UNICOM

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

D5.8: Liaison with EC, MSs and stakeholders annual report

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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)

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3.1	15.10.2020	First document draft.	AC
3.2	09.10.2020	Update on Executive Summary and abstract	AC
3.3	13.11.2020	Update on the data about the 18th eHN meeting.	AC
3.4	19.11.2020	Revision of the document	CW, EC, LW
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3.9	27.10.2022	First draft of the third version of the document	AC
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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This deliverable contains original unpublished work except where clearly indicated otherwise.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

This deliverable contains the description of the relationships established between the UNICOM project with the important national and European key bodies, related more directly to the WP 5, 6 and 7 (eHealth services cluster). These relationships are extremely important for the adoption of the ISO IDMP by the national and cross-borders eHealth services providers. This deliverable shows the actions taken to liaise with the EU bodies, such as the eHealth Network and the CEF eHDSI solution provider, as well as the national stakeholders through a series of meetings where the UNICOM project was presented and agreed in liaison with these groups that will support the development of the project.

This document (Version 3) is an ongoing annual report. Following on from D5.8 Versions 1 and 2, this document includes the project liaison activities from December 2020 to November 2022.

Keywords: IDMP, UNICOM, Liaison, Stakeholders, eHN, CEF eHDSI

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Deliverable review

	Internal reviewer:			External reviewer:		
	Answer	Comments	Type *	Answer	Comments	Type *

Is the deliverable in accordance with

	Internal Answer	Comments	Type	External Answer	Comments	Type
the Description of Action?	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
the international State of the Art?	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a

Is the quality of the deliverable in a status

	Internal Answer	Comments	Type	External Answer	Comments	Type
that allows it to be sent to European Commission?	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
that needs improvement of the writing by the originator of the	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
that needs further work by the Partners responsible for the deliverable?	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a

Is the structure and contents of the deliverable

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suitable to meet its intended scope?	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
Is in conformance with UNICOM deliverable template?	☐ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a

* Type of comments: M = Major comment; m = minor comment; a = advice

List of abbreviations

Abbreviation	Complete form
CEF	Connecting Europe Facility
CP	Change Proposal
CSS	Common Semantic Strategy
eD	eDispensation
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member State Expert Group
eHN	eHealth Network
eHN SG	eHealth Network Semantic Group
EHR	Electronic Health Record
EMA	European Medicines Agency
eP	ePrescription
EU	European Union
GDPR	General Data Protection Regulation
IDMP	Identification of Medicinal Products
ISO	International Organization for Standardization
LTF	Legal Task Force
MS	Member State
MVC	Master ValueSet Catalogue
MTC	Master Translation/Transcodification Catalogue
NCA	National Competent Authority
NCPeH	National Contact Point for eHealth
PhPID	Pharmaceutical Product identifier
PS	Patient Summary
STF	Semantic Task Force
UNICOM	Up-scaling the global univocal identification of medicines
WHO	World Health Organisation
WP	Work Package

1   Executive summary

The development of European projects involving several Member States must be supported by forming and maintaining relationships between the project coordinators, Work Package (WP) leaders and key National and European bodies in order to ensure the development of the work and adoption of the project deliverables meet the expectations of the Member States.

To fulfil this expectation, the UNICOM Project is collaboratively progressing the project in close communication with the key EU eHealth bodies, such as eHealth Network communities (eHN); eHealth Digital Service Infrastructure (eHDSI) communities and national authorities (e.g., National Drug Agency, eHealth Agency, and Ministries of Health).

This deliverable presents an overview description of the liaison activities conducted by the WP5 between the UNICOM project and above-mentioned key national and EU bodies. For instance, the close cooperation between UNICOM with CEF eHDSI and eHN communities can be evidenced by the minutes from several meetings and the participation of some UNICOM members in these groups, that enhances the communication and ensures that the outcomes produced in UNICOM are aligned with the key bodies' ambitions, as well as important findings from UNICOM project can be promptly communicated. During these meetings, it was highlighted that UNICOM outcomes were already identified as important for the future standardisation of the identification of medicinal products throughout the EU. It was acknowledged that the correct medicinal product identification would support the eHealth cross-border services, such as ePrescription/eDispensation (eP/eD) and Patient Summary (PS).

The third year of the project has resulted in greater collaborate efforts between the UNICOM project and the eHDSI and eHealth Network (eHN) communities, and National Competent Authorities (NCAs), which has positively enhanced on:

- strength the relationship between UNICOM and eHDSI/eHN communities,
- active participation of members of all communities (UNICOM / eHDSI / eHN) on meetings and supporting the Wave 6-7 IDMP related implementations,
- consolidate a minimal attribute list and pilot product list to support the eP/eD & PS services among the countries.

D5.8 V3 contains the ongoing account of all liaison activities since the beginning of the project. The specific activities for each year will be catalogued into subsections and organised by year. This version of D5.8 includes project activities from December 2019 to November 2022 (V1, V2 and V3).

2   Introduction

The overarching goal of WP5 is the safe implementation and seamless flow of medicinal products (MP) data across Europe. This work package (WP) concerns the overall orchestration to adopt ISO IDMP in eHealth Services, at both National and Cross-Border levels. The focus is on ePrescription/eDispensation (eP/eD) and Patient Summary (PS) cross-border topics and implementing the ISO IDMP in national eP systems for community pharmacies, as well as establishing a connection with the related EU policy and technical bodies in addition to the National Competent Authorities (NCA).

A key activity of task 5.5 (T5.5) is to establish a liaison relationship that will implement coordination activities and communication with the relevant bodies participating in Connecting Europe Facility eHealth Digital Services Infrastructure (CEF eHDSI) for eP and PS cross-border services. It also includes interlinking with DG SANTE, MyHealth@EU[3] (CEF eHDSI Solution Owner and Solution Provider) and DG CONNECT.

D5.8 V3 contains the ongoing account of the liaison activities led by the WP5 working group. These activities have been organised by year, and the subsequent reports (V4) will follow the same process.

The deliverable D5.8 from T5.5 (Liaison with EC, Member States and stakeholders related with project), an annual report, describes the liaison activities between UNICOM WP5 and the key bodies from EU at national and EU levels.

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[3] Brand name for eHDSI which allows citizens easily recognise the availability of cross border services

3 Cooperation with CEF eHDSI

3.1 General overview

The MyHealth@EU (eHDSI) is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF) body. The CEF body is responsible for managing the deployment of core eHealth services such as ePrescription/eDispensation (eP/eD) and Patient Summary (PS) within the EU cross-border context.

It is one of the most important European bodies responsible for the operation of the cross-border eHealth services among the EU, consequently we must ensure a close a relationship with CEF to ensure the adoption of the work developed by UNICOM project.

Working closely with CEF eHDSI, the UNICOM project plans to deliver, in the pilot phase, at least 10,000 ePrescriptions and about 1,000 Patient Summaries enhanced with IDMP identifiers.

Collaboration is comprised of communities that are responsible for specific activities evolving the eHealth services at cross-border level such as:

► eHDSI Member State Expert Group (eHMSEG);
► ePrescription (eP) Cluster;
► Patient Summary (PS) Cluster;
► Semantic Task Force (STF);
► Legal Task Force (LTF);
► Architecture group;
► Requirements Work Group;

Some partners of WP5 are members of the CEF eHDSI community and support the UNICOM project development into this key EU body. WP5 is regularly updated about the eHDSI decisions to ensure that the scope of the UNICOM is in correct alignment with the CEF eHDSI bodies needs and identify opportunities to drive new changes throughout the project life cycle. Even before the official beginning of the UNICOM (December 2019), there has been an alignment between CEF eHDSI and UNICOM proposal submission. Current CEF eHDSI requirements inform the project design and are reflected in the submission of the proposal as UNICOM outcomes.

The WP5 deliverables from the tasks T5.2, T5.3 and T5.4, presents a strong technical and semantic perspective at a cross-border level. Work includes the introduction of change proposals to the existing CEF eHDSI structures in order to implement the ISO IDMP in cross-border eHealth services in operation. The success of this initiative is dependent on close cooperation between the project and eHDSI and the sharing of intellectual property. CEF eHDSI business requirements working group and the eHMSEG Semantic Task Force work closely together with the UNICOM project to support the development/elaboration of the UNICOM Deliverables a) D5.1/D5.2 (Business Requirements) and b) D5.3/D5.4/D5.5 (Semantic and Technical guidelines), This collaborative approach ensures that all UNICOM outcomes could be applied in the CEF eHDSI framework.

3.2 First year of the project (V1)

Presents the official meetings with the eHDSI community where the UNICOM project was presented and discussed. It demonstrates that the eHDSI group were aware of the UNICOM project from its inception to project commencement (Mar. 2019 Dec. 2019).

The first year of the project was marked by the official presentation of the project to the eHDSI communities and the establishment of the cooperation between the eHDSI communities and UNICOM project.

3.3   Second year of the project (V2)

The second year of the project has resulted in greater collaborate efforts between the UNICOM project and the eHDSI and eHealth Network (eHN) communities, and National Competent Authorities (NCAs). It has facilitated the development of educational and cooperation activities towards the implementation of the ISO IDMP in the eHDSI systems. The minutes of meetings between UNICOM and key stakeholders can be found in Table 1.

In addition, the following activities were organised:

➢ **1st Workshop about EU eHealth cross-border services & UNICOM**
- Unicom organised a **first workshop** about eHealth Services that took place on 4th and 5th of February 2021 (Annex 2 – 1st Workshop about EU eHealth cross-border services & UNICOM Agenda). The overarching objective of this 2-day event included: Brief history of CEF eHDSI and their organisation,
  - organisational structure, data flows and technical details of the ePrescription/eDispensation and Patient Summary eHealth services as provided in the cross-border context on CEF eHDSI,
  - a preliminary glimpse of the new requirements resulting from ISO IDMP implementation and pilots planned to test the adapted technical infrastructure by UNICOM.

This workshop had more than 150 attendees per day, including but not limited to, members of the consortium, eHDSI communities, eHealth Network, European Commission and related stakeholders.

The first day of the workshop included presentations from the members of European Commission and eHDSI communities about the general structure of the MyHealth@EU, CBeHIS (Cross-Border eHealth Information Services) and cross-border services (ePrescription and Patient Summary).

The second day of the workshop focused on UNICOM and WP5 presentations updating on the status of the project, roadmap and the expectations regarding the implementation of the ISO IDMP. The final two presentations concentrated on a) the semantic perspective of eHDSI STF: presented by Marta Terrón Cuadrado (Semantic Task Force) and b) the evolution of the eHN guidelines and presented by Stefanie Weber (Member State chair of eHN Subgroup on Semantics).

This workshop provided the opportunity to explore the EU ecosystem and its relevance to the UNICOM project in greater detail. It was a valuable opportunity to not only present the project and the eHealth developments to the European Commission, but also to present the eHealth related European groups infrastructure to the UNICOM consortium. This is important as a baseline to allow the alignment among the different relevant stakeholders.

➢ **Change Proposal Cooperation**

Cooperation with the different eHDSI communities has resulted in the need to create a unified Change Proposal (CP) regarding existing business requirements of eHDSI. The results of the UNICOM deliverables *D5.1 - Business Requirements Specifications for IDMP adoption in eHealth Services* and *D5.2 Guidelines for IDMP-based Cross-Border ePrescription / eDispensation & Patient Summary*, were the basis for elaboration of the first CP draft.

A draft CP, containing 14 proposed changes, was presented to the eHDSI eP cluster members for comments. 12 proposals were updated in cooperation between UNICOM-WP5 and eHDSI members and 2 were considered out of scope at this time. This collaboration resulted in the development of an agreed and final CP (CP-eHealthDSI-066: Align eHDSI with ISO IDMP), which was submitted to the eHDSI change management on 08/Oct/2021 (Annex 3 –).

The eHDSI Architectural group also submitted a CP about complex medication description. Similarities existed between this CP and the one initiated by UNICOM and highlighted the opportunity for both proposals to be supported by the ISO IDMP standards

This joint approach is very productive for both groups, as both UNICOM and eHDSI can support one another work together to develop the required changes in their systems and will benefit the seamless implementation of the ISO IDMP. This is extremely important to align the UNICOM timeline with the next wave of implementation of eHDSI (Wave 6).

➢ **On-going and upcoming work**

Similar further collaborations are anticipated going forward to align the eHDSI elements with the EMA Implementation Guide V2.1 attributes. This development will align attributes from disparate sources. These collaborations facilitate the provision of the cross-border services, and the implementation of the ISO IDMP on the Member States, which includes those countries that are not participating in the UNICOM consortium.

3.4 Third year of the project (V3)

The third year of the project highlighted the strengthening cooperation between the UNICOM project and the MyHealth@EU communities. It was possible to implement the co-created Change Proposals (Annex 3 – CP-eHealthDSI-066: Align eHDSI with ISO IDMP) to support the IDMP implementation on the eHDSI infrastructure, and also incentivise the Member States to adopt the requirements, such as use the Substances, Products, Organisations and Referentials (SPOR) – Substance Management Services (SMS) to code the substances of the medicines.

