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Main author(s):

Ursula Tschorn	IDMP1
Julie James	IHD

Other author(s):

Name	Org acronym
Leonora Grandia	ZINDEX
Robert Van der Stichele	IHD
Frédéric Doc	VIDAL
Jane Millar, Monica Harry	SNOMED

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Julie James (IHD)	0.25

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Deliverable abstract

Pharmacy systems almost all keep patient medication lists; this deliverable will provide guidance for pharmacy system providers on how IDMP can help pharmacists to use medication list information to provide high quality pharmaceutical care.

Keywords: Pharmacy system provider, IDMP, Patient Medication List, Identifying medicinal products.

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List of abbreviations

Abbreviation	Complete form
EMA	European Medicines Agency
IDMP	Identification of Medicinal Products
MAL	Minimum Attributes List
MPID	Medicinal product identifier
NCA	National Competent Authority
PCID	Packaged Medicinal Product Identifier
PhPID	Pharmaceutical Product Identifier
RMS	Referential Management Service
UTI	Urinary Tract Infection
WP	Work Package

Executive summary

This delivery is focussed on the pharmacy system suppliers. Pharmacy systems almost all keep patient medication lists; this deliverable will provide guidance on how IDMP can help pharmacists to use IDMP data in the medication list information to provide high quality pharmaceutical care, both locally and in the cross-border context.

1 Introduction and Background

1.1 Background – the Medication List

For some time now, computerised medication systems (for prescribing, dispensing, administration and record of medicines for patients) have been repeatedly increasing treatment safety and decreasing the risk of harm caused by medication errors. With the advent of the implementation of the IDMP Standards, this process of increasing patient safety is extending to the ability to support cross border and global interoperability in medication information in eHealth.

However, the major challenge in many countries worldwide is and remains the merging of information from different systems (e.g., of general practitioners, specialists, or hospitals) and the creation of a uniform overview of the medicines of each patient. Hence the concept of the patient e-medication list to store all medication in use and relevant to a safety check.

For such an overview, information is necessary: on the one hand, on the prescribed medicines, on the other hand, on the medicines dispensed. Moreover, since doctors only document those medicines that they prescribe themselves, it is very difficult to obtain a standardised overview of all medicines for a patient. The risk for physicians of side effects and incompatibilities in the interplay of several medicines increases dramatically, especially when they do not have a full picture of all medications.

The medication list quickly conveys all medications the patient is currently taking, all past medications and the exact combination of medications being taken at the time of each patient visit.

1.2 Introduction to D9.4

Reference to Unicom delivery D5.7 Common minimum data set that needs to be implemented in the national NCA and eHealth solution.

An IDMP enabled medication list can be used to identify key facts about the patient and his medication, presenting opportunities to reduce the risks of errors of omission or commission. As a global standard, maintained by an international collaborative effort, IDMP offers a vendor-neutral resource for the pharmacy system to identify the patients´ medicines on his electronic medication list. Medicinal products´ attributes are listed as code and term following the Referential Management Service (RMS) lists, to allow international information exchange.

The pharmacies' electronic medication list per patient is closely related to the patient´s medication in other eHealth applications. This document therefore refers to the document "D5.7 Common minimum data set that needs to be implemented in the national NCA and eHealth solution", which describes the data elements needed for a medication list in eHealth solutions.

1.3 Scope of the document

This document intends to present a common minimum data element list that needs to be implemented in the pharmacy system using IDMP to make the bridge to other systems in the healthcare environment and specially to prescribing systems. Guidelines targeted at the pharmacy system provider will be focused to the minimal attributes needed to identify the patient´s medication list in a globally operable way.

1.3.1 Audience

This document is addressed to pharmacy system providers to facilitate the implementation of an IDMP based medication list in the pharmacy IT system.

1.4 Introducing "Helen´s Story"

Reference to Unicom delivery D1.6 Demonstrator "Helen's Story"

To demonstrate how this can be understood in reality, "Helen´s Story" from the D1.6 Demonstrator is referenced in several places where it fits.

Helen has type 1 diabetes mellitus and has an app on her phone on which she collects her medical information. She is on a business trip to the Netherlands. She thinks that unfortunately she might have another Urinary Tract Infection (UTI).

She doesn't know what product to take in the Netherlands but in the the UK, she would be given Monuril. This is also registered in her electronic medication list on her app. Since she is not feeling well she goes to the emergency department of a hospital in the Netherlands.

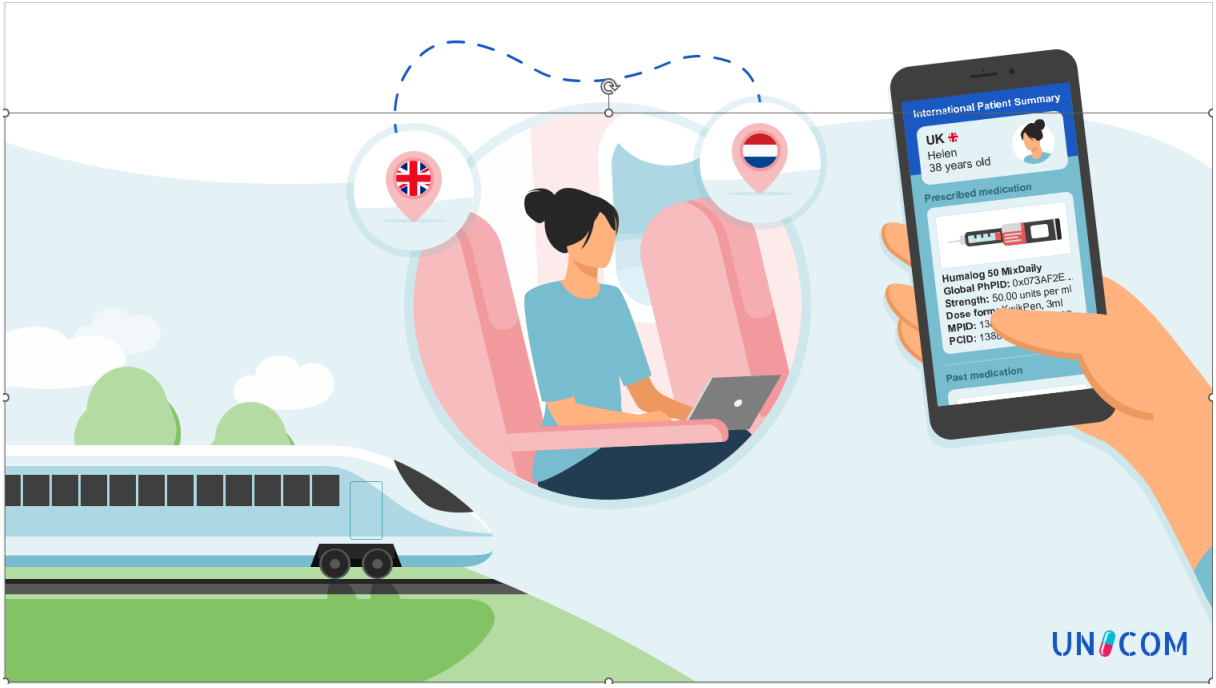


Figure 1 - Helens Electronic Medication List on her App

2 Minimum Attributes List (MAL)

The IDMP attributes listed in the table below are those needed for an IDMP based medication list stored in the pharmacy IT system. We consider the minimum set of information that the pharmacy system should have access to (whether it is "alone" or linked to an MPD) to ensure its ability to understand any cross-border prescription (Helen's story see below). They are essentially limited to the identifier of a medicinal product (package identifier, active substance name, pharmaceutical form, and active strength). In the section following the table, each attribute is examined in more detail.

