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Deliverable 4.14:

Delivery of selected ISO IDMP medicinal product data for crossborder pilots

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Main author(s):

Georg Neuwirther	AGES
Christer Backman	SE-MPA
Pelle Persson	SE-MPA
Peter Bachmann	BfArM
Triin Mäesalu	EESAM
Rutt Lindstrom	TEHIK

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Deliverable abstract

In Deliverable D4.14 an unspecified number of NCAs shall provide ISO IDMP medicinal product data of selected medicinal products The data should be used by other partners of UNICOM for cross-border pilots.

Keywords: NCAs, Pilot Product List, PPL, IDMP, data

TABLE OF CONTENTS

LIST OF FIGURES

List of abbreviations

Abbreviation	Complete form
AGES	Österreichische Agentur Für Gesundheit Und Ernährungssicherheit
EESAM	(Estonian) State Agency of Medicines
eDispensation	Electronic dispensation
EMA	European Medicines Agency
ePrescription	Electronic prescription
EU IG	EU IDMP Implementation Guide
FHIR	Fast Healthcare Interoperability Resources
FIMEA	Laakealan Turvallisuus-Ja Kehittamiskeskus
HPRA	Health Products Regulatory Authority
IDMP	Identification of Medicinal Products
ISO	International Organisation for Standardization
MPID	Medicinal Product Identifier
NCA	National Competent Authority
OMS	Organisation Management Services
PMS	Product Management Services
PPL	Pilot Product List
RMS	Referentials Management Services
SE MPA	Swedish Medical Products Agency
SMS	Substance Management Services
SPOR	Substances, Products, Organisations, Referentials. 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
WP	Work Package

1 Executive summary

In order to perform the different pilots in other Work Packages a number of medicinal product data need to be provided by NCAs. Ideally the products should be marketed in more than 2 of the NCA partners in WP4 and data should come from between 3 and 5 NCAs.

There is also a need for the agreed FHIR server as a central tool to achieve the progress on further development, testing and piloting IDMP structured and coded data preparation and exchange. However, this is not in the remit of WP4.

By the time of this report six (6) NCAs, AGES, EESAM, FIMEA, HPRA, INFARMED and SE-MPA have expressed their willingness to provide ISO IDMP compatible medicinal product data from their national data bases.

Since there is currently no automation possible to retrieve IDMP data from national databases, the data for three products will be the start. The data initially has to be collected manually by NCAs staff.

A Task Force on PPL (Product Pilot List) has been established and also bilateral meetings between WP4 and WP 5-7 and 9 has been organised. WP5 has produced a minimal attribute list suitable for their pilots. Recently also a group of NCAs together with WP9 have regular meetings with discussions on practical issues related to the attributes and using the FHIR concept.

2 Background

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.

The UNICOM project shall deliver a power of new standards regarding product information that will be demonstrated through deploying a common EU IDMP-compliant repository of medicinal products to go beyond a use case and realise the end-to-end process of full cross-border ePrescription and eDispensation.

In this way UNICOM will very strongly support more rapid achievement of the two major goals specified in the Call:

1. The cross-border mobility of European patients by facilitating ePrescription services based on IDMP coded data, support of safer dispensation, and generally enabling the safe exchange of univocally identifiable information on medicinal/pharmaceutical products across borders.
2. The implementation of IDMP standards in Member States drug databases (including linkages to the EMA master data management for Substances, Products, Organisations and Referentials - SPOR) in support of improved patient safety – such that the reliable exchange of medicinal product information is facilitated in a robust and consistent manner, like the identification of locally available medicinal products which are equivalent to the one identified in a foreign prescription.

The timeline of UNICOM is not matching the development of refactoring or building new databases by NCAs. The mapping and handling of legacy data and finalising the databases was planned towards the end of the UNICOM project but the providing of data for cross border pilots is scheduled to the middle of the project. This will make it impossible to have an automated process and force the NCAs to manually export data.

3 Data availability analysis

WP9 provided an (excel) list of attributes (medicinal product data) that would be used for pilots.

The list is based on the IDMP logical model and color coded in the same way.

