

# UNOCOM

Up-scaling the global univocal identification of medicines

## **FHIR Workshop**

# **How to read FHIR messages that describe medicinal products**

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1. Introduction
2. Know how to read FHIR messages that describe medicinal products
3. Discussion and feedback
4. Alignment in the network



Participants should be able to understand and read FHIR messages describing medicinal products;

- a. We will be using draft FHIR-messages provided by SPOR PMS → Losec Control 20mg

- ▶ **AGES MEA** is a division of the Austrian Agency for Health and Food Safety (AGES), which is the leading expert organisation for risk minimisation in the fields of health, food safety and consumer protection.
- ▶ 350 FTEs are working at AGES MEA
- ▶ AGES is wholly owned by the Republic of Austria.
  
- ▶ The **AGES MEA** business unit is the service provider for the **Federal Office for Safety in Health Care (BASG)**



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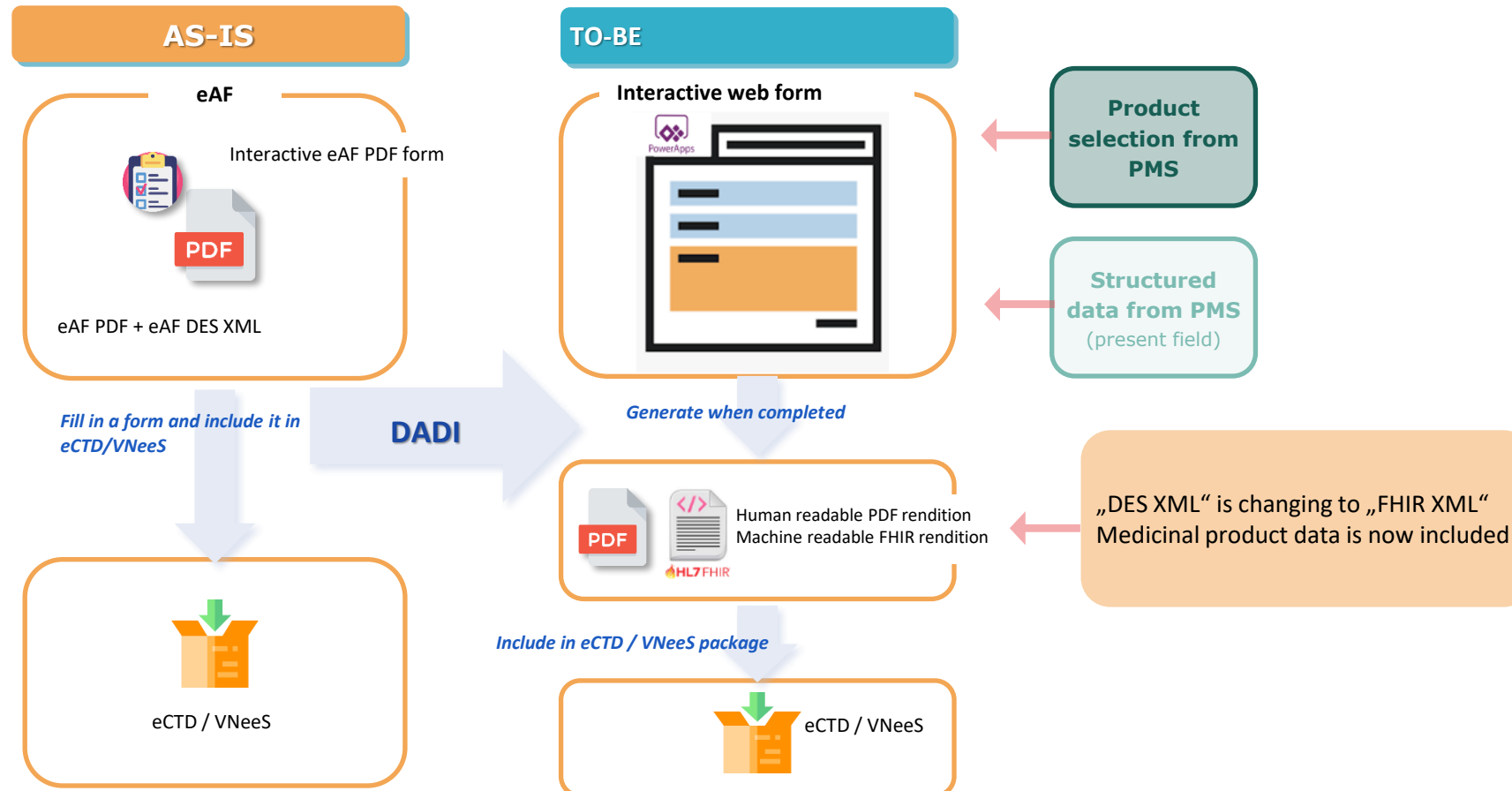
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1. Output of the eAF Portal, attached to the eAF PDFs
2. Used to import product data into
  - a. Procedure Mgmt system (E.g. Pharos, Amanda, IRIS,...)
  - b. Product Dictionaries (E.g. SPOR PMS)
3. Can be used to exchange Medicinal Product data between stakeholders



