SOME RULES FOR THE VIRTUAL MEETINGS
Our interactive session:

- Everybody is on mute
- You post your question in the Q&A facility
- When you speak, please keep concise
- You may show your approval!

After (and during) the introduction presentations, any UNICOM related question / comment may be shared with Q&A
Asking a question or making a comment: please use the Q&A facility

1. Move the mouse on the screen to have the options bar appearing

2. You then select «Q&A» and write your question

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Showing support and providing a comment on a question or answer

You can support a question by clicking the «thumbs up» which moves it up on the list for the presenters.

You can comment on a question or answer to engage in a conversation.

Typing and sending a new question does not retain the context of your comment.

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299.
Security

- Security is our priority
- This session is password protected

Recording of this session is made available on UNICOM’s youtube channel https://www.youtube.com/channel/UCBsNj4B33Q7-50XTXdqAGlg

At the end of the virtual session, a questionnaire will be sent to the participants, to help us understand participant’s reactions and needs
Introductions to our esteemed colleagues and today's speakers

Robert Vander Stichele
Mohammad Nouri Sharikabad
Malin Fladvad

...and our panellist

Annet Rozema
Olof Lagerlund
Jean-Gonzague Fontaine
Dipak Kalra

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Questions in the Q & A facility, please
For feedback, please go to: https://forms.gle/YAq3XqvGodyNDw2p9

Thanks for your time
Steps to make IDMP relevant for Clinical Care:
The importance of linking the Pharmaceutical Product Identifier (PhPID) to international drug Classifications

Robert Vander Stichele, I-HD
WP1 Community of Experts Webinar
February, 2022
Workpackage 8 in UNICOM

IDMP and Clinical Care

What have been achieved?

Motivation to focus on the procedure for PhPID production

What were the breakthroughs with regard to PhPID production?

Substance, dosage form, Strength

The role of WHO UMC and WHO Oslo

Applications in drug information applications and decision support systems
Achievements in Work Package 8
What have been achieved in Workpackage 8?
(half way through the UNICOM project)

**Interesting deliverables**

On Clinical Care  
D8.1  (Approved)

on Research  
D8.2  (Approved)

on Pharmacovigilance  
D8.7  (Approved)

on Pharmacogenetics  
D8.9  (Approval pending)

**Focus on the minimal data set for PhPID-Level IV production**

Resolving issues in description of
- substance
- dose form
- strength codes

to feed the algorithm that produces a global Pharmaceutical Product Identifier

**Starting to think about concrete applications**

to be developed in the second half of the UNICOM project
Motivation to focus on the production of the Pharmaceutical Product Identifier PhPID Level IV
Motivation for the focus on PhPID production

1. All pilots in UNICOM need sufficiently large datasets for experimenting concrete projects that demonstrate the value of IDMP.
   1. To enable the cross border Pilots of WP5 and WP7 (minimal dataset)
   2. To feed the ambitious demonstrators in task 1 of Workpackage 8
   3. To realize concrete Patient-facing apps (more than a mock up)
   4. To support initial steps of readiness of NCAs for IDMP

2. The fear of delay in the official channels
   1. Delay in the EU Implementation Guide (no mentions yet of PhPID production procedure).
   2. Initiating concertation in the Global IDMP Working Group (GIDWG) between FDA/EMA/WHO_UMC
   3. Covid-19 burden within NCAs

⇒ the possibility that before the end of the unicom project in 2023 there will be no sufficiently big data set of medicinal products from a minimal number of countries
Remedial actions

The UNICOM Pilot Product List
1. A list of 35 substances
2. Collection of relevant modifiers and codes for each of these 35 substances (with the help of WP2 and the EU Substance cleansing team SMS)

A proposal for the development of an IDMP FHIR Server solution
Full implementation of IDMP within NCAs focusing on a few products, based on evolving versions of the EU Implementation guide

