Ministry of Health

British Columbia
Professional and Software Conformance Standards

Electronic Health Information Exchange

Medication Ontology Guide

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- HLTH.HISSupport@gov.bc.ca

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1.0 Introduction

1.1 Purpose of Document

Electronic prescribing is envisaged as being part of a clinical system that includes a series of views, some of which present medication information for each patient. The aim of an e-prescribing system should be to promote known best practices (and enforce where necessary) for the safe and effective use of medicines.

This document provides guidance on the implementation of a Medication Ontology for electronic-prescribing which aims to provide the safeguards needed to ensure dose-based prescribing results in prescriptions without any unsafe ambiguities for those prescribing and dispensing medicines to patients.

1.2 Intended Audience

The intended audience for this document is developers, technical staff, and clinicians involved in application design, development, and integration of point-of-service (POS) systems connecting with the Ministry PharmaNet (PNET) system.

1.3 Overview

This document can be used for the design of a local data model to search for and prescribe individual medications for patients while also supporting the interoperability for electronic prescribing. It offers many benefits to providers and patients alike including:

- safer orders,
- more efficient order management,
- improved reporting at the practice and system level.

The implementation guide will also help vendors improve drug management within their products with less effort.

2.0 Drug orders and electronic prescribing

It is important to consider medication orders and electronic prescribing with a solid understanding of the concepts involved. At present, community care prescribing is generally done by entering drug orders on a paper pad to generate a prescription following a 'dose based' approach which is a variable process.

A dose-based approach advocates a prescribing system in which:

- A prescriber specifies a drug by its Virtual or Therapeutic moiety (i.e., generic name) plus dose, route, and frequency.
- A pharmacist (for example) then selects the correct quantity, strength prescribed, days supply, and manufactured product to dispense to the patient.

This means that the prescriber may typically first select a drug name and then define a dose quantity (e.g., '500 mg'), a route (e.g., 'oral') and a frequency (e.g., 'four times a day', commonly expressed on paper by its Latin abbreviation 'qds'), to produce:

- acetaminophen 500 mg – oral – qds

Note(s): *The use of abbreviated Latin forms in this example is intended to reflect existing paper-based practice, not as an example of best practice within electronic systems.*

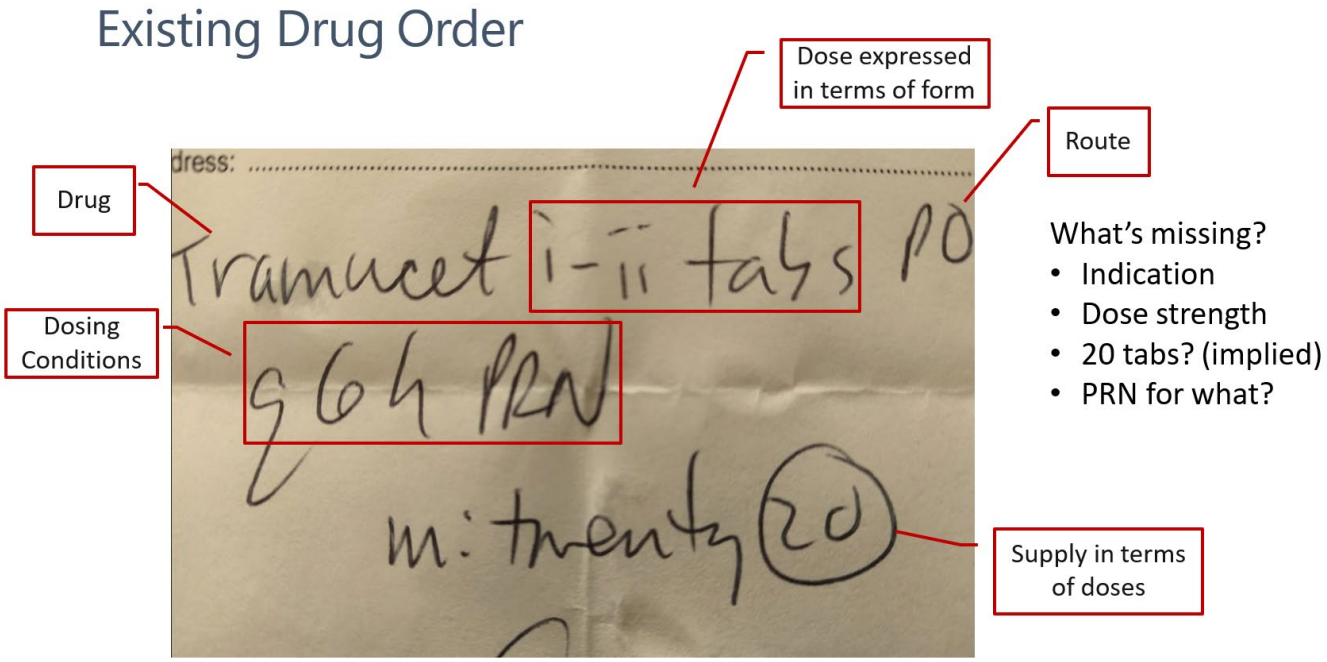
Legally, the prescription is an 'instruction to administer' a drug to a patient.

