

# All the things you always wanted to know about INNs

INN, EML, ATC and DDD Training day

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INN/HPS/MHP

World Health Organization

Geneva, Switzerland

*"Think INN, prescribe INN, dispense INN" for good professional practice and the safety of  
patients*



# Agenda

- Who is WHO?
- The INN: what it is and does
- INN and Trademarks: allies or aliens?
- INN and biological substances
- Dissemination

# Disclaimer

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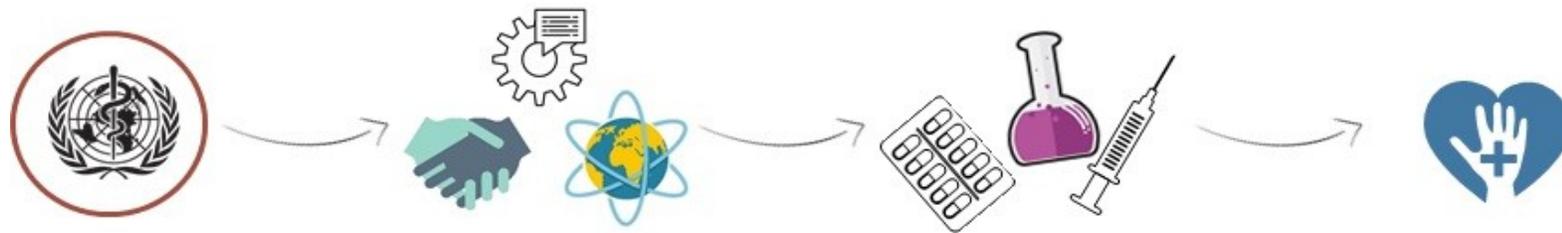
# World Health Organization

WHO is a specialised agency of the UNs serving as the directing and coordinating authority for international health matters and public health on behalf of its 194 Member States.

WHO is operating at 3 levels, HQ in Geneva, 6 regional offices and 150 country offices  
Principle objective - ***the attainment by all people of the highest possible level of health.***

WHO is responsible for providing leadership on global health matters, shaping the health research agenda, **setting norms and standards**, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

Setting norms and standards and promoting their implementation is affirmed **as a core function of WHO.**



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# Established by Expert Committees:

- **Official Advisory Body to Director General of WHO**
- **Established by World Health Assembly or Executive Board**

**INN:** WHO Expert Group on International Nonproprietary Names

**EML:** WHO Expert Committee on Essential Medicines

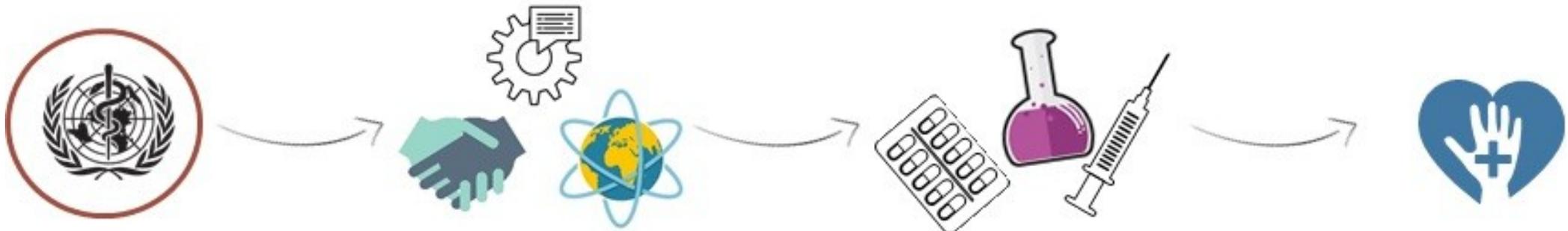
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**ATC-DDD:** WHO Advisory Group on Drug Statistics Methodology



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# Norms & Standards: WHO Core Business

The Constitution requires WHO“ to develop, establish and promote **INTERNATIONAL STANDARDS** with respect to biological and pharmaceutical products”.



