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SCIENCE MEDICINES HEALTH

PMS, UPD and FHIR





PMS

Product management service

- PMS stands for Product Management Service.
- It is the part of SPOR that manages Products (Substance, Organisation and Referentials)
- PMS has been modelled *based* on ISO IDMP and is meant to manage medicinal products for human and veterinary.
- The scope of PMS is slightly smaller than the full ISO IDMP.



ISO IDMP

ISO identification of medicinal products

5 standards describe data elements and structures to uniquely identify and exchange information on:

1. substances ([ISO 11238](#));
2. pharmaceutical dose forms, units of presentation, routes of administration and packaging ([ISO 11239](#));
3. units of measurement ([ISO 11240](#));
4. regulated pharmaceutical product information ([ISO 11616](#));
5. regulated medicinal product information ([ISO 11615](#)).

These standards are used to describe a medicinal product for human use:

1. medicinal product name;
2. ingredient substances;
3. pharmaceutical product (route of administration, strength);
4. marketing authorisation;
5. clinical particulars;
6. packaging;
7. manufacturing.



SPOR and ISO IDMP

- ISO IDMP covers the **entire medicinal product lifecycle**, including products in development, investigational products, products under evaluation and authorised products, **SPOR does not**;
- Although ISO IDMP standards relate to human medicinal products, SPOR applies to **both** human and veterinary domains.



References

1. SPOR master data: <https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/substance-product-organisation-referential-spor-master-data>;
2. ISO IDMP standards: <https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview>;



Conceptual Data Model (CDM):

- A **high level** overview of **business entities** and their relationships;
- It communicates a rough scope;
- It establishes a common understanding and terminology and can help link with other business units or processes;
- It can help shaping requirements;
- It **cannot** be implemented;

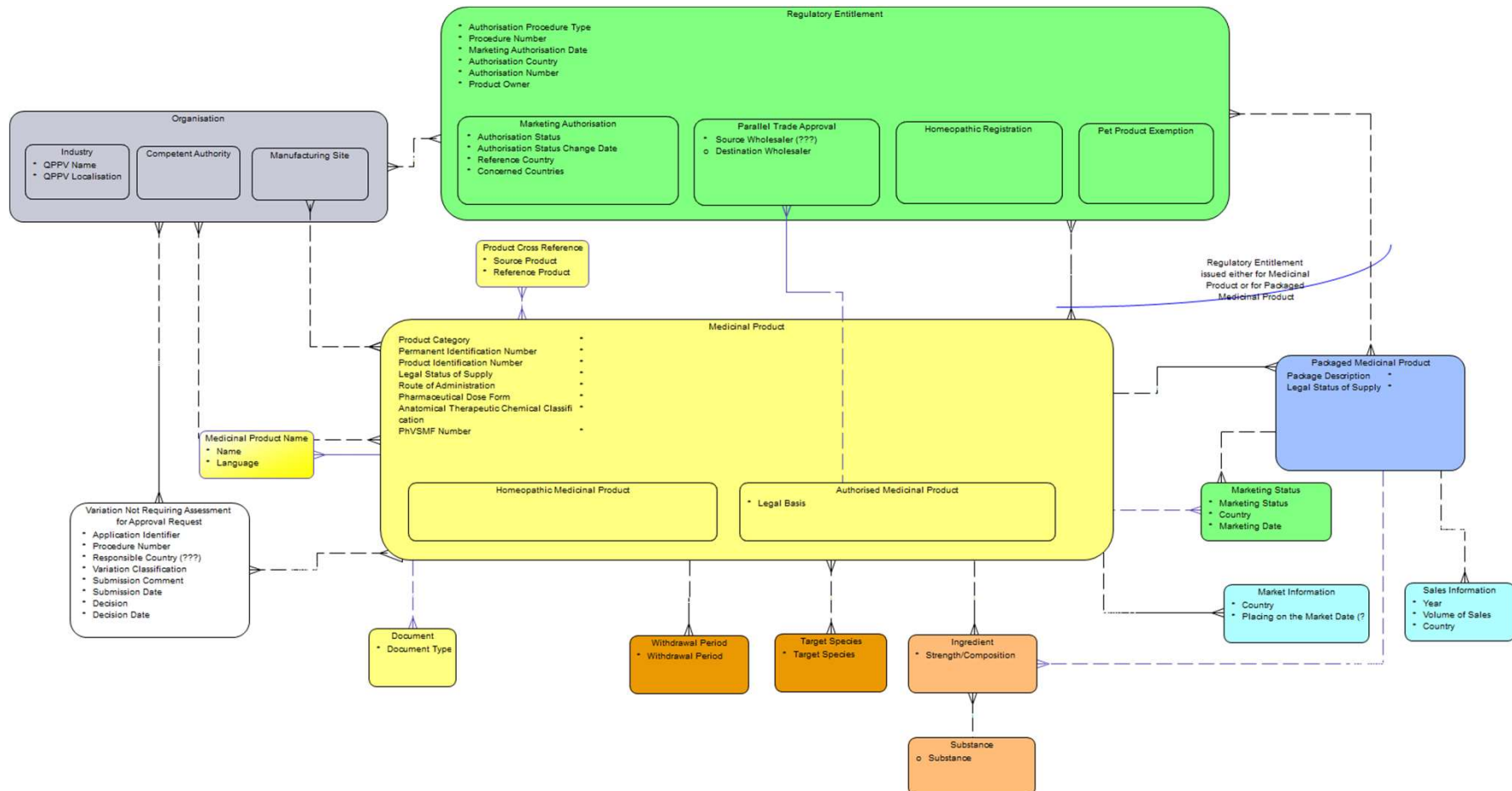
Logical Data Model (LDM):