2.1 MAL Table Overview

The table below lists the Minimal Attributes with

- the chapter and reference in the EMA IDMP Implementation Guidance that describes the attribute

- the attribute name as used in the EMA IDMP Implementation Guidance
- a reference to an EMA data source if appropriate
- the preferred code system for all coded attributes
- the attribute name from the IDMP conceptual model (ISO 11615)
- the FHIR Medication Definition resource and element that should be used in communication of that attribute
- an example

Table 1: IDMP attributes and their relationship with the electronic Medication List

EMA SPOR						
#	Attributes from EMA IG V2.1.1	EMA-SPOR database	Preferred coding system	Data Attribute	FHIR Path	Example
1.	Medicinal Product					
1.1	Product Management Service Identifier (PMS ID)			Medicinal Product Code	MedicinalProductDefinition.identifier	00005005; 00001234; 00000567; 00000174
1.2	Medicinal Product Identifier (MPID)					
1.5; 1.6	Authorised Pharmaceutical Form	RMS	EDQM	Pharmaceutical Dose Form; Combined pharmaceutical dose form	MedicinalProductDefinition.extension.authorisedDoseForm; MedicinalProductDefinition.combinedPharmaceuticalDoseForm	solution for injection in pre-filled syringe, tablet, cream, powder and solvent for solution for injection
1.14	Medicinal Product Name					
1.14.1	Full name			Brand Name of the Medicinal Product	MedicinalProductDefinition.name.productName	Diclofenac PharmaABC 32 Filmtabletten
2.	Marketing authorisation information					
2.8	Marketing Authorisation Holder	OMS (LOC-ID)	SPOR-OMS	Marketing Authorisation Holder of the medicinal product	RegulatedAuthorization.holder	ORG-100002271 STADApharm GmbH Germany LOC-100002468 Bad Vilbel
4.	Packaged Medicinal Product					
4.1	Packaged medicinal product Identifier (PCID)			Medicinal Product Code	PackagedProductDefinition.identifier	SE-100001745-00040001-0001; EU-100000396-00020080-0001
4.3	Pack size**		EDQM	Medicinal Product Package	containedItemQuantity	20 tablets 1 vial (solvent) + 1 vial (powder) 1 tube (cream) + 27 tablets 150 (15 x 10 x 1) capsules (unit dose) (multipack)
4.8	Package item (container)**					
4.8.1	Package item (container) type	RMS	EDQM	Medicinal Product Package	PackagedProductDefinition.packageItem.type	Bottle Blister Box Vial Blister Sleeve Pre-filled Syringe
4.8.5	Package item (container) quantity				PackagedProductDefinition.packageItem.quantity	• Carton x 1 o Vial (solvent) x 2 o Vial (powder) x 2
4.11						

4.11.1	Unit of Presentation	RMS	EDQM		ManufacturedItemDefinition.unitOfPresentation (as referenced from PackagedProductDefinition.packageItem.manufacturedItem)	units of presentation: actuation, patch, tablet
4.11.2	Manufactured Item Quantity	RMS	EDQM	Package size	PackagedProductDefinition.package.containedItem.amountQuantity	28 tablets, 5 ml, 1 vial Example: • In case of tablets/capsules the number of tablet/capsules in the immediate is specified: 28 tablets, 24 capsules • In case of formulations contained in a vial (e.g. liquids) the total quantity/volume should be expressed: 5 mg, 2 mL • In case of lyophilised formulations contained in a vial (e.g. powder), the total quantity/volume should be expressed: 1 vial
4.11.3	Manufactured Dose Form	RMS	EDQM	Pharmaceutical Dose Form	ManufacturedItemDefinition.manufacturedDoseForm (as referenced from PackagedProductDefinition.packageItem.manufacturedItem)	Example 1: Medicinal Product ABC 20mg/ml powder and solvent for solution for injection (combined pharmaceutical form) in a vial will contain two types of manufactured items with the following dose forms: • Powder for solution for injection • Solvent for Solution for injection Example 2: Medicinal Product DEF 500 mg tablets contain a single type of manufactured item with the following manufactured dose form: • Tablet
5	**Ingredient**					
5.1	Ingredient role	RMS	SPOR-RMS		Ingredient.role	Active
5.5	Substance					
5.5.1	Substance	SMS	SPOR-SMS	Active Ingredient	Ingredient.substance.codeCodeableConcept	diclofenac sodium; diclofenac diethylamine ; diclofenac
5.5.2						
5.5.2.2.2	Strength (Presentation single value or low limit)	RMS	EDQM	Strength of the Medicinal Product	Ingredient.substance.strength.presentation	Tablet 500 mg

						Strength presentation single value or low limit: numerator 500 mg, denominator 1 tablet Strength presentation high limit: <blank> Powder for solution for injection 88-90 mg in a vial Strength presentation single value or low limit: numerator 88 mg, denominator 1 vial Strength presentation high limit: 90 mg, denominator 1 vial
5.5.2.3.2	Strength (Concentration single value or low limit)	RMS	EDQM		Ingredient.substance.strength.concentration	Solution for injection 20 mg/ml Strength concentration single value or low limit: numerator 20 mg, denominator 1 ml Strength concentration high limit: <blank> Powder and solvent for solution for injection 95-100 mg/ml Strength concentration single value or low limit: numerator 95 mg, denominator 1 ml Strength concentration high limit: 100 mg, denominator 1 ml
5.5.3.						
5.5.3.1	Reference Substance	SMS	SPOR-SMS	Active Ingredient	Ingredient.substance.strength.referenceStrength.substance	
5.5.3.3.2	Reference Strength (Presentation single value or low limit)	RMS	EDQM	Strength of the Medicinal Product	Ingredient.substance.strength.referenceStrength.strength	
5.5.3.4.2	Reference Strength (Concentration single value or low limit)	RMS	EDQM		Ingredient.substance.strength.referenceStrength.strength	
6.						
-	Pharmaceutical Product identifier (PhPID)[3]			Medicinal Product Code		Not yet available (as of November 2022)

[3] Note: This version of the guidance does not report information on additional identifiers such as the Pharmaceutical Product Identifier (PhPID). Further details on the related definitions and defining elements will be available at later stage as it requires further discussions prior the implementation.

6.2	Administrable Dose Form	RMS	EDQM	Pharmaceutical Dose Form	AdministrableProductDefinition.administrableDoseForm	Solution for injection; Capsule, hard
6.3	Unit of Presentation	RMS	EDQM	Unit of Presentation	AdministrableProductDefinition.unitOfPresentation	Actuation; Drop; Puff
6.6	Route of Administration	RMS	EDQM	Route of Administration	AdministrableProductDefinition.routeOfAdministration.code	Auricular use; Cutaneous use

2.2 MAL Details

Below you can find more detailed information on the data elements listed.

2.2.1 Medicinal Product information

Product Management Service Identifier (PMS ID)

This is required as a specific and unique identifier of medicinal products related to EMA and regulatory authorities. It should be provided when it is available. The PMS ID will be automatically generated following a successful initial submission of the medicinal product information in the EMA PMS system.

