International Nonproprietary Names
Workshop Pharma I
AIPPI 5-11 September, Helsinki

World Health Organization
"Some activities undertaken by WHO are largely invisible, quietly protecting the health of every person on this planet, every day. 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 – Working for Health: An introduction to the WHO
WHO some basic facts

- 193 Member States

- Two governing bodies:
  - World Health Assembly
  - Executive Board

- WHO Secretariat:
  - HQ
  - six Regional Offices
  - WHO Expert Panels
    (e.g. on the International Pharmacopoeia and Pharmaceutical Preparations etc.)
  - Constitution 1946, in force since 7 April 1948 (World Health Day)

- ↑ Article 2 (u) International standards
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
- Insulin human (48)(22)
The WHO International Nonproprietary Name (INN) Programme

- WHO has responsibility to develop, establish and promote international standards for pharmaceutical and biological products
- Need for universally available and accepted name for drug substance
- INN is a unique generic name that is recognized globally and is public property
- Intended for use in drug regulation, prescription, pharmacopoeias, labeling advertising, scientific literature
Interested parties outside WHO

- INN Programme
- USAN Program
- Pharmacopoeias (BP, FP, JP, ...)
- DRAs (EMEA, US-FDA, ...)
- National trade-mark authorities
- Research based industry
- European Commission, WCO, WIPO, ...
International Nonproprietary Name (INN) Programme
What's in a name?
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, (hence their designation as nonproprietary)
- can be used without any restriction to identify pharmaceutical substances
The INN System

- WHO Secretariat
- INN Expert Group
  - Can call on further experts if necessary
  - INN Advisory Group on Biologicals
- Publications
INN selection process

- Secretariat receives INN applications
- Consultation / INN Expert Group
- Secretariat informs applicants
- Validation of Information
- Published in a List of proposed INN
- 4-month period for objections and comments
- Published in a List of recommended INN
Protection

WHA46.19 requests Member States:

1) to enact rules and regulations, as necessary to ensure that INNs ... used in the labelling and advertising of pharmaceutical products are displayed prominently;

2) to encourage manufacturers to rely on their corporate name and the INNs, rather than on trade marks, to promote and market multisource products introduced after patent expiration;

3) to develop policy guidelines on the use and protection of INNs, and discourage the use of names derived from INNs, and particularly names including established INN stem as trade-marks.
INN Protection

INNs have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use... they are formally placed by WHO in the public domain.

INN Leaflet for TM departments.
(-)-6(2amino-phenylacetamido)-3,3-demethyl-7-oxo-4-thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid

ampicillin

[3B-L-lysine,29B-L-glutamic acid]insulin (human)
General Principles in devising INN

- INN should not be too long
- Isolated letters, numbers to be avoided
- Anatomical, physiological, therapeutical connotations, trademarks conflicts to be avoided (cardioprofen, superprofen, cancerprofen, panadolprofen)
- Transliteration issues
  - "f" instead of "ph"
  - "t" instead of "th"
  - "i" instead of "y"
  - avoid "h" and "k"
INN Lists

- INNs Lists 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.

- About 8500 INNs have been published


- On-line INN information: **Mednet - INN Extranet**
Statistics on List 108 of p.INN

- 74 names
- 40% biologicals (proteins, GTP…)
- 11.3 months as an average
- Nearly 100% pub. after 1 or 2 rounds of discussion
## INN in a proposed List – in practice

<table>
<thead>
<tr>
<th>afuresertibum (108)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>afuresertib</td>
<td>(N-[(2S)-1\text{-amino}-3-(3\text{-fluorophenyl})\text{propan-2-yl}]5\text{-chloro}-4-(4\text{-chloro-1-methyl-1H-pyrazol-5-yl})\text{thiophene-2-carboxamide}) antineoplastic</td>
</tr>
<tr>
<td>afurésertib</td>
<td>(N-[(2S)-1\text{-amino}-3-(3\text{-fluorophényl})\text{propan-2-yl}]5\text{-chloro}-4-(4\text{-chloro-1-méthyl-1H-pyrazol-5-yl})\text{thiophène-2-carboxamide}) antinéoplasique</td>
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<tr>
<td>afuresertib</td>
<td>(N-[(2S)-1\text{-amino}-3-(3\text{-fluorofenil})\text{propan-2-il}]5\text{-cloro}-4-(4\text{-cloro-1-metil-1H-pirazol-5-il})\text{tiофено-2-carboxамida}) antineoplásico</td>
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<td>(\text{C}<em>{18}\text{H}</em>{17}\text{Cl}<em>{2}\text{F}\text{N}</em>{4}\text{OS}) 1047644-62-1</td>
</tr>
</tbody>
</table>
INN Cumulative List 14