- A **detailed view** of **business entities**, their attributes and their relationships;
- It can communicate detailed scope and translate it for developers;
- It captures detailed requirements and some business rules and allows developers to enforce them;
- It **cannot** be implemented but it is reasonable close to implementation views;

UPD – conceptual data model



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Different data models at play in UPD



- UPD CDM reflects requirements from the Implementing Act;
- UPD mandates a number of fields and entities that largely fall within the scope of PMS;
- The scope of UPD is a subset of the scope of PMS, plus a few extensions;
- Examples (not exhaustive):

Data	IDMP	PMS	UPD	Type
Product name, owner, manufacturers, ...	Yes	Yes	Yes	In scope for UPD, already supported by PMS and IDMP compatible.
Target species, withdrawal period, ...	No	Yes	Yes	In scope for UPD, already supported by PMS but not in IDMP.
Volume of sales, variation without assessment decision and decision date, ...	No	No	Yes	In scope for UPD, not supported by PMS or IDMP.
Package shelf life, contraindications, ...	Yes	Yes	No	Out of scope for UPD.
Physical characteristics (shape, colour, diameter, ...) of devices and package items, ...	Yes	No	No	Out of scope for UPD.



- An LDM has been created for UPD.
- This LDM is based on **a subset** PMS LDM, **plus** the specific UPD additions.
- It represents the scope of UPD and it is, by default, mostly IDMP compatible.
- The details of the LDM as it stands now can be found in the Appendix.