In most cases this instruction will be interpreted by a pharmacist, who will select and prepare the medicinal product to be administered – thereby selecting a form and a strength appropriate to the patient's condition (e.g., choose a suspension rather than tablets if the patient is having difficulty swallowing or a tablet whose strength is ½ the desired dose along with instructions to take 2 of these tablets at the ordered frequency). Therefore, the instruction to the pharmacist must be sufficiently safe and unambiguous to enable selection and preparation of a medicinal product which appropriately matches the prescriber's intent.

In electronic prescribing systems, the combination of a drug name and route can be used to 'map' to a set of medicinal products to capture the set of products for any given drug name and route combination. For many medicines, the combination of drug name, dose, route and frequency (e.g., 'acetaminophen 500 mg – oral – qds' as per the example above) is sufficient to define a 'set' of products which can safely be considered equivalent to each other in terms of administration.

However, the challenge of dose-based prescribing is that the necessary information may not be provided. For a significant number of prescriptions, more information may be required for the pharmacist or nurse to know precisely which products reflect the prescriber's intent.

See below example:



A drug might be specified as an actual manufactured product, a generic product (now referred to as a "non-proprietary therapeutic product") or simply as an active ingredient or therapeutic moiety. Sometimes the drug strength is specified in the product and the dose is specified in terms of the product (e.g., "amoxil 250 mg capsule, take one capsule orally 3 times per day") and other times the dose is specified in terms of the amount of drug should be taken (e.g., "amoxicillin 250 mg orally 3 times per day"). The duration of treatment can be expressed in terms of number of doses or length of time – e.g., "30 capsules" or "10 days". Route might be omitted when logically apparent by the form and vice versa.

Unfortunately, drug ordering functionality has often been added to electronic medical records (EMRs) and electronic health records (EHRs) in a way modeled after the paper process. The drug product information provided can be limited to a long list of manufactured products and their ingredients classified in a domain specific way. Deployment in this context can result in suboptimal and even unsafe workflow processes, especially when providers must wade through long lists of manufactured products.

To improve upon this situation, the concepts related to a drug order and their relationships are sketched out in an informal ontology below:

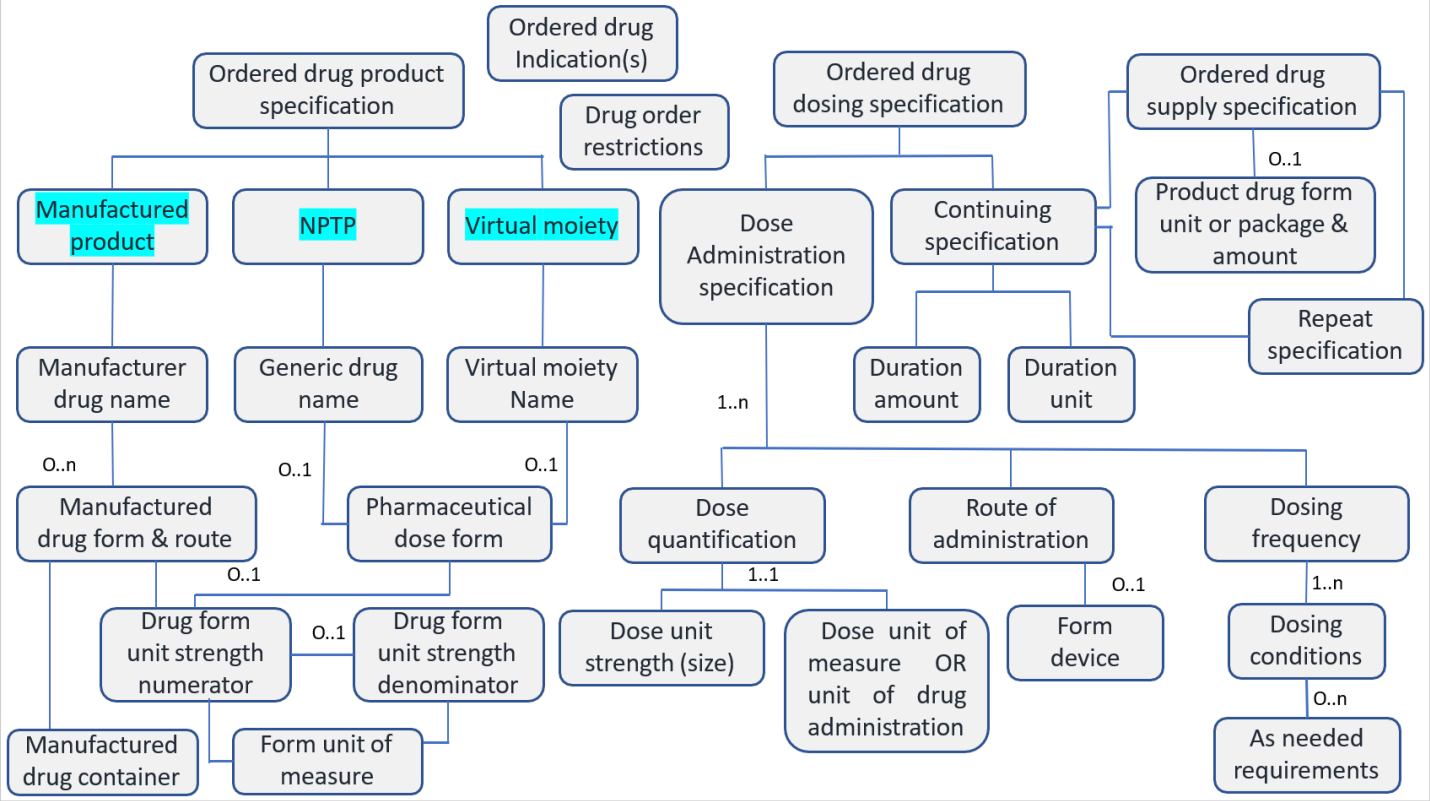


Figure 1

The drug order specific content is comprised of:

- drug product specification
- drug dosing specification
- drug supply specification
- drug order restrictions (such as “do not adapt”)

- drug order repeat specification
- indication for drug

3.0 Drug Data Structure

The concepts related to a medication order, dispense, administration or documentation of historical administration, and their relationships, are sketched out in the informal data model below:

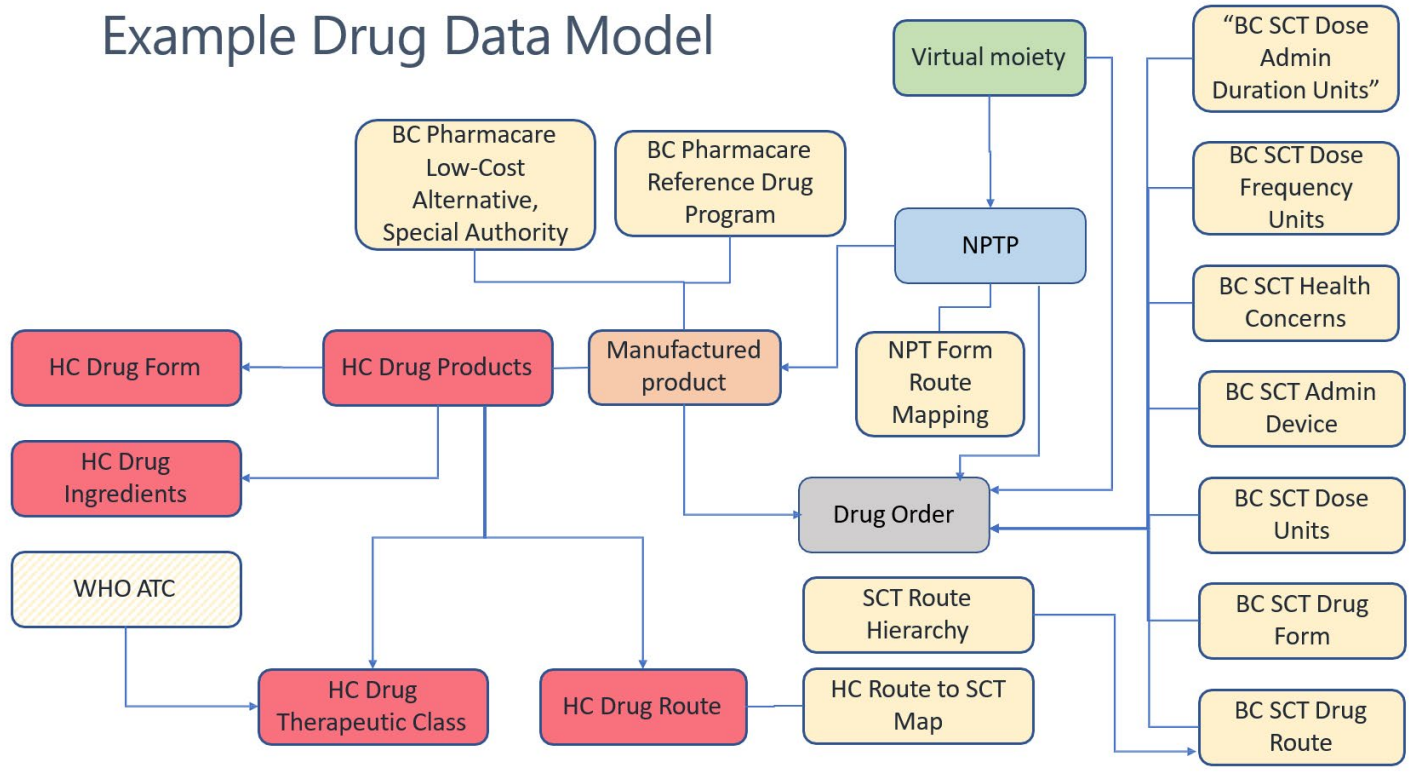


Figure 2

The drug data model uses standards to reduce variability making it less confusing for mapping 'idiosyncratic' differences (e.g., 'caplet'), allows unambiguous and safer pick lists for clinicians, and easier analysis for secondary uses such as medication profile management.

3.1 Drug Data Model Details

Drug products can be thought of as (see Figure 3):

- a specific manufactured product (MP) that identifies the precise ingredient, strength, dose form and relevant unit of presentation
- a non-proprietary therapeutic product (generic drug product or NTP) which includes information that is brand independent and is a clinically oriented representation of a manufactured product and qualitative strength, form and route (e.g., 2.5 mg oral tablet).
- a therapeutic moiety (the active substance(s) - TM). Referred to as "virtual" or "therapeutic" since there is no specified product and associated excipients.

