



# UNICOM

Project acronym: UNICOM

Project full title: Up scaling the global univocal identification of medicines  
in the context of Digital Single Market strategy

Call identifier: H2020-SC1-DTH-2019

## Deliverable 4.16:

### Best-practise ISO IDMP workshops according to needs of the NCAs

Version: 2.0

Status: Final

Dissemination Level<sup>1</sup>: PU

Due date of deliverable: 31.05.2022

Actual submission date: 30.06.2022

Work Package: WP4: IDMP implementation at National  
Drug Agencies

Lead partner for this deliverable: AGES

Partner(s) contributing: SEMPA

Deliverable type<sup>2</sup>: R

#### Main author(s):

Georg Neuwirther	AGES
Harald Laimer	AGES
Pelle Person	SEMPA

Resource consumption estimate:	Person months
AGES	0,1
SEMPA	0,1

<sup>1</sup> Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

<sup>2</sup> Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

### Revision history

Version	Date	Changes made	Author(s)
0.1	19.10.2020	Preparation of deliverable template	Farah Diehl-Fahim
0.2	16.04.2021	Structure, adding first content	Pelle Persson
0.3	06.05.2021	List of presentations and workshops added	Pelle Persson
0.4	10.05.2021	Content for presentations and workshops added	Pelle Persson
0.5	17.05.2021	Typos, list of abbreviations, lessons learned, ready for review of contributors	Harald Laimer
0.6	25.05.2021	Updates of lessons learned after review of contributors	Harald Laimer
0.7	27.05.2021	Review	EMP
1.0	31.05.2021	Submission	EMP
1.1	02.06.2022	Adding: “Best practice workshop on IDMP/Pharmaceutical Product” and “Training on FHIR messages based on EMA examples”	Harald Laimer
1.2	21.06.2022	Incorporated AEMPS’s comments	Harald Laimer
2.0	30.06.2022	Review and submission	EMP

#### Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

**Deliverable abstract**

Task 4.13 foresees several workshops with UNICOM WP 4 partners each year, with the main objective to share experiences and best practises implementing IDMP standards.

The consortia take note of the WP 4 partners (national competent authorities) concerns raised during these workshops, which are compiled in this deliverable D4.16 on an annual basis as lessons learned. These are the aspects where more attention should be given inside the consortium and outside (e.g. the SPOR initiative organised by EMA/HMA)

Keywords: NCAs, Lessons learned, IDMP, challenges

This document contains material, which is the copyright of the members of the UNICOM consortium listed above and may not be reproduced or copied without their permission.

The commercial use of any information contained in this document may require a license from the owner of that information.

This document reflects only the views of the authors, and the European Commission is not liable for any use that may be made of its contents. The information in this document is provided “as is”, without warranty of any kind, and accept no liability for loss or damage suffered by any person using this information.

© 2019-2023. The participants of the UNICOM project.

**TABLE OF CONTENTS**

Revision history .....	2
Deliverable abstract .....	3
List of abbreviations .....	5
1 Executive summary .....	7
2 Workshops with NCAs .....	8
2.1 Overview .....	8
2.2 List of held workshops (Reporting date 02.06.2022) .....	8
3 HALMED - Best practise and knowledge sharing session .....	10
4 Project SAFEST and FHIR Implementation .....	11
5 AEMPS - Best practise and knowledge sharing session .....	12
6 FIMEA - Best practise and knowledge sharing session .....	14
7 AGES - UNICOM WP4 Best practise workshop on IDMP Ingredient .....	16
8 AGES/SEMPA - Telematics Forum about UNICOM WP4 and IDMP including a special topic on "Ingredients" .....	17
9 AGES - UNICOM WP4 Best practise workshop on IDMP Manufactured Items and Packaged Medicinal Product .....	19
10 AGES - Best practise workshop on IDMP/Pharmaceutical Product .....	21
11 AGES - Training on FHIR messages based on EMA examples .....	23

