

# International Noproprietary Name Programme

## The School of INN

Technologies Standards and Norms Team  
Essential Medicines and Health Products Department



World Health  
Organization

# INN: The core of WHO's core business

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The Constitution requires WHO “to develop, establish and promote international standards with respect to biological and pharmaceutical products”.

This has been done for more than 60 years now

The norms and standards are established by Expert Committees

# What is a WHO expert committee?

- Official Advisory Body to Director-General of WHO
- Established by World Health Assembly or Executive Board
  - **WHO Expert Committee on Specifications for Pharmaceutical Preparations**  
Secretary: Dr Sabine Kopp
  - **WHO Expert Group on International Nonproprietary Names**  
Secretary: Dr Raffaella Balocco
  - **WHO Expert Committee on Biological Standardization**  
Secretary: Dr Ivana Knezevic



# Link with WHO Governing Bodies

WHO Expert Committee reports are presented to the Executive Board



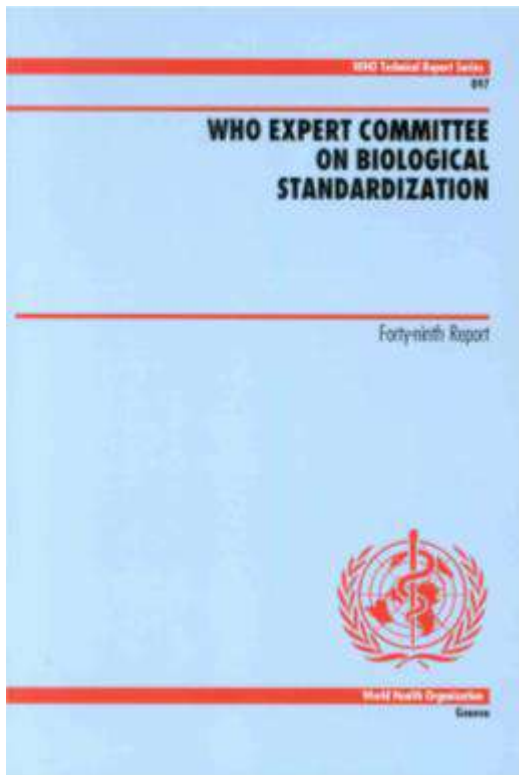


# WHO Global Standards and Norms

## Robust, Durable and Responsive to Public Health needs

