Up-scaling the global univocal identification of medicines

FHIR Workshop
How to read FHIR messages that describe medicinal products
30 March 2022

AGES: Georg Neuwirther, Harald Laimer, Noel Diamant
Agenda

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

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)
Disclaimer

This presentation is the intellectual property of the individual presenters and is protected under the copyright laws of Austria and other countries. All rights reserved. All trademarks are property of their respective owners.

The information provided represents the knowledge and status at the time of its preparation. It does not necessarily represent the view of the regulatory authority to which the presenter belongs. Do not use this information for decision making, but instead always refer to official documents, relevant regulations, regulatory guidelines and SPOR guidance material.
What is FHIR used for?

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

**AS-IS**
- eAF
  - Interactive eAF PDF form
- eAF PDF + eAF DES XML

**TO-BE**
- Interactive web form
  - Fill in a form and include it in eCTD/VNeeS
  - Product selection from PMS
  - Structured data from PMS (present field)

**DADI**
- Generate when completed
- Human readable PDF rendition
  - Machine readable FHIR rendition
- Include in eCTD / VNeeS package
- eCTD / VNeeS

**Generate when completed**
- eCTD / VNeeS

**Include in eCTD / VNeeS package**
- eCTD / VNeeS

*Slide amended from DADI / PMS Presentation to IRISS*

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
FHIR-Basics

**Examples of FHIR messages**

- FHIR XML and HTML transformation for Losec Control examples can be found [here](https://build.fhir.org/resourcelist.html)

**FHIR links**

- PMS / EU IG will update to 4.6 but is still on 4.2 / 4.4: [http://hl7.org/fhir/directory.html](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](https://hl7.org/fhir/2021May/medicinalproductdefinition.html)
- The latest version can be found under: [https://build.fhir.org/resourcelist.html](https://build.fhir.org/resourcelist.html)
Medicinal Product data

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
Hierachy I

- 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 representated as a hierarchy

In XML: Is a link to another resource
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

In XML: Is an independent resource somewhere in the message with a link back to the MP
# FHIR complex data types: Codeable Concept

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Flags</th>
<th>Card.</th>
<th>Type</th>
<th>Description &amp; Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>CodeableConcept</td>
<td>Σ</td>
<td>N</td>
<td>Element</td>
<td>Concept - reference to a terminology or just text</td>
</tr>
<tr>
<td>coding</td>
<td>Σ</td>
<td>0..*</td>
<td>Coding</td>
<td>Elements defined in Ancestors: id, extension</td>
</tr>
<tr>
<td>text</td>
<td>Σ</td>
<td>0..1</td>
<td>string</td>
<td>Code defined by a terminology system</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Plain text representation of the concept</td>
</tr>
</tbody>
</table>

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

[https://build.fhir.org/datatypes.html#CodeableConcept](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

```xml
<coding>
    <valueInteger value="1"/>
  </extension>
  <code value="100000000012"/>
  <display value="Human use"/>
</coding>
```
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)

<table>
<thead>
<tr>
<th>Name</th>
<th>Flags</th>
<th>Card.</th>
<th>Type</th>
<th>Description &amp; Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>reference</td>
<td>Σ I</td>
<td>0..1</td>
<td>string</td>
<td>Literal reference, Relative, internal or absolute URL</td>
</tr>
<tr>
<td>type</td>
<td>Σ</td>
<td>0..1</td>
<td>uri</td>
<td>Type the reference refers to (e.g. &quot;Patient&quot;) Resource Type (Extensible)</td>
</tr>
<tr>
<td>identifier</td>
<td>Σ</td>
<td>0..1</td>
<td>Identifier</td>
<td>Logical reference, when literal reference is not known</td>
</tr>
<tr>
<td>display</td>
<td>Σ</td>
<td>0..1</td>
<td>string</td>
<td>Text alternative for the resource</td>
</tr>
</tbody>
</table>

<attachedDocument><![CDATA[<div>
    <reference value="urn:uuid:c6a838d9-27ca-49a4-a6ba-216448f82001"/>
</div>]]></attachedDocument>
Classdiagramm based on PMS FHIR message
MedicinalProductDefinition
Medicinal Product

**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
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299.
Thank you!