



**World Health  
Organization**

# The classification of medicinal substances

## INN and ATC Proposal of a WHOA Course

**57 Meeting of the WHO Advisory Group  
for Drug Statistics Methodology  
3 April 2025**

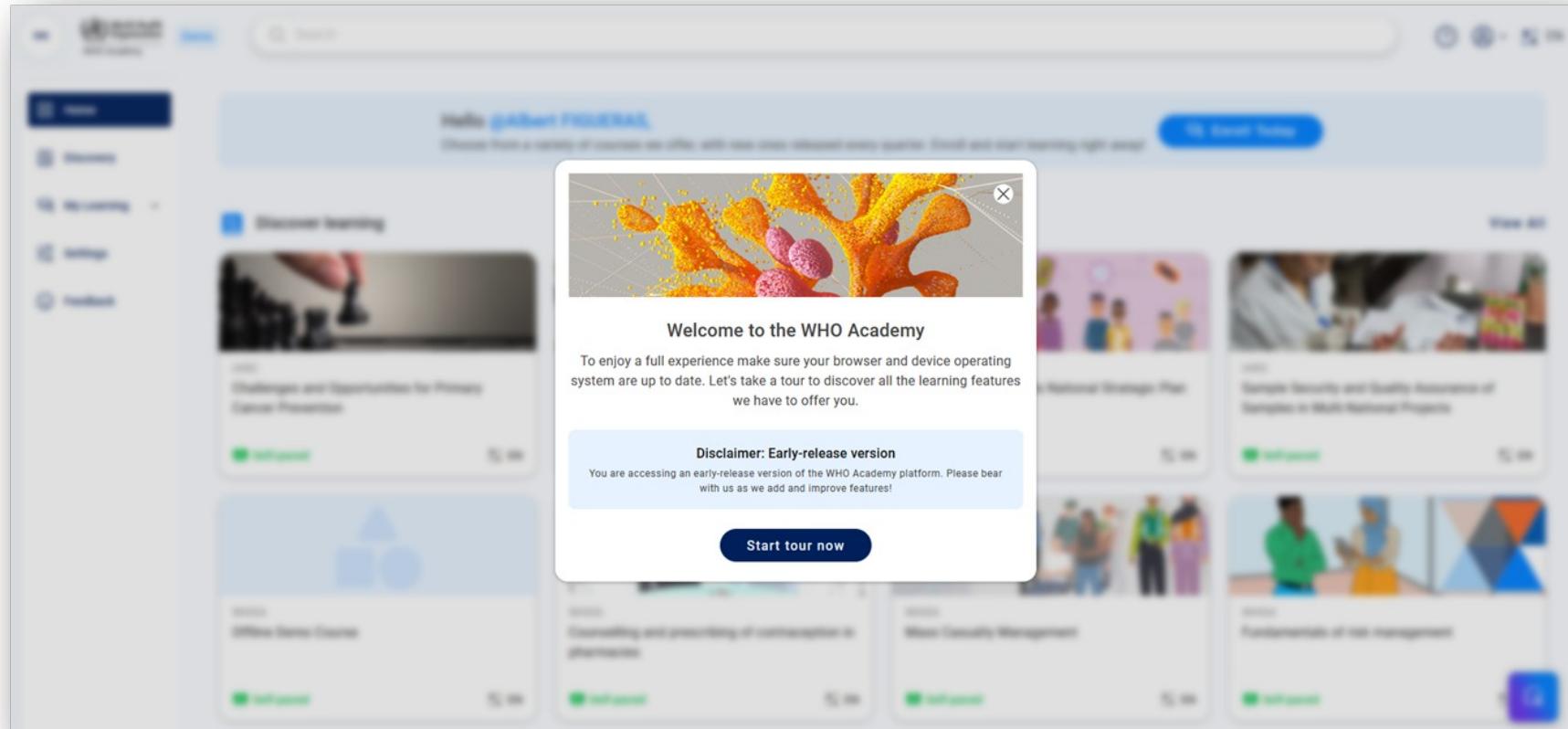


# Discussions and proposals of chemical working group

- A. Getting structure information in electronic format**
- B. Unification of representation for oligonucleotides**
- C. Unification of names and representation for isotopically labeled substances**
- D. Progress with preparation of files for PL133**



