eHealth Masterminds

IHTSDO Default National Drug Concept Model

for use by Member countries

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PROJECT OVERVIEW

Project Overview

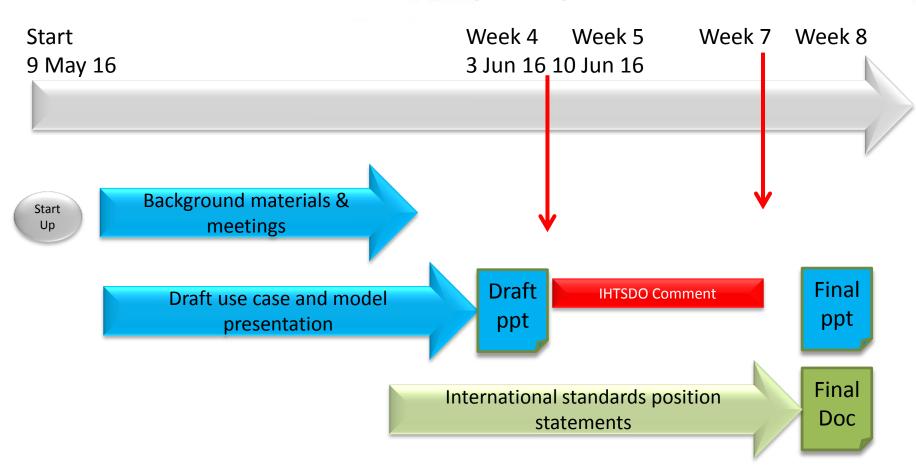
The objective of this project is to document a default drug concept model and use cases for use by IHTSDO Member countries creating their own national drug extensions. It includes recommended maps to other international standards including:

- 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

Timeline



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

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

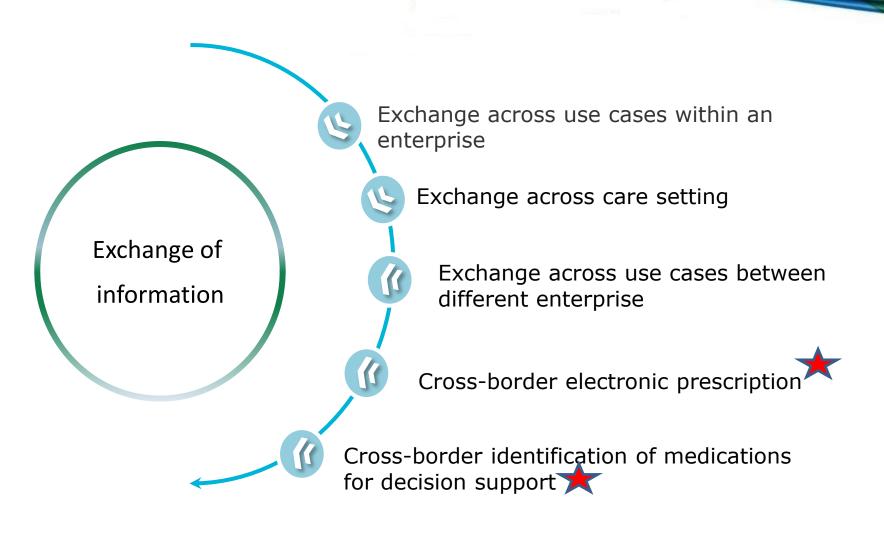
CURRENT USE CASES

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





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

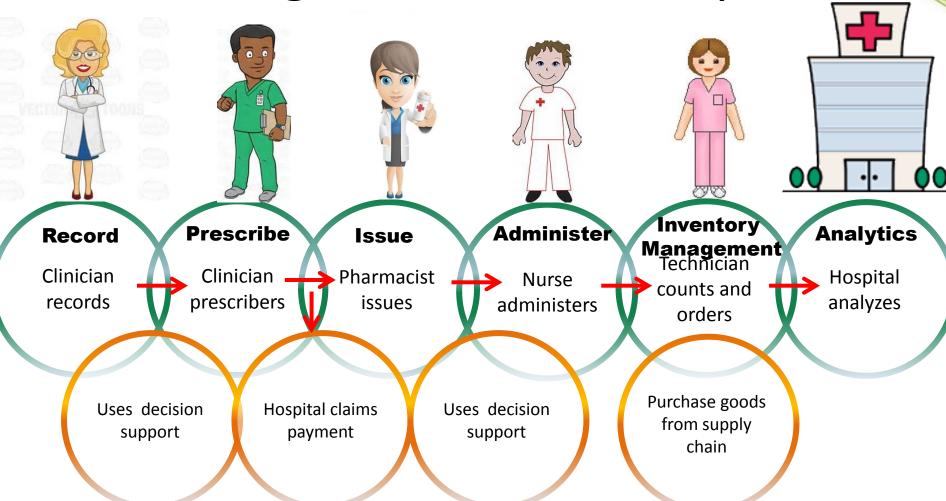
Exchange Implementation

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

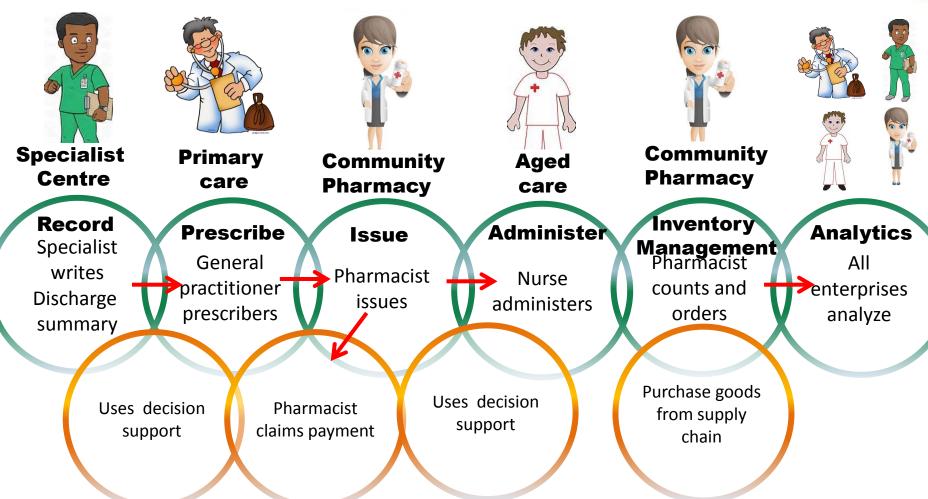
Example

Exchange within an enterprise





Exchange across enterprises



Example

Prescribing across care setting

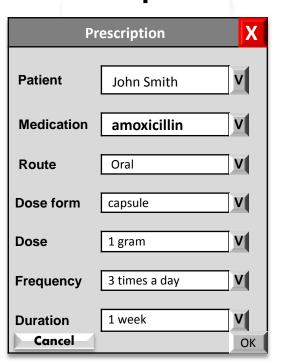


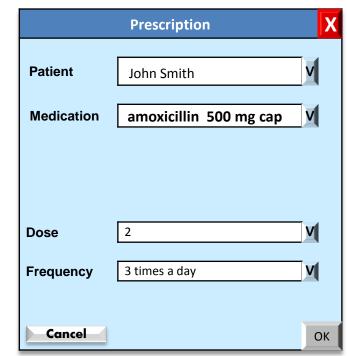
amoxicillin capsule
Take 1 g 3 times per day





Primary care







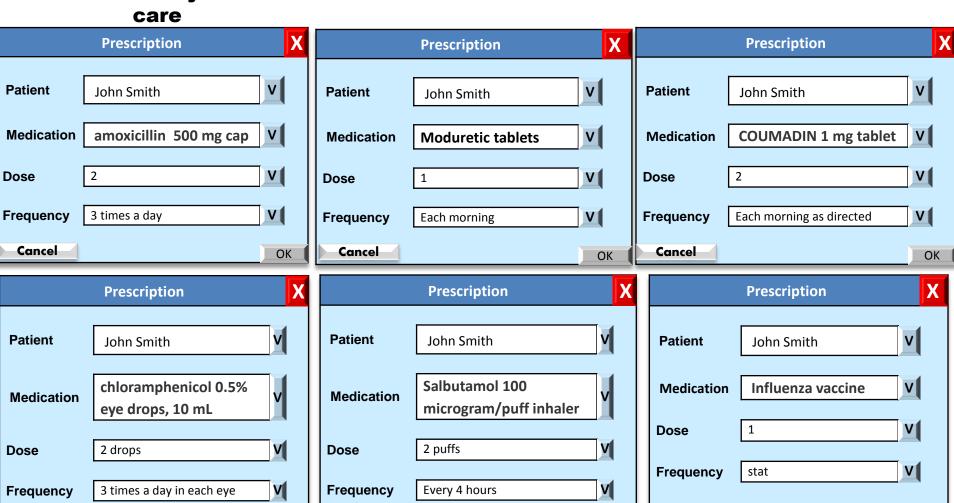
| Prescription | | X |
|-----------------|-----------------|----------|
| Patient | John Smith | V |
| Medication | amoxicillin cap | V |
| Route | Oral | V |
| Dose | 1 gram | V1 |
| Frequency | 3 times a day | V |
| Duration Cancel | 1 week | V |