### Global written standards

Tools for appropriate regulation of quality, safety and efficacy



### Global measurement standards

Tools for product development, licensing and lot release



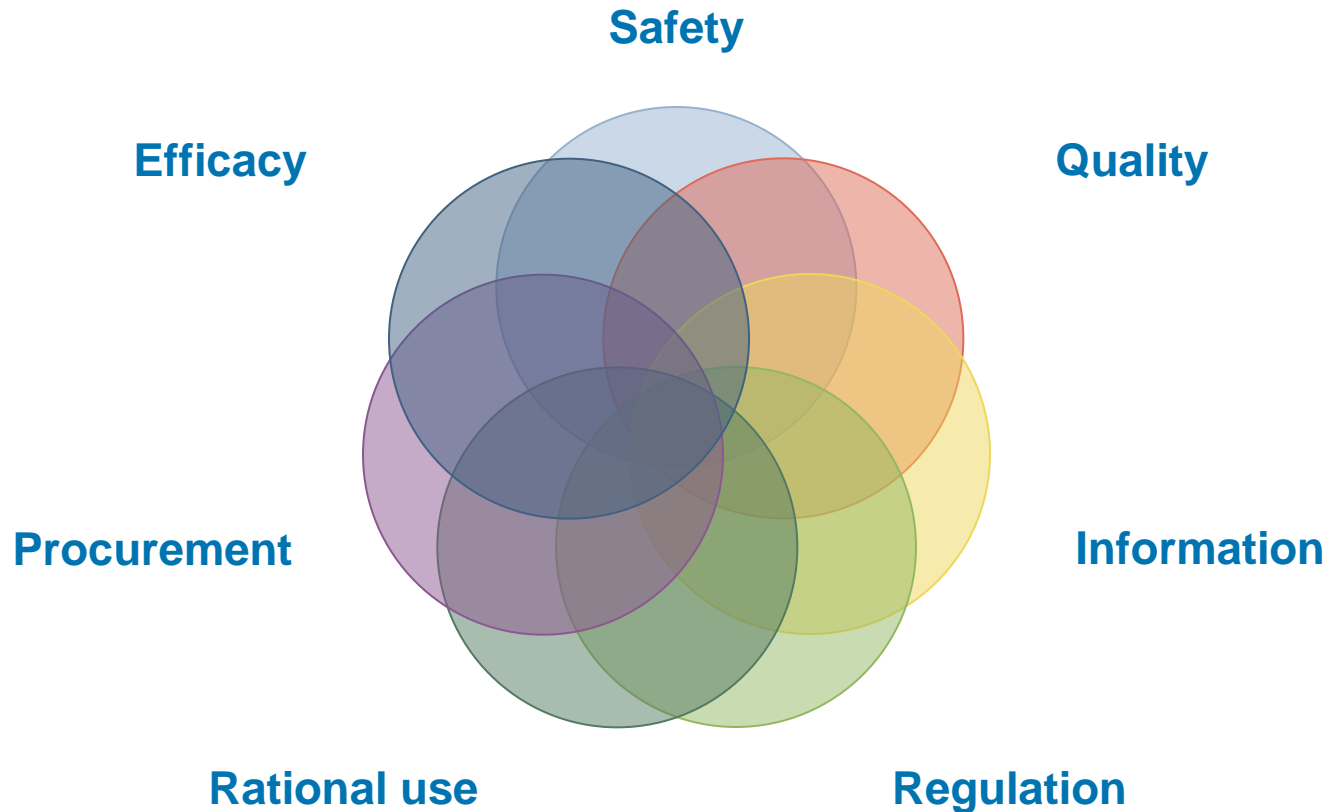
### INNs

A single name for a substance for use globally

*sofosbuvir*  
*now in Essential*  
*Medicines List to*  
*treat*



# What's in a name?

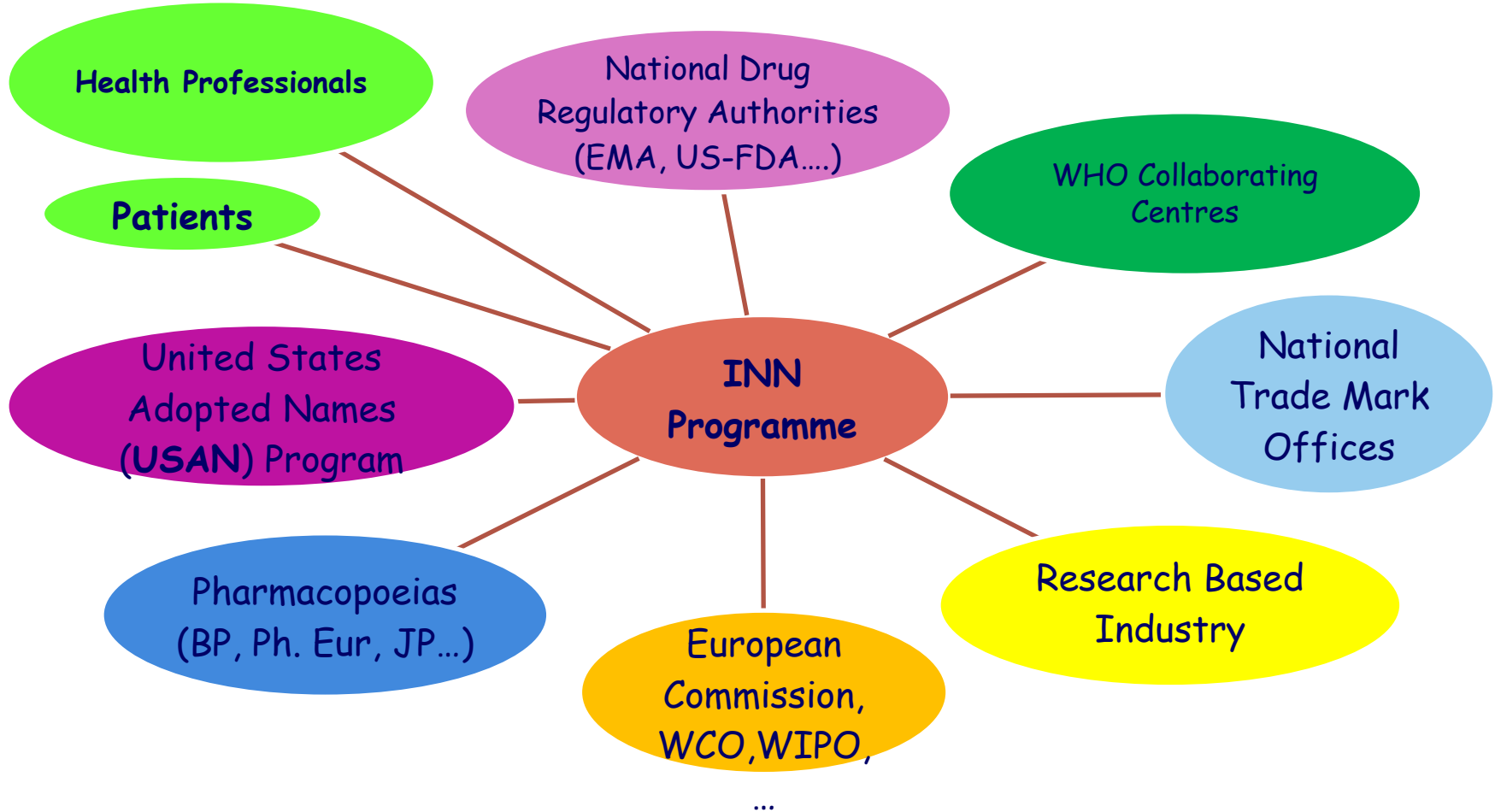


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## "Ad hoc" meetings

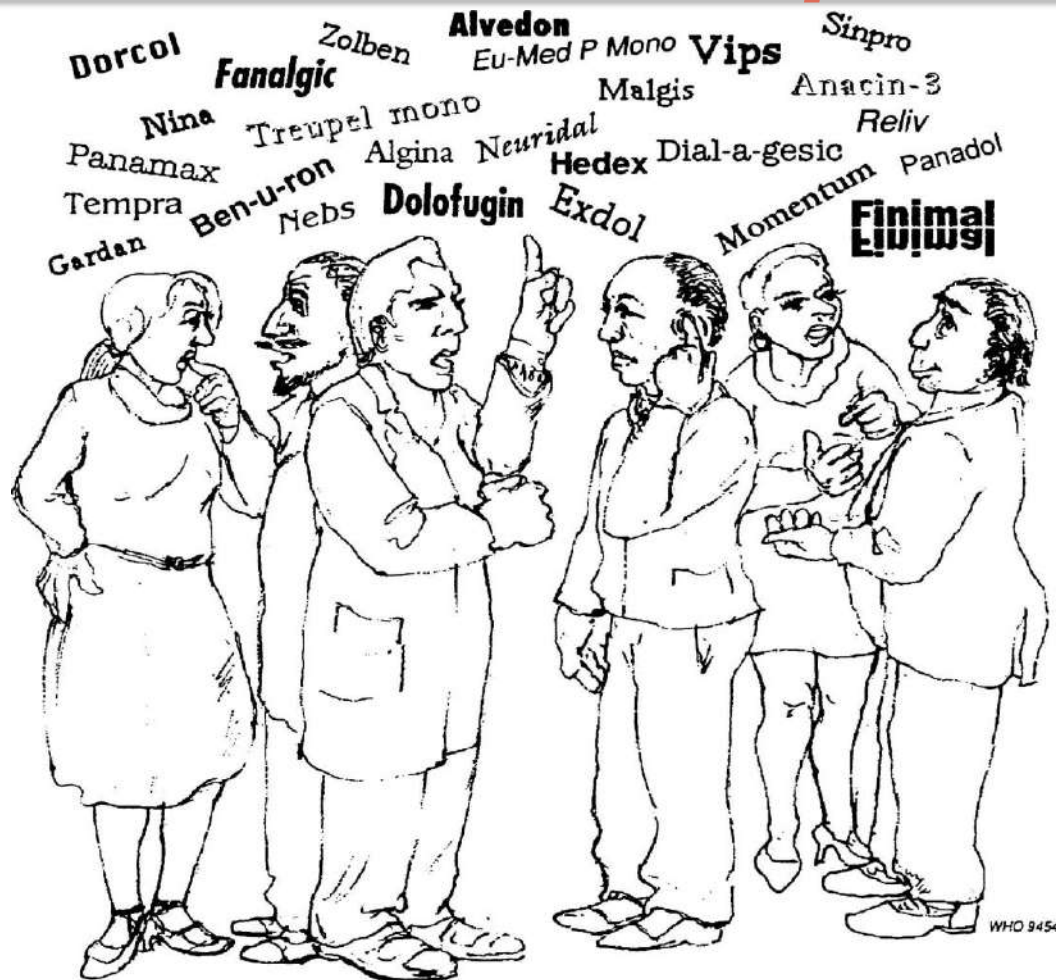
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# INN stakeholders





