IHTSDO Default National Drug Concept Model

for use by Member countries
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PROJECT OVERVIEW
Project Overview

The objective of this project is to document a default drug concept model and use cases for use by IHTSDO Member countries creating their own national drug extensions. It includes recommended maps to other international standards including:

– GS1 - GTIN
– ATC
– IDMP
Project assumptions

• It does **NOT** include:
  – editorial guidance for the representation of drugs (in the member extension or international release) or
  – Guidance on any changes for the International Drug model within the SNOMED CT International Release

• The issue of concrete domains will be addressed in the documentation but the model will need to align to RF2 current specification which does not include concrete domains

• It does **NOT** include recommendations of National drug dictionaries development processes or tooling requirements, however the model needs to be pragmatic in relation to how it can be easily developed and implemented

• The work was developed based on information provided by IHTSDO, the member countries, with some (limited) stakeholder engagement

• All work items were completed with input from IHTSDO staff covering the areas of Content and Collaborations
Contributions & Acknowledgements

The work was developed based on information provided by IHTSDO and the member countries. Meetings were held with member countries who have drug extensions and provided documentation and other key stakeholders.

Documentation included:

• Use Cases (Canada, Latin America & New Zealand)
• Existing Models documentation/presentations (Australia – AMT, Canada, New Zealand – NZULM, Singapore – SDD, UK – dm+d)
• International Standards - IDMP from IHTSDO

Meetings included:

• Australia – Kate Ebrill, Dion McMurtrie, Matt Cordell and other members of AMT team
• Canada - Beverly Knight & Linda Parisien
• New Zealand - David Mitchell
• Singapore - Priscilla Chua & Jing Jing Wong
• UK - Jo Goulding
• OpenMedicine- William Goossen
• Netherlands - Leonora Grandia
• Brandon Ulrich – B2i
NATIONAL DRUG CONCEPT MODEL
OVERVIEW & SCOPE
What is the problem we are trying to solve?

- **Different in-house drug terminologies**, codes and IT systems limits the extent to which **information can be exchanged**—for post-market monitoring, integrated care, healthcare efficiency, decision support and patient safety;

- **Lack of consistent naming** and interpretation

- **Limited decision support** and may be **inconsistent** between **facilities**
National Medication Dictionary - What is it?

• A directory or repository containing standardised data which can be accessed by authorised applications
• Data about medicines and their components
• Single, constant, unique ID for all concepts
• Includes **the application (tools)** for managing development, storage and access
• Includes supporting infrastructure and services such as Quality Assurance and editorial rules
• May includes maps to other identifiers & relevant classifications:
  – *SNOMED CT international release*
  – *ATC – Anatomical Therapeutic Chemical Classification (WHO)*
  – *Country regulation code*
  – *Reimbursement codes*
  – *GTIN*

It is NOT a decision support system or a data exchange standards
Scope of model product types

In scope
• single ingredient & multi-ingredient & multi-component
  – Medications
  – Medications with devices as a container
  – Vaccines
  – Vitamins
  – Feeds

Currently out of scope
• Different Model(s)
  – Devices
  – Devices with medications
  – Extemporaneous Recipes (eg creams & infusion, TPN, Chinese traditional medicines)
  – Blood
• May require additional attributes
  – Blood products
  – Clinical trials
  – Radiopharmaceuticals
  – Herbal & Health supplements
CURRENT USE CASES

NOTES
• Use cases represent the major range of use case examples and are not representative of best practice
• Where issues may arise from the practice they are coloured in grey
Use cases

- **Inventory Management**: Supports supply chain
- **Record**: Facilitates decision support
- **Exchange of information**: Facilitates product registration
- **Prescribe**: Supports decision support
- **Issue**: Supports Reimbursement
- **Administer**: Supports Reimbursement
- **Analytics**: Supports supply chain

*Indicates functionalities that support decision making.*
Exchange of information

- Exchange across use cases within an enterprise
- Exchange across care setting
- Exchange across use cases between different enterprise
- Cross-border electronic prescription
- Cross-border identification of medications for decision support

These have a dependency for a shared reference terminology for the core elements
Exchange Implementation

Major Implementation options include:

• Mapping the local EMR or application drug codes either:
  – locally prior to exchange
  – During the exchange
  – On receipt of the information

• Native use as a value set within the local EMR or application
Exchange within an enterprise

- **Record**: Clinician records
- **Prescribe**: Clinician prescribers
- **Issue**: Pharmacist issues
- **Administer**: Nurse administers
- **Inventory Management**: Technician counts and orders
- **Analytics**: Hospital analyzes

- Uses decision support
- Hospital claims payment
- Uses decision support
- Purchase goods from supply chain
Exchange across enterprises