Cancel

Prescribing variations

Primary care



OK

Cancel

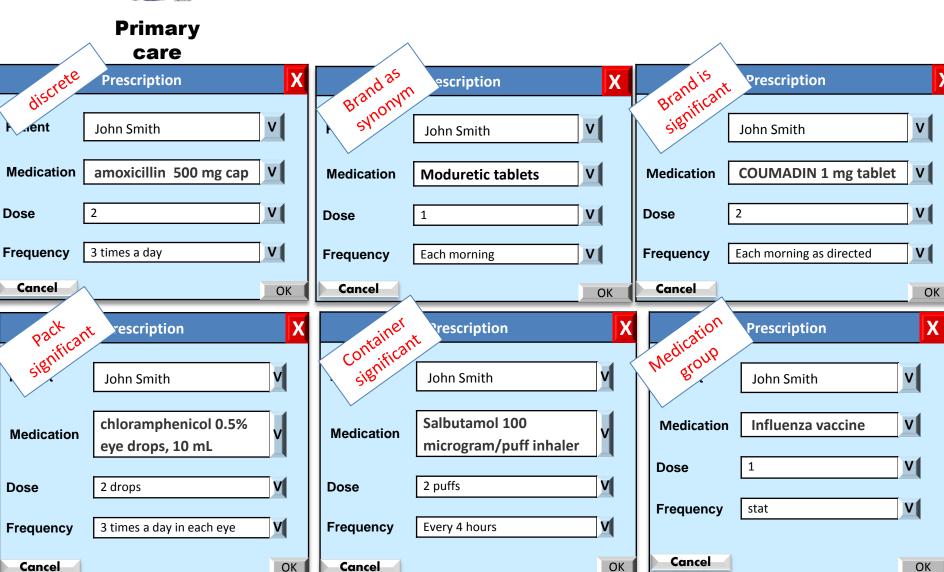
Cancel

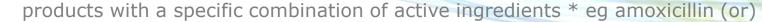
OK

OK



Prescribing variations







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 o.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)**



Prescribe

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

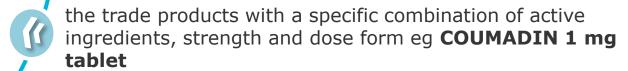
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concept that represent



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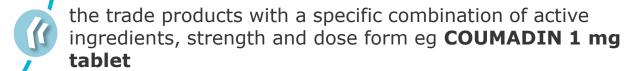
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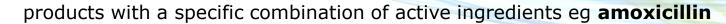
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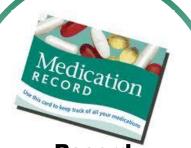
the trade products with a specific combination of active ingredients and dose form eg COUMADIN tablet

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 % eve 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



Record Allergies, history

concept that

represent











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

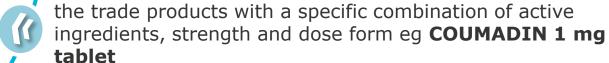
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Inventory Management

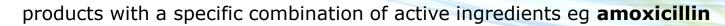
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Analytics

concept that represent



National Drug Concept Model

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)

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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

Base Data Model

The base data model includes the following medication classes:

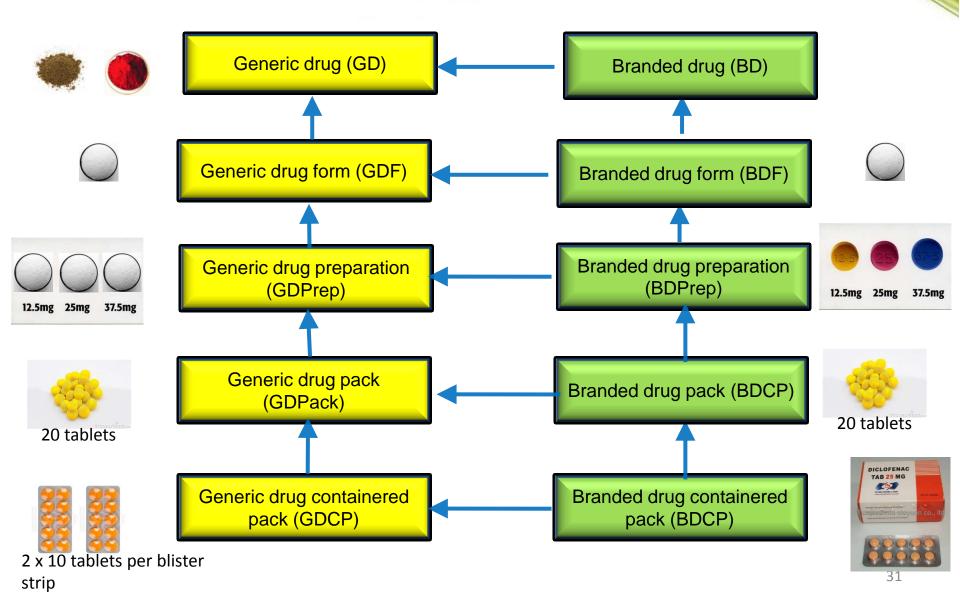
- Generic drug
- Generic drug form
- Generic drug preparation
- Generic drug pack
- Generic drug containered pack
- Branded drug
- Branded drug form★
- Branded drug preparation
- Branded drug pack
- Branded drug containered pack

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.

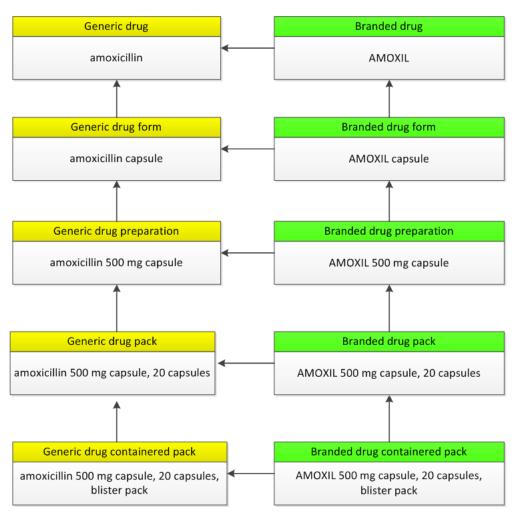
May not be available for distribution for multi components concepts

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

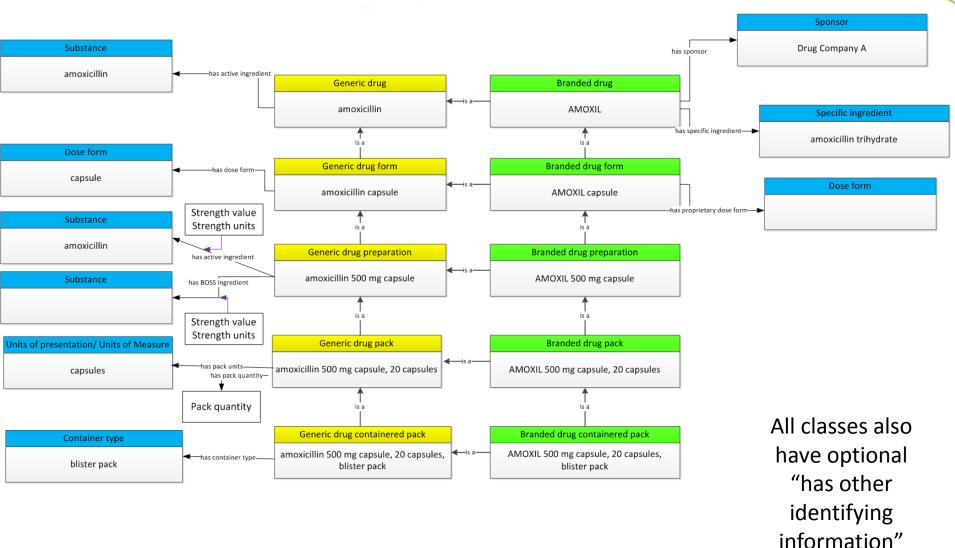
Base data model



Base Model - single ingredient



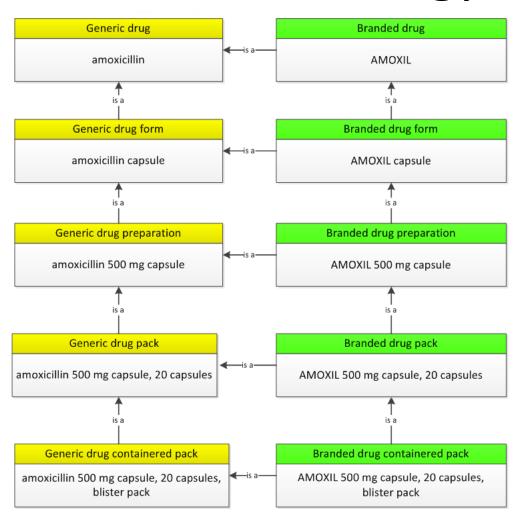
Base model defining relationships



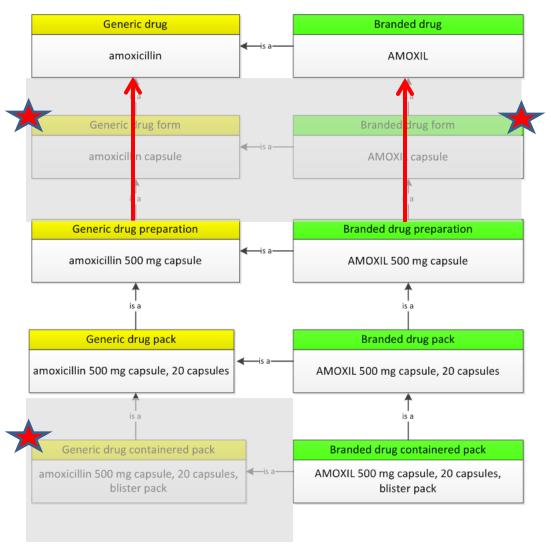
Distribution options

- 1. Full terminology all concepts and descriptions
- 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