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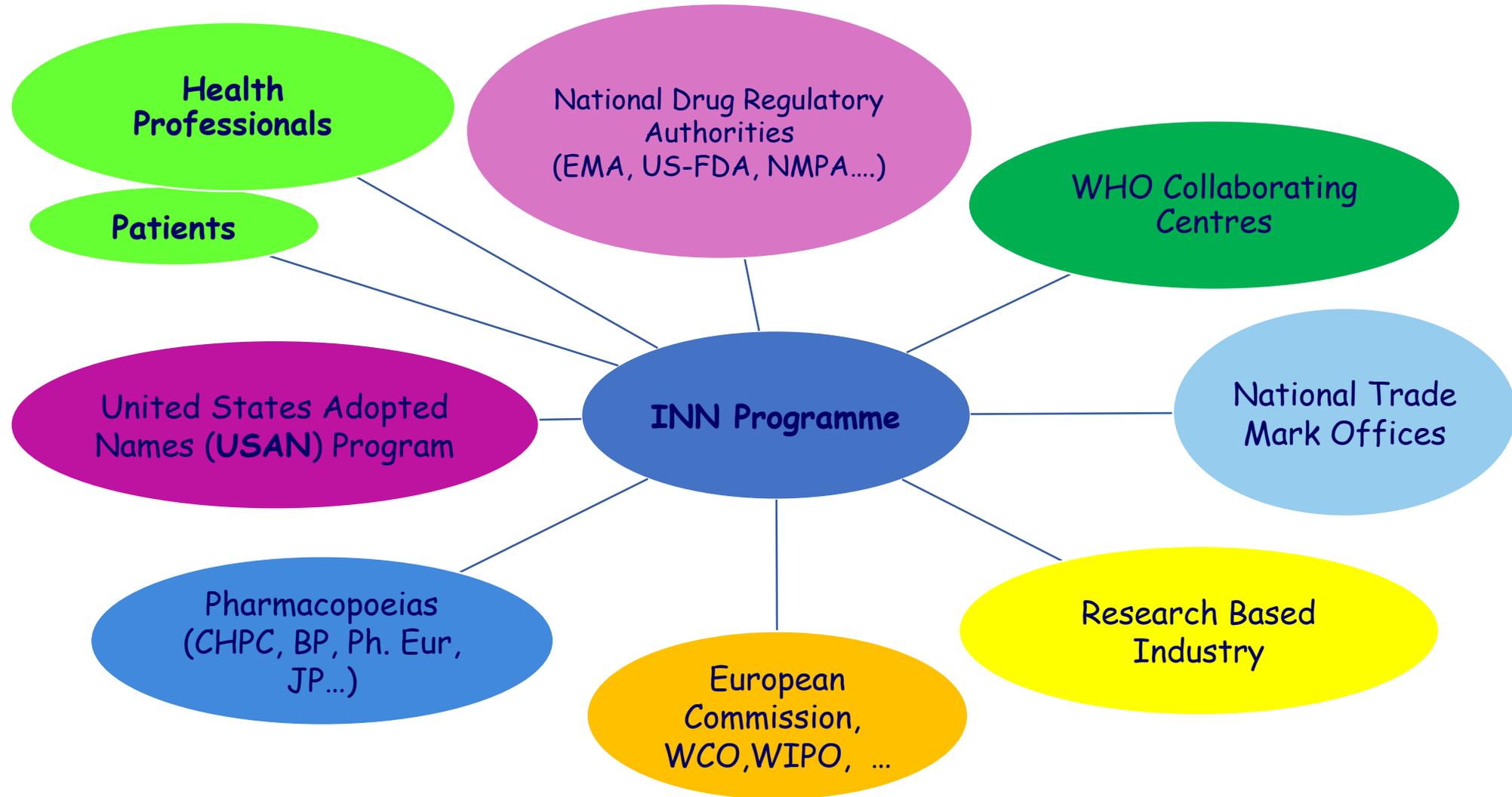
# INN for the safe and effective use of medicines

- The **International Nonproprietary Names (INN) Programme** was initiated in 1950 by the World Health Assembly to minimize the risk of name confusions and medication errors for pharmaceutical substances and to ensure patient safety.
- The **objective of the INN Programme** is to define a single, unique, globally accepted name for each pharmaceutical substance, including biologicals.
- **INN** support safe prescribing and dispensing, pharmacovigilance, access to medicines, and lower costs of medicinal products.

# International Nonproprietary Name (INN)

- Unique name
- Distinctive in sound and spelling
- Not liable to confusion with other names in common use
- Formally placed by WHO in the public domain
- Can be used without any restriction to identify pharmaceutical substances

# INN Stakeholders



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# INN – a map to medicine classes

## How are INN selected?

- The selection of a new INN follows a formal procedure.
- INN have to be distinctive in sound and spelling and should not have conflicts with other familiar names.
- INN can be used freely and cannot be registered as trade names.
- INN are based on specific word “stems”, whose purpose it is to group medicines with similar therapeutic or clinical actions.

