

UNIT-II

DRUG AND DISEASE CLASSIFICATION



CENTURION
UNIVERSITY
*Shaping Lives...
Empowering Communities!*

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- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

DRUG

- Drugs are **chemical substances that affect or alter the physiology** when taken into a living system. They can either be **natural or synthetic**.
- A drug is any substance that **causes a change in an organism's physiology or psychology when consumed**.
- A chemical substance **used in the treatment, cure, prevention, or diagnosis of disease** or used to otherwise enhance physical or mental well-being.
- A **pharmaceutical drug**, also called a **medication or medicine**, is a chemical substance used to **treat, cure, prevent, or diagnose a disease** or to promote well-being.

Classification Of Drugs :

Drugs can be classified mainly based on the following criteria:

- Pharmacological Effect
- Chemical Structure
- Drug Action
- Molecular Targets

- **Based on Pharmacological Effect** – Based on the action of drugs on our body, they are classified as per the therapeutic actions. Such as **antacids reduce acidity** in the stomach, analgesics are pain killers, antiseptics kill microorganisms, etc.
- **Based on Chemical Structure** – Based on the common chemical structures, drugs are classified into various classes. As chemical structures, functional groups, etc., are responsible for their chemical properties. Mostly, drugs having similar chemical structures show similar effects on the body. For example, **sulphonamide drugs, barbiturates**, etc.

- **Based on Drug Action** – Drugs are also classified based on their action on molecular targets and effects on our body. For example, **histamines are responsible for causing inflammation** in the body, and we take anti-histamines to block their actions.
- **Based on Molecular Targets** – Some drugs target **protein, carbohydrates**, etc. Generally, drugs that have similar structures target similar molecules in our body and produce responses accordingly.

Anatomical, therapeutic and chemical classification (ATC)of drugs

Structure

- In the Anatomical Therapeutic Chemical (ATC) classification system, the **active substances** are divided into **different groups** according to the **organ or system** on which **they act** and **their therapeutic, pharmacological and chemical properties.**

- Drugs are classified in groups at **five different levels**.
- The drugs are divided into **fourteen** main groups (**1st level**), with **pharmacological/therapeutic subgroups (2nd level)**.
- The **3rd and 4th levels** are **chemical/pharmacological/therapeutic subgroups** and the **5th level** is the **chemical substance**.
- The **2nd, 3rd and 4th levels** are often used **to identify pharmacological subgroups** when that is considered more appropriate than therapeutic or chemical subgroups.

Nomenclature

- **International nonproprietary names (INN)** are preferred. If INN names are not assigned, **USAN (United States Adopted Name)** or **BAN (British Approved Name)** names are usually chosen.
- WHO's list of drug terms (Pharmacological action and therapeutic use of drugs -List of Terms) is used when naming the different ATC levels.

ATC – main groups

- A Alimentary tract and metabolism
- B Blood and blood forming organs
- C Cardiovascular system
- D Dermatologicals
- G Genito urinary system and sex hormones
- H Systemic hormonal preparations, excl. sex hormones and insulins
- J Antiinfectives for systemic use
- L Antineoplastic and immunomodulating agents
- M Musculo-skeletal system
- N Nervous system
- P Antiparasitic products, insecticides and repellents
- R Respiratory system
- S Sensory organs
- V Various

The complete classification of metformin illustrates the structure of the code:

- A Alimentary tract and metabolism
(1st level, anatomical main group)

- A10 Drugs used in diabetes
(2nd level, therapeutic subgroup)

- A10B Blood glucose lowering drugs, excl. insulins
(3rd level, pharmacological subgroup)

- A10BA Biguanides
(4th level, chemical subgroup)

- A10BA02 metformin
(5th level, chemical substance)

Thus, in the ATC system all plain metformin preparations are given the code A10BA02.