### List of abbreviations

Abbreviation	Complete form
AEMPS	Agencia Espanola de Medicamentos y Productos Sanitarios
AFMPS	Federal Agency for Medicines and Health Products
AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
EESAM	(Estonian) State Agency of Medicines
EMA	European Medicines Agency
EU IG	EU IDMP Implementation Guide
FIMEA	Laakealan Turvallisuus-Ja Kehittamiskeskus
HALMED	Agencija Za Lijekove I Medicinske Proizvode
HMA	Heads of Medicines Agencies
HPRA	Health Products Regulatory Authority
IDMP	Identification of Medicinal Products
INFARMED	Autoridade Nacional do Medicamento e Produtos da Saude Ip
NCA	National Competent Authority
NoMA	Statens Legemiddelverk
OMS	Organisation Management Services
PMS	Product Management Services
RMS	Referentials Management Services
SEMPA	Swedish Medical Products Agency
SMS	Substance Management Services
SPOR	EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities. The four SPOR data management services are: SMS, PMS. OMS, RMS
TEHIK	Tervise ja Heaolu Infosüsteemide Keskus (Estonia)
UNICOM	Up scaling the global univocal identification of medicines

WP	Work package
----	--------------

## 1 Executive summary

In order to implement ISO IDMP standards at national authority (NCAs) level, preparatory work on IT systems and existing medicinal product data repositories is necessary. This preparation is a prerequisite to be able to provide ISO IDMP compliant data to eHealth organisations.

Relevant implementation tasks are carried out in WP 4 related tasks, in which 11 national competent authorities have setup local implementation projects to implement new IDMP compatible systems or to refactor existing software systems towards IDMP.

WP 4 also includes the organisation of annual best practise workshops. Sharing knowledge, exchanging information and best practises are objectives as well as discussing lessons learned within the group. The outcome will be used as input for ongoing work within the group, outside this WP but also outside the UNICOM consortium.

At the time of creation of this report, 14 best practise and knowledge sharing sessions took place held by partners from UNICOM WP4. Five sessions were covered in the report D4.15 annual lessons learned workshops with interested NCA and the other 9 sessions are covered in this report.

Subsequently both lessons learned workshops held by the individual partners (NCAs in WP4) and the best practise sharing presentation arranged centrally by WP4 will be covered in the same report.

The next update of this document is expected on 31.5.2023 and in month 48, with the objective to have one complete document with all workshops and lessons learned over the lifetime of UNICOM.

## 2 Workshops with NCAs

### 2.1 Overview

The Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) states that European Union (EU) Member States, marketing authorisation holders and EMA shall make use of the ISO IDMP standards.

Implementing the national standards at national level is rather complex and participating member identified similar challenges. All partners in WP4 are in different starting positions and at different stages of implementation, but they all face common challenges and obstacles.

Sharing knowledge, lessons learned, and solutions is therefore a key element to support a certain level of harmonised IDMP implementation at regulatory level. It is key to implement the standards in a unified way to enable data exchange between NCAs and other essential partners (eHealth, ePrescription, cross-border-prescription) of the system and also between NCAs and EMA for regulatory purposes.

In order to facilitate presentations of best practise, share knowledge and lessons learned the WP4 arranges a series of best practise and knowledge sharing workshops that will be held annually.

The first series of workshops was held in 2020 and has continued during the project.

The workshops include a best practise presentation held by the relevant NCA and a lively interactive session where participating partners can share experiences and lessons learned and discuss relevant topics related to the presentation.

### 2.2 List of held workshops (Reporting date 02.06.2022)

Date	Topic	Host	Participants
2020-11-27	HALMED - Best practise and knowledge sharing session	HALMED, Croatia	AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED
2021-02-05	Project SAFEST and FHIR implementation	NoMA, Norway	AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED and other UNICOM partners
2021-02-26	AEMPS - Best practise and knowledge sharing session	AEMPS, Spain	AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED and other UNICOM partners
2021-03-12	FIMEA - Best practise and knowledge sharing session	FIMEA, Finland	AGES, EESAM, FIMEA, BfArM, HPRA, NOMA,