## EXAMPLES of common biological stems:

- mab* (monoclonal antibodies, e.g. *trastuzumab*)
- gene* (gene therapy substances e.g. *onasemnogene* *abeparvovec*)
- ase* (enzymes e.g. *velaglucerase* *alfa*)

# INN

**Ebola**



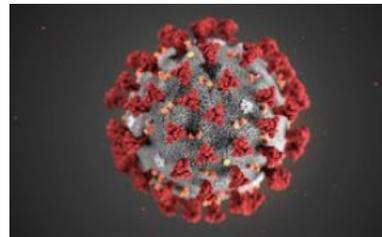
*galidesivir*

**Hepatitis C**



*sofosbuvir  
(now in EML)*

**COVID-19**

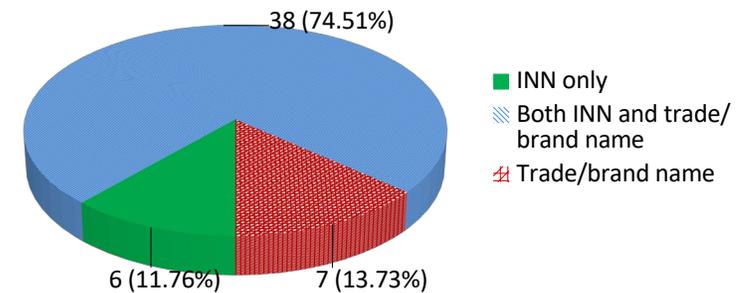
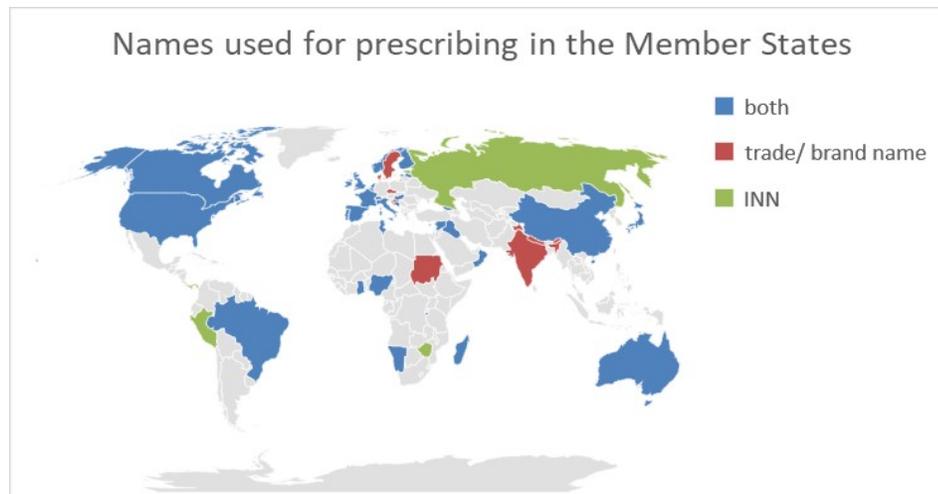


*tozinameran, elasomeran*

# In most Member States, INN are used for prescribing

WHO Drug Information, Vol.35No.4, 2021- [WHO Drug Information- Volume 35, No. 4](#)

- INN are mandatory in Armenia, Estonia, Panama, Peru, Russian Federation and Zimbabwe.
- Brand / trade names are obligatory in Croatia, Czech Republic, Denmark, India, Nepal, Sudan and Sweden.



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# How our work contributes to WHO goals and objectives/impact in countries

- The Constitution requires WHO “to develop, establish and promote international standards with respect to biological and pharmaceutical products”.
- International Nonproprietary Names (INN) belong to these “norms, standards and conventions” and are global public goods provided by WHO.
- INN is a global language needed for the clear identification, safe prescription, rational use, dispensing of medicines and pharmacovigilance
- Prescribing with INN improve access, lowering the costs of medicinal products, by increasing the use of non-originator pharmaceutical products



Abbildung ähnlich

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# Nonproprietary Name & Proprietary Name (valsartan) (Diovan<sup>®</sup>)

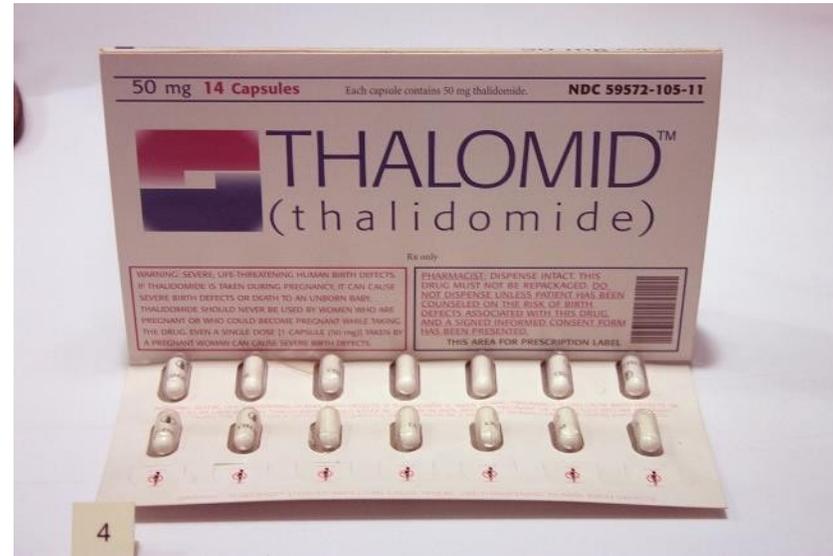
Identifies active pharmaceutical ingredient