Structure of the ATC code

- A** ALIMENTARY TRACT AND METABOLISM
(1st level, anatomical main group)
- A10** DRUGS USED IN DIABETES
(2nd level, therapeutic subgroup)
- A10B** BLOOD GLUCOSE LOWERING DRUGS, E
INSULINS
(3rd level, pharmacological subgroup)
- A10BA** BIGUANIDES
(4th level, chemical subgroup)
- A10BA02** METFORMIN
(5th level, chemical substance)

Inclusion and exclusion criteria

- Classification on requests from the users of the system. These include **manufacturers, regulatory agencies and researchers**. The **coverage** of the system is **not comprehensive**. A major reason why a substance is not included is that no request has been received.
- Active ingredients which fulfill one of the following criteria will normally be included in the ATC system:

- They are new **chemical entities** (active ingredients) or **biologicals** proposed for licensing in a range of countries. **A new chemical entity is normally not included in the ATC system before an application for marketing authorization is submitted** in at least one country.
- They are existing well defined chemical entities used in a variety of countries. An INN should preferably be established for the active ingredient. Alternatively other official names, e.g. USAN or BAN names should be available.

- They are herbal medicinal products assessed and approved by regulatory authorities based on dossiers including efficacy, safety, and quality data (e.g. the well-established use procedure in EU).
- Other medicinal products are considered on a case by case basis. Complementary, homeopathic and herbal traditional medicinal products are in general not included in the ATC system.

General principles for ATC classification

- Drugs are classified according to their main therapeutic use
- Only one ATC code for each administration form
- Several ATC codes:

Clearly different therapeutic uses reflected in different

- routes of administration (e.g. topical, systemic)
- strengths

“Simple” codes

- Linagliptin (e.g. Trajenta): Antidiabetic → DPP-4 inhibitor → A10BH05
- Lamivudine (e.g. Epivir): HIV → Antiviral → J05AF05
- Sumatriptan (e.g. Imigran): Antimigraine → 5HT₁ agonist → N02CC01
- Formoterol (e.g. Oxis): Antiasthmatic → β_2 agonist → R03AC13

Different indications – one ATC code

Example duloxetine:

- Major Depressive Disorder (Cymbalta: 30mg, 60mg)
 - Stress Urinary Incontinence (Yentreve: 20mg, 40mg)
 - Diabetic neuropathic pain (Cymbalta)
-
- Overlapping dosages used for the various indications

ATC code as *antidepressant* (N06AX21)

Several ATC codes – “one indication”

<u>Bone diseases/osteoporosis</u>	<u>ATC group</u>
Vitamin D and analogues	A11CC
Calcium supplement	A12A
Estrogens/Tibolon/SERM	G03C/G03F/G03X
Parathyroid hormones	H05AA
Calcitonin	H05BA
Bisphosphonates	M05BA/M05BB

Several ATC codes – different administration forms and therapeutic use

Prednisolone

- A07EA01 (Enemas and rectal foams)
- C05AA04 (Rectal suppositories)
- D07AA03 (Creams, ointments and lotions)
- H02AB06 (Tablets, injections)
- R01AD02 (Nasal sprays/drops)
- S01BA04 (Eye drops)
- S02BA03 (Ear drops)

Principles for classification

General Principles: Medicinal products are classified according to the main therapeutic use of the main active ingredient, on the basic principle of only one ATC code for each route of administration (i.e. pharmaceutical forms with similar ingredients and strength will have the same ATC code).

- Immediate and slow release tablets will normally have the same ATC code.
- A medicinal product can be given more than one ATC code if it is available in two or more strengths or routes of administration with clearly different therapeutic uses.

Two examples of this are as follows:

- Sex hormones in certain dosage forms or strengths are only used in the treatment of cancer and are thus classified under L02 - *Endocrine therapy*. Remaining dosage forms/strengths are classified under G03 - *Sex hormones and modulators of the genital system*.
- Finasteride is available in two different strengths. A low strength tablet for the treatment of male pattern baldness is classified under D11AX – *Other dermatologicals*. A high strength tablet used in the treatment of benign prostatic hypertrophy (BPH) is classified under G04C - *Drugs used in BPH*.

Different pharmaceutical forms for topical and systemic use are also given separate ATC codes.