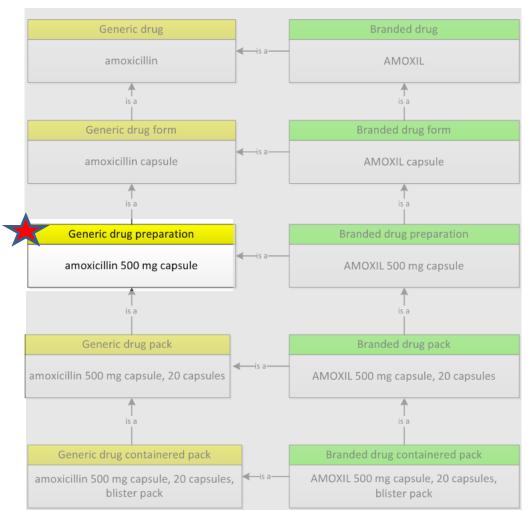
1. Full terminology



2. Clinically significant terminology

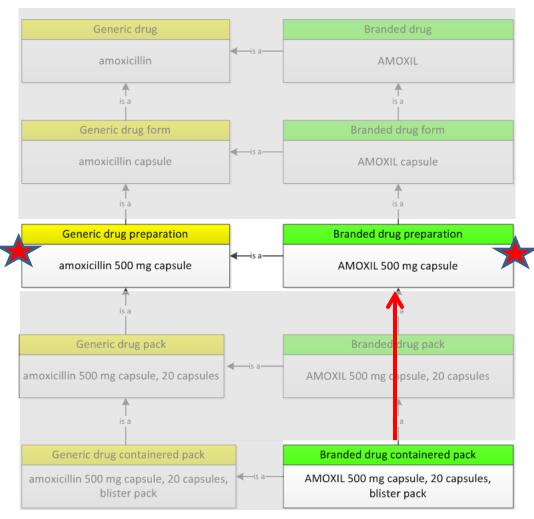


3. Prescribe use case specific value set





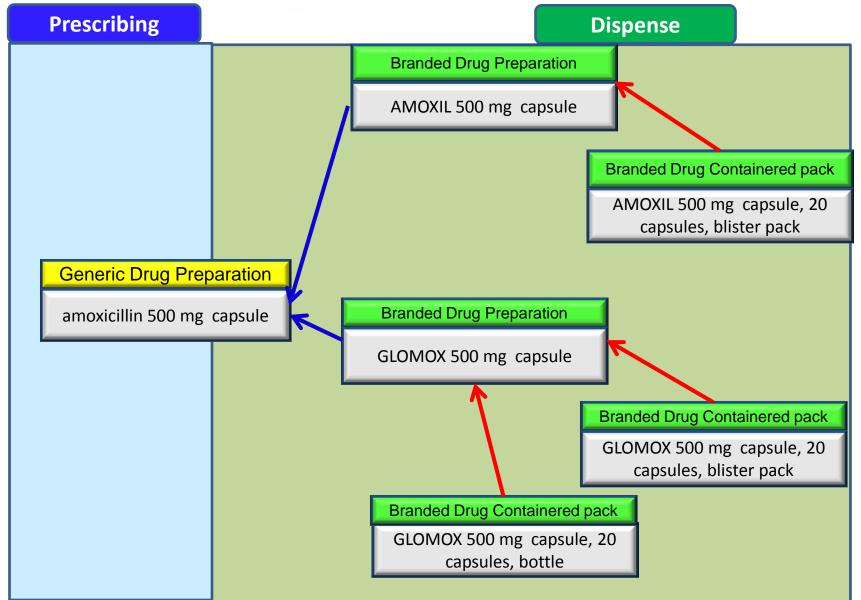
3. Dispense use case specific value set



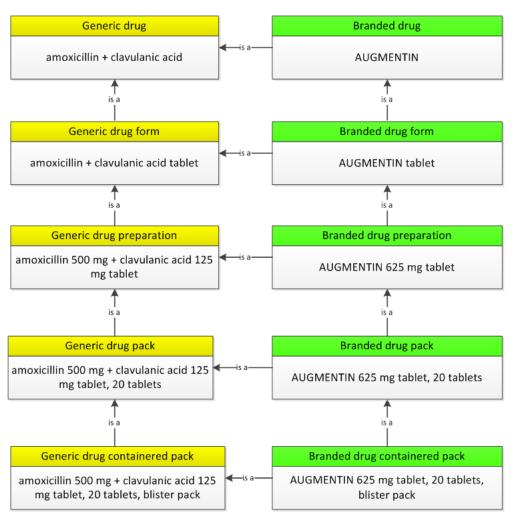


May differ by country and product type

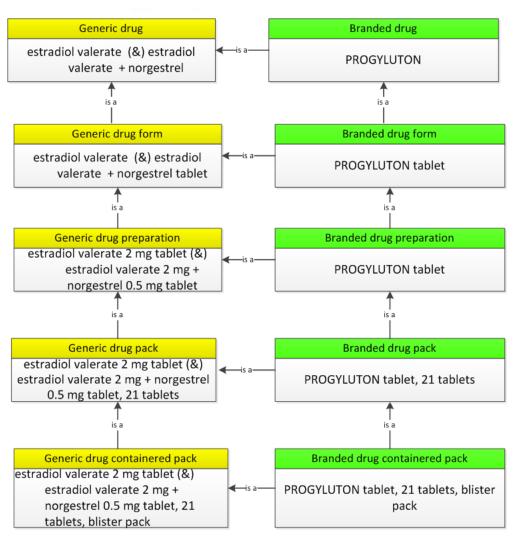
3. Use case specific value set



Base Model – multi ingredient

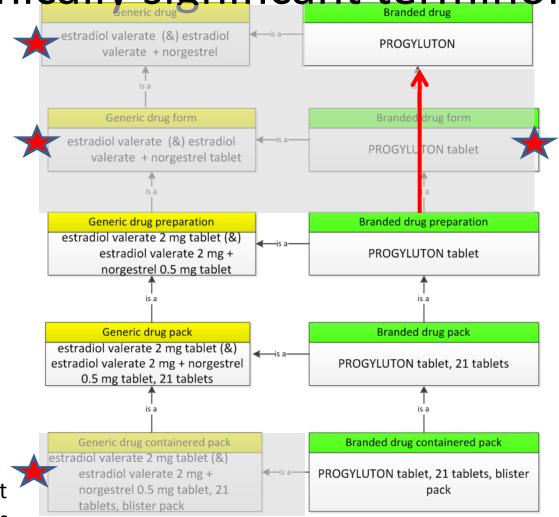


Base model – Multi component



Distribution Option 2:

Clinically significant terminology



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 classifer.

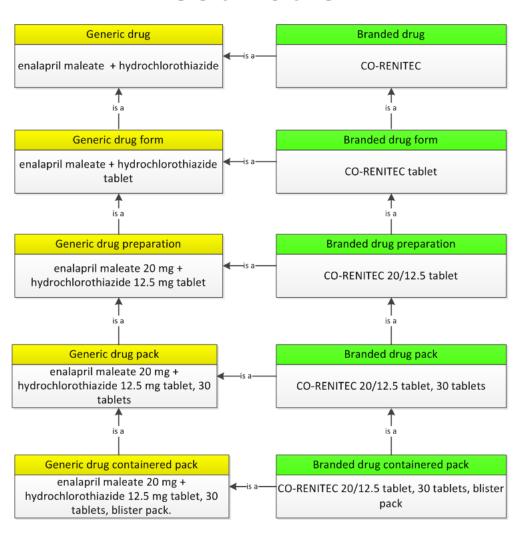
Note: For comparison this is not OWL 2 EL profile of description logic.

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".

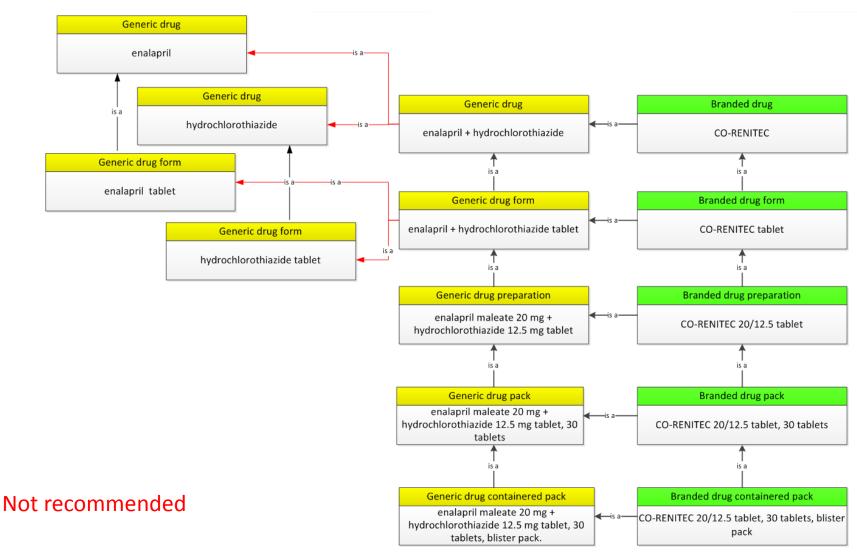
- Is quicker to classify
- No stated use case for extra relationships and these may have patient safety implications

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



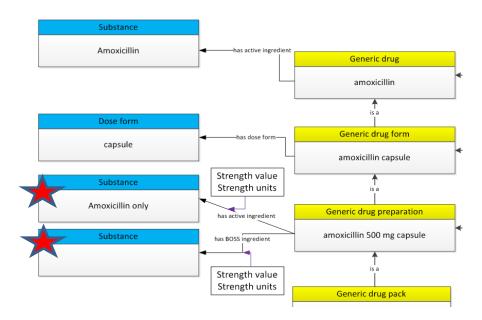
OWL 2 EL profile of description logic.

