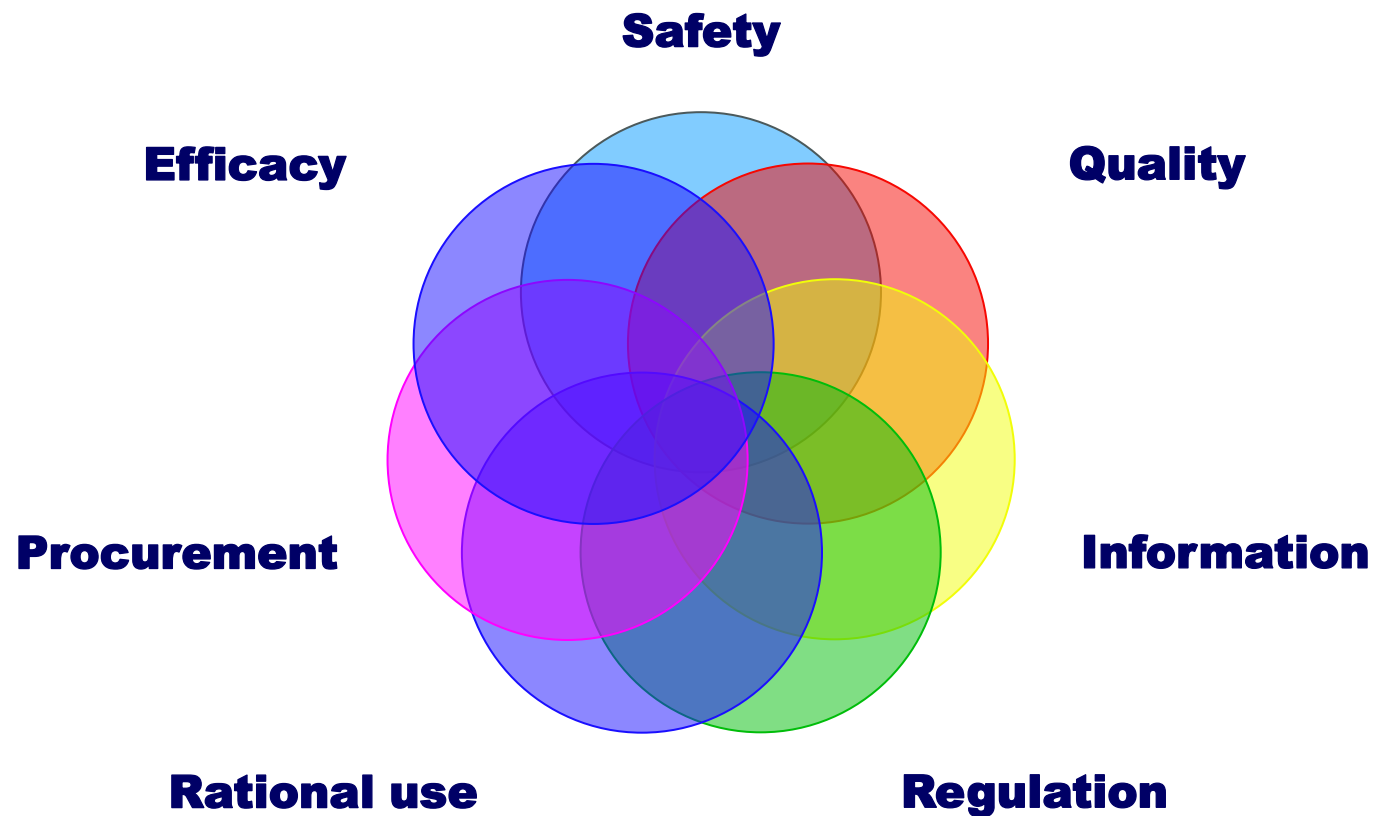


International Nonproprietary Names Programme Biological Qualifier - Recent Developments and what will be the next steps



**World Health
Organization**

What's in a name?



Verba volant scripta manent

"By assigning a single international name to drugs, WHO helps ensure that a prescription filled abroad is what doctor ordered back home."