During 2022, the MyHealth@EU communities and the Member States have worked to implement the IDMP extensions to support the exchange of the clinical documents in an interoperable way accordingly the CP-66 specifications. Those implementations will be tested in two eHDSI test events:

- **Preparatory Pre-Production Testing (PPT) for eP/eD & PS** (Optional event Oct/Nov 2022)
  - Member States might perform test with eHDSI Reference 'Test Data' or National Representative 'Test Data'
  - Most of Reference Test Data are included in the PPL/UFIS – they can be used by Member States
- **Formal Pre-Production Testing (PPT) for eP/eD & PS** (obligatory event Feb/Mar 2023)
  - Member States must perform test with National Representative 'Test Data', to be authorised to go in Routine Operations

These test events ensure that all health data exchanged between the Member States has the necessary high-level quality required for eHDSI. Member States have the option to participate in the Preparatory PPT, but is mandatory participate in the Formal PPT.

Wave 6 (2021-2022) will also receive new Member States to initiate the exchange of eP/eD & PS through the eHDSI infrastructure. Some of those Member States are partners of the

UNICOM consortium and can also participate using IDMP data on their systems with the Pilot Product List data.

During the last year, there were many meetings in which the IDMP implementation was raised. This process has supported the identification of some new issues that could be implemented in the upcoming waves. In order to generate the required Change Proposals to ensure the smooth implementation of IDMP, some themes were discussed, such as:

- Central transcoding (on the MyHealth@EU infrastructure) between eHDSI value sets and SPOR Referentials Management Services (RMS)
  - o This draft CP intends to provide a central mapping service between EMA SRS code systems and eHDSI Master ValueSet Catalogue (MVC). i.e., have a pre-filled Master Translation / Transcodification Catalogue (MTC) which allows mapping from SRS codes to e.g., EDQM, ATC, etc. codes, in order to avoid each Member State doing it locally.
- Inclusion of a value set regarding the 'ingredient role'
  - o This draft CP intends to create new Value Set of eHDSIIngredientRoleClass with concepts from HL7 Code System of Role Class, such as:
    - ▪ ACTI - active ingredient,
    - ▪ ACTIB - active ingredient - basis of strength,
    - ▪ ACTIM - active ingredient - moiety is basis of strength
    - ▪ ACTIR - active ingredient - reference substance is basis of strength

These suggested CP were discussed with the eHDSI communities for submission for wave 7, however, it was decided that these subjects need further discussion before submitting it to the change management process. The expectation is that those CP's can be presented for Wave 8 (September 2023).

Some meetings and events took place on the UNICOM/MyHealth@EU scope, that intended to increase the sharing of information and plan the pilot activities foreseen for Wave 6:

- **23rd eHMSEG Meeting (03/03/2022)**
  - o The eHMSEG meeting is an event that takes place three times a year. In this meeting there was a dedicated section about the implementation of the IDMP on MyHealth@EU infrastructure related to the UNICOM project outcomes. The presentation included an overview about the UNICOM goals, the recent project achievements, eHealth related deliverables release and elaboration, and the ongoing implementation activities.
- **Community of expertise: IDMP Semantic specifications for eHealth services (22/04/2022)**
  - o This event included members of UNICOM project as presenters and was attended by the eHDSI communities in order to exchange knowledge and experiences towards the IDMP implementation.
- **5th UNICOM fall Consortium Meeting (Brussels 1-2/09/2022)**
  - o This event included a presentation of all UNICOM WPs and a great joint presentation among WP567 cluster and eHDSI members: Rasa Visinskiene and Mathias Ghys, semantic experts. Leading a better comprehension of the modifications on the eHDSI infrastructure to be compliant with IDMP data.

In addition, it is important to mention that MyHealth@EU have developed their 'work plan' for 2023 which was approved at the 22nd eHN Meeting (07 Nov. 2022 – Brussels BE), where the key actions that the Commission consider relevant to be addressed in order to support the core services implementation and support the NCPeH are included. Section "2.2 – Requirements and Specifications" of the plan includes the following text:

> *4.   Analysis of the deliverables for describing and identifying medicinal products to overcome currently known limitations, delivered by the UNICOM project, with a view of MyHealth@EU future implementation.*

These activities were responsible for the strengthening the relationship between the project members and the MyHealth@EU communities, increasing the trust in the UNICOM results and collaboration, change proposals co-creation process, and other joint activities towards the full IDMP implementation in EU and Member States.

3.5   CEF eHDSI Meetings

This section contains the minutes of meetings from all eHDSI communities' engagements where UNICOM participated.

Table 1 – UNICOM on CEF eHDSI group meetings (report combined from pre-project + 1st project year – 'V1', 2nd project year – 'V2' and 3rd project year – 'V3')

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
Pre-project and first year of the project (M1 - M12)		
14/03/2019	eHealth DSI Semantic Community - Coordination	Marcello MELGARA: informed how the **UNICOM** project application is progressing on the work package description for the Horizon 2020 Call for ISO IDMP implementation.
27/03/2019	eHMSEG Semantic Task Force 8th F2F meeting	**UNICOM** Project preparation (Horizon 2020 Call for the ISO IDMP)
26/04/2019	eHealth DSI Semantic Community - Coordination	Marcello MELGARA: informed that the **UNICOM** proposal was submitted for the Horizon 2020 Call referred to the implementation of ISO IDMP Standards A Semantic session is planned during the Technical Boot Camp of May, led by Solution Provider
03/05/2019	eHealth DSI Semantic Community - Coordination	Marcello MELGARA: informed that the **UNICOM** application was submitted for the Horizon 2020 Call referred to the ISO IDMP implementation; of the PS Cluster meeting that was held on Monday; and that the "breaking the glass" scenario is being discussed in that fora.
20/05/2019	ePrescription Pharmaceutical and Technical Work Group Meeting	Juan Pablo MARTINEZ presented the draft of the change proposal circulated earlier in the morning by email: CP-eHealthDSI-000_Representation_of_fractions_v0.3.doc. Marcello MELGARA suggested to look at the international standards such as ISO IDMP and checking whether some useful recommendations could be found in them, as a reference. One option could be to contact WP4 leader (Austrian) from **UNICOM**. Konstantin HYPPÖNEN commented that ISO IDMP will change also many other things. In this CP, no big changes are proposed to the representation of fractions - just a clarification of the current specs with an indication of the suggested representation. Oskar THUNMAN commented that as formulated now, the CP is easy to accept and at the same time it would be of help, harmonising the

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		representations. Long-term activities are of course not to be forgotten, and ISO IDMP should definitely be followed as a separate activity. All countries are invited to send their comments to Juan Pablo MARTINEZ, to finalise the CP by the next meeting.
27/06/2019	eHealth DSI Semantic Community - Coordination	Marcello MELGARA: commented various topics → how the **UNICOM** proposal is under evaluation; he has not received feedback yet from SNOMED CT; he is being participating in the discussions on the "breaking the glass" scenario; and also commented on the Functional e2e testing (eP Workflow Extension).
20/11/2019	eHealth DSI Semantic Community - Coordination	Start of **UNICOM** on 1st December 2019.
24/02/2020	ePrescription Pharmaceutical and Technical Work Group Meeting	Next meeting will be held on 23/03/2020. The meeting on 20/04/2020 will be dedicated to ISO IDMP, with a presentation by the **UNICOM** project.
13/03/2020	eHMSEG Semantic Task Force - Coordination	Marcello MELGARA: worked on **UNICOM** tasks.
23/03/2020	ePrescription Pharmaceutical and Technical Work Group Meeting	Meeting on 20/04/2020: dedicated to ISO IDMP (link with the **UNICOM** project).
06/04/2020	ePrescription Pharmaceutical and Technical Work Group Meeting	The **UNICOM** project leader will present the project. Discussion will be held on further collaboration between the project and eHealth DSI, including the ePrescription Cluster. Any wishes for specific contents should be sent to Konstantin HYPPÖNEN by 10/04/2020. https://unicom-project.eu/
20/04/2020*	ePrescription Pharmaceutical and Technical Work Group Meeting	Karl Stroetmann presented the background in the form of Open Medicine and the purpose of the project named **UNICOM** which is to improve the identification of medicines. Thereafter he presented the project IDMP and future plans for the project together with Marcello Melgara. Slides used in the presentation: **UNICOM** General Intro eHDSI - eP group V04 incl MM WPs 5-7.pdf There will be some webinars about different aspects of IDMP. Access information will be distributed to the eP Cluster. There were no questions after the presentation by Karl. The duration of the project is December 2019 – November 2023 but due to the present situation with COVID-19 it could be difficult to finalise in time. When is it suitable to add the IDMP information as Change Proposals? Not before 18 months from now due to that for example some agreements have to be in place before creating Change Proposals. The **UNICOM** project sees that there are several activities that should be performed in cooperation between **UNICOM** and the eP Cluster. For planning of the work in the eP Cluster, it would be good to have some

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		sort of timeline for the different activities. This has to be discussed further in the future. Questions There was a question about strength and the answer was that SPOR is responsible for the content. Another question was about identification of MAH and in SPOR there is a fully functional naming including MAH. There was also a question about what directive that is connected to IDMP and the answer at the meeting was EU 520/2012.
24/04/2020	eHealth DSI Semantic Community - Coordination	Marcello MELGARA: **UNICOM** project is holding workshops every day in the afternoon on ISO IDMP; eHN meeting will be held remotely.
14/05/2020	eHealth DSI Semantic Community - Coordination	Marcello Melgara: attended the teleconference (tcon) of the eHN subgroup on Semantics; presented **UNICOM's** work in cross-border ePrescriptions. He also informed on the call for a project on European interoperability ("refined" EAF). Hans ANDERSSON: also attended the tcon, which included presentations on **UNICOM** by Marcello and Karl Stroetmann.
18/09/2020	eHealth DSI Semantic Community - Coordination	Marcello MELGARA: participated yesterday in the tcon of the Architecture work group, where discussion took place about the representation of the packages within the package of medicinal products; he also informed about the Semantic work group tcon meeting where it was discussed the new CPs (Procedure Value Set review, as well as the review of the Value Sets for Medicinal Products and Allergen No Drugs): it was decided to prepare a draft CP for medical devices based on the content of the SNOMED GPS; also it was discussed how to handle the inactive concepts in the Vaccine Value Set. He informed as well on the work on the X-eHealth project and **UNICOM**. Finally, he commented on the information to be present in a prescription cross-border.
08/10/2020	eHMSEG Communities meeting	**UNICOM** project update The **UNICOM** project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all. To achieve its objectives and the outcomes foreseen, **UNICOM** is organised along three vertical action lines: 1. Implementation of ISO IDMP at EU/National Medicinal Products (MPs) data base level. 2. Adaptation and piloting of cross-border digital health services. 3. Exploration for pharmacovigilance services, Medicinal Product Dictionaries [MPDs], healthcare services, patient empowerment, Big Data etc. Support by two horizontal clusters: 1. Further development of IDMP standards and implementation support. 2. Socio-economic impact assessment, scientific coordination, project management, dissemination, ethical issues. Impacts & Benefits for cross border services from IDMP: • ePrescriptions specify a package, a medicinal product, or an active substance plus further attributes as needed. • IDMP identifiers or descriptive attributes allow any actor, also patients, in any country to obtain the medicinal product's 'properties', or the group of drugs (generics) all meeting what has been specified.

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

		• National databases of authorised drugs contain between 10,000 to 20,000 (> 50,000 in DE) medicinal products, whereas the EMA database records > 500,000 for the EU.
		• This national diversity requires regularly substitution if a prescription is to be dispensed
		• **UNICOM** National Medicines Authorities will ensure an exemplar set of IDMP-coded data for piloting.
		• **UNICOM** will demonstrate the path towards safer and more effective ePrescribing/ eDispensation services, also facilitating safe substitution.
		• IDMP implementation will provide for more effective ways of communicating therapies, allergies and immunisations in Patient Summaries.
		Impact on eHDSI:
		D5.1 - Business Requirements Specifications for IDMP adoption in eHealth Services
		• Questionnaire about comparison of eHealth services among EU MSs
		  o Specific recommendations to adopt ISO IDMP in eHealth Services (National and Cross-border levels): feedback from MSs; 16 eP/eD, 13 PS, 9 Legal.
		• Identification of the CEF eHDSI business requirements that could be enhanced by **UNICOM**
		  o Base to elaborate D5.2 and draft a Change Proposal to CEF eHDSI Business Requirements.
		  o Considered in eHN PS Guidelines Release 3.
		• Draft list of IDMP related attributes to enhance structured/coded description of medications, taking advantage of coded info to generate IDMP Identifiers: e.g., Substances, Dose Forms, Strength (WP2, WP3, WP4, WP9, EMA SPOR)
		  o Base to elaborate D5.3 and draft a Change Proposal to CEF eHDSI Interoperability Specification.
		UNICOM WP5 – 6 – 7 roadmap toward CEF eHDSI adoption:
		• CEF eHDSI & WP5 jointly define CPs for Wave 6.
		• WP6 and CEF eHDSI jointly implement the reference implementation and testing tools
		• WP7 and Member States in Routine Operation:
		  o Validate and deploy, by applying the CEF eHDSI procedures for new waves assets adoption.
		  o IDMP enhanced eP/eD & PS services, including auxiliary IDMP identifiers/attributes.
		o For at least the Medicinal Product Pilot List, for which IDMP Identifiers and Attributes will be provided.
		o With the goal of exchanging 10.000 eP, 1.000 PS, IDMP enhanced.