<sup>®</sup>/<sup>™</sup> identifies product of a specific source

# INN is a global name for the entire lifecycle of a molecule

thalidomide (8)(4)



Contergan<sup>®</sup> ... And ..Immunoprin<sup>®</sup>, Talidex<sup>®</sup>, Talizer<sup>®</sup>,  
Neurosedyn<sup>®</sup>, Distaval<sup>®</sup> and  
many others

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# One INN can get various Trademarks



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# INN & Trademarks are 2 different Species



INN

- Unique Identifier of the active molecule; *scientific concept*
- Eternal Vehicle for Patient Safety



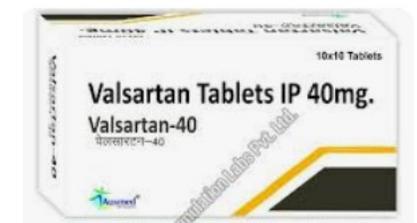
Trademark

- Unique Identifier of the origin; *legal concept*
- Eternal Vehicle for Quality



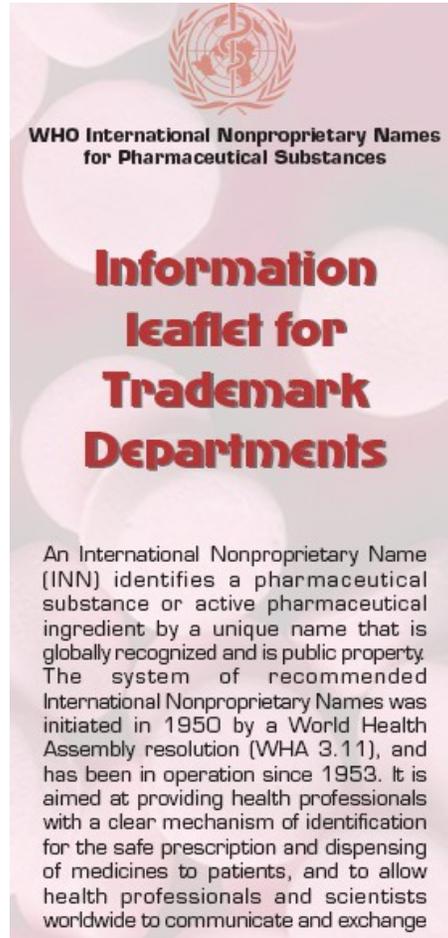
Product

- Keep them separate; do not add or remove any letters (Proper Trademark Use = Proper INN Use)
- **Blurring / Mixing them results in redundancy and risks**



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# Protection of INN and stems



Protected by a World Health Assembly resolution:  
WHA 46.19  
[INN Leaflet for TM departments.](#)

Limitation in the creation of new INN stems

[Guidance on the establishment of new INN stems](#)

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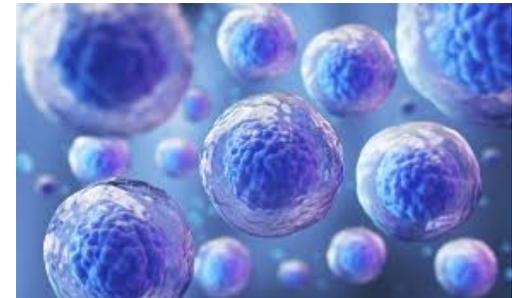
# Support and guidance to regulate complex biological products

- **Biological substances** represent the fastest-growing category in the pharmaceutical world and are derived or purified from living cells.
- Increasingly complex biological substances are currently developed.
- 2014 WHA resolution on regulatory system strengthening (WHA67.20) requests WHO:
  - “to increase support and guidance for **strengthening the capacity to regulate increasingly complex biological products** with the focus on biotherapeutic products, ... and, where appropriate, on new medicines for human use based on **gene therapy, somatic-cell therapy and tissue engineering.**”
- This mandate includes the nomenclature of biological products

# INN for biological substances

INN are assigned to complex biological substances such as:

- **Proteins:** monoclonal antibodies, receptor molecules, hormones, growth factors, ...
- **Nucleic acids:** antisense oligonucleotides, small interfering RNA, messenger RNA
- **Advanced therapy medicinal products**
  - Gene therapy substances
  - Cell-therapy substances
  - Cell-based gene therapy substances



# The INN global nomenclature of biological substances: A continuous challenge

- Biologicals represent a rapidly evolving field (personalized medicine, genome editing, CAR T cells,...).
- Biologicals are highly complex substances, that often display a certain degree of heterogeneity.
- How to assign an INN to a complex, heterogenous product?
  - Based on information provided by the applicant
  - Assessment of the INN Expert Group
- **INN definition** paragraph:
  - Integral part of the INN
  - Contributes to **Pharmacovigilance** and **Patient safety**