Dr Margaret Chan, Director General

The WHO International Nonproprietary Name (INN) Programme

To provide one single name worldwide for active pharmaceutical substances

- **Initiated in 1950 by resolution WHA3.11**
- **Operational since 1953**
- **Based on WHO Constitution**

INN Programme

- **Mandated by the Member States in 1953**
- **One of the oldest WHO programmes**
- **To devise a single name for a substance**
- **INNs are recognized in almost all Member States**
- **INNs can be used freely and cannot be registered as trade names**
- **Not concerned with formulations**



Interested parties outside WHO



Various trade names ® for one substance, ex. *paracetamol*



Various generic names for one substance, ex. *paracetamol*



One International Nonproprietary Name for one substance, ex. *paracetamol*



INNs...

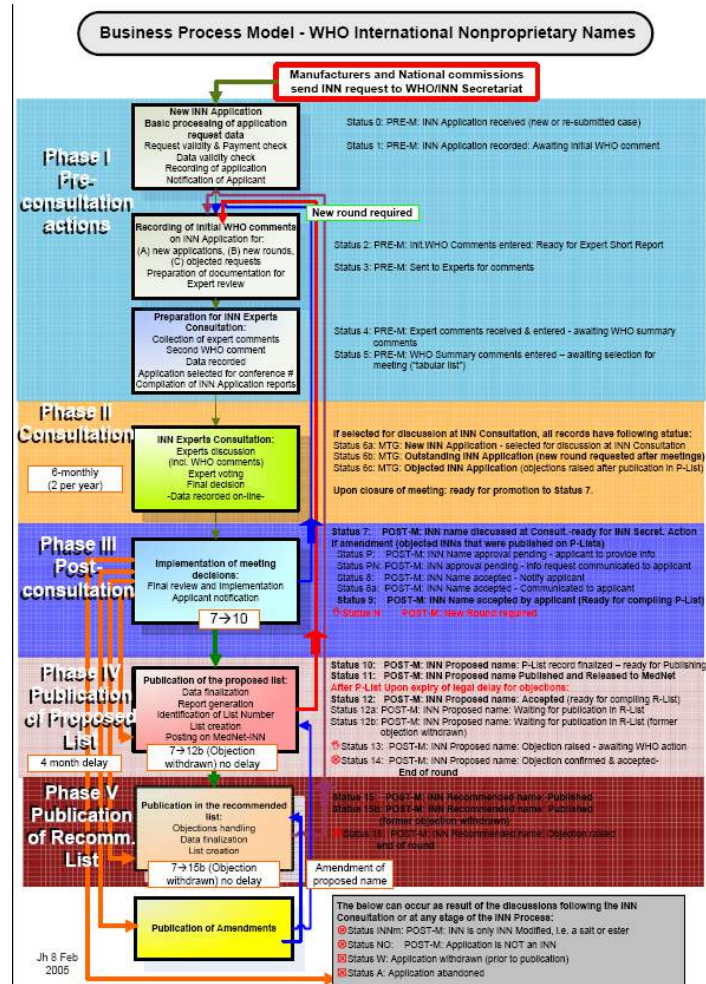
- **Unique name**
- **Distinctive in sound and spelling**
- **Not liable to confusion with other names in common use**
- **Formally placed by WHO in the public domain**
- **Can be used without any restriction to identify pharmaceutical substances**

The INN System

- **WHO Secretariat**
- **INN Expert Group**
- **INN Advisory Group on Biological**
- **Publications**