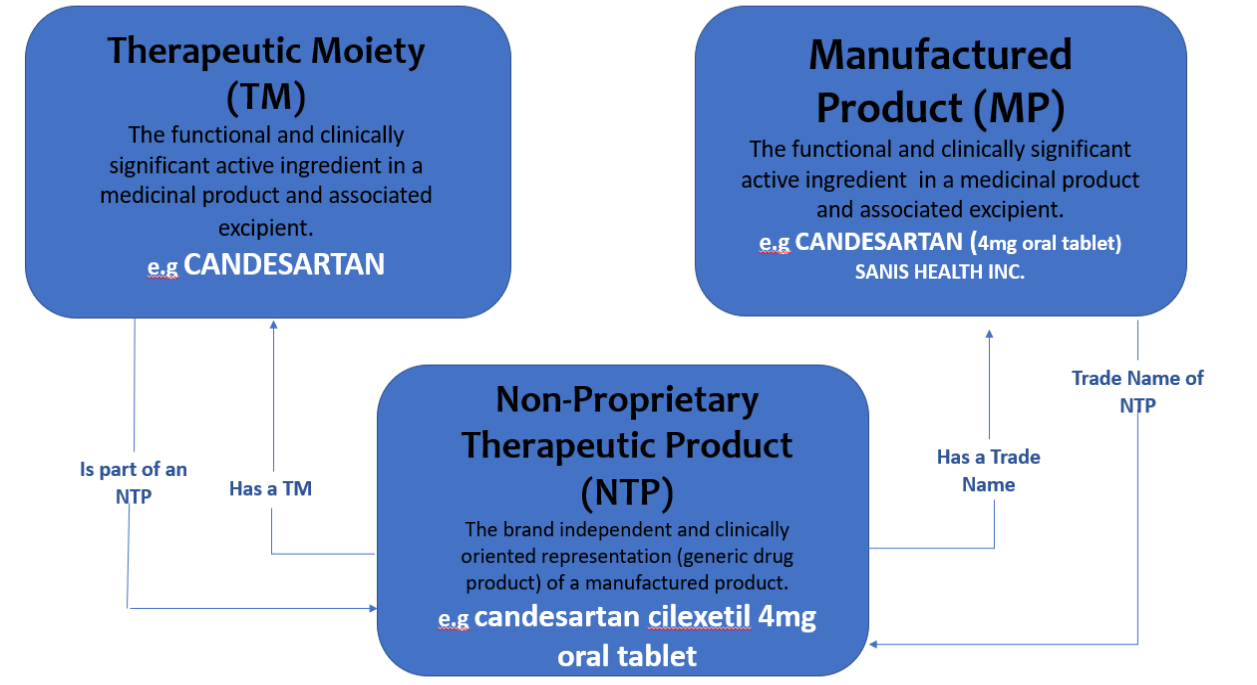


Figure 3

Sometimes the characteristics of a specific MP are desired given the product's proven tolerance or response by the patient, stability, form, or packaging. Usually, an NPT is what providers are most interested in ordering especially when there are multiple manufactured products or multiple ingredients. They often prefer that the pharmacist decides on the product, especially in consideration of availability, benefit programs for "low- cost alternatives" etc. Single product drugs are usually thought of by clinicians as a TM e.g., "ramipril", "pantoprazole" or "hydrochlorothiazide" and the possible routes, forms, and doses of the TM are well known. In such cases, it is easiest to make no assertion about a product, manufactured or non-proprietary. Given the presence of formularies in the acute care setting, TMs historically are the preferred drug specification. The active ingredient(s) specification in that case is still for a drug product eventually to be received but the delivery of that product is further left up to the supplier or administrator of the drug.

Drug products have a specific form and a TM, which is limited in possible deliverable form to the products that contain that TM. TMs therefore usually require form specification by the provider to give best results for the patient (e.g., a young child usually does better with a solution or suspension than they do with a tablet or a capsule).

The drug dosing specification builds upon the information provided in the ordered drug product specification. It is comprised of a dose administration specification and a "continuing" specification which outlines how long the dose administration will continue. Each dose administration consists of a strength (size) of the drug in the dose, a route of administration which may be more specific than the route that products are licensed to be administered (e.g., the product may be intended for injection, but the possible routes may include subcutaneous, intramuscular, or intravenous). The administration may be facilitated by a specific device such as a nebulizer or a metered dose inhaler. In the latter case the administration device frequently is equivalent to the packaging unit.

The dosing specification also includes frequency of dosing using a "conditional" requirement (e.g., "every 6 hours" or "four times per day"),which technically are different specifications. In the first instance, when 6 hours elapses from the most recent dose, the condition is met for administration. Other conditions may be specified (e.g., "take one tablet every 6 hours as needed for pain").

The drug dosing specification also has a “continuing” specification (i.e., the duration of the administration which may be measured in time or quantity of doses). Drugs which are intended to be continuous (indefinite) are generally ordered without a continuing specification so that the continuous nature is implied. However, without a continuing specification, an ordered drug supply specification is required for there to be a legal amount of dispense. In the case of a continuous drug administration, the specified supply determines when a repeat order is necessary. Repeats of an order can be specified up to a limit determined by regulation.