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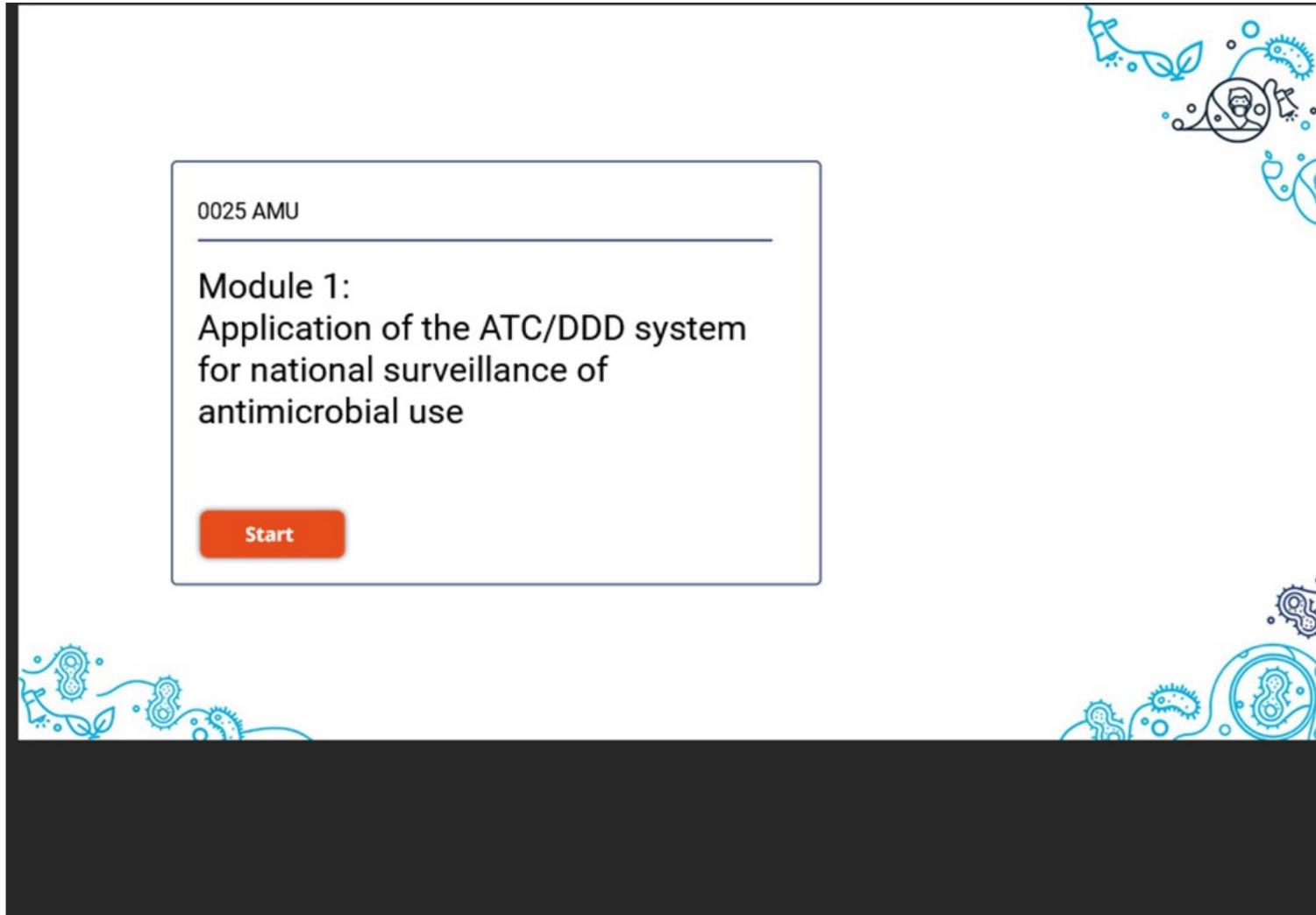
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- **On-line courses**
- **Self-paced**
- **Interactive**
- **No professor, mentor, external feedback**

# How it looks - An example



# How it looks – Narrated videos

## Welcome

The purpose of surveillance of the use of antimicrobials is to 'monitor' its patterns and inform strategies for improved practices.

Measuring the use of antimicrobials in countries and globally can be challenging. The medicines market is large and diverse, and medicines are sold under different names with different formulations and content (i.e. types and amounts of active ingredients).

Standardisation is key to classify



Select the Next button when you are done.