			AEMPS, SEMPA, AFMPS, HALMED, INFARMED and other UNICOM partners
2021-03-25	UNICOM WP4 Best practise workshop on IDMP ingredient	AGES, Austria	AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED and other UNICOM partners
2021-05-04	Telematics Forum on UNICOM and IDMP including a special topic on “Ingredients”	AGES, Austria	All NCAs, EMA
2021-05-10	UNICOM WP4 Best practise workshop on IDMP manufactured items and packaged medicinal product	AGES, Austria	All NCAs and other UNICOM partners
2021-06-02	Best practice workshop on IDMP/Pharmaceutical Product	AGES, Austria	Partners and NCAs
2022-03-30	Training on FHIR messages based on EMA examples	AGES, Austria	All NCAs and UNICOM partners

### 3 HALMED - Best practise and knowledge sharing session

	Host / Presenters
<b>2020-11-27</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> HALMED, Croatia  <b>Presenters</b> <ul style="list-style-type: none"> <li>• Maja Lovrek Romčević, HALMED</li> <li>• Sanja Grčić Plečko, HALMED</li> </ul>

#### Agenda

- ▶ About HALMED
- ▶ HALMED IT system and IT team
- ▶ RMS implementation and experience
- ▶ OMS implementation and experience
- ▶ Best practise on PMS and SMS
- ▶ Data model and refactoring transition strategy

#### Participants

NN participants from the following NCAs and stakeholders:

AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED, EMPIRICA, TEHIK, Industry 62

#### Lessons learned

- ▶ Internal business experts' engagement is crucial for success of system development
- ▶ Database built on RDM 3.0 data model makes transition to IDMP data model easier than starting from scratch
- ▶ Introduction of new processes related to calculation of maximum wholesale medicinal products' price helped us better understand ISO IDMP data model and to detect gaps in internal system
- ▶ It's never time to focus all your resources on developing new system – we found the way to continue work in old one, with the new UI „skin” and continue gradually refactor the code and database
- ▶ Participating in the project of building National medicinal product database gives us opportunity to foster SPOR and ISO IDMP data model on National level
- ▶ Good timing: we'll have the opportunity to firstly clean data, do the mapping with SPOR lists, refactor our database and then connect to National eHealth services

## 4 Project SAFEST and FHIR Implementation

	Host / Presenters
<b>2021-02-05</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> NOMA, Norway  <b>Presenters</b> <ul style="list-style-type: none"> <li>• Helga Festøy</li> <li>• Stine Johansen</li> </ul>

### Agenda

- ▶ About the project SAFEST
- ▶ Actors and setup
- ▶ Background and drivers
- ▶ Goals
- ▶ Standards
- ▶ FHIR in SAFEST

### Participants

NN participants from the following NCAs and stakeholders:

AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED, EMPIRICA, TEHIK, Industry 62 and UNICOM partners

### Lessons learned and recommendations

- ▶ Define your goals and targets
- ▶ Identify your consumers and collaborate
- ▶ Use the FHIR Community with a lot of people wanting to help
- ▶ Domain expertise is important when profiling
- ▶ Use cases will help when profiling
- ▶ FHIR enables reuse of resources
- ▶ FHIR R4 lacks properties for base information. Use of extensions are necessary
- ▶ FHIR R5 will cover all parts of the resources better. Less use of extensions is necessary
- ▶ "Someone has to jump first"

## 5 AEMPS - Best practise and knowledge sharing session

	Host / Presenters
<b>2021-02-26</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> AEMPS, SPAIN  <b>Presenters</b> <ul style="list-style-type: none"> <li>• José Manuel Simarro Escribano, AEMPS</li> <li>• Ana López de la Rica Manjavacas, AEMPS</li> <li>• Gianluca Risi</li> <li>• Kine Toure Lam, AEMPS</li> </ul>

### Agenda

- ▶ AEMPS Introduction
- ▶ GAP Analysis
  - ▶ National SPOR Management
  - ▶ Implementation of the identified changes to make national database ISO IDMP compatible
- ▶ eAF loading into national database
- ▶ SPOR Synchronisation
- ▶ SPOR API
- ▶ Inclusion of clinical particulars structured data from SmPC.
- ▶ Lessons learned

### Participants

NN participants from the following NCAs and stakeholders:

AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED, EMPIRICA, TEHIK, Industry 62 and UNICOM partners