# Submission process is unchanged



\*Slide amended from DADI / PMS Presentation to IRISS



## FHIR-Basics





All product fields are described in detail in [EU IG Chapter 2](#) (Data elements for the electronic submission of information on medicinal products for human use) on [EMA S&PMS webpage](#)



## Examples of **FHIR messages**

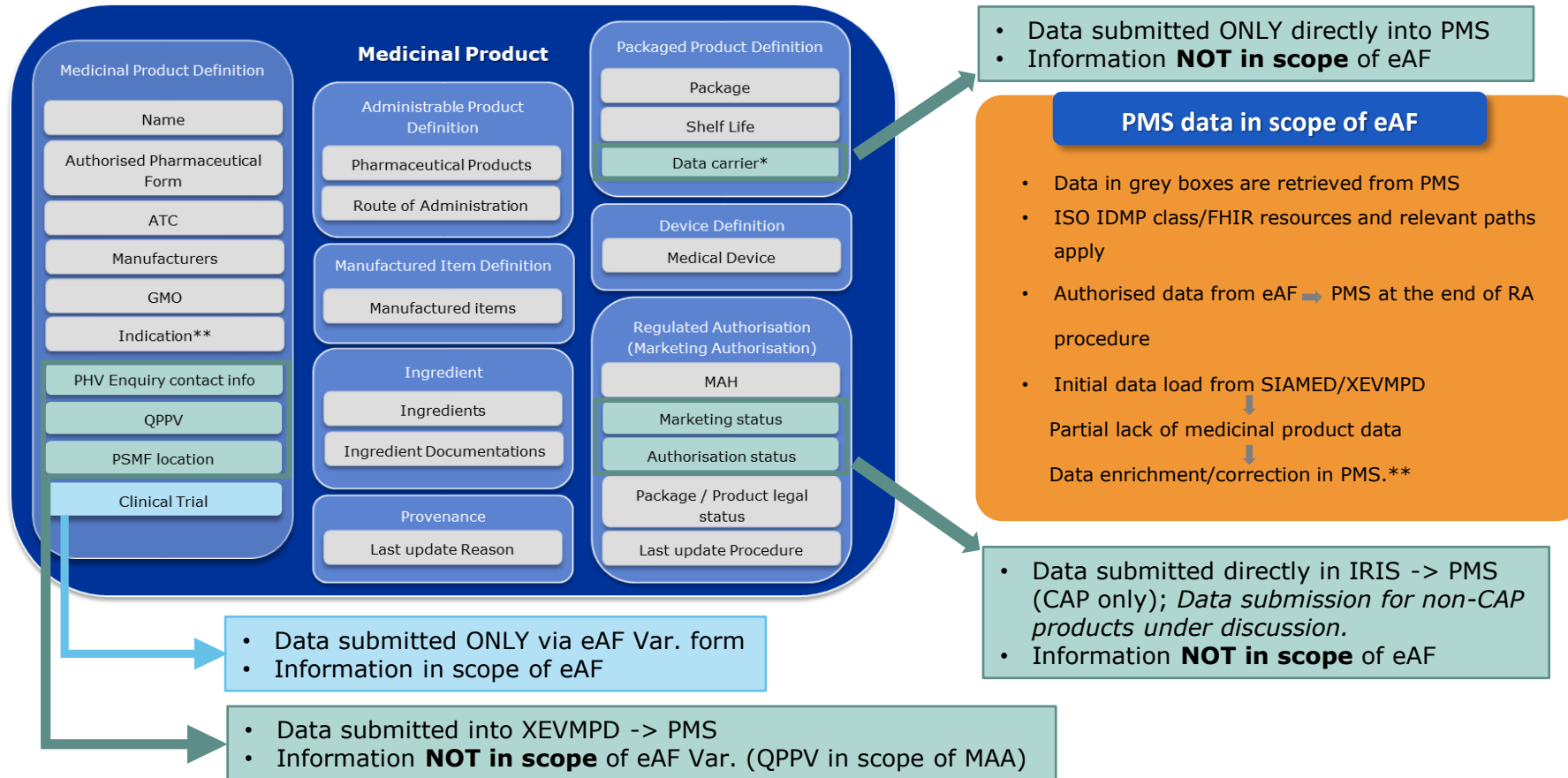
- FHIR XML and HTML transformation for Losec Control examples can be found [here](#)
- Variation Examples can be found under:  
<https://www.ema.europa.eu/en/events/digital-application-dataset-integration-dadi-webinar-common-factors-fast-healthcare-interoperability#documents-section>