In PMS, each individual medicinal product entry is assigned a single and unique PMS identifier (PMS ID) that remains unchanged through the lifecycle of the medicinal product. The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.

The PMS ID is only composed by digits.

Example of PMS IDs would be: 00005005; 00001234; 00000567; 00000174.

Note: While the format of the identifier is confirmed, the number of digits may vary based on the amount of medicinal product entries performed in PMS. These examples are illustrative only.

Medicinal Product Identifier (MPID)

This is required as a specific national identifier of medicinal products. It should be provided when it is available.

MPID will be assigned to each authorised medicinal product; it is a supplementary ID to any existing authorisation number or equivalent identifier as assigned by an authorising body in a region.

The MPID is defined by the following segments:

- country code segment (ISO 3166-1 alpha-2 code elements)
- marketing authorisation holder (i.e. location ID) code segment
- medicinal product code segment (i.e. unique medicinal product ID)

Any change of the values related to these three code segments will result in the assignment of a new MPID.

This attribute is automatically generated and maintained by the PMS system.

Authorised Pharmaceutical Form

The pharmaceutical form might be authorised or submitted for authorisation as follows:

- Combined pharmaceutical form: when two or more manufactured dose forms that are intended to be combined to create a single administrable dose form. In this case the RMS list “Combined pharmaceutical form” is used.

Example: powder and solvent for solution for injection

- Pharmaceutical dose form: when the authorised dose form does not need of combination prior administration into the patient. In this case the RMS list “Pharmaceutical dose form” is used.

Examples: tablet, capsule, solution for injection

- Combined terms: in special cases (e.g. identical products which may be distinguished only by reference to the container), the information about the immediate container can be included in the authorised pharmaceutical form. In this case the RMS list “Combined term” is used.

Example: solution for injection in pre-filled syringe

- Combined Package: medicinal products may consist of two pharmaceutical products that correspond with two different administrable dose forms (e.g. hard capsule and cream) that form

individual entities which do not need combining for administering to the patient. In this case the RMS list “Combination Package” is used.

Example: Cream + vaginal tablet

“Authorised Pharmaceutical Form” should be preferred over “manufactured dose form” and “administrable dose form” when describing a Medicinal Product

Full name

The full medicinal product name as indicated in Section 1: Name of the Medicinal Product of the corresponding SmPC or other regulatory document is specified, in line with the local language of the country where the product is authorised.

• Full name, country and splitting of the name in parts must be repeated as per applicable languages in multi-language countries (e.g. Belgium)

• Marketing authorisation holder may submit translations of the name in English on an optional basis.

• This is a repeatable field

2.2.2 Marketing authorisation information

Marketing Authorisation Holder

The Marketing authorisation holder is specified using the location identifier (LOC ID) linked to the organisation (ORG-ID) as listed in EMA´s Organisation Management System (OMS).

In the medication list, only the name of the organisation is required.

2.2.3 Packaged Medicinal Product information

Packaged medicinal product Identifier (PCID)

For each Packaged Medicinal Product, a unique PCID is assigned by the PMS system based on the data submitted.

It is supplementary to any existing authorisation/approval number at package level assigned by the Commission or national competent authorities.

In the medication list, it is required as a specific national identifier of medicinal products. It should be provided when it is available and should be preferred over MPID and PMSID. Also international identifiers such as GS1 identifiers may be used.

Pack size

This attribute is required to describe complex packaging medicines. It is provided when a medicinal product presents more than 2 different units of presentation.

Example 1: 28 tablets and 1 tube (cream) – In this case the pack size field is repeated including quantity and unit of presentation for tablets and quantity and unit of presentation (tube) for the cream.

For each Packaged Medicinal Product, the pack size defined as the total number of units of the manufactured item or package item and represented per unit of presentation is provided.

For medicinal products with multiple pharmaceutical products (e.g. tablet and cream) the pack size is differentiated and repeated by manufactured item/package item.

For medicinal products in solid dosage forms with multiple pharmaceutical products that present the same unit of presentation (e.g. contraceptive tablets of different colours and formulation), the pack size is accounted as the total number of tablets.

Example 2:

- *5 medium red tablets each containing 2 mg estradiol valerate and 2 mg dienogest*
- *17 light yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest*
- *2 dark red tablets each containing 1 mg estradiol valerate*

- *2 white tablets do not contain active substance*
- *In this case the pack size field is completed with the following value: 26 tablets*

For liquid formulations that needs of combinations (e.g. powder and solvent for solution for injection), the unit of presentation is differentiated, and this data field is repeated per manufactured item.

Example 3:

powder (25 mg vial) and solvent (1 ml pre-filled syringe). In this case the pack size field is repeated including quantity and unit of presentation for the powder (vial) and quantity and unit of presentation (syringe) for the solvent.

Value: 1 vial + 1 pre-filled syringe

The applicable numeric value(s) and unit of presentation is selected from the term ID as listed in the "Unit of Presentation" (RMS) list.

Example 4:

28 film coated tablets containing:

2 dark yellow tablets each containing 3 mg estradiol valerate

Package item (container)

- **Package item (container) type**

This attribute is required to describe complex packaging medicines. It should be associated with *"Package item (container) quantity"*, In that sense it can be repeatable to indicate the structure of packaging (example: \-Box; \--Pre-filled syringe; \--Vial). It is listed as term ID as listed in the "Packaging (RMS) list".

- **Package item (container) quantity**

This attribute is required to describe complex packaging medicines. It must be used to complement the information of the "*Package item (container) type*" to describe their content. (Example: Package item (container) type: *Blister* / Package item (container) quantity": *2*).

Example 5:

Medicinal product B comprises combined pharmaceutical form powder (40 micrograms) and solvent (1 ml) for solution for injection. This package example consists of two vials with solvent and two vials with powder, all vials packaged in a single carton box.

• Carton x 1

o Vial (solvent) x 2

o Vial (powder) x 2

2.2.4 Manufactured Item information

Unit of Presentation

For the most of cases "unit of presentation" will be the same for "manufactured item" and "pharmaceutical product". However, in some cases they can be different (e.g., eye drop product - for "manufactured Item" - *"Container"*, for pharmaceutical product: *"drop"*.

Pharmaceutical product Unit of presentation should be preferred. Ideally the 2 attributes should be available presented, however on the impossibility to provide both, it should be clearly specified which attribute is being provided.

When there is a difference between them, "Pharmaceutical product" "Unit of presentation" should be preferred over "Manufactured item" "Unit of presentation" to be given in the MAL.

Manufactured Item Quantity

The quantity (or count number) of the manufactured item in the medicinal product package, is specified as a value and units as per section 6.5 of the SmPC.

For solid dose forms and other items measured by counting, discrete countable entities, the unit for quantity is “unit” and the “unit of presentation” is the item counted within the immediate container.

For formulations contained in a vial, the unit for quantity is volume/quantity and the “unit of presentation” is the discrete countable entity, in which a pharmaceutical product or manufactured item is presented.

Example 6:

• In case of tablets/capsules the number of tablet/capsules is specified: 28 tablets, 24 capsules

• In case of formulations contained in a vial (e.g. liquids) the total quantity/volume is expressed: 5 mg, 2 mL

• In case of lyophilised formulations contained in a vial (e.g. powder), the total quantity/volume is expressed: 1 vial

Manufactured Dose Form

See comments on “Authorised Pharmaceutical Form”.

