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1 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)

2 Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent filings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot
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Revision history

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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

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## List of abbreviations

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<tbody>
<tr>
<td>AGES</td>
<td>Österreichische Agentur Für Gesundheit Und Ernährungssicherheit</td>
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<td>EESAM</td>
<td>(Estonian) State Agency of Medicines</td>
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<td>eDispensation</td>
<td>Electronic dispensation</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>ePrescription</td>
<td>Electronic prescription</td>
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<td>EU IG</td>
<td>EU IDMP Implementation Guide</td>
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<td>FHIR</td>
<td>Fast Healthcare Interoperability Resources</td>
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<td>FIMEA</td>
<td>Laakealan Turvallisuus-Ja Kehittamiskeskus</td>
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<td>Health Products Regulatory Authority</td>
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<td>IDMP</td>
<td>Identification of Medicinal Products</td>
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<td>ISO</td>
<td>International Organisation for Standardization</td>
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<td>MPID</td>
<td>Medicinal Product Identifier</td>
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<td>NCA</td>
<td>National Competent Authority</td>
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<td>OMS</td>
<td>Organisation Management Services</td>
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<td>PMS</td>
<td>Product Management Services</td>
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<td>PPL</td>
<td>Pilot Product List</td>
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<td>RMS</td>
<td>Referentials Management Services</td>
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<td>SE MPA</td>
<td>Swedish Medical Products Agency</td>
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<td>SMS</td>
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<td>SPOR</td>
<td>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</td>
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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](image)

This list was extensive and all fields may not be useful for all pilots. Four NCAs have 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.
### 3.2 Pharmaceutical Product - Administrable Dose Form

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

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#### 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.
3.3 Ingredient

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

| 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.
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.

![Figure 7 – FHIR structure example – comments point out unanswered questions](image-url)
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

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](image)

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
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.