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D3.2 Identification and description of special products

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Abstract (for dissemination)	Based on the WP2 solution, potential gaps and additional needs for the identification and description of medicinal and pharmaceutical products when applied to medicinal products other than branded pre-packed ones (“special” products) are explored and pinpointed. This was the scope of D 3.1. Based on that analysis, this report extends the WP2 solution towards supporting the identification and the description of such “special” products. Furthermore, it also presents the definition of alternative and complementary use cases where the unambiguous identification of such medicinal or/and pharmaceutical products is needed.
Keywords	Unambiguous identification of medicinal products, alternative and complementary use cases, special medicinal products, data model

Statement of originality

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Executive Summary

Scope of this document and articulation with other work

The openMedicine deliverable D3.2 extends the approach validated in D2.2, and the attributes consolidated in D2.2 and D2.3, applying them to new use cases.

The baseline requirements specified by WP2 have been used as starting point¹, providing an overview of the model and of the identification process defined in D2.2.

Method: The use cases in scope of D3.1, plus other scenarios considered relevant (e.g. current situation before IDMP adoption and transition strategies), have been examined and from these, some requirements were elicited. These requirements defined data needs.

The data needs were consolidated and checked against the expected scenarios. This showed the need of limited changes² to the openMedicine collection of identifiers. A single consistent set of attributes, covering all the cases considered, has been therefore determined as result of the harmonization process.

Results: The updated model attained from the analysis and consolidation was then validated: The analysis of the new use cases was extended to the operational model, providing an overview of what is needed, how those needs would be applied in a few practical scenarios, and what are the dependencies.

This analysis emphasized that even if the same model can apply to all the scenarios, several technical and data governance aspects must be addressed considering both clinical documents (prescriptions) and product descriptions.

The technical implementation options and possibilities; the gaps in the different standards; and the options for adoption are therefore presented, providing also some proposals.

Conclusions: This work has underlined the need for strong governance for the used models, value sets and other semantic assets, and this document shows the fundamental role of a well-defined and managed process for maintaining all the products information up-to-date in all the systems; as is demonstrated by the Substances, Products, Organisations and Referentials (SPOR) initiative led by European regulators.

The impact of the Falsified Medicines use case is also described, showing how the process of checking Falsified Medicines is not overlapping or conflicting either with Product Identification or Product Packaging. In fact, in a cross-country context any, product IDs lookup doesn't assure *per se* the authenticity of the product.

The inputs to the roadmap are summarized, explaining some of the technical challenges for SDOs and other stakeholders in the common goal of safely identifying products across borders.

Examples and additional information are left for annexes.

¹ In synthesis, in cross-border care, medications are usually specified in a clinical document with an ID or a few attributes, which is enough for it to be identified in the same country. The medication does not need to be fully described in a clinical document because it is assumed that the receiving party can understand those IDs and attributes. This is not the case in cross-border care, so we start with an overview of what is required to resolve that for pre-packed branded products.

² Few additional attributes seem in fact to be needed to cover the new use cases. They are used mainly to group products for a single formula (officinal or magistral), and for supporting radionuclides.

1 References

In order to develop D3.2 the following materials and documents have been analysed and referenced:

- openMedicine project deliverables:
 - D.2.1
 - D.2.2
 - D.3.1
- ISO standards:
 - ISO11615:2012
 - ISO 11616:2012
 - ISO11238:2012
- legal documents:
 - REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency:
http://ec.europa.eu/health/files/eudralex/vol-/reg_2004_726/reg_2004_726_en.pdf
 - DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf
 - REGULATION (EC) No 1394/2007 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004:
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf
- EMA Master Data Management Roadmap:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500186290.pdf
- Annex to the European Medicines Agency (EMA) Master Data Management Roadmap
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500186289.pdf
- John F. Marriott, Keith A. Wilson, Christopher A. Langley, and Dawn Belcher. Pharmaceutical Compounding and Dispensing, 2nd ed. London: Pharmaceutical Press; 2010; ISBN 978-0-85369-912-5
- PREPARACIÓN DE MEDICAMENTOS. FORMULACIÓN MAGISTRAL. VOLUMEN II; Hospital Universitario 12 de Octubre, Comunidad de Madrid
<https://practicasmfarmaceuticas.files.wordpress.com/2011/08/formulacion3b3n-magistral-20110713-112543.pdf>

2 Definitions and acronyms

2.1 Definitions

The definitions in this document are derived from, and maintained in, the online glossary:

<http://www.openmedicine.ramit.be/dictionary/>

The glossary lists the medicine related concepts and their definitions in different EN/ISO standards as well as in European Directives and Guidelines.

New Terms introduced in this document concern:

- **Data Governance:** a set of processes that ensures that important data assets are formally managed throughout and across the enterprise. It includes governance of glossary (concepts), reference data (code systems, terminologies), technical data and data rules.
- **Concept Mapping:** correspondence between two concepts and container structures in different models, for example a National Product ID can map to an ISO IDMP MPID.
- **Terminology Mapping:** correspondence between the code values belonging to a source and a target value set, for example the SNOMED CT concept “Benign hypertensive renal disease” (concept ID 193003) can be mapped into the ICD-10 concepts I12.9 (“Hypertensive renal disease without renal failure”) or N18.9 (“Chronic kidney disease, unspecified”). Terminology mapping is directional and rarely isosemantic.

2.2 Acronyms

IDMP – Identification of Medicinal Products, a set of ISO standards

eHNCP – eHealth Network National Contact Points

MPID – Medicinal product identifier

SmPC – Summary of Product Characteristics

ePG – ePrescription Guidelines

3 Introduction

3.1 Scope of the WP

The goal of WP 3 is that of identifying – based on the WP2 solution - potential gaps and additional needs for the identification and the description of medicinal and pharmaceutical products when applied to medicinal products other than branded pre-packed ones (“special” products). This was the scope of D 3.1. Based on that analysis, the second goal is extending the WP2 solution towards supporting the identification and the description of such “special” products.

WP2 has developed a generic solution for the identification and the description of medicinal and pharmaceutical products, considering commonly prescribed regulated medicinal products for human use. It focused on branded pre-packaged medicinal products including all products authorised in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC of the community code relating to medicinal products for human use by a medicines regulator in a pre-packaged form and includes both innovator and generic products.

3.2 Objectives of D3.2

But the processes requiring identification must be applicable not only to packaged branded products, but to a larger class of less “standardised” medicinal products. Therefore, in this deliverable an analysis of such different kinds of products will be conducted in order to determine what are the more important other kind of products that need to be taken into consideration. Then, for a relevant selection of them, the fitness of the WP2 solution will be verified, identifying possible gaps and resulting needs for additional descriptive attributes.

In line with this, this deliverable D3.2 “Identification and description of other medicinal products” has as objectives to:

- Update the operating model in WP2 given the newly identified needs
- Describe the needs for operationalizing the updated solution – providing also input for the roadmap and recommendations.

3.3 Overview of the adopted approach

This work, continued from D3.1, is done in the following steps:

- a) Identification of the scope for "other medicinal products" as defined by the use cases
- b) Analysis of potential gaps in the WP2 model in supporting these use cases
- c) Defining the necessary extensions of the WP2 model
- d) Update of the cross-border operating model and recommendations
- e) Analysis of the additional challenges for operationalizing the cross-border operating model
- f) Elicitation of new requirements and resulting recommendations for future actions.

4 Wrap-up of WP2 model

4.1 Key conclusions from D2.2

Deliverable D2.2 of openMedicine provided an analysis of the attributes to be used to identify a medicine and described some of the requirements for an operational cross-border solution using those attributes. Hereafter a summary of these results is reported.

Definition: In the cross-border information exchange, the following concepts apply:

Some scenarios require that products are **described**: that means that all of their attributes are transmitted, so that the counterpart has the same “complete” description of the product. Since the “complete” description of the product depends on who provides it, this is a variable list of attributes.

Other scenarios require that products are **specified**: that is, that enough information is transmitted to allow the receiver to have an unequivocal **identification** of the product meant by the sender.

Both these scenarios are present in openMedicine:

- For pre-packed regulated medicinal products, the product **description** is triggered and managed by the regulators. In Europe, this is handled by the EMA (e.g. see the EMA roadmap for Master Data - SPOR).
- The product description handles the product attributes - identifiers, identifying attributes and descriptive attributes. These attributes (or a subset) are then expected to be shared all the way to the clinical systems which then exchange clinical documents. This will allow these products to be referenced in clinical documents by using their identifiers.

Note: While standards exist for exchanging product information from manufacturer to regulator (SmPC), openMedicine has identified a gap in the exchange of product descriptions from the regulator side, and across product data providers and clinical systems. That gap is being addressed by several communications and two Project Scope Statements to HL7, as well as a communication for IHE Pharmacy to pursue ongoing work on such guidance, considering openMedicine's recommendations.

ISO IDMP provides the pivot concepts for this identification: the code systems vary across countries and systems - not only the codes but the levels of granularity. ISO IDMP defines several standardised levels of products (Pharmaceutical Product, Medicinal Product, and Packaged Product). Each of these levels has a different set of attributes and a unique identifier³. An identifier of one specific product level corresponds to a unique combination of attribute values.

For example, a Pharmaceutical Product ID level 4 corresponds to a unique combination of Substance, Strength, Administrable Dose Form, Route of Administration, Unit of presentation, and a device. A Medicinal Product ID corresponds to a unique combination of other attributes: Name, indications, etc.

³ Please note that an identifier is “a description sufficient to differentiate objects in a given environment” so that “is a list of identifying characteristics that together unambiguously identify” [ISO 11616:2012] those objects. It can therefore be a set of IDs as in the case of case of the Pharmaceutical Product.

Analysis:

Specifying a product using its identifier is equivalent to specifying all of the attributes that correspond to that identifier. For example, specifying a Pharmaceutical Product's PhPID is equivalent to specify the attributes corresponding to that level of the Pharmaceutical Product.

When an identifier is used to specify a product, it is not needed to convey the entire set of product attributes as well, assuming that the receiving system understands the identifier and it is able to derive other attributes from it.

This is common practice also in the clinical context: e.g. instead of explicitly providing all of the attributes - substance, strength, dose form, route of administration, etc. - a prescription can simply reference the product ID. If the receiver system understands that ID, it can look up (or infer) the characteristics of the specified product.

The attributes are classified in two main groups:

Product attributes are characteristics of the products themselves, such as identifiers, characteristics, authorized indications, etc.

Examples are the IDs, or names, or the authorized indications of a product, or status etc.

Clinical usage attributes are information about the intended or actual use of the product. These can help identify the product or determine an alternative product in the case of a cross-border prescription.

Examples are posology, or the actual indication that the product is prescribed for – which can be one of the authorized indications, or it can be an off-label use.

Major differences between these:

In D2.2, **the product attributes are considered defined by the regulatory entities**, since D2.2 focused on pre-packed branded medicinal products.

The clinical usage attributes are defined at the point where the medicinal product is specified, i.e. **at the clinical system** (e.g. prescription entry system).

Therefore, when specifying a product for a patient, the product attributes can be sent (directly or encoded by an ID), but the clinical usage attributes need to be sent explicitly.

Product attributes can be Identifiers, Identifying Attributes, or Descriptive Attributes.

The identifiers are assigned by an authority – national or global.

Nationally issued identifiers are unique and commonly known in the expected perimeter of the clinical activity, and they represent the granularity level required within that perimeter - the country.

The ISO IDMP implementation by central regulators defines a global perimeter and a single common terminology. ISO IDMP identifiers have globally unique values.

Implementers of clinical systems usually have to decide which code system to use for clinical data, depending on the availability or intended use. They can use a national identifier, or a global identifier if one is available. Global profiles and standards for clinical data (e.g. prescription standards) do not usually impose any specific choice, providing support to a large variety of solutions in term of coding and attributes. The requirements to be applied for a specific jurisdiction are instead usually captured by constraints specified by local specializations of those profiles and standards.

For example, a prescription may be on "substance" level or on "brand name" level or any level that is deemed adequate. None of the ePrescription standards enforces any constraints on the level to use.

Results:

The choice of product identifier and level is different across implementations, which poses the openMedicine key challenge.

As for the product attributes:

- There are also different attributes defined at a level of a jurisdiction (e.g. region, nation). ISO IDMP establishes a common set of attributes that can be universally understood.
- For several of these product attributes, there are a set of possible terminologies (SNOMED CT, ICD-9, ICD-10, GINAS, EDQM Standard Terms, etc.) that can be used.

D2.2 described the possible applicable terminologies for those attributes, and put in evidence the need for consistent terminologies conveying them.

The overall requirement **for identifying a product across borders** and achieve cross-border interoperability is that **systems in both countries need to have a common understanding of the same attributes used, and they must refer to common terminologies.**

The attributes are defined by the EMA, and the terminologies are defined elsewhere but governed by the EMA.

After some analysis, and thanks to the EMA and FDA collaboration, it is possible to identify the terminologies used for the key attributes.

This does not prevent other terminologies to be used. It is possible to articulate several terminologies, provided that solid governance of the terms and of the terminology mapping is available.

For this, see section 8 – Governance of terminologies, value sets and mappings.

The matter of concern for openMedicine is the product identification. Additional activities (such as validation, checking, dispensing) and other related aspects are considered relevant but not analysed as impactful for the operational model:

After successful identification of a product that has been specified in another country, there are other activities such as finding equivalents, deciding whether it is clinically reasonable to dispense, etc. The product attributes and the clinical context can be relevant for this, as well as the legal context. These aspects are beyond the goal of this document.

The identification of the intended product is decoupled from any other activity or need. This will ensure that openMedicine produces a common identification model which applies to any clinical context.

For example, a product prescribed across borders may be subject of different substitution or billing rules; a patient summary may require to identify Pharmaceutical or Medicinal Products. All of these aspects have been discussed by the project, but they will not affect the identification of the products that has been addressed here.

4.2 IDMP adoption perspectives

ISO IDMP is expected to be progressively adopted - where applicable - in the next years starting from the regulatory domain and then extended to the other contexts, with potential different roll-out plans and strategies by the countries. This will involve different entities such as manufacturers, regulators, and national health systems. However, as seen in D2.2 and in the previous section, there are different needs for clinical and regulatory actors, and those differences have to be correctly articulated.

The adoption of IDMP can happen in different ways. This document identifies some scenarios aiming to provide also sufficient conclusions for the recommendations and requirements to the roadmap. Details are provided in section 6 with dependencies also in the other sections.

4.3 Present challenges in Product Identification

Today, national ePrescription and eMedication systems use local dictionaries, and products have their own IDs. These IDs are not interchangeable since, usually, it is not expected that a country recognizes another country's product IDs. In the previous deliverables it has been shown how the usage of unrecognized IDs, product names or other attributes might be a risky procedure: for example the same name can be used in different countries for different products.

The usage of the IDMP IDs (PhPID, MPID) it is not currently possible, since the assignment by the competent authorities is not yet ready, and the implementation plan is being pursued by the regulators.

Within each country, the ePrescription and eMedication implementations resolve that problem by having common IDs. Those IDs may or not be compatible with the IDMP levels.

This challenge is known and there have been some initiatives to address it:

- epSOS has considered using ATC codes as a pivot for conveying ingredients information
- Commercial and national drug dictionaries contain several codes which can be used to identify a product.

However, these do not provide a reliable identification of the products for cross-border, so currently,

- Manual lookup / translations at point of dispense are the most realistic practice, since the pharmacist is always expected to review the medication before dispensing it, based on the prescription and / or patient-provided information. This, however, doesn't resolve the interoperability problem.

4.4 Scenarios covered

From the list of use cases in D1.3, and focusing on the identification part, the following scenarios have been covered.

4.4.1 Prescription using IDMP attributes

This target scenario considers the usage of the IDMP attributes. For example, an ePrescription also contains, beside the product IDs assigned by that jurisdiction, IDMP IDs assigned by the EMA. This means that the ePrescribing system would have direct or indirect access to these EMA-assigned IDMP IDs, possibly via the product dictionaries used in that jurisdiction.

This requires that prescribing systems may have an "international prescribing mode" where the prescription is checked against the IDMP attributes and identifiers.

As a consequence, this requires that the prescription systems have an IDMP-compliant database and the master data is synchronised with the EMA database.

This does imply however that all national prescriptions shall use the IDMP concepts: national prescriptions in fact can still use national codes, if they have not been foreseen for international use.

4.4.2 Prescription using national attributes, converted to IDMP

This alternative scenario, compatible with the transition phase, considers that clinical data - e.g. prescriptions – is centrally transformed for cross border exchanges (e.g. by country eHNCP).

This is the least impactful case: the ePrescribing systems, in fact, do not have to be immediately compliant with IDMP; even if prescriptions have to contain sufficient information to allow this transformation and each country has to implement a service performing this transformation.

It should be noted that, whether this is done at a national level, or at the prescribing site level, this transformation is not always straightforward given the potential differences among the levels of products defined in a jurisdiction and by IDMP, and among the attributes used. This is described further in section 6 - Cross-border product identification operating model.

4.4.3 Patient Summary or other medication lists

In a patient summary, it is relevant to include medication information for the patient.

The same challenges described for the previous use cases apply to Patient Summaries: since the clinical systems do not use (yet) global IDMP IDs, it is hardly possible to convey structured information directly.

For the scope of a Patient Summary not all the product details required for the dispensation process are needed; in this case it is usually sufficient to identify the Pharmaceutical Product or even just the substance.

For other uses, or more advanced decision support, additional information may be needed. However, this does not change the analysis and the model proposed: in fact, **by using IDMP identifiers and/or set of attributes, it is possible to unequivocally know the product that was specified to whatever level is needed.**

The Patient Summary may use all the product information available, or just the Pharmaceutical Product(s), depending on the goals of that summary. Both situations are covered by the same operating model.

4.5 Summary: cross-border identification needs

From the analysis in D2.2 and additional deliverables, the essence is identification: how to identify a product that has been specified in another system, in another country.

1. Regulatory entities handle the description of the medicinal products by defining the concepts, the attributes, and the value sets for identifiers and attributes.

ISO IDMP defines the concepts and attributes, and in the EU EMA defines the attribute set to be used and the value sets to be adopted.

2. The product data is shared from regulators to different jurisdictions, where such data is enriched as needed
 - a. A gap has been identified for conveying this information in a structured manner all the way to the clinical document creators and consumers (for example, prescription and dispensing systems)
3. In clinical data (e.g. a clinical document such as a prescription), a product may be identified using identifiers.
 - a. Currently, national identifiers are used, so

A national identifier can be used for identification of a product within the country(ies) where that national identifier is expected to be known.

- b. After IDMP adoption, these identifiers could eventually be global identifiers based on IDMP.

An IDMP identifier can be used for identification of a product when all countries can expect the IDMP identifiers to be recognized.

4. To assist in product identification, a clinical document or message can also convey product attributes, such as the name, explicit designation of the strength, quantity per pack, etc.
5. The national identifiers can be mapped to global IDMP identifiers, but it may not be possible to reach the same granularity. In this case, the attributes may provide additional details.
 - a. For example, a national ID may specify substance, strength, dose form, and quantity per pack (case in Spain, Portugal, and Italy). No single IDMP identifier conveys the same information, but the additional attribute "quantity per pack" can be used to provide those details.
6. In order to support the use of such attributes they have to use common terminologies.
 - a. Identifiers have to have a single source or a common terminology. EMA and FDA are specifying common value sets.

- b. Similar to identifiers, the other attributes have to have a common terminology. For example, for indications, either the same terminology is used, or terminology mapping between the used value sets is needed. Section 8 provides details on how this can be managed.

Besides national identifiers, identifying attributes may be used to enable its cross-border identification, or further specify the product.

After IDMP adoption, identifying attributes may be used to complement or further support the identification of products, for example adding more details to refine the product specification.

Upon IDMP adoption, these additional identifying attributes are expected to be expressed in the commonly accepted terminologies (i.e. those adopted by the EMA).

Before IDMP adoption, it is possible and very beneficial if these attributes already use the commonly adopted terminologies (i.e. those adopted by the EMA).

7. Clinical data containers may contain other attributes. An example is a prescription that contains an indication and posology. These attributes are independent from the product, but may be needed to the additional processing, such as finding an equivalent, etc.
8. In order to understand the attributes, the IDMP model has to be used consistently, and this must be unequivocal from the clinical document. This is where the OIDs or any similar approach is necessary.

5 Extensions to WP2 model

5.1 Scenarios

5.1.1 National and cross-border scenarios

During the openMedicine project, one question raised has been whether the scenarios of national prescriptions and cross-border prescriptions are compatible or mutually exclusive.

It is difficult and not advisable to pre-determine whether a clinical document is expected to be cross-country or not.