The Business Process Model



Broad consultation

Lot of correspondence

2 INN meetings/year

"Ad hoc" meetings

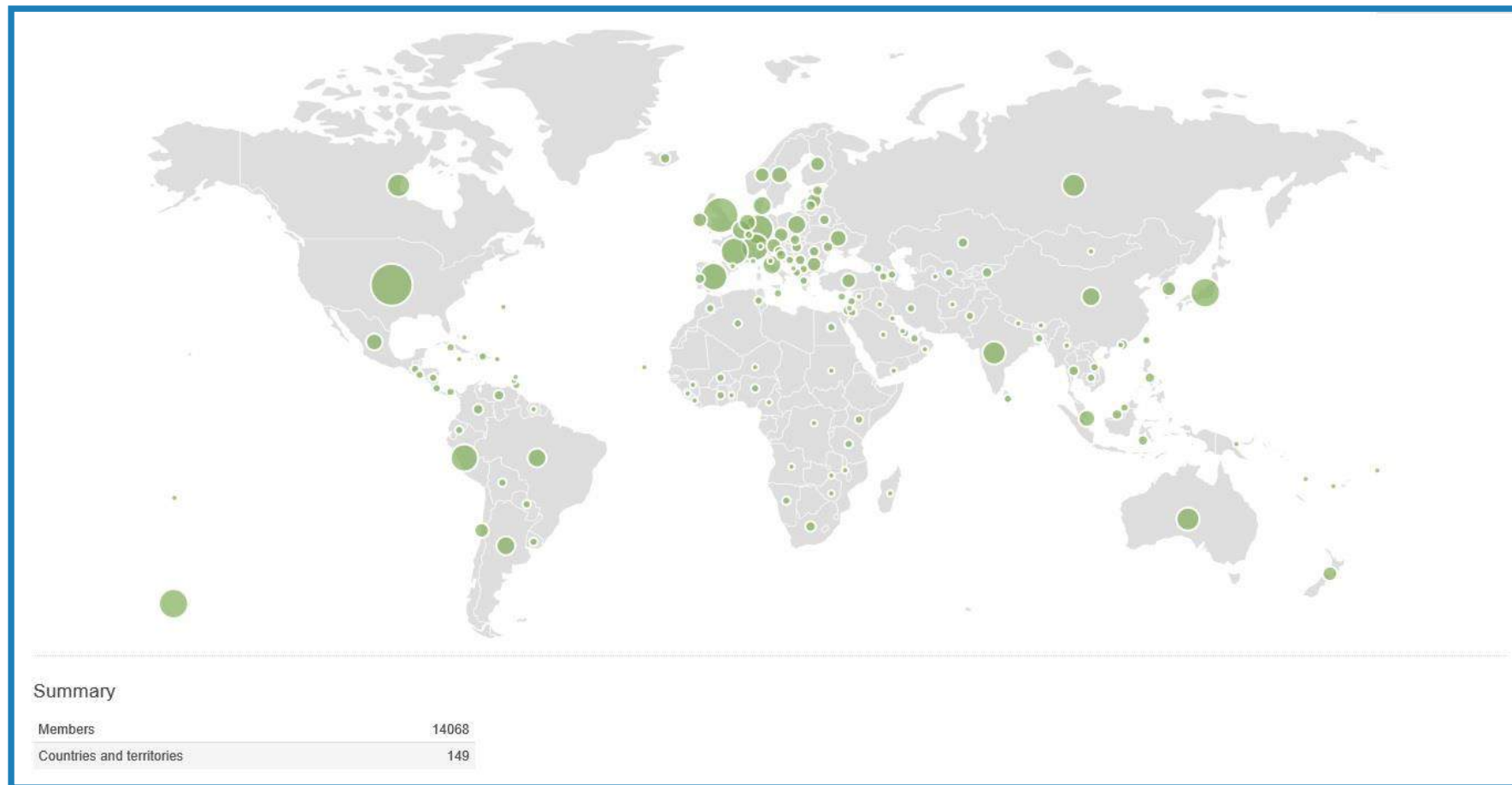
.....

Reaching the world

- **INNs Lists are published in WHO Drug Information**
- **All INNs are published in a Cumulative List**
- **On-line INN information: Mednet - INN Extranet**
- **Global Data Hub**

