



## Revision history

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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This deliverable contains original unpublished work except where clearly indicated otherwise.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

INFARMED is a government agency accountable to the Health Ministry, which evaluates, authorises, regulates and controls human medicines as well as health products, namely, medical devices and cosmetics for the protection of Public Health.

During the first year of UNICOM, first steps were taken towards refactoring of INFARMED's system into an ISO IDMP compliant model. In particular, these concerned ongoing data mapping and cleansing activities, simultaneously with gap analysis between current system and ISO IDMP.

Keywords: Infarmed, Portugal, UNICOM, SPOR, ISO, IDMP

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## TABLE OF CONTENTS

Revision history .....	2
List of abbreviations.....	5
1 Executive summary .....	6
2 About INFARMED .....	7
3 IDMP implementation at INFARMED .....	8
3.1 Context .....	8
3.2 COVID-19 pandemic impact on task 4.12 progress .....	8
3.3 Progress on IDMP implementation.....	9
3.3.1 Procurement.....	9
3.3.2 Data .....	9
3.3.3 RMS mapping and data cleansing.....	9
3.3.4 OMS mapping and data cleansing .....	11
3.3.5 SMS mapping and data cleansing.....	11
3.3.6 Gap analysis .....	11
4 Summary and outlook .....	12

## LIST OF FIGURES

Figure 1. Routes and Methods of Administration: screenshot of the mapping table. ....	10
Figure 2. Packaging: screenshot of the mapping table. ....	10
Figure 3. ATC: screenshot of the mapping table.....	11

## List of abbreviations

Abbreviation	Complete form
INFARMED, I.P.	National Authority of Medicines and Health Products, I.P.
UNICOM	Up-scaling the global univocal identification of medicines'
WP	Working package
SPOR	EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.  The four SPOR data management services are: Substance Management Services (SMS) Product Management Services (PMS) Organisation Management Services (OMS) Referentials Management Services (RMS)
ISO IDMP	International Organization for Standardization Identification of Medicinal Products
ATC	Anatomical Therapeutic Chemical (ATC) Classification
EMA	European Medicines Agency
OMS	Organisation Management Services
PMS	Product Management Services
RMS	Referentials Management Services
SMS	Substance Management Services

## 1 Executive summary

The pandemic had a severe impact on task 4.12 (Progressing ISO IDMP implementation at INFARMED in Portugal) progress, resulting in an overall project delay. In order to address and prevent any further delays, the project plan is currently under review.

Procurement for business analysis and solution architecture teams is concluded, procurement for a development team will be brought forward to prevent additional delays.

Data mapping and cleansing activities are ongoing for the RMS lists, to be followed by OMS related lists. PMS and SMS related lists will be mapped when available from EMA.

Gap analysis for RMS begun in November and is ongoing, expected to be concluded before the end of the first quarter 2021. OMS gap analysis to follow.

## 2 About INFARMED

INFARMED is a government agency accountable to the Health Ministry, which evaluates, authorises, regulates and controls human medicines as well as health products, namely, medical devices and cosmetics for the protection of Public Health. Amongst its attributions, Infarmed provides medicinal product master data to the national eHealth agency to support the national e-prescription/e-dispensation system. Therefore, implementation of ISO IDMP at Infarmed is a cornerstone for the global univocal identification of medicines for cross-border prescription in Portugal.

The tasks it pursues stem from its mission: to regulate and supervise the sectors of human medicines and health products, according to the highest standards of public health protection, and to ensure access for health professionals and citizens to quality, effective and safe medicines and health products.

The Institute's main goal is to ensure the quality, safety and efficacy of medicines authorised for marketing in Portugal, and the quality, safety and performance of health products in order to avoid the risks of their use while ensuring adequate standards of public health and consumer's protection.

Amongst Infarmed top activities the regulation and supervision of medicinal and health products from research up to their use by healthcare professionals and patients is of particular importance.

As a national agency that is responsible for the authorisation and regulation of medicinal products, Infarmed delivers national supporting data on medicines for e-prescription and e-dispensing, as well as identification of medicinal products in all national supply chain activities. Therefore, Infarmed will support within UNICOM the development and implementation of ISO-IDMP and supply ISO-IDMP compliant data for e-prescription and e-dispensing systems.