Finally, an ordered drug product, drug dosing and drug supply specification has an indication. This is expressed as a diagnosis (e.g., “eczema”) or finding (e.g., “rash”). Indication provides clarity to other providers including the dispensing pharmacist or administering clinician (which may be the pharmacist) around the intended purpose of the order. This can be important since many drugs have substantially different therapeutic intent and therefore care considerations. A beta blocker may be given for hypertension, arrythmias, congestive heart failure, headache management or performance anxiety. Without specified therapeutic intent, other providers may inappropriately be left to assume the presence of conditions.

Most of the concepts described above are associated with value sets. Historically, the required value sets emerge in local initiatives, in broader standards that may become out of date or simply by convention expressed by providers to their vendor. The BC Provincial Prescription Management (PPM) initiative includes the specification of value sets to improve interoperability as well as support common experience by providers across user interfaces and venues. The Health Information Standards team has aligned these value sets as much as possible with national and international efforts to make them as durable and transportable as possible. The metadata provided for CCDD NPT and TM can support vendors innovative functionality like cascading entry of drug, route, and form.

3.2 Drug Code System Details

The value sets and associated code systems include:

- Drug product specification for MP, NPT and VM utilizing the Canadian Clinical Drug Dataset (CCDD), and the Canadian Drug Product Database (DPD). The DPD has been merged with the CCDD in a flat table to provide WHO Anatomic, Chemical, Therapeutic classification (ATC) as well as to provide an additional check on which drugs in the CCDD are currently active. ATC should be associated with all specified products to facilitate clinical decision support and reporting.

- Drug forms aligned with Canadian drug forms embedded as text in the MP and NPT as well as listed in the DPD. These have been mapped to a SNOMED CT form value set.

- Drug administration routes also aligned with that in the CCDD and DPT and mapped to a SNOMED-CT route value set. The entries in this value set expand to the clinically possible specific routes that the providers wish to specify e.g., the drug product route may be listed as "for injection" but the clinician wishes it to be delivered intramuscularly.

- Dose-unit SNOMED-CT.

- Dose frequency SNOMED-CT.

- Drug indication utilizing the BC Health Concerns Value Set (HCVS) containing about 9400 SNOMED-CT findings and diagnoses concepts. These were carefully selected to include most health concerns seen in family medicine as well as specialist practice. An implementation guide for this can be found at B.C Implementation Guidance for SNOMED CT. This value set is reusable in other parts of the EMR – e.g., the problem list, encounter diagnoses, reason for referral etc. Note that all entries in the HCVS are mapped to ICD-9, ICD-10 and CED-DxS so that requirements for other systems such as Teleplan MSP billings and NACRS in emergency departments can be satisfied while giving providers the benefit of a much more clinician friendly way of health concern structured entry.

- Pharmacare benefit information including unit price for incorporation into the UI and clinical decision support.

The PharmaNet interface standards contain business rules for safe drug ordering such as management of preceding and following zeros in numeric values to minimize the risk of misinterpretation e.g., reading “4.0” as “40” or “.25” as “25”. There are many other considerations for an effective drug management UI that are not contained in the PharmaNet interface business rules. Vendors are encouraged to incorporate these business rules and guidance into their UI and data for a safer and more effective system. This should reduce the burden of processing data for the messages. Guidance can be found for the user interface and its content in other jurisdictions or domains. Some examples are provided in the references below.

We recognize that many vendors use third party products for drug utilization evaluation such as drug/drug interactions and these products may be dependent on the DPD DIN. This would be expected to pose problems when passing NPTs or VMs for interaction checking. This may be accommodated by finding a representative DIN (random or first found) of a child MP, preferably by incorporating route in the query.

The guidance in this document for the design of searching for and prescribing of individual medications does not assume the use of the DPD-MP-NTP-TM relationships value set will work with every third party drug database that uses the concepts of generic drug name, which equates to Virtual Therapeutic Moiety (VM) in the DPD-MP-NTP-VM, and branded drug name, which equates to Manufactured Product (MP) (i.e., Brand Name).