A proposal (WP8 and WP1) for collaboration with WHO_UMC
taking advantage of the WHO-UMC/FDA pilot
Focusing on procedures for PhPID production

Establishement of a minimal data set for Cross border eHealth Pilots
including Substance, dose form, Strength
In this Community of Experts Meeting three parts

Initiatives within Workpage 8 (Task 8.1)

Remaining issues in PhPID-Production for substance, dose form, strength (D8.1) as identified in the Gap Analysis in WP1

Creation of a repository of PhPID and minimal data (for WP6 software factory)
- starting with the 35 substances of the Unicom Pilot Product List
- for a collection of national medicinal products from a number of countries
- for the pilots of UNICOM on short notice (mid 2022)

Creation of a link from PhPID to international drug classifications

Report on the current activities of WHO_UMC
Malin Flavad, WHO_UMC

Report on efforts to create links between WHO ATC Classification and IDMP
Mohammad Nouri Sharikabad, Mohammad, WHO-OSLO
Remaining issues in PhPID-Production
Focus on PhPIDID production

Medicinal Product in country A
Medicinal Product in country A

- Substance ID
- Dose form
- Strength
Focus on PhPIDID production

Medicinal Product in country A

Substance ID  Dose form  Strength

PhPID level 4
128 bit number
Focus on PhPID production

Medicinal Product in country A

Substance ID

Dose form

Strength

PhPID level 4
128 bit number

ATC – classification
And other international drug Classifications
Focus on PhPIDID production

Medicinal Product in country A

Substance ID ➔ Dose form ➔ Strength

PhPID level 4
128 bit number

Intermediate aggregation level
Based on an ontology of substance and dose form

ATC – classification
And other international drug Classifications
Information inherent to the PhPID Level 4 number

<table>
<thead>
<tr>
<th>PhPID level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>128 bit number</td>
</tr>
</tbody>
</table>

Reference substance

Dose form (EDQM)

Strength
Information inherent to the PhPID Level 4 number

PhPID level 4
128 bit number

Reference substance

Dose form (EDQM)

Strength

Basic dose form
State of matter
Release characteristics
Intended Site
Administration Method
Information inherent to the PhPID Level 4 number

PhPID level 4
128 bit number

Reference substance

Dose form (EDQM)

Strength

Basic dose form
State of matter
Release characteristics
Intended Site
Administration Method

INN prescription instruction

ATC – Code
Information inherent to the PhPID Level 4 number

Medicinal Product in country A

PhPID level 4
128 bit number

Reference substance

Dose form (EDQM)

Strength

INN prescription instruction

ATC – Code

Basic dose form
State of matter
Release characteristics
Intended Site
Administration Method
Remaining Issues regarding PhPID production

Substance

Dose form

Strength
Substance
The great work in the European Substance Management System cleansing team

Terminology of substance: synonyms, spelling differences

Differentiating between Substance and Reference substance, when needed (moiety with or without a modifier)

Identify all relevant modifiers of a substance, if appropriate

Based on a practice reality check for number of occurrences in adverse event reports
The distinction between 2 kinds of precise active ingredients

- modified substance: amlodpine besilate
- moiety without modifier: carbamazepine

The distinction between 2 kinds of moieties

- the ionized moiety: amlodpine
- moiety without modifier: carbamazepine
The distinction between meanings of the same term representing different concepts