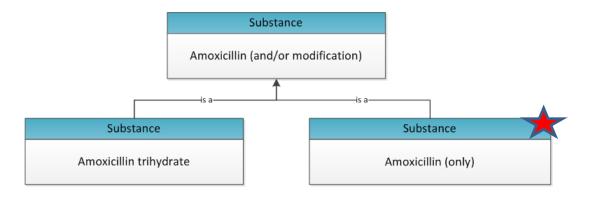


Substance Only

- 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

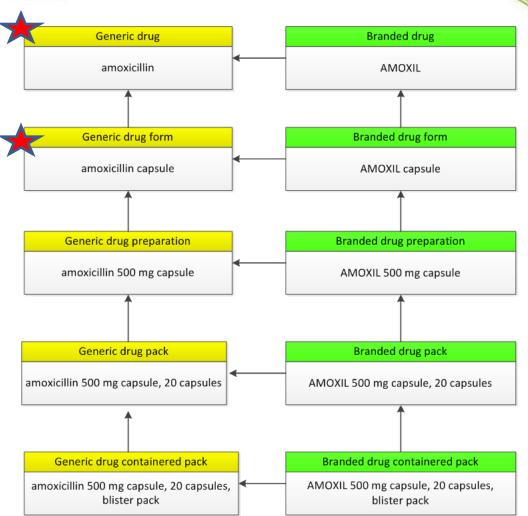
- 1. SNOMED CT International Release
- 2. Map to other identifiers and standards
 - GTIN
 - ATC
 - Regulator identifier
 - Decision support IDs
- 3. Components of multi component products
- 4. Reconstituted products
- 5. Clinically significant containers
- 6. Medication groups
- 7. Brand family group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

NOTE: This represents the major extension options rather than all extension options.

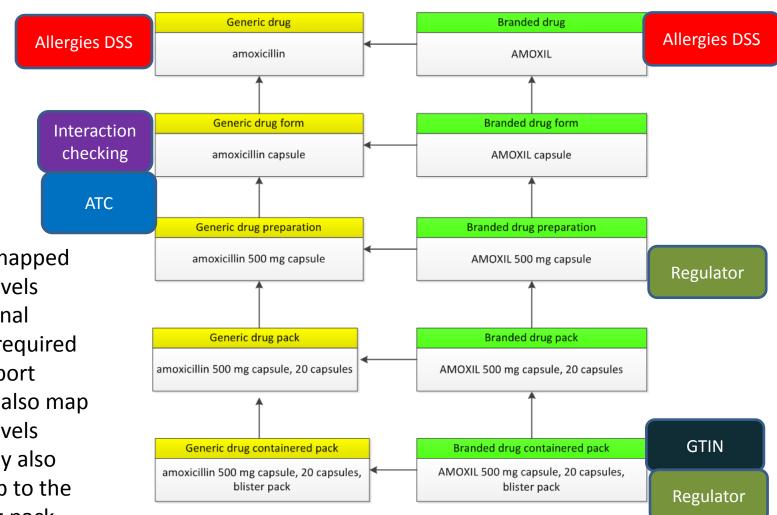
1. International Release

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

GTIN



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

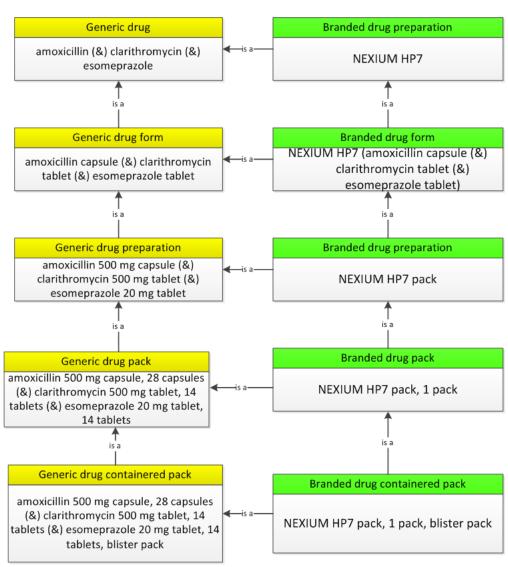
- The first 2 digits of the EAN-13 or GTIN (Global Trade Item Number) code are containing the country of the article. The country is coded with 2 or 3 numbers 629 represents UAE
- The next 4 to 5 digits code the producer of the article.
- The following 5 digits represent the article number which is given by the producer.
- The remaining last digit is the check digit.

ATC code

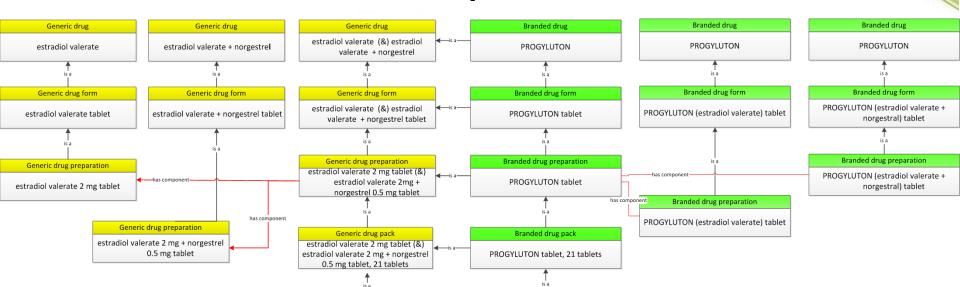
- A Alimentary tract and metabolism (1st level, anatomical main group)
- A10 Drugs used in diabetes (2nd level, therapeutic subgroup)
- A10B Blood glucose lowering drugs, excl. insulins (3rd level, pharmacological subgroup)
- A10BA Biguanides (4th level, chemical subgroup)
- A10BA02 metformin (5th level, 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