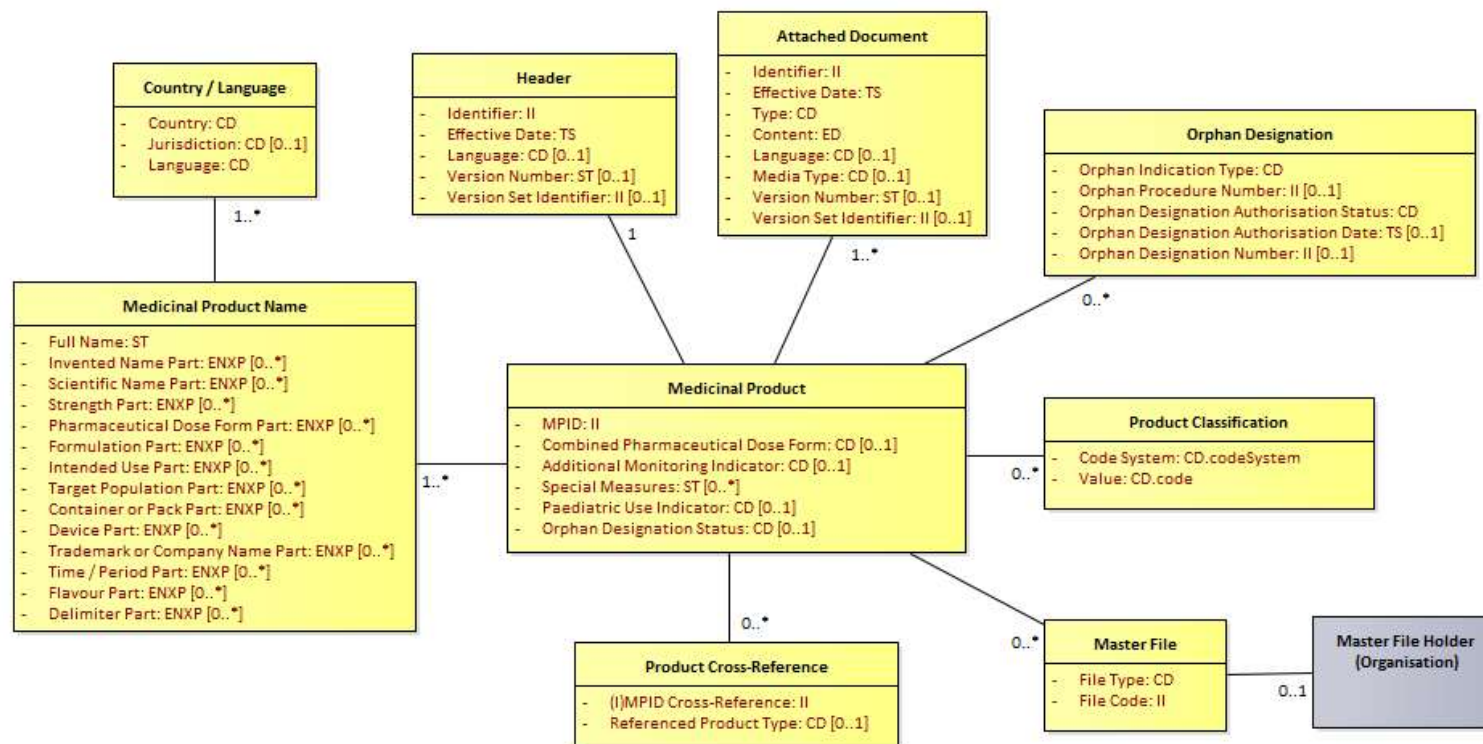
FHIR

Fast healthcare interoperability resources

- ISO IDMP covers the **modelling** of the information around medicinal products and substances but does **not cover** the way to **physically exchange the information** between parties;
- IDMP FHIR describes (for R5 <https://build.fhir.org/>):
 - Data formats called **resources** and that are aligned with the **ISO IDMP representations**;
 - An **API** to manipulate those resources, following a **RESTful protocol**.