- a medication is usually prescribed by clinicians following the rules of that jurisdiction independently on where it is expected to be dispensed;
- It's likely that data is captured for supporting processes defined in that jurisdiction and then also used (or re-used) for cross-border purposes as needed;
- Additionally, product identification in a country may have some requirements that are not applicable to cross-border context, like the coverage/eligibility check, billing and reimbursement, etc.

Therefore, it is important to that the possibility of local use of national identifiers is preserved.

The regulatory domain and the clinical domains were analysed differently, to avoid pushing unnecessary dependencies.

Since the regulatory domain is evolving to IDMP, and centrally governed product data, it is possible to implement cross-border identification while minimizing the operational impact on the clinical systems (prescribing systems, etc.) by leveraging the work already done by the regulators and authorities.

For product identifiers, no constraint is imposed. They can coexist with the global identifiers.

For product attributes, they can be specified locally using the current terminologies. However, for cross-border enablement, a common terminology must be used and mentioned implicitly or explicitly when conveying the attribute.

As described in section 6, the current attributes can be mapped to a global ID set, (by an intermediary "translator" or at the dispensing point), provided that the attributes are properly identified and their values are in commonly agreed terminologies.

The same model should support cross-border identification of a specified product, whether the specification is natively cross-border ready⁴ OR such cross-border readiness is a result of a conversion from "national" product specification. The cross-border document should not replace the national documents.

The internationalization implies consistency of syntax and attributes. To ensure this, several options can be used:

⁴ That is, expected product identifiers and attributes are provided directly by the data creator (e.g. the prescribing system).

1. Cross-border syntax and attributes: the product identification is done in a standard way, and the attributes are commonly known;
2. Cross-border syntax and national attributes: the product attributes are defined in a common way (see ePG or IDMP) and the values are national but can be looked up;
3. National syntax supporting cross-border product attributes: the product identification has a national syntax, but the attributes use the common syntax and values and can be used to identify the product.

And finally, on operational impact:

openMedicine concludes that product identification does not, and should not, imply a restructuring of the way products are prescribed. Clinical practices can remain, and the openMedicine approach to product identification can be used in the many use cases defined, providing cross-border identification possibilities without an impact on healthcare professionals and systems and their practices.

5.1.2 Current situation (“as-is”)

Currently no common IDMP identifiers (and attributes) are available for concrete use either for regulators, or for clinical systems.

Therefore, national product identifiers are used and in the future they need to co-exist with the cross-border product, at least until every prescribing and dispensing system in all the jurisdiction can understand the IDMP identifiers.

The current situation doesn’t impose any additional requirement on the openMedicine information model as defined in D2.2. and in this document, except that the national identifiers are not replaced by the IDMP ones and they should be preserved when used.

5.1.3 New use cases from D3.1

Deliverable D3.1 adds the following cases that may require extensions:

Subgroup of products	Name of the product	WP2 identification concept applicable	Need extension of WP2 model
Non-pre-packaged medicinal products	a) magistral formula ⁵	PhPID	Yes – guidance needed
	b) officinal formula	PhPID	Yes – guidance needed
	c) radionuclides in the form of sealed sources	PhPID	Yes – guidance needed

5.1.3.1. Magistral formula

A magistral formula is pharmaceutical compound, prepared by the pharmacist or someone under his/her direction, for a given patient according to a prescription and following the technical and scientific standards of the pharmaceutical art. The product is sold at the pharmacy to the patient who is given the appropriate information about the product. Magistral formulas can be typified in a formulary or not.

5.1.3.2. Officinal formula

An officinal formula is a pharmaceutical compound, developed or prepared by a pharmacist or someone under his/her direction, which is listed and described by the national formulary, sold at the pharmacy directly to its patients. Officinal formulas are typified in a formulary.

5.1.3.3. Radionuclides

Radioactive isotopes (radionuclides) can be used for medical purposes in the form of a radiopharmaceutical; they are permanently sealed in a capsule or closely bonded, and in a solid form.

⁵ Including advanced therapy medicinal products prepared on non-routine basis in a hospital.

5.2 Analysis

5.2.1 Magistral and Officinal Formulas – Extemporaneous preparations

From the definitions of magistral and officinal formulas: Officinal formulas are always typified, i.e. their composition is described in a formulary. Magistral formulas are usually typified, but they can be extended beyond the typified formulation by decision of the healthcare professional.

They are both commonly referred to as “extemporaneous preparations”. Other names may apply, but the main concept is that they are not readily available as a licensed product.

So, they can either be typified formulas (which includes all officinal and not-extended registered magistral formulas) or untypified formulas (for those magistral formulas that are not registered or are extended).

These typified formulas typically have an ID and a name, but of course that ID and name refers to the established typified formula. When this formula is extended, the ID and name become invalid.

For matters of identification, this is a sufficient starting point:

- Magistral formulas and officinal formulas are extemporaneous preparations.
- Officinal formulas are usually typified.
- Magistral formulas may be typified or not.

This section analyses the identification of such formulas.

There are other aspects, which are different from licensed products:

- In country A (prescription): the rules for using and defining extemporaneous preparations are diverse, and can differ across jurisdictions.⁶
- In country B (dispensing): the rules for accepting or not such a formula; to dispense exactly the formula; to procure a similar; etc. may differ across institutions and jurisdictions.

Note that the processes for the dispensation of such products differ from that used for the licensed products. For example, it is not assured that a pharmacist in country B would automatically prepare the medication for the patient; he/she may decide to not dispense it, or to require a new prescription.

Identification of typified and untypified formulas.

For typified formulas, a name and identifier may exist, and be associated with a defined and approved formulation. This identifier may be defined only within a specific context (region, country, or even institution), and it is not expected to be maintained or even visible at the central European regulators.

⁶ Even the designations can differ, so we adopt the terms typified and untypified formula.

For untypified formulas, no identifiers are expected. Even if an identifier exists, it may be defined only within a specific context (region, country, or even institution), and it is not expected to be maintained or even visible at the central European regulators.

Specification and cross-border identification of untypified formulas through identifiers is not possible. In order to reference such products in a clinical document, a **specification** of the formula must be made.

The attributes for describing an untypified formula are:

- Ingredients
 - Identifier, if any
 - Name
 - Strength
 - Role
- Preparation instructions

In general a formula is described through many other attributes; however, instead of attempting to define and structure all of them, only key attributes have been considered here.

For example, attributes related to the preparation and conservation (e.g. packaging restrictions), that are not in the scope of identification, and that may be structured with a fine or coarse granularity, can be conveyed in the Preparation instructions. But, given the purpose of the project (identification of a medication to support safe dispensing) only the essential attributes have been here considered (i.e. rules for preparation).

Other attributes usually needed for labelling (expiry/discard date, instructions, etc.) have also not been considered here.

The describing attributes are shown in Figure 1, in blue. Some of them can be encoded using local coding systems.

A component (ingredient) of a formula is typically a substance, but in some cases it can even be a pharmaceutical product, or other types of products.

In any case: from the identification perspective

The problem of identifying a formula can be substantially demoted to the problem of identifying a product, which has already been resolved by openMedicine by using the IDMP IDs in the openMedicine model.

For typified formulas, the identifier typically exists in a regional or local context, and can even be present in a Pharmacopoeia. This identifier may not always exist, and even when it does it is a local identifier.

Also typified formulas cannot be specified and identified across jurisdictions by using an identifier, so must be described by their attributes.

From D3.1, the attributes for officinal formulas are:

- Formula local identifier, if any
- Ingredients

- Identifier, if any
- Name
- Strength
- Role
- Preparation instructions

A common model can therefore be defined for both the formulas (see the data diagram in Figure 1). This diagram assumes that in the definition of magistral or officinal formulas, the component can be either a substance (e.g. clobazam), or a pharmaceutical product (clobazam 10 mg tablet), or a medicinal product, although the latter is not expected to be common.

The quantity must accompany this choice: for example, the following formulations are equivalent with respect of ingredient and strength.

Quantity	Units	Item
1		Clobazam 10 mg tablet
10	mg	Clobazam

The diagram in Figure 1 shows clinical concepts (in blue) and the data elements that are used in IT systems (in yellow). Put simply, the blue elements are concepts, and the yellow elements are technical data definitions or system implementations of those clinical concepts.

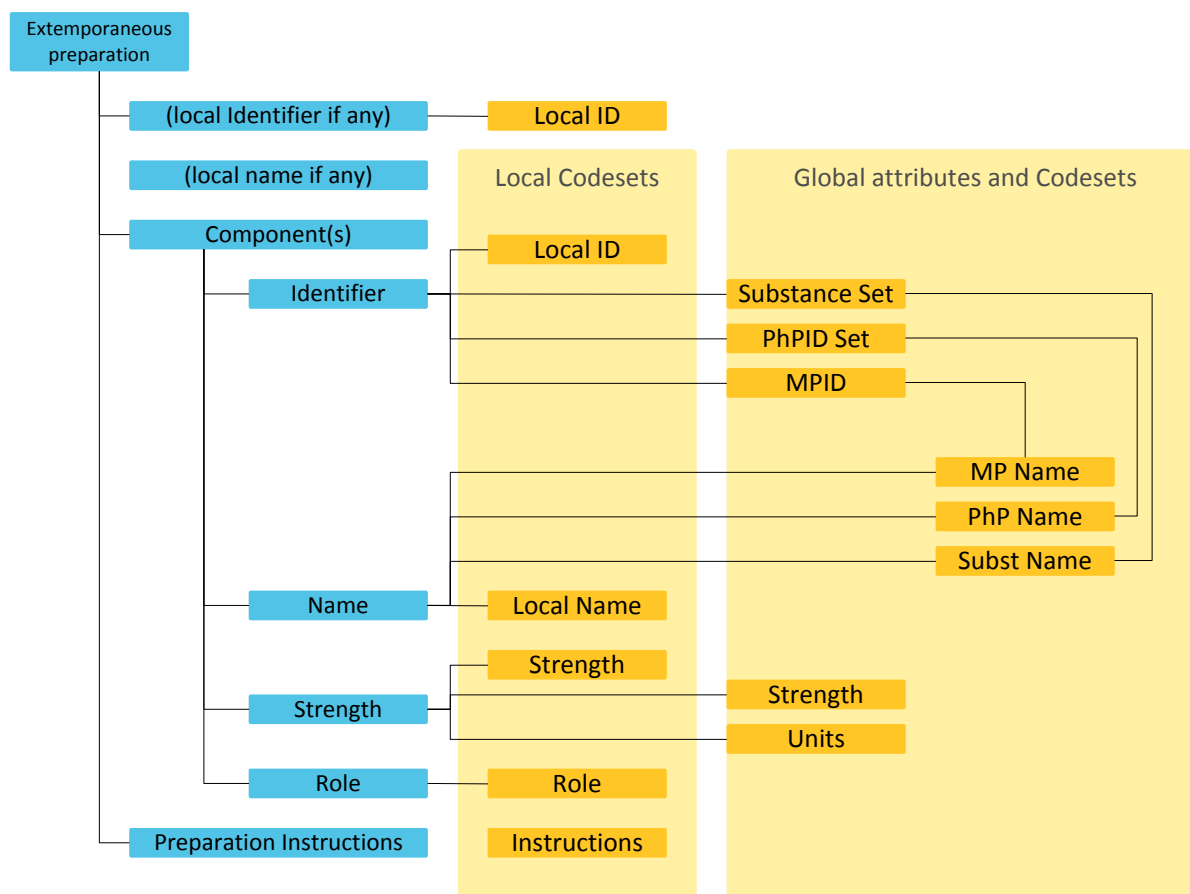


Figure 1 - Concepts and data elements of extemporaneous preparations

Both typified and untypified preparations contain:

- The local identifier for the formula, if any (which can only be expressed as a local ID)
- For each of the ingredients,
 - The ingredient identifier - which can be expressed as a local ID, but can also use the GINAS, PhPID or MPID to express a distinct component, a pharmaceutical or medicinal product. **The IDMP attributes can be used so there is no need to extend the model defined in D2.2.**
 - The ingredient name, which can be expressed as a local name, or as a correspondent to the PhPID or MPID or substance. **The IDMP attributes can be used so there is no need to extend the model defined in D2.2.**
 - The strength or concentration of the ingredient. This can also be expressed in local vocabulary, or use the IDMP Strength and Units (with the appropriate terminology). **The IDMP attributes can be used so there is no need to extend the model defined in D2.2.**
 - The role of the ingredient in the formula. This can be a local attribute. The IDMP model also contains the attribute "role" in the model at the level of Substance Set; however this is not the same attribute. **This is a new attribute for the model defined in D2.2.**
- The preparation instructions, which can contain more or less information. **This is a new attribute for the model defined in D2.2.**

- There is an implicit need to express that these ingredients, identifier and instructions belong to the same preparation - a grouping structure. **This is also a new requirement for the data model defined in D2.2.**

5.2.2 Radionuclides

As for radionuclides in sealed source, their identification requires the identification of the radionuclide itself, and the sealed source. Having no global identifier, the product must be described using the attributes defined in D3.1:

- Radionuclide identifier
- Radionuclide name
- Sealed source identifier
- Sealed source name

However, in the analysis of openMedicine, the sealed source has no significance in the problem of identification and as such is an extra requirement that can be avoided.

The radionuclide is available as a radiopharmaceutical – combining a radionuclide and a pharmaceutical product. While radionuclides are not, radiopharmaceuticals are part of the scope of IDMP. **Radiopharmaceutical is the product that contains the radionuclide.**

The radionuclide is not dispensable *per se*, but as a radiopharmaceutical. As such, to solve the problem of identification, we address the identification of the radiopharmaceutical.

The identification needs are as follows:

- The local identifier for the set (radionuclide in sealed source) - which can be expressed as a local ID (if no global IDs exist)
- The radiopharmaceutical identifier. This can use a local ID, or can use a global ID if the radiopharmaceutical is identified by the central regulator (cf. ISO 11616).
 - The identifier for the radiopharmaceutical can be the PhPID. **The IDMP attributes can be used so there is no need to extend the model.**
 - Similarly, the name can be the name associated with the PhPID. **The IDMP attributes can be used so there is no need to extend the model.**
- There is an implicit need to express that these ingredients, identifier and instructions belong to the same preparation - a grouping structure. **This is also a new requirement for the data model.**

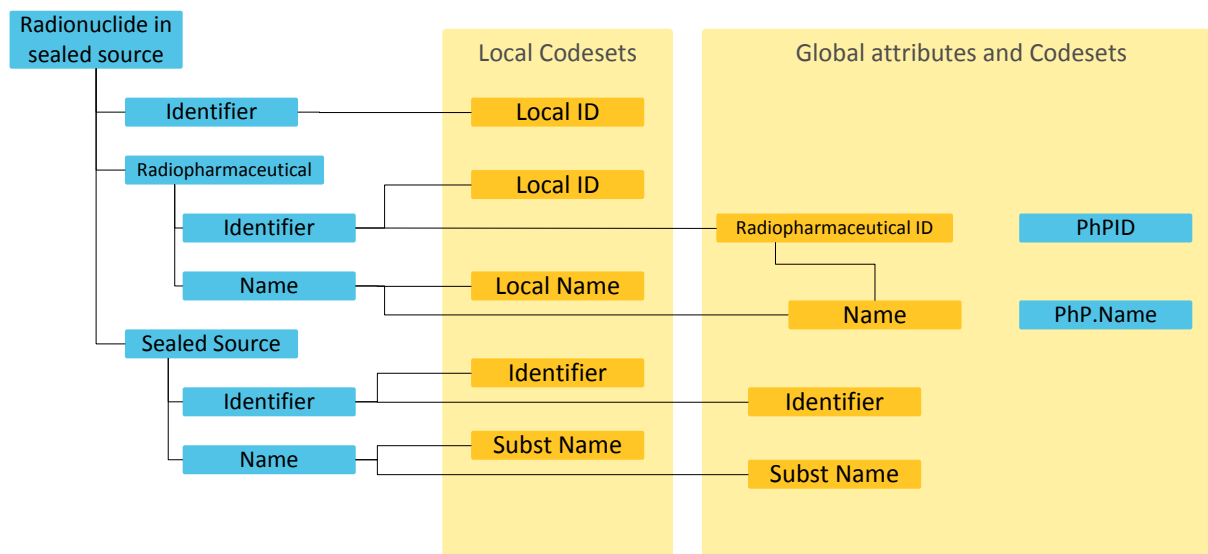


Figure 2 - Concepts and data elements of radionuclides in sealed source

5.3 Conclusions

Both magistral formulas and officinal formulas are extemporaneous preparations, usually combining different components. This means that to identify an officinal formula or a magistral formula, it is necessary to describe its components and any instruction for their preparation.

These formulas can be typified (defined in a formulary) or untypified. Untypified are meant for a single patient. The distinction between typified or untypified is relevant for this analysis; however, for the purpose of cross-borders interoperability of prescriptions, the same modelled can be used for both.

Thanks to IDMP, the components in a magistral or officinal formula can actually be described individually by using the same approach as described in D2.2, leaving as requirement:

To identify Officinal or Magistral formulas, besides the model already described for pre-packaged products, the following is needed in the data set:

- **A grouping structure** for

- The ingredients - described in the same way as for other products: substances, or PhPs, or MPs.

- **The role of each product** of the set in the composition.

- **The preparation instructions** for the complete set.

- An identifier of the formula may be useful (it is not functionally needed for cross-border interoperability).

These 4 attributes are added to the openMedicine model, in Chapter 5 of this document.

Note: Some of these attributes can be coded, however for not all of them a global terminology can be found. This applies for example for the preparation instructions; in this case it is common practice to use Latin as a *lingua franca*.

For Radionuclides, the identification of the medicinal product consists of two elements: the radiopharmaceutical and the sealed source (capsule).

There are several lists but no globally agreed vocabulary or code systems to specify a radionuclide. But the radiopharmaceutical can be identified by a product ID.

As such, it is necessary to have a common **vocabulary or code system for radiopharmaceutical ID**. No new attribute is needed if the PhPID is used, but the vocabulary must include these products.

Also for the sealed source, a common vocabulary or code system could be used but is not considered in the requirement set. The identifier of the radiopharmaceutical is sufficient.

Some of these elements are needed as part of the product model itself, if they can be applied globally, while others are needed as part of the clinical documents, if they have a clinical scope or cannot be applied globally.

As a reminder, for product attributes to be understood, three things are necessary:

- There must be a **data carrier structure**, i.e. a way to transmit such attribute
- There must be a **common attribute**, i.e. the attribute must have the same meaning on both sides
- There must be a **common terminology** for the value to be understood.

These attributes can be present in clinical documents, or be part of the product characteristics. The following table shows these considerations for the attributes analysed:

Type of extensions needed		Extension to product data (SmPC) or clinical data (e.g. Prescription)?
Grouping structure	<ul style="list-style-type: none"> • Data carrier structure is needed 	<u>Clinical (e.g. Prescription)</u>
Compound product identifier	<ul style="list-style-type: none"> • Data Carrier structure is needed • (Common attribute seems impractical) • (Common terminology seems impractical) 	Could be Product (for radiopharmaceuticals and officinal formulas); but best <u>Clinical</u> (which covers magistral formulas, officinal formulas and radiopharmaceuticals)
Compound product name	<ul style="list-style-type: none"> • Data Carrier structure is needed • Common attribute is optional if identifier present • (Common terminology seems impractical) 	Could be Product (for radiopharmaceuticals and officinal formulas); but best <u>Clinical</u> (which covers magistral formulas, officinal formulas and radiopharmaceuticals)

	Type of extensions needed	Extension to product data (SmPC) or clinical data (e.g. Prescription)?
Component product identifier	<ul style="list-style-type: none"> Can use existing Data Carrier structure (e.g. prescription Product ID) Can use existing attributes (e.g. PhPID, or substance or MPID) Common terminology is already in openMedicine model 	<u>Clinical</u>
Component product name	<ul style="list-style-type: none"> Can use existing Data Carrier structure (e.g. prescription Product ID) Can use existing attributes (e.g. PhPID, or substance or MPID) Common terminology is already in openMedicine model 	<u>Clinical</u>
Component Role	<ul style="list-style-type: none"> Data Carrier structure is needed Attribute "role" must be defined Common terminology should be reached, possibly reusing EMA-approved terminology 	Clinical
Preparation Instructions	<ul style="list-style-type: none"> Data Carrier structure is needed Attribute "preparation instructions" must be defined Common terminology is not available or foreseen. Use other options like <i>lingua franca</i> or restricted common vocabularies instead) 	Clinical

The grouping structure (a data element that indicates a group of components) is not a required product attribute. Even if it were eventually taken at a central level (e.g. EMA), the EMA would end up with identifiers for all magistral formulas, and this would still be needed for officinal formulas, so **having a central grouping structure and identifier is considered redundant and not candidate for the scope of EMA.**

Considering that:

- These cases have limited incidence;
- Compound products are typically not available from a central repository, but locally defined at the time of defining the treatment
- Some preparations could be defined centrally, some will still be available only at the time of defining the treatment, so the clinical attributes are needed anyway

It is suggested **to extend the clinical documents (ePrescriptions, Patient Summaries, etc.), rather than attempt to extend the product model at the regulatory levels. This means that there is no impact of these updates in the EMA approach.**

Preparation instructions can eventually also be further structured and harmonized by procuring a restricted vocabulary or phrases.