## **FHIR links**

- PMS / EU IG will update to 4.6 but is still on 4.2 / 4.4: <http://hl7.org/fhir/directory.html>
  - The update to 4.6 mainly includes approved elements that were extensions in previous versions. Business rules should not be changed
- DADI is using FHIR in the version 4.6: <https://hl7.org/fhir/2021May/medicinalproductdefinition.html>
- The latest version can be found under: <https://build.fhir.org/resourcelist.html>





Take home message: The eAF portal will be able to provide NtA elements but also not regulated data elements.

\*Slide amended from DADI / PMS Presentation to IRISS



- All resources are on the same level. They are linked by references.
  - ✓ e.g. a Manufactured Item has a link to the ingredient
- Elements inside resource have a hierarchy.

In HTML: Can be represented as a hierarchy

↳ **Manufactured Item**  
Dose Form: Gastro-resistant tablet  
Unit of presentation: Tablet

↳ **Ingredient**  
Role: Active  
Substance: Omeprazole magnesium  
Strength:  
Presentation Strength: 20.6 milligram(s) per 1 tablet  
Reference Substance: Omeprazole

In XML: Is a link to another resource

```
<resource>
  <ManufacturedItemDefinition><!-- ISO name: (n/a) --><!-- No id needed, in a
  <extension url="http://ema.europa.eu/fhir/extension/subject">
  <!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Co
  <manufacturedDoseForm>
  <!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Co
  <unitOfPresentation>
  <!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Co
  <ingredient><!--Ingredient/LosecControl20mg-d3e456-->
    <reference>
      <reference value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82010"/>
    </reference>
  </ingredient>
</entry>
<fullUrl value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82010"/>
<resource>
  <Ingredient>
    <extension url="http://ema.europa.eu/fhir/extension/masterFile">
    <extension url="http://ema.europa.eu/fhir/extension/subject">
    <role>
    <substance><!-- ISO name: /MedicinalProduct/PackagedMedicinalProd
  </Ingredient>
```



- ▶ Not all references can be drilled down
  - e.g. ReferenceAuthorisation always links from the authorisation away to the entity that is authorised\* (here in the screenshot MedicinalProductDefinition)
    - ✓ \* *Current exception in „Operation“ → Will be fixed*