- The manufactured dose form is described with the authorised pharmaceutical form(s) in section 3. Pharmaceutical Form of the SmPC or other regulatory document (description prior to any transformation into the final form administered to the patient).
- The required authorised pharmaceutical form is specified as a term ID as listed in the “Pharmaceutical Dose Form” (RMS) list.
- If multiple values apply to the same medicinal product, then multiple manufactured items are listed.
- Deprecated (i.e. non-current) dose form terms may be referenced.

This is a repeatable field.

2.2.5 Ingredient information

Ingredient role

The ingredient role is provided to indicate the role of the medicinal product ingredients (active, excipient, advent, etc.), the active ingredients are mandatory, and other as excipients are optional. However, some ingredients (excipients) with potential allergenic are indicated to be provided (colourings like fuchsin and malachite green etc.).

The role of the ingredient as part of the manufactured item/pharmaceutical product is specified as a term ID.

The applicable value(s) is selected from the term ID as listed in the “Ingredient Role” (RMS) list.

Substance

It describes the name and code of the exact ingredient of a medicinal product and is mandatory. It is identified with the “SPOR – Substances Management Services” (SMS).

The Substances contained within the medicinal product (either part of the pharmaceutical product(s) or the manufactured item(s)) is specified.

Each pharmaceutical product or Manufactured Item lists information on:

- active ingredient(s);
- excipient(s);
- in some instances, pharmaceutical product can also contain adjuvants.

The Substance(s) contained in pharmaceutical product or Manufactured Item are specified as a term ID.

The selected SMS ID refers to a particular substance, and the preferred term (PT) for that substance will always be the name displayed in PMS. In many cases, alternate names are stored for substances and the SMS ID can be found by using any of the names associated with a substance.

Note: every pharmaceutical product has at least one active ingredient. If a pharmaceutical product contains no active ingredient, one of the excipients is labelled as the active ingredient (example: water

for injection as a solvent in a separate container, glucose solution 5%, NaCl solution 0.9%.; contraceptive tablets containing only lactose).

Strength (quantitative composition)

Strength (Presentation single value or low limit) / Strength (Concentration single value or low limit)

It describes the strength of “moiety + modifier” (presentation or concentration) and it is referent to “substance”. All strengths have unit and a value for the nominator, and a unit and a value for the denominator. It is important to have value sets for these concepts (unit of nominator strength, unit of denominator strength). It should be complementary information over “Reference strength”.

The strength (quantitative composition) of the substances (including active substances, ingredients, adjuvant as applicable) are specified in this field with a numerator and denominator.

When the strength is expressed as a range, the lower limit for the quantity of the substance in the unit of presentation is specified in this field.

When the strength is not expressed as a range, the quantity of the substance is specified in this low limit field.

The numerator are expressed with a unit (numeric value) and a unit of measurement (e.g. mg).

The denominator are expressed with a unit (numeric value) and a unit of presentation (e.g. tablet, actuation).

The unit for the numerator is specified as a value and a Term ID as listed in the “Units of Measurement” RMS list. The units for the denominator are specified as a value and a Term ID as listed in the “Units of Presentation” RMS list.

Example 7

Tablet 500 mg

Strength presentation single value or low limit: numerator 500 mg, denominator 1 tablet

Strength presentation high limit: <blank>

Powder for solution for injection 88-90 mg in a vial

Strength presentation single value or low limit: numerator 88 mg, denominator 1 vial

Strength presentation high limit: 90 mg, denominator 1 vial

Reference Strength

Reference Substance

The reference substance of the active substance(s) contained in pharmaceutical product or Manufactured Item, as expressed in section 2. Qualitative and Quantitative Composition of the corresponding SmPC is specified.

The reference substance is provided for active substances only. It describes the active ingredient without the modifier (moiety). It is provided to support the description of “Reference strength” and useful for generic prescriptions.

Reference Strength (Presentation single value or low limit) / Reference Strength (Concentration single value or low limit)

The reference strength (quantitative composition) of the active substances is specified in this field with a numerator and denominator.

When the reference strength is expressed as a range, the lower limit for the quantity of the reference substance in the unit of presentation is specified in this field.

When the reference strength is not expressed as a range, the quantity of the reference substance is specified in this field.

The numerator is expressed with a unit of numeric value and a unit of measurement (e.g. mg).

The denominator is expressed with a unit of numeric value and a unit of presentation (e.g. tablet).

The reference strength is provided for active substances only.

The units for the numerator are specified as a value and a Term ID as listed in the “Units of Measurement” RMS list.

The units for the denominator are specified as a value and a Term ID as listed in the “Units of Presentation” RMS list."Strength (Presentation and Concentration).

This attribute is the most used on prescriptions. It considers only the strength of the moiety. This information will be consumed by the eHealth services and should be considered preferred over “strength”.

2.2.6 Pharmaceutical Product information

Pharmaceutical Product identifier (PhPID)

It is required as a specific identifier of the pharmaceutical products (same substance, strength, administrable dose form and unit and value of measurement). IDMP requires the substance with the role of precise active ingredient substance (PAI) to be mentioned by moiety + modifier (if there is one).

Administrable Dose Form

See comments on “Authorised Pharmaceutical Form”

Unit of Presentation

See comments on “Manufactured Item / Unit of Presentation”.

Route of Administration

For most of the medicinal products there is only one possible “Route of Administration” (RoA), however, in some cases, there are many possible RoA, in that case the intended prescribed RoA should be specified over all possible RoA for a specific medicine.

The route of administration of the pharmaceutical form is specified in accordance with Section 4.2. Posology and method of administration of the SmPC as Term ID.

Administration route section describes the route(s) of administration i.e. the path by which the medicinal product (described as technical concept of a "pharmaceutical product") is taken into or makes contact with the body.

The applicable value(s) are selected from the term ID as listed in the “Routes and Methods of Administration” (RMS) list."

2.3 Using the data from the MAL: Helen in the Hospital

Reference to Unicom delivery D1.6 Demonstrator “Helens Story”

At the hospital emergency department Helen shows her Medication app which includes her International Patient Summary (IPS). In this case the IPS shows, next to the brand name, strength and dose form, the global PhPID (L4) of the current medication that is prescribed to Helen in her home country e.g. Humalog Mix 50 daily (global PhPID: 0x073AF2E5B92AE19E8B67635AFFB3D6CA) for her Diabetes mellitus type I. The IPS also contains her previous prescribed medicinal products and therefore shows the global PhPID (L4) for Monuril® fosfomycin (as trometamol) 3g per sachet granules for oral solution (global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED).

Disclaimer: the MPID, PCID and GTIN shown here are all ‘dummy data’ but as close to reality as possible.

Figure 2 - Helen in the Hospital

2.4 Using the data from the MAL: Helen in the Pharmacy

Reference to Unicom delivery D1.6 Demonstrator "Helens Story"

The pharmacist retrieves, from the national MPD, a list of equivalent national medicinal products (Brand name, strength, and dose form) having the same PhPID Fosfomycin 3g oral solution (Monuril) as the product that Helen has in her own country. The pharmacist chooses the best option considering the information in Helen's IPS regarding allergies of the retrieved products. The pharmacist then gives Helen her medication.