- **Record**
  - Specialist Centre
  - Discharge summary

- **Prescribe**
  - Primary care
  - General practitioner prescribers

- **Issue**
  - Community Pharmacy
  - Pharmacist issues

- **Administer**
  - Aged care
  - Nurse administers

- **Inventory Management**
  - Community Pharmacy
  - Pharmacist counts and orders

- **Analytics**
  - All enterprises
  - Analyze

- **Uses decision support**
- **Uses decision support**
- **Uses decision support**
- **Purchase goods from supply chain**
Prescribing across care setting

amoxicillin capsule
Take 1 g 3 times per day
# Prescribing variations

### Primary care

<table>
<thead>
<tr>
<th>Prescriptions</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>John Smith</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>2 drops</td>
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<tr>
<td><strong>Frequency</strong></td>
<td>3 times a day in each eye</td>
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<table>
<thead>
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<td><strong>Medication</strong></td>
<td>Moduretic tablets</td>
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<tr>
<td><strong>Dose</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>Each morning</td>
</tr>
<tr>
<td><strong>Cancel</strong></td>
<td>OK</td>
</tr>
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<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>John Smith</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td>COUMADIN 1 mg tablet</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>Each morning as directed</td>
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<td><strong>Cancel</strong></td>
<td>OK</td>
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</table>

<table>
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<td><strong>Medication</strong></td>
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<td><strong>Dose</strong></td>
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<tr>
<td><strong>Frequency</strong></td>
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### Prescribing Variations

#### Primary Care

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<tr>
<td><strong>Medication</strong></td>
<td>loratadine 10 mg cap</td>
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<tr>
<td><strong>Dose</strong></td>
<td>1 tablet</td>
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<tr>
<td><strong>Frequency</strong></td>
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#### Cancel

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<tr>
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<td>loratadine 10 mg cap</td>
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<tr>
<td><strong>Dose</strong></td>
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<td>V</td>
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<tr>
<td><strong>Frequency</strong></td>
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#### Brand As Synonym

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<tr>
<td><strong>Dose</strong></td>
<td>1 tablet</td>
<td>V</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>Each morning</td>
<td>V</td>
</tr>
</tbody>
</table>

#### Brand Is Significant

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<tbody>
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<td><strong>Medication</strong></td>
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</tr>
<tr>
<td><strong>Dose</strong></td>
<td>2 tablets</td>
<td>V</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
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</tr>
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</table>

#### Medication Group

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<tbody>
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<td><strong>Medication</strong></td>
<td>fluticasone propionate 0.05% nasal spray</td>
<td>V</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>2 sprays</td>
<td>V</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>3 times a day</td>
<td>V</td>
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</table>

#### Container Significant

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<tbody>
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<td>V</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>3 times a day</td>
<td>V</td>
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#### Pack Significant

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<td><strong>Dose</strong></td>
<td>2 sprays</td>
<td>V</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>3 times a day</td>
<td>V</td>
</tr>
</tbody>
</table>
products with a specific combination of active ingredients * eg amoxicillin (or)

products with a specific combination of active ingredients and clinically significant dose form eg amoxicillin capsule (or)

products with a specific combination of active ingredients, strength and clinically significant dose form eg amoxicillin 500 mg capsule

products with a specific combination of active ingredients, strength and clinically significant dose form & pack size eg chloramphenicol 0.5 % eye drops, 10 mL

products with a specific combination of active ingredients, strength and clinically significant dose form, pack size & container eg Salbutamol 100 microgram/dose pressurised inhalation solution 200 doses, inhaler

the trade products of with a specific combination of active ingredients * eg COUMADIN (or)

the trade products with a specific combination of active ingredients and dose form eg COUMADIN tablet (or)

the trade products with a specific combination of active ingredients, strength and dose form eg COUMADIN 1 mg tablet

the trade products with a specific combination of active ingredients, strength and dose form & pack size eg CHOROMYCETIN 0.5 % eye drops, 10mL

the trade product with a specific combination of active ingredients, strength and clinically significant dose form, pack & container eg Ventolin 100 microgram/dose pressurised inhalation solution 200 doses, inhaler

a medication group of products eg Influenza vaccine

*may create decision support overload
Products with a specific combination of active ingredients, strength and clinically significant dose form* eg **amoxicillin 500 mg capsule**

Products with a specific combination of active ingredients, strength and clinically significant dose form & pack size* eg **chloramphenicol 0.5 % eye drops, 10 mL**

Products with a specific combination of active ingredients, strength and clinically significant dose form, pack size & container* eg **Salbutamol 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

Products with a specific combination of active ingredients, strength and dose form eg **COUMADIN 1 mg tablet**

Products with a specific combination of active ingredients, strength and dose form & pack size eg **CHORMYCESTIN 0.5 % eye drops, 10mL**