<table>
<thead>
<tr>
<th>Three meanings of a substance term</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amlodipine (1)</strong></td>
<td>Term for the physical reality of a chemical molecule, which constitutes the active part of an ingredient with therapeutic role. This molecule has a chemical structure, molecular mass, a code in the CAS-system, and a mechanism of action.</td>
</tr>
<tr>
<td><strong>Amlodipine (2)</strong></td>
<td>Term for the collection of modified substances (amlodipine besilate, mesilate and maleate), which all contain amlodipine (1)</td>
</tr>
<tr>
<td><strong>Amlodipine (3)</strong></td>
<td>Term for the collection of medicinal products that contain any one of the 3 modified substances (named with amlodipine (2)), and no other ingredients with an active role. A medicinal product can be entered in the collection even if the modifier is unknown.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Two meanings of a modified substance term</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amlodipine besilate (1)</strong></td>
<td>Term for the physical reality of a chemical molecule, consisting of the active part and the salt. This molecule has a chemical structure, molecular mass, a code in the CAS-system, and a mechanism of action</td>
</tr>
<tr>
<td><strong>Amlodipine besilate (2)</strong></td>
<td>Term for the collection of medicinal products containing this specific modified substance</td>
</tr>
</tbody>
</table>
Three ways of dealing with combinations of medicinal product

1. Single X and combinations with x in separate classes

2. Single X as a subset of all combinations containing x

3. Single and combinations in one class, linked to a database of substantced with the role of precise active ingredients
Three ways of dealing with aggregation of medicinal product combinations

1. Single X and combinations with x in separate classes

2. Single X as a subset of all combinations containing x

3. Single and combinations in one class, linked to a database of substances with the role of precise active ingredients

Different solutions are tested for the use case of PhPID production.

Different solutions can fit different use case
Dose form
Progress with regard to Dose form

- The choice between Manufactured dose form vs Administrable dose form

- The choice of granularity of dose form
  - Full EDQM?
  - Combination of Characteristics (as in the FDA/WHO_UMC pilot)?

- The choice of the coding system

- European EDQM and/or a Global coding system?

- The creation of an ontology of dose forms based on EDQM

- The acknowledgement of the need for training of industry and regulatory experts to standardize the dose forms in national MPDs to EDQM
Strength
Harnessing the intricate relationship between expression of strength, on the one hand, and substance and dose form, on the other hand
Harnessing the intricate relationship between expression of strength, on the one hand, and substance and dose form, on the other hand.

Input: Substance ID

- Substance
  - Versus Reference substance
- Dose form
  - Pattern of dose form

Output: Strength

- Concentration Strength or Presentation Strength
Creation of a repository of PhPIIDs and minimal data (for WP6 software factory)
Build a repository of Pharmaceutical product Identifiers

Pharmaceutical product

With all the inherent information (substance, dose form, strength) and characteristics of dose form
Creation of a repository of PhPIIDs and minimal data (for WP6 software factory)
Add an ontological Layer

Mechanically constructed from the ontology of substance and dose form
To aggregate clinically similar PhPIPs
For the purpose of
INN prescribing and fair substitution
Link to the Anatomical Therapeutic Chemical Classification (ATC)
And from there semantic interoperability to all other clinical drug classifications.

Drug Ontology

- RX-NORM
- SNOMED-CT
- ATC+ROA

VirtualMP Group

Pharmaceutical product

Country A

Country B
Planned applications in the clinical field
Planned applications for IDMP in Clinical Care during UNICOM (pilots)

- Connecting European Decision Support systems to the medicinal drug dictionaries of Europe

- Connecting European Drug Information Services to the healthcare providers, care givers, and patients of the member states

- Connecting European digital platforms for teaching prescribing and medication management to physicians to pharmacists and nurses of the member states

- Making the cross border projects work in relatively short term (ePrescription, eDispensing, International Patient Summary)

Making evidence, clinical information, prescriptions, and patients cross the borders
THANK YOU
The ATC/DDD classification
- aligning ATC with IDMP

Mohammad Nouri Sharikabad, Dr. Philos. M. Pharm.
Department director, Department of Drug Statistics and
WHO Collaborating Centre for Drug Statistics Methodology

Norwegian Institute of Public Health
4 February 2022
Aim of this presentation

• The ATC/DDD system; what, why and how

• Use of the ATC/DDD system

• How and where is ATC incorporated in different systems in Norway

• Summary and some concluding remarks
The Anatomical Therapeutic Chemical (ATC) /Defined Daily Dose (DDD) ; what, why and how