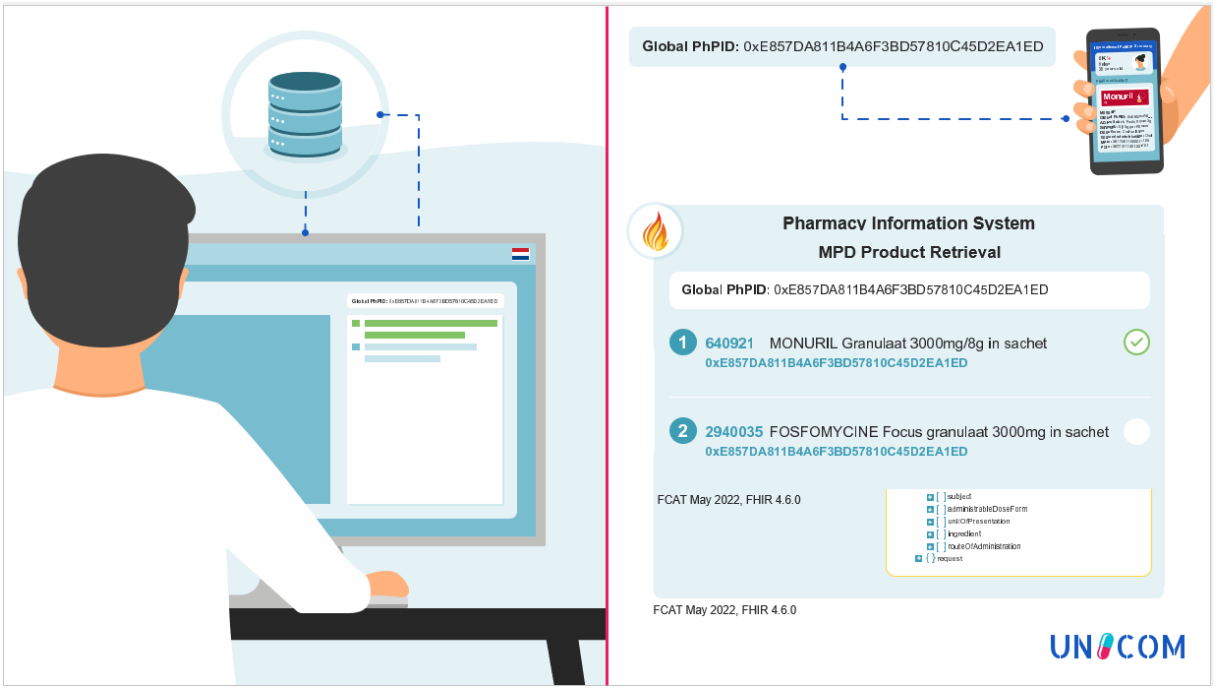


Figure 3 - Helen in the Pharmacy

Helen scans the barcode on the medicinal product she received to include it in the medication list in her app.

Figure 4 - Helen scans the Barcode of her Medication with her App

3 Examples

Reference to Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe

Chapter 8 – Practical examples, Version 2.1.1., retrieved 7.8.2022

3.1 Data model representation for Losec

In the IDMP data model below, all the data elements listed in this document are tagged with a green marker.

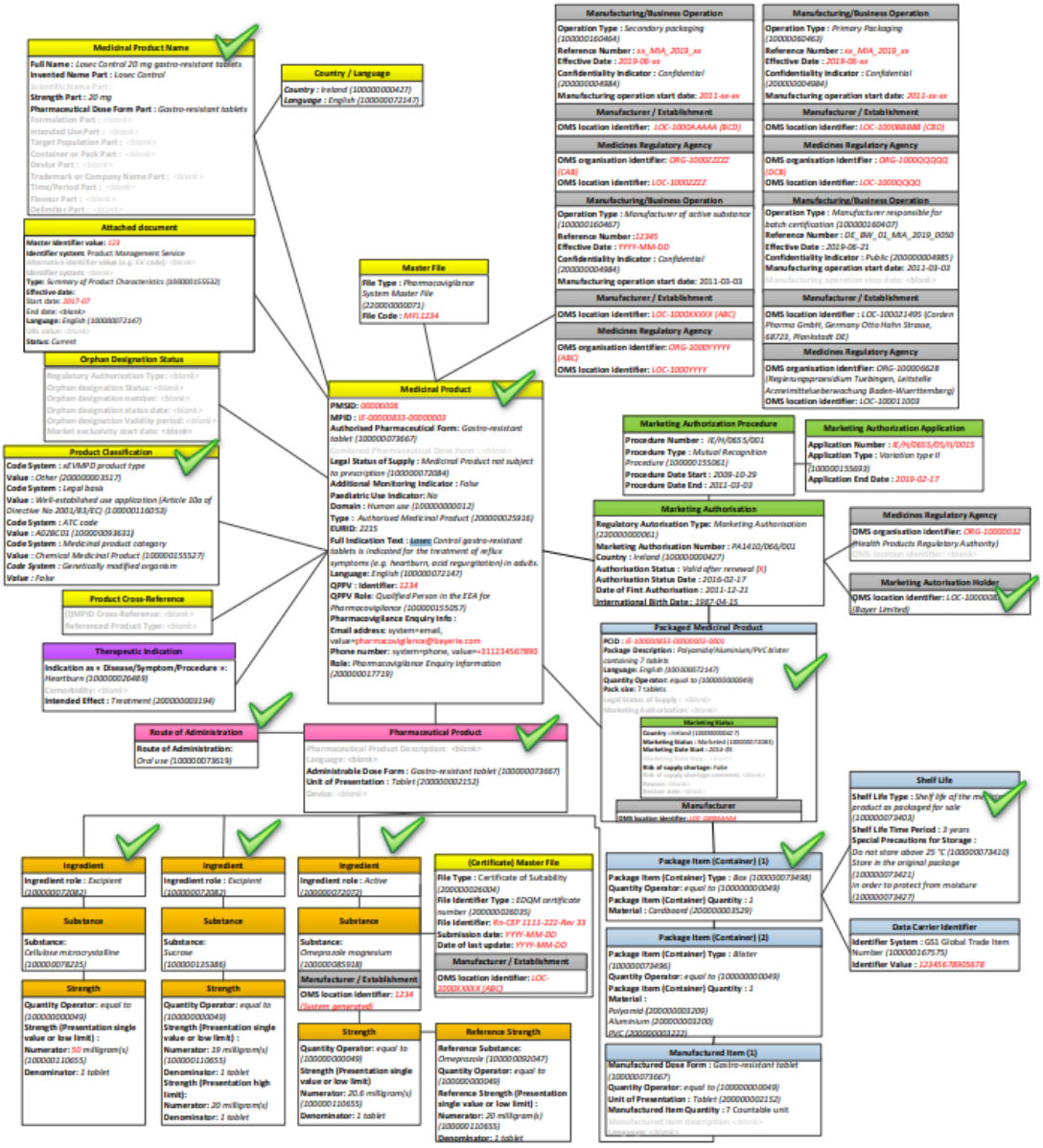
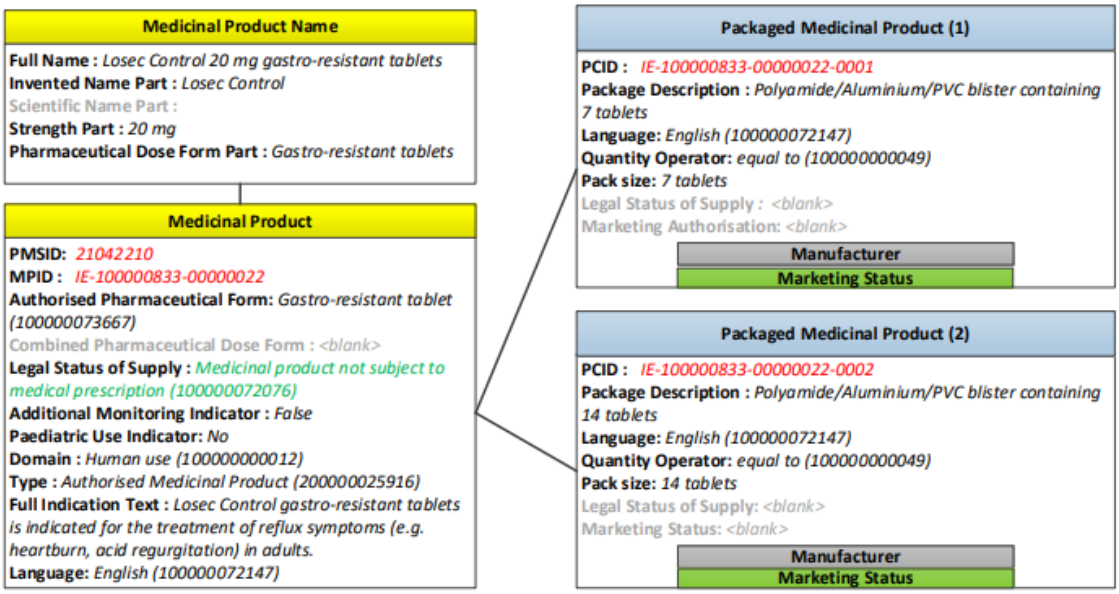