Unmute (Ctrl+Alt+M)

# How it looks – explaining concepts (1)

3 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use

## Understanding terms

Before looking at the ATC classification system for medicines, we shall familiarize ourselves with relevant terms related to medicines.

Select each term to learn its definition.

Active ingredient    International non-proprietary name    Brand name

Single Products    Fixed-dose combinations

You need to complete all interactions to continue.

3 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use

## Single Products

**Definition**  
Pharmaceutical products that contain only one active ingredient.

**Example**  
Amoxicillin, Cephalexin, Azithromycin

Select the Previous button to go back.

# How it looks – explaining concepts (2)

12 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use



## More than one ATC for single active ingredients

In principle, only one ATC code is given to an active ingredient administered by different routes if they have the same therapeutic use.

More than one ATC can be assigned when active ingredients administered by different routes have different therapeutic uses.

Below are examples of how single active ingredients could have more than one ATC.

 Select each button to learn more.

**Ciprofloxacin**

**Metronidazole**

12 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use



## Example 1: Ciprofloxacin

Ciprofloxacin is a fluoroquinolone antibiotic. Ciprofloxacin for systemic administration is available in oral and parenteral form and has the ATC code J01MA02.

Ciprofloxacin is also available for topical administration as eye drops and ear drops. They have different ATC codes as their use is different.

In the code for eye drops of ciprofloxacin for conjunctivitis, S01AE03, "S" stands for sensory organs and S01 includes ophthalmological. S02AA15 is the ATC code for ciprofloxacin ear drops used for local ear infections. The ATC code for topically administered ciprofloxacin is S03AA07, which refers to ciprofloxacin eye or ear drops used for both ophthalmic and otic use.

Several fixed-dose combinations with ciprofloxacin as one of the active ingredients are used for treatment of mixed aerobic and anaerobic bacterial infections. These FDCs are classified under J01R.

**Ciprofloxacin for systemic use (ATC)**

 Select the button to see ciprofloxacin combinations.

**Found 8 entries containing 'ciprofloxacin'.**

J01MA02 ciprofloxacin  
J01MA02 ciprofloxacin  
S01AE03 ciprofloxacin  
S02AA15 ciprofloxacin  
S03AA07 ciprofloxacin  
J01RA10 ciprofloxacin and metronidazole  
J01RA12 ciprofloxacin and ornidazole  
J01RA11 ciprofloxacin and tinidazole

 Last updated: 2024-01-26

 Select the image to zoom in.

Select the Previous button to go back.



# How it looks – exercises, knowledge check

7 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use

Check your progress

Read the following statements and identify the correct ones:

 Select the correct answer(s).

- A. An active ingredient (or active substance) is a proprietary name that is trademark-protected.
- B. An expert committee establishes ATC codes and defines Defined Daily Dose (DDD) as a unit of measure.
- C. A main reason that a substance is not included in the ATC classification is that no request has been made to the WHO CC for Drug Statistics Methodology.

You need to complete all interactions to continue.

# How it looks – exercises, gaming

10 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use



## Check your knowledge

Look at the ATC code J01DB05 and match the different parts of the code with their names.

 Drag and drop the corresponding name to the correct ATC code.

ATC code	Name
J	Other beta-lactam antibacterials
J01	Cefadroxil
J01D	Antibacterial for systemic use
J01DB	First-generation cephalosporins
J01DB05	Anti-infective for systemic use

You need to complete all interactions to continue.

# How it looks – exercises, gaming

10 / 27 Module 1: Application of the ATC/DDD system for national surveillance of antimicrobial use



## Check your knowledge

Look at the ATC code J01DB05 and match the different parts of the code with their names.

 Drag and drop the corresponding name to the correct ATC code.

ATC code	Name
J	Anti-infective for systemic use
J01	Antibacterial for systemic use
J01D	Other beta-lactam antibacterials
J01DB	First-generation cephalosporins
J01DB05	Cefadroxil

You need to complete all interactions to continue.

**Lesson 1.-** Introduction

**Lesson 2.-** Introduction to the INN system - From its foundation to the challenge of naming complex therapies

**Lesson 3.1.-** The ATC System – Introduction to the classification .principles and use

**.Lesson 3.2.-** The DDD unit – Concept and basic use

**Lesson 4.-** Comparison and interrelation between the INN and the .ATC/DDD

**Lesson 5.-** Practical Applications of the ATC/DDD and the INN



# INN-ATC course – Examples of scenarios, activities and interaction

## Scenario 1:

But who are these mysterious wordsmiths, seemingly playing linguistic puzzles while crafting medicine names?