IDMP medicinal product

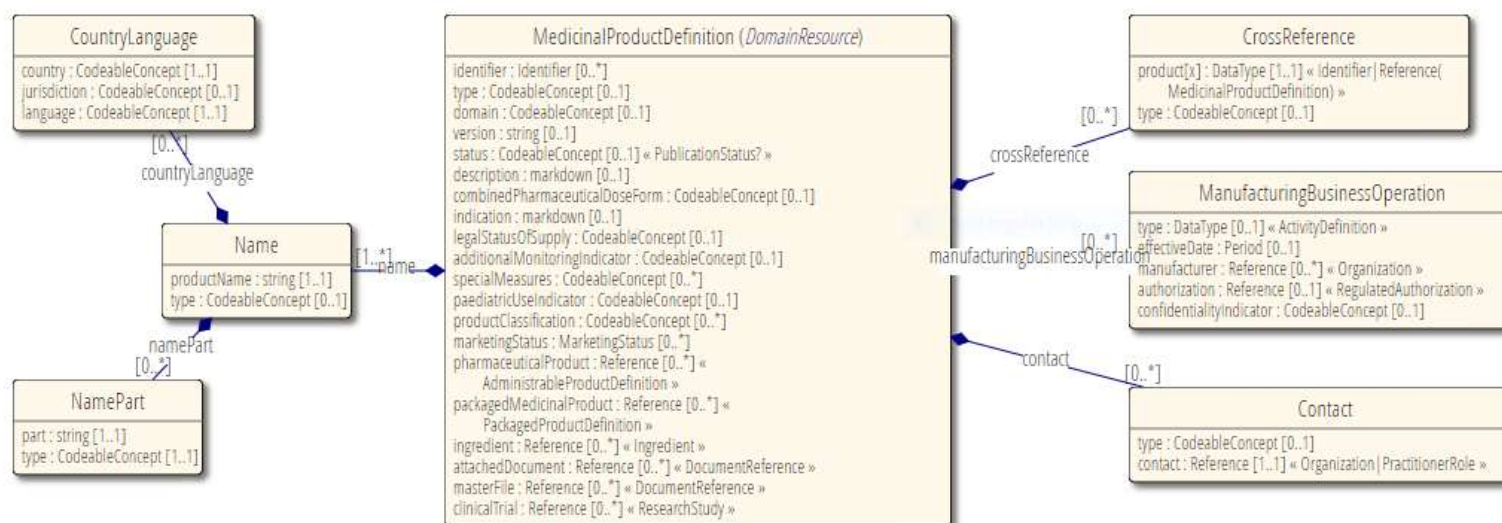




Resource – MedicinalProductDefinition

<https://build.fhir.org/medicinalproductdefinition.html>

UML Diagram (Legend)





Example resource – MedicinalProductDefinition – in XML

<https://build.fhir.org/medicinalproductdefinition-example.xml.html>

```
<?xml version="1.0" encoding="UTF-8"?>
<MedicinalProductDefinition xmlns="http://hl7.org/fhir">
  <id value="example" />
  <identifier>
    <system value="http://ema.europa.eu/example/MPID" />
    <value value="{mpid}" />
  </identifier>
  <productClassification>
    <coding>
      <system value="ATCClassificationSystem" />
      <code value="B01AF02" />
    </coding>
  </productClassification>
  <name>
    <productName value="Equilidem 2.5 mg film-coated tablets" />
    <namePart>
      <part value="Equilidem" />
      <type>
        <coding>
          <code value="INV" />
        </coding>
      </type>
    </namePart>
    <namePart>
      <part value="2.5 mg" />
      <type>
        <coding>
          <code value="STR" />
        </coding>
      </type>
    </namePart>
  </name>
</MedicinalProductDefinition>
```

```
    <namePart>
      <part value="film-coated tablets" />
      <type>
        <coding>
          <code value="FRM" />
        </coding>
      </type>
    </namePart>
    ...
  </name>
  ...
</MedicinalProductDefinition>
```



RESTful API operations

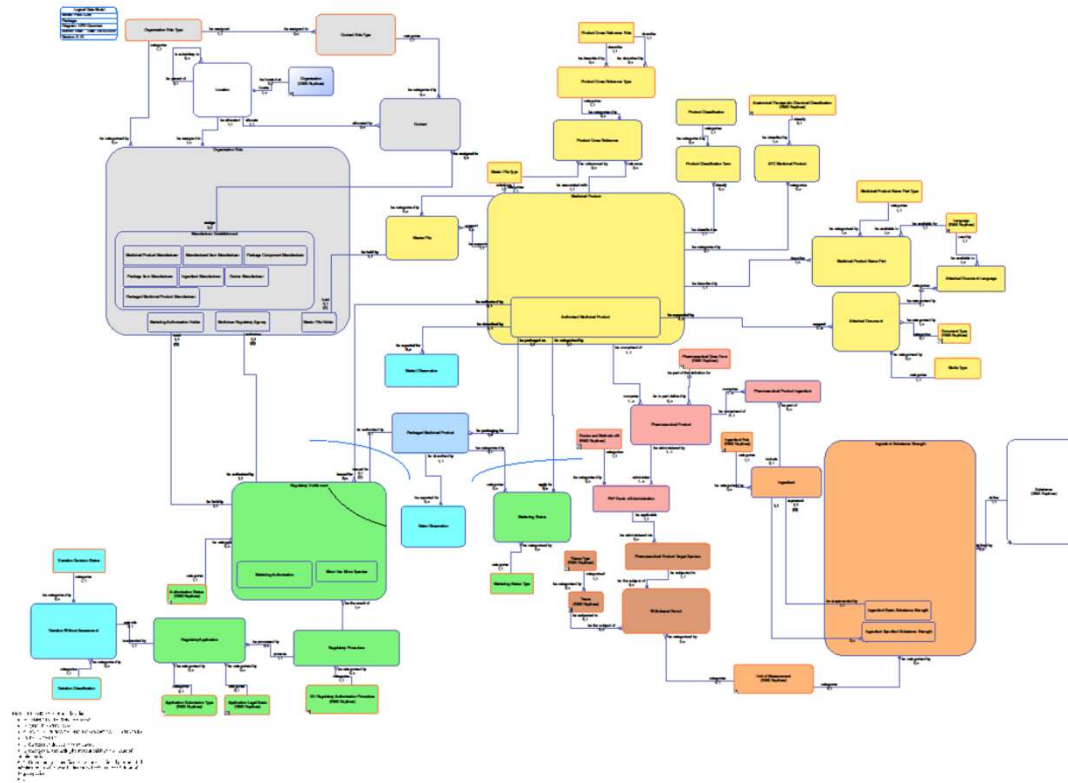
<https://build.fhir.org/operationslist.html>