Figure 5 - Data model representation for Losec



3.2 Alignment of Manufactured Item Quantity, Unit of Presentation and Pack Size

This section provides guidance with examples on how encoding medicinal product packaging information, together with the relationship between Pack Size, Package Item (container) quantity, and unit of presentation and quantity of the manufactured item is delivered.

For pharmacy system provider it is important to know how to record values for Pack size, Package Item (immediate container) Quantity, Manufactured Item Quantity and Unit of Presentation including multi-packs and multi-dose packs.

The example below depicts simple package configurations for solid dosage forms, comprising an outer box (secondary packaging) and blisters (primary/immediate packaging). These are very common.

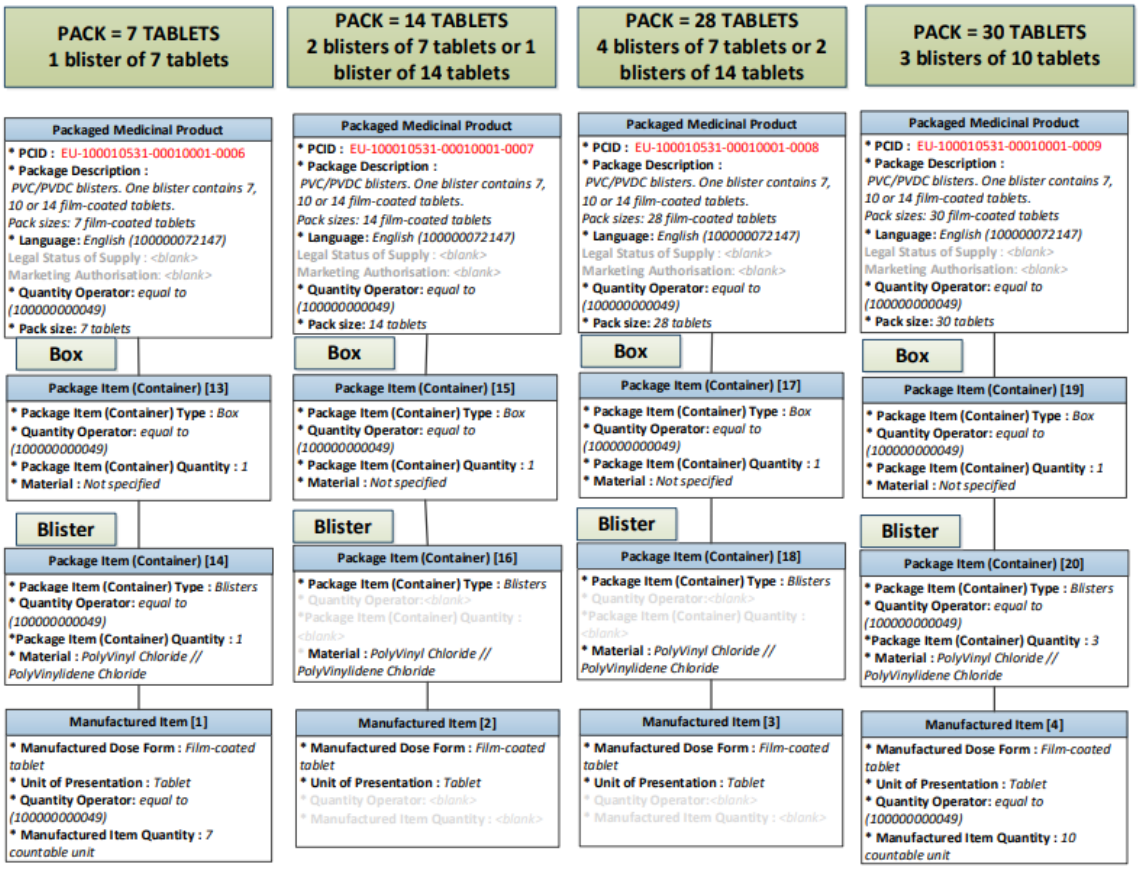


Figure 6 -Simple package configurations

In the example above, the pack of 7 tablets can only contain 1 blister of 7 tablets. In this case, the Manufactured Item Quantity = 7 units, and the Package Item (Container) Quantity = 1.

Multiplying the Manufactured Item and Package Item (Container) quantities should equal the quantity encoded in the Pack Size of the Package Medicinal Product. However, the 14-tablet pack can contain either 2 blisters of 7 or 1 blister of 14 tablets. When this is the case, the fields ‘Manufactured Item Quantity’ and ‘Package item (Container) Quantity’ are left blank, and the number of tablets (14 in this case) is encoded in the ‘Pack size’ at ‘Packaged Medicinal Product.

3.3 Expression of Strength

This section provides guidance on how information on strength, and reference strength of active ingredients present in pharmaceutical products and manufactured items of medicinal products is defined.

Currently there are different practices across the EU when it comes to expressing the strength in the labelling of medicinal products, especially for parenteral preparations, products with a multidose presentation and older products if both types to express the strength are included in the SmPC. These split views are well acknowledged by all the stakeholders and must be considered when interpreting this information.

In the Losec example, both substance strength and substance reference strength can be found in the document for the active ingredient and are listed. The strength is listed for the excipient (sucrose).

Losec

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 20.6 mg omeprazole magnesium equivalent to 20 mg omeprazole.
Excipients: Each gastro-resistant tablet contains 19–20 mg sucrose.
For a full list of excipients, see section 6.1.

#	Substance	Strength (Presentation)	Reference Substance	Reference Strength (Presentation)
1	Omeprazole magnesium	20.6 mg/tablet	Omeprazole	20 mg/tablet
2	Sucrose	19-20 mg/tablet	Not applicable	Empty

Figure 7 - Losec example, substance strength and substance reference strength

To give structure to the different approaches of expressing strength, a set of patterns has been developed. The patterns show how the Manufactured Item (MI) and the Pharmaceutical Product (PhP) are expressed for a particular type of product. Products can then be matched to the appropriate pattern which then can be used to group medicinal products in generic groups based on strength comparison.