In HTML: Can be represented inside the medicinal product







↳ **Authorisation**  
Type: Marketing Authorisation  
Identifier: PA1410/066/001  
Status: Valid  
Region: Ireland  
Status date: 2016-02-17

In XML: Is an independent resource somewhere in the message with a link back to the MP

```
<entry>
  <fullUrl value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82006"/>
  <resource>
    <RegulatedAuthorization><!-- ISO name: (n/a) --><!-- No id needed, in a transaction name: /MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationNumber -->
      <identifier>
        <system value="http://ema.europa.eu/fhir/marketingAuthorizationNumber"/>
        <value value="PA1410/066/001"/>
      </identifier>
      <subject><!--MedicinalProductDefinition/6006100000833-->
        <reference value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82000"/>
      </subject>
    </RegulatedAuthorization>
  </resource>
</entry>
```

- ▶ Codeable Concept can contain
  - a catalogue or
  - a text if there is no code yet

Name	Flags	Card.	Type	Description & Constraints
 CodeableConcept	Σ <b>N</b>		Element	Concept - reference to a terminology or just text Elements defined in Ancestors: <a href="#">id</a> , <a href="#">extension</a>
 coding	Σ	0..*	Coding	Code defined by a terminology system
 text	Σ	0..1	string	Plain text representation of the concept

Name	Flags	Card.	Type	Description & Constraints
 Coding	Σ <b>N</b>		Element	A reference to a code defined by a terminology system Elements defined in Ancestors: <a href="#">id</a> , <a href="#">extension</a>
 system	Σ	0..1	uri	Identity of the terminology system
 version	Σ	0..1	string	Version of the system - if relevant
 code	Σ	0..1	code	Symbol in syntax defined by the system
 display	Σ	0..1	string	Representation defined by the system
 userSelected	Σ	0..1	boolean	If this coding was chosen directly by the user

<https://build.fhir.org/datatypes.html#CodeableConcept>



- ▶ Mainly used for RMS catalogues
  - FHIR-Extension introduced to hold term version
  - Coding as
    - ✓ System → RMS List Id
    - ✓ Code → RMS Term Id
    - ✓ Display → RMS Term Name

Name	Flags	Card.	Type	Description & Constraints
Coding	Σ N		Element	A reference to a code defined by a terminology system Elements defined in Ancestors: <a href="#">id</a> , <a href="#">extension</a>
system	Σ	0..1	uri	Identity of the terminology system
version	Σ	0..1	string	Version of the system - if relevant
code	Σ	0..1	code	Symbol in syntax defined by the system
display	Σ	0..1	string	Representation defined by the system
userSelected	Σ	0..1	boolean	If this coding was chosen directly by the user

```
<coding>
  <extension url="http://ema.europa.eu/fhir/extension/termVersion">
    <valueInteger value="1"/>
  </extension>
  <system value="https://spor.ema.europa.eu/v1/lists/100000000004"/>
  <code value="100000000012"/>
  <display value="Human use"/>
</coding>
```

# Example: Classification

```
<classification><!-- ISO name: /MedicinalProduct/classification/CodeSystem --><!-- FHIR extra mapping info:
  <coding>
    <extension url="http://ema.europa.eu/fhir/extension/termVersion">
      <valueInteger value="1"/>
    </extension>
    <system value="https://spor.ema.europa.eu/v1/lists/100000116045"/>
    <!-- ISO name: /MedicinalProduct/classification/Value -->
    <code value="100000116053"/>
    <display value="Well-established use application (Article 10a of Directive No 2001/83/EC)"/>
  </coding>
</classification>
<!-- ISO name: /MedicinalProduct/classification -->
<classification><!-- ISO name: /MedicinalProduct/classification/CodeSystem --><!-- FHIR extra mapping info:
  <coding>
    <extension url="http://ema.europa.eu/fhir/extension/termVersion">
      <valueInteger value="1"/>
    </extension>
    <system value="https://spor.ema.europa.eu/v1/lists/100000093533"/>
    <!-- ISO name: /MedicinalProduct/classification/Value -->
    <code value="100000093631"/>
    <display value="A02BC01"/>
  </coding>
</classification>
```

The same node e.g. classification can have a different meaning depending on the system value. In this example classification can be legal base or ATC code.