Second year of the project (M13 – M24)		
25/01/2021	ePrescription Pharmaceutical and Technical Work Group Meeting	**Presentation of the ePrescription Service for UNICOM** • Workshop Feb 4 and 5 between eHDSI and **UNICOM** about the implementation of ISO IDMP • Presentation of the eP/eD Service needs to be prepared Marcello informed that the first day will concentrate on informing about the current status of eHDSI and the second day will concentrate on how **UNICOM** and eHDSI will collaborate. **ePrescription (eP) Service**

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

		• Service
		  o Description of the eP service
		• Current Status
		  o MS operationalised status and future implementation
		• Current issues related to Medication
		  o Description of the issues related with the medicinal products identification on the service
		  o how **UNICOM** can support eP services with the adoption of ISO IDMP
		• End to end functional test expectations and outcomes
		• Workflow testing
		• Some examples:
		  o Description of a few examples that are related with **UNICOM**
		  o Together we need to create a list of issues on this subject found in production and the PPTs.
		    ▪ Description of products
		    ▪ Unique global identifier
		    ▪ Include attributes from correct coding
		Estonia suggested that it will be easier later since Active ingredients will be detached from the ATC-code.
		Marcello informed that **UNICOM** will work in a practical way, for instance providing Change Proposals for discussion with Task Forces and Work Groups.
		The Chair asked if anyone in the group is active in the national implementation of IDMP. Estonia informed that they are remotely active.
		Ireland also reported that they are active.
		Workflow testing – Identification is a real problem in dispensing.
		It was decided that Chair will contact Estonia and Finland to discuss the content of the presentation.

01/02/2021	PS Cluster meeting	Information on the 1st workshop about eHealth Services and **UNICOM** February 4th and 5th from 14:00h to 16:30h CET.
04-05/02/2021	1st eHealth services workshop	The objectives of this Workshop are to present in some detail the history, and particularly the organisational structure, data flows and technical details of the ePrescription/eDispensation and Patient Summary healthcare services as provided in the context of the CEF eHDSI; and to give a preliminary glimpse of the new requirements resulting from IDMP implementation and pilots planned to test the adapted technical infrastructure by **UNICOM**.
08/02/2021	ePrescription Pharmaceutical and Technical Work Group Meeting	The workshop was a start-up meeting. The **UNICOM** mission is to support eHDSI in implementing ISO IDMP. The workshop was productive with many interesting presentations. The eP Cluster members are encouraged to review the presentations, which will be sent to the eP Cluster participants as soon as they are available.
02/03/2021	X-Border Group Meeting	If this agreement is needed it is more urgent for **UNICOM** due to the needed adoption of IDMP by Wave 6. Planning a workshop as we did before where all communities present and also X-eHealth and **UNICOM**. But this request goes beyond that in that sharing documents / deliverables to ensure alignment and no divergence. Request for a framework for information sharing.

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
19/04/2021	ePrescription Pharmaceutical and Technical Work Group Meeting	**Improvement of presentation of packages** Introduction to the Architecture WG of Semantic Taskforce work on a refactoring of the substance Administration templates for eP and PS: to have a better structure for representing medicinal products. "Higher" level presentation of a few slides from Mathias GHYS Comments: We will deal with the topic on an ongoing basis. It is related to the **UNICOM** project, and collaboration is needed with the Semantic Taskforce Architecture WG. Suggestion to make use of examples from the Critical Test Data to help identify challenging products.
27/04/2021	X-Border Group Meeting	working on CP in different WGs. Semantic and Architecture WG - 2 major topics: CP 28+29, handling of complex packages of medicinal products, supported by **UNICOM**, CP prepared on the bases of the adoption of ISO IDMP.

27/05/2021	eHMSEG Communities meeting	**The activities planned for 2021 to prepare the artefact of the eHDSI Wave 6 are:**
		• Coordinate with eHN SG on Semantics, eHN SG Technical Interoperability, **UNICOM** and X-eHealth in order to accelerate output and avoid duplicate work, e.g., cooperate with **UNICOM** for the adoption in eP/eD and PS of ISO IDMP attributes on medicinal products
		The ePrescription Cluster leader presented the summary of the work in cluster:
		• Presentation of the ePrescription Service for UNICOM - Workshop Feb 4 and 5 between eHDSI and UNICOM about the implementation of ISO IDMP.
		The priorities for the eHDSI Wave 6 are:
		• Change Proposals from UNICOM.
		UNICOM PROJECT UPDATE
		   o The UNICOM project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all.
		   o The **UNICOM** project Coordinator has presented the scope of the work packages, which are WP 1 - IDMP improvements, WP 2 - EU-SRS (Substance Registration System), WP 3 - European Marketing Authorisation Application submission system, WP 4 - Establishing an IDMP / HL7 FHIR infrastructure for testing and piloting and Outreach to stakeholders and trans-Atlantic, WP 5-7 – x-Border IDMP implementation requirements.
		   o As part of work in WPs 5-7 the co-operation with CEF eHDSI eP Cluster and eHMSEG Semantic Task Force is fundamental to reach the project objectives. Liaison is needed to start the preparation of the Change Proposals for including IDMP attributes (based on NCAs implementations for SPOR).
		   o WPs 5-7: X-Border IDMP implementation requirements – response to eHDSI Wave-6 priorities:
		   o Collaboration with WPs 1,2,3,4 to define the medicinal products attributes list required for eHealth services
		   o Attributes relevant to NCAs: What information is possible to provide
		   o Attributes relevant to CEF eHDSI (eHealth)
		• **Status of activities:**

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		o Improved eP/eD and PS Business Requirements: ready for consideration as a source for a Change Proposal o Define extended Data Set for eP/eD and PS including IDMP attributes and identifiers (cfr. eHN eP Guidelines Rel 2. & eHN PS Guidelines Rel. 3) • Validate extended Data Set with NCAs and eHMSEG eP Cluster & STF o Define eP/eD and PS Implementation Guide with eHMSEG eP / PS Cluster & STF o Define enhanced architectural requirements and CDA Display Tool Requirements o Provide beta reference implementation of enhanced OpenNCP components, CDA Display Tool, Gazelle eP/eD & PS documents scrutiny test tools **Next topics that will be addresses are:** • ePrescription guidelines – request for mandate of revision http://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_2016112 1_co091_en.pdf - Joint approach with **UNICOM** project would be welcome Cooperation between eHDSI Clusters (Architecture WG of Semantic Taskforce) and **UNICOM** in order to prepare CP
29/06/2021	X-Border Group Meeting	**UNICOM** workshop TODAY https://unicom-project.eu/event/community-of-expertise-cross-border-eprescription-standards-terminologies-processes/ If you will not be able to join, due to the short notice, recording of the event will be made available on **UNICOM** website
20/07/2021	X-Border Group Meeting	Announce to the eP group that we are investigating the limitations of current eP data elements in light of what is going on in **UNICOM** and EMA spaces.
10/08/2021	X-Border Group Meeting	semantic TF, in cooperation with eP Cluster, is starting to revise eP guidelines in the light of **UNICOM** recommendations.
23/08/2021	eP / eD Pharmaceutical and Technical Work Group Meeting	**UNICOM** workshop 27.8. On Friday August 27 a webinar around ATC and INN will be held with connection to **UNICOM**. Information will be sent to eP Cluster and those interested can join.
01/09/2021	eP Cluster and STF meeting (restricted meeting)**	It was the first alignment meeting between the **UNICOM** WP5 and the eHDSI communities to discuss the CP about Business Requirements. The 1st CP was drafted by **UNICOM** and evaluated by the eP cluster. In this meeting the eP cluster has presented their analysis on the 1st CP draft. From 14 proposals, 8 did no need any update, 4 required small changes and 2 were considered out of scope of the CP. Based on this discussion, **UNICOM** has updated the CP accordingly to the comments.
06/09/2021	eP / eD Pharmaceutical and Technical Work Group Meeting	Update of work in **UNICOM** • Presentation of suggested improvements prepared by WP5 **UNICOM** from their analysis of the eHDSI business requirements, in order to adopt ISO IDMP. The material has been sent to the eHMSEG eP Cluster and Semantic Task Force for subsequent joint activities. Followed by a "homework" for MS to assess and comment on the suggested improvements.

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		o The changes in both CPs overlap. Yes, but they target different specifications within the eHDSI. This is to start preparing the requirements for IDMP, although it is a few years into the future. o Gave an update on the preparation and processing of a change proposal targeting the functional requirements, which is the joint work of the eP-cluster, Semantic Taskforce and **UNICOM** WP 5.2. The CP along with an attribute sheet of relevant IDMP attributes for ePrescriptions was originally prepared by **UNICOM** WP 5.2 as an aid to the implementation of ISO IDMP. Next step is to distribute the presentation with suggested changes to the functional requirements for discussion among MS.
06/09/2021	eP Cluster and STF meeting (restricted meeting)**	This meeting had the objective to present the work on the EMA Implementation guide V2[4] minimal attribute list (conducted by **UNICOM**) and eHDSI eP/eD/PS elements to the eP cluster and STF and get alignment of their development.
07/09/20221	X-Border Group Meeting	• Adoption of the ISO IDMP system, i.e., replacing the current system for exchanging information for medical products with the one being developed by **UNICOM**. • Collaboration with eP Cluster on preparing the CPs, also with **UNICOM** project on IDMP. Changes are proposed by the Arch WG in order to secure the eP for the current implementation; and with **UNICOM** as preparation for adopting new identifiers that will be used by countries in the future. Small fixes are performed on the implementation guides (e.g., allergy manifestation).
08/09/2021 13/09/2021 16/09/2021 22/09/2021	eHDSI communities (restricted meeting)**	Those meetings have the goal of comment and upload the CP according to the comments from different eHDSI communities' experts, such as: STF, eP Cluster, Architectural group. The content of the CP was revised by the eHDSI and **UNICOM** member and the suggested updates were integrated on the document.
20/09/2021	eP / eD Pharmaceutical and Technical Work Group Meeting	Update of work in **UNICOM** • In this meeting: Presentation of Draft Change Proposal based on the WP5 **UNICOM** analysis of the eHDSI business requirements, in order to adopt ISO IDMP. The material has been reviewed within the Semantic Task Force. Follow up on MS feedback and questions, along with deciding on next step. o We have a new solution around size of the package. o eP/eD cluster will support and propose to send to Change Manager. o Architecture WG thanks the eP Cluster for the inclusion and support for finalising CP.
21/09/2021	X-Border Group Meeting	Semantic TF/ Arch WG: • Both semantic and arch are working closely with eP cluster on **UNICOM**. And also, the CP that mentioned earlier. • We sent the questionnaire on CP-28 and CP-29 we received some answers. • It is felt that the MVC is to be extended to include the code sets in MS so as ICD9 etc. We are planning to submit a CP by the end of Sep to allow a practical application of CP-29 this the activities of the semantic group.

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[4] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
04/10/2021	eP / eD Pharmaceutical and Technical Work Group Meeting	Update of work in **UNICOM** • In this meeting: Following the MS assessment of the draft change proposal, the eP cluster will decide on submitting it as a Change Proposal. o Only a few remarks in the last round of comments. There are challenges in the representation of complex packages, which has been pointed out. However, this CP targets the functional requirements and sets the general direction, and the details on e.g., complex packages will be addressed in the CDA IG, falling under Architecture WG responsibility. o Discussion on forwarding a phrase to suggest for PS to consider the inclusion of these changes also for the PS service. This can be done during assessment and/or implementation of the CP. This approach was verified by the Change Manager. Marcello will prepare these additional sentences and notify the PS cluster leads. o eP cluster decides to submit the Change Proposal.
Third year of the project (M25 – M36)		
17/01/2022 14/02/2022	PS Cluster	• An additional topic related to Medication and introduction of ISO IDMP in the Patient Summary (see CP-066) might be considered as a priority. • Extra information will be provided by eP Cluster.
01/02/2022	X-border	• Frederic, Bulckaen (SANTE): We had a meeting on CP-66 with a presentation from Marcello Melgara (IT). The parameters for Wave 5 are clear, there is no expectation on MS to implement **ISO IDMP** for Wave 6. There will be amendments of bindings for terminology to accommodate **ISO IDMP** in the MyHealth@EU infrastructure. • Scope and timeline for W6 o Deadline for Wave 6 CPs submission: (copy from Operational tcon minutes) o CP-066 - ISO IDMP - very high priority o CP-065 - PS guidelines V3 - high priority adding the Requirements catalogue 6.0.1being released 28th Feb. o CP-067 - EX of coded info not yet done the analysis for the English translation o CP-068 - adopted in January
03/02/2022	STF	• CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMP • Should be clarified: no information about Coding System of Substances, which should be used to code ingredients of products. UNICOM is working on what minimum list of attributes can be included in Requirement Catalogue for Wave 6
17/02/2022	STF	• CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMP • New concepts to MVC from Code Systems: o Create a new Value Set for substances based on EMA SMS for Wave 6. o ADD THE REFERENCE TO THE SMS Code System o EDQM & EMA SPOR