The following reference table provides the necessary guidance to select between Presentation Strength, and Concentration Strength.

Pattern	Type of product	Examples	Manufac. Item Unit of Present.	Pharm. Prod. unit of Present	Strength by Presentation	Strength by Concentration
1a	Solid, countable	Tablets, capsules, suppositories	Basic dose form related to the pharmaceutical form of the MI (tablet, capsule, etc.)	Basic dose form related to the pharmaceutical form of the Pharm Prod (tablet, capsule etc.)	Mandatory	Empty
1b	Solid dose forms in "container"	Powder or granules in sachet, ampoules, vials, Spincap, Rotocap – the whole content of the capsule is delivered to the patient via one or more actuations	Container (vial, sachet, etc.)	Container (vial, sachet, etc…) – not always informative depending on the dosing instructions	Mandatory	Empty
1c	Metered dose delivered by a metered actuation - dose cannot be adjusted	Dry-powder inhalers (DPI) pressurised metered-dose inhalers (pMDI), nasal sprays	Actuation (inhaler)	Actuation (inhaler, etc.)	Mandatory	Empty
2a	Products enclosed in a "presentation", where the total amount per presentation is clinically relevant	Unit dose solutions, parenteral liquid, unit dose nebuliser solutions NOT partial use preparations	Container (vial, etc.)	Container (vial, etc.)	Mandatory Expressed per total volume of the presentation (not per unit of presentation). This makes calculations easier	Mandatory (QRD)

Figure 8 - Guidance to Presentation Strength, and Concentration Strength (1)

Pattern	Type of product	Examples	Manufac. Item Unit of Present.	Pharm. Prod. unit of Present	Strength by Presentation	Strength by Concentration
2b	Products enclosed in a "presentation", where the concentration is clinically relevant rather than the total amount in the presentation	Multi-dose syringe, Partial dose syringe, infusion bags, Multidose vial	Container (bottle, etc.)	N/A since it is the concentration that is relevant	Conditional	Mandatory
3a	Continuous presentation (dosing is individual/not accurate and the total volume in the container is of less importance for dosing purposes)	Bulk powders/granules, semi-solids "bulk" liquids (e.g., eye drops)	Not useful clinically	N/A since it is the concentration that is relevant	– Conditional	Mandatory
3b	Products enclosed in a "presentation", where the dose has a delivery rate	Transdermal patches	Patch	N/A since it is the concentration that is relevant	Conditional	Mandatory – as a delivery rate over time

Figure 9 - Guidance to Presentation Strength, and Concentration Strength (2)

In the following example the Losec strength fits with the Pattern 1a (Solid, countable). In this case, only the Presentation Strength is given for both manufactured Item and Pharmaceutical Products.

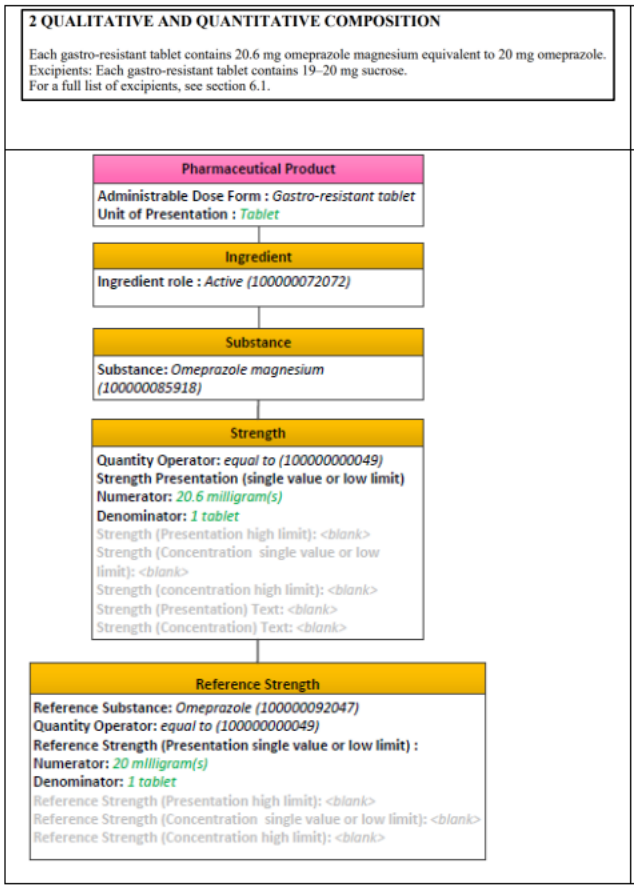


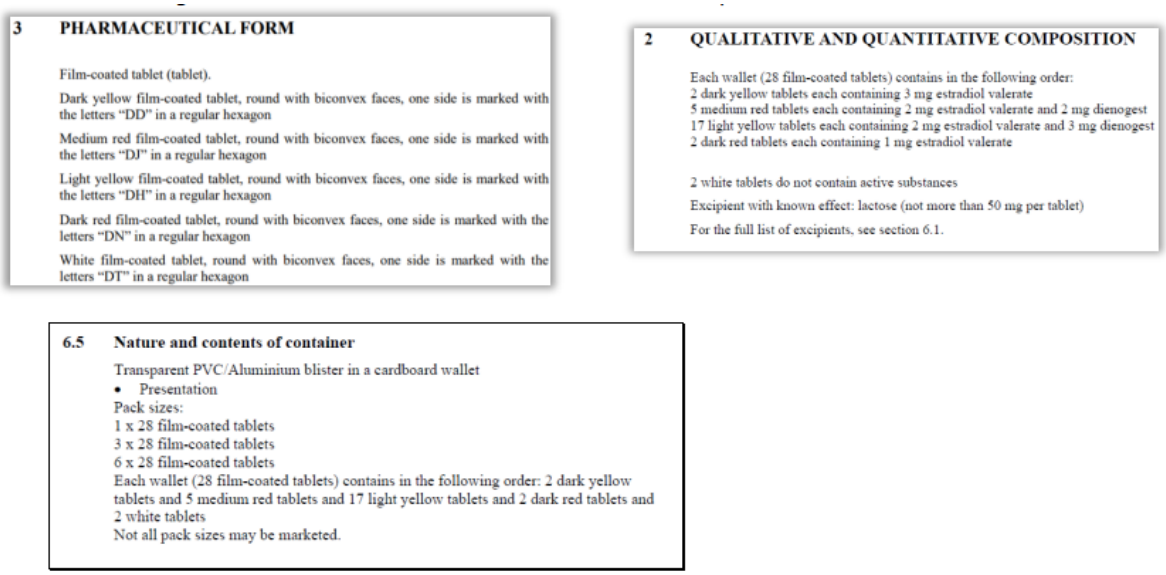
Figure 10 - Losec Strength Example

3.4 Medicinal Product with multiple pharmaceutical products

A pharmaceutical product can be defined as the qualitative and quantitative composition of a medicinal product in the authorised dose form approved for administration. There are several instances where medicinal products may contain multiple pharmaceutical products characterised by different strengths, pharmaceutical forms, or substances.