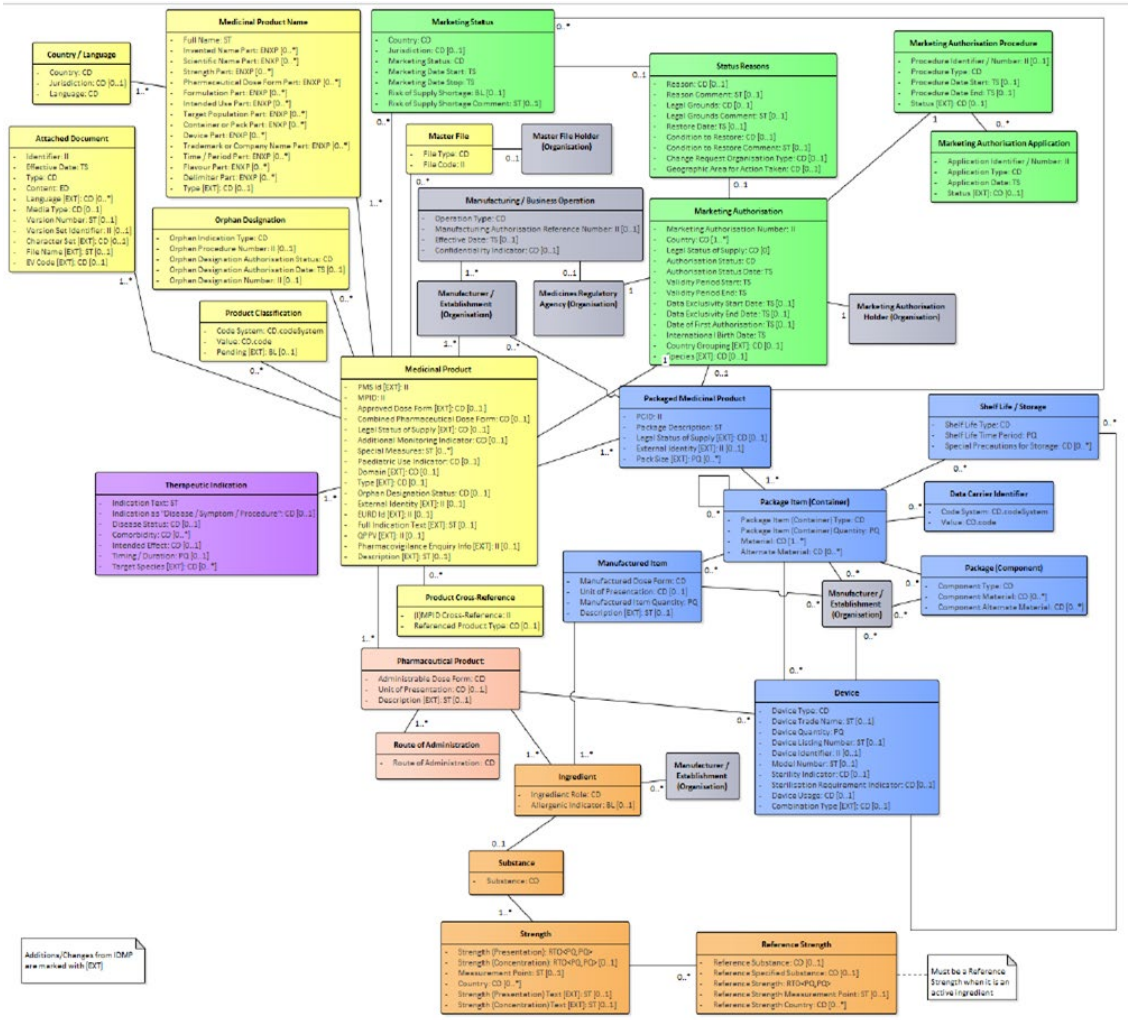

Figure 1 IDMP Logical Model

This list was extensive and all fields may not be useful for all pilots. Four NCAs has then identified which data in the list they are able to provide in a relatively short period of time (green) and data that cannot be made available (red) and data that can be provided at a later stage (orange).

3.1 Medicinal Product

The medicinal product elements are the core elements of IDMP and represent the top level of the data elements.

EMA Implementation Guide Section V1 (2020-02)	Class	Category	Status AGES	Status SE-MPA	EE	FI	Sub-Category	Sub-Sub-Category	User Guidance	Conformance	Data Type	Value(s)	ISO Element Name	ISO Path	FHIR Element Name	FHIR Path	Examples or Comments	Link to SPOR List
1,1	MedicinalProduct	Medicinal product identifier (MPID)	n/a no algorithm published	n/a no algorithm published	n/a no algorithm published	n/a no algorithm published			MPID must be assigned to each authorised medicinal	Never	Identifier	ID generated by the system	MPID	/MedicinalProduct/MPID	Identifier	MedicinalProductDefinition.identifier		
1,2	MedicinalProduct	Domain	ok	ok	ok	ok			The domain must be provided as a term ID. • The	Mandatory	CodeableConcept	Listed in the Domain RMS List	Domain	/MedicinalProduct/Domain	domain	MedicinalProductDefinition.domain	Human use (100000000012)	https://spor.ema.europa.eu/rmswi/
1,4	MedicinalProduct	Combined pharmaceutical dose form	data mapping necessary - medium	Data available, mapping done	Data available, mapping done	Data available			The combined pharmaceutical dose form(s)	Conditional	CodeableConcept	As applicable in SPOR RMS Combined pharmaceuti	Combined Pharmaceutical Dose Form	/MedicinalProduct/CombinedPharmaceuticalDoseForm	combinedPharmaceuticalDoseForm	MedicinalProductDefinition.combinedPharmaceuticalDoseF	Powder' and 'solvent' are two manufactur	https://spor.ema.europa.eu/rmswi/
1,6	MedicinalProduct	Additional monitoring indicator	n/a - high	No reliable source of data	ok	ok			The value indicating whether the medicinal product is	Mandatory	Boolean	True, False	Additional Monitoring Indicator	/MedicinalProduct/AdditionalMonitoringIndicator	additionalMonitoringIndicator	MedicinalProductDefinition.additionalMonitoringIndicator	This medicinal product is subject to additional	
1.11.3	Medicinal product	Product classification	ok	Data available, mapping done	ok	ok	ATC Code(s)		The ATC code as indicated in section 5.1 Pharmacod	Mandatory	CodeableConcept	Listed in the RMS list Anatomical Therapeutic Chemical	Product Classification	/MedicinalProduct/ProductClassification	productClassification	MedicinalProductDefinition.productClassification	100000094688 methyldopa (levorotatory)	https://spor.ema.europa.eu/rmswi/
1.12.1	MedicinalProduct	Medicinal product name	in national language, but not all have the full name in the DB	Full name is available	Full name as in SPC section 1 is not available in the current DB, but will be populated during migration	ok	Full name		The full medicinal product name as indicated in Section 1: Name of the	Mandatory	String	The full medicinal product name as free text.	FullName	/MedicinalProduct/MedicinalProductName/FullName	productName	MedicinalProductDefinition.name.productName		