Example:

Prednisolone in single ingredient products is given several ATC codes due to different therapeutic use and different local application formulations.

A07EA01	Intestinal antiinflammatory agents	(enemas and foams)
C05AA04	Antihemorrhoidals for topical use	(suppositories)
D07AA03	Dermatological preparations	(creams, ointments and lotions)
H02AB06	Corticosteroids for systemic use	(tablets, injections)
R01AD02	Nasal decongestants	(nasal sprays/drops)
S01BA04	Ophthalmologicals	(eye drops)
S02BA03	Otologicals	(ear drops)

Classification of plain products

Plain products are defined as:

- Preparations containing one active component (including stereoisomeric mixtures).
- Medicinal products which in addition to one active component contain auxiliary substances intended to increase the stability of the preparations (e.g. vaccines containing small amounts of antibacterials), increase the duration (e.g. depot formulations) and/or increase the absorption (e.g. different solvents in various dermatologicals) are also considered as plain products.

Classification of combination products

- Products containing two or more active ingredients are regarded as combination products. Combination products are classified according to three main principles.
 - a) **Combination products** containing two or more active ingredients belonging to the same 4th level are normally classified using the 5th level codes 20 or 30.
- Example:
 - N01BB02 *lidocaine*
 - N01BB04 *prilocaine*
 - N01BB20 *combinations (e.g. lidocaine and prilocaine)*

b) **Combination products** containing two or more active ingredients not belonging to the same 4th level are classified using the 50-series.

- Example:

- R06AA02 *diphenhydramine*

- R06AA52 *diphenhydramine, combinations*

- **Different combination products** sharing the same main active ingredient are usually given the same ATC code. Thus, products containing phenylpropanolamine + brompheniramine and phenylpropanolamine + cinnarizine are both given the code R01BA51 *phenylpropanolamine, combinations*.

Application of ATC:

- National standard for medical policy
- Health policy
- Drug utilization research
- Pharmacovigilance
- International classification
- Assigning procurement agency assisting

DISEASE

What is Disease?

- ***“A disease is a condition that deteriorates the normal functioning of the cells, tissues, and organs.”*** Diseases are often thought of as **medical conditions** that are **characterized** by their **signs and symptoms**.
- The disease can also be defined as: ***“Any dangerous divergence from a functional or normal state of an entity.”***
- When a person is infected with a disease, he exhibits a few symptoms and signs that range from normal to severe depending upon the medical condition. Hence, in order to identify different diseases, the normalcy of an entity needs to be studied and understood as a clear demarcation between disease and disease-free is not always apparent.

Types of Diseases

Infectious Diseases

- Diseases that **spread from one person to another** are called **communicable diseases**.
- They are usually **caused by microorganisms** called **pathogens** (fungi, rickettsia, bacteria, viruses, protozoans, and worms).
- When an infected person discharges bodily fluids, pathogens may exit the host and infect a new person (sneezing, coughing etc). Examples include Cholera, chickenpox, malaria etc.

Non-infectious Diseases

- These diseases are **caused by pathogens, but other factors such as age, nutritional deficiency, gender of an individual, and lifestyle also influence** the disease.
- Examples include [hypertension](#), diabetes, and cancer.
- They **do not spread to others** and **they restrain within a person** who has comes in contact with them.
- Alzheimer's disease, asthma, cataract and heart diseases are other non-infectious diseases.

Classification of Diseases

Classification of Diseases		
Type	Explanation	Example
Anatomic Classification	This type refers to the affected organ or tissue	Heart disease
Topographical Classification	Further classified into types such as vascular disease, chest disease, gastrointestinal disease, and abdominal diseases. These are then handled by specializations in medicine that follow these topographical classifications	An ENT specialist (Ear-Nose-Throat) A Gastroenterology specialist etc.
Physiological Classification	This type includes diseases that affect a process or a function (such as metabolism, ...)	Diabetes
Pathological Classification	This type considers the nature of the disease. For instance, cancer is associated with uncontrolled cell growth, and there are variations or types in the disease.	Neoplastic diseases (uncontrolled cell growth that is characteristic of cancer) Inflammatory diseases (autoimmunity)
Epidemiological Classification	This classification refers to the rate of occurrence, distribution and the control of the disease in a population.	Epidemic diseases such as the plague and Influenza pandemic of 1918–1919