- ▶ A „reference“ links one resource to another
  - allows for drill down (or up)
  - Mostly just values of UUIDs (if known)
  - Can be a local self assigned id (if unknown)

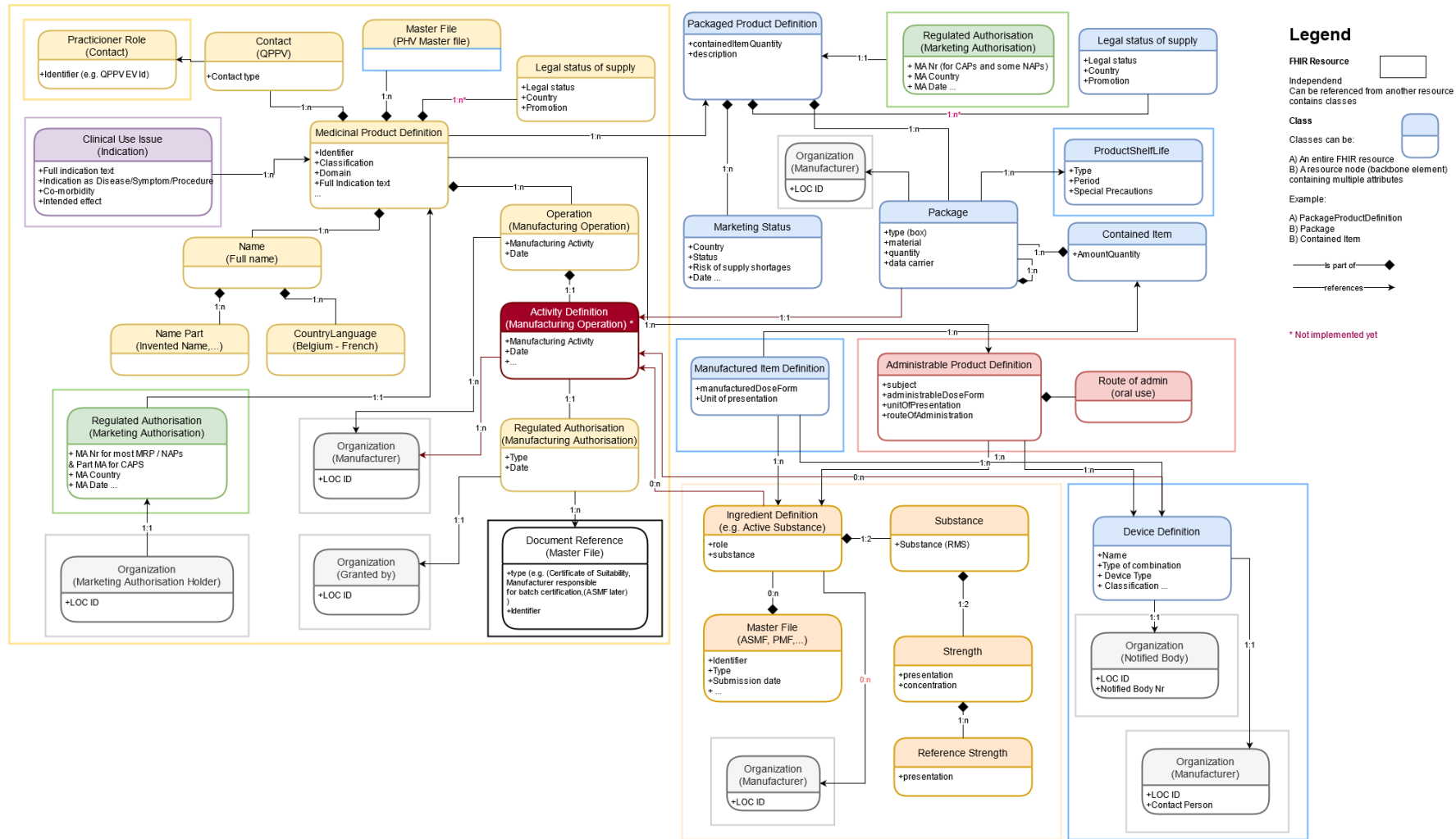
Name	Flags	Card.	Type	Description & Constraints	?
Reference	Σ <b>N</b>		Element	A reference from one resource to another + Rule: SHALL have a contained resource if a local reference is provided Elements defined in Ancestors: <a href="#">id</a> , <a href="#">extension</a>	
reference	Σ I	0..1	string	Literal reference, Relative, internal or absolute URL	
type	Σ	0..1	uri	Type the reference refers to (e.g. "Patient") <a href="#">ResourceType</a> (Extensible)	
identifier	Σ	0..1	Identifier	Logical reference, when literal reference is not known	
display	Σ	0..1	string	Text alternative for the resource	

```
<attachedDocument><!--DocumentReference/LosecControl20mg-d3e39-->  
  <reference value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82001"/>  
</attachedDocument>
```