Figure 2 – Data availability Medicinal Product

The MPID can at the time being not be made available since no algorithm is agreed upon or published. There are no open questions for the rest of the data elements to continue data enrichment or mapping tasks.

3.2 Pharmaceutical Product - Administrable Dose Form

The pharmaceutical product concept is a new concept for most of the NCA's

EMA Implementation Guide Section V1 (2020-02)	Class	Category	Status AGES	Status SE-MPA	EE	FI	Sub-Category	Sub-Sub-Category	User Guidance	Conformance	Data Type	Value(s)	ISO Element Name	ISO Path	FHIR Element Name	FHIR Path	Examples or Comments	Link to SPOR List
4,1	MedicinalProduct	Pharmaceutical product	not available, new concept in IMDP	Not available in SE-MPA data	Will be available after migration in our new DB	Question: What data is needed for prescription	AdministrableDose Form		The administrable dose form corresponds with the	Mandatory	CodeableConcept	Listed in the RMS Pharmaceutical Dose Form list	AdministrableDose Form	/MedicinalProduct/PharmaceuticalProduct/AdministrableDo	administrableDoseForm	AdministrableProductDefinition.administrableDoseForm	100000073863 Solution for injection; 100000073375	https://spor.ema.europa.eu/rmswi/
FDA Presentation 02-2020	MedicinalProduct	Pharmaceutical product	not available, new concept in IMDP		Extended Attributes of Administrable Dose Form term?		AdministrableDose Form	Administration Method (AME)		Mandatory	CodeableConcept	Listed in the RMS Administration Method list		?			200000002052 Swallowing	https://spor.ema.europa.eu/rmswi/
FDA Presentation 02-2020	MedicinalProduct	Pharmaceutical product					AdministrableDose Form	Intended Site (ISI)		Mandatory	CodeableConcept	Listed in the RMS Intended Site list		?			200000002064 Oral 200000002062 Nasal 200000002	https://spor.ema.europa.eu/rmswi/
FDA Presentation 02-2020	MedicinalProduct	Pharmaceutical product					AdministrableDose Form	Transformation (TRA)		Mandatory	CodeableConcept	Listed in the RMS Transformation list		?			200000002071 Dilution 200000002075 No transformati	https://spor.ema.europa.eu/rmswi/
FDA Presentation 02-2020	MedicinalProduct	Pharmaceutical product	?				AdministrableDose Form	Release Characteristics (RCA)		Mandatory	CodeableConcept	Listed in the RMS Release charactaristics list		?			200000002077 Delayed	https://spor.ema.europa.eu/rmswi/
FDA Presentation 02-2020	MedicinalProduct	Pharmaceutical product	?				AdministrableDose Form	Basic Drug Form (BDF)		Mandatory	CodeableConcept	Listed in the RMS Basic drug form list		?			200000002082 Block 200000002083 Cachet 200000002	https://spor.ema.europa.eu/rmswi/
FDA Presentation 02-2020	MedicinalProduct	Pharmaceutical product	?				AdministrableDose Form	State of Matter (SOM)		Mandatory	CodeableConcept	Listed in the RMS State of matter list		?			200000002021 Solid	https://spor.ema.europa.eu/rmswi/
4,2	MedicinalProduct	Pharmaceutical product			Will be available after migration in our new DB		Unit of Presentation		The unit of presentation describing the unit in which a	Mandatory	CodeableConcept	As listed in the RMS Units of Presentation list,	Unit of Presentation	/MedicinalProduct/PharmaceuticalProduct/UnitOfPresentat	unitOfPresentation	AdministrableProductDefinition.unitOfPresentation	200000002163 Actuation; 200000002121 Drop;	https://spor.ema.europa.eu/rmswi/
4,5	MedicinalProduct	Pharmaceutical product			Fully mapped, but on MP level currently. Will be migrated to PhP level in our new DB	RoA Term existing but no links between data	Route of Administration		The route of administration of the pharmaceutical form	Mandatory	CodeableConcept	As listed in Routes and Methods of Administration RMS List	Route of Administration	/MedicinalProduct/PharmaceuticalProduct/RouteOfAdminist	Code	AdministrableProductDefinition.routeOfAdministration.code	100000073564 Auricular use; 100000073	https://spor.ema.europa.eu/rmswi/

Figure 3 – Data availability Pharmaceutical Product - Administrable Dose Form

Further clarification is needed, not on conceptual level but on data element level.