International Classification of Diseases (ICD)

- ICD is an **international tool** for the “**standard diagnostic tool for management, epidemiology, and clinical purposes.**”
- ICD’s official name is the **international statistical classification of disease and health problems.**
- ICD is maintained **by WHO globally.** WHO is coordinating and directing authority for health within the United Nations system.
- The ICD is properly designed as a health care classification system and it provides a **very unique system of diagnostic code for classifying the disease** which includes classification of a **wide variety of signs, symptoms, social circumstances complaints an external cause of injury.**

- This ICD system is specially **designed to map health conditions for the corresponding generic categories together with a specific variation.**
- The ICD is **revised periodically** and is currently in its **10th revision.**
- The **ICD-11 is the final draft** which is expected to be submitted to the WHO's World Health Assembly (WHA) and it has the endorsement in 2015. This version was released on **18 June 2018.**

- ICD (International Statistical Classification of Diseases and Related Health Problems), shortly known as International Classification of Diseases is **the base/foundation for the identification of health trends and statistics.**
- ICD is an **international uniform standard for reporting diseases and health conditions.**
- It is the **diagnostic classification standard for all clinical and research purposes.**
- ICD maps the **human health condition from birth to death.** No matter, however we die of, it will be recorded/coded under ICD.

Application

- Morbidity and mortality statistics
- Reimbursement (compensation/settlement) of systems
- Automated decision support in health care.
- The ICD is a major project to statistically classify all health disorders, and provide diagnostic assistance.

Historical synopsis

- In 1860, **Florence Nightingale** → made first model of **systemic collection of hospital data**.
- In 1893, French physician, **Jacques Bertillon** → introduced **Bertillon classification of cause of death**
- In 1898, **American public health association** → recommended **revision of ICD system every 10 years**.
- The revision followed minor changes until 6th version of ICD → morbidity and mortality condition and section on mental disorders
- WHO → responsibility for **preparing and publishing the ICD revisions every 10 years**.

General Principles of Disease Classification

- A statistical classification of diseases must be confined to a limited number of mutually exclusive categories. The categories have to be chosen to facilitate the statistical study of disease phenomena.
- A specific disease entity that is of particular public health importance or that occurs frequently should have its own category. Every disease or morbid condition must have a well-defined place in the list of categories.
- A statistical classification of diseases should retain the ability both to identify specific disease entities and to allow statistical presentation of data for broader groups, to enable useful and understandable information to be obtained.

Idea and Need for Classification in ICD:

Classification or Sorting of disease is needed due to the following facts:

- Determines the **natural cause of the disease mechanism in a human body.**
- Determines the **exact problem and solution of the disease.**
- Determines the **normal stages and the critical stage of the disease**
- Formulation of **health statistics.** ICD is the **bedrock for health statistics.**
- Concludes the **risk factors of the illness.**
- Calculates the **prevalence and incidence rate**, which ultimately helps to develop mitigating measures against the disease.
- Helps to **categorize vulnerable disease.**
- Determines the **health cost and resources required to combat disease.**
- **Critical analysis of the disease based on the severity.**

ICD YEARS

- ICD 1-1900
- ICD 2- 1910
- ICD 3-1921
- ICD4- 1930
- ICD5-1939
- ICD6-1949
- ICD7-1958
- ICD8A-1968
- ICD10-1999
- ICD11-2019

Volumes of ICD-10

Volume 1: Tabular list

- An **alphanumeric listing of diseases and disease groups**, along with inclusion and exclusion notes, some coding tabulation lists for mortality and morbidity, definition and regulation.