MedNet

<https://mednet-communities.net/inn/>



Use of stems

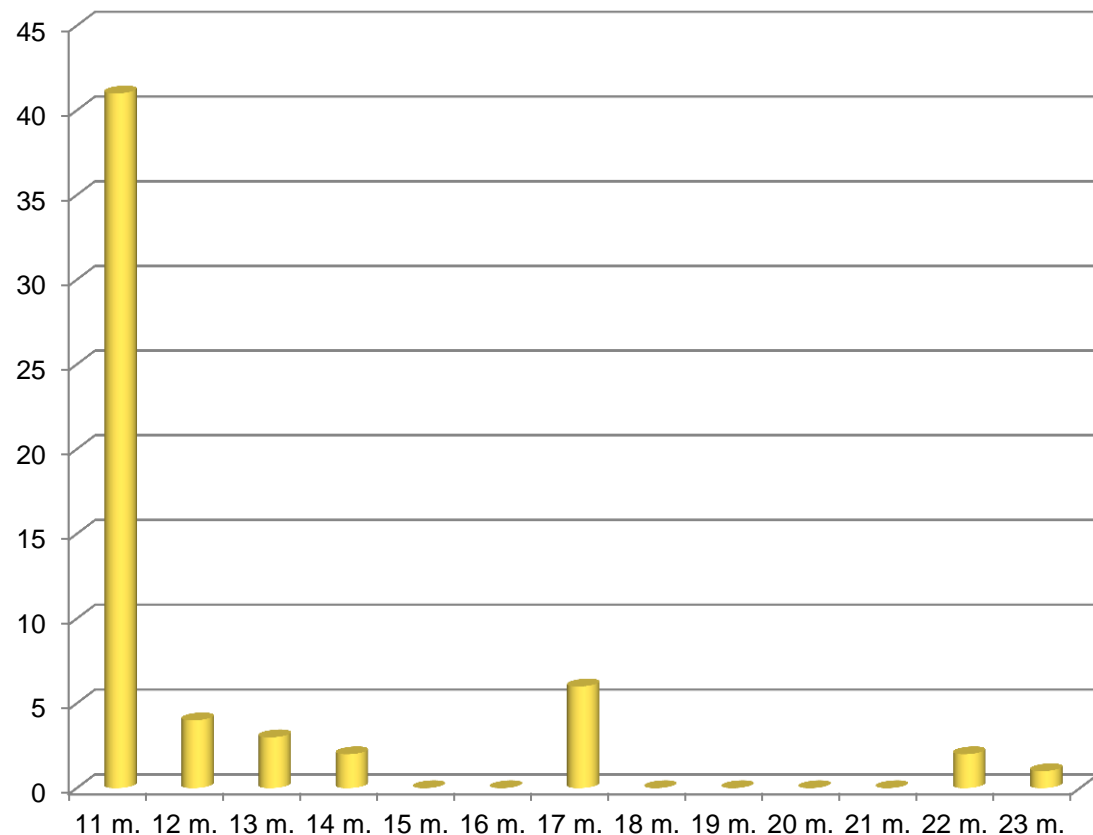
➤ Names of "pharmacologically/chemically -related" substances have a common stem

- To indicate chemical and /or pharmacological group relationship
- Published for 'established series of related compounds'
- INN and stems have protection within trade mark arena
- WHO publication "*The use of stems in the selection of INN* "
Stem book 2013
- pre-stems list

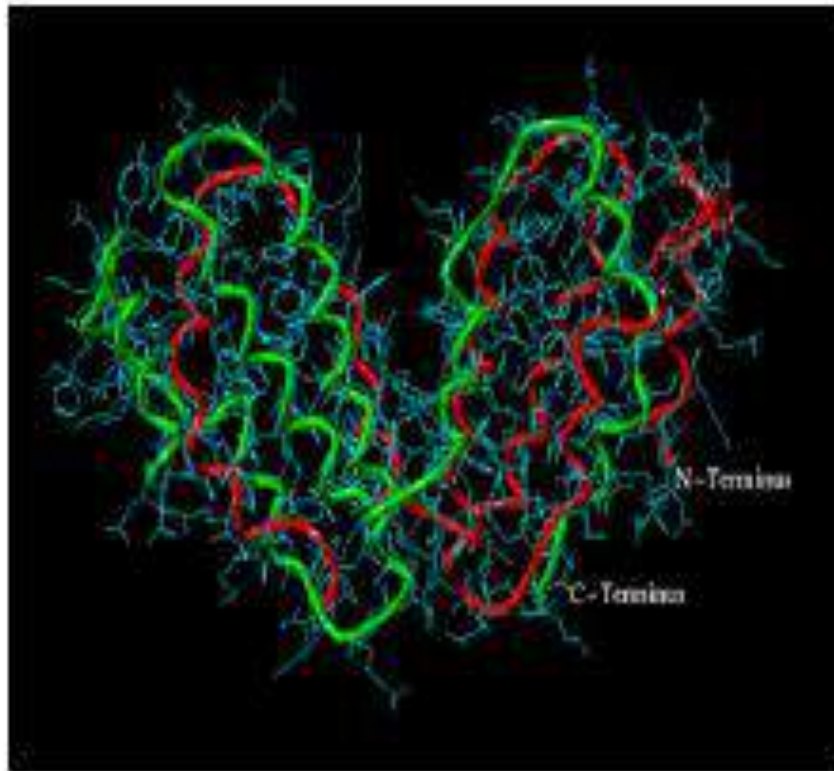
How long...?