Classdiagramm based on PMS FHIR message

# Classdiagramm



## MedicinalProductDefinition



## Product

**Name: Losec Control 20 mg gastro-resistant tablets**

Invented name part: Losec Control

Strength name part: 20 mg

Pharmaceutical dose form name part: Gastro-resistant tablets

Country: Ireland

Language: English

Identifier: IE-100000833-00000003

Identifier: 2215

Domain: Human use

Authorised Dose Form: Gastro-resistant tablet

Legal Status of Supply: Medicinal Product not subject to prescription

Additional Monitoring Indicator: False

Paediatric Use: medicinal product not authorised for paediatric use

Indication(s) text: Losec Control gastro-resistant tablets is indicated for the treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.

Characteristic: False

Classification: Other

Classification: Well-established use application (Article 10a of Directive No 2001/83/EC)

Classification: A02BC01

Classification: Chemical



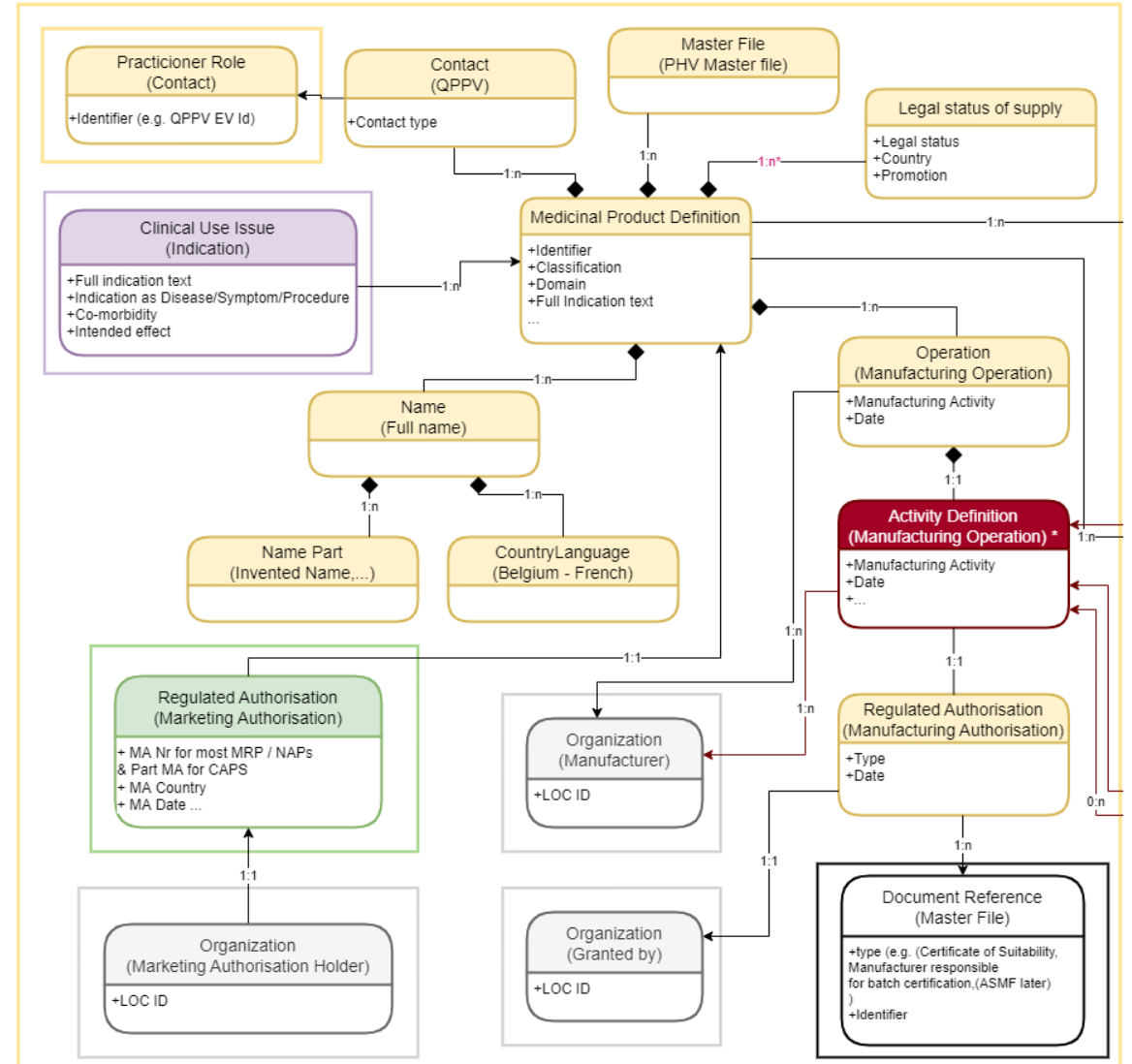
```

<entry>
  <fullUrl value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82000"/>
  <resource>
    <MedicinalProductDefinition><!-- ISO name: /MedicinalProduct -->

    <!-- No id needed, in a transaction this is identified by fullUrl, however -->
    <!-- <id value="6006"/> -->

    <!-- ISO name: /MedicinalProduct/QPPV -->