Volume 2: Instruction manual

- It provides
 - Instructions on how to use volume 1 and 3.
 - Guidelines for certification and rules for mortality coding
 - Guidelines for recording and coding for morbidity coding
 - Statistical presentation

Volume 3: Alphabetical index

- Is the comprehensive Alphabetical index of the diseases and conditions found in the tabular list Certain Infectious and parasitic diseases.[A00- B99]

CHAPTERS OF ICD-10

- Neoplasms [C00-D48]
- Diseases of the blood and blood forming organs and certain disorders involving the immune mechanism.
- Endocrine nutritional and metabolic diseases [E00-E90]
- Mental and behavioral disorder [F00-F99]
- Disorders of nervous system [G00-G99]
- Disease of eye [H00-H99]
- Disease of the ear and mastoid process [H60-H95]

The main innovations of ICD 10th Revisions are :

1. Relevant information for ambulatory(adapted) and managed care encounter
2. Expanded injury codes
3. New combination codes for diagnosis / symptoms to reduce the number of codes needed to describe a problem fully.

ICD-10CM

- The ICD-10 Clinical Modification (ICD-10-CM) is a modification of the ICD-10, authorized by the World Health Organization, used as a **source for diagnosis codes in the United States of America.**
- It replaces the earlier **ICD-9-CM**
- The world health organization is currently revising the ICD towards **ICD-11.**
- The development is taking place on an internet based workspace called **" icat " platform.**
- **The draft of the ICD -11 system → submitted to who's World Health Assembly (WHA)→ by 2017 and a final version → in 2018.**

- Officially endorsed by all who members during the **72nd world health assembly on 25 may 2019** .
- The **ICD-11 officially came** into effect on **1 JANUARY 2022**
- Currently, **no country has officially switched** to the ICD-11 yet
- The ICD-11 is a **large taxonomy consisting of about 85,000 entities, also called classes or nodes.**
- An **entity can be anything that is relevant to health care.** It usually **represents a disease or a pathogen.**

Features :

- About **300 specialists of 55 countries**, organized in **30 main working groups** have provided their input to make **ICD-11 scientifically up-to-date**, and structural problems that became apparent using ICD-10 have been solved.
- ICD-11 is **much easier to use than ICD-10**.
- The systematic reliance on the use of code combinations and extension codes makes ICD finally clinically relevant.
- Primary care, cancer coding, traditional medicine and a section for assessment of functioning are now included.

Principles of classification of ICD

- The ICD is a variable-axis classification. The structure of ICD structure was developed of that proposed by **William Farr** during early days of international discussions. According to him, for all **practical, epidemiological purposes, statistical data** on diseases should be grouped in the following way:
 - **epidemic diseases**
 - **constitutional or general diseases**
 - **local diseases arranged by site**
 - **developmental diseases**
 - **injuries**

How are Diseases Classified in ICD?

The diseases are categorized:

On the basis of	Disease
Body system or region	Abdominal disease Gastrointestinal disease
Anatomic	Lung disease Liver disease
Function	Metabolic disease
Pathological/ nature of the disease process	Inflammatory disease Tumors formation
Etiologic/ cause	Bacterial infection
Epidemiology	Epidemic disease
Statistical	High prevalence and incidence rate disease.



ADVANTAGES

- Fast aggregation of health data
- To know the real time information about current health situation
- Wider analysis of community health
- Global health assessment

LIMITATIONS

- Discussion is limited to classified diseases
- Common term description of diseases
- Covers most common diseases
- Country specific modifications of certain diseases

Daily defined doses (DDD)

The basic **definition** of the defined daily dose (DDD) is:

- *The DDD is the **assumed average maintenance dose per day for a drug used for its main indication in adults.***
- The DDD is a **unit of measurement and does not necessarily reflect the recommended or Prescribed Daily Dose (PDD).**

- **Therapeutic doses for individual patients and patient groups will often differ from the DDD as they will be based on individual characteristics (such as age, weight, ethnic differences, type and severity of disease) and pharmacokinetic considerations.**
- **Only one DDD is assigned per ATC code and route of administration (e.g. oral formulation). The DDD is nearly always a compromise based on a review of available information including doses used in various countries when this information is available.**

- The DDD is sometimes a “dose” that is rarely if ever prescribed, because it might be an average of two or more commonly used doses.
- Drug utilization data presented in DDDs only give a rough estimate of consumption and not an exact picture of actual use.
- DDDs provide a fixed unit of measurement independent of price, currencies, package size and strength enabling the researcher to assess trends in drug consumption and to perform comparisons between population groups.