3.3 Ingredient

The Ingredient concept is a new concept for most of the NCA's

EMA Implementation Guide Section V1 (2020-02)	Class	Category	Status AGES	Status SE-MPA	EE	FI	Sub-Category	Sub-Sub-Category	User Guidance	Conformance	Data Type	Value(s)	ISO Element Name	ISO Path	FHIR Element Name	FHIR Path	Examples or Comments	Link to SPOR List
5,1	MedicinalProduct	Pharmaceutical product	Mapping necessary to SMS (not yet available but support from		Will be available on PhP level in our new DB		Ingredient	Ingredient role	The role of the ingredient as part of the	Mandatory	CodeableConcept	As listed in the RMS Ingredient Role list	Ingredient Role	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Ingredi	Role	Ingredient.role	100000072072 Active; 100000072073 Adjuvant;	https://spor.ema.europa.eu/rmswi/
ISO11615:2017 9.7.2.2.3	MedicinalProduct	Pharmaceutical product					Ingredient	Allergenic indicator	This flag indicates if the ingredient is a known or	conditional	flag						100000072072 Active; 100000072073 Adjuvant;	https://spor.ema.europa.eu/rmswi/
5,2	MedicinalProduct	Pharmaceutical product	mapping to OMS necessary	No structured data on API manufacturer in SE-MPA database today. Mapping not done.	Not relevant, confidential data		Ingredient	Manufacturer	The manufacturer of the active substance (including active substance intermediate	conditional	CodeableConcept	As listed in SPOR OMS service (LOC ID)	manufacturer	MedicinalProductDefinition.manufacturingBusinessOperation.manufacturer	n.a.	n.a.	ORG-100002271 STADApharm GmbH Germany LOC-100023384 Hanover ORG-	https://spor.ema.europa.eu/omswi/#/search Organisations
5.3.1	MedicinalProduct	Pharmaceutical product		Mapping not done for active substances.	Ingredient substance data for actives not available in current DB, will be gradually completed in new DB		Ingredient	Substance	The Substances contained within the medicinal product (either part of the	Mandatory	CodeableConcept	Special for Unicom: As listed in GSRS (UNII)	Substance	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Substance	Code	Ingredient.substance.code	UTG126Z97Q diclofenac sodium; 6TGQ35Z71K diclofenac diethylamine	https://fdasrinas.ncats.nih.gov/ginas/app/substances
5.3.2.1.1	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented	Data not available for liquid presentations.			Ingredient	Substance	The strength (quantitative composition) of the	Mandatory	Ratio	The units for the numerator must be specified as	Strength (Presentation)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	Presentation	Ingredient.substance.strength.presentation	Tablet 500 mg Strength presentation single	https://spor.ema.europa.eu/rmswi/
5.3.2.1.2	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented	Data not available for liquid presentations.			Ingredient	Substance	The strength (quantitative composition) of the	Conditional	Ratio	The units for the numerator must be specified as	Strength (Presentation)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	PresentationHighLimit	Ingredient.substance.strength.presentationHighLimit	Tablet 500 mg Strength presentation single	https://spor.ema.europa.eu/rmswi/
5.3.2.2.1	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented				Ingredient	Substance	The strength (quantitative composition) of the	Mandatory	Ratio	The units for the numerator and the denominator	Strength (Concentration)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	Concentration	Ingredient.substance.strength.concentration	Solution for injection 20 mg/ml Strength concentrati	https://spor.ema.europa.eu/rmswi/
5.3.2.2.2	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented				Ingredient	Substance	The strength (quantitative composition) of the	Mandatory	Ratio	The units for the numerator and the denominator	Strength (Concentration)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	ConcentrationHighLimit	Ingredient.substance.strength.concentrationHighLimit	Solution for injection 20 mg/ml Strength concentrati	https://spor.ema.europa.eu/rmswi/
5.3.3.1	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented	Mapping not done for active substances.	Maping just started, will be available in new DB (cleansing needed during migration)		Ingredient	Substance	The reference substance of the active	Conditional	CodeableConcept	As listed in the SMS List	Reference Substance	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	Substance	Ingredient.substance.strength.referenceStrength.substanc	Containing 538.20 mg of valproate semisodium per tablet	
5.3.3.1.2	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented	Data not available for liquid presentations.			Ingredient	Substance	The reference strength (quantitative composition	Conditional	Ratio	The units for the numerator must be specified as	Strength (Presentation)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	Presentation	Ingredient.substance.strength.presentation	Containing 538.20 mg of valproate semisodium per tablet	
5.3.3.1.3	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented	Data not available for liquid presentations.			Ingredient	Substance	The reference strength (quantitative composition	Conditional	Ratio	The units for the numerator must be specified as	Strength (Presentation)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	PresentationHighLimit	Ingredient.substance.strength.presentationHighLimit		
5.3.3.2.1	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented				Ingredient	Substance	The reference strength (quantitative composition	Mandatory	Ratio	The units for the numerator and the denominator	Strength (Concentration)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	Concentration	Ingredient.substance.strength.concentration		
5.3.3.2.2	MedicinalProduct	Pharmaceutical product	Harmonisation necessary how represented				Ingredient	Substance	The reference strength (quantitative composition	Conditional	Ratio	The units for the numerator and the denominator	Strength (Concentration)	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Subst	ConcentrationHighLimit	Ingredient.substance.strength.concentrationHighLimit		

Figure 4 – Data availability Ingredient

Since it is a new concept, data is not available or only partial available in NCA databases.