    <contained>
    <contained>
    <!-- ISO name: /MedicinalProduct/MasterFile -->
    <contained>
    <extension url="http://ema.europa.eu/fhir/extension/authorisedDoseForm">
      <valueCoding>
        <extension url="http://ema.europa.eu/fhir/extension/termVersion">
          <valueInteger value="1"/>
        </extension>
        <system value="https://spor.ema.europa.eu/v1/lists/200000000004"/>
        <code value="100000073667"/>
        <display value="Gastro-resistant tablet"/>
      </valueCoding>
    </extension>

    <!-- ISO name: /MedicinalProduct/MPID -->
    <identifier>
      <system value="http://ema.europa.eu/fhir/mpId"/>
      <value value="IE-100000833-00000003"/>
    </identifier>
    <!-- ISO name: /MedicinalProduct/EURDId -->
    <identifier>
      <system value="http://ema.europa.eu/fhir/eurdId"/>
      <value value="2215"/>
    </identifier>
    <!-- ISO name: /MedicinalProduct/Domain -->
    <domain>
      <coding>
        <extension url="http://ema.europa.eu/fhir/extension/termVersion">
          <valueInteger value="1"/>
        </extension>
        <system value="https://spor.ema.europa.eu/v1/lists/100000000004"/>
        <code value="100000000012"/>
        <display value="Human use"/>
      </coding>
    </domain>
  
```



**Thank you!**

**UN****COM**