# 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





# INNs

**Ebola**



*galidesivir*

**Hepatitis C**



*sofosbuvir  
(now in EML)*

**Monoclonal Antibodies**



*trastuzumab emtansine  
FDA ado-trastuzumab*

# 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'
    - Fantasy prefix + **-stem** as a suffix: tazob**actam** (63)(29)
    - Fantasy prefix + **-stem-** as an infix: misop**rostol** (47)(22)
    - **Stem-** as a prefix +fantasy suffix: **cef**uroxime (34)(16)
  - INN and stems have protection within trade mark arena
  - WHO publication "*The use of stems in the selection of INN* "  
Stem book 2013 + Addendums
  - pre-stems list

# INN Stem: Marketing exercise ?

- -ac            anti-inflammatory agents, ibufenac derivatives  
-coxib        selective cyclo-oxygenase inhibitors .....
- -pristone    -prisnil        -pris-
- "Guidance on the establishment of new INN stems"  
(INN Working Doc. 07.215)

# Biological groups with INN stems

| Name of the group  | Stem                        | Name of the group  | Stem            |
|--|-----------------------------|--|-----------------|
| Antimicrobial, bactericidal permeability increasing polypeptides | <i>-ganan</i><br>(pre-stem) | Heparin derivatives including low molecular mass heparins  | <i>-parin</i>   |
| Antisense oligonucleotides                                       | <i>-rsen</i>                | Hirudin derivatives  | <i>-irudin</i>  |
| Aptamers, classical and mirror ones                              | <i>-apt-</i>                | Immunomodulators, both stimulant/suppressive and stimulant | <i>-imod</i>    |
| Blood coagulation cascade inhibitors                             | <i>-cogin</i>               | Interleukin receptor antagonists                           | <i>-kinra</i>   |
| Blood coagulation factors  | <i>-cog</i>                 | Interleukin type substances                                | <i>-kin</i>     |
| Cell therapies   | <i>-cel</i>                 | Monoclonal antibodies                                      | <i>-mab</i>     |
| Colony stimulating factors                                       | <i>-stim</i>                | Oxytocin derivatives                                       | <i>-tocin</i>   |
| Enzymes  | <i>-ase</i>                 | Peptides and glycopeptides                                 | <i>-tide</i>    |
| Erythropoietin type blood factors                                | <i>-poetin</i>              | Pituitary hormone-release stimulating peptides             | <i>-relin</i>   |
| Gene therapies   | <i>-gene</i>                | Receptor molecules, native or modified                     | <i>-cept</i>    |
| Gonadotropin-releasing hormone (GnRH) inhibiting peptides        | <i>-relix</i>               | Small interfering RNA                                      | <i>-siran-</i>  |
| Growth factors and Tumour necrosis factors (TNF)                 | <i>-ermin</i>               | Synthetic polypeptides with a corticotropin-like action    | <i>-actide</i>  |
| Growth hormone (GH) derivatives                                  | <i>som-</i>                 | Vasoconstrictors, vasopressin derivatives                  | <i>-pressin</i> |