See short demo (for R4)



Annex

UPD LDM (PMS subset + extension): Overview

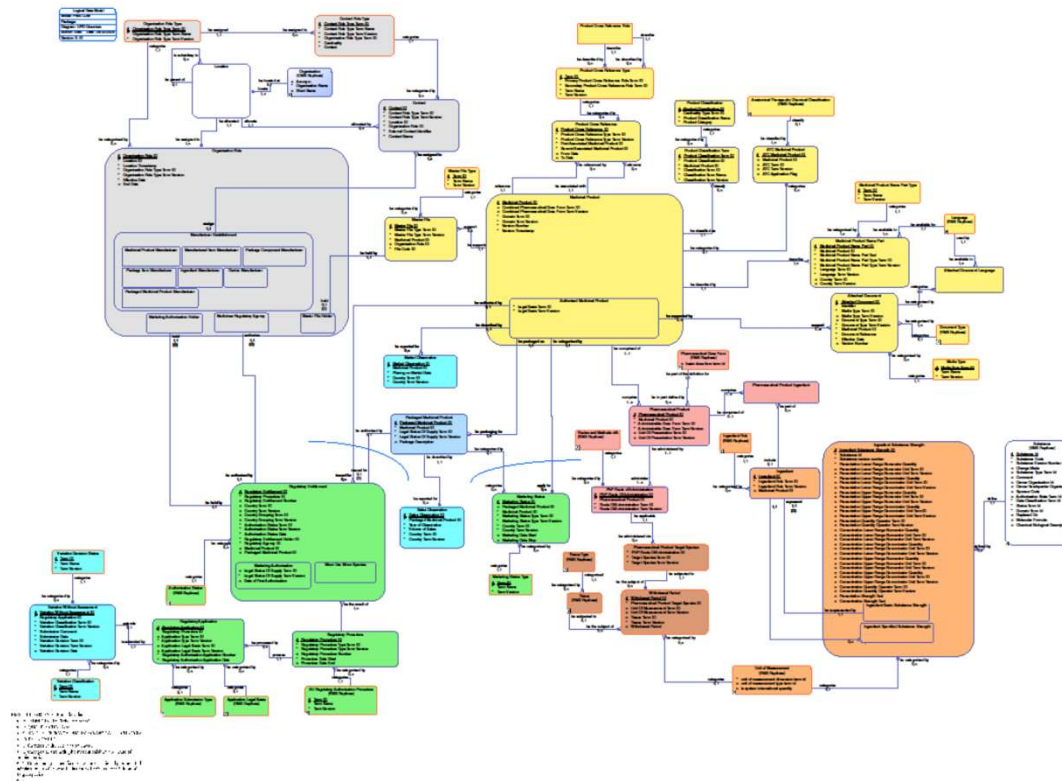


Hard to read? Double-click and zoom

UPD LDM (PMS subset + extension): Detailed



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Hard to read? Double-click and zoom



Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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