Branded drug containered pack

PROGYLUTON tablet, 21 tablets, blister

pack

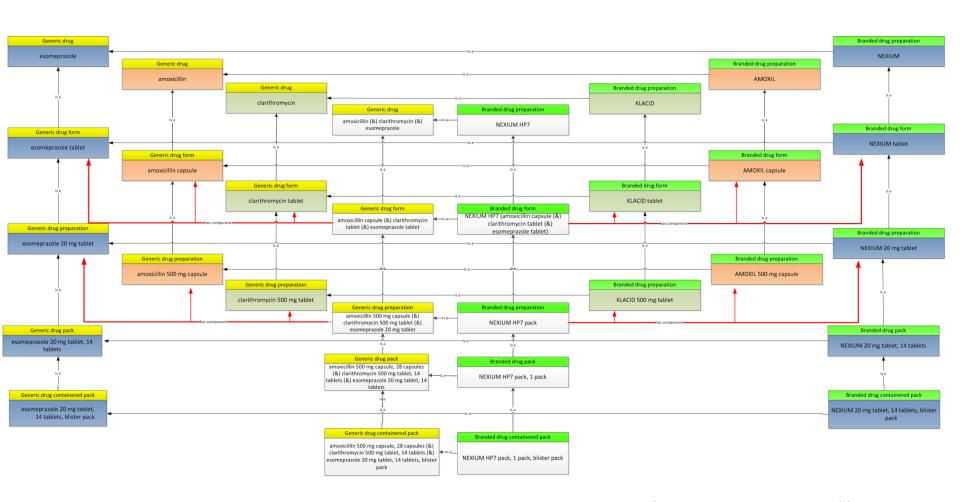
Generic drug containered pack

norgestrel 0.5 mg tablet, 21

estradiol valerate 2 mg tablet (&) estradiol valerate 2 mg +

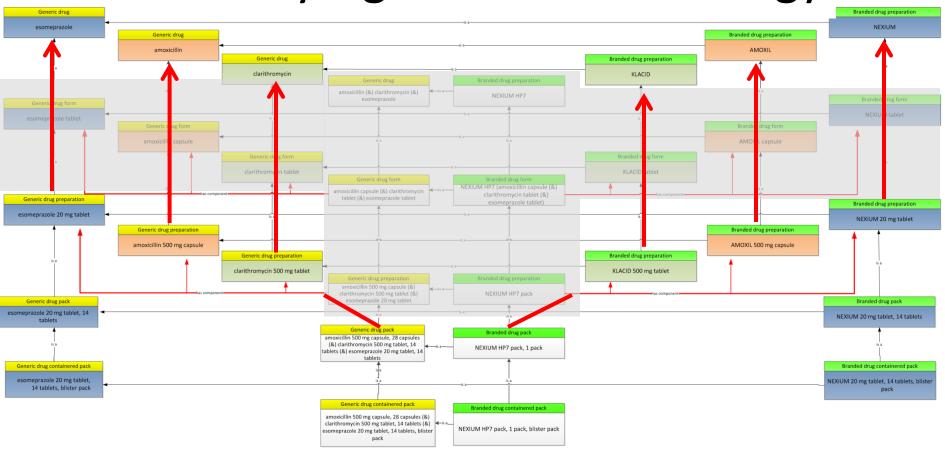
tablets, blister pack

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

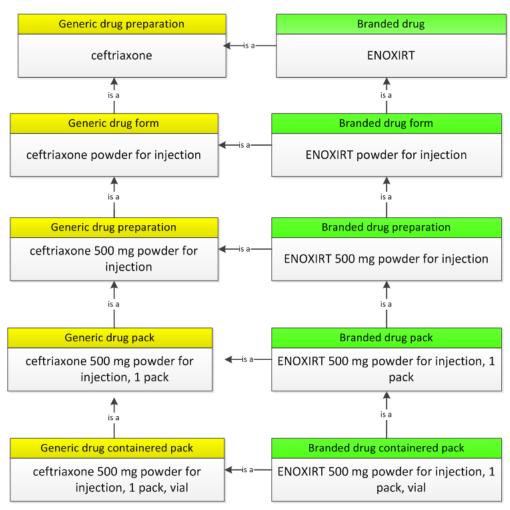


Transitive closure and extended has component relationships

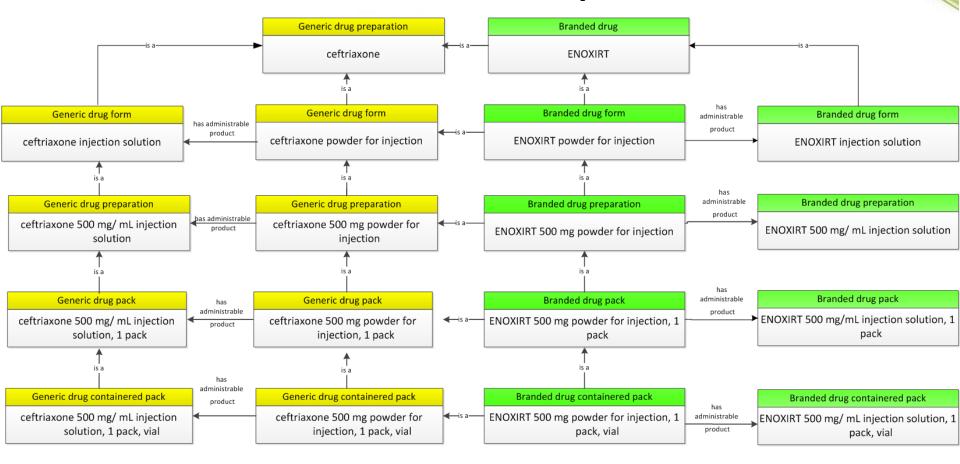
4. Reconstituted products

- 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



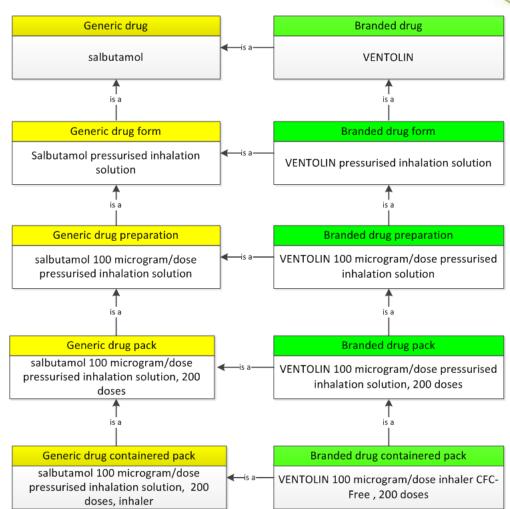
5. Clinically significant containers

Option 1: modify dose form to include clinically significant container

Option 2: Use only:

- Generic drug containered pack or
- Branded drug containered pack

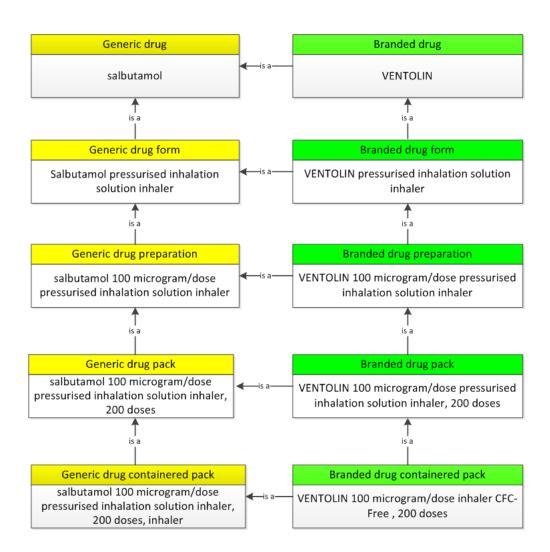
Option 3: Create containered classes . NOTE when these classes are created the equivalent classes without containers should be marked as not for distribution.



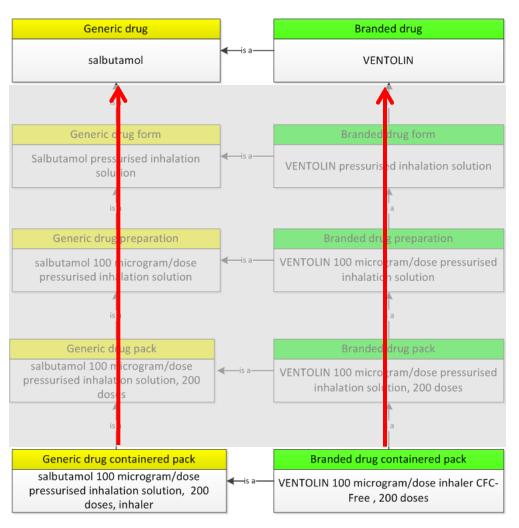
5. Option 1: modify dose form to include clinically significant container

Not recommended

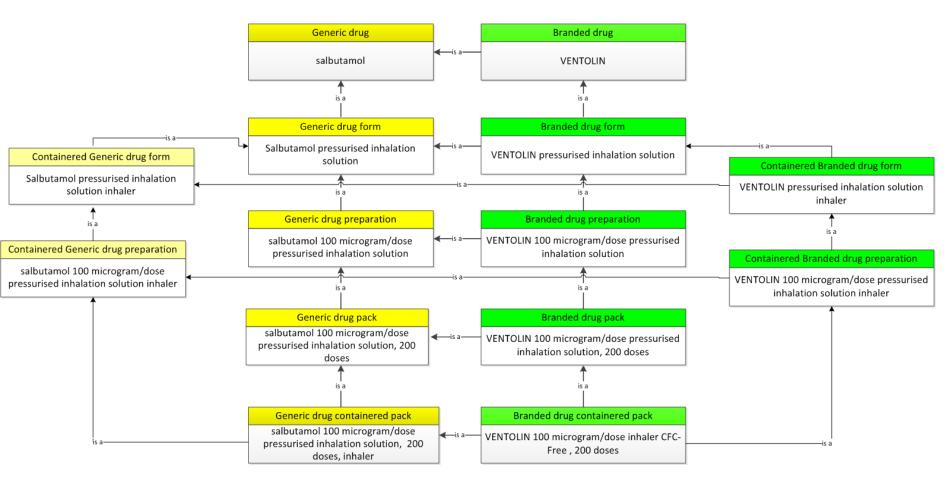
Note: In this example "pressurised inhalation solution inhaler" is a dose form which will require a synonym at Generic drug containered pack class to avoid duplication of the word inhaler



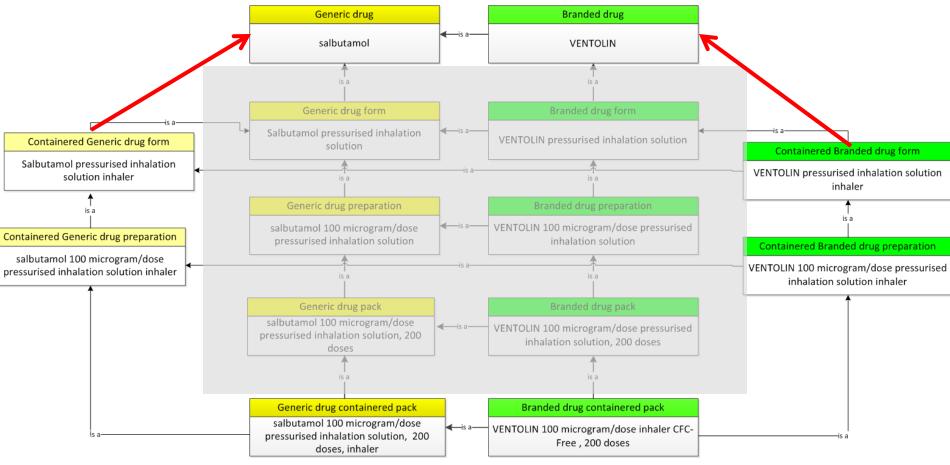
5. Option 2: Clinically significant terminology