- **Portable format**
  - Information over 8500 published INN (names, structures, …)

- **Published every two years**

- **Searchable database**
  - All or part of name (e.g. -profen)
  - In the six UN official languages
  - CAS RN
  - Alternate names
  - ATC (Anatomic Therapeutic Chemical) codes
  - Etc…
Use of stems

➢ Names of "pharmacologically-related" substances have a common stem

- To indicate chemical and/or pharmacological group relationship
- Published for 'established series of related compounds'
- WHO publication 'The use of stems in the selection of INN'
- INNs and stems have protection within trade mark arena
- Stem book 2011+ Addendum (when necessary)
- pre-stems list
Number of Biological requests

Medicines on the market

New medicines in development

Bio.INN applications / total INN applications

Dr R. Balocco Mattavelli, INN Programme Manager
AIPPI Forum & ExCo – Workshop Pharma I
6 September 2013, Helsinki

World Health Organization
## General policies

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood products</td>
<td>natural excluded</td>
</tr>
<tr>
<td>Fusion proteins</td>
<td></td>
</tr>
<tr>
<td>Gene therapy products</td>
<td></td>
</tr>
<tr>
<td>Glycosylated proteins/peptides</td>
<td></td>
</tr>
<tr>
<td>Non-glycosylated proteins/peptides</td>
<td></td>
</tr>
<tr>
<td>Immunoglobulins</td>
<td>excluded</td>
</tr>
<tr>
<td>Monoclonal antibodies</td>
<td></td>
</tr>
<tr>
<td>Skin substitutes</td>
<td>excluded</td>
</tr>
<tr>
<td>Transgenic products</td>
<td></td>
</tr>
<tr>
<td>Vaccines</td>
<td>most excluded</td>
</tr>
<tr>
<td>Cell therapy products</td>
<td>under discussion</td>
</tr>
</tbody>
</table>
Current INN position for biological products

- 20 biological groups with stems
- 5 groups with an INN nomenclature scheme
- Generals policies developed for 10 groups of biological products
- 'INN for biological and biotechnological substances a review'
  [http://www.who.int/medicines/services/inn/INN_Biorev11-06.pdf](http://www.who.int/medicines/services/inn/INN_Biorev11-06.pdf)
Current challenges

- The complexity of substances
- The number-induced difficulty
- The emerging of new types of substances (new policies?)
IT for INN…the amazing world

- Online submissions
- INN IDMIS - Integrated Data Management System
- INN Virtual consultations
- INN Global Data Hub
- E-archive project
- INN Mednet: [http://mednet-communities.net/inn](http://mednet-communities.net/inn)
- and more....
INN Data Hub: collaborative network...
...for a global data hub

Software Company

Pharmaceutical Industry

National Authorities and various organizations

WIPO
FDA
USP
DRAs
IMGT

SIB-University of Geneva
BPh
ANSM
VIDAL

Dr R. Balocco Mattavelli, INN Programme Manager
AIPPI Forum & ExCo – Workshop Pharma I
6 September 2013, Helsinki
Best friends

- WHO colleagues
- WHO Experts and Advisors
- Nomenclature bodies, DRAs and Pharmacopeias
- WIPO
- WCO
- Industry and consumer groups
- And many, many more...
Thank you


Děkuji! Tak skal du have! Dankon! Hvala, Hvala lepa, Najlepša hvala Gracies! Faleminderit Hvala! Ačiū, De'koju, Labai ačiū ขอบคุณ ;ขอบคุณมาก (khàwp khun) ; (khàwp khun mâak) shukriya (شكریه) (shokran Ευχαριστώ! 감사합니다)

Thank you! Thank you! Thank you! Merci! Obrigado! Gracias 謝謝！ありがとうございました! ARIGATOU! Danke! Dziękuję! Dank je / u! Mulțumesc! Teşekkür ederim! Tack! Tack så mycket Grazie! Kiitos! 謝謝！ お礼！ ARIGATOU 感謝します！

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http://mednet.who.int/

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