[ANIMATED VIDEO WITH VOICE AND CHARACTERS]

Three medical residents – Sarah (oncology), Mike (respiratory), and Elena (rheumatology) – meet for coffee after a long week of rotations.

**Sarah:** So today, I had to present a new breast cancer medicine in rounds. I tried three times before I could say 'datopotamab deruxtecán' without stumbling.

**Robert:** Oh, come on, that's nothing! Try announcing 'benralizumab' in front of the whole department while sleep-deprived. Called it 'ben-rala-something' and my student just smirked.

**Elena:** At least yours sound somewhat pronounceable. Yesterday I had to explain to a patient about entering a clinical trial of 'tafasitamab vedotin'. The patient just stared at me and said 'Can't you just write that down?'.

**Robert:** "What's with all these 'mabs' anyway? It seems like every new medicine ends in 'mab' these days.

**Sarah:** Ah, that is because they are monoclonal antibodies. But wait until you see what is coming. Now we have got 'barts' and 'tafusps' and...

**Elena:** Seriously? Who comes up with these names? It's like they are playing some twisted version of Scrabble!

**Robert:** "Hey, at least we're not in dermatology. My friend there has to deal with creams combining three of these unpronounceable names in one product.

**Sarah:** (showing her phone) Look at this one I'm supposed to present next week... 'tebentafusp'. My tongue will have cramps.

**Elena:** You know what is funny? We will probably complain that these were the simple names in twenty years. I can see us, already chiefs of the department saying: 'Back in my day, drugs only had four syllables...'

[SCENARIO 1 ENDS]



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## 2.2. INN system schemes

### [ANIMATED VIDEO WITH VOICE]

Usually, an INN consists of a random (fantasy) prefix and a common **stem**. Substances belonging to a group of pharmacologically related substances show their relationship using a common suffix called “stem”.

For example, the structure of the INN “sildenafil” is:

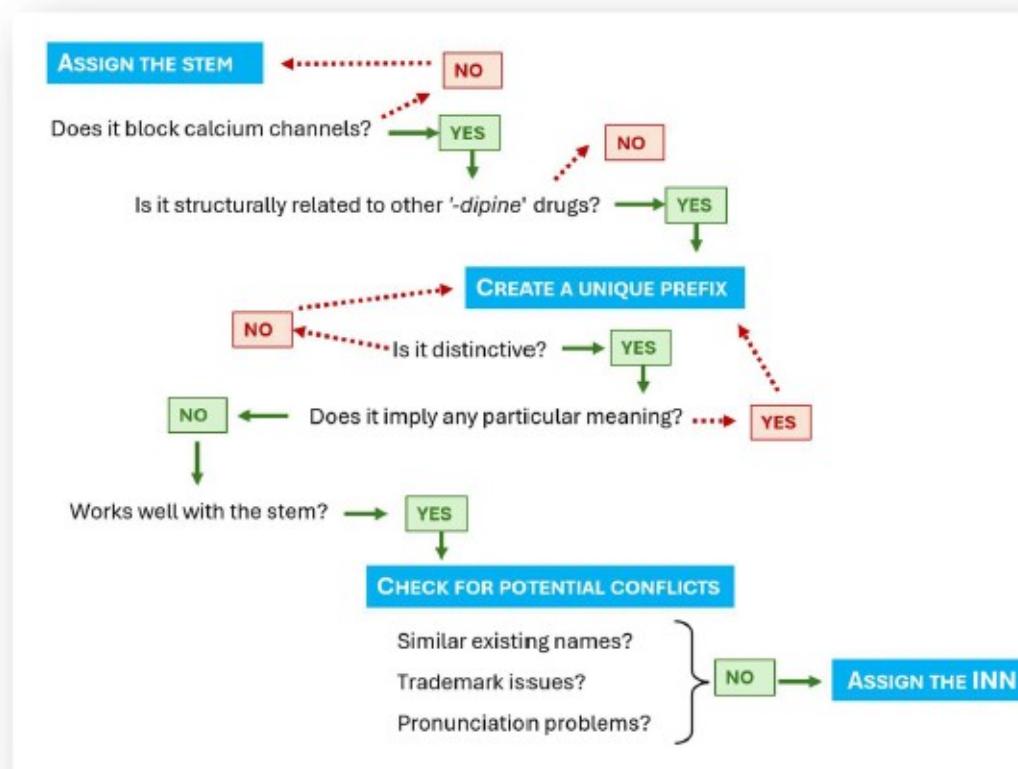


The stem is “-afil”, described as “inhibitors of phosphodiesterase PDE5 with vasodilator action”. Therefore, other substances sharing the same mechanism of action will be named as:



Sometimes, the random prefix + stem scheme is increased with an infix or “sub-stem”, established to differentiate between different related groups of substances.