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

		• In EMA SPOR it was agreed the adopted International Standards have an internal coding. This applies to ATC, EDQM and others. These code systems are aligned with the standards.
		When e.g., a new dose form has to be added EMA asks to EDQM to validate it. Afterwards it is included in EMA SPOR ValueSet. EDQM includes the new concept in the following EDQM release.
		This process assures the controlled alignment of International Code Systems and the internal code systems.
		It is proposed to keep the use of EDQM for the ValueSets coded with the corresponding EMA SPOR ValueSet based on EDQM, maintaining the automatic update, with the support of NCAs participating to EMA SPOR Project.
		  ○ Concepts from EDQM class "UOP Unit of Presentation" (51 concepts):
		    ▪ A unit of presentation used to represent the quantity of product (e.g., "contains 1000 mL per bag", "contains 20 mg per tablet") that is administered following a single operation of a metered-dose pump, valve or other equivalent dosing mechanism.
		    ▪ For example: Blister, Bag, Ampoule and etc.
		    ▪ We could create a new Value Set for those concepts or we should include those concepts in current value set of eHDSIUnit? Not clear how and where to use it in CDA.
		    ▪ https://www.edqm.eu/sites/default/files/standard_terms_introduction_and_guidance_for_use.pdf:

03/03/2022	23rd eHMSEG meeting	• Representative of the UNICOM project presented the upcoming proposals to align MyHealth@EU services with **ISO IDMP**. Some optional new fields are proposed for Wave 6, and a new code system for substance coding. Work is being conducted on eP/eD and PS implementation guides, in cooperation with eHMSEG eP/PS Clusters and Semantic TF.
		• MVC 6.x is in preparation for Wave 6, to include substance coding details. In addition, there are some synergies with CP-eHealthDSI-063 on structured package information, some changes are being introduced in the package structure details for Wave 6 based on that.
		• Some further change proposals are expected for Wave 7.
		  ○ ES: As all Member States are starting to use SNOMED CT, would code sets proposed by UNICOM be aligned with this direction?
		  ○ UNICOM project representative: UNICOM is not selecting code systems itself; they are defined in the **ISO IDMP** standard and by EMA and national medicine agencies. Mappings with SNOMED CT could be introduced if needed.

03/03/2022	STF	• CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for **ISO IDMP**
		• New concepts to MVC from Code Systems:
		  ○ Create a new Value Set for substances based on EMA SMS for Wave 6.
		• ADD THE REFERENCE TO THE SMS Code System to Solution Provider to request EMA of SMS Code System Value Set? for the active ingredient role class:
		  ○ 1-S ACTI active ingredient Role Class
		  ○ 2-L ACTIB active ingredient - basis of strength Role Class
		  ○ 2-L ACTIM active ingredient - moiety is basis of strength Role Class
		  ○ 2-L ACTIR active ingredient - reference substance is basis of strength Role Class

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

07/03/2022	eP Cluster	• Frederic informed that the review for the requirements catalogue is by the end of the week (March 13).
		• eHMSEG meeting:
		  o The topic that directly affects the eP cluster was information about the work on **IDMP** with the UNICOM project.
		  o The new KPI template is ready for download for Member States in production
		• STF:
		  o CP-66 is submitted (W6,7)
		  o revision 6.1 requirements catalogue
		  o work on an additional value set for substances based on EMA

10/03/2022	STF	• CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue **for ISO IDMP**
		  o Create a new Value Set for substances based on EMA SMS for Wave 6.
		  o ADD THE REFERENCE TO THE SMS Code System:
		  o Solution Provider requested EMA of SMS Code System. EMA's respond: "We will reply to you as soon as we can. For complex queries, it may take longer to answer. In any case we will write back to you within 2 months from the date of receipt. "
		  o Value Set for the active ingredient role class
		  o Discussion page: Value Set for the Ingredient Role Class
		  o send email to eP cluster with questions raised during meeting get
		• EMA SPOR
		  o In EMA SPOR it was agreed the adopted International Standards have an internal coding. This applies to ATC, EDQM and others.
		  o These code systems are aligned with the standards.
		  o When e.g., a new dose form has to be added EMA asks to EDQM to validate it. Afterwards it is included in EMA SPOR ValueSet. EDQM includes the new concept in the following EDQM release.
		  o This process assures the controlled alignment of International Code Systems and the internal code systems.
		  o It is proposed to keep the use of EDQM for the ValueSets coded with the corresponding EMA SPOR ValueSet based on EDQM, maintaining the automatic update, with the support of NCAs participating to EMA SPOR Project.
		  o Concepts from EDQM class "UOP Unit of Presentation" (51 concepts):
		  o Discussion page: Value Set for the Unit of Presentation
		  o get feedback from eP Cluster
		  o send email to eP cluster with questions raised during meeting
		  o get feedback from Requirement WG

14/03/2022	PS Cluster	• An additional topic related to Medication and introduction of ISO IDMP in the Patient Summary (see CP-066) might be considered as a priority
		  o Extra information will be provided by eP Cluster
		  o CP-066 and CP-063 are related

17/03/2022	STF	• CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for **ISO IDMP** • Discussion page: Value Set for the Ingredient Role Class get feedback from eP Cluster • send email to eP cluster with questions raised during meeting

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		- feedback is included in discussion page from Requirement WG & eP cluster. - Concepts from EDQM class "UOP Unit of Presentation" (51 concepts): - Discussion page: Value Set for the Unit of Presentation - get feedback from eP Cluster - send email to eP cluster with questions raised during meeting - feedback from Requirement WG: no one gives feedback
29/03/2022	X-border	- Mostly focused on PPT testing. - We discuss topic UNICOM presentation, and topic CP-66. - Prepared page in Confluence to deal with this please input to this page insert link: https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSIEHMSEG/MS+Status+Unit+of+presentation+and+Ingredient+Roles
31/03/2022	STF	- CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for **ISO IDMP**: - new Value Set of eHDSIQuantityUnit is created with 51 concepts from the class "UOP Unit of presentation" of EDQM's Code System - new Value Set of eHDSISubstance is created with 59,813 concepts from EMA SMS list of Substances. Online browser: List of substances IRIS (europa.eu) - CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMP - EMA's SMS list of Substances - Online browser: List of substances · IRIS (europa.eu) - Substance ID/names included in eHDSISubstance value set will not be changed - In the coming weeks a consolidated export of list will be available in the SPOR Portal - official translation of EMA SMS are available in most of EU languages (FR, HR, HU, LV, DE, FI, IT, EL, PL, PT, ES, NL, MT, ...)
12/04/2022	X-border	- Mostly focused on PPT testing. Unit of presentation. Second draft on guidelines We discuss topic **UNICOM** presentation, and topic CP-66. - Prepared page in Confluence to deal with this please input to this page insert link: https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSIEHMSEG/MS+Status+Unit+of+presentation+and+Ingredient+Roles
14/04/2022	STF	- CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for **ISO IDMP** - EMA's SMS list of Substances - Criteria for concepts of Substance to be included in MVC value set of eHDSISubstance: Authorisation State = AUTHORISED, Term Status = Current, Language = en
10/05/2022	X-border	- Proceeding with the implementation of the MVC. Revising/refining part regarding value set (CP 65). Discussion about opportunity of including the orpha code for rare diseases - next meeting. - Concerning the point on **UNICOM** and IDMP, in eHDSI the assets to be released in June for Wave 6 will contain:

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		• IDMP enhanced Business Requirement both for PS and eP MVC 6.1.0, including EU-SMS (Substances) and other **IDMP** Attributes related ValueSets (in line with the eHN eP and PS Guidelines ver. 3 • The **IDMP** enhanced Art Decor Implementation Guide both for eP/eD and PS • The Wave 6 Preparatory PPT (I believe October/November 2022) will include the possibility for MSs to test PS and eP with the optional **IDMP** Attributes. • Same in the Formal PPT in March 2023, to go live in Autumn 2023 with Wave 6 assets. • An important message to be conveyed to the MSs it is the importance for MoH/eHealth Agencies to liaise with the National Competent Authorities for Medications, to obtain the limited sub-set of coded data they are creating to feed the EMA-SPOR, to be added to the PS and eP as optional data. • In **UNICOM** there are 11 NCA and some MoHs, but there will be more MSs in Operation soon! • As for Italy, the Italian MoH and AIFA are working to partially enrich the Italian PS and eP for MyHealth@EU already for Wave 5. • Other MSs may do it for the Wave 6 Preparatory PPT, at least for the so called "Critical Test Data". • It is planned to add a topic in the next June Semantic Task Force Web meeting to suggest to MSs how implement CP-63 (complex packaging) and CP-66 (**IDMP** adoption)
13/06/2022	eP Cluster	Marcelo pointed out the CPs 63, 66. associated with the introduction of **IDMP**. It is important that national authorities already account for the transition to an **IDMP** system in the primary data.
28/07/2022	STF	• About possible CP for Wave 7: ○ Provide a central mapping service between EMA SRS code systems and eHDSI MVC: i.e., have a pre-filled MTC which allow to map from SRS codes to e.g., EDQM codes, in order to avoid each MS and NCA does it locally. ○ On 1st and 2nd of September f2f meeting is scheduled of **UNICOM** project in Brussels
22/08/2022	eP Cluster	Status of UNICOM and wave 6, presentation by Marcello Melgara of **UNICOM**.
25/08/2022	STF	○ Introduced the new leader Giorgio Cangioli of the STF Architecture WG temporary replacing Christof Gessner. ○ UNICOM Consortium meeting will take a place on 1st-2nd of September in Brussels. The second half of the first day will be intended for workshop on common topics of eHDSI and UNICOM project
05/09/2022	eP Cluster	• Is Marcello's **UNICOM** presentation available? ○ **UNICOM** presentation should have been e-mailed but it can also be included in the minutes. ○ Info on how to sign up for an EU account to be distributed to the group. ○ Joint presentation during meeting on September 19 - invitation to come.
19/09/2022	eP Cluster	• Marcelo reported on the progress of the meeting of the **UNICOM** project.

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		• Test data (selected 35 active substances) and also a sample table on Italian MPs are already available. • At the time of classic testing, informal testing of the MP in the **IDMP** structure can take place in parallel. • STF is currently preparing the CP for **IDMP** implementation

22/09/2022	STF	• Possible CPs for Wave 7 related to medication:
		  ○ introduce the appropriate CDA element for the indication of the type of Substance (moiety or salt) and the type of strength. Discussion page: Value Set for the Ingredient Role Class
		  ○ Decision: no CP for Wave 7. We will take it into consideration when EMA data model for **ISO IDMP** standard introduces (supports) detailed role classes of strength of substance.
		  ○ provide a central mapping service between SPOR RMS code systems and the concepts from the MVC. Discussion page: Mappings between the new SPOR RMS code system and the concepts from the MVC
		  ○ EMA has to provide officially and formally mappings between their codes and codes from international code systems as EDQM and UCUM. Member States should ask this information to EMA.
		  ○ to Member States to review and comment information provided on this page.
		  ○ Decision: no CP for Wave 7. To MSs to review and comment information provided on discussion page.

03/10/2022	eP Cluster	• A first version of a list of Wave 6 (IDMP) coded Critical test data has been prepared, along with the official contact information for national MPA's. ○ Question for Member State participating in Preparatory-PPT if they can incorporate test data that includes Wave 6 (**IDMP**) coded data.
06/10/2022	STF	• Codded CTD (**IDMP**) for ePrescription: ○ request to the participating MSs to incorporate test data that includes Wave 6 (**IDMP**) coded data for the Preparatory-PPT test event

07/12/2021	X-border	• Formal invite not sent as I would like to send the agenda once complete.
		  ○ The draft Agenda has been sent to leads, please reply to confirm.
		  ○ Plan is for 30 minutes or less presentations.
		  ○ Retrospective of what has been done, what worked well, what has been achieved, what could be better and lastly what are the plans for 2022.
		  ○ We will also have inputs from our sibling Projects **UNICOM**, X-eHealth etc. so we can get an idea of what is going on as everyone cannot be everywhere meeting wise.
		  ○ Konstantin has suggested two new inputs from eID Wallet and DCC colleagues on the day (yet to be confirmed).
		  ○ Please workgroup leads, if there are issues, please let us know, we will try and work with you.

20/10/2022	STF	• CP-eHealthDSI-066: Prepare eHDSI Requirements Catalogue for ISO **IDMP** ○ adopted. • clarification of Requirements Catalogue for Wave 6

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		o evolution points should be implemented in normative artifacts for Wave 7. New detailed CPs may need to be prepared for that related to CP-066.

11/04/2022 09/05/2022 04/07/2022 29/08/2022 26/09/2022	PS Cluster	• An additional topic related to Medication and introduction of **ISO IDMP** in the Patient Summary (see CP-066) might be considered as a priority
		  o Extra information will be provided by eP Cluster
		• CP-066 and CP-063 are related
		  o No impact is noted on PS. Review on the work catalogue workflow and impact on value set can be read here: Requirements Catalogue - Version history - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu). The Semantic Workforce is reviewing several value sets to update and will share the information with us as soon as consolidated.