5.4 Updated model

The following tables contain these attributes and represent the updated openMedicine attribute set distinguishing product and clinical attributes.

The first table - Product attributes – shows the attributes centrally or locally defined for an identified product: **once the product is identified, all these product attributes can be determined.**

The second table - Clinical attributes – shows the attributes that are defined for each clinical context, for example created at prescription. Even if some of them are related to equivalent product attributes, their usage in the clinical document is context-related and not product-related. For example, a product has indications for use, but the “indication” for that patient included in the prescription is always the result of a clinical decision made by a health professional. **It is not possible to infer a clinical attribute from the product ID, no matter how detailed is that product ID.**

Table 1 - openMedicine Collection of identifiers - Product Identifying Attributes

Product Attributes		Attribute Name	Scope	Vocabulary
Product Attributes	Pharmaceutical Product	PhPID	PhPID	Xborder
		PhP Stratum	PhP->Stratum	Local / Xborder
		Substance(s)	PhP->Substance	Local / Xborder
		Route of Administration	PhP->Route	Local / Xborder
		Administrable Dose Form	PhP->AdminDoseForm	Local / Xborder
		Strength		
		Quantity	PhP->Strength->Qty	Xborder
		Units	PhP->Strength->Units	Xborder
		Reference Strength		
		Quantity	PhP->RefStrength->Qty	Xborder
		Indication (for use case 5)		
		Units	PhP->RefStrength-Units	Xborder
	Medicinal Product	Medical Device	PhP->Device	Local / Xborder
		Unit of Presentation	PhP->UnitofPresentation	
		MPID		
		Medicinal Product Name	MP->Name	Local
		Marketing Authorization		
		Country	MP->MA->Country	Local
		Holder	MP->MA->Holder	Local / Xborder
		Number	MP->MA->Number	Local / Xborder
		Procedure ID	MP->MA->ProcedureID	?????
		Indication	MP->Indication	Local / Xborder
		Pharmaceutical Dose form	MP->DoseForm	
		Legal Status of Supply	MP->LegalStatus	Local / Xborder
		Classification	MP->AdditionalClassification	Local
	Package	PCID		
		Package Item Container		
		Type	PC->Container->Type	Local / Xborder
		Quantity	PC->Container->Qty	Local / Xborder
		Material	PC->Container->Material	Local / Xborder
		Alternate Material	PC->Container->AltMaterial	Local / Xborder
		Manufactured Item		
		Manufactured Dose Form	PC->Item->ManufDoseForm	Local / Xborder
		Unit of Presentation	PC->Item->UoPresentation	Local / Xborder
		Manufactured Item Quantity	PC->Item->Quantity	Local / Xborder

Table 2 - openMedicine Collection of identifiers - Clinical usage attributes

		Attribute Name	Scope	Vocabulary
Prescription	Product	Preparation / compound product		
		Preparation ID		
		Preparation Name		
		Preparation Instructions		
		Components		
		Component identification	Component ->Identification	
		Identifier	Component ->Identification->ID	Local / Xborder
		Identifier type (e.g. substance ID, MPID...)	Component ->Identification->Codeset	Local / Xborder
		Component Name	Component ->Name	Local / Xborder
		Component Role	Component ->Role	Local / Xborder
		Component Strength	Component ->Strength	Local / Xborder
		Component Pharmaceutical Dose Form	Component -> PharmDoseForm	
		Pharmaceutical Dose Form	PharmDoseForm	Local / Xborder
	Treatment	Posology	Treatment->Posology	
		Quantity to administer per intake	Treatment->Posology->QtyPerEvent	Xborder
		Frequency of intakes	Treatment->Posology->Frequency	Xborder
		Duration of treatment	Treatment->Posology->Duration	Xborder
		Treatment Start	Treatment->Posology-TreatmentStart	Xborder
		Quantity to administer	Treatment->QtyToAdminister	Local / Xborder
		Indication	Treatment->Indication	Local / Xborder
		Route	Treatment->Route	Local / Xborder
Patient Summary	Product	Same as Prescription Product in this table		
	Treatment	Number of units per intake	Treatment->UnitsPerintake	Local / Xborder
		Frequency of intakes	Treatment->Frequency	Local / Xborder
		Duration of treatment	Treatment->TreatmentDuration	Local / Xborder
		Treatment Start	Treatment->TreatmentStart	Local / Xborder

6 Cross-border product identification operating model

This chapter demonstrates, using an example, the openMedicine operating model - from the initial scenario of national prescription, to the complete overview of cross-border possibilities. This gives the ability to walk through the several dependencies that build up as the full challenge gets visible.

6.1 Example

Two patients - Patient A and Patient B - are being discharged from a hospital in Portugal. The discharge prescriptions for both are 10 mg Clobazam once a day, during 30 days.

For patient A, clobazam is commercially available in the pharmacy as⁷:

- Substance: Clobazam
- Product Name: Castilium
- Pharmaceutical Dose Form: Comprimido
- Strength: 10 mg
- National ID: CNPEM 50067338
- Package Quantity 30 units
- Generic: No
- MAH: Sanofi - Produtos Farmacêuticos, Lda.

So that is what is prescribed: for patient A, the prescription will contain the national ID of the product, or a system converts it to the IDMP MPID. This is then handled in the same way as the scenarios described for openMedicine.

Patient B is unable to swallow tablets properly, which means liquid form is required; so the prescriber indicates that this should be a special liquid preparation, with 10 mg Clobazam per 5 ml dose. Searching in his local formulary, he finds there is no prepacked product containing Clobazam in a liquid form, but there is a local formulation (only valid for that hospital). He selects that formulation from the system. Upon selecting it, the system locates the information about the ingredients.

Clobazam	10 mg
Concentrated Peppermint Water	2% v/v
Glycerol	6% v/v
Syrup	25% v/v
Suspending agent	2% w/v
Freshly boiled and cooled purified water	to 100%

For patient A, this is a simple prescription. The product is available as a medicinal product.

For Patient B, the full preparation needs to be described:

⁷ http://www.infarmed.pt/genericos/pesquisamg/detalhes_MG.php?med=1494&emb=2457

First, the formula contains several ingredients. Since there is no ID for the complete formula, all the ingredients must be specified by the system, in order for the receiving systems to fully understand it (as per the list of attributes shown before).

Attribute	Value (as captured in ePrescription)
Preparation ID	(Internal hospital code is available; Pharmacopoeia / formulary code may exist)
Preparation Name	Clobazam prep 10mg / 5 ml
Preparation Instructions	Misce fiat mixture
Component	
Component Role	Rem. Cardinale
Product Name	clobazam (substance)
Identifier	(TBC) (national code)
Identifier Type	National Code
Strength	10 mg
Pharmaceutical Dose Form	Tablets
Component	
Component Role	Rem. Corrigenis
Product Name	Xarope de Menta
Identifier	N/A
Identifier Type	N/A
Strength	2% v/v
Pharmaceutical Dose Form	N/A
Component	
Component Role	Rem. Adjuvans
Product Name	Glicerol BP
Identifier	N/A
Identifier Type	N/A
Strength	6% v/v
Pharmaceutical Dose Form	
Component	
Component Role	Rem. Adjuvans
Product Name	Xarope simples
Identifier	N/A
Identifier Type	N/A
Strength	25% v/v
Pharmaceutical Dose Form	
Component	
Component Role	Rem. Adjuvans
Product Name	Agente suspensor
Identifier	N/A
Identifier Type	N/A
Strength	2% v/v
Pharmaceutical Dose Form	
Component	
Component Role	Rem. Constituens
Product Name	Água Destilada
Identifier	
Identifier Type	N/A
Strength	
Pharmaceutical Dose Form	

The treatment is for 30 doses, so the pharmacist will prepare 30 tablets and the other ingredients in the required proportions for a total of 150 ml.

6.2 Prescription and dispense in the same jurisdiction

In the country where the prescription is made and dispensed there is a Local Dictionary - a database with the product characteristics and identifiers. This is expected to be aligned with the central regulator's database, but that is outside of the scope for a national implementation. Additionally, it is assumed that there are no language barriers.

In this case, the local systems - sender and receiver - have common access to the dictionary, which means that they contain the same product information.

The local Product Dictionary contains the National ID(s) for drugs and a locally unique identifier that corresponds to a substance and other attributes. These attributes may or not be aligned with the IDMP attributes, which is not relevant for this case.

When a product is specified in the sending system, the ePrescription system encodes that specification by using a national ID.

The sending system can also provide additional information (the clinical usage attributes). A typical case is a prescription, where the attributes are posology, etc.

For National Prescriptions of pre-packaged regulated products (for Patient A), the prescription may simply contain a national product ID.

Even if this is not an IDMP-compliant identifier, the receiver is expected to understand and decode this identifier, as they are in the same jurisdiction.

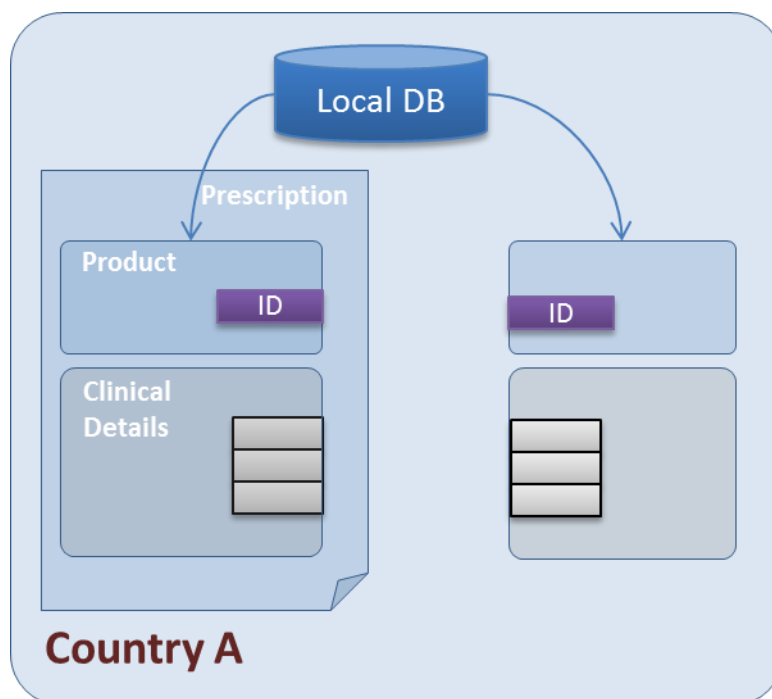


Figure 3 - Simple prescription (pre-packaged product) same jurisdiction

For the compound product:

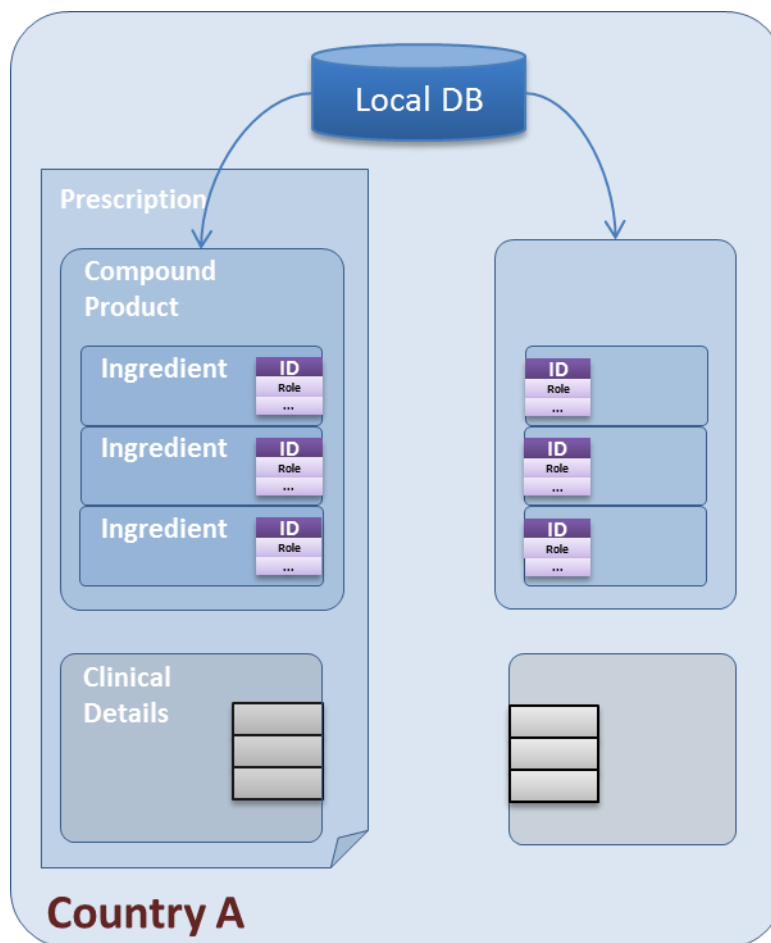


Figure 4 - Prescription (formula), same jurisdiction

For National Prescriptions of officinal or magistral preparations, the preparation needs to be described by including the components identification and other attributes, or simply the unique identifier (e.g. a name) of the formula, if it exists. Each component can be specified by an ID or by its attributes.

The attributes for the formula and component identification are those described in chapter 5.

Also here, if these are not IDMP-compliant identifiers, the receiver is expected to understand and decode this identifier, as they are in the same jurisdiction.

This also has an impact on the code system to be used. In the product description table, the ingredients need to be encoded using cross-border code systems.

For example for patient B, the product Clobazam would no longer be identified using a national identifier, but with a global identifier, as shown below:

Attribute	Value (as captured in ePrescription)	
	National Prescription	Cross-border prescription
Preparation ID	...	
Preparation Name	...	
Preparation Instructions	...	
Component		
Role	Rem. Cardinale	
Name	Clobazam	
Identifier	50067338	2MRO291B4U
Identifier type	CNPEM	GINAS substance
Strength	10 mg	10 mg
Pharmaceutical Dose Form	Comprimidos	Tablets
...	...	

6.3 Cross-border (no IDMP IDs, IDMP attribute exchange)

When moving to the cross-border scenario, we cannot assume anymore that a single, shared product database or dictionary is available and that the identifiers used are the same. The unique ID in the country A is not in principle recognizable in the country B. So it is no longer possible to specify a medicinal product by using an ID for that jurisdiction.

One way to solve this interoperability problem is by using the attributes, as done in epSOS: the sending system provides all the attributes that such identifier encodes, providing for example Substances, Strength, Dose Form, and Quantity per pack.

This example is valid for the pre-packaged products and also compound products, since the only difference is not at the level of product attributes, but on clinical data.

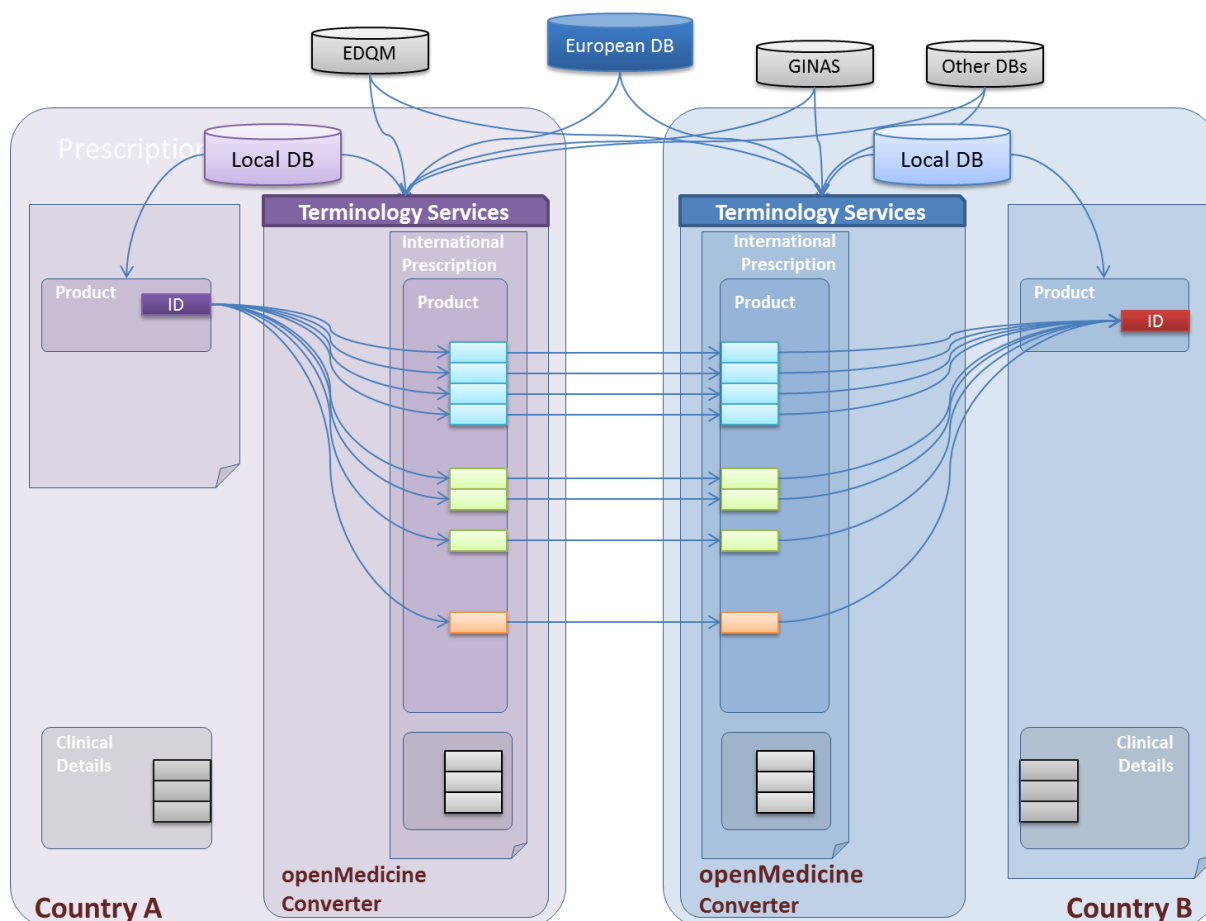


Figure 5 – Cross-border prescription (formula)

For Cross-border Prescriptions of regulated products, products can be described by using their attributes, provided that:

- 1. A common minimal set of identifying attributes has been agreed among all the trading partners.**
- 2. These attributes have the same meaning in both countries. This is where ISO IDMP is intervening, and where governance of concepts is important.**
- 3. The values of these attributes are common in both countries (e.g. substance IDs, units). This is not dependent on IDMP, but on its implementation, and the governance of the terminologies, thus this is provided by EMA, or from the EMA-endorsed terminology systems. (This underlines the need for governing these attributes, either at each country or centrally.)**

Points 1 and 2 above are key points for IDMP harmonization: the way to ensure such common semantics is by the adoption of IDMP, as per the deliverable D2.3 which describes the product attributes.

Point 2 above is where terminologies play an essential role. Section 8 explores that.

For Cross-border Prescriptions of Compound products, the same model applies: each ingredient must be described by using their attributes, taking care of the harmonization of these concepts (IDMP) and the vocabularies (terminology governance).

For compound products, the same approach is possible - instead of containing the attributes of a single product, the prescription must contain the attributes of the components used for the formula preparation.

6.4 Cross-border (conversion to IDMP)

Another option for cross-border interoperability is to use a conversion service which, in each country, matches a set of national attributes or identifiers into the openMedicine set of IDMP attributes or identifiers.