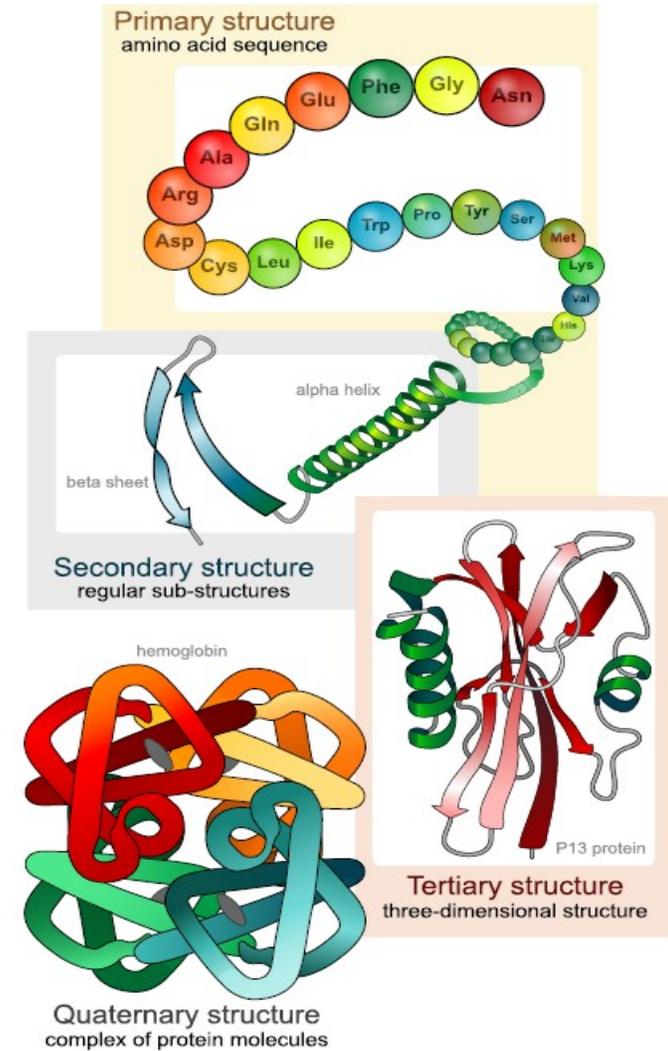
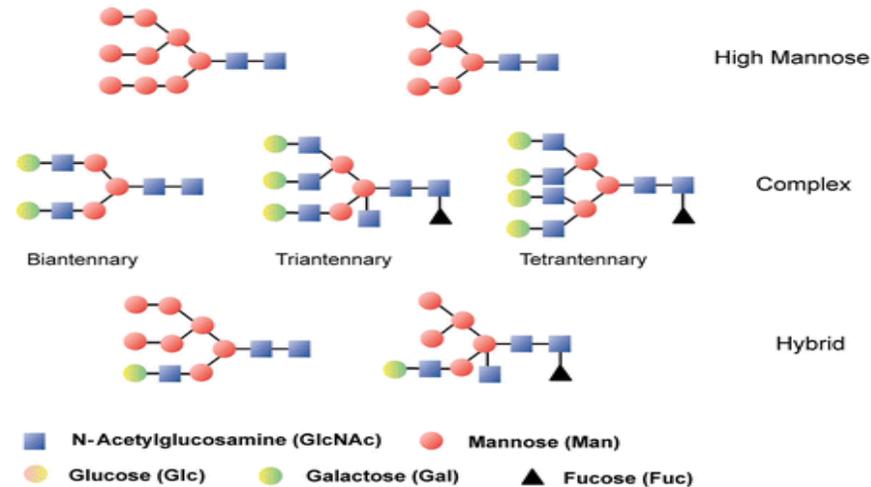


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# Background BQ

Biotherapeutic proteins are very different to chemical medicines:

- Size
- Complexity – structure

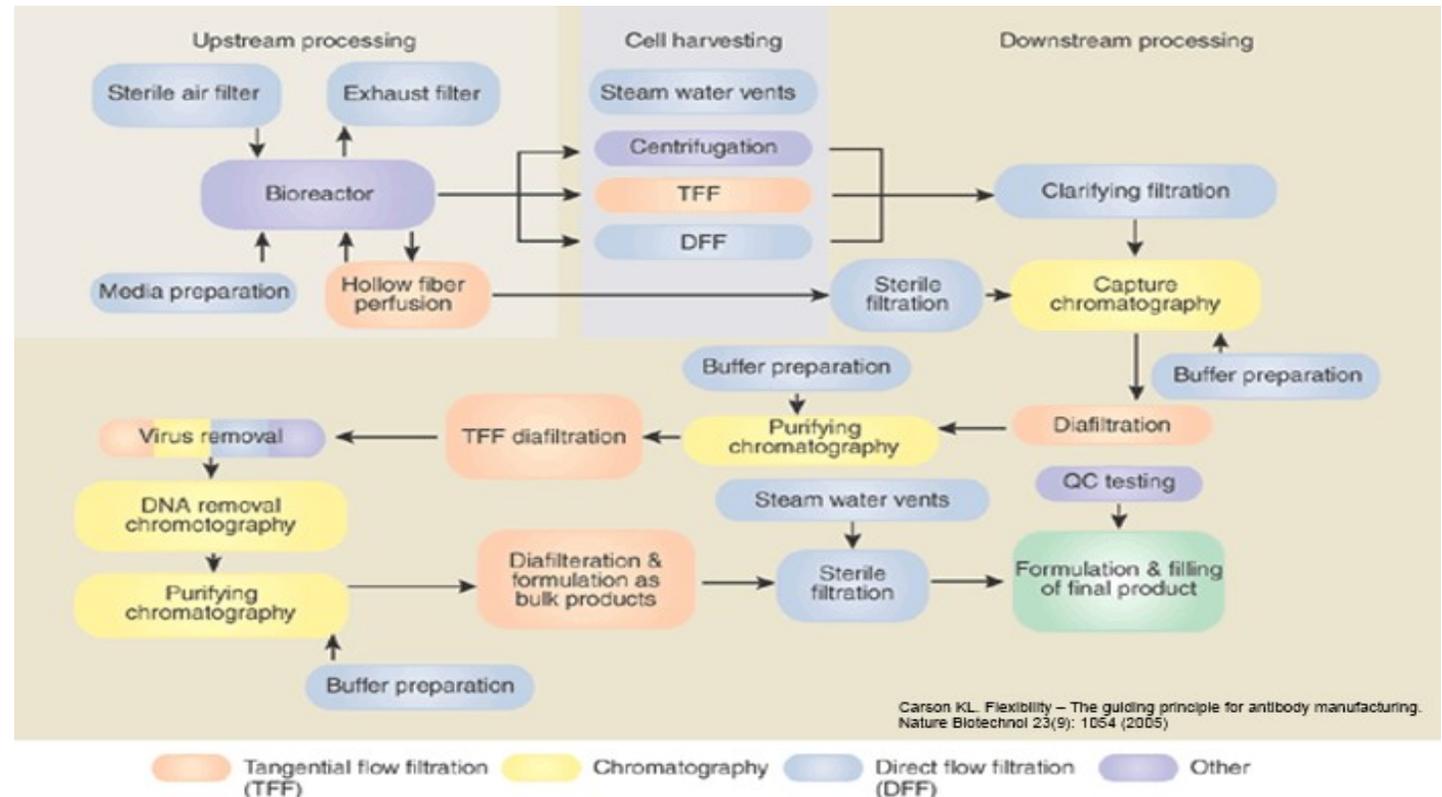


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# Background BQ

Biotherapeutic proteins are very different to chemical medicines::

- Size
- Complexity – structure
- Complexity – manufacture



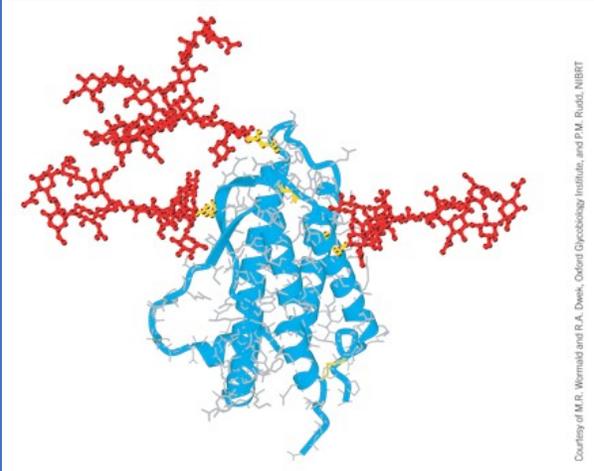
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# Background BQ

Biotherapeutic proteins are very different to chemical medicines::

- Size
- Complexity – structure
- Complexity – manufacture
- Heterogeneity

EPO



Courtesy of M.R. Wormald and R.A. Dewar, Oxford Glycobiology Institute, and P.M. Rudd, NIBRT

- Mass = 27948±285 deglycosylated 18240±4
- 2 disulphide bonds
- 3 N-glycosylation
- 2 O-glycosylation sites
- Many types of glycans
- C-terminal truncation

Even the most controlled biotechnological process produces a spectrum of 100 000s of molecules – all potentially having different activity, circulatory half-life and potential to induce an immune reaction. Therefore every different process effectively produces a different product.