30/08/2022 15/09/2022 27/09/2022	X-border	Continue revision of Implementation Guide and indication implementation for CP 63. Preparing new CPs. Continuation of work with UNICOM. Few Member States are planning to adopt MVC 6.1.0. (Make possible description of several medical products), which is a pity from eHN semantic WG point of view. Working cooperating to prepare the CPs for new use cases. Discussion whether to prepare a separate CP for rare diseases.

*This meeting was dedicated to UNICOM Project.

**Those meetings were dedicated to the collaborative development 'CP-eHealthDSI-066: Align eHDSI with ISO IDMP' Change Proposal.

4 Cooperation with eHealth Network

4.1 General overview

The eHealth Network (eHN) is a voluntary network created under article 14 of Directive 2011/24/EU[5]. It provides a platform for the Member States' competent authorities responsible for eHealth and is scientifically and technically supported by a Joint Action.

This EU organisation aims to ensure the development of the digital health among the EU and connect the gaps between the policy/governance and the operational levels. It is responsible for designing the EU policy about eHealth and connect the Member State authorities at different levels.

In order to ensure the design and development of the eHealth strategies within the EU eHealth ecosystem, the eHN has specific subgroups that focus on developing strategies to support specific subjects on eHealth, such a subgroup is the eHN Subgroup on Semantics. This group was established at the end of 2019. It aims to develop a 5-year strategic plan for the Common Semantic Strategy (CSS) and then advance new 5-year strategy after this period. The eHN Subgroup on Semantics has a key role in the UNICOM project in developing this work at a semantic level.

4.2 First year of the project (V1)

Acknowledging this close liaison, the coordinator Karl Stroetmann and Marcello Melgara presented the UNICOM project to the eHN Subgroup on Semantics at an official meeting (see chapter 4.5). The progress of UNICOM, specifically WP5, is reported to the group, in subsequent meetings, by the Czech Rep. representative (Hynek Kružík). The presence of members in both groups (UNICOM and eHN Sub-group (SG) on Semantic) develops a close cooperation and ensures the alignment of the project with the current EU semantic strategy.

The UNICOM coordinator presented the project, specifically WP5 activities at the 18th eHN meeting (12-13 Nov. 2020). The business value of ISO IDMP to cross-border services is significant and well received by the eHN Community. One other important collaboration is between UNICOM with the Working Group on eHN PS Guidelines. They are currently working on updating the eHN PS implementation guidelines with the proposal to implement ISO IDMP among the EU bodies and NCA's.

Table 2 presents the official meetings on eHN where the UNICOM project was presented and discussed. It demonstrates that the eHN were aware of the UNICOM project from its inception to project commencement (Mar. 2019 Dec. 2019).

4.3 Second year of the project (V2)

The UNICOM project is a consistent topic on the agenda of the eHN SG on Semantics, being discussed and presented in almost all eHN SG on Semantics meetings (Table 2). This close relationship supports the development of the project and ensures the alignment towards the implementation of ISO IDMP.

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[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0024

Version 2 of eHN ePrescription Guideline[6] was published in 2016. Since then, a lot of work has been progressed in the ePrescription definition and the ISO IDMP standards. The eHN meeting in Spring 2021 agreed that the Subgroup on Semantics should investigate the revision of the ePrescription guideline and report back to them in its Fall meeting. The UNICOM project was invited to review and make comment on the eHN eP Guideline as this revision intended to update the information about the ISO IDMP. UNICOM feedback was evaluated and integrated into the final document.

Synergies exist between the different stakeholders participating in the European eHealth ecosystem, which support the adoption of common standards, and facilitate the implementation of the ISO IDMP on the different EU groups and Member States.

An opportunity now exists to include UNICOM in this ecosystem so that an alignment between all parties is possible in respect of the definitions proposed. One example about this connection is that the CP about Business Requirements jointly developed between UNICOM and eHDSI eP Cluster, has been a topic of discussion on the eHN SG on semantic meetings (see Table 2). It demonstrates the need to assure alignment of common European goals for eHealth.

4.4 Third year of the project (V3)

The UNICOM project activities and outcomes have been discussed regularly in both eHN SG on Semantics and eHN SH on Technical Interoperability.

A highlight of the third year of the project was the consolidation of the eHN Guidelines (for eP/eD, PS and Lab. Reports) which received direct inputs from the UNICOM project members. The contributions made by the project on the guidelines related to the use and implementation of ISO IDMP were important to support the Member States in implementing the ISO IDMP in accordance with the guidelines and the EMA Implementation Guide V2.1[7]. Furthermore, the eHN SG on Semantics is encouraging Member States to implement IDMP in order to help solve the issues related to medicinal products identification and enhance the interoperability among different Member States and EU infrastructures.

The eHN SG on Technical Interoperability has also commented on the activities of the UNICOM project as an example of good practices and how the UNICOM tools could also be reutilised to support synergy with other EU initiatives.

4.5 eHealth Network Meetings

This section contains the minutes of meetings of all eHealth Network communities' engagements where UNICOM was on the agenda.

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[6] **eP Guidelines context**: To support the processes of prescription and dispensation through the electronic exchange of supporting data for European citizens who are travelling inside Europe, where a patient from Country A (the patient's country of affiliation) is seen in another Member State Country B (the country of treatment)

As information sharing is not limited to the cross-border use case, Member States could also use these guidelines for National and regional level interoperability to ensure consistency as well as avoid fragmentation and duplication of efforts.

[7] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-1.pdf

Table 2 – UNICOM on eHN related group meetings (report combined from pre-project + 1st project year – 'V1', 2nd project year – 'V2' and 3rd project year – 'V3').

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
Pre-project and first year of the project (M1 - M12)		
12/05/2020	9th meeting of the eHealth Network sub-group on Semantics	The **UNICOM** scientific coordinator provided an overview about the project vision and goals. UNICOM's vision is to improve patient safety and improving healthcare. UNICOM is focusing on the aspects of univocal identification of medicines and pharmaceuticals products. It should in the future become easier to identify medicinal products. The main objectives UNICOM are concerned with is cross-border digital health services and regulatory processes of EMA and National Medicinal Products Authorities. Other objective is global pharmacovigilance, etc. UNICOM will help break down barriers hindering free flow of detailed, semantically coded interoperable drug information across the globe by: facilitating data sharing and providing semantically interoperable information. UNICOM has 3 main action lines: 1 implementation of IDMP at EU/National MPs database level, 2 adaption of cross-border digital health services, 3. Exploring pharmacovigilance services. **MS-Co-Chair**: Welcomes the work being performed by UNICOM and highlights the importance of this work towards the goals of the Semantic sg to improve the eHealth Network ePrescription guidelines (as defined in the common Semantic Strategy). **COM**: Welcomes the way how UNICOM as structure the work in particularly in direct correlation with the eHDSI mechanism (change management) so that the project outcomes can be taken forward upon completion. **MS-Co-Chair**: Highlighted the importance that we coordinate the work between the groups and to cooperate where possible. Supported the idea for regular meetings every 6 months. Hynek (CZ) and Marcello (eHDSI Semantic TF) volunteered to work in close cooperation with the UNICOM team and report to the Semantic sg.
14/07/2020	11th meeting of the eHealth Network sub-group on Semantics	**DE (chair)**: We had a presentation of UNICOM in the previous meeting. We have Hynek and Marcello as contact points for this project, and Marcello also for X-Health. **UNICOM**: We touch base recently, but it was not yet a project meeting. A joint plan with EMA for the assessment and creation with the EU-SRS. Some deliverables will be handed over to EMA for maintenance. § A questionnaire has been prepared to assess the implementation status of PS and eP in MSs, with particular focus on medicinal product. This questionnaire will be distributed to the eHMSEG eP Cluster and PS Cluster. UNICOM would like to share it also with the eHN SG on Semantic, to get the inputs for the "Requirement Specifications for the extension of eHDSI PS /eP services to adopt IDMP." Results about patient empowerment outcomes are expected in the coming months.
17/07/2020	Patient Summary TF meeting - 11th meeting of the eHealth Network sub-group on Semantics	**Brainstorm - how to take this task** ▪ Should we focus only in the PS or should we also take the General Guidelines? ▪ **DE**: we look at both documents but focus on PS guideline and foresee the impact in the general guidelines.

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

		▪ **IT:** Marcello will propose an overall strategy for tackle both documents is a logic way.
		▪ **CZ**: short remark that by revising the general and PS we will touch also the eP. The comparison between the IPS and eP. Since there is an overlap between the Medication Summary in PS and eP we may also consider to propose its update.
		▪ **DE**: If we propose an eP revision, we should also include **UNICOM**.
		▪ Should we focus only in the Semantic Provisions of the PS or should we work on the full document?
		   ▪ **DE**: we need to coordinate the work of other groups.
		▪ SCOPE
		   ▪ Enlarge beyond unscheduled care

11/08/2020	12th meeting of the eHealth Network sub-group on Semantics	**UNICOM**: Business requirements document is being prepared. It is expected to be available in September and Semantic sg will be asked for feedback.
08/09/2020	13th meeting of the eHealth Network sub-group on Semantics	**EU Vaccination Card project: candidate datasets** Vaccines are medicinal products, addressed by EMA / SPOR, giving high priority in building EU-SRS, to be able to make available ISO IDMP identifiers for Vaccines. This is also a topic of Medicine National Competent Authorities in **UNICOM** Project,
12-13/11/2020	18th eHealth Network meeting	The UNICOM project was presented on the eHN meeting under the agenda point: *8.4. Update on **UNICOM** project – [for information]* However, until the moment of the handover of this deliverable the meeting minutes were not available.
Second year of the project (M13 – M24)		

17/11/2020	15th meeting of the eHealth Network sub-group on Semantics	• Next connection points with **UNICOM**:
		  o Dec 2020, touch base for business requirements in the form of a change proposal for eHDSI.
		  o Jan/Feb 2021, providing an indication on how to provide semantic interoperability to PS, as a convergence between the eHDSI and the eHN Subgroup Semantics.
		  o Late spring: inclusion of specifications for wave 6 in the eHDSI.
		  o Explore the possibility to participate in the open webinars from **UNICOM**

13/04/2021	20th meeting of the eHealth Network sub-group on Semantics	• Following the Common Semantic Strategy (CSS) the next guidelines to be reviewed is the ePrescription. The work should start as soon as the PS guidelines work is completed, and special attention should be given to the **UNICOM** project outcomes. • eP guidelines: preparing the groundwork for the revision of the guidelines taking in consideration the outcomes from UNICOM project and eHN recommendations for that specific revision process; • Chat from Marcello Melgara to Everyone:

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
		o As **UNICOM,** we will propose a set of Change Proposal for the introduction of IDMP in the eP. The idea was to start working with the eHDSI eP Cluster to consolidate with them.

22/06/2021	22nd meeting of the eHealth Network sub-group on Semantics	• On the ePrescription guidelines work planning, it was confirmed the new mandate received from the eHealth Network, namely: a) review the General dataset guidelines and the ePrescription dataset guidelines; and b) prepare a guiding document for the development of new guidelines for datasets. The work on the ePrescription guidelines revision will kick-off with an editing group and a report should be provided to the eHN on the fall meeting presenting the progress made and the challenges found along the way together with a first draft. The work on the ePrescription guidelines revision will count on EMA and **UNICOM** project close collaboration taking into consideration the direct links between the guidelines and the work being performed by the EU medicine agency on standards and the UNICOM work on trialling and ramp-up the implementation of ISO IDMP.
		• Current status:
		  o 1: In **UNICON** we want to pilot and start implementation work at the level of National Medicines Authorities and National Medicines Dictionary
		  o 2: We are working to get agreement on attributes (50 attributes) that are key for ePrescribing and how to code them
		  o 3: We need to be clearer on what code systems can be used (agreements with EMA, FDA)
		  o 4: EMA has opted for HL7 FHIR resources but that path may have some limitations
		  o 5: In **UNICOM** we need to progress fast to fulfil the commitments in the agreement with the EC.
		  o Added value:
		    ▪ We can bring to the sg the outcomes from our discussions and piloting activities
		  o Answer to EMA comment:
		    ▪ Regarding substances we are in good shape. Without substances management system at EMA, ISO IDMP cannot be completed.
		    ▪ Some WPs are working in eP and PS implementation.
		    ▪ We are working to identify the minimum attributes (as coded elements) in ISO IDMP for the eP and PS purposes.
		    ▪ The idea now is that every MS and NCA will follow a roadmap to implement it, pushing for the EMA FHIR recommended approach.
		    ▪ We have already prepared a MyHealth@EU change proposal to be submitted to the eP cluster. It can also be shared to this group.
		  o **Highlights**: there are still blocking situations on cross-border exchange data: there is a concern between DG CNECT and DG SANTE in order to share early state deliverables.
		  o We (at X-eHealth) need authorisation from DG CNECT to share the deliverables here before they are formally approved. Are these limitations also applicable to **UNICOM** deliverables?
		• eP guidelines editing group:
		  o Marcello volunteers as editor, multiple role: eHDSI and also UNICOM WP567, working on eP evolutions for eHDSI

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM
13/07/2021	23rd meeting of the eHealth Network sub-group on Semantics	• In epSOS some experiments were made in a controlled environment. From eHDSI, we are learning with real world situations and **UNICOM** is taking them as requirements for the work being developed by the project. Hopefully, the inspiration from practical challenges will help to make the new version of the eP guidelines more practical and efficient vs the more theoretical approach from the previous version. • eHN sg technical IOP: UNICOM and X-eHealth are working in the preparation of guidelines. While preparing a general framework for eHN guidelines we should possible integrate some of the practices and lessons learnt from these projects (e.g. more modular approach)

10/08/2021	24th meeting of the eHealth Network sub-group on Semantics	• Regarding ePrescription guidelines revision, the drafting team reported little progress and mentioned the holidays period as the main reason for this. It was proposed a different approach to capture possible changes to current document, namely to invite relevant stakeholders (EMA, **UNICOM**, eHDSI eP Cluster and eHDSI Semantic Task Force, EC SANTE pharmaceutical unit) to propose changes. eHN sg Semantics-secretariat will reach out to the identified stakeholders and invite them to provide comments until 31st August. The change proposals received will be assessed by the ePrescription drafting group by 3rd September 14:00 CEST.
		