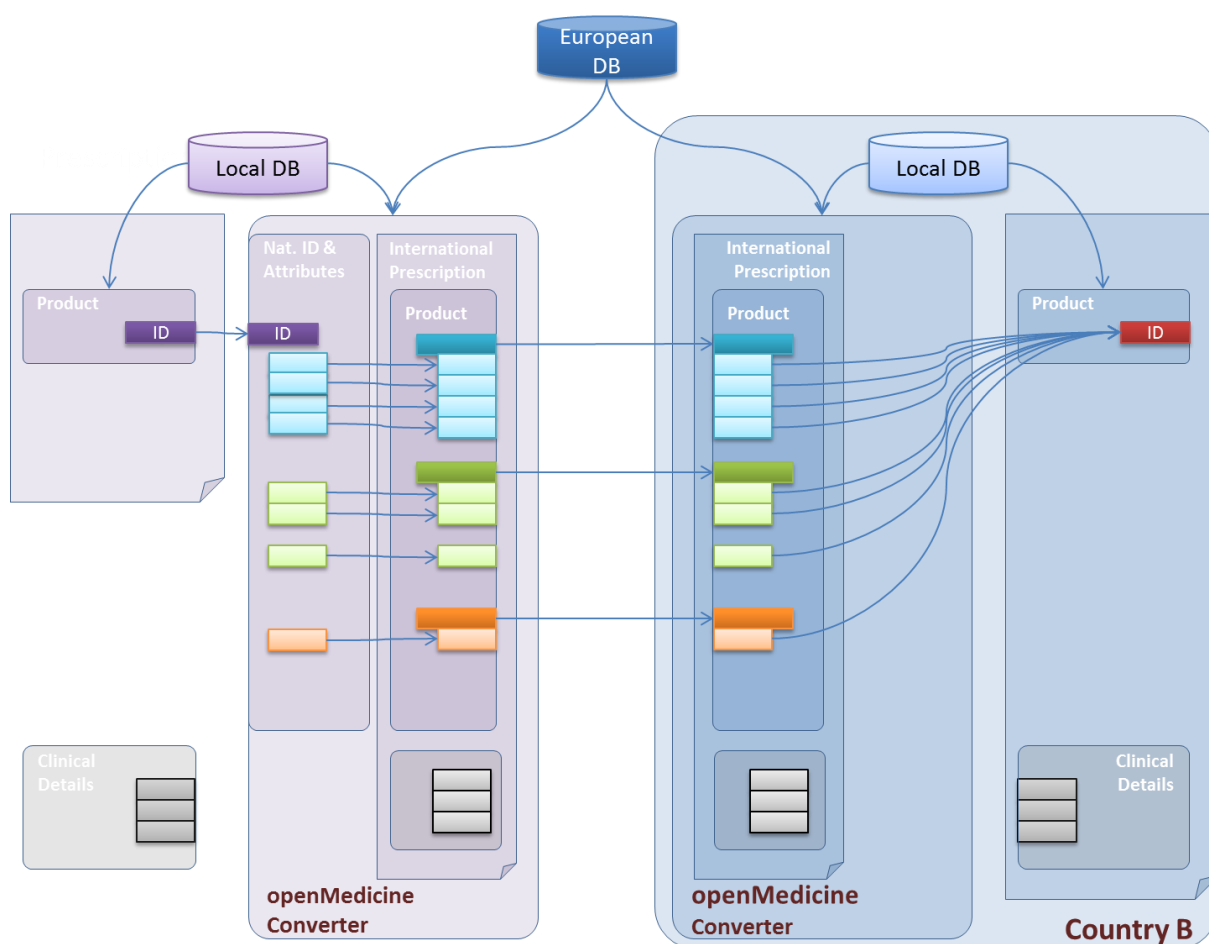


Figure 6 – Cross-border prescription (formula)

In this case, the prescriptions can still be created and maintained using national IDs or attributes. When making an international prescription, these attributes will be re-encoded.

This approach requires the existence of a conversion service. This service can be at each country - in the prescribing system, or a national portal - or even at a European level.

A European conversion service would have to contain the attributes and logic for all the countries. A national conversion service would just have to contain the attributes and logic for that country. In both cases, it is not required for a specific country to be able to recognize another country's attributes, IDs, or terminologies.

This is the least invasive approach, since it allows each prescribing system to still use the national identifiers, and respect the different regulatory and legal constraints in the country. At most, **each country needs to know its own local attributes and value sets, and eventually the European (IDMP) attributes and value sets.** No country requires the knowledge about another country's attributes or practices.

The national prescriptions do not need to change - only the cross-border prescription, as indicated in the next section. **The national Product Dictionaries also do not need to change simultaneously.**

The effort to adopt IDMP at the clinical systems should be greatly reduced, since it is possible to have a progressive, asynchronous adoption - each country migrates to the common data set at their own pace.

This approach is therefore appealing for a phased implementation.

6.5 Cross-border (IDMP IDs and attributes)

Finally, it could be considered that all the prescribing systems would have an IDMP data set, providing IDMP IDs and attributes, which would remove the need for a conversion service.

The national IDs can still exist for other processes like reimbursement, etc.

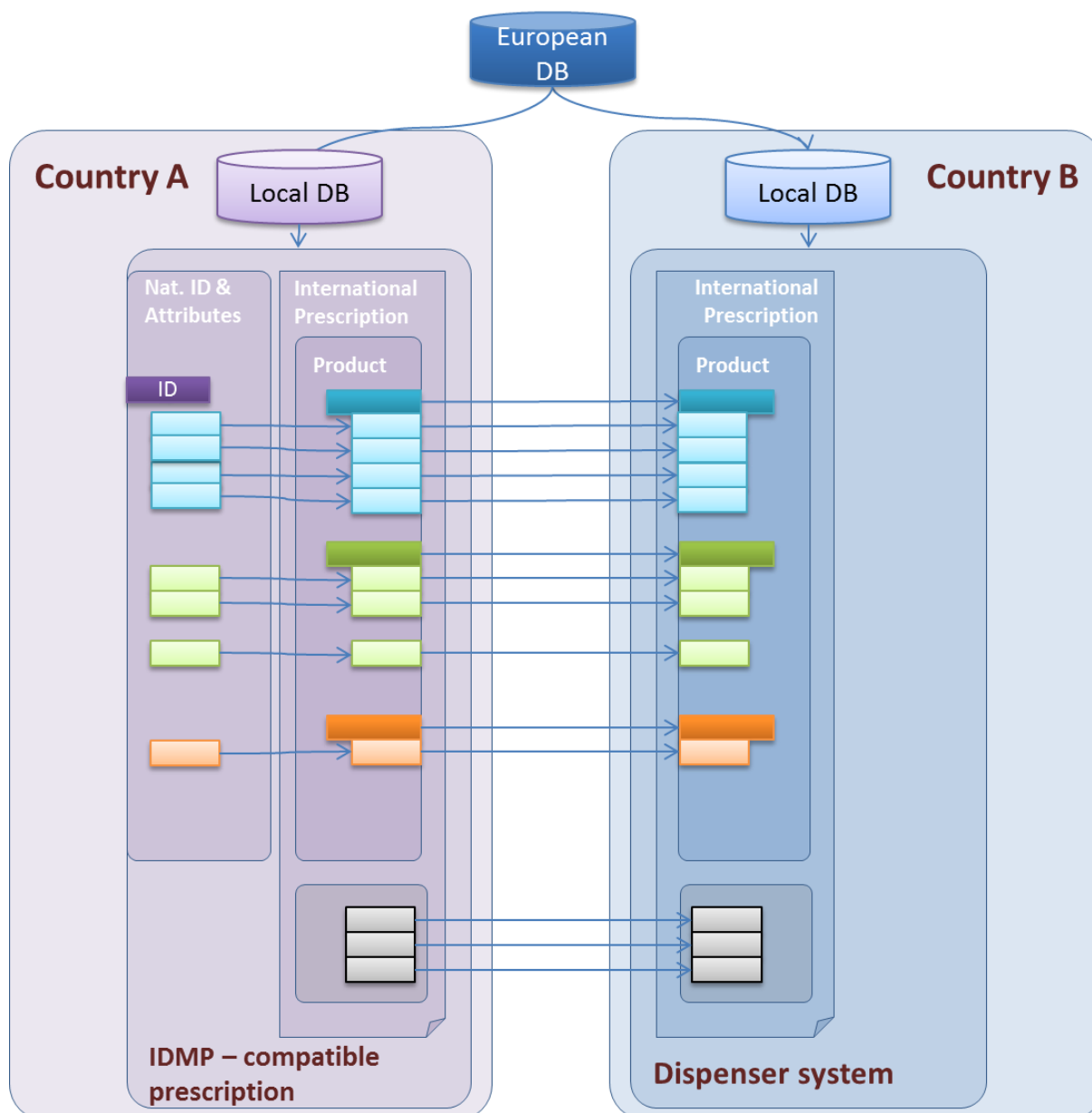


Figure 7- Cross-border prescription using IDMP attributes

This solution avoids the burden of performing a model mapping between the national prescription and the cross-border one, but it moves the complexity to the local DBs of all the clinical systems: all national databases in all prescription systems would need to be updated.

For new adoptions and for migration within the EU, it is possible to have this as an attainable scenario. **But normally, this solution should be considered as an asymptotic directive - not to be reached immediately, but to validate the direction.**

Like all the use cases presented, this analysis is independent from any implementation and transport option (e.g. CDA, V2, and FHIR).

The following sections handle the technical needs to operationalize these concepts and scenarios.

7 Implementation aspects of the proposed model

With reference to the Refined eHealth European Interoperability Framework, two main classes of aspects can be considered for the implementation of the proposed IDMP-based model:

1. Those related to the Semantic - Information layer, in this case referring to the capability of the implemented model to convey the IDMP concepts; and
2. Those related to the Technical – Application Layer, that is those referring to the availability of supporting services that assure that all the actors involved are aware and can use, the IDMP product data in meaningful way.

These two classes of issues will be examined in the following paragraphs.

Note: authors are aware that the other layers also impact in the interoperability, for example the realization of the Technical – Application layer presumes that: (a) legal agreements have been established for allowing this kind of communication; and that (b) business processes (who is doing what and how) have been defined. The analysis of those layers (legal, organizational etc.) is however out of scope for this section.

7.1 Semantic – Information Layer

In this section some of the (non-independent) aspects related to the capability of the exchanged contents (e.g. the CDA template for the Patient Summary) to support the proposed IDMP-based model are described, in particular:

1. What are the possible approaches for expressing the IDMP identifiers (§ 7.1.1)
2. Current limitations with the identification of IDMP IDs and used code systems (OID, URL) (§ 7.1.2)
3. What are the known issues and possible solutions with the most commonly used standards (§ 7.1.3)

In this description it has been assumed that the IDMP identifiers and attributes are known, and common vocabularies have been agreed.

Since this condition will be realized in a long term timeframe. Some considerations on how to manage the transitional phase have also been provided. (§ 7.1.4).

7.1.1 Possible approaches for expressing the IDMP identifiers

Assuming that IDMP IDs are known and correctly identified, in a first approximation, the following possible approaches for representing them in the exchanged content can be considered:

- 1) represent the identifiers that have to be exchanged as additional identifiers / codes associated to a single piece of information (class, segment, field). [Alternative Identifiers]
- 2) make a model mapping, that is map the distinct IDMP concepts into a separate piece of information (class, segment, field) and then assign the appropriate IDMP ID to the mapped “piece” [Model Mapping]
- 3) use a combination of the above solutions. [Mixed approach]

For the sake of brevity, the third solution will not be analysed here since the same considerations done for the other two can be replicated for this mixed approach, weighting how much of the model mapping and of the alternative identifiers approaches is used.

Hereafter some examples of the first two cases:

Example of usage of translation elements in a CDA (Alternative Identifiers)

```
<hl7:manufacturedMaterial>
  <!-- Example with all the IDMP Levels (PhPID,MPID, PCID) and other attributes used in epSOS
  (e.g. ingredients, ATC, strengths) -->
  <hl7:code codeSystem="OID_Local_CodeSystem" code="Local_ID"
    displayName="" CodeSystemName="Local Code System">
    <hl7:translation codeSystem="OID_MP"
      code="MPID" displayName="" CodeSystemName="MP"/>
    <hl7:translation codeSystem="OID_PhP_ID_Lvl4"
      code="PhPID_Lvl4" displayName="" CodeSystemName="PhP"/>
  </hl7:code>
  <hl7:name>Product Name</hl7:name>
  <cpm:formCode codeSystem="0.4.0.127.0.16.1.1.2.1" code="10219000" displayName="tablet"Co
  deSystemName="EDQM"/>
  <!-- Omissis -->
</hl7:manufacturedMaterial>
```

Example of usage of extensions in a CDA (Model Mapping)

```
<hl7:manufacturedMaterial>
  <!-- Example with all the IDMP Levels (PhPID,MPID, PCID) and other attributes used in epSOS
  (e.g. ingredients, ATC, strengths) -->
  <hl7:code codeSystem="" code="MPID" displayName="" CodeSystemName="MP EMA"/>
  <hl7:name>Medicinal Product Name</hl7:name>
  <cpm:formCode codeSystem="0.4.0.127.0.16.1.1.2.1" code="10219000" displayName="tablet"Co
  deSystemName="EDQM"/>
  <cpm:asContent>
    <!-- Packaged Medicinal Product (PC) -->
    <cpm:containerPackagedProduct>
      <!-- PC ID-->
      <cpm:code codeSystem=" " code="PCID" displayName=" " />
      <cpm:name>...</cpm:name>
      <cpm:formCode codeSystem="0.4.0.127.0.16.1.1.2.1"
        code="" displayName="" CodeSystemName="EDQM"/>
    </cpm:containerPackagedProduct>
  </cpm:asContent>
  <cpm:asSpecializedKind classCode="GRIC">
    <!-- Pharmaceutical Substance (ATC Code)-->
    <cpm:generalizedMaterialKind classCode="MMAT">
      <cpm:code code=" " codeSystem="2.16.840.1.113883.6.73"
        displayName=" " codeSystemName="WHO ATC"/>
    </cpm:generalizedMaterialKind>
  </cpm:asSpecializedKind>
  <cpm:asSpecializedKind classCode="GRIC">
    <!-- Pharmaceutical Product (PhP)-->
    <cpm:generalizedMaterialKind classCode="MMAT">
      <cpm:code codeSystem="OID_PhP_ID_Lvl4"
        code="PhPID_Lvl4" displayName="" CodeSystemName="PhP"/>
      <cpm:name>...</cpm:name>
    </cpm:generalizedMaterialKind>
  </cpm:asSpecializedKind>
  <!-- list of active ingredients -->
  <cpm:ingredient classCode="ACTI" determinerCode="KIND">
    <cpm:quantity>
      <!-- strength -->
      <cpm:numerator unit="mg" value="20" xsi:type="PQ"/>
      <cpm:denominator unit="1" value="{tablet}" xsi:type="PQ"/>
    </cpm:quantity>
  </cpm:ingredient>
</hl7:manufacturedMaterial>
```

```

</cpm:quantity>      <cpm:ingredientSubstance>
  <cpm:code codeSystem=" "
    code="SubstanceID" displayName=" " CodeSystemName="GINAS"/>
  <cpm:name>...</cpm:name>
</cpm:ingredientSubstance>
</cpm:ingredient>
</hl7:manufacturedMaterial>

```

The choice of the approach may depend on the type of standard used; on the maturity of the setting; and on the drivers (e.g. existing implementations). Hereafter a summary of the preconditions needed for applying the first two solutions.

Preconditions		[Alternative Identifiers]	[Model Mapping]
1	Identifiers have been uniquely identified	X	X
2	Receivers can correctly distinguish them from the identification space used (e.g. the OID)	X	O ⁸
3	The standard allows for multiple IDs	X	O ⁹
4	The element used for conveying the IDs is not in conflict with the type of information provided (e.g. the MPID cannot be one of the IDs of the Substance Administration Act if defined by the used standard)	X	O ¹⁰
5	The standard used provides a reasonable mapping between the implemented and the IDMP models.		X

Conditions 1 and 2 are analysed in § 7.1.2 “Identification of IDMP IDs and Code Systems”; the other three in § 7.1.3 “Support of existing Standards”

The two approaches have been compared and summarized in the following table according to a set of identified characteristics.

Characteristic	[Alternative Identifiers]	[Model Mapping]
Impact on existing implementation	<i>Medium.</i> It requires less structural changes on the exchanged data (e.g. add new IDs to existing items). However the receiving application has to be aware of the IDMP layers and develop a processing logic for distinguishing them based on the type of identifiers.	<i>High</i> The IDMP concepts have to be correctly mapped in the implemented model, this may implies major changes in the exchanged data. The receiving application has to be aware of the IDMP layers.

⁸ May be required depending on the standard used

⁹ Not required but often useful.

¹⁰ It is assumed that in general this is guaranteed by the model mapping

Characteristic	[Alternative Identifiers]	[Model Mapping]
Maturity of the selected standards	<i>Medium</i> Shall allow for multiple IDs Should foresee elements that can reasonably represent the IDMP concepts for which the IDs should be transferred.	<i>High</i> Shall enable the mapping of the IDMP concepts (forward tracing from the IDMP to the implemented model).
Medium and long term maintainability	<i>Low</i> The same “carrier” is used to convey different data Solution not applicable if other IDMP attributes (that are not just IDs) are needed	<i>High</i> Reduce ambiguity and allow to adequately conveying identifiers and attributes.

Conclusions

The model mapping is the preferred long term solution, when applicable, the first option should be considered in general only as a transitional solution in case the implementation adopted doesn't support the IDMP model; or if imposed by existing local constraints (e.g. limited changes required in the existing implementation). In both cases however it is suggested that a migration plan would be defined, in order to move towards more mature solutions.

7.1.2 Identification of IDMP IDs and Code Systems

As also described in D1.3 and D2.3 there is a practical issue related to the identification of the code systems and of the IDs required by the IDMP implementations.

This may require the definition of different types of unique identifiers (e.g. OIDs, URI) independent of the type of standard adopted, and for which a one-to-one mapping shall also be defined. (e.g. <http://unitsofmeasure.org> [URI] and 2.16.840.1.113883.6.8 [OID] for UCUM).

Identifiers for MPID, PCID and the four PhPIDs shall be defined, as well as for coding systems such as EDQM¹¹, GINAS, etc.

7.1.3 Support of existing Standards

A short description of the mentioned standards have been provided in § 9.4.2 of D2.2.

The following paragraphs extend that analysis also pointing out how each of them can support the options described above concerning the expression of IDs (§ 7.1.1 “Possible approaches for expressing the IDMP identifiers”).

HL7 V2 messaging

HL7 V2 is a messaging standard that uses a positional semantic (it is not model based standard). It defines messages for a set of events (e.g. patient registration; issue an order)

¹¹ At the time of the revision of this deliverable on April 2017 an OID has been assigned to the EDQM standard terms code system (“0.4.0.127.0.16.1.1.2.1”)

composing reusable fragments (called segments) carrying common pieces of information (e.g. patient, visit or order info). The last published version of V2 is V2.8.2¹².

There are no standard V2 segments (or set of segments) that currently map the IDMP structure and data set. The intended approach for transmitting IDMP data in V2 should be first, that of identifying the IDMP data has to be transferred (e.g. the IDMP identifiers); then, verifying if they can be supported by the segments used in the message (event) considered. In case not, evaluate the adoption of the HL7 V2 extension mechanisms (e.g. Z-segments) allowed by that standard¹³.

Example: prescription (as encoded order) (event O11)

The information about the ordered medication is transported by the segment RXE (“RXE details the pharmacy or treatment application's encoding of the order.”) and in particular by the field RXE-2 (Give Code) (“This field identifies the medical substance or treatment that has been ordered to be given to the patient, as encoded by the pharmacy or treatment supplier”).

The datatype of this field (CWE – Code With Exceptions) allows to provide up to 2 alternative identifiers, so if the first is used for a local code the other two might be used for describing the same product through alternative code systems¹⁴. MPID, PhPID and PCID, as known, identify different “things” (MP, PhP, PC), in the example below they are used as it was an alternative way for describing the same prescribed product.

Example

```
RXE|1^BID&1000,2200,^^200910150932^^0^0^|0456540^PROPRANOLOL 40MG
Compresse^localcodeSystem^PhPID1^PROPRANOLOL 40mg Tablets^PhPIDCodeSystemName^^^^PCID_xyz^INDERAL@ 40 mg
50 ^compresse^PCIDCodeSystemName^localcodeSystemOID^^^PhPID_SUB_L4_OID^^^PCID_OID|40||MG|EACH|HOLD FOR SBP
#lg;90 |||||
```

Local code PhP MP

The best option for conveying additional IDs for this segment would be that of using the RXE-31 field (“Supplementary Code”) if not already used for other purposes (e.g. National Drug Code (NDC)). For this field the same considerations made for CWE data type apply.

However, the preferable way to manage the IDMP data would be that of defining local extensions in which to record all the IDMP information to be reused across different messages.