[ANIMATED SCREENS WITH VOICE]



[VOICE]

First, it is necessary to confirm that the stem applies using the available information. Remember that, at this stage, applications are for substances in the initial stages of clinical development, and the available data is scarce.

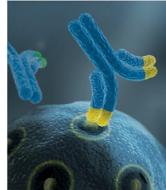
If your answer to both questions is "Yes", the stem is correct, and you can proceed to the creation of a prefix (random prefix). If it is a distinctive name and it does not imply any particular meaning, then you should check for possible conflicts.



### 3.1. Evolution of monoclonal antibodies naming

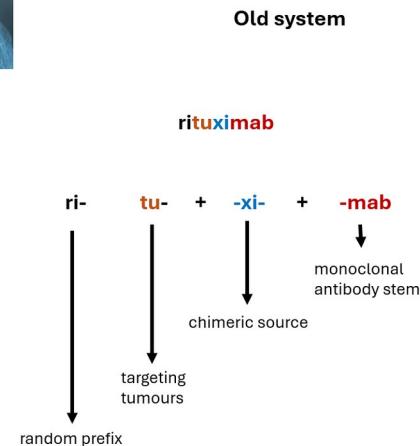
[SLIDES WITH VOICE]

A “monoclonal antibody” is an antibody produced from a cell lineage made by cloning a unique white blood cell. Currently, they are used in diagnosing illnesses such as cancer and infections and treating cancer and inflammatory diseases, among other conditions.



The first licenced monoclonal antibody was muromonab-CD3, approved in 1986 to prevent kidney transplant rejection. Since then, monoclonal antibodies have revolutionised medicine but naming them has become increasingly complex.

Originally, all antibody-based drugs ended with “-mab” (like adalimumab or rituximab), making them easily recognisable by doctors and pharmacists.



## General principles of the ATC codes

The following animation will show what an ATC code looks like.

[ANIMATION STARTS]

Let's start with an example.

*Haloperidol* is a medicine used in the treatment of certain psychoses.

Its ATC code is "N05AD01"

haloperidol

N05AD01

of

haloperidol	N05AD01
diclofenac	M01AB05
propranolol	C07AA05
trastuzumab	L01FD01

All ATC codes are a combination of letters and numbers. For example, the ATC code for *diclofenac* is "M01AB05", while "C07AA05" corresponds to propranolol and "L01FD01" to trastuzumab.

However, these letters and numbers are not assigned randomly.

## Step-by-step demonstration

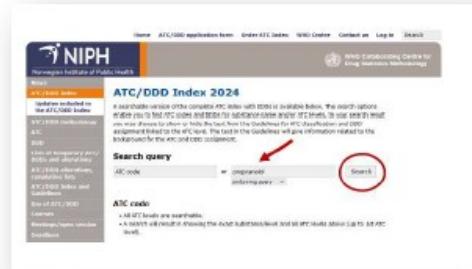
1. Open the ATC/DDD webpage in your



2. Write the name of the substance you are looking for. In this case, "propranolol".

Please note that the webpage only admits names in English. Otherwise, it will not retrieve any results.

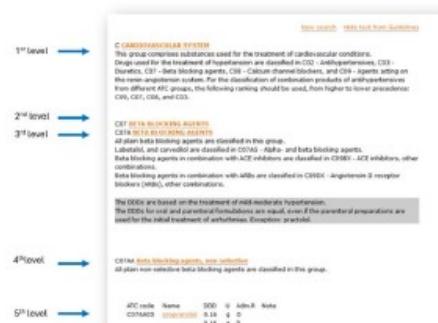
3. Click the *Search* button.



4. The new screen shows different entries. Let's click on the first one.



5. The webpage will automatically open a new screen, where you can identify the ATC code (C07AA05), and also the different levels, starting for the main anatomical group (Cardiovascular system).