5. Option 3: Clinically significant containers



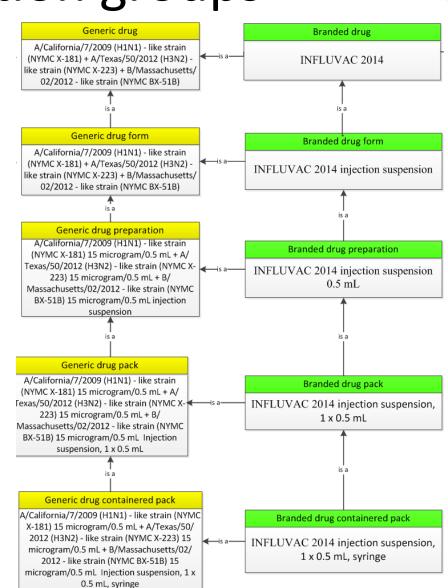
5. Option 3: Clinically significant terminology distribution option



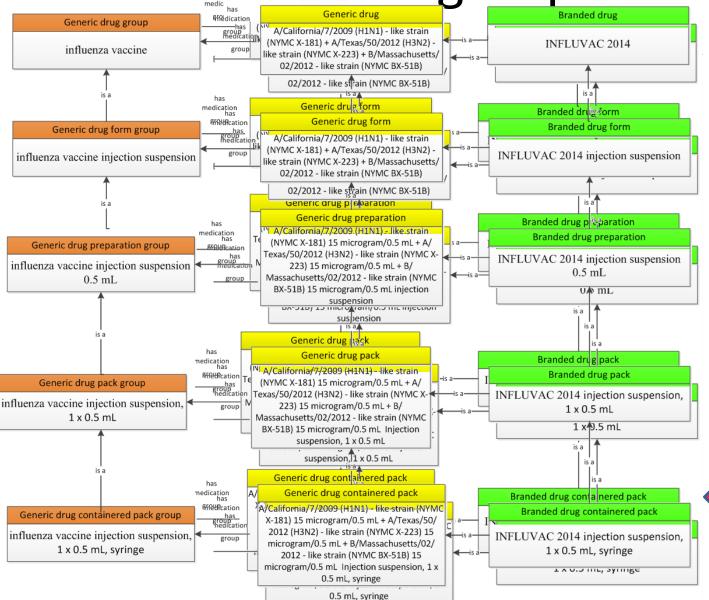
6. Medication groups

- 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.



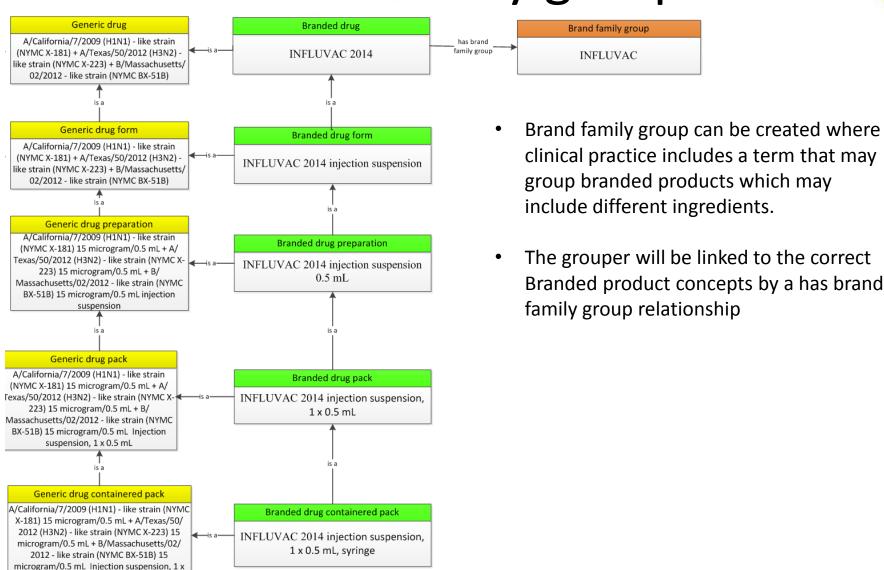
6. Medication groups



south 2015

2014

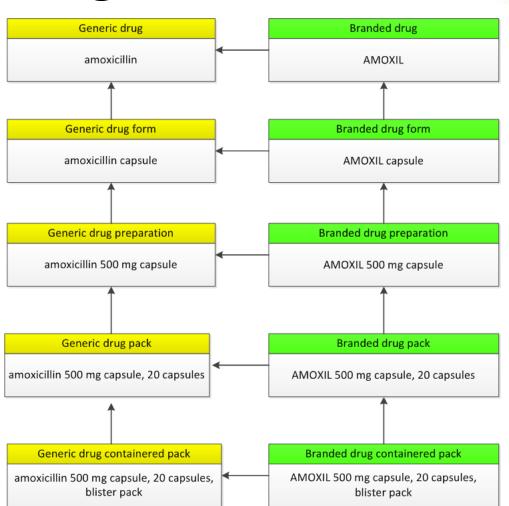
7. Brand family group



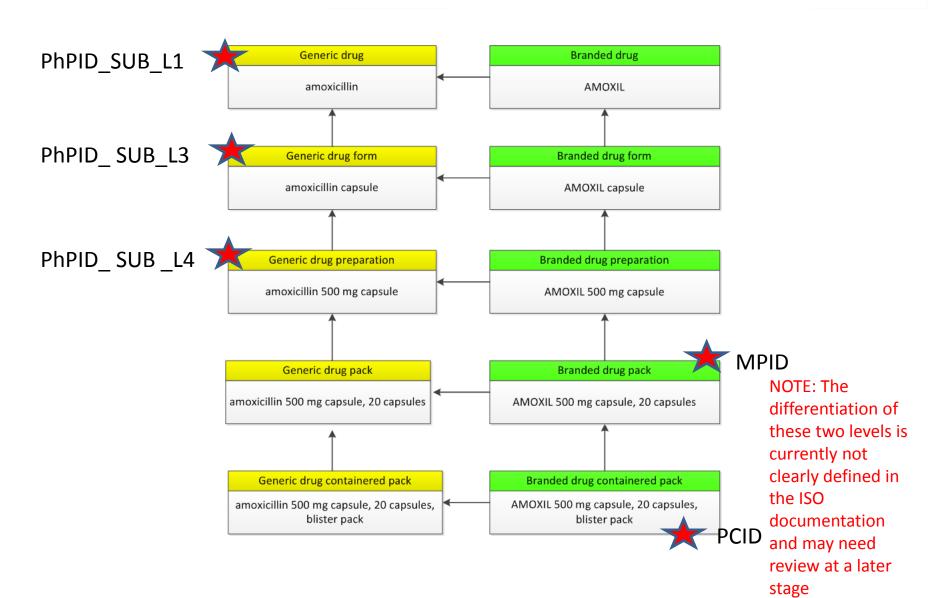
0.5 mL, syringe

8. IDMP alignment

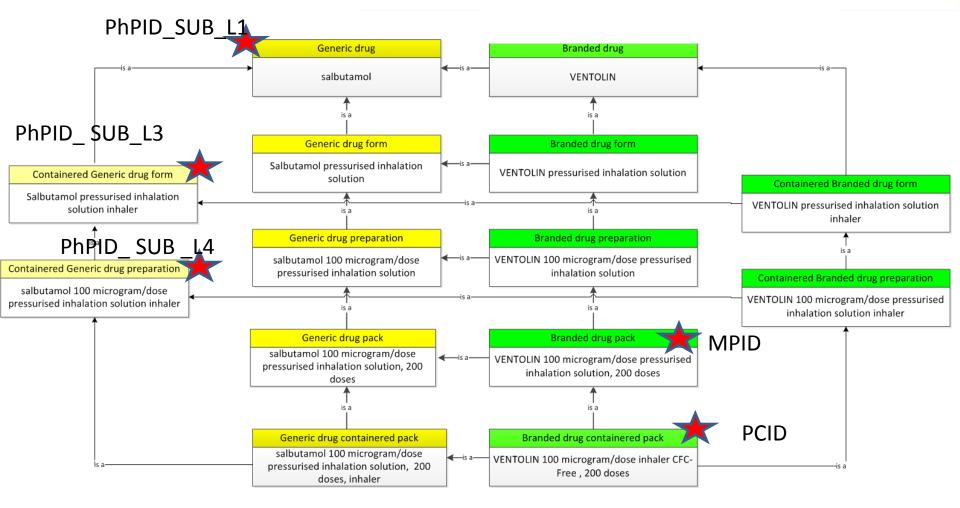
- Option 1: Map to IDMP concepts
- Option 2: Map to IDMP concepts AND add additional classes and relationships to ensure compliance to the data elements