3.4 Packaged Medicinal Product

For Packaged Medicinal Product IDMP introduces a more complex data model. The packages are a key element for eHealth activities.

EMA Implementation Guide Section V1 (2020-02)	Class	Category	Status AGES	Status SE-MPA	EE	FI	Sub-Category	Sub-Sub-Category	User Guidance	Conformance	Data Type	Value(s)	ISO Element Name	ISO Path	FHIR Element Name	FHIR Path	Examples or Comments	Link to SPOR List
6,1	MedicinalProduct	Packaged medicinal product	no algorithm published yet	Will Unicom create an algorithm?			Packaged Medicinal Product Identifier PCID		For each Packaged Medicinal Product, a unique PCID	Never	Identifier	ID generated by the system	PCID	/MedicinalProduct/PackagedMedicinalProduct/PCID	Identifier	PackagedProductDefinition.identifier	DE-676800000346-001-002 EU-	
6,2	MedicinalProduct	Packaged medicinal product	in national translation		Not currently available as free text field		Package description		A description of the packaged medicinal	Mandatory	Markdown	The description of the packaged medicinal	Package description	/MedicinalProduct/PackagedMedicinalProduct/PackageDes	Description	PackagedProductDefinition.description	Section 6.5 Nature and contents of container: 84 or 100	
6.2.1	MedicinalProduct	Packaged medicinal product					Package description	Language	The language of the package description as specified	Mandatory	CodeableConcept	As listed in the Language RMS list	Not Applicable	Not Applicable	valueCode	PackagedProductDefinition.description.extension.valueCod	100000072147 English	http://hl7.org/fhir/extension-
6.5.2	MedicinalProduct	Packaged medicinal product		No number set on package level in SE. Is this to be left empty then?	Is it needed for CP? We would use only the stable 'root' number at the medicinal product level (e.g. EU/1/YY/NNNN)	Only for centralized	Marketing Authorisation (Package level)	Marketing Authorisation Number (Package Level)	There are cases where marketing authorisation is assigned at the level of packaged	Mandatory	Identifier	The number assigned by the competent authority of a country/jurisdiction shall be	Marketing Authorisation Number	/MedicinalProduct/PackagedMedicinalProduct/MarketingAuthorisation/MarketingAuthorisationNumber	Identifier	RegulatedAuthorization.identifier	EU/1/YY/NNNN/XXX	
6.5.1	MedicinalProduct	Packaged medicinal product	?	Is row 41-43 then not relevant (accept for CAPs)?	CP?		Marketing Authorisation (Package level)	Regulatory Authorisation Type	The type of regulatory authorisation must be specified.	Conditional	CodeableConcept	• As listed in the Regulatory Entitlement Type RMS	Not Applicable	Not Applicable	Type	RegulatedAuthorization.type	RMS list (To be created)	
6.5.3	MedicinalProduct	Packaged medicinal product			CP?	?	Marketing Authorisation (Package level)	Country	The country code of the country where the marketing	Mandatory	CodeableConcept	As listed in the Country RMS list	Country	/MedicinalProduct/MarketingAuthorisation/Country	Region	RegulatedAuthorization.region	100000000529 – Kingdom of Spain 100000000	https://spor.ema.europa.eu/rmswi/
6.5.4	MedicinalProduct	Packaged medicinal product			CP?		Marketing Authorisation (Package level)	Authorisation status	The status of the marketing authorisation of the	Mandatory	CodeableConcept	As listed in the Regulatory Entitlement Status list in	Authorisation Status	/MedicinalProduct/MarketingAuthorisation/AuthorisationStatu	Status	RegulatedAuthorization.status	100000072099 Valid 100000072100 Expired	https://spor.ema.europa.eu/rmswi/
6.5.5	MedicinalProduct	Packaged medicinal product			CP?		Marketing Authorisation (Package level)	Authorisation status date	The date at which the authorisation status of the package	Mandatory	dateTime	A date shall be specified using the ISO 8601 date format.	Authorisation Status Date	/MedicinalProduct/MarketingAuthorisation/AuthorisationStatu	statusDate	RegulatedAuthorization.statusDate	2020-04-25	