1<sup>st</sup> level → C - CARDIOVASCULAR SYSTEM  
The group comprises substances used for the treatment of cardiovascular conditions. Drugs used for the treatment of hypertension are classified in C02 - Antihypertensives, C03 - Diuretics, C04 - Beta blocking agents, C05 - Calcium channel blockers, and C09 - Agents acting on the renin-angiotensin system. For the classification of combination products of antihypertensives from different ATC groups, the following ranking should be used, from higher to lower precedence: C09, C05, C04, and C03.

2<sup>nd</sup> level → C07 - BETA BLOCKING AGENTS  
C07AA - BETA BLOCKING AGENTS  
All other beta blocking agents are classified in this group.  
Labetalol, and carvedilol are classified in C07AB - Alpha- and beta blocking agents.  
Beta blocking agents in combination with ACE inhibitors are classified in C09B - ACE inhibitors, other combinations.  
Beta blocking agents in combination with ARBs are classified in C09D - Angiotensin II receptor blockers (ARBs), other combinations.

3<sup>rd</sup> level → C07AA - BETA BLOCKING AGENTS, non-selective  
All plain non-selective beta blocking agents are classified in this group.

4<sup>th</sup> level → C07AA05 - beta blocking agents, non-selective  
All plain non-selective beta blocking agents are classified in this group.

5<sup>th</sup> level →

ATC code	Name	SPD	Admin.	Note
C07AA05	propranolol	2,10	0 - 2	
C07AA05	propranolol	3,10	0 - P	

centres in the last quarter to start the procurement admin for the next quarter. Therefore, John asked the pharmacists of each centre for the list containing the number of supplied boxes, vials and bottles for each medicine used. Once he has the complete list, John starts with the first one: alprazolam. His screen shows the following table:

Primary Healthcare Centre	Product	Number packages
1	Alprazolam_AAA, 12 tablets, 2 mg	132
2	Alprazolam_DDD, 30 tablets, 0.5 mg	256
3	Alprazolam_AAA, 18 tablets, 1 mg	78
4	Alprazolam_AAA, 025mg/ml, bottle 60 ml	86
5	Alprazo	

### [SOLUTION]

This is the final table. The total number of DDD sold are 167.65:

Product	Content x unit (g)	Nr units x package	g per package	ATC code	DDD value (g)	DDD per package	Nr packages sold	Total Nr DDDs sold
Metronidazole_AAA, 15 tablets, 0.4 g	0.4	15	6	P01AB01	2 g	3	32	96
Metronidazole_AAA, 28 tablets, 0.2 g	0.2	28	5.6	P01AB01	2 g	2.8	25	70
Metronidazole_PPP, 0.5 g, flacon 100 mL	0.5	1	0.5	J01XD01	1.5 g	0.33	5	1.65
TOTAL							62	167.65

**[NOW YOU TRY IT]**

Below, there is another example. It includes a few medicines classified in the N07XX subgroup, belonging to the nervous system drugs (N), under Other nervous system drugs (N07).

MARQUELAIN CODES  
 N07 - OTHER NERVOUS SYSTEM DRUGS  
 N07X - OTHER NERVOUS SYSTEM DRUGS  
 N07XX - OTHER NERVOUS SYSTEM DRUGS

ATC	NAME	DD	LI	AMOUNT	FORM
N07XX01	amitriptyline	150	g	P	
N07XX02	fluoxetine	30	g	O	
N07XX03	sertraline	50	g	O	
N07XX04	escitalopram	30	mg	O	
N07XX05	venlafaxine	30	mg	O	
N07XX06	duloxetine	30	mg	O	
N07XX07	levomephentermine	30	mg	O	
N07XX08	atomoxetine	40	mg	P	
N07XX09	viloxazine	40	mg	P	
N07XX10	levamisole	40	mg	O	
N07XX11	gabapentin	40	mg	O	
N07XX12	pregabalin	40	mg	O	
N07XX13	gabapentin	40	mg	O	
N07XX14	gabapentin	40	mg	O	
N07XX15	gabapentin	40	mg	O	
N07XX16	gabapentin	40	mg	O	
N07XX17	gabapentin	40	mg	O	
N07XX18	gabapentin	40	mg	O	
N07XX19	gabapentin	40	mg	O	
N07XX20	gabapentin	40	mg	O	
N07XX21	gabapentin	40	mg	O	
N07XX22	gabapentin	40	mg	O	
N07XX23	gabapentin	40	mg	O	
N07XX24	gabapentin	40	mg	O	
N07XX25	gabapentin	40	mg	O	
N07XX26	gabapentin	40	mg	O	
N07XX27	gabapentin	40	mg	O	
N07XX28	gabapentin	40	mg	O	

This subgroup lists 24 drugs; we will examine only eight of them.