Objectives of DDD: By applying DDD it is possible to

- Examine changes in drug utilization over time.
- Make international comparisons.
- Evaluate the effect of an intervention on drug use.
- Document the relative therapy intensity with various groups of drugs.
- Follow the changes in the use of a class of drugs.
- Evaluate regulatory effects and effects of interventions on prescribing patterns.

General principles for DDD assignment

- DDDs are **only assigned to drugs with an ATC code** and a DDD will normally **not be assigned for a substance before a product is approved and marketed in at least one country.**
- The basic principle is to assign **only one DDD per route of administration within an ATC code.**
- **DDDs for single substances** are normally based on **monotherapy.**
- Exceptions to this rule are given in the guidelines of the relevant ATC groups.

- For substances **indicated for rare disorders** with highly individual dosing schedules, the Working Group could decide **not to assign a DDD**.
- **DDDs are not established for topical products, sera, vaccines, antineoplastic agents, allergen extracts, general and local anesthetics** and contrast media.
- When a new DDD is assigned, various sources are used to get the best overview of the actual or expected use of a substance. The assigned DDD is based on the following principles:

- The **average adult dose recommended for the main indication** as reflected by the ATC code. When the recommended dose refers to body weight, an adult is considered to be a person of 70 kg. It should be emphasized that **even special pharmaceutical forms mainly intended for children** (e.g. mixtures, suppositories) are assigned the DDD used for adults. Exceptions are made for some products only used by children, e.g. growth hormones and fluoride tablets.
- For some **groups of medicinal products specific principles for DDD assignment are established** (e.g. the DDDs for **the selective serotonin agonists in the treatment of migraine** are based on the **approved initial dose**). These principles are given in the guidelines for the relevant ATC groups.

- The **recommended maintenance dose** (long term therapeutic dose) is usually **preferred when establishing the DDD**. The **initial dose may differ from the maintenance dose** but this is **not reflected in the DDD**.
- If the **approved dose recommendation** provides **limited information about maintenance dose**, the **DDD** will usually be **the average of the maintenance dose range**. Examples of interpretation of approved dose titration recommendations:
 - “Titrate up to a high dose if it is tolerated”: the high dose would normally be chosen as the DDD.
 - “Consider to increase the dose only if efficacy is not satisfactory with initial dose”: the **DDD would normally be based on the initial dose**.

- The treatment dose is generally used. If, however, prophylaxis is the main indication, this dose is used, e.g. for fluoride tablets (A01AA01) and some anti malaria.
- A DDD is usually **established** according to the **declared content (strength) of the product**. **Various salts of a substance** are usually **not given different DDDs**.
- **Different stereoisomeric forms** are normally assigned separate DDDs and ATC codes. The DDDs for stereoisomeric forms are described in the respective ATC groups.
- **Prodrugs**, have **not been given a separate ATC code**.

- The DDD is often identical for various dosage forms of the same drug. Different DDDs can be **established when the bioavailability is substantially different for various routes of administration** (e.g. oral and parenteral administration of morphine) or if the dosage forms are used for different indications.
- The **DDDs are frequently used as indicators for antibacterial use** in hospitals, and it has been decided that assigning **different DDDs for oral and parenteral formulations** could be important in some cases to improve the usefulness of the methodology in drug utilization monitoring and research.
- **Parenteral products with different routes of administration** (e.g. i.v. and i.m.) have the **same DDD**.

DDDs for combinations products:

- The DDDs assigned for combination products are **based on the main principle of counting the combination as one daily dose**, regardless of the **number of active ingredients included in the combination**.
- If a treatment schedule for a patient includes e.g. **two single ingredient** products, then the consumption will be measured by counting the **DDDs of each single ingredient product separately**.