		Progress report:
		
		• Objective: evolve the 5+ years old version of the eHN ePrescription guideline and propose a new version for adoption in Spring 2022 (draft version to be presented in the eHN meeting fall 2021).
		• Drafting group meets 3 times; work has been distributed but not much feedback was obtained.
		• UNICOM developments:
		  ○ EMAIL: EMAIL 2021-08-10 - UNICOM - eHDSI: eHN communities' collaboration.pdf
		  ○ Attachments:
		    ▪ **Minimal Attribute list - eHealth.xlsx**
		    ▪ **CP-eHealthDSI-000_CP_D5.2_v0.1_20210729.doc**
		    ▪ Drafting group members:
		    ▪ Stefanie and Christine (DE)
		    ▪ Marcello (**UNICOM**, eHDSI Semantic Task Force)
		    ▪ Marta (eHDSI Solution Provider)
		    ▪ Hynek (CZ)
		    ▪ Leonardo (IT)
		    ▪ Danie (SE)
		    ▪ Annika (FI)
		    ▪ L. Fidalgo (ES)
		    ▪ Secretariat: EC (Licinio)
		    ▪ eHDSI (eP Clusters, Semantic Task Force)
		
		Next steps:
		• Invite eHN sg Semantics, **UNICOM**, EMA and EC SANTE Pharmaceutical unit experts to comment (propose changes to the current content) directly in the open document. Comments expected until end of August (31/08/2021)

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

14/09/2021	25th meeting of the eHealth Network sub-group on Semantics	• Preferred ISO IDMP Code System, what does it means in practice:
		  ○ That a country must use the IDs defined by the ISO IDMP?
		  ○ That countries must adopt the SPOR's master data?
		  ○ When the ISO IDMP is ready for being use in ePrescription context and who decides on this?
		  ○ How should the SG react to the **UNICOM** change proposal for eHDSI referring to ePrescription: CP-eHealthDSI-000_CP_D5.2_v0.1_20210729.doc?
		Feedback & Discussion
		• the eHDSI change proposal (prepared by **UNICOM**) needs to be submitted before the end of September, so that the follow up steps can be performed on time for the release in 2022 and being operational by 2023.
		• Change Proposal document is available in today and last meeting minutes. Please provide any comments to that document.
		• EMA: proposed a discussion with the people (architects) in the SPOR.
		• To align the eP guidelines with the SPOR developments.

09/11/2021	27th meeting of the eHealth Network sub-group on Semantics	**ePrescription guidelines (revision of existing guidelines)** • The eHealth Network subgroup on Semantics informed that there are ongoing reflections and discussions on the ePrescription guideline revision. This process requires additional time to mature, as well as needs eHealth Network guidance regarding the findings encountered so far. The eHealth Network provided the following indications: ○ Alignment of work with **UNICOM**, ePI work of EMA and the Patient Summary guideline 3? (inclusion of planned care and possible other use cases that might arise in the future). It was mentioned that the linkage with ePI could provide benefits for Patients, namely when abroad getting access to the product information in digital format and in their preferred language.
	Third year of the project (M25 – M36)	
14/12/2021	28th meeting of the eHealth Network sub-group on Semantics	• Make the guidelines project agnostic • Use the guidelines also beyond cross-border uses only. • Some ISO standards references are outdated • Build on the **ISO IDMP** work experience and inputs from **UNICOM** • There are many overlapping areas between PS and eP. If any ideas on how to resolve those issues: One way forward could be to update the eP to become aligned with PS, but this will lead to some changes that may break existing implementations.
11/01/2022	29th meeting of the eHealth Network sub-group on Semantics	• All 3 guidelines (ePrescription, General and Laboratory) drafting is progressing. However, 2 weeks more are necessary to reach a good completeness level required for the first consultation. It was agreed that drafting teams can continue evolving the text until 21 Jan and that consultation will start on the 24 (for 3 weeks). Regarding the first consultation period it was also agreed which stakeholders will be consulted. There are domain specific stakeholders that should be consulted for specific guidelines (e.g., EMA & **UNICOM** for ePrescription, X-eHealth and Laboratory national expert bodies for Laboratory guidelines). • Keep the consultation within real stakeholders working so far: ○ **UNICOM** and X-eHealth

Date (DD/MM/YYYY)	Meeting	Minutes related with UNICOM

08/02/2022	30th meeting of the eHealth Network sub-group on Semantics	• Consultation of the eHN Guidelines and specific inputs:
		• Specific for ePrescription
		  ○ EMA
		  ○ **UNICOM** project

10/05/2022	33rd meeting of the eHealth Network sub-group on Semantics	• Regarding **UNICOM** and ISO IDMP is there something more we can address? ○ EE: **UNICOM** and **ISO IDMP** - I don't think there's much to discuss at this point. Writing it to the eP guidelines was already a bit of a stretch.

07/06/2022	34th meeting of the eHealth Network sub-group on Semantics	• 2. Debrief from eHealth Network 1 and June "semester" meeting
		  ○ EC: When is realistic to have **ISO IDMP** in the guidelines?
		  ○ SG: **UNICOM** gave a big push, EU DCC also gave a good push. This is a real need. In 2 or 3 years we may have important components of **ISO IDMP** might be ready.

08/07/2022	Sub-group on Technical Interoperability (bi-weekly meeting)	• eWallet and ePrescription
		  ○ Vincent: time is an issue - deadline is the AUG 17 for the LSPs. The eIDAS Toolbox not ready yet - we can see no implementable specifications.
		  ○ The formation of a separate eHealth-focused consortium seems problematic. The **UNICOM** demonstrator could be an opportunity for synergy.
		  ○ Tobias: there is ongoing work on the Toolbox specifications - status can be confirmed. Also, the ePR and Wallet combined use case requirements can influence the Toolbox.
		  ○ ACTION: Konstantin to be contacted about the title of the document describing the ePR and Wallet combined use case.

12/07/2022	35th meeting of the eHealth Network sub-group on Semantics	• **UNICOM** and **ISO IDMP** in MyHealth@EU: the latest release of MVC already includes elements from ISO IDMP (substances). • There will be a meeting of the MyHealth@EU Semantic Task Force

5 Cooperation with the National Competent Authorities

5.1 General overview

The National Competent Authorities (NCA) have a fundamental role in their respective MS on the healthcare ecosystem. Related to the UNICOM project, there are two different types of NCAs that should be highlighted: The National Drug Agency, that is responsible for regulation, identification and authorisation of medicines products in the respective Member State, and the eHealth Agency, responsible for the provision of eHealth services at national and cross-border levels. Both agencies either work under the Ministry of Health scope of work or work closely together. As the UNICOM project strives to improve the identification of medicinal products at National and Cross-border levels in the EU, a fundamental requirement is the collaboration and cooperation between these agencies to ensure the successful adoption of the IDMP. Currently UNICOM has 11 Drug agencies and 7 eHealth agencies as partners of the project, working together to safeguard the deployment of the IDMP-related database. The partnership of both agencies is fundamental to the success, as legislation of some countries only accepts changes or improvements on their medicinal products database from the NCAs.

5.2 First year of the project (V1)

The results of a survey (Comparison of national eHealth Services [electronic Prescription (eP), Patient Summary (PS) services] and their respective legal base in EU countries) conducted by WP5 was distributed among key stakeholders from several Member States informed the evaluation of specific characteristics and similarities in respect of their eP/eD and PS, including the respective legal context (Annex 1 – Questionnaire about national eHealth Services).

In relation to the legal framework analysis, a total of 9 Member States responded to the survey. The analysis of the responses indicated that the implementation of databases from external sources (such as UNICOM) might be possible if it is approved by the NCAs, in this case the drug agencies. This reinforces the importance of having a close working relationship with and between these agencies to guarantee a successful outcome.

UNICOM WP4 (IDMP implementation at National Drug Agencies) is directly responsible for the implementation of IDMP in the NCAs, working together ensuring that the implementation of ISO IDMP will be done to the highest level of excellence.

UNICOM WP12 (Overall scientific coordination, dissemination and sustainability) is managing a communication framework (webinars, presentation of UNICOM website and outcomes) to connect the work of the NCAs and other important stakeholders currently not actively participating in the project. This work will support the dissemination of UNICOM deliverables and improve the relationships with key national stakeholders to support the probable future adoption of ISO IDMP in their respective databases.

5.3 Second year of the project (V2)

One of the WP5 activities is to define a 'minimal attribute list' to be used on the eHealth services to support the ISO IDMP implementation for national and cross-border deployments.

The identification of the medicinal products can be enhanced by the use of a complementary set of ISO IDMP compliant attributes. This increases the opportunity for dispensing medicines cross-border while also ensuring the safety of the dispensation process.

To support this activity, the UNICOM WP5-6-7 cluster work closely with the UNICOM WP4 (IDMP implementation at National Drug Agencies) and the respective National Drug Agencies (NCAs) to ensure alignment. These agencies identified the current attributes in use in their systems in order to support the eP/eD & PS services in their respective countries.

The Portuguese NCA (INFARMED, I.P.) and eHealth Agency (SPMS, E.P.E.) are collaborating on the development of some of these activities, such as the development of the 'minimal attribute list' and revision of WP5 deliverables, with direct national scope (D5.6 and D5.7).

The WP5 encourages the close relationship between the eHealth agencies and NCAs of all countries that have both agencies in the consortium or not. The relationship between the NCAs and eHealth agencies (or Ministry of Health, depending on the country) is considered fundamental to the success of the project because the eHealth services consumes the data from the NCAs.

5.4   Third year of the project (V3)

The approval and the implementation of the CP-66 on the eHDSI wave 6 (2022-2023) was an important milestone and help to increase the awareness of Member States about possibility of the use of the ISO IDMP attributes to exchange clinical documents (in production from 2023 autumn). From this wave, Member States can include precise coded information about the substances using the SPOR-SMS with the new value set 'eHDSISubstance' and the 'Unit of Presentation' with the 'eHDSIQuantityUnit' value set. In parallel to it, some Member States started build a IMDP database with the SPOR codes including these new attributes that intends to support a safe and precise exchange of medicinal products information. Besides the inclusion of these new value sets, almost all other information regarding the identification of medicinal products is already IDMP compliant, considering the eHDSI MVC, that includes codification from EDQM, UCUM and ATC. In addition, it is important to highlight that the information about the ATC codes (eHDSIActiveIngredient) will be kept on the medicinal products information, as an important attribute to identify the medicine class.

The inclusion of these new value sets and attributes to the medicinal products description under eHDSI has increase the alignment between the UNICOM and national bodies (extended to the Member States not participating in the project), driving discussion about the best implementation strategy of the IDMP attributes.

One of the interesting outcomes of this alignment was the encouragement of NCAs to use international coding systems to represent the medicinal product information, thus fulfilling the EMA roadmap to use the SPOR database to represent all medicinal product information. For the wave 8 (2024 – 2025), discussion about the new CPs was initiated, in which one of the possible new CPs is about eHDSI adopting a central transcoding service to map the information from SPOR codes to the eHDSI MVC, in order to allow Member States that are implementing the SPOR codes, to use this information without the need for prior transcoding in their respective NCPeH.

The reported initiatives strengthen the UNICOM project's relationship with the national health authorities and pave the way for interoperability of medicinal product description in the EU. Annexes

Annex 1 – Questionnaire about national eHealth Services

Comparison of national eHealth Services [electronic Prescription (eP), Patient Summary (PS) services] and their respective legal base in EU countries

Introduction

UNICOM[8] – an EC supported Innovation Action - focuses on implementing the International Organization for Standardization (ISO) suite of IDMP (**ID**entification of **M**edicinal and **P**harmaceutical Products) standards. Work involves further development, testing, implementation, and diffusion of these standards, inter alia, for advancing cross-border digital health services, particularly ePrescription.

This survey on eHealth Services (electronic Prescription (eP) and Patient Summary (PS)) aims to gather information about the current state of national eHealth services in EU countries. The results of this survey will inform the UNICOM Business Requirements' report through the comparison of eP and PS activities in different countries.