- **59 names**
- **30% biologicals**
- **12.5 months as an average**
- **Nearly 95% pub. after 1 or 2 rounds of discussion**

Time for publication of a p.INN in List 110

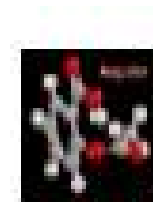


Biologicals are more complex



Interferon beta

MW 19'000D



Aspirin

MW 180D

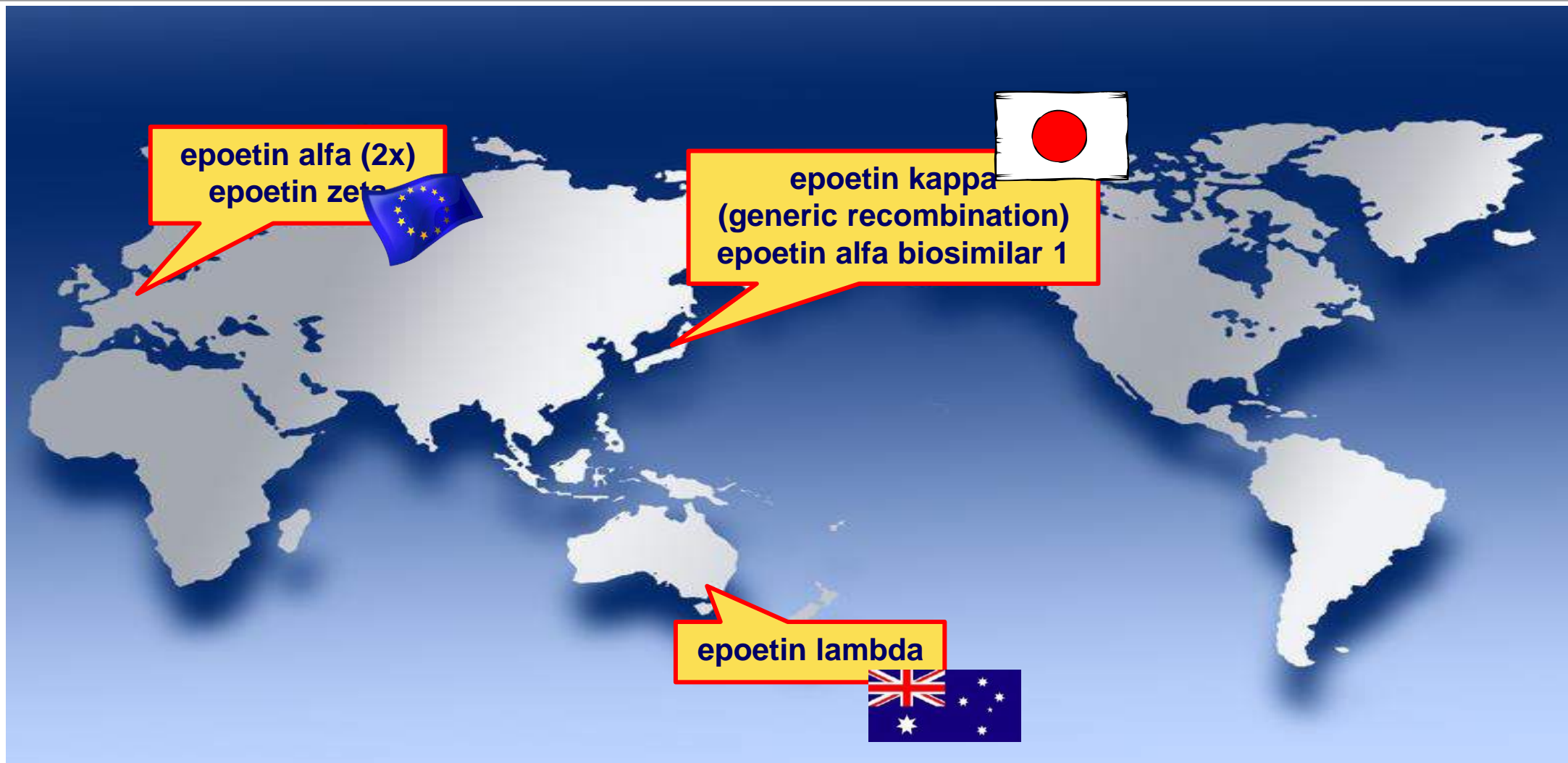
Naming Biosimilars?