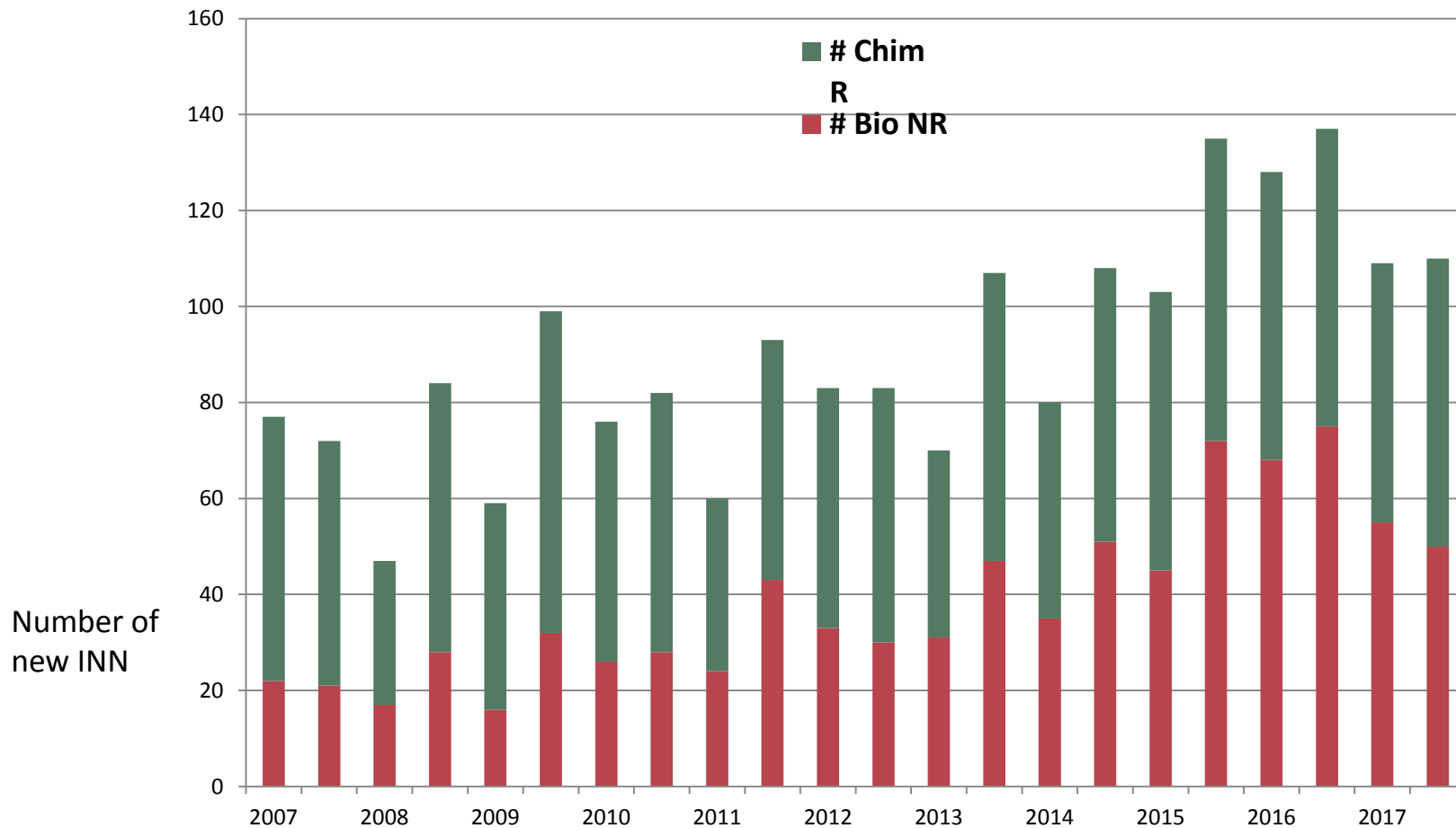


# Reaching the world

- 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
- School of International Nonproprietary Names - SoINN