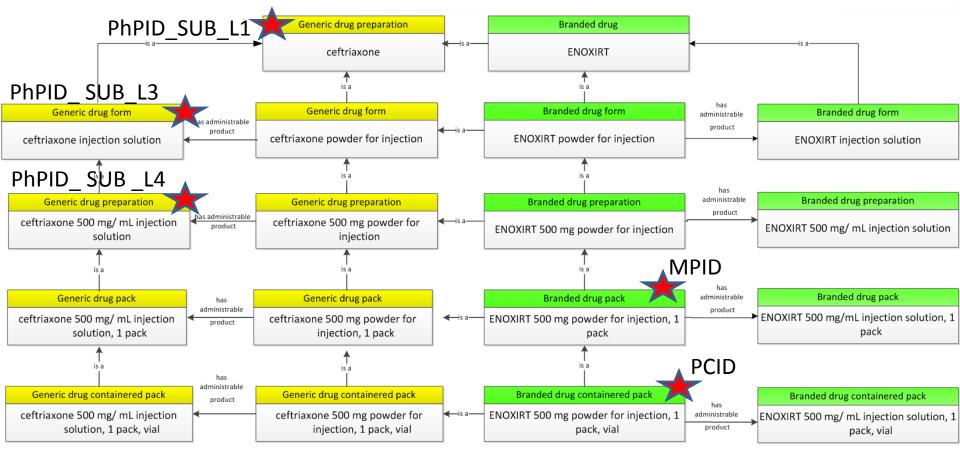
8. IDMP Option 1- Map example 1



8. IDMP Option 1: Map example 2



8. IDMP Option 1: Map example 3

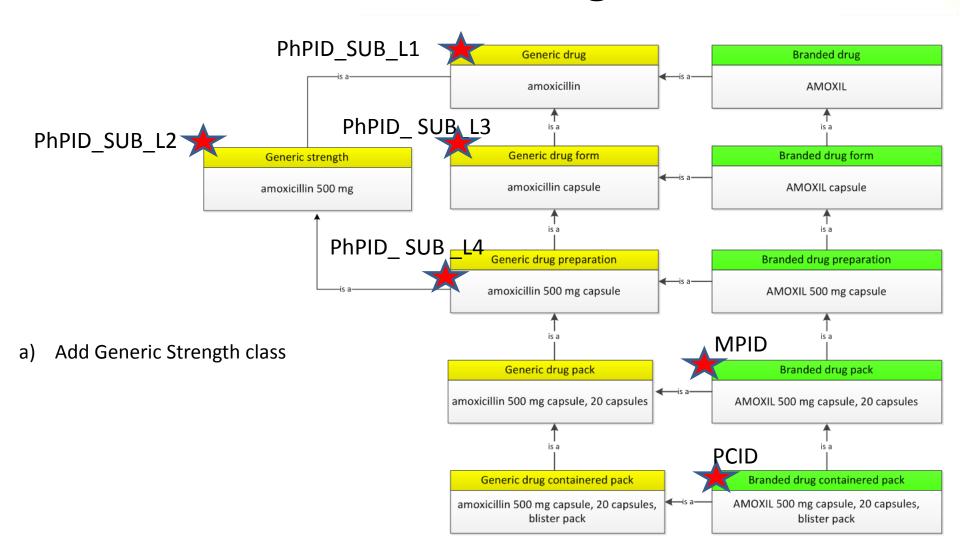


8. IDMP Option 2

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)

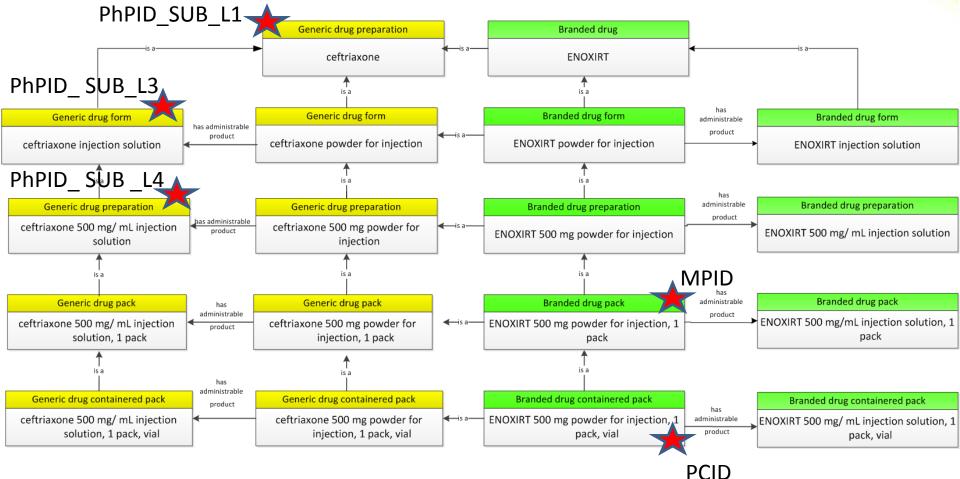
8. IDMP Option 2a-Add Generic Strength class



IDMP Option 2b - Add specific substance layer

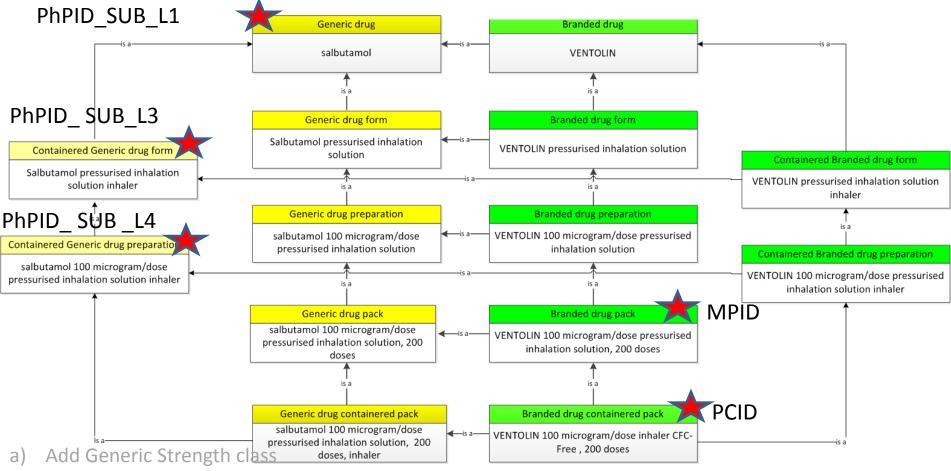
- a) Add Generic Strength class
- b) Add specific substance layer (NOTE: May not be relevant in clinical practice). This is a regulatory use case and the relevance would need to be reviewed again after completion of the Substance database and when the first few examples have been implemented in the IDMP database.

IDMP Option 2c-Add administrable dose forms



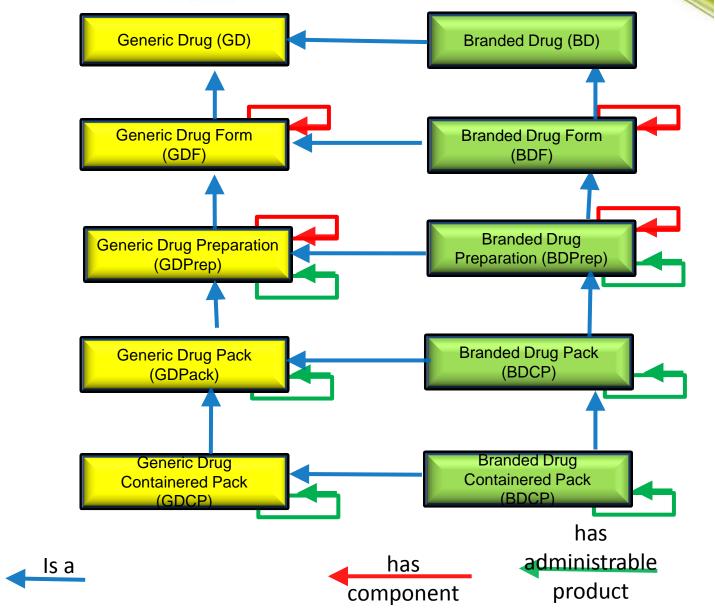
- a) Add Generic Strength class
- b) Add specific substance layer (when required
- c) Add administrable dose forms

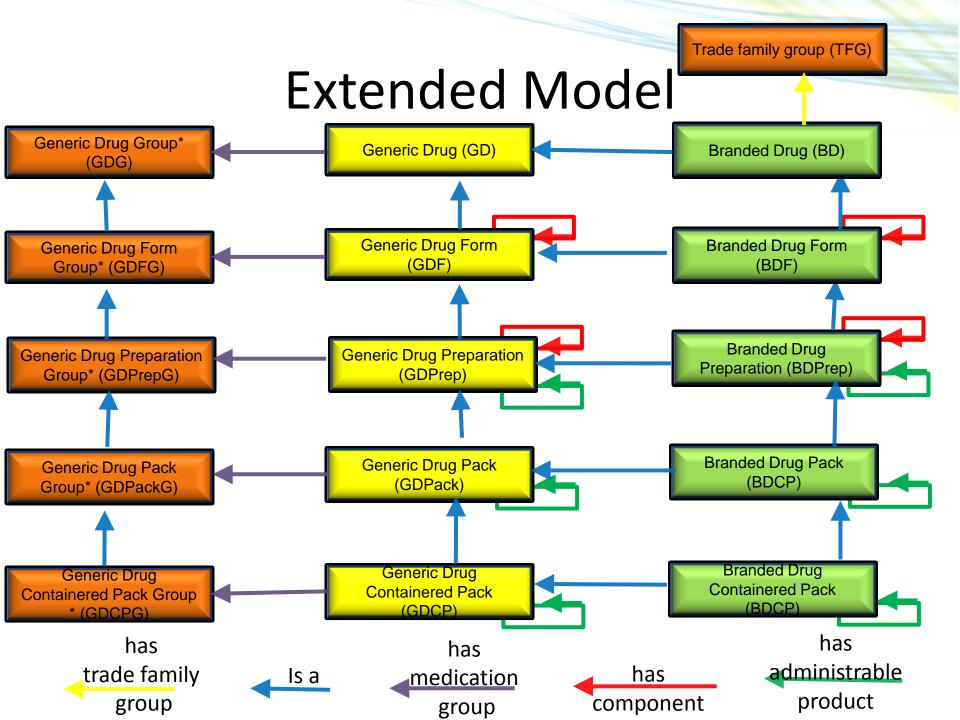
IDMP Option 2d – add administrable device