Now, look at the table including the INN, stem definitions and intended use of this heterogeneous group of

ATC code	INN	stem definition	intended use
N07XX10	laquinimod	-imod immunomodulators, both stimulant/suppressive and stimulant	multiple sclerosis / Huntington's disease
N07XX11	pitolisant	-isant histamine H3 receptor antagonists and inverse agonists	narcolepsy
N07XX12	patisiran	-siran small interfering RNA including siRNA, miRNA and piRNA	polyneuropathy in people with hereditary transthyretin-mediated amyloidosis
N07XX15	inotersen	-rsen antisense oligonucleotides	treatment of nerve damage in adults with hereditary transthyretin-mediated amyloidosis
N07XX18	vutrisiran	-siran small interfering RNA including siRNA, miRNA and piRNA	polyneuropathy in people with hereditary transthyretin-mediated amyloidosis
N07XX21	eplontersen	-rsen antisense oligonucleotides	treatment of transthyretin-mediated amyloidosis
N07XX22	tofersen	-rsen antisense oligonucleotides	amyotrophic lateral sclerosis
N07XX24	trofinetide	-tide peptides and glycopeptides; -netide neurological	treatment of Rett syndrome

substances sharing the same ATC chemical subgroup.

Now, pair the mechanisms of action included in the next table with the name of the active ingredients of the previous table:

List of INNs: trofinetide; tofersen; eplontersen; vutrisiran; inotersen; patisiran; pitolisant; laquinimod

mechanism of action	INNs
immunomodulator	
histamine H3 receptor antagonist	
small interfering RNA	
antisense oligonucleotide	
neurological peptides	

**[FEEDBACK]**

mechanism of action	INNs
immunomodulator	laquinimod
histamine H3 receptor antagonist	pitolisant;
small interfering RNA	patisiran; vutrisiran
antisense oligonucleotide	inotersen; eplontersen; tofersen
neurological peptides	trofinetide

## Scenario 2:

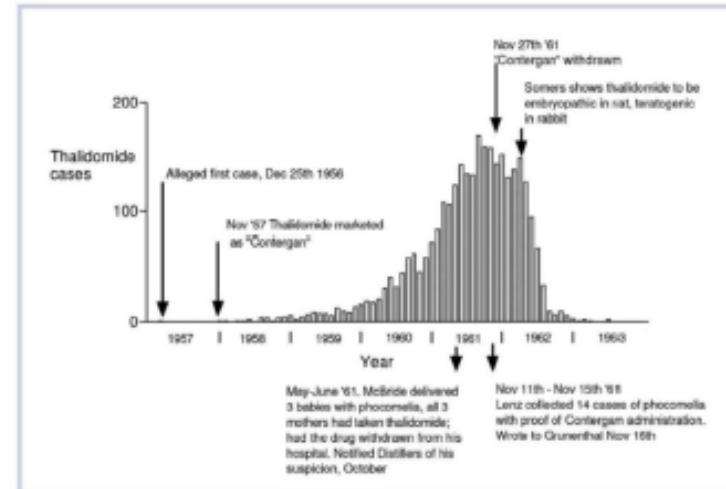
Using the INN stems in pharmacovigilance: research on the safety profile and aid in early signal detection

### Background information - Pharmacovigilance

[VIDEO WITH VOICE]

Pharmacovigilance involves the surveillance and study of adverse drug reactions and the early detection of any unexpected or previously unknown harm associated with medicines.

Pharmacovigilance has been developed to detect any signal of potential harm, especially of new medicines as soon as possible and, therefore, try to prevent disasters that affected many patients before the discovery of the iatrogenic causality. One of the best known of such disasters is the epidemic of phocomelia, a rare congenital malformation associated with the use of thalidomide by pregnant women in the early 1960s. By the time the causal relationship was established, three years after the first cases, more than 10,000 babies were affected by this serious adverse drug reaction.