- **As Biosimilars are Biologicals, they should be named as Biologicals**
- **But if Biosimilars & Innovator biologicals are given the same INN, a mean to distinguish/identify is needed (e.g trade name)**

Some Problems with Biosimilars

- **A regulatory route may or may not exist**
- **The same substance (product) may be viewed as biosimilar in some jurisdictions but not others**
- **Separate national solutions have been adopted**
- **No INN specific policy for biosimilars currently exists**
- **Some DRAs have requested WHO to develop an identification system applicable to biosimilars**

INN a global name?



.....

- **This is an issue that does need to be addressed globally, and soon**
- **The WHO INN Programme has a clear mandate**
- **The need for a harmonized (global) system is crucial**



Biological Qualifier scheme

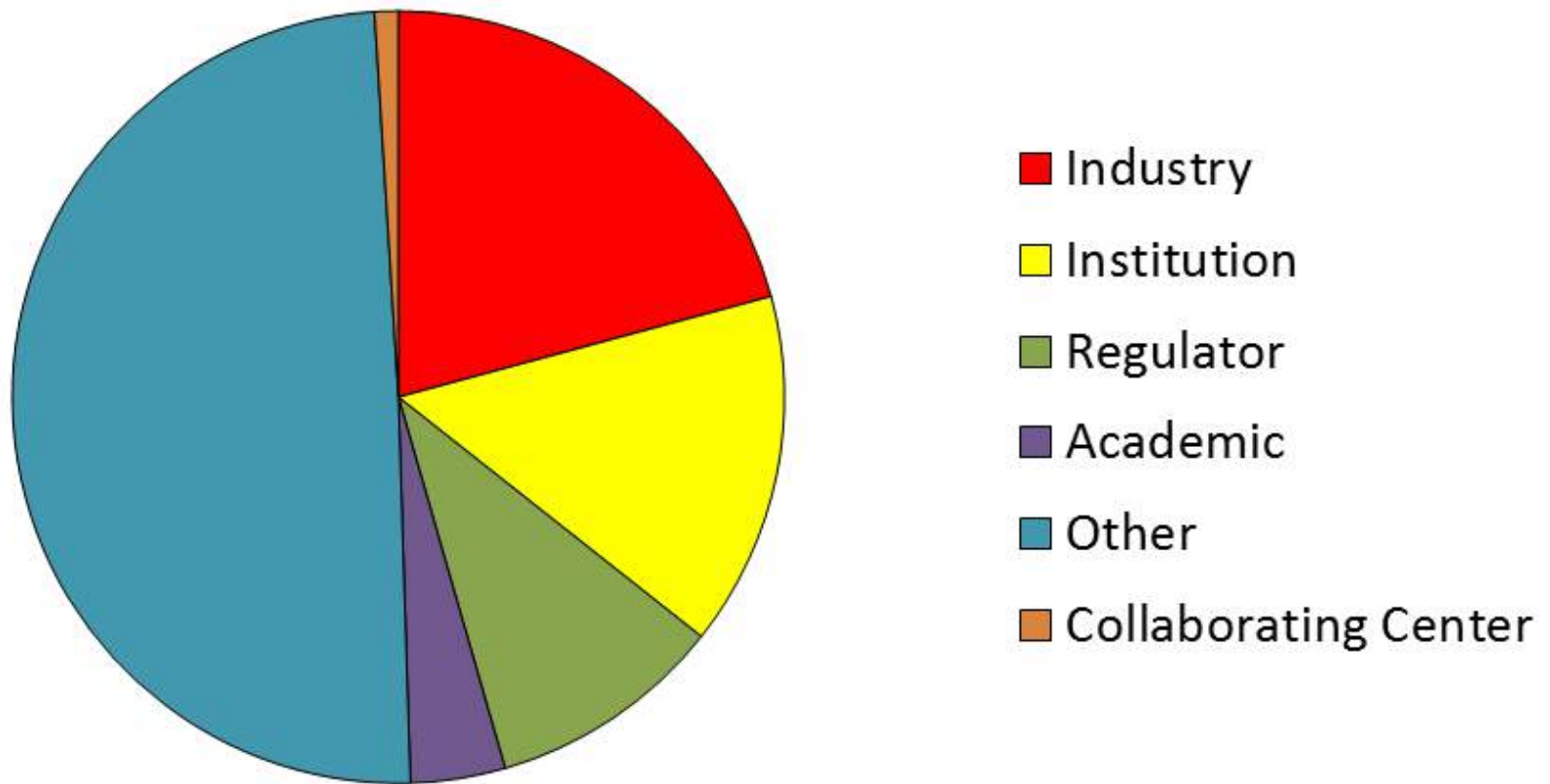
All biological substances that are assigned INN should:

- 1. Be clearly identified**
- 2. Have the INN of the reference product as the first part of the name**
- 3. Have parallel nomenclature scheme (Biological Qualifier) that uniquely identifies the substance**

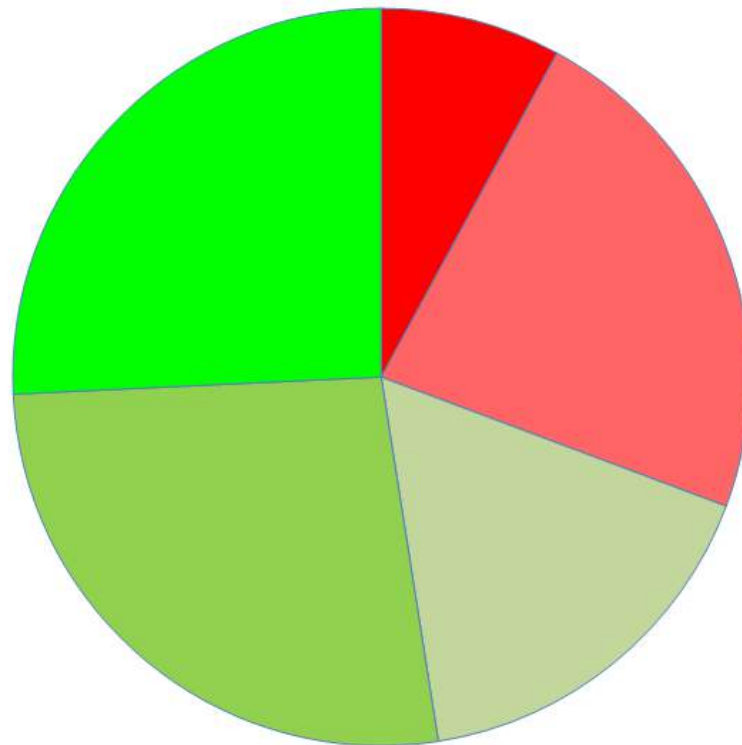
Biological Qualifier Database

- **INN Secretariat manages a secure database**
- **Applicant for a code submits online and follow progress**
- **DRAs: validate data and have unrestricted access to information in database**
- **Manufacturers/applicants/industry: what restrictions if any?**
- **‘Public’: INN website lists codes and INN (and products?)**

Who?