In Syntesis:

- [1] V2 doesn't allow a model mapping
- [2] The solution can change depending on the type of message and the IDMP data that has to be transmitted
- [3] In some cases it is possible to pass multiple IDMP indentifers as alternative identifiers (but this has to be carefully evaluated on a case by case basis)
- [4] A more generic solution is that of defining and resuing local extensions (Z-segments) in which to record the needed IDMP information (identifier and attributes). To be eventually included as part of future V2 versions.

¹² http://www.hl7.org/implement/standards/product_brief.cfm?product_id=403

¹³ Cfr, HL7 V2 Messaging, Chapter 2A “Control”, § 2.11 “Local Extensions”

¹⁴ The CWE data type is supposed to be used for conveying the same concept using different vocabularies “the identifiers in component 4 and component 1 should have exactly the same meaning”. Distict codes shall be in fact trasmitted repeating the CWE datatype. The same applies for the <translation> element for the V3 data types that are “are quasi-synonyms of one real-world concept. Every translation in the set is supposed to express the same meaning “in other words.” “

HL7 V3 messaging

HL7 V3 is a model based implementation. (Based on the HL7 V3 reference model RIM).

Domain specific models (e.g. Patient Administration, Pharmacy, Regulated products etc.) are defined starting from the common HL7 V3 reference model RIM, and then specialized for specifying the messages' contents for a specific event (e.g. patient registration; issue an order; notify an adverse event report etc.)

HL7 V3 has defined reusable components (called CMET) that can be used across different domains to compose the message models.

The message domain model that better represents the IDMP concepts is the Common Product Model (CPM) "intended to express a pattern that can be used by the HL7 V3 messages that have a requirement to identify and represent products". (ref. HL7 V3 Edition 2015). CPM is used for the Structured Product Labelling and Incident Case Reporting Systems. Not all the messages however use the CPM for describing medicine (e.g. for prescription V3 messaging the R_Medication CMET is used).

Therefore, implementers should verify for each of the selected messages which type CMET is actually used for describing medicines (e.g. CPM , R_Medication CMET, other models); then evaluate how the IDMP concepts that have to be transported can be represented in that model. Depending on the type of information to be conveyed, the model actually used more and other drivers (e.g. existing implementation) more or less extensive model mapping approaches can be used: i.e. map IDMP concepts in the model as possible, use alternative identifiers in the other cases.

With respect of the IDMP identifiers, they are usually conveyed in HL7 V3 as coded information, rather than actual identifiers, in that case alternative IDs can be passed as <translation> elements of the coded data type (see the CDA examples above).

A more detailed analysis on CPM is provided in the dedicated section below.

HL7 CDA Templates

The CDA is a model based implementation (Based on the HL7 V3 reference model RIM). The model used is a subset of the RIM. What is not in the CDA model can be represented using extensions¹⁵.

The CDA is never used "as such" but always through defined templates (e.g. epSOS templates for Patient Summary and ePrescription). A template always includes constraints and sometimes extensions (see e.g. the epSOS templates)

Medicines data is represented in CDA using the class manufacturedMaterial

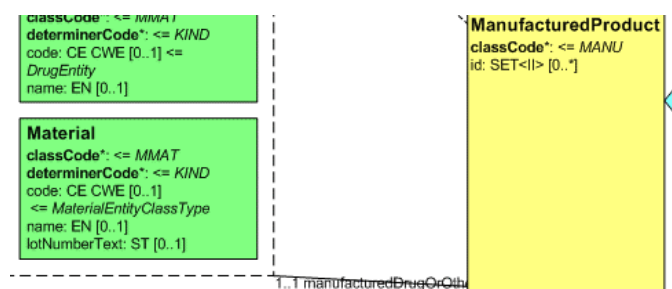
This class can be used for representing any kind of material/product at all the levels (ingredients, packaged products, class of products).

For the purpose of the proposed models only two attributes are interesting

- manufacturedMaterial.code
- manufacturedMaterial.name

Neither of these is repeatable.

¹⁵ Cfr. § 1.4 CDA Extensibility. HL7 CDA R2 Standard



Two possible implementation options can therefore be considered for representing IDMP data in CDA extending or not-extending the CDA model. This choice will depend on the type of IDMP information that should be exchanged.

Without Extensions

In case no extensions to the CDA model are used:

1. the IDMP concepts cannot be mapped
2. no IDMP attributes can be provided
3. IDMP IDs shall be represented as alternative codes

Hereafter an example on how multiple IDs could be passed using the <translation> element.

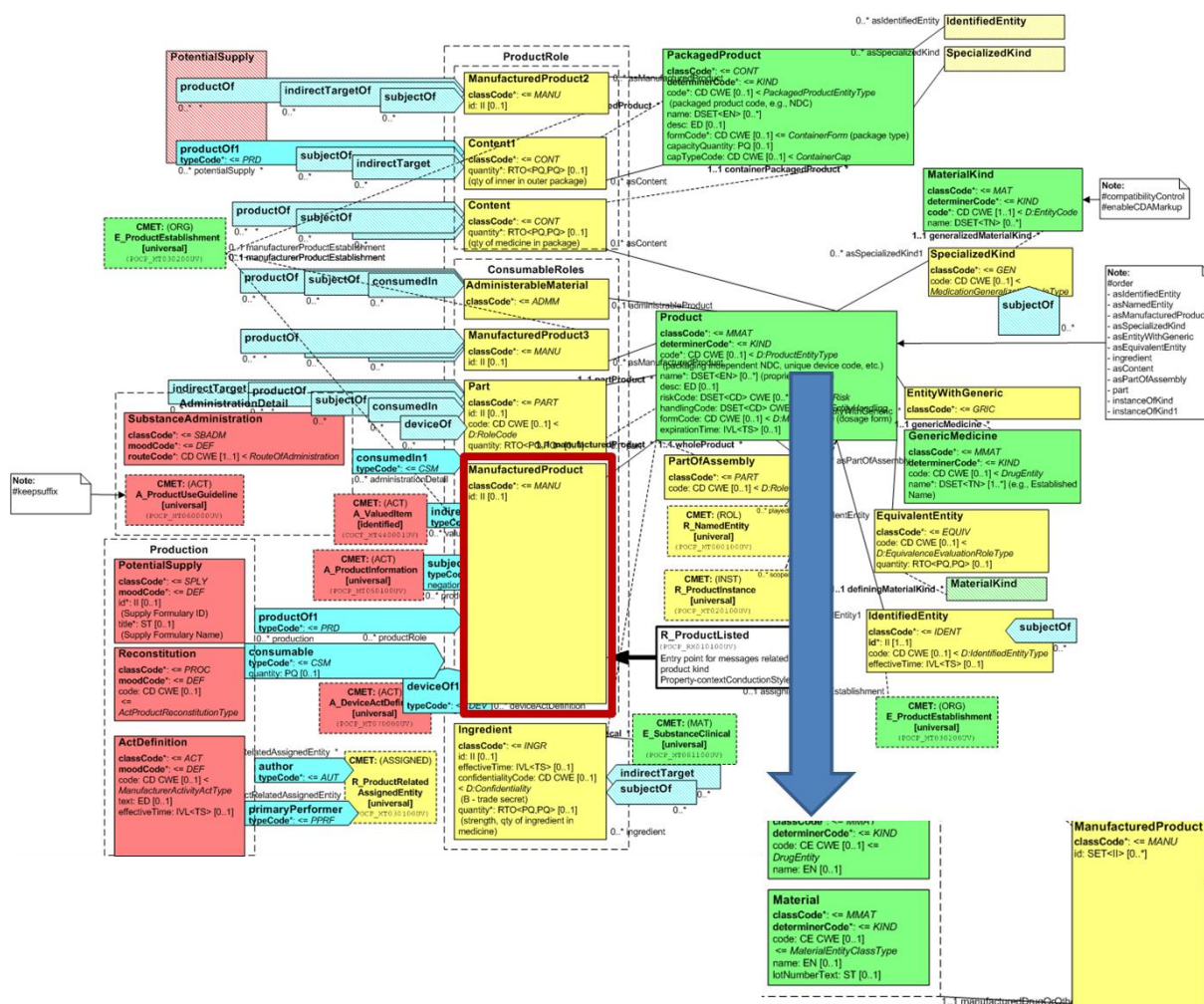
See CDA examples in § 7.1.1

With Extensions

The extension of the CDA model is the solution that was adopted in epSOS to exchange additional medicine attributes (e.g. form, ingredients, and ATC code). This was foreseen by the CDA standard.

To extend the CDA model means to enhance the base CDA model with additional RIM derived classes and relationships. This can be done only without altering the meaning or overlapping the meaning of the existing CDA classes.

The best option for supporting the proposed solution would be that of using as extension to the Common Product Model, merging the ManufactureMaterial class with the Product class.



The actual CMET proposed is the R_ProductList being that used for the Structure Product labelling.

In this case:

1. the IDMP concepts can be (substantially) mapped in the implemented model
2. IDMP attributes can be provided
3. is not requested to describe the IDMP IDs using alternative codes

See the CDA example in § 7.1.1

For more detail about this implementation and known issues refer to the CMP section below and to the Annex I – Example of implementation of the CEF eHDSI Data Element.

HL7 FHIR

HL7 FHIR is the emerging standard of HL7, it is focused on implementation needs and it is a loosely model based. Resources are the information building blocks used by this standard. A resource can refer or use other resources.

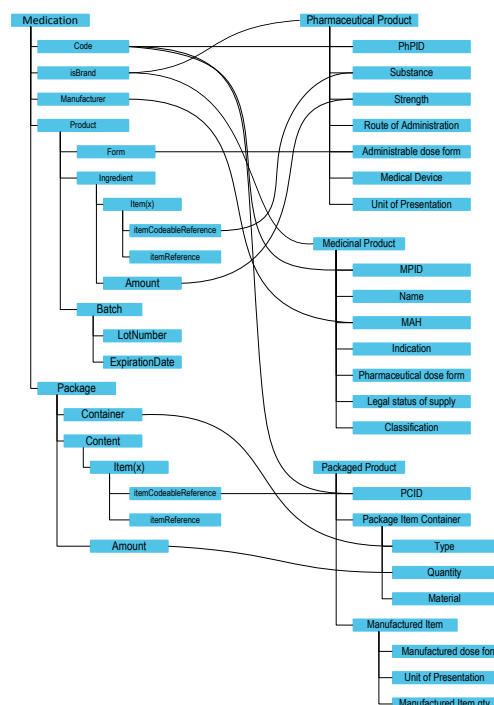
FHIR defines an extension mechanism for supporting information needs that are not covered by the standard resources.

The resource “primarily used for the identification and definition of a medication” is the *medication*. It provides basic information about a Product like a code for identifying the medication (as for the CDA it can be used for any level of product: packaged product, medicinal product etc.); the ingredients and the package content.

Name	Flags	Card.	Type	Description & Constraints
Medication			DomainResource	Definition of a Medication
code	Σ	0..1	CodeableConcept	Codes that identify this medication SNOMED CT Medication Codes (Example)
isBrand	Σ	0..1	boolean	True if a brand
manufacturer	Σ	0..1	Reference(Organization)	Manufacturer of the item
product		0..1	BackboneElement	Administrable medication details
form		0..1	CodeableConcept	powder tablets carton + SNOMED CT Form Codes (Example)
ingredient		0..*	BackboneElement	Active or inactive ingredient
item[x]		1..1		The product contained
itemCodeableConcept			CodeableConcept	
itemReference			Reference(Substance Medication)	
amount		0..1	Ratio	Quantity of ingredient present
batch		0..*	BackboneElement	
lotNumber		0..1	string	
expirationDate		0..1	dateTime	
package		0..1	BackboneElement	Details about packaged medications
container		0..1	CodeableConcept	E.g. box, vial, blister-pack SNOMED CT Form Codes (Example)
content		0..*	BackboneElement	What is in the package
item[x]		1..1		The item in the package
itemCodeableConcept			CodeableConcept	
itemReference			Reference(Medication)	
amount		0..1	SimpleQuantity	Quantity present in the package

Figure 8 - Structure of the HL7 FHIR® Medication Resource (STU 3 V 1.7.0)

Evaluating the current FHIR resource, a draft mapping reveals a gap with IDMP:



- Medication.code can correspond to the code of a Pharmaceutical Product (PhPID), of a Medicinal Product (MPID) or of a Packaged Product (PCID)

- Medication.isBrand indicates whether the code above is a brand product or a generic formulation (which roughly corresponds to MPID and PhPID respectively, but leaves some doubts in terms of Non-branded products).
- Medication.Manufacturer can correspond to Marketing Authorisation Holder, which is the equivalent (and arguably more relevant) context.
- Medication.Product.Form corresponds to Pharmaceutical Dose Form (it may be the Administrable and/or Manufactured Dose Form)
- Medication.Product.Ingredient.Item(s).itemCodeableReference corresponds to the substance in the Pharmaceutical Product
- Medication.Product.Ingredient.amount corresponds to strength
- Medication.package.container can be associated to Packaged Product Item Container type
- Medication.Package.content.item(x).itemCodeableReference could correspond to the ID of the contained item. It could be a MP, a PHP a manufactured item etc
- Medication.Package.Amount corresponds to the Quantity of items in the container. (e.g. it might be the number of pills in a bottle, in a blister or in a box; or the number of blisters in a box)

Gap analysis

- Code can refer to PhPID, MPID, PCID or any other (also non IDMP) level.
- isBrand is a qualifier of the product identified, and does not clarify whether the identifier is defined as described in ISO IDMP, or any other level of "brand product", according to the analysis in D1.1 and D2.2.
- The attributes are structured in a way that is not necessarily that of IDMP, even if the concepts are normally the same.
- The resource doesn't map the IDMP concepts, and local extensions could result in redundant or unused attributes, which would be confusing.

It would be useful if this or other resources, or FHIR profile, including IDMP-based extensions could be defined to better support the IDMP model.

Several approaches can be considered:

1. Adopt IDMP in the core resources: Given the global scope of IDMP and its adoption by FDA, EMA, it can be easily argued that IDMP compliance should be in the core FHIR resources.
2. Define additional resources for IDMP compliance: additional resources can be developed to complement this medication resource.
3. Use implementation guidance: Some implementation guidance can be done with the current resources in mind.

	Requires HL7 effort	Guidance is normative	Guidance is global	Advantages	Disadvantages
Option 1	Y	Y	N	Simple adoption Clear guidance	Requires HL7 PSS
Option 2	Y	Y	Y		Requires HL7 PSS More Complex for implementers
Option 3	N	N	N		Complex for implementers

Option 1:

The Medication resource is structured in a form that could approach IDMP with some changes:

The IDMP product levels are **Pharmaceutical Product**, **Medicinal Product** and **Packaged Product**. (Given the way that Medicinal Product and Packaged Product are defined, it is normal that these two levels may overlap in implementations.)

So, instead of the Medication Resource with a code that can mean any attribute (which can make sense in clinical documents), the definitional resource of a medication should transmit clearly the IDMP attributes. But does not need to transmit them all, and rather preserve the ability to use either level.

Option 2:

Another resource could be defined (or reused) for IDMP- compatible definition of Medication.

Option 3:

For providing guidance (which is the current option if no effort is done by HL7)

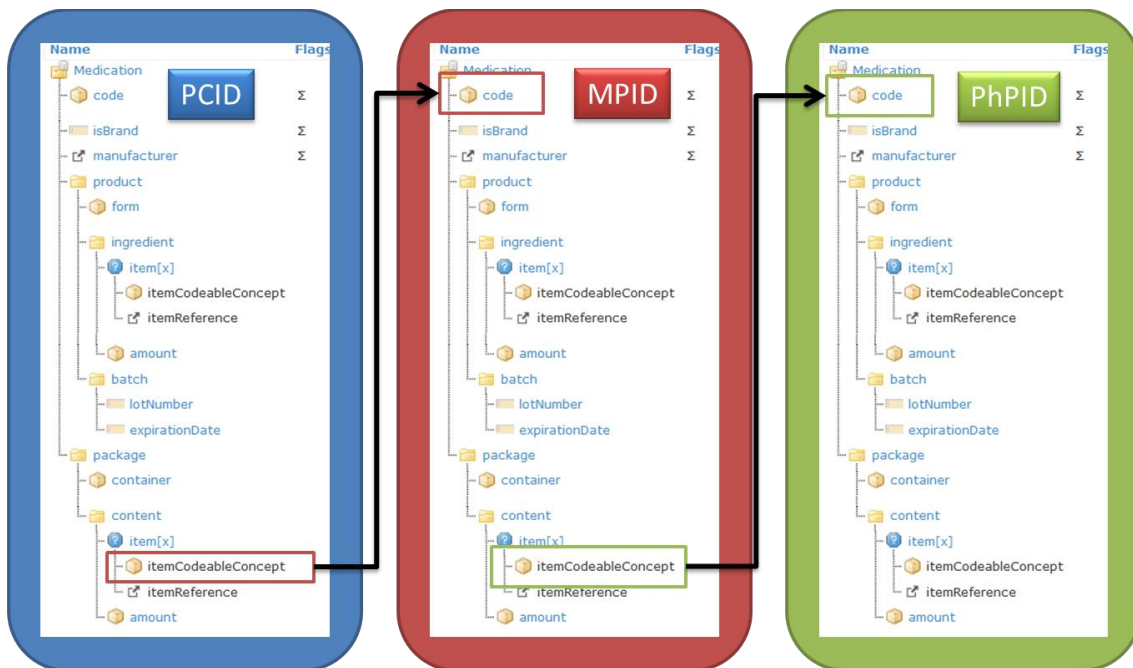
In absence of an IDMP-compliant resource, there are several implementation approaches that can be followed. In particular, for the representation of the IDMP identifiers, both described approaches could be feasible:

- alternative codes could be used for the medication.code element

```
<Medication xmlns="http://hl7.org/fhir">
  <!-- omissis -->
  <code>
    <!-- 0..1 CodeableConcept Codes that identify this medication -->
    <coding>
      <system value="local_codeSystem_URI"/>
      <code value="local_ID"/>
    </coding>
    <coding>
      <system value="MP_URI"/>
      <code value="MPID"/>
    </coding>
  </code>
```

```
<!-- omissis -->
</Medication>
```

- Or to take advantage of the two level structure of this resource to convey the IDMP layers (with some caveats)



Such an approach can use some of the relevant attributes of the medication resource across all the IDMP levels; several of the attributes may not be relevant for that level, for example "package" is not relevant for PhPID level. This is therefore not a very efficient solution.

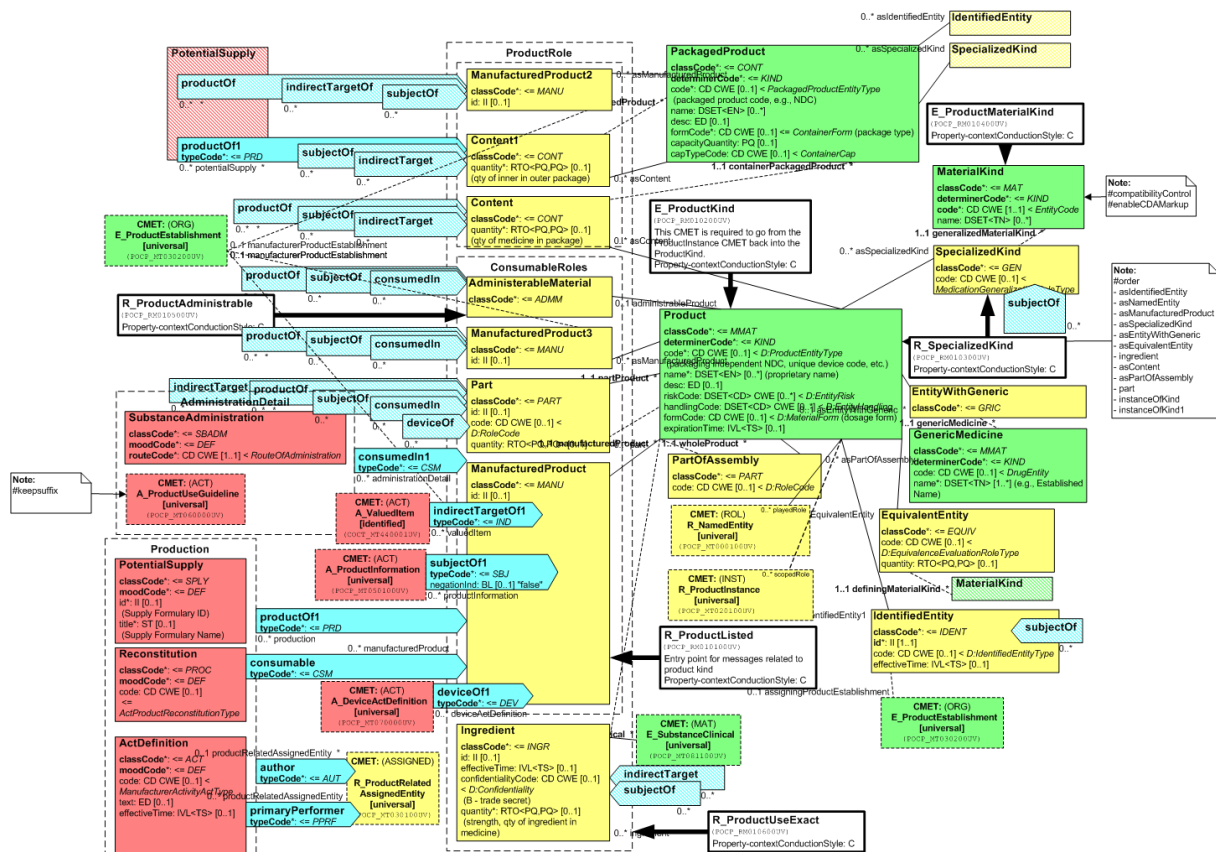
In brief:

- FHIR use resources as information building blocks, resources are expected to be profiled for their actual use
- Unlike V3 messaging, FHIR resources are more concrete, focusing on the majority of concepts. This can reduce some flexibility when compared with the semantic accuracy of V3, for example.
- Several options can be used to express IDMP identifiers in FHIR
 - Add codes and attributes to the medication resource
 - Adopt a new resource that corresponds to IDMP and map it to Medication
 - Use resource and linked resources to simulate the IDMP levels
- It is suggested that FHIR revise the current Medication resource to better fit with the IDMP structure / approach
- It is suggested that standard profiles or resources for better supporting the IDMP model be developed.