To illustrate this concept, the example of contraceptive medicinal product Qlaira is used. This medicinal product is composed of several different manufactured items which are not transformed, giving several different pharmaceutical products, including a placebo. These pharmaceutical products all have the same administrable dose form and units of presentation, which are the same for the manufactured items and the pharmaceutical products.

The following information is included in the SmPC of this example:



3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Dark yellow film-coated tablet, round with biconvex faces, one side is marked with the letters "DD" in a regular hexagon

Medium red film-coated tablet, round with biconvex faces, one side is marked with the letters "DJ" in a regular hexagon

Light yellow film-coated tablet, round with biconvex faces, one side is marked with the letters "DH" in a regular hexagon

Dark red film-coated tablet, round with biconvex faces, one side is marked with the letters "DN" in a regular hexagon

White film-coated tablet, round with biconvex faces, one side is marked with the letters "DT" in a regular hexagon

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each wallet (28 film-coated tablets) contains in the following order:
2 dark yellow tablets each containing 3 mg estradiol valerate
5 medium red tablets each containing 2 mg estradiol valerate and 2 mg dienogest
17 light yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest
2 dark red tablets each containing 1 mg estradiol valerate

2 white tablets do not contain active substances

Excipient with known effect: lactose (not more than 50 mg per tablet)

For the full list of excipients, see section 6.1.

6.5 Nature and contents of container

Transparent PVC/Aluminium blister in a cardboard wallet

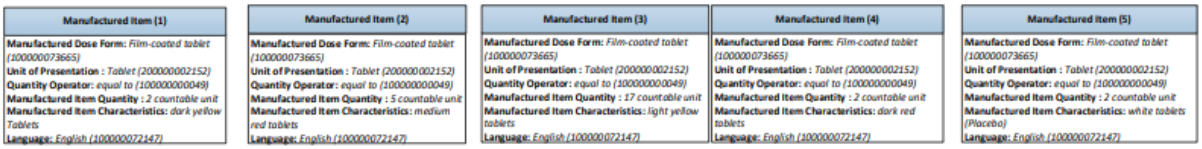
- Presentation

Pack sizes:
1 x 28 film-coated tablets
3 x 28 film-coated tablets
6 x 28 film-coated tablets
Each wallet (28 film-coated tablets) contains in the following order: 2 dark yellow tablets and 5 medium red tablets and 17 light yellow tablets and 2 dark red tablets and 2 white tablets
Not all pack sizes may be marked.

Figure 11 - Example of contraceptive medicinal product Qlaira

3.4.1 Representation of Manufactured Items

When a product contains multiple pharmaceutical products, the manufactured items are usually identical to the pharmaceutical products unless the pharmaceutical product is made by combining manufactured items prior to administration. Therefore, ingredient information used for the manufactured item is also used for pharmaceutical product. The ingredients of each manufactured item of a medicinal product must be described and submitted. For reasons of legibility, ingredients details for only one of the manufactured items are shown below.



Manufactured Item (1)	Manufactured Item (2)	Manufactured Item (3)	Manufactured Item (4)	Manufactured Item (5)
Manufactured Dose Form: *Film-coated tablet (100000073665)* **Unit of Presentation :** *Tablet (200000002152)* **Quantity Operator:** *equal to (100000000049)* **Manufactured Item Quantity :** *2 countable unit* **Manufactured Item Characteristics:** *dark yellow Tablets* **Language:** *English (100000072147)*	**Manufactured Dose Form:** *Film-coated tablet (100000073665)* **Unit of Presentation :** *Tablet (200000002152)* **Quantity Operator:** *equal to (100000000049)* **Manufactured Item Quantity :** *5 countable unit* **Manufactured Item Characteristics:** *medium red tablets* **Language:** *English (100000072147)*	**Manufactured Dose Form:** *Film-coated tablet (100000073665)* **Unit of Presentation :** *Tablet (200000002152)* **Quantity Operator:** *equal to (100000000049)* **Manufactured Item Quantity :** *17 countable unit* **Manufactured Item Characteristics:** *light yellow tablets* **Language:** *English (100000072147)*	**Manufactured Dose Form:** *Film-coated tablet (100000073665)* **Unit of Presentation :** *Tablet (200000002152)* **Quantity Operator:** *equal to (100000000049)* **Manufactured Item Quantity :** *2 countable unit* **Manufactured Item Characteristics:** *dark red tablets* **Language:** *English (100000072147)*	**Manufactured Dose Form:** *Film-coated tablet (100000073665)* **Unit of Presentation :** *Tablet (200000002152)* **Quantity Operator:** *equal to (100000000049)* **Manufactured Item Quantity :** *2 countable unit* **Manufactured Item Characteristics:** *white tablets (Placebo)* **Language:** *English (100000072147)*

Figure 12 - Manufactured Item with multiple Pharmaceutical Products

A manufactured Item description text can be used to differentiate between manufactured items when necessary. In this example (contraceptive), this includes the colour of each manufactured item.

3.4.2 Representation of Pharmaceutical Products

In situations where the medicinal product contains several pharmaceutical products which do not require reconstitution (combining) prior to administration (e.g., powder and solvent), the field "combined pharmaceutical dose form" is not relevant and is left blank.

In this example of contraceptive, a pharmaceutical product section is completed for each "pharmaceutical product" present in the medicinal product, including one for the placebo, as the pharmaceutical products contained in Qlaira do not undergo any transformation before administration. The pharmaceutical section is "repeated".

For each pharmaceutical product section, the administrable dose form, the unit of presentation, the route of administration and the ingredients present in each of the pharmaceutical product is completed.

Note: for reasons of simplicity, not all items are shown in this example.

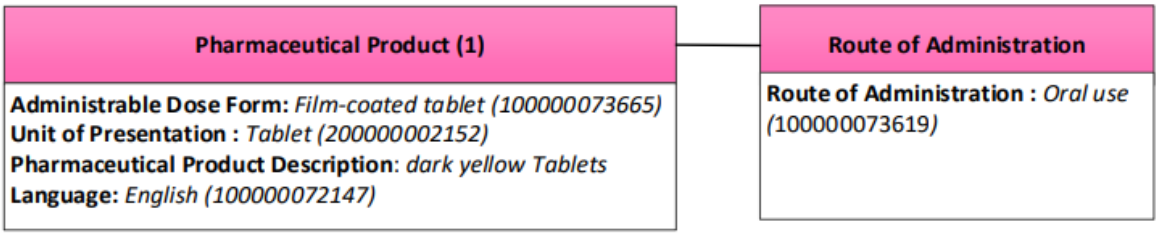


Figure 13 - Product with multiple Pharmaceutical Products

4 Conclusions

This document describes the minimal attributes needed in a medication list stored in a pharmacy system and their structural relationships required for the unique identification of medicinal products. Data elements that identify and characterise a medicinal product include the product name, the pharmaceutical product (substance, dosage form, route of administration and strength), and the medicinal product packaging.

The PhPID uniquely associates medical products with the same or similar pharmaceutical composition based on the following data elements: substance(s), strength(s) (units of measurement/presentation), reference strength(s), and dosage form.

The benefits of IDMP include:

- Unambiguous global identification and with that will help pharmacists to use medication list information to provide high quality pharmaceutical care.
- Communicate medicinal product data globally.
- Harmonized source for product information based on vocabularies and standards that are consistent across the globe.

IDMP supports the exchange of medicinal product information between pharmacist, patient, and other health care professionals.