### Lessons learned

- ▶ eAF loading into national database
  - ▶ Based on Microsoft SQL Server Integration Services (SSIS) ETL technology
  - ▶ Massive use of XSLT transformations to reduce schema complexity of the input document
  - ▶ Use of an intermediate storage area (staging) where all data from eAF are loaded
  - ▶ Loading of needed data into national databases: RAEFAR\_II (for human eAFs), RAEVET\_II (for veterinary ones)
  - ▶ “Everything or nothing” loading strategy in destination dB (Transactional behaviour)

- ▶ Development of a FHIR PMS client application is ongoing
  - ▶ Based on Microsoft .NET framework (widely used at AEMPS)
  - ▶ Use of a third-party library (fhir-net-api) to handle (de)serialization of FHIR objects

## 6 FIMEA - Best practise and knowledge sharing session

	Host / Presenters
<b>2021-03-12</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> FIMEA, Finland  <b>Presenters</b> <ul style="list-style-type: none"> <li>• Mika Kuivamäki, FIMEA</li> <li>• Marko Kallio, FIMEA</li> <li>• Sofia Lahtonen, FIMEA</li> <li>• Leena Pietilä, FIMEA</li> </ul>

### Agenda

- ▶ Introduction
- ▶ About Fimea & Marketing authorisations
- ▶ Fimea's tasks in UNICOM
- ▶ Fimea's register platform & Marketing authorisation and medicinal product register (Saga)
- ▶ Saga Demo
- ▶ Fimea's medicinal product information for eHealth – big picture
- ▶ Challenges & Lessons learned

### Participants

NN participants from the following NCAs and stakeholders:

AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED, EMPIRICA, TEHIK, Industry 62 and UNICOM partners

### Lessons learned

- ▶ Medicinal product data is widely used and there needs to be a clear picture of the stakeholders and their data usage
- ▶ Several simultaneous projects and use cases to consider while making changes to the data model
  - ▶ Marketing authorisations, medicinal product lists and reports, automatic publications, NVR/UPD, Adverse reaction applications R2->R3, Drug availability and Covid-19 reporting, Legacy system renewals.
- ▶ Ambition level high for a small agency
  - ▶ Phase the work in smaller junks and isolate changes!

- ▶ Everything needs to be in sync to work!
  - ▶ Architecture and project management office
  - ▶ Small team can be beneficial at times
    - ▶ IT and business has learned to speak the same language
  - ▶ Organization and responsibilities around eHealth are complex and projects in different agencies need to be in sync
    - ▶ Fimea / Kela Kanta-services / Pharmaceuticals Pricing Board / Finnish institute for health and welfare (THL)
    - ▶ Public & Private medicinal product dictionaries and their distribution

## 7 AGES - UNICOM WP4 Best practise workshop on IDMP Ingredient

	Host / Presenters
<b>2021-03-25</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> AGES, Austria  <b>Presenters</b> <ul style="list-style-type: none"> <li>Georg Neuwirther, AGES</li> </ul>

### Agenda

- ▶ Introduction
- ▶ Where to find ingredients in IDMP standards
- ▶ Links, definition (what is an ingredient)
- ▶ Where to find ingredients in the EU IG
- ▶ Where to find ingredients in FHIR
- ▶ AS-IS situation in PHAROS
- ▶ TO-BE situation in PHAROS
- ▶ Discussion and feedback/alignment in the network

### Participants

NN participants from the following NCAs and stakeholders:

AGES, EESAM, FIMEA, BfArM, HPRA, NOMA, AEMPS, SEMPA, AFMPS, HALMED, INFARMED, EMPIRICA, TEHIK, Industry 62 and UNICOM partners

### Lessons learned

- ▶ The ingredient is the use of a substance within a medicinal product describing its amount and its role (active or excipient). (Definition by AGES)
- ▶ Ingredients are not the same as substances!
- ▶ Ingredients use and enrich substances
- ▶ Ingredients are essential components for manufactured items and pharmaceutical products
- ▶ TO-BE Pharos (local system) – Focus on ingredient
  - ▶ From a conceptual perspective the to-be situation will look very similar
  - ▶ Apart from the following modifications:
    - ▶ Splitting of strength into presentation and concentration
    - ▶ Strength denominator (unit of presentation/measurement) only once for all ingredients
    - ▶ Reference substance will become structured information