• A WHO recommended standard with hierarchic drug classes (5 levels)

• A central methodological tool for drug utilization and pharmacoepidemiology

• DDD is a unit of measurement and quantifies drug consumption

• Globally used and accepted, maintained by the ATC/DDD Centre under the guidance of WHO appointed experts

• New ATC codes and DDDs are assigned on request by pharmaceutical companies, health authorities and other users of the ATC classification system
DDD and its use

The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults

• Unit of measurement independent of strength, package, price
• International comparisons and comparisons over time
• Indicators for use of medicines
Role of the ATC/DDD system

The purpose of the ATC/DDD-system is to collect and improve drug use. It is with this purpose in mind that all decisions about ATC/DDD assignment and alterations are made.
Visions and ambitions of the ATC/DDD system

“International language for drug utilization monitoring and research” almost for five decades
How and where is ATC is incorporated in different systems in Norway

Examples

• Norwegian Product Register (Farmalogg) a coop. between many stakeholders
• Prescribing support system (FEST) administered by the Norwegian Medicines Agency
• National Health registries and data bases
• Electronic Patient Records in primary and secondary health care
• Medicine catalogue (Felleskatalogen)
• Norwegian medicine handbook (NLH)

(And internationally: Medicinal dictionaries e.g., WHODrug Global and international drug textbooks such as Martindale)
Norwegian product register / The-Article-Number-Register

The Norwegian Pharmacy Association and the three (main) drug wholesaler in Norway established the Norwegian product register (Famalogg). There is further collaboration with:

- Norwegian Medicines Agency,
- The Norwegian Health Economics Administration
- WHO Collaborating Centre for Drug Statistics Methodology

This is how the Norwegian product register is maintained, updated and administered. Updated register is distributed twice monthly to pharmacies, pharmaceutical wholesalers and other subscribers

https://www.farmalogg.no/en/The-Article-Number-Register/
Example of a quality assured file for updating of the Norwegian Product Register

<table>
<thead>
<tr>
<th>MPPi</th>
<th>Article name</th>
<th>Quantity</th>
<th>Unit</th>
<th>Strength</th>
<th>ATC code</th>
<th>Substance</th>
<th>DDD UM</th>
<th>ROA</th>
<th>Content</th>
<th>Dose form</th>
<th>OK/NOK</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>315044</td>
<td>Klacid gran til mikst 50mg/ml</td>
<td>100</td>
<td>ML</td>
<td>50mg/ml</td>
<td>J01FA09</td>
<td>clarithromycin</td>
<td>0,5</td>
<td>O</td>
<td></td>
<td>Granulat til m</td>
<td>OK</td>
<td></td>
</tr>
<tr>
<td>294159</td>
<td>Ciproxin gran t mikst 250mg/5ml</td>
<td>100</td>
<td>MLSETT</td>
<td>250mg/5ml</td>
<td>J01MA02</td>
<td>ciprofloxacin</td>
<td>1</td>
<td>O</td>
<td></td>
<td>Granulat og v</td>
<td>OK</td>
<td></td>
</tr>
<tr>
<td>446438</td>
<td>Mektovi 2care4 tab 15mg</td>
<td>84</td>
<td>ENPAC</td>
<td>15mg</td>
<td>L01EE03</td>
<td>binimetinib</td>
<td>0,09</td>
<td>O</td>
<td></td>
<td>Tablett</td>
<td>OK</td>
<td></td>
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<tr>
<td>31172</td>
<td>Kesimpta inj 20mg/penn</td>
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<td>MLPEN</td>
<td>20mg/penn</td>
<td>L04AA52</td>
<td>ofatumumab</td>
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<td></td>
<td></td>
<td>Infeksjonsvæs</td>
<td>NOK</td>
<td>Changed to ATC 5. level code/substance name</td>
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<tr>
<td>188556</td>
<td>Zoledronsyre sun inf 5mg/100ml</td>
<td>100</td>
<td>MLHGL</td>
<td>5mg/100ml</td>
<td>M05BA08</td>
<td>zoledronic acid</td>
<td>4</td>
<td>P</td>
<td></td>
<td>Infusjonsvæs</td>
<td>OK</td>
<td></td>
</tr>
<tr>
<td>523148</td>
<td>Levopidone miks 5mg/10ml endos</td>
<td>7x10</td>
<td>ML</td>
<td>5mg/10ml</td>
<td>N07BC05</td>
<td>levomethadone</td>
<td>0,015</td>
<td>O</td>
<td></td>
<td>Mikstur</td>
<td>OK</td>
<td></td>
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<tr>
<td>553488</td>
<td>Fampridine accord depotab 10mg</td>
<td>28x1</td>
<td>ENDOS</td>
<td>10mg</td>
<td>N07XX07</td>
<td>fampridine</td>
<td>0,02</td>
<td>O</td>
<td></td>
<td>Depottablett</td>
<td>OK</td>
<td></td>
</tr>
</tbody>
</table>