The trade product with a specific combination of active ingredients, strength and clinically significant dose form, pack & container eg **Ventolin 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

*does not record actual product concept that represent
products with a specific combination of active ingredients, strength and clinically significant dose form* eg **amoxicillin 500 mg capsule**

products with a specific combination of active ingredients, strength and clinically significant dose form & pack size* eg **chloramphenicol 0.5 % eye drops, 10 mL**

products with a specific combination of active ingredients, strength and clinically significant dose form, pack size & container* eg **Salbutamol 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

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the trade products with a specific combination of active ingredients, strength and dose form & pack size eg **CHOROMYCETIN 0.5 % eye drops, 10mL**

the trade product with a specific combination of active ingredients, strength and clinically significant dose form, pack & container eg **Ventolin 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

*does not record actual product

Administer

concept that represent
products with a specific combination of active ingredients eg **amoxicillin**

products with a specific combination of active ingredients and clinically significant dose form eg **amoxicillin capsule**

products with a specific combination of active ingredients, strength and clinically significant dose form eg **amoxicillin 500 mg capsule**

products with a specific combination of active ingredients, strength and clinically significant dose form & pack size eg **chloramphenicol 0.5 % eye drops, 10 mL**

products with a specific combination of active ingredients, strength and clinically significant dose form, pack size & container eg **Salbutamol 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

the trade products of with a specific combination of active ingredients eg **COUMADIN**

the trade products with a specific combination of active ingredients and dose form eg **COUMADIN tablet**

the trade products with a specific combination of active ingredients, strength and dose form eg **COUMADIN 1 mg tablet**

the trade products with a specific combination of active ingredients, strength and dose form & pack size eg **CHOROMYCETIN 0.5 % eye drops, 10mL**

the trade product with a specific combination of active ingredients, strength and clinically significant dose form, pack & container eg **Ventolin 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

a medication group of products eg **Influenza vaccine or** a trade family group eg **PANADOL**
products with a specific combination of active ingredients, strength and clinically significant dose form* eg **amoxicillin 500 mg capsule**

products with a specific combination of active ingredients, strength and clinically significant dose form & pack size* eg **chloramphenicol 0.5 % eye drops, 10 mL**

products with a specific combination of active ingredients, strength and clinically significant dose form, pack size & container* eg **Salbutamol 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

the trade products with a specific combination of active ingredients, strength and dose form eg **COUMADIN 1 mg tablet**

the trade products with a specific combination of active ingredients, strength and dose form & pack size eg **CHOROMYCETIN 0.5 % eye drops, 10mL**

the trade product with a specific combination of active ingredients, strength and clinically significant dose form, pack & container eg **Ventolin 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

*does not record actual product
products with a specific combination of active ingredients eg **amoxicillin**

products with a specific combination of active ingredients and clinically significant dose form eg **amoxicillin capsule**

products with a specific combination of active ingredients, strength and clinically significant dose form eg **amoxicillin 500 mg capsule**

products with a specific combination of active ingredients, strength and clinically significant dose form & pack size eg **chloramphenicol 0.5 % eye drops, 10 mL**

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the trade products of with a specific combination of active ingredients eg **COUMADIN**

the trade products with a specific combination of active ingredients and dose form eg **COUMADIN tablet**

the trade products with a specific combination of active ingredients, strength and dose form eg **COUMADIN 1 mg tablet**

the trade products with a specific combination of active ingredients, strength and dose form & pack size eg **CHOROMYCETIN 0.5 % eye drops, 10mL**

the trade product with a specific combination of active ingredients, strength and clinically significant dose form, pack & container eg **Ventolin 100 microgram/dose pressurised inhalation solution 200 doses, inhaler**

a medication group of products eg **Influenza vaccine** or a trade family group eg **PANADOL**
This is presented in two major parts:
1. Base Drug Concept Model
2. Drug Concept Model extension options

It is anticipated that member countries will need to make necessary additions or modifications to the base drug model to support their specific use cases, regulatory requirements, tooling and implementation requirements, etc.
1. BASE NATIONAL DRUG CONCEPT MODEL

NOTES

• Editorial guidance for the representation of drugs (in the member extension or international release) is **NOT** part of this project. However, descriptions in examples are represented as a preferred terms or synonym (unless more details are required to differentiate descriptions these parts of the description are in brackets)
National Medication Dictionary Principles