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# National biological identifier schemes

NRA (Country)	Issue	Approach	Pros and Cons
FDA (USA)	Pharmacovigilance of all new biological medicines	Addition of a four-letter (with vowels) suffix hyphenated to USAN (e.g. infliximab-dyyb or -abda & epoetin alfa-epbx).	Simple and easy to administer. Use of vowels incompatible with BQ. At least one suffix is commercial (-sndz).
EMA (European Union)	Pharmacovigilance of all new biological medicines	No separate scheme, use of tradenames & 2D barcode tracing is sufficient.	2D barcode more complex & expensive to implement esp. in developing countries.
PMDS (Japan)	Distinguishing biosimilar from reference medicines	Addition of suffix (BS1, BS2 etc.) for biosimilars.	Simple. Potential for confusion with many biosimilars
TGA (Australia)	Distinguishing a medicine with differing glycosylation profile.	Insistence on the use of a different Greek letter to that assigned by WHO.	Non-compliance with WHO naming convention.

# WHO International Nonproprietary Name

Because INNs are allocated on the basis of the amino acid sequence, the sole use of the INN is not able to distinguish between these differing products.

It was concluded that some kind of distinguishing identifier should be used with the INN. In July 2014 a proposal was published for a Biological Qualifier (BQ). After extensive consultation, the Proposal was finalised in June 2015 and adopted in April 2016, but was shelved shortly afterward.

The aim of the BQ is to uniquely identify ALL biological medicines with a unique code.

# The INN Lists

- New INNs are published in *WHO Drug Information*: 2 proposed and 2 recommended lists every year in English, French, Spanish and Latin.
- All INNs are published in a cumulative list with additionally INNs in Arabic, Chinese and Russian.
- More than 10.000 INN have been published

Health products policy and standards (who.int)

- On-line INN information: : <https://extranet.who.int/soinn/>

# School of INN (SoINN) Platform

<https://extranet.who.int/soinn>



English (en) Log in

School of International Nonproprietary Names

ANNOUNCEMENTS INN for Variant COVID-19 Vaccines

World Health Organization INN Programme Official Site

Corresponding member of School of INN

World Health Organization Request a New INN Name

Steering Committee of the School of INN

Navigation

- Home
- Courses

Search for INN Names and stems

Search for..

Query  INN

Check  Stem

Results: Limited to 5 items

<https://www.youtube.com/embed/lv51EVLmess?rel=0&autoplay=1>  
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# INN MedNet

- **Mednet Search Tool**

<https://extranet.who.int/soinn/>

- On-line queries of WHO INN data for lists of Proposed and Recommended INN  
Example: “**beglogene**”

		<b>INN N°</b>	<b>Substance name</b> <b>click to see names in multiple languages</b>	<b>Proposed list</b>	<b>Recommended list</b>
		<a href="#">10505</a>	betibeglogene darolentivec	 <a href="#">116</a>	 <a href="#">78</a>
		<a href="#">10900</a>	betibeglogene autotemcel	 <a href="#">125</a>	 <a href="#">86</a>
		<a href="#">11826</a>	lovotibeglogene autotemcel	 <a href="#">125</a>	 <a href="#">87</a>
		<a href="#">12025</a>	nulabeglogene autogedtemcel	 <a href="#">126</a>	

**WHO Drug Information:** <https://www.who.int/teams/health-product-and-policy-standards/inn/inn-lists/>

# INN Global Data Hub

Displaying 1-14 of 14 results

Change layout Sort results

« FILTERS

- ▶ APPLICATION DATE (2)
- ▶ DESIGNATION COUNTRY (
- ▶ EXPIRY DATE (0)
- ▶ FEATURE (2)
- ▶ IP OFFICE (2)
- KIND : Individual
- ▶ NICE CLASSIFICATION (4)
- OWNER : GENENTECH INC
- OWNER COUNTRY CODE :

Search criteria

Denomination: trastuzumab Office: Europe - EUIPO

Applicant Name: Nice classes: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45

Similar Marks: 100 results Owners marks: Not applicable 6ter Paris WIPO: 0 results INN WHO: 10 results G.I.: warning of 30 results Plant Varieties: 0 results Data Lists: 1 results Additional Searches:

Showing 25 entries Search in the results: Show / hide columns

INN number	INN denomination in Latin	INN denomination in English	INN denomination in French	INN denomination in Spanish
TM Word: trastuzumab				
7637	trastuzumabum	trastuzumab	trastuzumab	trastuzumab
9295	trastuzumabum emtansinum	trastuzumab emtansine	trastuzumab emtansine	trastuzumab emtansina
9956	trastuzumabum beta	trastuzumab beta	trastuzumab bêta	trastuzumab beta
10273	trastuzumabum duocarmazinum	trastuzumab duocarmazine	trastuzumab duocarmazine	trastuzumab duocarmazina
10516	trastuzumabum deruxtecancum	trastuzumab deruxtecan	trastuzumab déruxtécan	trastuzumab deruxtecán
11938	trastuzumabum corixetanum	trastuzumab corixetan	trastuzumab corixétan	trastuzumab corixetán
12243	trastuzumabum rezetecancum	trastuzumab rezetecan	trastuzumab rézétécan	trastuzumab rezetecán
12382	trastuzumabum imbotolimodum	trastuzumab imbotolimod	trastuzumab imbotolimod	trastuzumab imbotolimod
12435	trastuzumabum botidotinum	trastuzumab botidotinum	trastuzumab botidotinum	trastuzumab botidotinum
12531	trastuzumabum vedotinum	trastuzumab vedotin	trastuzumab védotine	trastuzumab vedotina