1: Medicinal Product Pack Identifier, 2: Unit of Measurement, 3: Route of Administration, 4: Content of active substance with same unit of measurement as for DDD
ATC – simplification

Facilitating retrieval of medicines

ATC together with DDD

<table>
<thead>
<tr>
<th>DDD unit of measurement</th>
<th>DDD route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit (U), abbreviations</strong></td>
<td><strong>Route of administration (Adm.R), abbreviations</strong></td>
</tr>
<tr>
<td>g = gram</td>
<td>Implant = implant</td>
</tr>
<tr>
<td>mg = milligram</td>
<td>Inhal = inhalation</td>
</tr>
<tr>
<td>mcg = microgram</td>
<td>Instill = instillation</td>
</tr>
<tr>
<td>U = unit</td>
<td>N = nasal</td>
</tr>
<tr>
<td>TU = thousand units</td>
<td>O = oral</td>
</tr>
<tr>
<td>MU = million units</td>
<td>P = parenteral</td>
</tr>
<tr>
<td>mmol = millimole</td>
<td>R = rectal</td>
</tr>
<tr>
<td>ml = milliliter</td>
<td>SL = sublingual/buccal/oromucosal</td>
</tr>
<tr>
<td>(e.g. eyedrops)</td>
<td>TD = transdermal</td>
</tr>
<tr>
<td></td>
<td>V = vaginal</td>
</tr>
</tbody>
</table>
ATC/DDD Index 2022

A searchable version of the complete ATC index with DDDs is available below. The search options enable you to find ATC codes and DDDs for substance name and/or ATC levels. In your search result you may choose to show or hide the text from the Guidelines for ATC classification and DDD assignment linked to the ATC level. The text in the Guidelines will give information related to the background for the ATC and DDD assignment.

Search query

ATC code or name containing query

Search

31 ATC 5th levels in one ATC 1st levels

C09XA53 aliskiren and amlodipine
C09XA54 aliskiren, amlodipine and hydrochlorothiazide
C08CA01 amlodipine
C08CA51 amlodipine and celecoxib
C08GA02 amlodipine and diuretics
C10BX03 atorvastatin and amlodipine
C10BX11 atorvastatin, amlodipine and perindopril
C10BX18 atorvastatin, amlodipine and ramipril
C07FB07 bisoprolol and amlodipine
C09DB07 candesartan and amlodipine
C09DX06 candesartan, amlodipine and hydrochlorothiazide
C09DB09 fimasartan and amlodipine
C09DB05 irbesartan and amlodipine
C09DX07 irbesartan, amlodipine and hydrochlorothiazide
C08CA17 irbesartan, losartan and amlodipine
C09BB03 lisinopril and amlodipine
C09DB06 losartan and amlodipine
C07FB13 metoprolol and amlodipine
C07FB12 nebivolol and amlodipine
C09DB02 olmesartan medoxomil and amlodipine
C09DX03 olmesartan medoxomil, amlodipine and hydrochlorothiazide
C09BB04 perindopril and amlodipine
C09BX01 perindopril, amlodipine and indapamide
C09BX04 perindopril, bisoprolol and amlodipine
C09BB07 ramipril and amlodipine
C09BX03 ramipril, amlodipine and hydrochlorothiazide
C10BX09 rosvastatin and amlodipine
C10BX07 rosvastatin, amlodipine and lisinopril
C10BX14 rosvastatin, amlodipine and perindopril