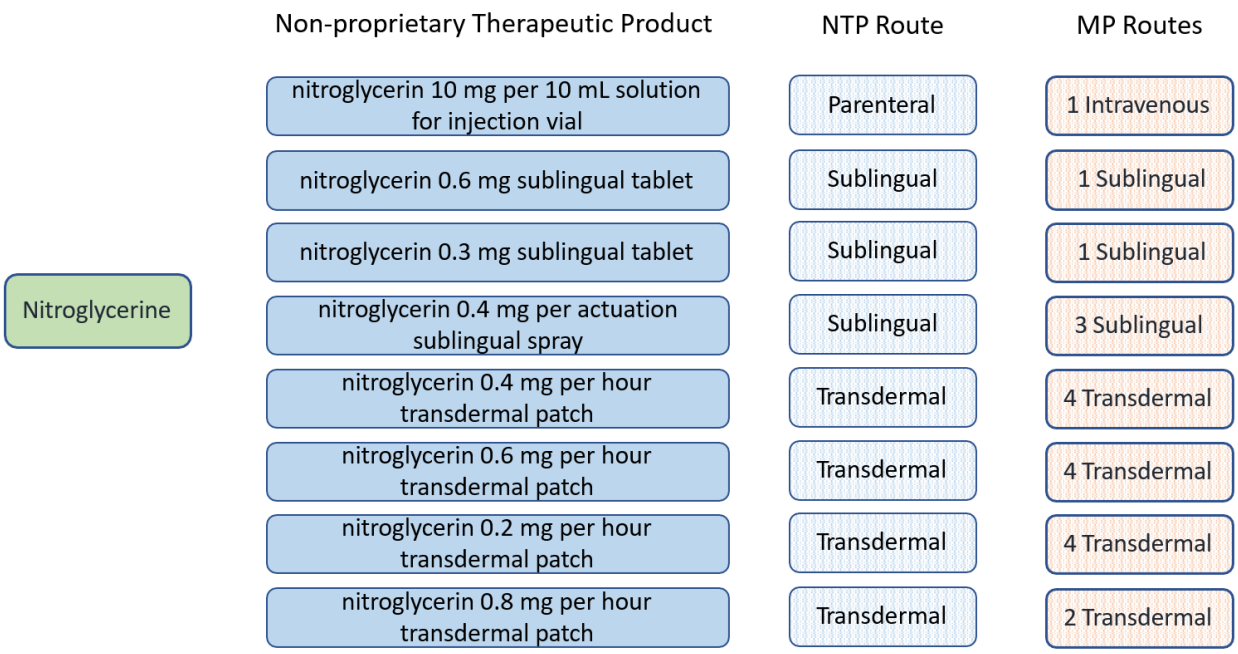

Non-proprietary Therapeutic Product
NTP Route
MP Routes
Nitroglycerine
nitroglycerin 10 mg per 10 mL solution for injection vial
Parenteral
1 Intravenous
nitroglycerin 0.6 mg sublingual tablet
Sublingual
1 Sublingual
nitroglycerin 0.3 mg sublingual tablet
Sublingual
1 Sublingual
nitroglycerin 0.4 mg per actuation sublingual spray
Sublingual
3 Sublingual
nitroglycerin 0.4 mg per hour transdermal patch
Transdermal
4 Transdermal
nitroglycerin 0.6 mg per hour transdermal patch
Transdermal
4 Transdermal
nitroglycerin 0.2 mg per hour transdermal patch
Transdermal
4 Transdermal
nitroglycerin 0.8 mg per hour transdermal patch
Transdermal
2 Transdermal

Figure 4

4.0 Drug files related to the ontology.

4.1 Drug Product Database (DPD) Health Canada

- Drug Product Database (DPD) Data Extract All Files - Health Canada
    - Drug Product Database - All Files - Open Government Portal (canada.ca)
- Drug Product Database (DPD) API Guide
    - Drug Product Database (DPD) API Guide (canada.ca)
- Drug Product Database (DPD) Data Extract - Health Canada
    - What is the DPD Data Extract? - Drug Product Database (DPD) Data Extract - Health Canada - Canada.ca
- Read Me File - Drug Product Database (DPD) Data Extract - Health Canada
    - Read Me File - Drug Product Database (DPD) Data Extract - Health Canada - Canada.ca

4.2 Canadian Clinical Drug Data Set (CCDD) Canada Health Infoway

- Canadian Clinical Drug Data Set
    - Canadian Clinical Drug Data Set (infoway-inforoute.ca)

4.3 PharmaCare Drug Data set (PDDF) B.C PharmaNet system

- PDDF Pharmacare file
    - Downloadable Drug Data Files - Province of British Columbia (gov.bc.ca)