Figure 5 – Data availability Packaged Medicinal Product, part 1

EMA Implementation Guide Section V1 (2020-02)	Class	Category	Status AGES	Status SE-MPA	EE	FI	Sub-Category	Sub-Sub-Category	User Guidance	Conformance	Data Type	Value(s)	ISO Element Name	ISO Path	FHIR Element Name	FHIR Path	Examples or Comments	Link to SPOR List
6.6.1	MedicinalProduct	Packaged medicinal product	IDMP new concecpt - not sure if all have already implemented in databases	Data not available, mapping not done Is only one level ok for PPL?	Will be available for inner package item container after migration in new DB, data cleansing needed		Package item (container)	Package item (container) type	This element describes the physical type of the container of the medicinal	Mandatory	CodeableConcept	As listed in the Packaging list.	Package item (container) type	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_Containe	Type	PackagedProductDefinition.packaged tem.type	Identifier Term Name Short Name Source Id (EDQM) 10000007349 0 Ampoule	por.ema.europa.eu/rmswi/#/lists/1000000733 46/terms
6.6.2	MedicinalProduct	Packaged medicinal product			Not all references available		Package item (container)	Package item reference(s)	This is not a regular attribute but a reference to a list of	Conditional	Packageltem	A list of package item	Package item (container)	/MedicinalProduct/PackagedMedicinalProduct/PackageItem	Package	PackagedProductDefinition.packaged tem.package	Carton containing two vials This is a simplified	
6.6.3	MedicinalProduct	Packaged medicinal product			Will be available after migration in our new DB		Package item (container)	Manufactured item reference(s)	This is not a regular attribute but a reference to a	Conditional	ManufacturedItemDefinition	A list of manufactured items	Manufactured item	/MedicinalProduct/PackagedMedicinalProduct/PackageItem	Containeditem	PackagedProductDefinition.Packaged tem.containeditem	For example, a vial containing powder will	
6.6.5	MedicinalProduct	Packaged medicinal product	not all have it structured at th moment		Not always available for all levels		Package item (container)	Package item (container) quantity	The number of the package item must be specified	Mandatory	Quantity value and unit. The units must be specified	Numeric	Package item (container) quantity	/MedicinalProduct/PackagedMedicinalProduct/PackageItem	Quantity	PackagedProductDefinition.packaged tem.quantity	Example 1: Medicinal product A 500mg tablets with	https://spor.ema.europa.eu/rmswi/
6.6.6	MedicinalProduct	Packaged medicinal product	not implementd			Attributes in DB, but no data yet	Package item (container)	Data carrier identifier	The outer-most packaging carrier identifier	Optional	Identifier	GTIN / NTIN	Data Carrier Identifier	/MedicinalProduct/PackagedMedicinalProduct/PackageItem	Identifier	PackagedProductDefinition.packaged tem.identifier	Example(s): GTIN: 028901563801609 GTIN: 0	
6.9.1	MedicinalProduct	Packaged medicinal product	not all have it structured at th moment		Will be available after migration in our new DB		Manufactured item	Unit of presentation	The unit of presentation describing the unit in which a	Conditional	CodeableConcept	As listed in the Units of Presentation RMS list, or	Unit of Presentation	/MedicinalProduct/PackagedMedicinalProduct/PackageItem	unitOfPresentation	ManufacturedItemDefinition.unitOfPresentation (as	20000000208 Barrel 15006000 CURRENT 20000000	https://spor.ema.europa.eu/rmswi/
6.9.2	MedicinalProduct	Packaged medicinal product	Manufactured is a new concept		Will be available after migration in our new DB, corrections of unit terms used needed		Manufactured item	Manufactured item quantity	The quantity (or count number) of the manufactured item in	Mandatory	Quantity	Numeric value and unit. The units must be specified as a Term			unitOfPresentation	ManufacturedItemDefinition.unitOfPresentation (as referenced	100000110653 kilogram(s) 100000110654 gram(s) 100000110	https://spor.ema.europa.eu/rmswi/
6.9.3	MedicinalProduct	Packaged medicinal product	Manufactured is a new concept	Data incomplete, some mapping still to be done.	Will be available after migration in our new DB		Manufactured item	Manufactured dose form	The manufactured dose form described	Mandatory	CodeableConcept	Listed in the Pharmaceutical Dose Form RMS list.	Manufactured Dose Form	/MedicinalProduct/PackagedMedicinalProduct/PackageItem	ManufacturedDoseForm	ManufacturedItemDefinition.manufacturedDose Form (as	Example(s): - Manufactured pharmaceuti	https://spor.ema.europa.eu/rmswi/

Figure 6 – Data availability Packaged Medicinal Product, part 2

For Packaged Medicinal Product IDMP introduces a more complex data model than what is currently implemented in NCA databases.

Structuring package information according to IDMP triggers a lot of data enrichment and mapping tasks. This undertaking has not been possible to do yet. The technical pre-requisites need to be set up to enable necessary data changes. Some of the data could possibly be aggregated manually.

4 Creating the first examples

Creating the first examples has been a fully manual effort as the NCA systems are not adapted to create FHIR messages nor is the information available in their databases. The basis of the examples was:

- HL7 FHIR 4.6 documentation (Medication Definition module)
- EMA ISO IDMP Implementation Guide 2.1
- EMA SPOR RMS, SMS and OMS
- LOSEC 20mg full application FHIR example provided by EMA

The first step was to identify the final list of PPL attributes. For this, the input gathered from other work packages was taken into account, to make sure our PPL data would be suitable for as many use cases as possible while keeping it significantly simpler than the full regulatory data would be.

The second step was to choose three products to represent according to the ISO IDMP standards as FHIR resources. These three products were: Canifug Cremolum, Cefuroxime 1500mg MIP, Betaklav 875mg/125mg. Analysing the data for these products allows the NCAs to compare the data from different countries and understand the IDMP- and FHIR-related challenges ahead.