As a general conclusion it is recommended that openMedicine will socialize and formalize those findings with HL7 International to promote a better harmonization between FHIR and IDMP.

Common Product Model (and SPL)

The Common Product Model (CPM) is a model designed for providing a common representation of products into the HL7 V3 product family across different domains (Pharmacy, Patient Safety, Product Registration etc). The CPM also includes a set of derived CMETs that are currently used for example for Individual Case Safety Report (ICSR) and Structured Product Labeling (SPL).



For the time being CPM CMETs are not used in the pharmacy HL7 V3 messages (prescription, dispensation) for which domain specific CMETs are on the contrary adopted (mainly based on the R_Medication CMETs).

The HL7 V3 CPM is the elective standard for the implementation of IDMP, a reference model mapping is being defined in the IDMP Implementation guides¹⁶ for regulatory and pharmacovigilance activities.

Hereafter some examples on how some MP, PC and PhP information is represented in CPM according to the current version of the IDMP implementation guide

```
<section><subject> <!-- CPM -->
  <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product -->

    <!-- omissis -->
  </asSpecializedKind>
```

¹⁶ DTS20443 Health informatics — Identification of Medicinal Products — Implementation Guide for EN ISO 11615 Data Elements, Structures and Message Specifications for Unique Identification and Exchange of Regulated Medicinal Product Information.

DTS20451 - Health informatics – Identification of Medicinal Products – Implementation Guide for EN ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

```

    <generalizedMaterialKind> <!-- Pharmaceutical Product-->
      <code code="PhPID" codeSystem="PhPID Code System OID" .../>
    </generalizedMaterialKind>
  </asSpecializedKind>
  <ingredient classCode="ACTI"><!-- Ingredient -->
    <quantity><!-- Strength -->
      <!-- omissis -->
    </quantity>
    <ingredientSubstance><!-- Substance -->
      <code code="Substance Code" codeSystem="Code System (OID)"/>
      <name><!-- Substance Name --></name>
    </ingredientSubstance>
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  </ingredient>
  <!-- omissis -->
</manufacturedProduct>
</section></subject>

<section><subject> <!-- CPM -->
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    <manufacturedProduct><!-- Medicinal Product -->
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      <name><!-- Medicinal Product Name --></name>
    <asSpecializedKind>
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        <!-- omissis -->
      </generalisedMaterialKind>
    </asSpecialisedKind>
    <!-- omissis -->
    <asContent><!-- Packaged Medicinal Product -->
      <!-- omissis -->
    </asContent>
    <!-- omissis -->
  </manufacturedProduct>
</section></subject>

```

As also evident from the example above the mapping between IDMP and the CPM as defined by that implementation guide is not always straightforward: e.g. ingredients are not linked to the class used for the PhP but to that used for the MP. Moreover depending on the use the same CPM class is used for representing different IDMP data e.g. the same class is used for MP and for manufactured items. Additionally, is not clear how the different PhPIDs should be represented in that model as translation of the generalizedMaterialKind main code or as separate generalizedMaterialKind classes.

To resume:

- the CPM is the normative way to implement the IDMP for regulatory and pharmacovigilance activities

- The IDMP implementation guides, still under development, provide the reference mapping between IDMP and CPM; some shortages in this mapping have been identified.
- It might be a useful future revision of the CPM, and probably in the IDMP implementation guide, for providing a more straightforward mapping with the IDMP structure

Conclusions

- Depending on the standard, different options could be adopted
- Standards profiles/templates/implementation guides are needed to specify which options have to be actually used in a specific setting and how to use them.
- It is suggested that a gap analysis be performed in the scope of aligning IDMP in HL7, and eventually to update the resources or provide a guidance on how to map IDMP to standard resources
- It is suggested that IHE Pharmacy considers these findings for their work on formularies.
- It would be useful if ISO considers validating the different aspects of these solutions for using IDMP data throughout the clinical processes.

7.1.4 Management of the transitional phase

The realization of all the conditions that will allow the IDMP product data to become available and usable by all the actors is – as known - a long term target; intermediate solutions should therefore be considered to support the transitional phase.

In this section an overview for the management of the cross-borders exchange of prescriptions in the transitional phase is provided; considering the current epSOS specifications as baseline. The type of information to be considered and the solution to be realized may change dependent on the use case and the setting.

The best solution for approaching the transitional phase for the eHDSI prescription from the information viewpoint is to consider (as possible) from the start the target model, refining then the vocabulary binding and the elements' optionality during the different stages.

Hereafter a short description of the different stages is provided:

Stage	Description	Dependency
Baseline architecture	Current epSOS/EXPAND specifications. Known issues and characteristics of this implementation have been described in D1.1	No
Stage 1 Enhanced model	The template will be enhanced adopting the CPM and better clarifying the different IDMP level in the template representation.	Established team for the development of the template Approval process for the new template

Stage	Description	Dependency
Stage 2 Shared Vocabularies (Referential)	<p>The implementation will adopt the vocabularies defined by the IDMP implementation Guides. This phase could be split in two a first phase in which the vocabularies used for the ART 57 DB are adopted; a second in which globally used vocabularies are implemented.</p> <p>The implementation of this phase will give a sensitive improvement for most of the issues identified in epSOS.</p>	<p>Step 1 - Availability of terminology services for the distribution of value sets to be used</p> <p>Step 2 – coded information associated to products available for the countries of affiliation and treatment.</p>
Stage 3 IDMP IDs	IDMP IDs are actually implemented and available for practical use. This phase can be staged depending on the maturity of the IDMP implementation process.	ISO IDMP implemented by EMA Regulatory and Clinical Drug Db integrated

7.2 Technical – Application Layer

The implementation of IDMP-aware clinical and regulatory processes requires the deployment of several services designed to assure the assignment and the sharing of the IDMP product data through the different domains. The main actors and the type of “conversations” needed are summarized in the following figure¹⁷.

For each type of conversation it has been summarized if standard services are available or are going to be defined (green); if guidance or standard updates are needed (yellow); or if solutions are currently missing (red).

¹⁷ A conversation diagram provides an overview of which partners co-operate on which tasks.

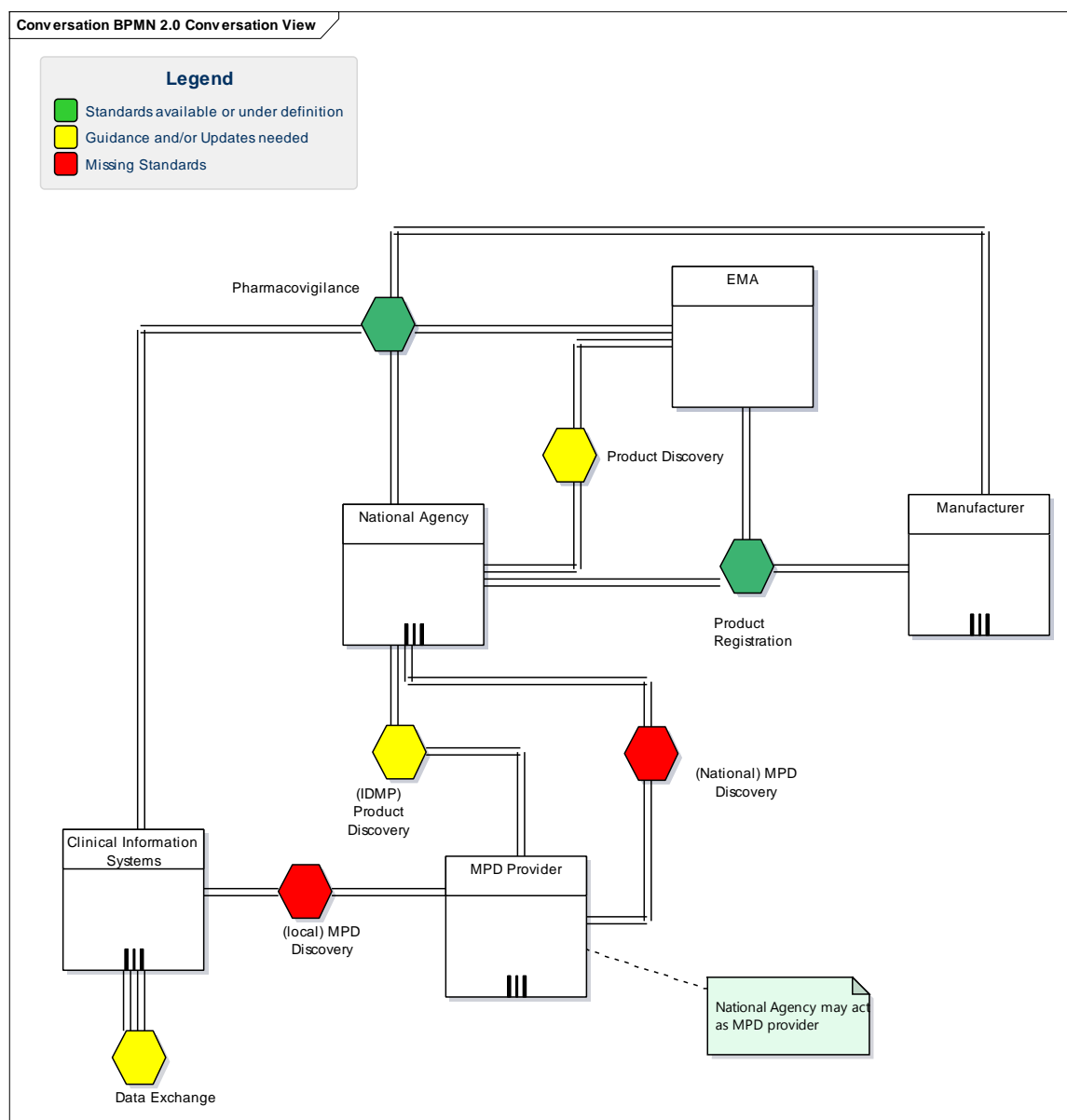


Figure 9 - Regulatory and clinical systems conversations

In synthesis, services have to be provided to allow manufacturers to register their products (including also the investigational studies), independently on the fact the process will be centralized or decentralized; also allowing regulators to be kept mutually updated (*Product registration*; *IDMP Product Discovery*).

IDMP product data shall be timely accessible to the MPD providers (*Product and MPD discovery*) in order that updated product data (including also IDMP data) used in that jurisdiction can be available for usage to the Clinical Information Systems (*MPD Discovery*). The Clinical Information Systems use the product data information in their exchanges for supporting specific use cases (e.g. prescription/dispensation; care plan; summary of an episode of care). (*Data Exchange*). When needed the IDMP product data can be used by the clinical information system to report back adverse events (*Pharmacovigilance*).

In the following table further details about these conversations are provided.

Conversation	Actors	Short Description	Notes
Product Registration	EMA; Manufacturers; National Agencies	Manufacturers register products using centralized or decentralized procedures. This also includes the communication of registered product between EMA and Agencies.	IDMP implementation guides are going to be defined based on HL7 CPM and HL7 SPL. Regional or national specification will be defined based on them.
Pharmacovigilance	EMA; National Agencies; Manufacturers; Clinical Information Systems	Regulated reports are issued to agencies. This also includes communications among agencies worldwide.	IDMP implementation guides are going to be defined based on HL7 CPM and HL7 ICRS messaging.
Product Discovery	EMA; National Agencies	EMA provides query services for products' data.	Services to be defined, likely based on HL7 CPM and SPL. A project statement to cover this need has been prepared and discussed in HL7. See attached PSS Appendix II
(IDMP) Product Discovery	National Agencies, MPD Providers	Agencies provide query services for products' data.	Services to be defined, likely based on HL7 CPM and SPL. HL7 FHIR to be considered
(local) MPD Discovery	National Agencies, MPD Providers	Agencies provide MPD providers with use case specific and/or additional product attributes defined in that jurisdiction (e.g. local identifiers).	No standard services available. Might be based on HL7 CPM, hopefully on HL7 FHIR.
(National) MPD Discovery	MPD Providers, Clinical Information Systems	MPD providers make available to Clinical Information Systems IDMP product data, enriched with use case and /or additional attributes defined in that jurisdiction.	No standard services available. Might be based on HL7 CPM, or other standards depending on the setting. Hopefully on HL7 FHIR.

Conversation	Actors	Short Description	Notes
Data Exchange	Clinical Systems Information	Clinical Systems exchange product data for supporting clinical processes.	<p>The content exchanged should be able to correctly support IDMP and additional product attributes and identifiers.</p> <p>See § 7.1.3 Support of existing Standards for more details.</p>

8 Governance of terminologies, value sets and mappings

As described in this document, the resolution of cross-border product identification implies semantic interoperability, which requires consistent glossary (concept model) and master data.

- IDMP provides a reference concept model which can be understood by the parties exchanging information. Chapter 7 contains some gap analysis and steps forward in propagating this reference concept to the technical standards.
- There are several value sets they may differ according to the products, the IT systems, the regions, etc. It is important to manage reference data.

Throughout openMedicine, several challenges have been detected. The operationalization of a solution - for the cross-border identification of medicinal products - requires the governance of data. Hereafter some of these challenges have been summarized:

Glossary management:

- "Product ID" in a prescription can refer to either a Pharmaceutical Product, or Medicinal Product. It is important to know how they relate to each other.
- The notion of "product" can change across countries. For example, the national ID can correspond to a manufactured product in one country, or to a cluster of products in another country.
- "Indication" in a product SmPC has a meaning (possible indications for which the product is authorised) that differs from the same term when used in a prescription (the indication for which the patient can have the medication).

More than a simple repository of concepts and definitions, proper Data Governance usually brings essential aspects such as:

- Synonyms, acronyms, multi-language
- Processes for defining terms (proposing, accepting, validating terms)

Master Data Management

- Manufacturer names can change after mergers and acquisitions. This can imply the need to update the products' attributes.

Master Data Governance should support the changes of master data, and its propagation to where such master data is used.

Reference Data Management

Reference Data is a part of Master Data. For example:

- "Indication" can be encoded using SNOMED CT in one country, or MEDDRA or ICD-10 in other countries.
- Dose forms can be encoded using the EDQM terms or another value set (e.g. SNOMED CT).

These aspects have a strong impact not only in the solution design, but also in the operation of any IDMP adoption.

The notion of Governance helps not only address the challenges above, but also to ensure regular operations, by establishing processes, quality controls (e.g. data quality), etc.

This section provides a brief introduction to the challenges in data governance, and some recommendations for practical implementation of the openMedicine dependencies.

8.1 Central agencies - Data governance

Regulators (EMA or National) have to maintain a consistent data repository of product information, and also support the distribution of such data upstream and downstream.

These are some of the scenarios encountered by regulators:

- For each of the product attributes, they should establish the value set or terminologies to be used, if they differ from the central terminology
 - For example, "Indication" uses SNOMED CT and ICD-9, "Dose Form" uses EDQM set.
- For each of the product attributes, monitoring the data quality in several dimensions, like:
 - Consistency (e.g. "Are all the Indication fields in all products according to ICD-10?" Is the data for the Organizations reflected in our Database? Do our products have the same IDs in all the databases?)
 - Uniqueness (e.g. "Do we have duplicate Medicinal Products, having two different IDs when the only difference is a non-identifying attribute)
 - Timeliness ("Upon the adoption of ICD-10 2017 edition, did we have all the necessary updates so that none of our products uses deprecated codes"?)
 - Validity ("Are all our product names according to the technical constraints - length, cardinality, etc. - defined in our databases?"
 - Accuracy ("Are our product document dates accurate, e.g. without data entry errors?"
- Managing master data, for example upon a merger of two companies, ensuring that the characteristics of the affected products are correspondingly managed.
- Some terminologies and value sets such as SNOMED CT, ICD, EDQM, are mastered elsewhere - this means that the system must handle the import, adoption and distribution of terminologies and value sets.

- Regulators must distribute the product data, and maybe also the complete master data, including possible code systems, etc. so that the downstream actors (e.g. national regulators) can also govern their data. An example can be the list of PhPIDs, or list of manufacturers (independent of the product details).
- Master data and reference data management can be a complicated challenge: not only are the codes versioned at the source (different editions of ICD-10 and different editions of SNOMED CT), but also they have asynchronous release cycles.
- Model and terminology mappings must be managed and versioned: they may be generated elsewhere (e.g. there are default mappings between ICD-9 and ICD-10, or SNOMED CT and ICD-10). These mappings must be approved and deployed throughout the databases, in a way that does not break interoperability.

8.2 National regulators - Data governance

National regulators must also have governance processes:

- National regulators must broker the data mastered from the Central regulator, receiving updates, propagating them when convenient, etc.
- National regulators add attributes to the products such as price, reimbursement, etc. These attributes are not expected to be harmonised across Europe, but must be maintained locally.
- National regulators may define local product codes which must be mapped to the IDMP product codes. This mapping must be maintained consistently.
- National regulators may use reference data from the central regulator, and also directly from other sources. For example, they can use substance codes directly from G-SRS (which is the software that makes the GINAS codes available), and dosage forms from EDQM. These codes must be mapped to the official attributes and code systems.

National systems may need to define how the different codes articulate: for example the billing systems may include national codes for products and procedures, and the national regulators must manage the mappings as part of their operational activities.

8.3 Clinical systems - Data governance

Clinical systems are expected to use several terminologies that need to be maintained. A manual maintenance is no longer practical for dozens of concepts, dozens of code systems, millions of codes.

For example in a prescription, a physician may indicate the diagnosis for a prescription using ICD-9 or locally defined codes. If the international prescription format supports only SNOMED CT or ICD-10, then the codes must be converted for the prescription to be understood internationally.

Model and terminology mappings may be imported and distributed throughout, for example, the hospital systems.

The model and terminology mappings of healthcare reference data is a common need for all clinical systems.

8.4 Data Governance - Recommendations

Given the impact of the data in the openMedicine operationalisation, it is important that EMA pursues the SPOR programme, which handles the key data governance aspects at their side.

Once the master data (product data, referentials, etc.) is managed at the EMA, the regulators and drug database providers are expected to adopt it, mapping it to the local data needs, enriching it, adding local concepts, mapping to local IDs, etc.

The needs from the clinical systems depends on the approach for the adoption of openMedicine: if the approach is done according to the section 6.4 – Cross-border (conversion to IDMP), the need for governance is stronger at the national regulators or contact points, and the clinical systems can continue their current operations. If the approach is closer to that described in 6.5 – Cross-border (IDMP IDs and attributes), the clinical systems are expected to have a stronger need for governance. However, providers (e.g. hospitals) are already increasingly adopting enterprise data governance approaches.

Besides those mentioned above other organizations might be directly or indirectly involved in such a process e.g. WHO Uppsala for the management of PhPID.

9 Other cases influenced by the operating Model

9.1 Falsified medication

The EU directive 2011/62/EU for falsified medications introduces the need for some control mechanisms. This Falsified Medicines Directive (FMD) is not related to identify the product type (as is the goal of openMedicine) but to identify, track and trace the physical products.