- **Example I:**

Treatment with two products, each containing one active ingredient:

- Product A:

Tablets containing 20 mg of substance X (DDD = 20 mg)

- Product B:

Tablets containing 25 mg of substance Y (DDD = 25 mg)

- The dosing schedule 1 tablet of A plus 1 tablet of B daily will be calculated as a consumption of 2 DDDs.

- **Example II:**

Treatment with a combination product containing two active ingredients:

- Product C:

Tablets containing 20 mg of substance X and 12.5 mg of substance Y. The DDD of the combination products is assigned as 1 UD = 1 tablet.

- The dosing schedule 1 tablet of C daily will be calculated as 1 DDD (even though it will be equivalent to 1.5 DDD of the single active ingredients).

International Nonproprietary Name

- An international nonproprietary name (INN) is an **official generic and non-proprietary name given to a pharmaceutical drug or an active ingredient**
 - to make communication **more precise** by providing a **unique standard name for each active ingredient**
 - to **avoid prescribing errors**.
- The INN system has been coordinated by the **World Health Organization (WHO) since 1953**.
- Drugs are generally marketed by their **brand names**. Countries have their own systems of **generic nomenclature** for pharmaceutical substances. However owing to the various languages, there is a **need to have a uniform standardized system of generic names** that are accepted worldwide.

- The WHO administers an **international generic nomenclature system** called INNs also known as **rINN**, for **recommended International Nonproprietary Name** or **p INN** for **proposed International Nonproprietary Name**).
- **A nonproprietary name** is also known as a **generic** name.
- Initiated in 1950 by a World Health Assembly resolution
- Cumulative list of INN now stands at some 7000 names designated since that time .

AIMS OF INN SYSTEM

- To provide **health professionals with a unique and universally available designated name**
- To **identify** each pharmaceutical substance.
- For the **clear identification, safe prescription and dispensing of medicines** to patients.
- For **communication and exchange of information** among health professionals and scientists worldwide.
- **Nonproprietary** names are **intended for use in Pharma, labeling, product information, advertising and other promotional material, drug regulation and scientific literature**, and as a basis for product names, e.g. for generics.

SELECTION OF INN

- The names are selected by the World Health Organization on the advice of experts from the WHO Expert Advisory Panel.

STEPS:

- **a request/application** is made by the **manufacturer or inventor**; after a review of the request **a proposed INN** is selected and published for comments.
- after a time-period for objections has lapsed, the name will obtain the status of a recommended INN and will be published as such if no objection has been raised.
- Since the name is available in the **public domain it may be used freely**. However, it **should not be registered as a trade-mark** since this would prevent its use by other parties.

NAMING

- INN is designated for the active part of the molecule only to avoid the multiplication of entries in cases where several salts, esters, etc. are actually used. In such cases, the user of the INN has to create a modified INN (INN_M).
- Ex: mepyramine maleate (a salt of mepyramine with maleic acid)

The primary principles for selection:

- Distinctive in sound and spelling; Not too long
- Not liable to confusion with other names in common use.
- Ex: -ac for anti-inflammatory agents, ibufenac derivatives -coxib for COX-2 inhibitors, a type of anti-inflammatory drugs (e.g. celecoxib)
- Do not select names for mixtures of substances.
- Do not select names for those substances that have a long history of use for medical purposes under well established names such as those of alkaloids (e.g. morphine, codeine), or trivial chemical names (e.g. acetic acid)

USE OF INNs IN INDIA

- In India, Section 13 (b) of the Trade Marks Act, 1999 prohibits the registration of names of chemical elements or INNs which have been declared by the World Health Organization (WHO) and notified by the Registrar of Trade Marks.
- Nevertheless, there are reported incidents of marketing of drugs under names that are similar to INNs. The WHO has brought the same to the attention of the Drug Controller General of India.
- The basic requirement of Section 13 (b) of the Trade Marks Act, 1999 is that INNs must be notified by the Registrar.