6 ATC 5th levels in 3 different ATC 1st levels

1. D11AX18 diclofenac
2. M01AB05 diclofenac
3. M01AB05 diclofenac
4. M02AA15 diclofenac
5. S01BC03 diclofenac
6. S01CC01 diclofenac and antinfectives
7. M01AB55 diclofenac, combinations
Medicine search at the Norwegian Medicines Agency (https://www.legemiddelsok.no)
Exchangeable packages (generic substitution) for doctors and pharmacies

<table>
<thead>
<tr>
<th>Handelsnavn</th>
<th>Form og styrke</th>
<th>Antall</th>
<th>V.nr</th>
<th>MT-Innehaver</th>
<th>Merknad til byte</th>
<th>Byttegruppekode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Bluefish</td>
<td>Enterotablett, 25 mg</td>
<td>30 stk</td>
<td>397033</td>
<td>Bluefish Pharmaceuticals AB</td>
<td>Nei</td>
<td>000480</td>
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<td>Voltaren</td>
<td>Enterotablett, 25 mg</td>
<td>30 stk</td>
<td>411650</td>
<td>Novartis Norge (2)</td>
<td>Nei</td>
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<td>100 stk</td>
<td>569010</td>
<td>Bluefish Pharmaceuticals AB</td>
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<td>Ignorin</td>
<td>Tablett, filmdraps, 50 mg</td>
<td>20 x 1 stk</td>
<td>597009</td>
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<td>Catarafm</td>
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<td>100 stk</td>
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<td>Voltaren</td>
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<td>100 stk</td>
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<tr>
<td>Arthrotec</td>
<td>Tablett med modifisert friskinn, 50 mg / 0.2 mg</td>
<td>20 stk</td>
<td>154591</td>
<td>Pfizer AS</td>
<td>Nei</td>
<td>000485</td>
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<tr>
<td>Arthrotec</td>
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<td>100 stk</td>
<td>154705</td>
<td>Pfizer AS</td>
<td>Nei</td>
<td>000485</td>
</tr>
<tr>
<td>Voltarol Forte</td>
<td>Gel, 23.2 mg / g</td>
<td>100 g</td>
<td>392871</td>
<td>GlaxoSmithKline Consumer ApS</td>
<td>Nei</td>
<td>002235</td>
</tr>
<tr>
<td>Voltarol Forte</td>
<td>Gel, 23.2 mg / g</td>
<td>150 g</td>
<td>549214</td>
<td>GlaxoSmithKline Consumer ApS</td>
<td>Nei</td>
<td>002235</td>
</tr>
<tr>
<td>Voltarol Forte</td>
<td>Gel, 23.2 mg / g</td>
<td>180 g</td>
<td>084668</td>
<td>GlaxoSmithKline Consumer ApS</td>
<td>Nei</td>
<td>002235</td>
</tr>
</tbody>
</table>
Challenges - ATC/DDD

• Combinations, especially «old» and «national» (e.g. cough and cold preparations, vitamins and minerals)?
  – Latest 10 to 15 years – all substances listed, less of a challenge.

• Assigning ATC codes without INN or USAN

• Also challenges in the assignment of IDMPs!
ATC/DDD system alongside IDMP

- ATC/DDD system not made for the purpose of identifying medicine packages as IDMP/PhPID does

- ATC/DDD has been a cornerstone for reliable drug data for research and decision-making in Nordic countries alongside the unique medical product pack identifier ("IDMP light").