There are however interdependencies with the supply chain that should be considered, or at least it needs to be assured that the solution promoted by openMedicine will not negatively impact on that process.

The Falsified Medicines Directive requires tracking of the physical instances of a product. There are no physical instances of Pharmaceutical Products, and depending on the adoption, neither of the Medicinal Products.

The notion of "product" for the Falsified Medicines directive thus corresponds to the "Packaged Product" in IDMP. **The PCID is the pivoting point between IDMP and the FMD.**

9.1.1 Relation between openMedicine and Falsified Medicines Directive or unauthorised drugs

The product identifier adds some context to the product: for example, the same Pharmaceutical Product may be distributed as different PCIDs in different countries.

This allows a basic check of whether a product is authorized for a specific market. If this is not preserved, it is likely that difficulties will emerge in the supply chain. For example:

If for sake of interoperability, the PCID were replaced by the PhPID in the product barcodes, it would no longer be possible to check whether the product has the "correct" PCID, i.e. a PCID that is authorized for that country.

For this reason, the Package Identifiers (e.g. the GTIN code) must always be preserved in the identification of the physical products and not replaced by the PhPID.

Another consequence:

Any conversion or lookup of products must include the context: it is not sufficient to look up a PhPID from a PCID. It is also necessary to see if in the current country, the PCID and MPID is authorised for the market, or if the PhPID is marketed as another PCID (which could indicate problems with the origin of the medicinal product).

For example if a GTIN code is not known in country B but can be looked up through the database via the PhPID, this lookup should also clearly inform that the product is not to be dispensed with that GTIN code, but there may be other GTIN codes that are authorized.

Another legitimate question is whether the identifiers, being "encrypted" would provide a layer of security to the introduction of products in the market. It is straightforward to infer the following:

If the generation of identifiers is done by a "protected" algorithm so that only regulatory entities can create such identifiers, this prevents non-authorised entities to create such an ID without the proper formalities. **This "protected" algorithm is indeed a positive step in security before the production phase.**

However, as soon as the product is in production, the identifier is public and can be copied. **So this is not useful for protection against falsified medicines.**

10 Inputs to the roadmap

This section summarizes for different types of actors (e.g. prescribers, dispensers) preconditions and functional requirements that should be taken into account to support the (cross-border) processes with the proposed model, based on the analysis done in sections 6 and 8.

10.1 Preconditions

- [1] The products' registration process is implemented in such a way that for any registered product the associated IDMP identifiers and attributes are defined and available.
- [2] There are services implemented that allow Medicinal Product Dictionaries *providers* to obtain timely information by the *regulatory agencies* about IDMP product data and - potentially - additional attributes specific for that use case or jurisdiction (e.g. local products identifiers, cluster of products). This information is used to realize the Medicinal Product Dictionaries used in that jurisdiction.
- [3] There are services implemented that allow the actors involved in the clinical process to access product information (including IDMP data) from the Medicinal Product Dictionaries used in that jurisdiction.

Requirements for regulatory agencies, Medicinal Product Dictionaries *providers* and *other actors* for realizing such preconditions are described in section 11 "Feasibility analysis"

10.2 ePrescription/eDispensation

In this analysis it is assumed that no special operations have to be accomplished by the prescribers in the case of cross border care: i.e. the way medicines are specified doesn't change from the prescriber perspective if done for being dispensed in the same or a different jurisdiction.

It is also assumed that it is a local choice to decide if (a) the cross-border eP is directly generated by the ePrescription system; or (b) it is generated converting "centrally" the local eP into the cross-border format.

In both cases it is strongly suggested that a common underlying model for ePrescription is used and that the local implementation is able to support the IDMP model for the product identification.

- [1] The ePrescription system that "generates" the ePrescription has to be able to integrate the product specification data of that jurisdiction with the applicable IDMP identifiers and identification attributes needed for allowing a safe selection/identification of the product by the dispenser. To obtain this data, the ePrescription system relies on the information provided by a local implementation of the Medicinal Product Dictionary used in that jurisdiction.

Note this rule applies also for non-registered products (e.g. magistral formula) in this case the prescription system should be able to describe the formula in a structured and coded way as described in this deliverable, using the coding systems defined by the IDMP IG (e.g. GINAS for substances). For official formula this decomposition might be obtained by the local implementation of the MPD.

Some examples: (a) the prescription is done per substance and strength and a PhPID Level 2 can be associated with those attributes, this PhPID should be added to the eP, together with substance and strength also expressed with the coding defined by the IDMP IG (e.g. GINAS for substances) ; (b) the prescription is done using a SNOMED CT AMP (Actual Medicinal Product) code, the associated MP ID should be provided as well; (c) the prescription is done using a SNOMED CT VMPP¹⁸ (Virtual Medicinal Product Pack) code (or any other cluster ID), the prescription should include all the identification attributes (e.g. substance, presentation form, number of units per pack) as defined by the IDMP implementation guide and optionally the associated IDs (e.g. PhPID level 4).

Note: this capability implies that the specifications defined for that jurisdiction for the eP have to enable the communication of such a kind of information: that is, the implemented eP has to be aware of the IDMP model.

Note: to support cross-border prescription of formulas common codes for representing the preparation procedures shall be defined / selected

- [2] If local ePrescription systems are not able to manage such a kind of information, or the specification defined in that jurisdiction for eP doesn't support the IDMP model; then a conversion service has to be provided. This service shall enable the conversion of the local ePrescription format into the cross-border one and the addition of the applicable IDMP identifiers and identification attributes needed for allowing a safe selection/identification of the product by the dispenser. This service relies on the information provided by a local implementation of the Medicinal Product Dictionary used in that jurisdiction. In case of magistral formulas the ePrescription system shall be able to provide structured and coded data in order to allow the conversion service to convert them into the Cross-border format.

- [3] The dispensation system shall be able to understand both the local and the cross-border eP formats.

- [4] The dispensation system (eD system) shall be able to select/identify the registered product to be dispensed basing both on the specification data defined in that jurisdiction and on the IDMP identifiers and identification attributes. To accomplish, as needed, the selection, the identification and the reverse identification of a registered product the dispensation system relies on information made available by the local implementation of the Medicinal Product Dictionary used in that jurisdiction. For example if a PhPID Level 2 is provided a look up in the local MPD shall be performed by the eD system to see what are the packaged products that are available in that country for dispensation, this look-up also provides all the attributes, used in that jurisdiction and associated to those products, that might be useful for completing the dispensation process.
In case of prescription of magistral or officinal products the eD system shall be able to display to the pharmacist the formula composition and the rules for preparation based on the coded information included in the eP.
Note: common codes for representing the preparation procedures for formula shall be defined / selected.

¹⁸ The concept classes AMP, VMPP (and AMPP) are UK specific concepts. They do not exist in the international release of SNOMED CT, this only goes to the VMP (Virtual Medicinal Product) level

Note: this capability implies that the specifications defined in that jurisdiction for the eD have to enable the communication of such a kind of information: that is, the implemented eD has to be aware of the IDMP model.

- [5] For registered products. The dispensation system that “generates” the eDispensation has to be able to integrate the packaged product identification data defined in that jurisdiction with the applicable IDMP PC identifiers and identification attributes. To obtain this data, the ePrescription system relies on the information provided by a local implementation of the Medicinal Product Dictionary used in that jurisdiction.
- [6] For registered products. In case the dispensation system (eD system) is not able to manage such a kind of information, or the specification defined in that jurisdiction for eD doesn’t support the IDMP model; then a conversion service has to be provided. This service shall enable the conversion of the local eDispensation format into the cross-border one and the addition of the applicable IDMP identifiers and identification attributes needed for allowing the identification of the dispensed product. This service relies on the information provided by a local implementation of the Medicinal Product Dictionary used in that jurisdiction.
- [7] For formulas. The dispensation system should be able to describe the formula in a structured and coded way as described in this deliverable, using the coding systems defined by the IDMP IG (e.g. GINAS for substance) or to refer to that provided in the eP.

10.3 Patient Summary

In this analysis it is assumed that it is a local choice to decide if (a) the cross-border PS is directly generated by the local PS creator; or (b) it is generated converting “centrally” the local PS into the cross-border format.

In both cases it is strongly suggested that a common underlying model for PS and eP/eD is used and that the local implementation is able to support the IDMP model for the product identification in both cases.

Note: this section focuses on the product identification Clinical information (e.g. posology) associated to the medications is therefore not covered in this section even though essential in a Patient Summary.

As known the mechanics adopted for generating a Patient Summary can strongly vary depending on the jurisdiction: PS as an outcome of a Clinical decision of a GP; PS as an automatic collection of data from one or more EHRs; mixed approaches etc. Therefore, the functional requirements to support this process can strongly change depending on the applied approach. The following requirements try to generalize as possible this multiplicity.

- [1] The system producing the local PS (hereafter called PS creator system) has to be able to integrate the medication data, defined in that jurisdiction, included in the PS (e.g. brand name, local identifier, class of products, substances) with the applicable IDMP identifiers and attributes needed for allowing a safe characterization of the product by the receiver. This may include substances and strengths; the applicable PhPID and PhP name, the pharmaceutical substance (ATC), the route of administration, and so on. To obtain this data, the PS creator system relies on the information provided by a local implementation of the Medicinal Product Dictionary used in that jurisdiction.

Note: this capability implies that the specifications defined in that jurisdiction for the PS have to enable the communication of such a kind of information: that is, the implemented PS has to be aware of the IDMP model.

Some Examples: (a) the medicine is identified per ATC code, a PhPID Level 1 should be added to the PS; (b) the medicine is identified a SNOMED CT VMP (Virtual Medicinal Product) code the PS should include all the identification attributes (e.g. substance, presentation form) as defined by the IDMP implementation guide and optionally the associated IDs (e.g. PhPID level 4).

- [8] A conversion service may be provided in a jurisdiction to enable the conversion of the local PS format into the cross-border one (IDMP aware), when needed; and the addition of the applicable IDMP identifiers and attributes needed for allowing a safe characterization of the product, if not already included. This service relies on the information provided by a local implementation of the Medicinal Product Dictionary used in that jurisdiction.
- [9] The receiving system shall be able to “understand” the cross border PS format, based on the IDMP model; and display, in a language understandable for the healthcare professional, all the relevant information included in the received PS and needed for a safe characterization of the product. To realize this the receiving system may rely on a local instance of the Medicinal Product Dictionary defined in that jurisdiction; or to take advantage of an external “translation” service that allows retrieval of the associated translated designation (term) for the codes used. For example to get the Dutch name for a specific PhP, or the Portuguese names for the substances. Depending on the implementation choice, and on the type of information handled, this operation can be done before the receiving system gets the PS (in this case translations can be added to the PS) or triggered by the receiving system before displaying the content; it can be based on information managed by regulatory product databases (e.g. for getting names from MP, PC or PhP IDs) or by terminology services (e.g. for substances, forms, route of administration).

10.4 Management of the transitional phase

As known, the realization of the above indicated pre-conditions is a long term target; thus a possible intermediate solution should also be considered to manage the transitional phase.

The best way to do it is to consider a staged approach as that described in § 7.1.4.

The first stage assumes that the implemented model is made aware of the IDMP structure, the hope is that local formats for PS and eP/eD also take this model in consideration for future specifications’ evolution. Independent of this involved systems have to provide functionalities for capturing the information as expected for the cross-border use (i.e. as structured and coded information).

The second stage considers that shared vocabularies are used. Also in this case it is recommended that local implementations will contemplate adoption of such vocabularies where applicable. In any case what is needed is that local instance of the Medicinal Product Dictionaries will support the common vocabularies for the managed registered products.

Since the IDMP IDs will not be available at this stage, exchanged data will include the identification attributes (substance, presentation form, package size etc) as required by the exchanged content.

The IDMP IDs will be progressively defined and made available for usage whilst at the same time in the clinical domain, by means of the MPD, the exchanged content might also be progressively enhanced with these IDs without in any way changing the global structure of the eP/eD or that of the PS.

11 Feasibility analysis

The openMedicine project aims at ensuring better identification of medicinal products throughout the clinical and regulatory domains.

As discussed, the precondition for getting this result is that ***all the actors involved share the same reference model for the description and identification of products*** independent of the use case realized; and that ***common vocabularies are used***. The reference (conceptual) model is the **ISO IDMP standard**, that in clinical practice has to be integrated with attributes specific for that use case and/or jurisdiction to support other non-regulatory business and clinical processes (e.g. prescription, dispensation, medication lists).

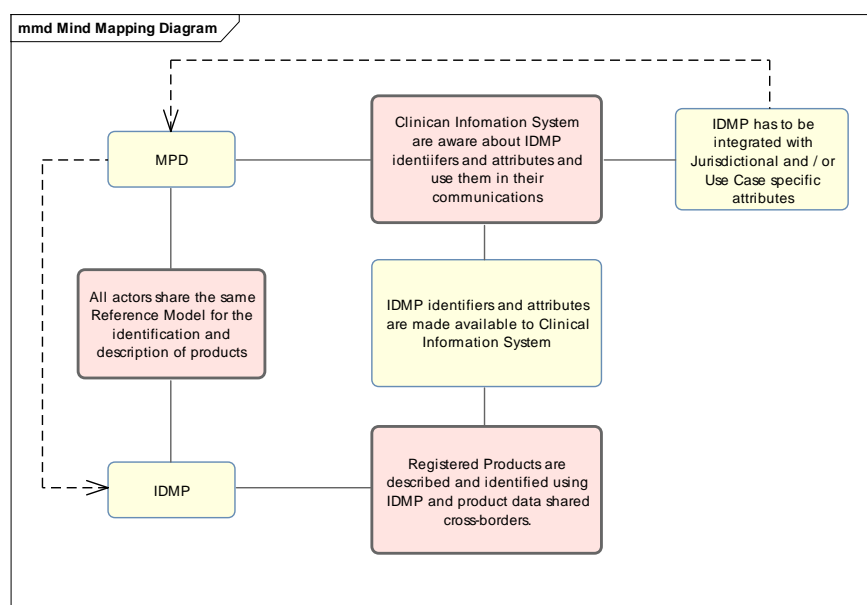


Figure 10 – Baseline requirements for the cross-domains identification of medicinal products

In order to assure the flow of the IDMP concepts through these different domains and processes the following high-level requirements have to be fulfilled:

1. An IDMP based product registration process has to be implemented and product data shared cross-borders.
2. IDMP based product data has to be integrated with attributes specific for that jurisdiction and/or use case and made available for usage to the Clinical Information Systems.
3. Information systems in their processes shall be able to communicate as needed the IDMP identifiers and attributes.

An overview of how the different actors should cooperate for achieving these results is provided in the conversation diagram of Figure 9 – Regulatory and clinical systems conversations.

High level requirements and conversations have therefore been developed in the following sub paragraphs pointing out existing technical gaps, the known issues and providing suggestions.

11.1 IDMP based registration process

In order to ensure that IDMP identifiers and attributes are correctly associated to products and available for usage across different domains, it is required that this information is associated to the product since the beginning, and that the registration process fulfils a set of requirements described below and summarized in the figure below¹⁹.

Legend: for each requirement mentioned is provided:

- (a) a description of the requirement;*
- (b) the current realization status (within square brackets)*
- (c) realization notes and comments (in italics)*
- (d) where applicable dependencies.*

A requirement can include sub-requirements. Each requirement can be read as a recommendation.

¹⁹ The preconditions for those requirements are policies, processes and roles for supporting the registration process at European Level. This part has not been analyzed since this section focus on technical gaps.

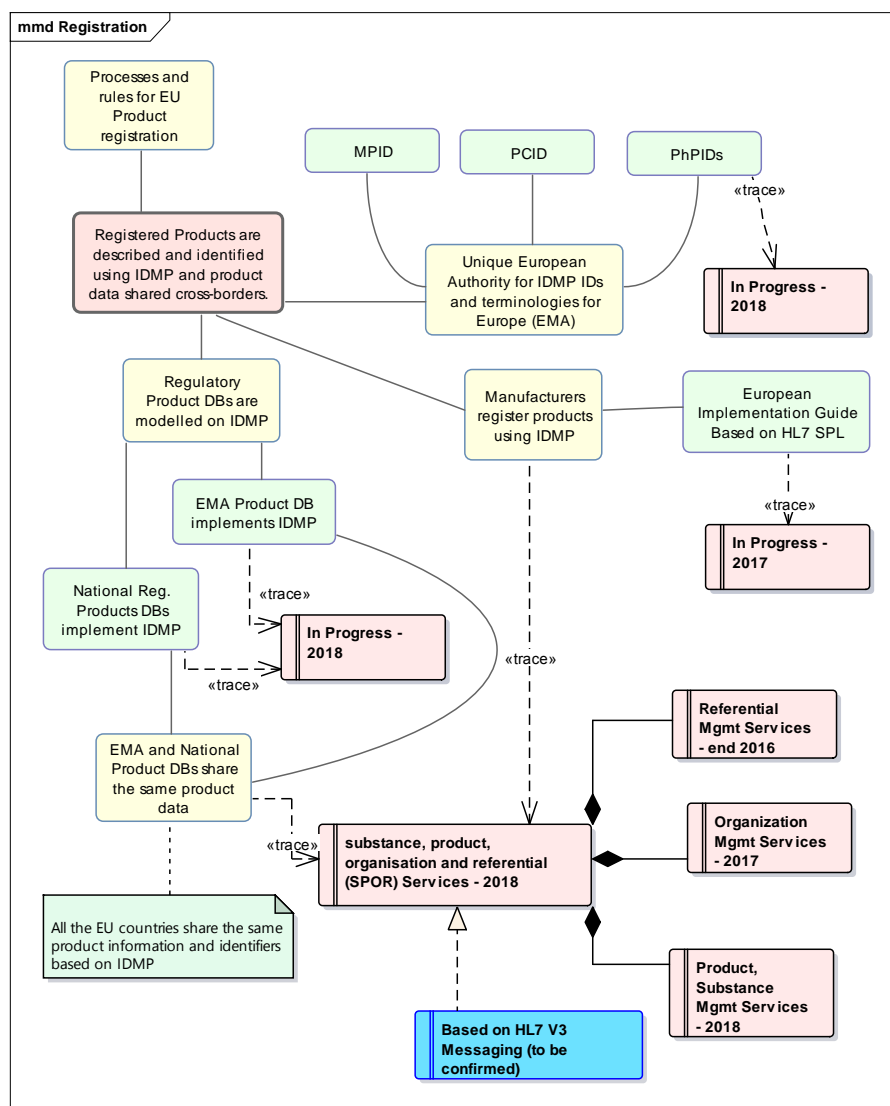


Figure 11 - Requirements for the implementation of an IDMP based registration process

- 1) Data models used for the Regulatory Databases have to be compliant with the IDMP reference model. *[In Progress]*
 - a) The European regulator (EMA) has to **adopt ISO IDMP** *[In Progress]*
 - i) The current EMA Art. 57 database substantially provide support for the IDMP model.
 - ii) There is an on-going project for the EMA implementation of IDMP. This staged process also includes the revision of the current database for better supporting IDMP implementation.
 - b) National Agencies have to adopt IDMP *[In Progress]*
 - i) National Regulatory Agencies developed national plans to conform to the European Requirements on IDMP.

DEPENDENCIES:

- implementation of the substance, product, organisation and referential (SPOR) services
- 2) **EMA** shall offer electronic services for supporting the IDMP-based centralized registration process *[In Progress]*

- a) *There is a European in progress project for the implementation of substance, product, organisation and referential (SPOR) data management services.*

DEPENDENCIES:

- ISO IDMP Implementation Guides;
- European IDMP Implementation Guides;
- SPOR services specification

- 3) **National Agencies** shall offer electronic services for supporting the IDMP-based decentralized registration process *[In Progress]*

- a) *National Regulatory Agencies developed national plans to implement substance, product, organisation and referential (SPOR) services*

- 4) Standard based services have to be offered by EMA and National Agencies in order to assure the communication of relevant data between central and decentralized organizations

- 5) **Manufacturers** shall be able to :

- a) submit new products according to the SPOR services specifications
- b) confirm converted data about existing products (done by EMA), and to enrich them with additional needed information.
- c) represent their products according to the IDMP structure.
 - i) *how this is done is an internal choice*
- d) use common IDMP vocabularies

DEPENDENCIES:

- access to common vocabularies
- technical specifications available

- 6) A European Authority responsible for the curation of contents and the distribution of the vocabularies required by for the implementation of the European IDMP implementation Guides is needed. **EMA is such authority.**

- a) *Substance identifiers are here considered as part of one of the vocabularies to be managed and shared.*
- b) *The requirements related to the management of vocabularies are described in section 8 – “Governance of terminologies, value sets and mappings”*

- 7) A European authority for the assignment and custodianship of the IDMP Identifiers (PhPID, MPID, and PCID) is needed. **EMA is such authority.** *[In Progress]*

- a) National regulators should not be entitled to assign local IDMP IDs.
 - i) *In principle, it doesn't mean that EMA shall physically generate all the IDs, but it is responsible for assuring that in case of decentralized generation of IDs they are (globally) unique and known to EMA*
- b) Procedure and tools for assuring the global uniqueness of the assigned IDs have to be established. *[In Progress]*
 - i) *EMA cooperates with other international organizations (e.g. FDA) for assuring this. The process is still on-going.*

DEPENDENCIES:

- IDMP Implementation Guides

11.2 Vocabularies' Management (referential)

A concrete implementation of the IDMP model requires that common vocabularies are used and shared across domains and jurisdictions.