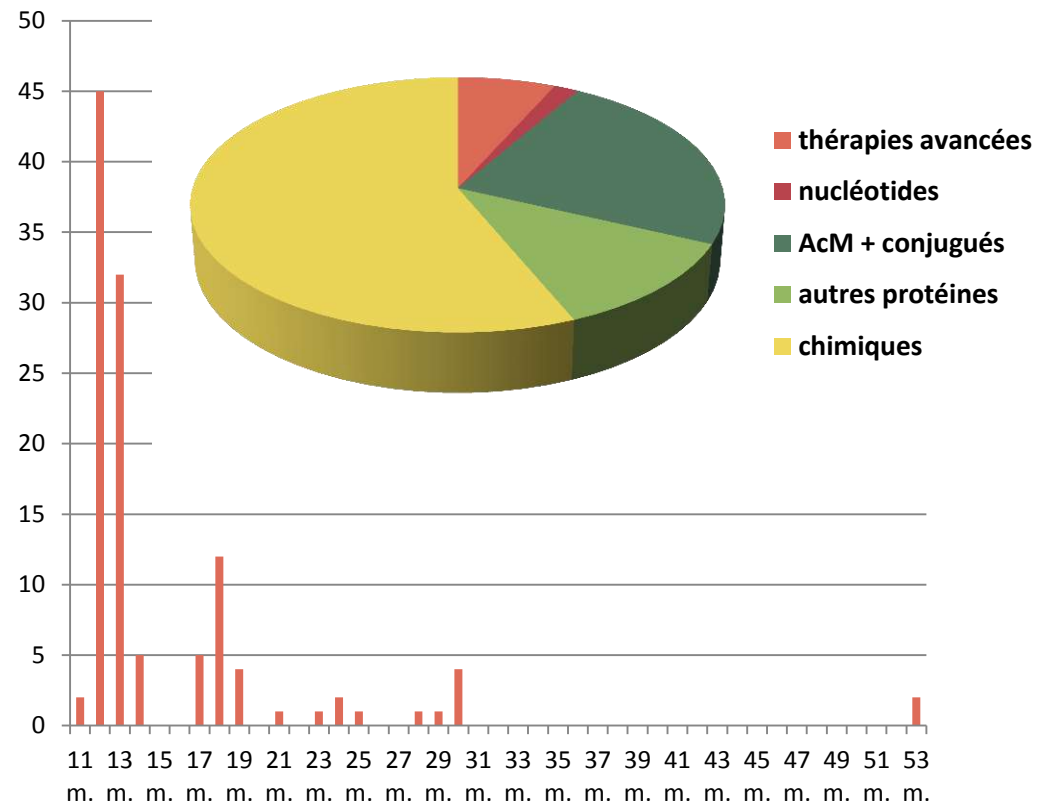
# INN: the last 11 years



# List 118 of Proposed INN in Nrs

- 10 experts and advisers
- Trilingual plus Latin
- 119 PINN published
- 46% biologicals

dossiers

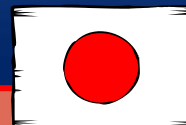


# INN A Global Name?

epoetin alfa (2x)  
epoetin zeta



epoetin kappa  
(generic recombination)  
epoetin alfa biosimilar 1



epoetin lambda





# Naming of biologicals



# School of INN





# Background to the Survey

In the discussion on establishing a School of INN (SoINN) it was suggested to conduct a survey to solicit information on the familiarization and usage of INN.

The intent of the survey:

To have a quick overview of the use of INN in practice and education

To identify gaps for developing a strategic framework for the SoINN

To identify potential projects for the School of INN





# INN Survey

Short online survey was designed

10 statements on INN familiarization/  
usage

Answer on a 5-point Likert Scale + I do  
not know” response.