- DDD is independent of strength, package and price. The number of DDDs in each package should be defined for those products where DDDs are assigned. This is to study and compare consumption over time in different countries.
Alignment of ATC 5th level /ROA with IDMP (PhPID level 4)

“Take home message”

ATC/DDD should be an integrated part of the long-term development of IDMPs and other e-health systems such as electronic patient journals, registries.

- ATC is available in the SPCs (Point 5.1) and in national drug databases and e-health systems
- IDMP/PhPID defines package according to 5 ISO standards in a very detailed manner
- ATC/DDD facilitates aggregation in therapeutic, pharmacological and chemical groups needed for retrieval of information and statistical purposes such as drug utilisation monitoring
- ATC/DDD for drug statistics- and consumption-purposes together with PhPID for detailed identification of pharmaceutical products will give a synergy in the field drug related e-health
Conclusion:
ATC and DDD for drug statistics- and consumption- purposes and PhPID for detailed identification of pharmaceutical products will give a synergy in the field drug related e-health.

ATC classification
DDD assignment (and ROA)

PhPID Level_L4
Substance(s) Term+ Strength + reference strength + Administrable Dose Form

NCA
EHR/eHealth/others
Thank you for your attention

E-mail: whoccc@fhi.no
Procedures for PhPID generation

Malin Fladvad, Uppsala Monitoring centre
Implementation of Global PhPID – achievements & plans

Global PhPID available for all stakeholders

GIDWG pilots: Best practices for PhPID generation

UNICOM and FDA/UMC pilots for global PhPID generation

2019

FIRST PHASE CONCLUDED 2021

2021

Global vaccines initiative

WHO-UMC endorsed as future maintenance organization for Global PhPID

ONGOING

Formation of GIDWG Phase 1: FDA/EMA/WHO-UMC

WHO-UMC endorsed as future maintenance organization for Global PhPID
Harmonisation of data using the ISO IDMP suite of standards

PhPID Set
- PhPID Level_L1  →  Substance(s) Term
- PhPID Level_L2  →  Substance Term(s) +Strength+ reference strength
- PhPID Level_L3  →  Substance Term(s) + Administrable Dose Form
- PhPID Level_L4  →  Substance(s) Term+ Strength + reference strength + Administrable Dose Form
Generation of Global substance ID

- **PhPID**: ISO 11616
- **Substance ID**: ISO 11238
- **Strength**: ISO 11240
- **Dose form**: ISO 11239

Minimal fields

- **UMC-SRS**

**INN**
- Insulin lispro
- Insulin lispro protamine

**Global substance identifier**
- GSID-2ZT4AY1CH-1
- GSID-35V9XJV9Z-5

**Insulin lispro**

**Uppsala Monitoring Centre**
Proposed process for expression of Strength

<table>
<thead>
<tr>
<th>PhPID</th>
<th>Substance ID</th>
<th>Strength</th>
<th>Dose form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 11616</td>
<td>ISO 11238</td>
<td>ISO 11240</td>
<td>ISO 11239</td>
</tr>
</tbody>
</table>

Strength expression based on pattern framework

Pattern | Type of product
---|---
A |  
B |  
C |  
D |  

50 units/ml

<table>
<thead>
<tr>
<th></th>
<th>Code for unit</th>
<th>Code for ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>50.00</td>
<td>37</td>
<td>1.00</td>
</tr>
</tbody>
</table>
Proposed process for expression of Dose form

Assign dose form characteristics according to EDQM

Suspension for Injection

0085 0011 0033 0047

Basic Dose Form code  Adm method code  Intended site code  Release characteristics code
PhPID generation for Humalog Mix50 KwikPen
50 mg/ml of Insulin lispro/Insulin lispro protamine suspension, solution for injection