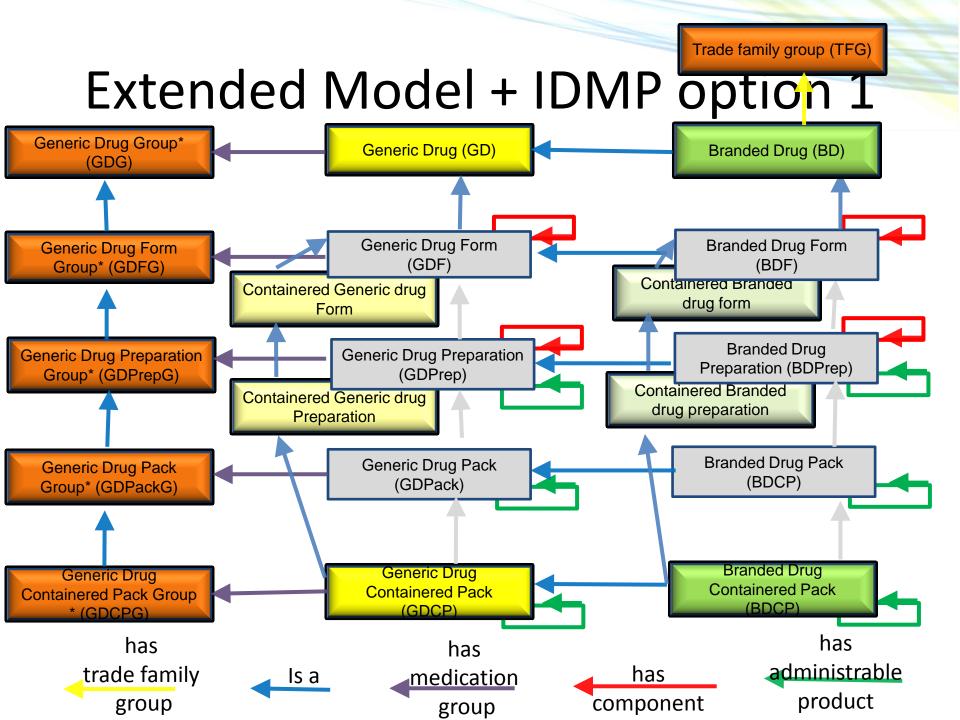


- b) Add specific substance layer (when required
- c) Add administrable dose forms
- d) Add device when required

Extended Model





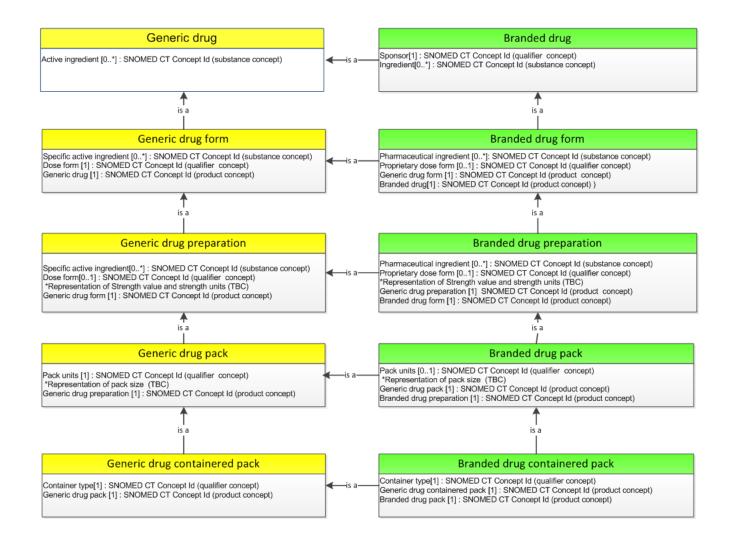


Other extension model options

- 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

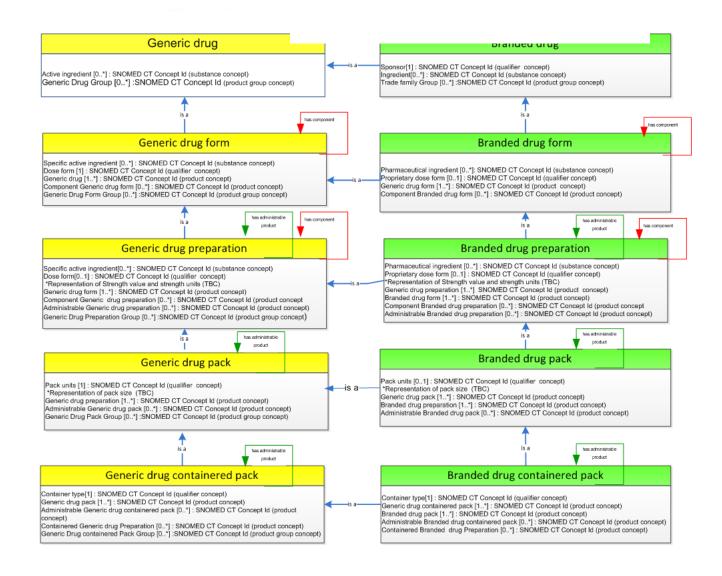
APPENDIX

Core Product Classes



Core Product Classes

+ administrable product and component relationships



All Product Classes

+ administrable product and component relationships

Containered generic drug form

Specific active ingredient [0..*]: SNOMED CT Concept Id (substance concept) Dose form [1]: SNOMED CT Concept Id (qualifier concept) container type[1]: SNOMED CT Concept Id (qualifier concept) Generic drug form [1..*]: SNOMED CT Concept Id (product concept)

Containered generic drug preparation

Specific active ingredient[0..*]: SNOMED CT Concept Id (substance concept)
Dose form[0..1]: SNOMED CT Concept Id (qualifier concept)
*Representation of Strength value and strength units (TBC)
container type[1]: SNOMED CT Concept Id (qualifier concept)
Container de Generic drug form [1..1]: SNOMED CT Concept Id (product concept)

Generic drug Active ingredient [0..*] : SNOMED CT Concept Id (substance concept) Generic Drug Group [0..*] :SNOMED CT Concept Id (product group concept) has component Generic drug form Specific active ingredient [0..*]: SNOMED CT Concept Id (substance concept) Dose form [1]: SNOMED CT Concept Id (qualifier concept) Generic drug [1..*]: SNOMED CT Concept ld (product concept) Component Generic drug form [0..*]: SNOMED CT Concept ld (product concept) Generic Drug Form Group [0..*] :SNOMED CT Concept ld (product group concept) product Generic drug preparation Specific active ingredient[0..*] : SNOMED CT Concept ld (substance concept) Dose form[0..1] : SNOMED CT Concept Id (qualifier concept) *Representation of Strength value and strength units (TBC) Generic drug form [1..*] : SNOMED CT Concept ld (product concept) Component Generic drug preparation [0..*] : SNOMED CT Concept ld (product concept Administrable 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 [1]: SNOMED CT Concept Id (qualifier concept) *Representation of pack size (TBC) Generic drug preparation [1..*]: SNOMED CT Concept Id (product concept) Administrable Generic drug pack [0..*] : SNOMED CT Concept Id (product concept) Generic Drug Pack Group [0..*] :SNOMED CT Concept Id (product group concept) has administrable product Generic drug containered pack Container type[1] : SNOMED CT Concept Id (qualifier concept) Generic drug pack [1..*]: SNOMED CT Concept ld (product concept) Administrable Generic drug containered pack [0..*]: SNOMED CT Concept ld (product

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

Sponsor[1]: SNOMED CT Concept Id (qualifier concept)
Ingredient[0,..*]: SNOMED CT Concept Id (substance concept)
Trade family 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) Generic drug form [1.-†]: SNOMED CT Concept Id (product concept) Branded drug[1.-†]: SNOMED CT Concept Id (product concept) Component Branded drug form [0.-†]: SNOMED CT Concept Id (product concept)

Branded drug preparation

has administrable

product

has administrable

has administrable

product

Pharmaceutical ingredient [0..7] : SNOMED CT Concept Id (substance concept)
Proprietary dose form [0..1] : SNOMED CT Concept Id (qualifier concept)
"Representation of Strength value and strength units (TBC)
Generic drug preparation [1..1] SNOMED CT Concept Id (product concept)
Branded drug form [1..1] : SNOMED CT Concept Id (product concept)
Component Branded drug preparation [0..1] : SNOMED CT Concept Id (product concept)

Branded drug pack

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

Branded drug preparation [1..*]: SNOMED CT Concept Id (product concept)
Administrable Branded drug pack [0..*]: SNOMED CT Concept Id (product concept)

Branded drug containered pack

Container type[1]: SNOMED CT Concept Id (qualifier concept)
Generic drug containered pack [1...]: SNOMED CT Concept Id (product concept)
Branded drug pack [1...]: SNOMED CT Concept Id (product concept)
Administrable Branded drug containered pack [0...]: SNOMED CT Concept Id (product concept)
Containered Branded drug Preparation [0...]: SNOMED CT Concept Id (product concept)