Small sample of institutions and  
organizations (Universities, MedNet,  
Prescrire, FIP, IUPHAR).

English & French.

1 month (March 2016)

Data was collected and analyzed for  
presentation.

|    | Statements   | Strongly<br>Disagree | Disagree | Somewhat<br>Disagree,<br>Somewhat<br>Agree | Agree | Strongly<br>Agree | I Do<br>Not<br>Know |
|----|--|----------------------|----------|--|-------|-------------------|---------------------|
| 1  | I am aware that INN stands for International Nonproprietary Name for pharmaceutical substances.  |                      |          |  |       |                   |                     |
| 2  | The International Nonproprietary Name of a pharmaceutical substance is also known as the generic name.   |                      |          |  |       |                   |                     |
| 3  | The International Nonproprietary Name of a pharmaceutical substance may appear in several brand names that come from different manufacturers.  |                      |          |  |       |                   |                     |
| 4  | Pharmaceutical substances belonging to the same therapeutic or chemical class share the same stem in the International Nonproprietary Name.  |                      |          |  |       |                   |                     |
| 5  | The stem in the name “trastuzumab” is “mab”, indicating that the substance is a monoclonal antibody.   |                      |          |  |       |                   |                     |
| 6  | The World Health Organization collaborates closely with INN experts and national nomenclature committees to select a single name of worldwide acceptability for each active pharmaceutical ingredient. |                      |          |  |       |                   |                     |
| 7  | The name “acetaminophen” is an US Adopted Name while “paracetamol” is the International Nonproprietary Name.   |                      |          |  |       |                   |                     |
| 8  | At the university I attended, health sciences programmes use only brand names of drugs in the instruction.   |                      |          |  |       |                   |                     |
| 9  | In my country, when physicians prescribe medications they always use International Nonproprietary Name.  |                      |          |  |       |                   |                     |
| 10 | When a pharmaceutical substance is converted to a salt or an ester, a modified International Nonproprietary Name is given.   |                      |          |  |       |                   |                     |







# Respondents

- Total Respondents = 1,074
  - English responses = 435 (40.5%)
  - French responses = 639 (59.5%)
- Responses came from 68 countries
- Gender = Male (432), Female (642)
- Age Range = 16 to 76 years old
- Professionals
  - Academics, Healthcare Providers, Scientists, Industrialists, Regulators, Students
  - Years of Experience for Professionals: 1-50 years
  - Years of Study for Students: 1-5 years

| Country of residence   | Number of Responses |
|------------------------|---------------------|
| South Africa           | 65                  |
| Singapore              | 57                  |
| Italy                  | 46                  |
| USA                    | 33                  |
| Spain                  | 23                  |
| France                 | 20                  |
| Germany                | 20                  |
| Switzerland            | 18                  |
| UK of GB and N Ireland | 17                  |
| China                  | 10                  |
| Japan                  | 10                  |
| Others                 | 116                 |
| Total                  | 435                 |

| Pays de résidence | Number of Responses |
|-------------------|---------------------|
| France            | 633                 |
| Algeria           | 2                   |
| Spain             | 2                   |
| Italy             | 1                   |
| South Africa      | 1                   |
| Total             | 639                 |

Canada, Croatia, Australia, India, Russian Federation, Finland, Ireland, New Zealand, Peru, Portugal, Brazil, Costa Rica, Netherlands, Norway, Austria, Belgium, Chile, Colombia, Czech Republic, Denmark, Iceland, Malta, Mexico, Nigeria, Poland, Republic of Serbia, Sweden, Argentina, Bangladesh, Bulgaria, Cote d'Ivoire, Cuba, El Salvador, Hungary, Indonesia, Kenya, Kyrgyzstan, Latvia, Libyan Arab Jamahiriya, Malawi, Malaysia, Mongolia, Namibia, Philippines, Qatar, Republic of Korea, Romania, Rwanda, Saudi Arabia, Slovenia, Thailand, Turkey, Uganda, Uruguay, Venezuela, Vietnam