Below is a commented xml-example for a marketing authorisation FHIR resource.

```
<RegulatedAuthorization xmlns="http://hl7.org/fhir">
    <id value="CanifugCremolum-EE-MarketingAuthorisation"/>
    <identifier>
        <system value="http://ema.europa.eu/fhir/marketingAuthorizationNumber"/
        <value value="366201"/>
    </identifier>
    <subject>
        <reference value="CanifugCremolum-EE"/>
    </subject>
    <type>
        <coding>
            <system value="https://spor.ema.europa.eu/v1/lists/220000000060"/>
            <code value="220000000061"/>
            <display value="Marketing Authorisation"/>
        </coding>
    </type>
    <region>
        <coding>
            <system value="https://spor.ema.europa.eu/v1/lists/100000000002"/>
            <code value="100000000388"/>
            <display value="Estonia"/>
        </coding>
    </region>
<!--There are many different ways to express "valid".-->
    <status>
        <coding>
            <system value="https://spor.ema.europa.eu/v1/lists/100000072049"/>
            <code value="200000017708"/>
            <display value="Valid - Renewed/Varied"/>
        </coding>
    </status>
    <statusDate value="2017-12-06"/>
<!--LOC-code might be switched to ORG-code in the future-->
    <holder>
        <identifier>
            <system value="https://spor.ema.europa.eu/v1/locations"/>
            <value value="LOC-100004795"/>
        </identifier>
        <display value="Dr. August Wolff GmbH & Co. KG Arzneimittel"/>
    </holder>
</RegulatedAuthorization>
```

Figure 7 – FHIR structure example – comments point out unanswered questions

All three products were very different in the context of representing their data in FHIR format. They are complicated products for which relevant FHIR examples have not been available. While PPL FHIR messages are trying to be fully compliant with the EMA IG, it should be noted, that the official FHIR profile for EMA PMS has not been published.

4.1 1.1 Canifug Cremolum (national procedure)

Canifug Cremolum was chosen as one of the example products to show the ISO IDMP structure for a complex package. The challenges included:

- Medicinal product containing two pharmaceutical products
- Complicated packaging layers
- Two active ingredients including the same substance but with different strength
- According to the EMA IG, reference strength should be given, even though clinically irrelevant

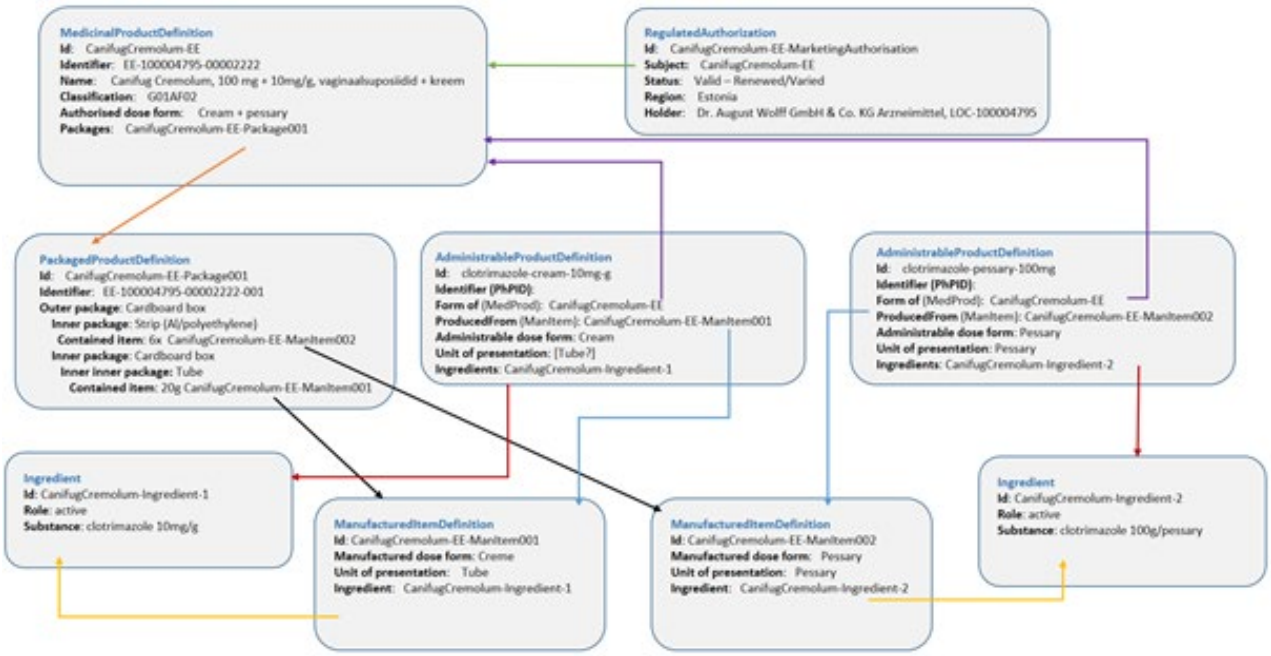

Figure 8 - Canifug Cremolum simplified schema

The schema above shows the references between different FHIR resources for this particular product. For the minimal PPL attribute list six different FHIR resources are needed, the exact composition of these resources depends on the product and packaging.

4.2 1.1 Cefuroxime 1500mg (NO/H/0218/002)

Cefuroxime 1500mg was chosen to represent the following challenges/features:

- Authorised dose form different from administrable dose form;
- Choice of unit of presentation;
- The pharmaceutical product contains water for injection, which is not part of the product data;
- Only reference strength available in SPC.