## 8 AGES/SEMPA - Telematics Forum about UNICOM WP4 and IDMP including a special topic on “Ingredients”

	Host / Presenters
<b>2021-05-05</b> Virtual (WebEx Platform)	<b>NCA</b> SEMPA, Sweden and AGES, Austria  <b>Presenters</b> <ul style="list-style-type: none"> <li>• Christer Backman, SEMPA</li> <li>• Pelle Persson, SEMPA</li> <li>• Georg Neuwirther, AGES</li> </ul>

### Agenda

- ▶ Overview UNICOM
- ▶ Overview IDMP
- ▶ Special topic on Ingredients

### Participants

47 participants from NCAs in EU Medicinal Regulatory Network and EMA

[National competent authorities \(human\) | European Medicines Agency \(europa.eu\)](#)

### Lessons Learned

- ▶ UNICOM
  - ▶ Vision
    - ▶ Improving patient safety
    - ▶ Facilitating better healthcare for all
  - ▶ Mission
    - ▶ Enabling the univocal identification of medicinal products by supporting and accelerating the
    - ▶ further development,
    - ▶ implementation, and
    - ▶ diffusion of ISO IDMP standards (IDentification of Medicinal and pharmaceutical Products)
    - ▶ across European health systems, to
    - ▶ facilitate the free flow of semantically coded interoperable medicinal product information

▶ IDMP Ingredients

- ▶ The ingredient is the use of a substance within a medicinal product describing its amount and its role (active or excipient). (Definition by AGES)
- ▶ Ingredients are not the same as substances!
- ▶ Ingredients use and enrich substances
- ▶ Ingredients are essential components for manufactured items and pharmaceutical products
- ▶ TO-BE Pharos (local system) – Focus on ingredient
  - ▶ From a conceptual perspective the to-be situation will look very similar
  - ▶ Apart from the following modifications:
    - ▶ Splitting of strength into presentation and concentration
    - ▶ Strength denominator (unit of presentation/measurement) only once for all ingredients
    - ▶ Reference substance will become structured information

## 9 AGES - UNICOM WP4 Best practise workshop on IDMP Manufactured Items and Packaged Medicinal Product

	Host / Presenters
<b>2021-05-10</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> AGES, Austria  <b>Presenters</b> <ul style="list-style-type: none"> <li>Georg Neuwirther, AGES</li> </ul>

### Agenda

- ▶ Introduction
- ▶ Where to find manufactured item and packaged medicinal product in IDMP standards
- ▶ Links, definition
- ▶ Where to find manufactured item / packaged medicinal product in the EU IG
- ▶ Where to find manufactured item / packaged medicinal product in FHIR
- ▶ AS-IS situation in PHAROS
- ▶ TO-BE situation in PHAROS
- ▶ Discussion and feedback/alignment in the network

### Participants

59 participants from NCAs in EU Medicinal Regulatory Network and EMA and UNICOM partners

[National competent authorities \(human\) | European Medicines Agency \(europa.eu\)](#)

[UNICOM partners \(unicom-project.eu\)](#)

### Lessons learned

- ▶ A “Manufactured Item” is defined by individual ingredients and physical characteristics and is linked to specific package item containers (Definition by EU IG)
- ▶ “Unit of presentation” are countable items like vial, tablet, capsule, inhaler, actuation but never ml, mg.
- ▶ “Manufactured dose form” are countable items like film-coated tablet, capsule hard, inhaler, solution for injection but never ml, mg.
- ▶ Manufactured Items can be reused/referenced if
  - ▶ e.g. solid forms: pack sizes contain different numbers of **identical** tablets
  - ▶ e.g. power

- ▶ e.g. liquid forms: pack sizes contain different numbers of **identical** vials (e.g. 15\*10ml vial)
- ▶ Manufactured Items can NOT BE reused/referenced to different packages if:
  - ▶ The strength presentation of ingredients of the manufactured item is different (e.g. 15\***10** ml vial, 15\***20**ml vial)
- ▶ Same strength presentation is a pre-requisite to reuse the same manufactured item.
- ▶ A “Packaged Medicinal Product” is an object which is authorised and maintained during the lifecycle of the “Medicinal Product”. The physical representation of a “Packaged Medicinal product” is called Package Item” (e.g. sales representation) (Definition by AGES)
- ▶ Packaged Medicinal Products are mandatory objects but are still “virtual/abstract” e.g. in AT: cannot be bought in a pharmacy. “Package Items” are the sales representations