**[EXERCISE]**

The following screens show the results of the VigiAccess search for canagliflozin and dapagliflozin.

**canagliflozin**

**Reported potential side effects**

- › Blood and lymphatic system disorders (0%, 133 ADRs)
- › Cardiac disorders (2%, 803 ADRs)
- › Congenital, familial and genetic disorders (0%, 40 ADRs)
- › Ear and labyrinth disorders (0%, 88 ADRs)
- › Endocrine disorders (0%, 34 ADRs)
- › Eye disorders (1%, 310 ADRs)
- › Gastrointestinal disorders (5%, 2 301 ADRs)
- › General disorders and administration site conditions (8%, 3 665 ADRs)
- › Hepatobiliary disorders (0%, 159 ADRs)
- › Immune system disorders (1%, 250 ADRs)
- › Infections and infestations (16%, 7 050 ADRs)
- › Injury, poisoning and procedural complications (6%, 2 462 ADRs)
- › Investigations (8%, 3 647 ADRs)
- › Metabolism and nutrition disorders (13%, 5 816 ADRs)
- › Musculoskeletal and connective tissue disorders (2%, 1 061 ADRs)
- › Neoplasms benign, malignant and unspecified (incl cysts and polyps) (1%, 291 ADRs)
- › Nervous system disorders (5%, 2 229 ADRs)
- › Pregnancy, puerperium and perinatal conditions (0%, 19 ADRs)
- › Product issues (0%, 120 ADRs)
- › Psychiatric disorders (1%, 595 ADRs)
- › Renal and urinary disorders (9%, 4 128 ADRs)
- › Reproductive system and breast disorders (2%, 668 ADRs)
- › Respiratory, thoracic and mediastinal disorders (1%, 560 ADRs)
- › Skin and subcutaneous tissue disorders (7%, 2 868 ADRs)
- › Social circumstances (0%, 95 ADRs)
- › Surgical and medical procedures (8%, 3 615 ADRs)
- › Vascular disorders (2%, 845 ADRs)

**dapagliflozin**

**Reported potential side effects**

- › Blood and lymphatic system disorders (0%, 323 ADRs)
- › Cardiac disorders (3%, 1 955 ADRs)
- › Congenital, familial and genetic disorders (0%, 137 ADRs)
- › Ear and labyrinth disorders (1%, 350 ADRs)
- › Endocrine disorders (0%, 102 ADRs)
- › Eye disorders (1%, 870 ADRs)
- › Gastrointestinal disorders (7%, 4 756 ADRs)
- › General disorders and administration site conditions (14%, 9 302 ADRs)
- › Hepatobiliary disorders (1%, 336 ADRs)
- › Immune system disorders (1%, 372 ADRs)
- › Infections and infestations (13%, 8 450 ADRs)
- › Injury, poisoning and procedural complications (4%, 2 903 ADRs)
- › Investigations (9%, 6 196 ADRs)
- › Metabolism and nutrition disorders (10%, 6 644 ADRs)
- › Musculoskeletal and connective tissue disorders (3%, 1 874 ADRs)
- › Neoplasms benign, malignant and unspecified (incl cysts and polyps) (1%, 695 ADRs)
- › Nervous system disorders (7%, 4 346 ADRs)
- › Pregnancy, puerperium and perinatal conditions (0%, 8 ADRs)
- › Product issues (0%, 299 ADRs)
- › Psychiatric disorders (2%, 1 292 ADRs)
- › Renal and urinary disorders (8%, 5 049 ADRs)
- › Reproductive system and breast disorders (4%, 2 579 ADRs)
- › Respiratory, thoracic and mediastinal disorders (2%, 1 465 ADRs)
- › Skin and subcutaneous tissue disorders (6%, 3 740 ADRs)
- › Social circumstances (0%, 212 ADRs)
- › Surgical and medical procedures (1%, 345 ADRs)
- › Vascular disorders (2%, 1 250 ADRs)

Identify the three most frequently reported ADR systems (in %) for both drugs:

Position	Canagliflozin	Dapagliflozin
1		
2		
3		

**[FEEDBACK]**

Position	Canagliflozin (% of ADRs)	Dapagliflozin
1	Infections and infestations (16%)	General disorders and administration site conditions (14%)
2	Metabolism and nutrition disorders (13%)	Infections and infestation (13%)
3	Renal and urinary disorders (9%)	Metabolism and nutrition disorders (10%)