To realize this a European Authority responsible for the curation and the distribution of vocabularies is needed: as described this role will be played by EMA, with the help of the IDMP Task Force.

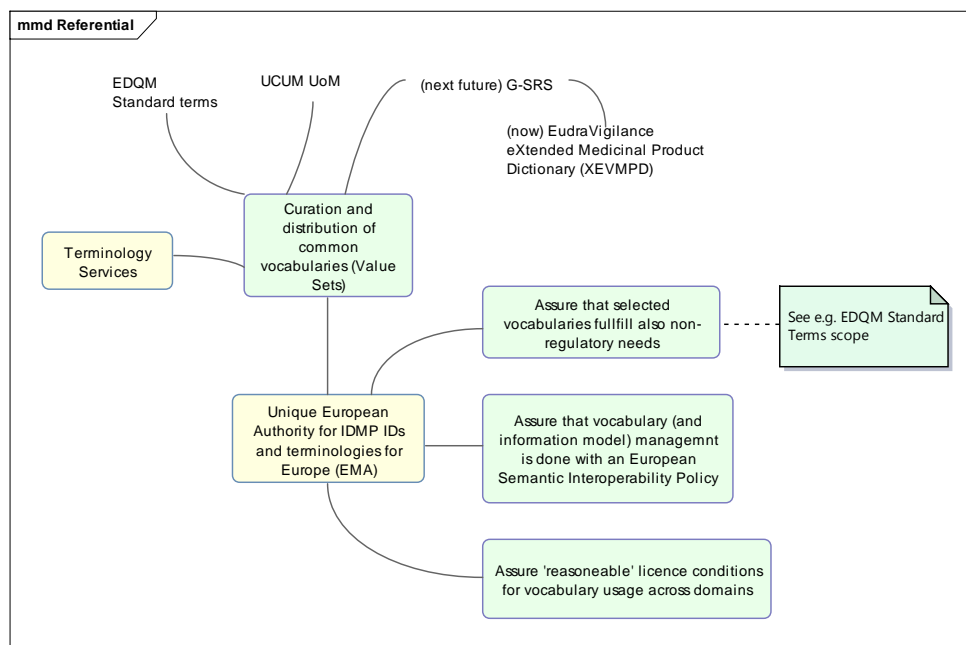


Figure 12 - Requirements for the implementation of common vocabularies

- 1) In order to better serve **the vocabulary curation and distribution**, beyond the regulatory domain, it is desirable that **Terminology Services** will be realized *[to be done]*
 - a) *Technical specifications for such services have to be defined.*
- 2) This authority, cooperating with the SDOs (owners of the terminologies selected), shall assure that usage conditions (e.g. licence) fulfil, where applicable, the requirements for the Identification of ICT Technical Specifications of the EU standardization regulation, annex II²⁰. This shall not be limited to the regulatory domain. It is recommended that an assessment of the usage conditions for the selected vocabularies is performed. *[to be done]*
 - a) *For example there are terminologies such as MedDRA that are free for use for Regulatory Agencies or for use within agency electronic (software) tools designed to allow a company to meet their regulatory (adverse reaction) reporting requirements.*
- 3) This authority, cooperating with the SDOs and engaging appropriate stakeholders, shall assure that those vocabularies also fulfil non-regulatory needs. It is recommended that an assessment of the fitness for purpose of the selected vocabularies beyond the regulatory domain is performed. *[to be done]*
 - a) *For example the EDQM Standard Terms “is intended for regulatory purposes, specifically for marketing authorisation applications, SmPCs, labelling etc. Any*

²⁰ EU Regulation No 1025/2012 of the European Parliament and of the Council of 25 October 2012, on European standardisation, Annex II: Requirements for the Identification of ICT Technical Specifications <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>

*extension of the scope would require consultation within the EDQM and its relevant groups of experts*²¹

- 4) This authority should cooperate with other European organizations and entities for the development of a European semantic interoperability policy and related operational management processes, so that the management of the adopted vocabularies and information models will be coherent with such a policies and processes. *[to be done]*

11.3 Clinical Processes

In the previous sections the requirements for allowing the association of the IDMP identifiers and attributes to the registered products have been summarized. In order to be used by Clinical Information Systems (e.g. prescription systems, dispensing systems, EHRs) within a specific setting, IDMP product data have to be integrated with attributes specific for that jurisdiction and/or use case and this set of data made available to those systems for usage.

Moreover the set of IDMP information that is relevant for a specific care process has to be appropriately communicated in the selected standard.

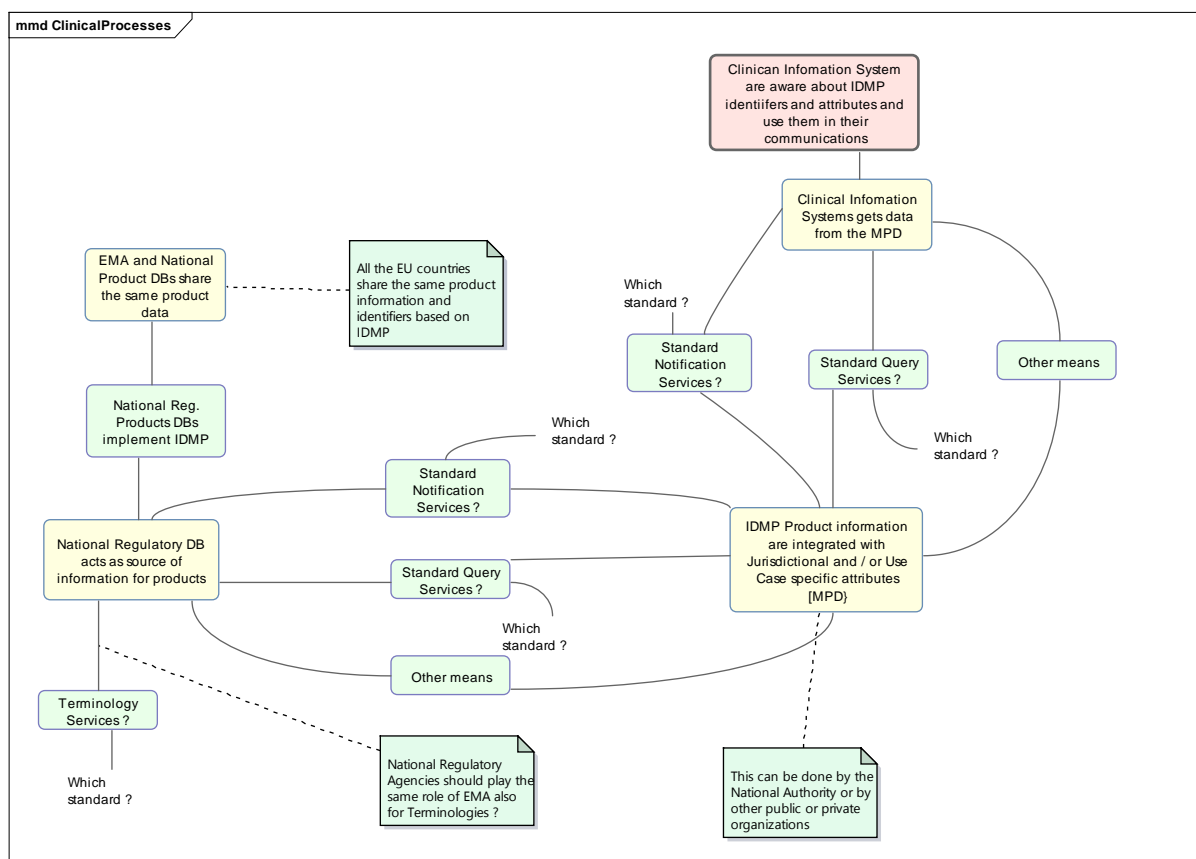


Figure 13 - Requirements for the support for clinical processes

Those requirements have as GENERAL DEPENDENCIES:

- IDMP-based registration process in place
- MPD standard and related Implementation guides available

²¹ Mail from Dr Christopher Jarvis Scientific Administrator - Standard Terms EDQM

11.3.1 MPD development and data distribution

1. Clinical systems have to be aware of the IDMP model and should be able to manage IDMP product identifiers and attributes according to the purpose of use of those systems. *[to be done]*
 - a. *For example a GP EHR-S could use local coding systems for prescription, but it should be able to retrieve from that code the related IDMP complaint data set when an adverse report has to be issued.*
2. Clinical systems have to be able to get product information from a local instance of a Medicinal Product Dictionary that integrates the IDMP data with data specific for that jurisdiction and/or use case. *[to be done]*
 - a. *For example product cluster or classification, local dictionaries, price, rules for prescription should be available for supporting the local prescription process. This information should be connected and made available in addition to the IDMP product data.*
3. The local Medicinal Product Dictionary implementation should be compliant with the ISO standard for Medicinal Product Dictionaries 19256 model. *[to be done]*
4. Depending on the jurisdiction, there are several possible approaches for the development of the local MPD and for the distribution of the included data: MPD could be provided as an open service by the local regulatory agency, or distributed as component by a private organization and embedded into third party products (e.g. GP EHR-S).
 - a. Independently on that MPD developers has to have timely access to the information included in the regulatory IDMP-based DB. Each regulatory agency should define standard based mechanism for allowing MPD developers to get the IDMP product data, aligned with the EMA database, from the Regulatory Agency databases used in that jurisdiction. *[to be done]*
 - b. In the case Regulatory Agency extends with local attributes the IDMP model for the usage in that jurisdiction: *[to be done]*
 - i. this extended product DB shall be complaint with the ISO MPD model. In this case it is assumed that the agency will act as authority also for the vocabularies used and it will be in charge of this management. Similar considerations done for the Vocabulary management for the European scenario can be applied to the local context.
 - ii. The regulatory agency should define standard based mechanisms for allowing MPD developers or other potential users to access this data
 - iii. SDOs should define profiles and models for their product lines (e.g. HL7 V3, FHIR, CDA, SPL) for supporting those services. *[to be done]*
 - c. In general, MPD developers should define and provide standard services for allowing Clinical Information Systems to access MPD data *[to be done]*
 - i. SDOs should define profiles and models for their product lines (e.g. HL7 V3, FHIR, CDA, SPL) for supporting those services. *[to be done]*

11.3.2 Clinical data exchange

The capability of all the involved actors of getting IDMP product data, enhanced with additional attributes specific for that jurisdiction and /or use case, as described so far is a necessary, but not sufficient, condition for implementing semantic interoperability. In fact, to achieve this, it is also required that the “formats” used for exchanging the content (e.g.

clinical documents, orders, resources, messages) are “aware” of those identifiers and attributes (IDMP, MPD).

1. Section 7 of this deliverable describes some of the known issues in implementing the proposed model. Based on these considerations it is recommended that **SDOs will works on developing, or updating, profiles, templates and implementation guides for guiding the implementation of the IDMP concepts** in their standards; and where needed and applicable, to better fit into those standards the IDMP model. *[to be done/ in progress]*
2. As described in D2.3 and in Section 7 of this deliverable most of the used standards requires that structured (and coded) information (e.g. code systems, value sets) are identified using suitable identification systems (OID, URI): it is recommended that organizations responsible for the content and service specifications work with appropriate entities for assigning these identifiers where missing. *[to be done/ in progress]*
3. In the clinical practice, for supporting local processes, local identifiers and attributes might be used. In order to assure the semantic interoperability beyond that specific context (jurisdiction, domain) it is recommended that:
 - a. Either the content creator adds to the provided information IDMP identification attributes/identifiers that can be understood by “other” users. *[to be done
Preconditions: needed data can be retrieved by the local MPD; the exchange format supports the communication of both IDMP and local classes and attributes;
This should be the recommended approach]*
 - b. Or a transformation service is available to integrate the content with the missing IDMP identification attributes/identifier that can be understood by the receiver. *[to be done
This is a reasonable approach for cross-border exchange concentrating all the mapping knowledge into a single point. The transformation service should rely on a local MPD; the exchange format supports the communication of both IDMP and local classes and attributes]*
 - c. Or the receiver is provided with a decoding service that allows the retrieval of the IDMP identification attributes/identifiers starting from the provided information. *[to be done]
Not recommended (above all for cross-border services)
A standard service supporting this activity should be defined and provided.
There are no standards for that.*
 - d. An extension to case a) is that when the provider gives IDMP identification identifiers/attributes but the receiver needs to convert them into a local product identifiers/attributes (e.g. local drug code or class). *[to be done]
The precondition for this use case is the availability of a local MPD providing discovery services (“find product by traits”). If not directly integrated in the receiving information system, a standard service specification shall be specified.
There are no standard services defined for this.*
 - i. It is recommended to have guidance on using IDMP to decode product identification.
 - ii. It is recommended that SDOs, together with regulators, define a standard way to “query” for product information and to retrieve matching products based on the attributes in the query.

4. Generally speaking, it is recommended that for each specific use case (e.g. cross-border ePrescription/eDispensation process) stakeholders and SDOs works together for stating the needed services and process rules for the identification of products and appropriate specifications will be developed for supporting them. *[to be done]*

12 Annex I – Example of implementation of the CEF eHDSI Data Elements

The following table specializes the table provided in D2.3 making available an implementation example of the **CEF eHDSI Data Elements** based on CDA R2 extended with the CPM. Mapping between IDMP concepts and the CPM has been based on the latest available current version of the IDMP implementation guide. For each element the xPath of the associated element is provided (namespaces are not evidenced). An illustrative template specification of this implementation example is published in ART DECOR® (<https://art-decor.org/art-decor/decor-templates--epsos-?id=2.16.840.1.113883.3.1937.777.11.10.147>).

CEF eHDSI Data Element	Cardinality ²² eP / eD / PS	XPath
Country A Cross-border/regional/national medicinal product code (National medicinal product code) ²³	O / NA / NA	<i>The implementation of this data element depends on the actual information conveyed PCID, MPID, PhpID, cluster ID.</i>
Country B Cross-border/regional/national medicinal product code (National medicinal product code)	NA / O / NA	<i>The implementation of this data element depends on the actual information conveyed PCID, MPID, PhpID, cluster ID.</i>
Brand name of the medicinal product prescribed in country A (Brand Name) ²⁴	R / NA / O	<i>The implementation of this data element depends on the actual information conveyed : e.g name of the package product; name of the medicinal product</i>
Brand name of the medicinal product dispensed in country B (Brand Name)	NA / R / NA	<i>The implementation of this data element depends on the actual information conveyed : e.g name of the package product; name of the medicinal product</i>
Pharmaceutical Substance (ATC code)	RNFA / O / RNFA [1..1]	manufacturedProduct/manufacturedMaterial.asSpecializedKind.generalizedMaterialKind.code[@codeSystem=2.16.840.1.113883.6.73]

²² Legenda: R: Required, RNFA: Required, Null-Flavor Allowed; O: Optional; NA: Not Applicable

²³ The national medical product code can include different types of codes according to the Member State.

²⁴ Despite the name this data element can include different types of names depending on the Member State: e.g. name of the packaged product; name of the medicinal product.

CEF eHDSI Data Element	Cardinality ²² eP / eD / PS	XPath
Pharmaceutical Substance (description)	O / O / O [0..1]	manufacturedProduct/manufacturedMaterial/asSpecializedKind/generalizedMaterialKind/name
Active ingredients list (code) (Active Ingredient)	RNFA / RFNA / RFNA [1..*]	manufacturedProduct/manufacturedMaterial/ingredient/ingredientSubstance/code
Active ingredients list (textual description) (Active Ingredient)	O / O / O [0..*]	manufacturedProduct/manufacturedMaterial/ingredient/ingredientSubstance/name
Strength of the medicinal product (as structured information) (Strength of the medicinal product)	RNFA / RNFA / RFNA [1..1]	manufacturedProduct/manufacturedMaterial/ingredient/quantity
Strength of the medicinal product (Description) (Strength of the medicinal product) ²⁵	O / O / O [0..1]	manufacturedProduct/manufacturedMaterial/desc
Medicinal product package (Medicinal product package) ²⁶	RNFA / RFNA / NA [1..1]	manufacturedProduct/manufacturedMaterial/asContent/containerPackagedProduct/formCode
Pharmaceutical dose form (Pharmaceutical dose form)	R / R / O [0..1]	manufacturedProduct/manufacturedMaterial/formcode
Route of Administration (Route of Administration)	O / O / O [0..1]	substanceAdministration.routeCode
Package Size (Package Size) ²⁷	R / R / NA	manufacturedProduct/manufacturedMaterial/asContent/quantity

The following table extends the CEF eHDSI Data Element showing how the IDMP not already included above can be represented in the CDA R2 using extensions.

²⁵ Example: "300 mg + 125 mg"

²⁶ This may be a composite information (e.g. 1 box with 3 blisters of 5 pills)

²⁷ This may be a composite information (e.g. 10 bottles of 10 ml)

IDMP attributes	XPath
Name of the PC	manufacturedProduct/manufacturedMaterial//asContent/containerPackagedProduct/name (most inner)
PCID	manufacturedProduct/manufacturedMaterial//asContent/containerPackagedProduct/code (most inner)
Name of the MP	manufacturedProduct/manufacturedMaterial/name
MPID	manufacturedProduct/manufacturedMaterial/code
Name of the PHP	manufacturedProduct/manufacturedMaterial/asSpecializedKind/generalizedMaterialKind/name
PHPIDs	manufacturedProduct/manufacturedMaterial/asSpecializedKind/generalizedMaterialKind/code

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²⁸ To be clarified if the PhPIId levels should be represented as translation of the main code or using distinct asSpecializedKind elements

13 Annex II – Project proposed to HL7 for the formulary management

Hereafter enclosed, an overview of the Project proposals that are under discussion in HL7 international that have been proposed to cover some of the missing services identified in this deliverable.

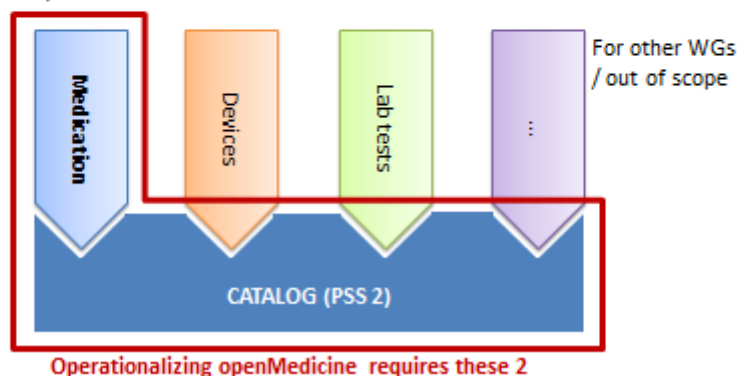
Schema, goals and timelines

PSS 1: Providing the openMedicine goals and medicinal product attributes

Deliverables: FHIR Resources, guidance; Timeline: 1 year; Participants: Pharm, RC-RIM.

PSS 2: Infrastructural component for “catalog” exchange.

Deliverables: FHIR Resources, guidance (SPL, etc.); Timeline: 1 year; Participants: OO, Pharm, FHIR-I, RC-RIM.



14 Annex III - Concepts and data elements applied to ePrescription

The following diagram shows the concepts discussed in this document, in a way to reveal the operational model and dependencies using some detailed fields:

- The ISO IDMP standard defines concepts (of products and attributes).
- These concepts and attributes are then implemented in the product tables of the EMA DB.
- The attributes must have a consistent vocabulary so they originate from master data tables which contain the vocabulary.
- The products in the database can be shared with systems in country A and country B by a standard interface
- In a prescription, several concepts of "product" can be specified - national concepts or IDMP standardized concepts such as PhPID, MPID, PCID, and Substance.
- The identifiers for these products can be originating from the EMA DB via the Product Discovery
- A prescription may also contain attributes that can be obtained from the same Product Discovery
- Since both countries understand a common language for attributes and identifiers, interoperability is possible