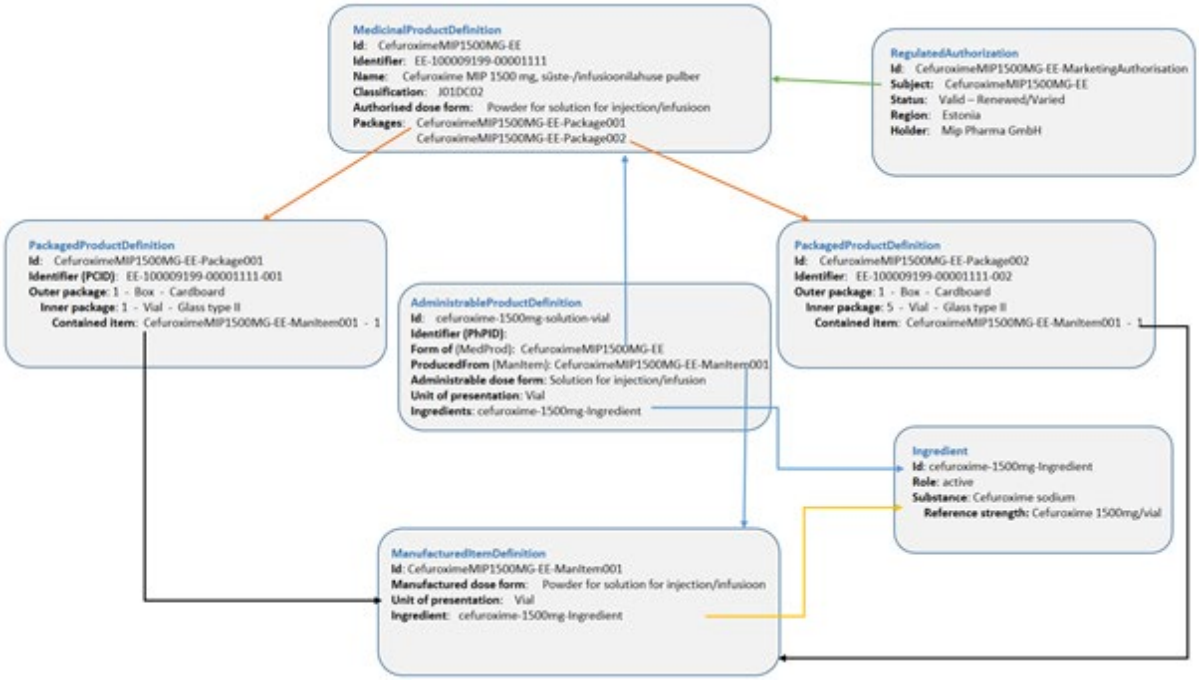

Figure 9 – Cefuroxime 1500mg simplified schema

The Cefuroxime 1500mg schema looks significantly different from the Canifug Cremolum's schema as they represent very different products/packages.

4.3 1.1 Betaklav (CZ/H/0503/002)

Betaklav 875mg/125mg was chosen to demonstrate a product that was authorised in all the five countries. Other reasons for inclusions were:

- Reference strength.
- Large amount of different pack sizes
- Different packaging materials for same pack sizes

```
<!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_Container -->
<package>
    <!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_Container/PackageItem_ContainerType -->
    <type>
        <coding>
            <system value="https://spor.ema.europa.eu/v1/lists/100000073346"/>
            <code value="100000073559"/>
            <display value="Strip"/>
        </coding>
    </type>
    <!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_Container/PackageItem_ContainerQuantity -->
    <!-- Rutt:  No quantity element when not clear how many inner packages, PMS IG p57-->

    <!-- ISO name: /MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_Container/Material -->
    <!-- Rutt: two layers, both aluminium -->
    <material>
        <coding>
            <system value="https://spor.ema.europa.eu/v1/lists/200000003199"/>
            <code value="200000003200"/>
            <display value="Aluminium"/>
        </coding>
    </material>
    <material>
        <coding>
            <system value="https://spor.ema.europa.eu/v1/lists/200000003199"/>
            <code value="200000003200"/>
            <display value="Aluminium"/>
        </coding>
    </material>
    <containedItem>
```

Figure 9 – Betaklav FHIR manual example

The Betaklav FHIR example was created in the FHIR bundle format. Comparing different technical choices were very important part of creating the first examples.

5 Conclusion

During this reporting period NCAs have been heavily affected by the Covid-19 pandemic situation and a lot of internal resources have been redirected to activities like approval of new vaccines and pharmacovigilance and the respective regulatory and IT-support related to those activities. This, together with the unexpected delays at EMA-level on EU IDMP IG and publication of PMS data has slowed down the progress with PPL.

Progress was made in the discussions on the relevant attributes for the different pilots (WP5 and WP9) and an analysis has been made by WP4 on the availability of structured data elements as required by the pilots.

Initial example data was manually created and FHIR xml-messages explored. This activity is in the starting phase and no automated creations are yet possible.

For UNICOM, it is the decision to focus on FHIR based messages, this implies that partners participating in the PPL/piloting have to plan and set up how to create FHIR messages in their systems.

According to WP9 a common infrastructure (FHIR server) could support the exchange of FHIR examples for the PPL.

As the creation of FHIR messages need to be supported by technical and data driven prerequisites currently only manually created examples are possible.

Mass produced examples cannot be expected until implementation of new systems or refactoring of current systems are finalised. This is dependent on national project plans to which UNICOM is contribution to foster and accelerate.