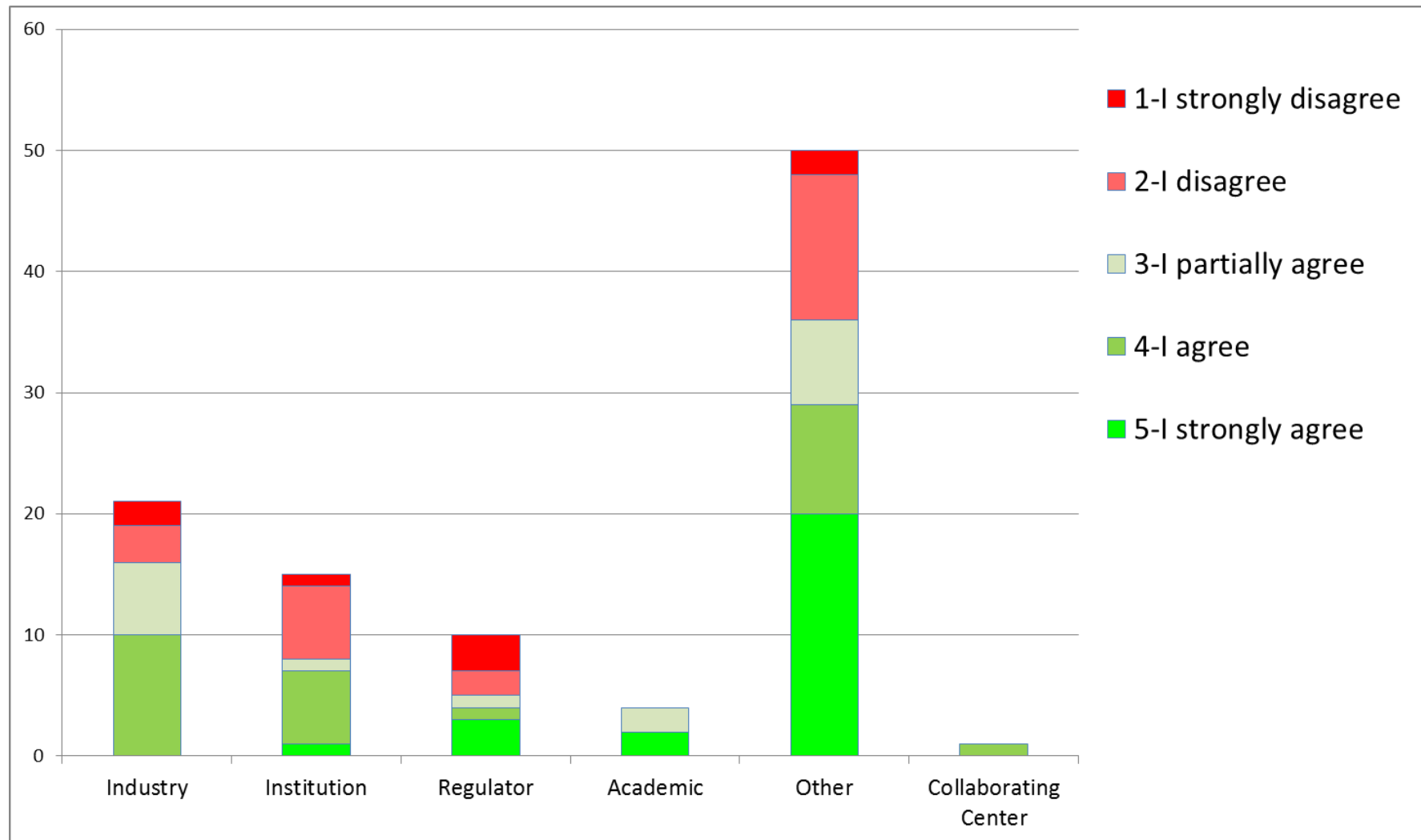


Answers



- 1-I strongly disagree
- 2-I disagree
- 3-I partially agree
- 4-I agree
- 5-I strongly agree

Who answers what ?





INN is simple

"Simplicity is the ultimate sophistication"



Leonardo Da Vinci

Thank you

*Danke! Grazie! Merci! Obrigado ! Gracias 谢谢! ありがとう ! ARIGATOU ! Dziękuję! Dank
je / u! Mulțumesc! Teşekkür ederim! Tack!Tack så mycket! Kiitos! תודה
!להTakk! d'akujem, d'akujem vám ; Hvala! شكراً!shokran Ευχαριστώ! 감사합니다
Děkuji! Tak skal du have! Dankon! Hvala, Hvala lepa, Najlepša hvala Gràcies!
Faleminderit Hvala! Ačiū, De'koju, Labai ačiū ขอบคุณ ; ขอบคุณมาก(khàwp khun) ; (khàwp
khun mâak) shukrīya () شكريه (bahut) Cảm ơn cô ; Cảm ơn cô nhiều;
Благодаря!Благодаря! Obrigado!” Gracias Pakka pé! baie dankie ; Takk fyr! Sipas
dekem !متشكراً!Благодарам! Hvala Vam! V Teşekkür Paldies!Pateicos! /
Tepcinu! Terima kasih Дуже дякую ;Дякую ; Спасибі! Баярлалаа ; Гялайлаа ; Танд
их баярлалаа Terima kasih धन्यवाद (dhonyobād) Salamat! Trugarez ! Mersi
!Trugarez Danke!*