• **A national standard** to unambiguously identify, code & interpret medicines
• Nationally **consistent unambiguous drug descriptions** based on clearly defined rules (model and editorial) (NOTE: editorial guidance is NOT part of this project)
• Can be used as a **reference and interface terminology** or available as the **standard for mapping and use within an EMR**
• **Support all use cases** and linkage between use cases concepts (e.g. prescribing to issuing drugs)
• **Facilitates seamless exchange** between systems and across systems
• **Extensibility** In both the drug content and data model to allow for innovations in pharmaceutical and device technology over time
• **Needs to be simple** ie complexity can be hidden from clinicians and most Electronic Medical Record (EMR) vendors
• Promotes implementation eg can easily create preferred use case value sets such as prescribing value set
• Optional extensions:
  – Support linkage to Decision Support Vendors
  – Linkage to international standards whenever possible (e.g. SNOMED CT and WHO ATC)
  – Can support mapping to Regulator Identifier and a linkage to Barcoding / GTIN and reimbursement system
The base data model includes the following medication classes:

- Generic drug
- Generic drug form
- Generic drug preparation
- Generic drug pack
- Generic drug containered pack
- Branded drug
- Branded drug form
- Branded drug preparation
- Branded drug pack
- Branded drug containered pack

Not all classes need to be available for distribution unless a country has the associated use case for example Generic and branded drug form. These classes are required for alignment to international release.

May only be populated for clinically relevant container types eg syringe & inhaler.

May not be available for distribution for multi components concepts.
Base data model

- Generic drug (GD)
- Generic drug form (GDF)
- Generic drug preparation (GDPrep)
- Generic drug pack (GDPack)
- Generic drug contained pack (GDCP)

- Branded drug (BD)
- Branded drug form (BDF)
- Branded drug preparation (BDPrep)
- Branded drug pack (BDCP)
- Branded drug contained pack (BDCP)

- 20 tablets
- 2 x 10 tablets per blister strip
Base Model - single ingredient

- Generic drug
  - amoxicillin

- Branded drug
  - AMOXIL

- Generic drug form
  - amoxicillin capsule

- Branded drug form
  - AMOXIL capsule

- Generic drug preparation
  - amoxicillin 500 mg capsule

- Branded drug preparation
  - AMOXIL 500 mg capsule

- Generic drug pack
  - amoxicillin 500 mg capsule, 20 capsules

- Branded drug pack
  - AMOXIL 500 mg capsule, 20 capsules

- Generic drug containered pack
  - amoxicillin 500 mg capsule, 20 capsules, blister pack

- Branded drug containered pack
  - AMOXIL 500 mg capsule, 20 capsules, blister pack
Base model defining relationships

All classes also have optional “has other identifying information”
Distribution options

1. Full terminology all concepts and descriptions
2. Clinically significant terminology where concepts and relationships used to maintain the integrity of the model are excluded.
3. Use case specific reference sets eg only those terms need for the prescribe use case in primary care
1. Full terminology

- Generic drug
  - amoxicillin

- Branded drug
  - AMOXIL

- Generic drug form
  - amoxicillin capsule

- Branded drug form
  - AMOXIL capsule

- Generic drug preparation
  - amoxicillin 500 mg capsule

- Branded drug preparation
  - AMOXIL 500 mg capsule

- Generic drug pack
  - amoxicillin 500 mg capsule, 20 capsules

- Branded drug pack
  - AMOXIL 500 mg capsule, 20 capsules

- Generic drug contained pack
  - amoxicillin 500 mg capsule, 20 capsules, blister pack

- Branded drug contained pack
  - AMOXIL 500 mg capsule, 20 capsules, blister pack
2. Clinically significant terminology

If country do not use these classes
3. Prescribe use case specific value set set

May differ by country and product type
3. Dispense use case specific value set

May differ by country and product type
3. Use case specific value set

- **Generic Drug Preparation**
  - amoxicillin 500 mg capsule

- **Branded Drug Preparation**
  - AMOXIL 500 mg capsule

- **Branded Drug Containered pack**
  - AMOXIL 500 mg capsule, 20 capsules, blister pack

- **Branded Drug Preparation**
  - GLOMOX 500 mg capsule

- **Branded Drug Containered pack**
  - GLOMOX 500 mg capsule, 20 capsules, blister pack

- **Branded Drug Containered pack**
  - GLOMOX 500 mg capsule, 20 capsules, bottle
Base Model – multi ingredient

- Generic drug:
  - amoxicillin + clavulanic acid

- Branded drug:
  - AUGMENTIN

- Generic drug form:
  - amoxicillin + clavulanic acid tablet

- Branded drug form:
  - AUGMENTIN tablet

- Generic drug preparation:
  - amoxicillin 500 mg + clavulanic acid 125 mg tablet

- Branded drug preparation:
  - AUGMENTIN 625 mg tablet

- Generic drug pack:
  - amoxicillin 500 mg + clavulanic acid 125 mg tablet, 20 tablets

- Branded drug pack:
  - AUGMENTIN 625 mg tablet, 20 tablets

- Generic drug contained pack:
  - amoxicillin 500 mg + clavulanic acid 125 mg tablet, 20 tablets, blister pack

