्रतिशत रकम अस्पतालको मूल खातामा जम्मा गर्नुपर्नेछ।

१६. आयव्ययको हिसाब: (१) प्रत्येक आर्थिक वर्ष समाप्त भएको एक महिनाभित्र फार्मेसीको आयव्ययको हिसाब गरिनेछ।

(२) आयव्ययको हिसाब राख्दा नाफा भएको रकममध्ये नब्बे प्रतिशत रकम अस्पतालको मुल खातामा जम्मा गर्नुपर्नेछ।

(३) आर्थिक वर्ष समाप्त भएको तीन महिनाभित्र आन्तरिक लेखा परीक्षण गराई सक्नुपर्नेछ।

(४) अस्पताल फार्मेसीको लेखापरीक्षण महालेखा परीक्षकको कार्यालयबाट हुनेछ।

(५) प्रत्येक आर्थिक वर्षको अन्तमा फार्मेसीमा खरिद भएको अद्यावधिक परीमाण, बिक्री भएको परीमाण तथा बांकी परीमाणको सन्तुलन परीक्षण (Trial Balance) तयार गर्नु पर्ने छ।

१७. ब्राण्ड तोकी सिफारिश गर्न नहुने: विशेष औचित्य भएमा बाहेक विरामीलाई खास ब्राण्ड तोकी सिफारिश गर्न हुदैन।

१८. अनुगमन तथा मुल्यांकन गरी प्रतिवेदन पठाउनुपर्ने: अस्पतालमा फार्मेसी सञ्चालनको अवस्था एवं उक्त सेवालाई प्रभावकारी रुपमा सञ्चालन गर्नकालागि मन्त्रालय, मन्त्रालय मातहतका विभाग, क्षेत्रीय स्वास्थ्य निर्देशनालय एवं जिल्ला स्वास्थ्य/जनस्वास्थ्य कार्यालयहरुले चौमासिक रुपमाअनुगमन तथा मुल्यांकन गरी सोको प्रतिवेदन मन्त्रालयको औषधी गुणस्तर निर्धारण शाखामा प्राप्त हुने गरी पठाउनु पर्नेछ।

१९. अस्पताल फर्मुलरी सम्बन्धी व्यवस्था: अस्पतालले अस्पताल फर्मुलरीमा देहाय बमोजिमको व्यवस्था मिलाउनुपर्नेछ।

(क) रोगीहरुको रोगको प्रकृति अनुसार अस्पतालका लागि आवश्यक पर्ने औषधि तथा औषधिजन्य सामग्री तथा पदार्थहरु र औषधिको डोसेज फर्मको सूची अस्पताल फर्मुलरी अद्यावधिक गरि राख्नु पर्ने।

(ख) अस्पताल फर्मुलरीमा न्यूनतम जानकारीका रुपमा औषधिको सूची, औषधीको मात्रा, बनावट र क्षमता (Dosage Form and Strength) साथै सञ्चय सम्बन्धी निर्देशन हुनुपर्दछ। थप जानकारीका रुपमा औषधीको प्रयोग गर्न सकिने वा नसकिने अवस्था (Indication or Contraindications), औषधीको नकारात्मक प्रभाव, औषधी सेवन गर्दा अपनाउनुपर्ने सावधानी, औषधीको तुलनात्मक मुल्य

आदि विवरण समावेश गर्नुपर्ने ।

(ग) अस्पताल फर्मुलरी तयार नभएसम्म औषधि तथा औषधिजन्य सामग्री र पदार्थको सूची तयार गरी कार्य गर्नुपर्ने ।

(घ) अस्पताल फर्मुलरीमा अत्यावश्यक औषधिको राष्ट्रिय सूचीमा समावेश भएका औषधिहरुलाई प्राथमिकता दिनुपर्ने ।

२०. निजी अस्पताल सम्बन्धी विशेष व्यवस्था: (१) नेपाल सरकारको स्वीकृतिप्राप्त गरी सञ्चालनमा रहेका निजी, सहकारी, सामुदायिक, शिक्षण लगायतका गैरसरकारी क्षेत्रका अस्पतालहरुले पनि अनिवार्य रुपमा यस निर्देशिका बमोजिम आफ्नै फार्मेसी सेवा सञ्चालन गर्नुपर्नेछ ।

(२) उपदफा (१) बमोजिमको अस्पतालको हकमा विरामीहरुलाई प्रचलित मापदण्डका आधारमा अस्पतालमा आउने कुल विरामी संख्याको दश प्रतिशत अतिगरिब र असहाय विरामीलाई निःशुल्क औषधीसहितको उपचार उपलब्ध गराउनु पर्नेछ ।

२१. फार्मेसी सञ्चालन सम्बन्धी सफ्टवेयर: प्रत्येक अस्पताल फार्मेसीले मन्त्रालयले तोके बमोजिमको एकरुपता कायम हुने सफ्टवेयरको प्रयोग गर्नुपर्नेछ । यस्तो सफ्टवेयरमा एण्टीमाइक्रोवियल एवं लागु औषधीको विवेकपूर्ण प्रयोग र अभिलेखीकरण समेत सुनिश्चित गरिनेछ ।

२२. निर्देशन दिन सक्ने: यस निर्देशिकामा उल्लेख गरिएका बाहेक सबै अस्पतालहरुलाई मन्त्रालयले समयसापेक्ष फार्मेसी सञ्चालन सम्बन्धी विषयमा आवश्यक निर्देशन दिन सक्नेछ र सो निर्देशन पालन गर्नु सम्बन्धित अस्पतालको कर्तव्य हुनेछ ।

२३. प्रचलित कानुन बमोजिम हुने: यस निर्देशिकामा उल्लेख नभएका विषयमा प्रचलित कानुनमा लेखिए बमोजिम हुनेछ ।

२४. खारेजी र बचाउ: (१) अस्पताल फार्मेसी सेवा निर्देशिका, २०७० खारेज गरिएको छ ।

(२) अस्पताल फार्मेसी सेवा निर्देशिका, २०७० बमोजिम गरिएका कामकारवाही यसै निर्देशिका बमोजिम भए गरेको मानिनेछ ।