## 10 AGES - Best practise workshop on IDMP/Pharmaceutical Product

	Host / Presenters
<b>2021-06-02</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> AGES, Austria  <b>Presenters</b> <ul style="list-style-type: none"> <li>Georg Neuwirther, AGES</li> </ul>

### Agenda

- ▶ Introduction
- ▶ Where to find pharmaceutical product in IDMP standards
- ▶ Links, definition
- ▶ Where to find pharmaceutical product in the EU IG
- ▶ Where to find pharmaceutical product in FHIR
- ▶ AS-IS situation in PHAROS
- ▶ TO-BE situation in PHAROS
- ▶ Discussion and feedback/alignment in the network

### Participants

Participants from NCAs in EU Medicinal Regulatory Network and UNICOM partners

- ▶ [National competent authorities \(human\) | European Medicines Agency \(europa.eu\)](#)
- ▶ [UNICOM partners \(unicom-project.eu\)](#)

### Lessons learned

- ▶ Differentiation between the concepts of Medicinal Product, Pharmaceutical Product and Manufactured Item was explained and discussed. A pharmaceutical product is a medicinal product in the final form which is suitable for administering to a patient (after any mixing of multiple components, dissolution etc. has been performed). (Definition by HL7). See also the definition from the EU IG: A pharmaceutical product refers to the qualitative and quantitative composition of a medicinal product in the pharmaceutical form, approved for administration to the patient, in line with the regulated product information.
- ▶ Mapping of concept names: Pharmaceutical Product (EU IG) = Administrable Product Definition (FHIR)

- ▶ Implementing these concepts is a major technical challenge for national IT systems: The concept of a pharmaceutical product does not yet exist in PHAROS! PHAROS describes data on the manufactured item level.
- ▶ Implementing these concepts is also a challenge in the context of data migration:
  - ▶ e.g. creating pharmaceutical products based on existing information via automatic and manual tasks.
    - ▶ Assign relevant Manufactured Items to a Pharmaceutical Product
    - ▶ Create an ingredient list from referenced Manufactured Items.
    - ▶ Modify ingredient list attributes (e.g. strength concentration, substance name) if necessary
    - ▶ Active ingredients strength might change due to reconstitution; might result in a new ingredient resource for the pharmaceutical product
- ▶ Mostly ingredient lists of pharmaceutical products and manufactured items will be identical. The IT systems must support these scenarios to keep the additional workload for the users as low as possible.
- ▶ Pharmaceutical products will reference ingredients from manufactured items if data is identical.

## 11 AGES - Training on FHIR messages based on EMA examples

	Host / Presenters
<b>2022-03-30</b> Virtual (Microsoft Teams Platform)	<b>NCA</b> AGES, Austria  <b>Presenters</b> <ul style="list-style-type: none"> <li>• Georg Neuwirther, AGES</li> <li>• Noel Diamant, AGES</li> </ul>

### Agenda

- ▶ Introduction
- ▶ Know how to read FHIR messages that describe medicinal products
- ▶ Discussion and feedback
- ▶ Alignment in the network

### Participants

94 Participants from NCAs in EU Medicinal Regulatory Network and UNICOM partners

[National competent authorities \(human\) | European Medicines Agency \(europa.eu\)](#)

[UNICOM partners \(unicom-project.eu\)](#)

### Lessons learned

- ▶ There are two physical representations: JSON and XML
- ▶ Medicinal Product data consists of the following resources: medicinal product definition, administrable product definition, manufactured item definition, ingredient, provenance, packaged product definition, device definition, regulated authorisation
- ▶ 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
- ▶ 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.
- ▶ Not all references can be drilled down
  - ▶ e.g. ReferenceAuthorisation always links from the authorisation away to the entity that is authorised
- ▶ A Codeable Concept can contain
  - ▶ a catalogue or

- ▶ a text if there is no code yet
- ▶ A Codeable Concept is mainly used for RMS Catalogues
- ▶ 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)