- Branded drug contained pack:
  - AUGMENTIN 625 mg tablet, 20 tablets, blister pack
Base model – Multi component

- **Generic drug**: estradiol valerate (&) estradiol valerate + norgestrel
  - **Generic drug form**: estradiol valerate (&) estradiol valerate + norgestrel tablet
    - **Generic drug preparation**: estradiol valerate 2 mg tablet (&) estradiol valerate 2 mg + norgestrel 0.5 mg tablet
      - **Generic drug pack**: estradiol valerate 2 mg tablet (&) estradiol valerate 2 mg + norgestrel 0.5 mg tablet, 21 tablets
        - **Generic drug containered pack**: estradiol valerate 2 mg tablet (&) estradiol valerate 2 mg + norgestrel 0.5 mg tablet, 21 tablets, blister pack
  - **Branded drug**: PROGYLUTON
    - **Branded drug form**: PROGYLUTON tablet
      - **Branded drug preparation**: PROGYLUTON tablet
        - **Branded drug pack**: PROGYLUTON tablet, 21 tablets
          - **Branded drug containered pack**: PROGYLUTON tablet, 21 tablets, blister pack
Distribution Option 2:
Clinically significant terminology

If country do not use these classes
Other relationships Base model

• Optional relationships to support implementation
  – has distribution status
  – has product type
  – has use case type
  – has class type (eg generic drug class)

• Additional relationships may be required after completion of the editorial rules to support an automated editorial process eg:
  - has other identifying information
  - has trade suffix
  - etc
Model Assumptions

• Concrete domains will be resolved to:
  – reduce the complexity of the model
  – allow classification of all defining attributes including strength and pack size

• Ingredients and dose forms will be the clinically significant representations for all generic classes for example:
  – amoxicillin rather than amoxicillin trihydrate
  – tablet rather than hard tablet
Where inconsistencies exist in the marketplace this will be handled using the editorial rules and the addition of synonyms rather than the addition of multiple layers into the model to handle other types such as specific and/or clinically relevant ingredients or dose forms.

• Other items that will be handled using the editorial rules rather than a modeling solution:
  – Where inconsistencies exist in strength representation in the marketplace for example: amitriptyline 10 mg tablet where the basis of strength is amitriptyline hydrochloride but the clinically significant ingredient is amitriptyline

• Generic Drug preparation and Branded Drug preparation classes are concepts that represent products with these attributes and are not units of use ie they do not include unit of use information. It is assumed that this will be dealt with in the information model

• Classification approach supports universal restriction ( explanation follows)

• Substance hierarchy used for the active ingredient and BOSS ingredient relationships, which includes strength value and units, supports the selection of ingredient ONLY. ( explanation follows)
Classification approach

• OWL 2 DL supports universal restriction
  Using universal restriction, the active ingredient relationships say (for example) "An enalapril product is a product that has active ingredient only enalapril."
  – Classifies fewer relationships
  – Is slower to classifier

Note: For comparison this is not OWL 2 EL profile of description logic.
which uses existential restriction, the active ingredient relationships say (for example) "A enalapril product is a product that has active ingredient some enalapril". Because, a "enalapril + hydrochlorothiazide" product contains some enalapril it is classified as a type of “enalapril product” and a “hydrochlorothiazide product” .
  – Is quicker to classify
  – No stated use case for extra relationships and these may have patient safety implications

NOTE: the International Release uses OWL EL which does not support universal restrictions; there are no plans to change to OWL DL in the foreseeable future.
OWL 2 DL supports universal restriction
OWL 2 EL profile of description logic.

Not recommended
The selection of the substance in the TWO highlighted relationships needs to ensure that they do not have any children in the substance hierarchy. This is to ensure that a reasoner does not infer that if there is 500 mg of 'Amoxicillin' that there is also 500 mg of the child 'Amoxicillin trihydrate'.

In the example below you would need to select the highlighted substance. The parent Amoxicillin means “Amoxicillin and /or modification” because it has a child which is a modification.

NOTE: the International Release does support this approach and there are no plans to change this in the foreseeable future.
2. NATIONAL DRUG CONCEPT MODEL
OPTIONAL EXTENSIONS
Additional optional model extensions

1. SNOMED CT International Release
2. Map to other identifiers and standards
   - GTIN
   - ATC
   - Regulator identifier
   - Decision support IDs
3. Components of multi component products
4. Reconstituted products
5. Clinically significant containers
6. Medication groups
7. Brand family group
8. IDMP alignment

NOTE: This represents the major extension options rather than all extension options.
### 1. International Release

**Option 1:** where there is an equivalent concept in the International Release then this is used (Note: assuming no inheritance issues)

**Option 2:** map to equivalent concept in the international release where they exist
2. Map to other identifiers and standards