PhPID

Input string

GSID-2ZT4AY1CH-1
GSID-35V9XJV9Z-5

Numerical expression

Strength

Dose form

Substance ID

MD5 digestion

0x073AF2E5B92AE19E8B67635AFFB3D6CA
Proposed Global PhPID service responsibilities

- Setting the service offer, maintenance framework & validation process
- Regular reviews
- Validation according to agreed process
- Responding to questions and escalating issues
- Data updates including cross-references needed for pharmacovigilance

WHO International working group

- Governance
- Global database of PhPIDs

WHO-UMC validation team

WHO-UMC technical support

- Oversee assignments and solving issues
- Identify needs for updates of business rules
- Escalates to ISO for updates of the standard
- Ensure the availability of the service from a technical perspective
- User/API administration
Proposed Global PHPID operations

Request → Validation → Global PHPID

- Industry
- Regulators
- VigiBase®
- WHO Collaborating Centre for International Drug Monitoring
- WHO Collaborating Centre for International Drug Monitoring
Scaling up the PhPID production
- organizing data streams of structured drug information from volunteer countries
GIDWG projects to conduct in 2022

1. Global Substance ID

2. Global Dose Form Identifier

3. Strength Definitions Identifier

4. HL7 FHIR for IDMP

5. Operating model
Planned Pilots to Conduct in 2022

1. Global Substance ID
   - Scope
     - Mapping EU-SRS EUTCT, FDA UNII, and one additional region (if possible) to Global identifier for a set of selected Chemicals in WHO Model List of Essential Medicines
     - Review all substance classes including more complex scenarios like certain biologics
   - Success Criteria
     - Meet requirements for unique substance identification
     - Identify and address issues and challenges
     - Identify and address regional legacy substance definition/identification
     - Propose a feasible, scalable, and most efficient operation model to maintain global substance identifiers (and definition and identification)
Planned Pilots to Conduct in 2022

2. Global Dose Form Identifier

• Rationale
  o To ensure consistent mapping to EDQM characteristics for products with less granular dose form expressions

• Scope
  • Map DF to another region using the DF characteristic approach
  • Further investigate DF characteristic combination and EDQM DF characteristic with multiple values

• Success Criteria
  • Identify and address issues and challenges
  • Documented rules to apply proper DF characteristics, for the generation of global PhPID, regardless regional DF variations
Planned Pilots to Conduct in 2022

3. Strength Definitions Identifier

• Rationale
  o To build on the FDA/WHO-UMC pilot developed concepts the use of strength presentation versus strength concentration for different products

• Scope
  • Identify and address different representation of strength for products in different regions
  • Work with ISO, clarify the use of presentation strength and concentration strength
Strength considerations

All EDQM dose forms have been mapped to the suggested pattern Framework

- A, B, C patterns are well-defined
  - Range concentration to be investigated more

A number of challenges will be further identified:

- D pattern: more investigation needed
- May be a need for additional pattern(s) when strength is expressed as ‘cells’, TCMs, ‘animal live’
4. HL7 FHIR for IDMP

• **Scope**
  • Participate in the development, verification, and ballot of HL7 FHIR resources related to IDMP

• **Success Criteria**
  • Successful exchange of medicinal product and substance information between EU-SRS/SMS, FDA-SRS and UMC-SRS using HL7 FHIR as the underlining message technology for ISO IDMP standards
  • Demonstrate in HL7 FHIR connectathons and other stakeholder events

• **Dependencies**
  • ISO 11615 and ISO/TS 20443
  • ISO 11238 and ISO/TS 19844
Planned Pilots to Conduct in 2022

5. Operating model

• Scope
  • Demonstration of the consensus-based operating model for WHO-UMC as the international maintenance organization as an end-to-end pilot

• Success Criteria
  • Successful process from request to publication of global PhPID for a set of selected cases
Questions in the Q & A facility, please
For feedback, please go to: https://forms.gle/YAq3XqvGodyNDw2p9

Thanks for your time