For the purpose of this survey, the definitions of ePrescription and Patient Summary was extracted from the CEF eHDSI Glossary[9].

The concept of the **ePrescription** service is understood as the ordering of a prescription in software, the electronic transmission of that prescription from the Prescription provider to a Dispense provider, the dispensing of the medicine and the electronic transmission of the dispensed medicine information from the dispensing provider to the prescription provider.

Patient Summary is an identifiable "dataset of essential and understandable health information" that is made available "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care"; it can also be defined at a high level as: "the minimum set of information need to assure Health Care Coordination and the continuity of care".

Respondent Information

Name	*
Email address	
Role	
Organisation	
Country	*

* Obligatory fulfilment

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[8] https://unicom-project.eu/

[9] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Glossary

Data Protection notice: In line with the requirements of the EU GDPR. We request that you leave us your information, so we can better understand your background and verify that you fit into one of the target groups of survey respondents, but please note that any response you provide in this Survey will be fully anonymised.

<div align="center">

Legal framework questions

</div>

Q1. a) Are there current legislations in your country that cover the implementation of ePrescription?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

R: _____

b) Are these laws/legislations reinforced?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

R: _____

c) Are there any constraints in your country's legislation that may complicate the adoption of new ePrescription services regarding the medicinal products identification?

☐ **Yes;** ☐ **No.** *If **Yes**, please specify. If **NO**, why not?*

R: _____

Q2. a) Is there any current legislation in your country that covers the implementation of Patient Summary?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

R: _____

b) Are these laws/legislations reinforced?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

R: _____

c) Are there any constraints in your country's legislation that may complicate the adoption of new Patient Summary services regarding the medicinal products identification?

☐ **Yes;** ☐ **No.** *If **Yes**, please specify. If **NO**, why not?*

R: _____

Q3. Is there any specific national legislation required for the implementation of a new standard on ePrescription services in your country?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

R: _____

Q4. Is there any specific national legislation required for the implementation of a new standard on Patient Summary services in your country?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

R: _____

Q5. Do you foresee/have specific agreements with other countries to assure the interoperability of cross border ePrescription?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

      a) the scope of the agreements?

R: _____

      b) if they are bilateral or multilateral agreements?

R: _____

Q6. Do you foresee/have specific agreements with other countries to assure the interoperability of cross border Patience Summary?

☐ **Yes;** ☐ **No.** *If Yes, please specify*

      a) the scope of the agreements?

R: _____

      b) if they are bilateral or multilateral agreements?

R: _____

Q7.a) Is it possible to use for ePrescribing services the Medicinal Product Databases enhanced by Medicinal Products Dictionaries (MPD) private providers?

R: _____

b) Should these enhancements be certified by the National Drug Agencies?

R: _____

Q8. Any other comments or details you would like to add:

R:

THANK YOU VERY MUCH FOR YOUR HELP!

1ˢᵗ Workshop about EU eHealth cross-border services & UNICOM
Agenda

When: Day 1: Thursday, 04 February 2021 – 14:00 – 16:30 CET (UTC +1)

Day 2: Friday, 05 February 2021 – 14:00 – 17:10 CET (UTC +1)

Where:

Day 1: https://global.gotomeeting.com/join/536669269

Day 2: https://global.gotomeeting.com/join/835673621

We intend to collect questions and comments through the Mentimeter app.

App: www.menti.com/ access code (**54 14 86 1**) or https://www.menti.com/ptjzmupnwo

Introduction and context

Initiated in Dec. 2019, the project UNICOM (Up-scaling the global univocal identification of medicines - https://unicom-project.eu/) has the main goal of accelerating implementation of optimised ISO IDMP (ID of Medicinal Products) standards, allowing univocal identification of medicinal products across the EU regardless of product names on national markets and across all EU languages. The WPs 5, 6 and 7 are responsible for implementation of the ISO IDMP on the eHealth services at national and cross-border levels:

- **The WP 5 – IDMP adoption by eHealth Services**
  - o Responsible for defining the requirements, guidelines and eHDSI draft change proposals for ISO IDMP adoption in eHealth services.
- **The WP 6 – Software and extensions for CEF eHDSI**
  - o Coordinate the UNICOM software factory and reference implementation of IDMP by the User Portal, in conjunction with the eHDSI Technical Community

- **The WP 7 – eHDSI cross-border/national eHealth services piloting**
  - o Define Testing and Piloting strategies, deploy and evaluate country-specific and cross-border eHealth services pilots making use of IDMP coded ePrescription/PS data as optional data within the Cross-Border eHealth Interoperability Services in operation.

Workshop Objectives

The objectives of this Workshop are to present in some detail the history, and particularly the organisational structure, data flows and technical details of the ePrecription/eDispensation and Patient Summary healthcare services as provided in the context of the CEF eHDSI; and to give a preliminary glimpse of the new requirements resulting from IDMP implementation and pilots planned to test the adapted technical infrastructure by UNICOM.

Day 1 – 04 February 2021 https://global.gotomeeting.com/join/536669269 **Workshop about eHealth Services & UNICOM** **What is CEF eHDSI and Its services and what is their relationship with UNICOM project**		
14:00 – 14:05	**Welcome and Agenda introduction**	Diogo Martins *SPMS* Alexander Berler *GNOMON* Marcello Melgara *ARIA*
14:05 – 14:15	**Introduction to the eHealth services from epSOS to now**	Marcello Melgara *ARIA*
14:15 – 14:45	**MyHealth@EU (eHealth Digital Service Infrastructure)**	Natalia Zylinska-Puta *EC DG SANTE B3- eHDSI Owner* Simona-Maria Tiplea *EC DG SANTE A4 – eHDSI Solution Provider*
14:45 – 15:15	**CBeHIS (Cross-Border eHealth Information Services)**	Klára Jiráková Eamon Coyne *eHMSEG Chairs*
15:15 – 15:25	**Break**	
15:25 – 15:55	**ePrescription (eP) Services**	Annika Ohlson *eP Cluster chair*
15:55 – 16:25	**Patient Summary (PS) Services**	Klára Jiráková Eamon Coyne *eHMSEG Chairs* Antoine Chaudieres *PS Cluster Chair*
16:25 – 16:30	**Wrap up and closing**	

Day 2 – 05 February 2021 https://global.gotomeeting.com/join/835673621 Workshop about eHealth Services & UNICOM Functional requirements that need to change to adopt ISO IDMP on cross-border services		
14:00 – 14:05	**Welcome and Agenda introduction**	Diogo Martins *SPMS* Alexander Berler *GNOMON* Marcello Melgara *ARIA*
14:05 – 14:15	**Introduction about UNICOM**	Karl Stroetmann *UNICOM coordinator*
14:15 – 14:30	**Expected UNICOM Outcomes**	Saila Rinne *Head of Sector for eHealth in CNECT.H3*
14:30 – 14:50	**Roadmap for ISO IDMP implementation on eHealth services**	Marcello Melgara *ARIA* Diogo Martins *SPMS*
14:50 – 15:50	**WP5 outcomes: Business requirements and IDMP Attributes**	Diogo Martins *SPMS* Alexander Berler *GNOMON* Marcello Melgara *ARIA* José Teixeira *IHE* Giorgio Cangioli *HL7*
15:50 – 16:00	**Break**	
15:16 – 16:30	**Semantic and pharmaceutical standpoint by eHMSEG semantic Task Force**	Marta Terrón Cuadrado *DG Santé eHDSI Solution Provider* *eHMSEG Semantics Task Force*
16:30 – 17:00	**Evolution of eHN Guidelines**	Stefanie Weber *eHN Subgroup on Semantic*
17:00 – 17:10	**Wrap up and closing**	

Annex 3 – CP-eHealthDSI-066: Align eHDSI with ISO IDMP

The following change proposal 'CP-eHealthDSI-066: Align eHDSI with ISO IDMP' was initially developed in the deliverable '*D5.2 - Guidelines for Cross-Border ePrescription / eDispensation'* and presented to the eHDSI eP cluster and Semantic Task Force (STF) to support the update and cocreation of this document.

The eP cluster, STF and UNICOM collaborated on maturing the Change Proposal document. eP Cluster, in conjunction with UNICOM, submitted this document to the eHDSI 08 Oct. 2021.

This change proposal identifies improvements with respect to the current eHDSI business requirements and intends to support the further implementation of the ISO IDMP at eHDSI.

Change Proposal Description

Please consider that this is the section used by the eHDSI stakeholders when assessing the impact of the requested change proposal.

REASON/BUSINESS JUSTIFICATION (WHY this change is needed)
The implementation of the ISO IDMP standard in EMA SPOR databases is changing how medicinal products are (a) identified and (b) described by the National Competent Authorities, which will inform future eHealth System implementations at both national and regional level.

The goal with this change proposal is to enable the eHDSI services to make use of ISO IDMP to solve known challenges in representing medicinal products for the cross-border use cases. This includes known challenges such as complex packages, different representations of dose forms and strengths and identifying prescribed and dispensed medicinal products using unique identifiers. The CP is therefore related to the CP "Medication Information Representation Improvements", which is being processed in parallel.

It is important to provide support for the new way of identifying and describing medicinal products because this information is used in the ePrescription/eDispensation & Patient Summary (Medication Section) data sets.

There are significant benefits to making use of ISO IDMP standard including, but not limited to, improving the presentation of information about medicinal products, and streamlining the dispensation process in many cases.

The implementation of ISO IDMP is predicted in the Commission Implementing Regulation (EU) Nº 520/2012, articles 25 and 26, which obliges EU MS, marketing authorisation holders and EMA to make use of the ISO IDMP standards. In order to ensure a correct implementation of ISO IDMP in the eHDSI specifications, this CP aims at introducing new phrasings for relevant identified business requirements to the ePrescription & Patient Summary services. It is noted (also mentioned in UNICOM D5.1 - Business requirements for the adoption of IDMP in eHealth Services) that the adoption of IDMP does not impose that countries must use exclusively IDMP in their national processes – in short, national processes shall still be able to use national models). Therefore, IDMP adoption appends, but not necessarily restricts, data exchange at national and cross-border levels. Those identified changes were previously evaluated through intense study and their implementation will support the further ISO IDMP implementation. |

This CP focuses on eP/eD related requirements. The work done is also beneficial to update PS related requirements. It is suggested that, when implemented, PS Cluster is involved to get aligned requirements.

In preparation of this CP, a few missing data elements were discovered in the Data elements descriptions in the eHDSI Requirements Catalogue. This CP also contains a few suggested clarifications and suggested additions to the Data elements descriptions to better reflect the current CDA implementation, although this is not directly IDMP-related.

DESCRIPTION OF THE REQUESTED CHANGE

Background information

Glossary

General	
EMA SPOR	Data management services by European Medicines Agency. The four SPOR data management services are: - SMS: substance management service - PMS: product management service - OMS: organisation management service - RMS: referentials management service (value sets) More information can be found on EMA SPOR web site.
Identifiers	
MPID	Medicinal product identifier. Unique identifier assigned to a branded product. The MPID is tied to the marketing authorisation life cycle and the same product is assigned a new MPID when the marketing authorisation changes.
PMS ID	Product Management Service identifier. PMS ID is a unique identifier of the medicinal product in EMA SPOR PMS system. Unlike the MPID, PMS ID remains unchanged during the entire lifecycle of the product. PMS ID is not in the original data model of ISO IDMP, but an extension by EMA.
PhPID	Pharmaceutical product identifier is a unique identifier of the product on a generic level. The PhPID is calculated on the basis of ingredients, strength, administrable dose form. Unique PhPIDs and different levels of PhPID will be available in the future.
PCID	Packaged medicinal product identifier. PCID consists of two parts: the corresponding MPID and the package description code segment. A unique PCID is assigned for each package that has a different set of size, package type/material or manufactured items.
Dose forms	

Authorised dose form	The pharmaceutical dose form as authorised by regulatory authorities. This includes combined pharmaceutical forms like *Powder and solvent for solution for injection*. Authorised dose form is not in the original data model of ISO IDMP, but an extension by EMA.
Administrable dose form	Pharmaceutical dose form in which the product is administered to the patient. For example, in case of the example given for the authorised dose form section, the corresponding administrable dose form is *Solution for injection*.
Manufactured dose form	Pharmaceutical dose form of a manufactured item (before transformation into the pharmaceutical product). One medicinal product may consist of several manufactured products with different manufactured dose forms, e.g *Solution for solution for injection*, *Powder for solution for injection*.
Strengths	
Reference strength	Reference strength represents the strength of the active moiety to express the strength of the product. If the active substance in the product is salt or esther, the reference strength would be different from the presentation/concentration strength. For example: if the strength for omeprazole magnesium is 20.6mg/tablet; the reference strength of the product would be described as omeprazole 20mg/tablet.
Concentration strength	Concentration strength represents the amount of an active ingredient per single unit of measure. This is the regular way of describing the strength for liquid dose forms, e.g 10mg/g.
Presentation strength	Presentation strength represents the amount of an active ingredient per one unit of presentation. This is the regular way of describing the strength for tablets, capsules and other solid countable items. This information would also be available for other dose forms, e.g 10mg/vial, 120mg/bottle, 50mcg/actuation.
Units	
Unit of measurement	Units of measurements are standardised quantities of measurement. The eHDSI and EMA SPOR both make use of the UCUM list of units of measure.
Unit of presentation	Unit of presentation describes the single countable entity in which a pharmaceutical product or manufactured item is presented. Although unit of presentation has an overlapping content with package types as well as dose forms, it should not be confused with either of them.