Notes:
- ATC may be mapped to multiple levels when additional specificity is required
- Decision support vendors may also map to multiple levels
- Regulator may also require a map to the Branded drug pack
The standard EAN/GTIN product code has 13 digits. For smaller sized products there is a short version of the EAN/GTIN code the EAN 8

- The first 2 digits of the EAN-13 or GTIN (Global Trade Item Number) code are containing the country of the article. The country is coded with 2 or 3 numbers 629 represents UAE
- The next 4 to 5 digits code the producer of the article.
- The following 5 digits represent the article number which is given by the producer.
- The remaining last digit is the check digit.
• A - Alimentary tract and metabolism (1st level, anatomical main group)

• A10 Drugs used in diabetes (2nd level, therapeutic subgroup)

• A10B Blood glucose lowering drugs, excl. insulins (3rd level, pharmacological subgroup)

• A10BA Biguanides (4th level, chemical subgroup)

• A10BA02 metformin (5th level, chemical substance)

• Thus, in the ATC system all plain metformin preparations are given the code A10BA02.
3. Components

- Create Generic drug concepts for the individual components (even if they do not exist in the market, as will be required for allergies)
- Components will only be added from the generic drug preparation and above (unless they are commercially available as the individual components)
- The multi component generic drug preparation will be linked to its individual components by a has component relationship
- Will not be created if the products have two components and one is an inert
3. Components

- Generic drug:
  - estradiol valerate
  - estradiol valerate + norgestrel

- Generic drug form:
  - estradiol valerate tablet
  - estradiol valerate + norgestrel tablet

- Generic drug preparation:
  - estradiol valerate 2 mg tablet
  - estradiol valerate 2 mg + norgestrel 0.5 mg tablet
  - estradiol valerate 2 mg tablet (6), estradiol valerate 2 mg + norgestrel 0.5 mg tablet (6)

- Branded drug:
  - PROGYLUTON

- Branded drug form:
  - PROGYLUTON tablet
  - PROGYLUTON (estradiol valerate) tablet

- Branded drug preparation:
  - PROGYLUTON tablet, 21 tablets
  - PROGYLUTON tablet, 21 tablets, blister pack

- Branded drug containered pack:
  - PROGYLUTON tablet, 21 tablets, blister pack
3. Components

Example assumes Nexium 20 mg tablets, 14 tablets, blister pack is available in the marketplace in addition to being a component within Nexium HP7
Distribution Option 2: Clinically significant terminology

If country do not use these classes

Transitive closure and extended has component relationships
4. Reconstituted products

- Will be one of the following options
  a) The reconstituted product in recommended concentration (based on volume of included diluent or recommended volume required for reconstitution)
  b) The reconstituted product in recommended concentration (based on guidelines with no diluent included)

NOTE: for IDMP compliance will need to be based on dilution recommended in product information.
4. Reconstituted products

- Generic drug preparation
  - ceftriaxone

- Branded drug
  - ENOXIRT

- Generic drug form
  - ceftriaxone injection solution

- Branded drug form
  - ENOXIRT injection solution

- Generic drug pack
  - ceftriaxone 500 mg/mL injection solution, 1 pack

- Branded drug pack
  - ENOXIRT 500 mg/mL injection solution, 1 pack

- Generic drug contained pack
  - ceftriaxone 500 mg/mL injection solution, 1 pack, vial

- Branded drug contained pack
  - ENOXIRT 500 mg/mL injection solution, 1 pack, vial

- has administrable product

- is a
5. Clinically significant containers

**Option 1**: modify dose form to include clinically significant container

**Option 2**: Use only:
- Generic drug containered pack or
- Branded drug containered pack

**Option 3**: Create containered classes. NOTE when these classes are created the equivalent classes without containers should be marked as not for distribution.
5. Option 1: modify dose form to include clinically significant container

Not recommended

Note: In this example “pressurised inhalation solution inhaler” is a dose form which will require a synonym at Generic drug containered pack class to avoid duplication of the word inhaler
5. Option 2: Clinically significant terminology

- Generic drug
  - salbutamol

- Branded drug
  - VENTOLIN

- Transitive closure
5. Option 3: Clinically significant containers
5. Option 3: Clinically significant terminology distribution option

Diagram showing the relationship between generic and branded drugs, including their forms, preparations, and packs.
6. Medication groups

- Medication groups can be created where clinical practice includes a prescribing term that may group generic products, eg Ingredient no strength eg Influenza vaccine
- The grouper will be linked to the correct Generic product concepts by a has medication group relationship
- This method could also be used to create strength and form groups although these currently not a stated use case, for example:
  - Ingredient with strength groups eg Chlorhexidine salts 1% cream
  - Strength groups eg. Aspirin 81 mg to 100 mg tablet
  - Form groups eg. Paracetamol 500 mg tablet/capsule
This may be required for IDMP compliance with reconstituted products.
6. Medication groups
7. Brand family group

- Brand family group can be created where clinical practice includes a term that may group branded products which may include different ingredients.