# Respondents

## English Survey

| Profession    | Number | Percent |
|---------------|--------|---------|
| Student       | 125    | 29      |
| Pharmacist    | 74     | 17      |
| Academic      | 67     | 15      |
| MedNet Member | 42     | 10      |
| Scientist     | 39     | 9       |
| Regulator     | 30     | 7       |
| Manufacturer  | 27     | 6       |
| Physician     | 24     | 6       |
| Allied Health | 3      | 1       |
| Dentist       | 3      | 1       |
| Nurse         | 1      | 0       |
| Total         | 435    | 100     |

## French Survey

| Profession   | Number |
|--------------|--------|
| étudiant     | 527    |
| pharmacien   | 43     |
| médecin      | 19     |
| scientifique | 19     |
| autre        | 17     |
| chercheur    | 14     |
| Total        | 639    |





# Survey overview

- Generally, most of the participants are aware of the INN.
- A total of 109 comments was solicited and they provided an overview of the usage of INN in practice and education.
- Most university's educational programmes use INN in the teaching but the industry and healthcare sectors may prefer the use of brand names.
- There is a gap in the education of healthcare professionals; even though INN is used in teaching, the students are not familiar with the stem system. A greater understanding of the construct of the INN by the students will help them better appreciate the learning of pharmacology and therapeutics.
- Pharmacy School vs Medical School





# School of INN (SoINN)

The vision of this SoINN is to have the INN used by all stakeholders across the world as a common nomenclature for all pharmaceutical substances.

Current members of the Steering Committee:

- Prof. Sarel Malan, Chair
- Prof. Wai-Keung Chui, Rapporteur
- Dr Gilles Mignot
- Prof. Menico Rizzi
- Dr Raffaella Balocco



Future Members: Dr Jim Robertson, Dr Ana Lopez, Prof. Armando Genazzani

Former Member: Prof. Marie-Paule Lefranc







# School of INN ....more

- Virtual School
- Teaches the INN and Science of Nomenclature for Pharmaceutical Substances
- Develops innovative strategies to promote INN as a central theme for teaching all health professionals
- Publishes book, articles, leaflet for purpose of raising awareness of INN in the scientific community and the educational community
- Develops e-learning platforms for the continuing education of students and health professionals
- Offers e-learning courses
- Identifies Pilot sites for INN education: Friends of INN Universities
- Opens to partners and collaborations
- and.....





# SoINN Platform (under development)

The screenshot displays the 'School OF INN' website. At the top, there is a teal header with the 'INN' logo on the left and a 'Log In' button on the right. Below the header, a navigation bar includes an 'ANNOUNCEMENTS' section with a 'News Item two...' link. The main content area features three blue banners: the first is the 'World Health Organization INN Programme Official Site' logo; the second is the 'MedNet' logo with the tagline 'Communities for Scientific collaboration, information exchange and sharing'; and the third is the 'World Health Organization' logo with a 'Request a New INN Name' link. Below these banners, a section titled 'The School of INN' contains a video player showing a cartoon of five anthropomorphic animals (a bear, a penguin, a dog, a chicken, and a cat) standing in a line. The video player has a progress bar at 1:13 / 2:53. To the right of the video, there is a 'Navigation' sidebar with links to 'Home', 'Site announcements', 'Courses', 'Miscellaneous', 'Test\_Co\_1', 'Mednet', 'Mednet\_Search', and 'School of INN'. Below the navigation sidebar is a 'Search INN' section with a search input field, 'Query' and 'Stem' buttons, and a placeholder text 'Your results will appear here'. The footer of the page contains a long horizontal bar with a play button icon and a list of links.





# School of INN



# INN IS SIMPLE

“Simplicity is the ultimate sophistication”



Leonardo Da Vinci



# Thank you - Grazie

- Web site:  
<http://www.who.int/medicines/services/inn/>
- Publications:  
[http://www.who.int/medicines/services/inn/publication/en/index.html.](http://www.who.int/medicines/services/inn/publication/en/index.html)
- Extranet: [Mednet - INN Extranet](#)
- Vidéo sur YouTube:  
<http://origin.who.int/medicines/multimedia/en/>
- [SOINN : Live in January](#)