Full ISO IDMP data model is a complex set of data elements in a specific structure. The granularity of this information is suitable for the regulatory authorities. Even though it is expected, that having unified and more detailed medication data available on a national and international level will change the way this data is represented in all the information systems,

there is no clear guidance on if, how or when these changes should be implemented in national prescription systems.

eHDSI is not aiming to implement full ISO IDMP in the eHDSI services, but to make use of ISO IDMP data model and EMA SPOR value sets to improve our services and make it possible for member states to send their data in a similar (but simplified) format. However, it must be stated, that if a member state is not capable of sending this data, it can still use the services, and the new attributes and layers of information will be optional on country A side.

To plan the upcoming changes, some changes have to be made in the business requirements that are listed below. In many cases, the actual change is still up for discussion, but it is important to show the relations between current business requirements, parallel change requests and possible future implementation changes that are still up for discussion.

For more information about implementing ISO IDMP in EMA SPOR, please refer to EU ISO IDMP Implementation Guide.

List of improvements and discussion points

05.01   Create the eHDSI Patient Summary content

Requested change

The table named "The dependencies between the information exchanged in both services" should be removed/replaced, as it is partly misleading.

Further analysis needed

There is an overlapping content in Patient Summary's medication summary and ePrescription and eDispensation. These data sets should be harmonised where necessary and the ePrescription content changes described below (requirement 06.01) should be taken into account.

Impact

No impact at this point.

Requested change aims to clarify the actual existing content.

Any decisions emerging from the analysis of the PS content will be communicated to the member states separately and member states will have an opportunity to agree or disagree with the change.

05.02   Transcode, translate and exchange cross-border the Patient Summary.

Change requests

No changes are required to the business requirement text at this time.

Further analysis

Additional translations and transcodings might be required, in the event of new code systems and value sets being developed and introduced, switching to EMA SPOR value sets where necessary.

The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries and improving the data structure.

Impact

No impact, as the possible future changes will be approved by member states before implementation.

06.01   Create the eHDSI ePrescription content.

GENERAL

Further analysis needed

The data sets used for the Medication Summary section in Patient Summary, ePrescription and eDispensation should be harmonised (use of the same attributes and elements to describe the medicinal products, for the different use cases) across the use cases; eP/eD and PS.

While product information should be harmonised, it is important also to acknowledge that the level of detail about products in an ePrescription may differ from the level of detail in a eDispense – in a prescription, the product information can be more or less granular, but dispenses are reported with much more detail (as reported in UNICOM D5.2). Therefore, we suggest to start by splitting the notion of Prescribed Product and Dispensed Product.

The exact content and cardinality of data elements is yet to be discussed more thoroughly and agreed with the member states.

Impact

The change has no impact on member states at this point.

The exact changes are negotiable and have to be agreed by member states. Any changes in the cardinality of data elements must take into account that member states who are already active in the eHDSI services must be able to continue data exchange.

IMPROVE DESCRIPTION OF DATA ELEMENTS

Requested changes

Add *ATC code* to the specification as it is already supported by the technical specifications, but absent from the business requirements.

Add *Packaged product description* text field into the data set specification to provide a sufficiently detailed description of the prescribed medicinal product/package.

Add and clarify information according to the parallel CP "Medication Information Representation Improvements". The business requirements should help understand how to

describe layers of complex packages and how to use MPID and PCID or their national equivalents.

Impact

No impact. The changes are simply rephrasing the business requirements to give better explanation of the existing solution and the parallel CP (agreed by Member States independently from this CP).

NEW DATA ELEMENTS FOR DISCUSSION

IDMP identifiers

Further analysis needed

ISO IDMP and EMA SPOR introduce a list of identifiers to be used on different levels for identifying a medicinal product or its package.

Enable provision of ISO IDMP identifiers in addition to the currently supported "national code": PCID, MPID, PhPIDs; assuring that the type of each IDMP ID is correctly identified, including the multiple levels of PhPID.

Introducing new identifiers requires corresponding data structure to be implemented. Any changes in the implementation needs to take into account that not all member states have this data available at the same time and using new identifiers must remain optional.

Parallel CP "Medication Information Representation Improvements" proposes adding PCID, but also states that using this data element is optional and a national package identifier can be used.
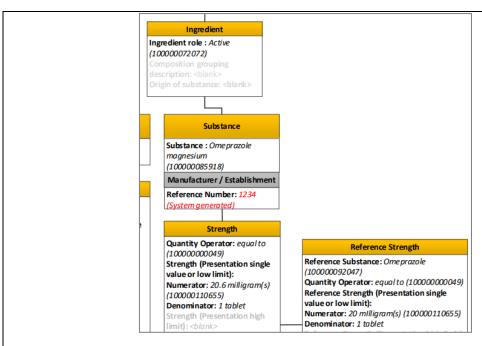
Impact

No impact at this point.

Ingredients and strengths

Further analysis needed

ISO IDMP and EMA SPOR SMS provide an opportunity to identify all the ingredients in the product: active ingredients as well as other ingredients such as adjuvants or additives (e.g lactose). It should be thoroughly analysed how this information could improve the quality of eHDSI services.

The strength of active ingredients could also be described more precisely by adopting the ISO IDMP model for expressing strength. For example, by adding reference strength, it would be possible to express the strength by the quantity of salt (omeprazole magnesium) as well as by the active moiety within the salt (omeprazole). The example below is a piece of ISO IDMP data model from EU ISO IDMP Implementation Guide (Chapter 8, Annex I "Complete Representation").

Impact

No impact at this point. Member states are invited to discuss the need and opportunities to express additional information about ingredients and strengths.

Package size

Requested changes

The most important changes in representing the contents of the package are proposed as a separate CP "Medication Information Representation Improvements". These changes follow the structural and conceptual logic of ISO IDMP and would help us overcome the main problems we're facing today: representing multi-layer packages (e.g 5 vials of 3ml as one product) and complex packages (e.g creme + tablets marketed as one product).

The business requirements must be renewed according to these changes, so that the description of the data element *Medicinal product package* would explain how the nested structure helps calculate the total amount of the product within a package or the overall amount prescribed on an ePrescription.

Impact

No impact to the member states as this change requests only states the need to renew the business requirements. The actual change request for implementation changes is processed separately.

The change itself will improve the reliability of crossborder eP by removing ambiguities and increasing dispensability.

Dose forms and unit of presentation:

Further analysis needed

ISO IDMP structure includes different dose forms with different meanings. For better understanding, please see the dose form section in the glossary. Also, concept of *Unit of presentation* is introduced to describe the product as well as the quantity of the product.

It is important to analyse the possibilities to better reflect the dose form concept and highlight the distinction between the authorised, manufactured and administrable dose form on the eP and eD documents. Clarifications are needed on how to understand if *Unit of presentation* or *Dose form* should be used in the description of medication or posology. These value sets have overlapping content, but they should not be confused as they represent a different concept.

The future solution should also support different levels of granularity of dose forms (e.g. capsule, hard; capsule), providing relationships between them.

In order to make use of the variety of dose forms and units, the representation of medication must follow the general structure of ISO IDMP.

Impact

No impact at this point. Member states are invited to discuss the need and opportunities to express additional information about dose forms.

06.02   Transcode, translate and exchange cross-border the ePrescription.

Change requests

No changes are required to the business requirement text at this time.

Further analysis

Additional translations and transcoding might be required, in the event of new code systems and value sets being developed and introduced, switching to EMA SPOR value sets where necessary.

The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries and improving the data structure.

The changes applied to data elements on eP might also lead to improved prescription list, which is described under this requirement.

Impact

No impact at this point, as the possible future changes will be approved by member states before implementation.

07   Handle Dispensation of medicine and substitution

Change requests

No changes are required to the business requirement text at this time.

Further analysis

The business requirement has a reference to a flag indicating whether substitution was performed as part of the dispensation process. The process of substitution is not standardised, but further details may be provided during UNICOM. It is still useful to maintain the attribute "Substitution performed" (in the dispense dataset) differently from "substitution allowed" (which is appropriate in the prescription dataset).

Impact

No impact, as the possible future changes will be approved by member states before implementation.

07.01   Create the eHDSI eDispensation content.

Requested changes

Align the product description with the ePrescription model (see the changes to the requirement 06.01 Create the eHDSI ePrescription content).

Add *also Patient gender* to the specification as it is already supported by the technical specifications, but absent from the business requirements.

Remove or clarify "Dispensed medicine ID" as it can be confused with "Medicinal product code".

Rephrase „Medicinal product description" to „Dispensed product description". The requirement text should explain, that unlike the ePrescription, where the main product code refers to different 'concepts' of products (e.g. prescription can refer to brand, generic or substance levels), in dispensation the most specific product identifier is usually captured (i.e. medicinal product package code or similar).

Improve description of the package size and quantity of the dispensed medication within the "Dispensed product description" element. The requirements for describing the package size are explained above at "06.01 Create the eHDSI ePrescription content". In the context of eDispensation, the requirement text should explain how the number of packages and different layers of package description result in an overall amount of dispensed items.

Move "Number of packages" from "Medicinal Product Description" group to "Dispensed Medicine Data" group.

Impact

No impact to the member states at this point. The changes aim to add clarity to the requirement text and do not impose any changes in the implementation.

Further analysis needed

In the ISO IDMP mode, an additional "Pack(age) size" attribute is available, but as this is just a textual element (e.g *1 vial and 1 syringe*), it would not contribute to calculating the amount. However, introducing the data element may help understanding the most difficult cases, even if it was readable for a human eye only.

It would also be possible to add the data element "Package size" and analyse if member states would be able to provide structured, automatically processable data in it, or would it

merely be the multiplication of quantities provided in the nested layers of the description of package.

The total amount of dispensed product is a required information. The total amount can be expressed either as an explicit data element, or as the combination of the number of packages dispensed and the quantity per package. It is up for discussion if the distinct data elements should be provided to express:

- Total dispensed amount: The total quantity of dispensed product items (including units) that has been dispensed.
- Number of dispensed packages – the number of items that have been dispensed, where each item is identified by the dispensed medicinal product code above. The total amount of dispensed product corresponds to the number of packages multiplied by the package size.

The way of describing dispensed amount (total quantity vs number of packages x package size) will depend on local regulations and each clinical case, so one cannot be enforced over the other. Given that there are two ways of achieving the same goal, further guidance should be given on the use of these attributes, and Member States should have support in selecting which one(s) to use.

Impact

No impact, as the possible future changes will have to be approved by member states before implementation.

07.02 Transcode, translate and exchange cross-border the eDispensation.

Change requests

No changes are required to the business requirement text at this time.

Further analysis

Additional translations and transcoding might be required, in the event of new code systems and value sets being developed and introduced, switching to EMA SPOR value sets where necessary.

The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries and improving the data structure.

Impact

No impact, as the possible future changes will have to be approved by member states before implementation.

09 Ensure High quality information (structured, equivalent, understandable) is exchanged between countries.

Requested changes

No changes requested in the text of business requirement at this point.

Further analysis needed

However, adopting ISO IDMP identifiers and adopting the common EU terminology provided by EMA SPOR value sets will significantly provide more possibilities to deal with the unified meanings regarding medicines.

Once these improvements have made their way in the eHDSI service, the business requirement should be updated with relevant information.

Impact

No impact to the member states at this point.

OVERVIEW OF THE EXPECTED OUTCOMES/BENEFITS

The CP aims to clarify the current business requirements and start a fruitful discussion with member states about implementing future changes related to the ISO IDMP and the parallel work in the UNICOM project. It also aims to provide functional requirements to match the discussions around "complex packages" in the CP from the STF Architecture WG "Medication Information Representation Improvements" (targeting the CDA IG).

As the result of this project the health professional in the country of treatment will receive more detailed and understandable information about the medicinal product that appears on a Patient Summary or an ePrescription document:

• Ingredients and ingredient roles (coded and translatable)

• Product identifiers on different levels (e.g. PhPID, MPID, PCID)

• Package content (clear quantities, device), package types (coded and translatable)

• Dose form (multiple dose forms of different types, coded and translatable)

• Units of presentation in addition to units of measurement (coded and translatable)

• Strength (reference strength in addition to current solution)

When a dispensation is performed abroad, the same approach will be taken when providing the eDispensation document allowing country of affiliation to better integrate information about dispensations performed abroad in their national infrastructure.

Additional information about substances, dose forms etc might also be added to the prescription list, allowing the pharmacist to better understand its contents in order to choose the correct medicinal product to be dispensed.

The new information elements and their consistent use in ePrescription, eDispense and Patient Summary, aligned with IDMP concepts and common SPOR vocabulary, will help the entire cycle of product information:

• The pharmacist in the Country of Treatment to better assist in the selection of the medicinal product to be dispensed to the patient.
• The responsible physician to better understand what has been dispensed.
• The Patient Summary to contain coherent and reconciled data.