- The grouper will be linked to the correct Branded product concepts by a has brand family group relationship.
8. IDMP alignment

- Option 1: Map to IDMP concepts

- Option 2: Map to IDMP concepts AND add additional classes and relationships to ensure compliance to the data elements
8. IDMP Option 1- Map example 1

NOTE: The differentiation of these two levels is currently not clearly defined in the ISO documentation and may need review at a later stage.
8. IDMP Option 1: Map example 2

PhPID_SUB_L1

Generic drug
- salbutamol

Branded drug
- VENTOLIN

PhPID_SUB_L3

Generic drug form
- Salbutamol pressurised inhalation solution

Branded drug form
- VENTOLIN pressurised inhalation solution

PhPID_SUB_L4

Generic drug preparation
- salbutamol 100 microgram/dose pressurised inhalation solution

Branded drug preparation
- VENTOLIN 100 microgram/dose pressurised inhalation solution

Generic drug pack
- salbutamol 100 microgram/dose pressurised inhalation solution, 200 doses

Branded drug pack
- VENTOLIN 100 microgram/dose pressurised inhalation solution, 200 doses

Generic drug contained pack
- salbutamol 100 microgram/dose pressurised inhalation solution, 200 doses, inhaler

Branded drug contained pack
- VENTOLIN 100 microgram/dose inhaler CFC-Free, 200 doses
8. IDMP Option 1: Map example 3

PhPID_SUB_L1
Generic drug preparation
ceftiraxone

PhPID_SUB_L3
Generic drug form
ceftiraxone injection solution

PhPID_SUB_L4
Generic drug preparation
ceftiraxone 500 mg/mL injection solution

Generic drug pack
ceftiraxone 500 mg/mL injection solution, 1 pack

Generic drug containered pack
ceftiraxone 500 mg/mL injection solution, 1 pack, vial

Branded drug
ENOXIRT

Branded drug form
ENOXIRT powder for injection

Branded drug preparation
ENOXIRT 500 mg powder for injection

Branded drug pack
ENOXIRT 500 mg powder for injection, 1 pack

Branded drug containered pack
ENOXIRT 500 mg powder for injection, 1 pack, vial

PCID

MPID
8. IDMP Option 2

Option 2: Map to IDMP concepts AND add additional information to ensure compliance to the data elements including:

a) Add Generic Strength class
b) Add specific substance layer *(NOTE: May not be relevant in clinical practice)*
c) Add administrable dose forms
d) Add device when required
e) Split Containers into containers and administrable devices
f) Align to IDMP strength representation eg concentration, presentation and reference strength, strength range (relationships and editorial rules)
g) Add “has ingredient type” relationship & qualifier to generic side
h) Add “has adjuvant” relationship & qualifier
i) Add “has flavour” relationship & qualifier to branded classes (to be confirmed when more information available)
8. IDMP Option 2a-
Add Generic Strength class

- Add Generic Strength class

a) Add Generic Strength class

- PhPID_SUB_L1
  - Generic drug
    - amoxicillin

- PhPID_SUB_L2
  - Generic strength
    - amoxicillin 500 mg

- PhPID_SUB_L3
  - Generic drug form
    - amoxicillin capsule

- PhPID_SUB_L4
  - Generic drug preparation
    - amoxicillin 500 mg capsule

- MPID
  - Branded drug pack
    - AMOXIL 500 mg capsule, 20 capsules

- PCID
  - Branded drug contained pack
    - AMOXIL 500 mg capsule, 20 capsules, blister pack
IDMP Option 2b - Add specific substance layer

a) Add Generic Strength class

b) Add specific substance layer (NOTE: May not be relevant in clinical practice). This is a regulatory use case and the relevance would need to be reviewed again after completion of the Substance database and when the first few examples have been implemented in the IDMP database.
a) Add Generic Strength class
b) Add specific substance layer (when required)
c) Add administrable dose forms
IDMP Option 2d – add administrable device

a) Add Generic Strength class
b) Add specific substance layer (when required)
c) Add administrable dose forms
d) Add device when required
Extended Model

Generic Drug (GD)  Branded Drug (BD)

Generic Drug Form (GDF)  Branded Drug Form (BDF)

Generic Drug Preparation (GDPrep)  Branded Drug Preparation (BDPrep)

Generic Drug Pack (GDPack)  Branded Drug Pack (BDCP)

Generic Drug Contained Pack (GDCP)  Branded Drug Contained Pack (BDCP)
Extended Model + IDMP option 1

Generic Drug Group* (GDG)

Generic Drug Form Group* (GDFG)