Showing 1 to 10 of 10 entries First Previous 1 Next Last

Herceptin trastuzumab

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, 2008)

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onal

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# The electronic EML- eEML

The screenshot displays the WHO eEML interface. At the top left is the WHO logo. A search bar at the top center contains the text "Search by name/indication" and is circled in red. A large red arrow points from this search bar to the right, where the text "Search by MEDICINE NAME" is written in red. Below the search bar, the main heading reads "EML Model List of Essential Medicines". A sub-heading states: "Found 1190 recommendations for 591 medicines and 124 therapeutic equivalents. Removed medicines and rejected applications are not shown. [Show them.](#)"

On the left side, there is a "FILTERS" sidebar with the following sections:

- EML section:** Any
- Indication:** Indication...
- First added:** Any
- Target population:** Age: Any, Sex: Any
- Tags:** Cancer (241), Cancer supportive care (4), Biosimilar (46)

An "Apply filter" button is located at the bottom of the sidebar. The main list of medicines includes: Abacavir, Abacavir + lamivudine, Abiraterone, Acetazolamide, Acetic acid, Acetylcysteine, Acetylsalicylic acid, Aciclovir, Aclidinium, Activated charcoal, Adalimumab, Afatinib, Albendazole, and Alcohol based hand rub.

An inset window shows a search for "paracetamol". The search bar contains "paracetamol". The heading is "EML Model List of Essential Medicines". The sub-heading states: "Found 2 recommendations for 1 medicine and 0 therapeutic equivalents".

The inset window also has a "FILTERS" sidebar with the same sections as the main page. Below the filters, it says "No tags selected among the results" and has an "Apply filter" button.

The main content of the inset window is titled "Paracetamol" with a "General information" link. It is divided into two columns: "Section" and "Indications".

Section	Indications
Antimigraine medicines > For treatment of acute attack	Migraine
Oral > Liquid: 125 mg per 5 mL; 120 mg per 5 mL	
Oral > Solid: 300 to 500 mg	
Non-opioids and non-steroidal anti-inflammatory medicines (NSAIMs)	Pain
Oral > Liquid: 125 mg per 5 mL; 120 mg per 5 mL	
Oral > Solid: 100 to 500 mg	
Local > Rectal > Suppository: 100 mg	

At the bottom of the main page, there are links for "Caveats", "About the eEML", "Licensing WHO eEML", "Contact Us", and "Privacy Policy".

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Mark as done

## trastuzumab

Latin	trastuzumabum
French	trastuzumab
Spanish	trastuzumab
Russian	трастузумаб
Arabic	تراستوزوماب
Chinese	曲妥珠单抗
Phonetic	trastuzumab
Molecular formula	Empty
ATC Codes	L01FD01

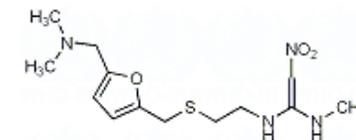
National commission(s)	Alternate name(s)
JAN	trastuzumab (genetical recombination)
JAN	trastuzumab (genetical recombination) [trastuzumab biosimilar 1]
JAN	trastuzumab (genetical recombination) [trastuzumab biosimilar 2]
JAN	trastuzumab (genetical recombination) [trastuzumab biosimilar 3]

### National commission(s) using same name

BAN  
DCF

# ATC code

## ranitidine



Latin	ranitidinum
French	ranitidine
Spanish	ranitidina
Russian	ранитидин
Arabic	رانيتيدين
Chinese	雷尼替丁
Phonetic	ranitidine

Molecular formula  $C_{13}H_{22}N_4O_3S$

ATC Codes A02BA02

National commission(s)	Alternate name(s)
DCIT	ranitidina
USAN	ranitidine bismuth citrate
BAN	ranitidine bismutrex
JAN	ranitidine hydrochloride

### National commission(s) using same name

BPC  
ChP  
DCF  
FEUM  
Ph. Eur.  
USAN  
USP

# Oracle of Delphi – aka ‘Q&A session’



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Thank you

**WHO**

20, Avenue Appia  
1211 Geneva

**Switzerland**

# What is the SoINN ?

## A virtual school

Free of charges

<https://extranet.who.int/soinn/>