Generic Drug Preparation Group* (GDPrepG)

Generic Drug Pack Group* (GDPackG)

Generic Drug Contained Pack Group* (GDCPG)

has trade family group

Generic Drug (GD)

has component

Generic Drug Form (GDF)

Containered Generic drug Form

Generic Drug Preparation (GDPrep)

Containered Generic drug Preparation

Generic Drug Pack (GDPack)

Generic Drug Contained Pack (GDCP)

Branded Drug (BD)

has administrable product

Branded Drug Form (BDF)

Containered Branded drug form

Branded Drug Preparation (BDPrep)

Containered Branded drug preparation

Branded Drug Pack (BDCP)

has medication group

Trade family group (TFG)
Other extension model options

• The following options can also be included if a use case exists:
  – Freeness (or include as other identifying information)
  – Flavour (or include as other identifying information)
  – Sub packs
Core Product Classes
+ administrable product and component relationships

Generic drug
- Active ingredient [0..*]: SNOMED CT Concept Id (substance concept)
- Generic Drug Group [0..*]: SNOMED CT Concept Id (product group concept)

Generic drug form
- Specific active ingredient [0..*]: SNOMED CT Concept Id (substance concept)
- Drug form [1..*]: SNOMED CT Concept Id (qualifier concept)
- Generic drug [1..*]: SNOMED CT Concept Id (product concept)
- Component Generic drug form [0..*]: SNOMED CT Concept Id (product concept)
- Generic Drug Form Group [0..*]: SNOMED CT Concept Id (product group concept)

Generic drug preparation
- Specific active ingredient [0..*]: SNOMED CT Concept Id (substance concept)
- Drug preparation [0..*]: SNOMED CT Concept Id (product concept)
- Representation of strength value and strength units (TBC)
- Component Generic drug preparation [0..*]: SNOMED CT Concept Id (product concept)
- Administerable Generic drug preparation [0..*]: SNOMED CT Concept Id (product concept)
- Generic Drug Preparation Group [0..*]: SNOMED CT Concept Id (product group concept)

Generic drug pack
- Pack units [0..1]: SNOMED CT Concept Id (qualifier concept)
- Representation of pack size (TBC)
- Drug preparation [1..*]: SNOMED CT Concept Id (product concept)
- Component Generic drug pack [0..*]: SNOMED CT Concept Id (product concept)
- Generic Drug Pack Group [0..*]: SNOMED CT Concept Id (product group concept)

Generic drug containered pack
- Container type [1]: SNOMED CT Concept Id (qualifier concept)
- Generic drug pack [1..*]: SNOMED CT Concept Id (product concept)
- Administerable Generic drug containered pack [0..*]: SNOMED CT Concept Id (product concept)
- Containered Generic drug Preparation [0..*]: SNOMED CT Concept Id (product concept)
- Generic Drug containered Pack Group [0..*]: SNOMED CT Concept Id (product group concept)

Branded drug
- Brand name [0..*]: SNOMED CT Concept Id (qualifier concept)
- Drug [1..*]: SNOMED CT Concept Id (product concept)
- Component Branded drug form [0..*]: SNOMED CT Concept Id (product concept)
- Branded drug form Group [0..*]: SNOMED CT Concept Id (product group concept)

Branded drug form
- Pharmaceutical ingredient [0..*]: SNOMED CT Concept Id (substance concept)
- Proprietary dose form [0..1]: SNOMED CT Concept Id (qualifier concept)
- Drug form [1..*]: SNOMED CT Concept Id (product concept)
- Component Branded drug form [0..*]: SNOMED CT Concept Id (product concept)

Branded drug preparation
- Pharmaceutical ingredient [0..*]: SNOMED CT Concept Id (substance concept)
- Proprietary dose form [0..1]: SNOMED CT Concept Id (qualifier concept)
- Drug preparation [0..*]: SNOMED CT Concept Id (product concept)
- Representation of strength value and strength units (TBC)
- Component Branded drug preparation [0..*]: SNOMED CT Concept Id (product concept)
- Administerable Branded drug preparation [0..*]: SNOMED CT Concept Id (product concept)

Branded drug pack
- Pack units [0..1]: SNOMED CT Concept Id (qualifier concept)
- Representation of pack size (TBC)
- Drug preparation [1..*]: SNOMED CT Concept Id (product concept)
- Component Branded drug pack [0..*]: SNOMED CT Concept Id (product concept)

Branded drug containered pack
- Container type [1]: SNOMED CT Concept Id (qualifier concept)
- Drug containered pack [1..*]: SNOMED CT Concept Id (product concept)
- Administerable Branded drug containered pack [0..*]: SNOMED CT Concept Id (product concept)
- Containered Branded drug Preparation [0..*]: SNOMED CT Concept Id (product concept)