### 3 IDMP implementation at INFARMED

#### 3.1 Context

The work to be reported upon is part of UNICOM workpackage 4 “IDMP implementation at National Drug Agencies.” The Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) states that European Union (EU) Member States, marketing authorisation holders and EMA shall make use of the ISO IDMP standards. NCAs at national level are responsible to maintain medicinal product data, and in many members states NCAs also provide medicinal product master data to eHealth providers. In order to implement ISO IDMP at national level, preparatory work on IT systems and medicinal product data repositories is necessary. This is also a prerequisite to provide ISO IDMP compliant data to eHealth organisations. It is key to implement the standards in a unified way to enable data exchange between NCAs and other essential partners (eHealth, ePrescription, cross-border-prescription) of the system, and software used for tracking regulatory activities (CTS).

The Communication and Tracking System (CTS) is the system used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures. CTS supports the co-ordination and tracking of marketing authorisation, post-licensing and work sharing procedures as monitored by the *Coordination Groups for Mutual Recognition and Decentralised Procedures* for Human (CMDh) and Veterinary medicines (CMDv). The system serves as data provider for other applications. Owned by the Heads of Medicines Agencies, management responsibility for the CTS has been given to the CMDs.

Implementation of ISO IDMP at NCAs is performed in national implementation projects where the funding by UNICOM is a financial contribution in addition to the national investments (an estimated total of more than 20 Million Euros at 11 NCA's). The participation in the project enables faster national implementation and supports necessary collaboration. Objectives of WP 4 are, inter alia, to progress essential tasks to provide ISO IDMP-compatible IT-systems based on national implementation plans, to support legacy data migration towards ISO IDMP based on national migration plans, and to progress essential tasks on data connectivity to EMA's SPOR services based on national implementation plans.

In this context, task 4.12 concerns “Progressing ISO IDMP implementation at INFARMED in Portugal.” INFARMED will refactor the national medicinal product database to become ISO IDMP compliant, migrate legacy data into the new ISO IDMP compliant model while continuing to implement the data connection to EMA's SPOR services where appropriate, support automation of data entry into internal databases, and interoperability between internal and EMA systems. Infarmed will also develop a prototype of an IDMP compliant data feed to the national ePrescription system and other systems in the national eHealth context.

#### 3.2 COVID-19 pandemic impact on task 4.12 progress

The main activities planned for 2020 were as follows:

- ▶ Procurement for the Business Analysis and Solution Architecture – Q1;
- ▶ RMS mapping and data cleansing – Q2 to Q4;
- ▶ SPOR API: access request and specification analysis – Q4;
- ▶ Gap analysis:
  - RMS – Q2 to Q3;
  - OMS – Q4 to Q1 2021

Unfortunately, the pandemic had a severe negative impact on most of these activities, particularly on procurement activities and the INFARMED business experts' availability for planning of overall work across departments, resulting in an overall project delay.

In order to address and prevent any further delays, the project plan is being reviewed taking in consideration the following mitigation measures:

- ▶ When possible, anticipating the start date for procurement procedures, in order to account for the currently extended timelines of this process;

- ▶ To reinforce the business expert/business analysis and development team capacities, in order to recuperate some of the delay;
- ▶ Whenever possible, consider the lessons learned shared by the other Unicom partners.

### 3.3 Progress on IDMP implementation

#### 3.3.1 Procurement

Procurement for the Business Analysis and Solution Architecture teams have been concluded in late October 2020, in spite of the severe delays in the process caused by the pandemic situation.

The team members have been onboarded in November and are currently working on the gap analysis activities to be detailed below.

As a way to minimize further impact on the project due to the delay in procurement activities, the procurement for the development team will be brought forward a few months from the initially planned starting date in order to be concluded in time.

#### 3.3.2 Data

Data mapping and cleansing activities between Informed's system and EMA's SPOR data bases have been postponed to begin in June of 2020, albeit with limited business resources.

#### 3.3.3 RMS mapping and data cleansing

Mapping and data cleansing activities will take place in the following order:

1. Pilot Data lists to be used by the xBorder prescription pilot:
  - ▶ EDQM Lists:
    - ▶ Pharmaceutical Dose Form and related lists;
    - ▶ Routes and Methods of Administration;
    - ▶ Packaging;
    - ▶ Units of Presentation;
  - ▶ Units of Measurement;
  - ▶ ATC;
  - ▶ Legal Status for the supply;
  - ▶ Special precaution for storage;
  - ▶ Country;
2. Remaining RMS lists;
3. OMS related lists;
4. SMS related lists (when available);
5. PMS related lists (when available).

Mapping activities entail mapping of national term lists with SPOR lists, cleansing of national lists, transfer of SPOR terms that do not exist in national lists, and change requests to SPOR in case of national term in use inexistent in SPOR.

The mapping of the first batch of lists is still mostly ongoing, but has been concluded for the following lists:

- ▶ Routes and Methods of Administration;
- ▶ Packaging;
- ▶ ATC.

SPOR?	GUID	LOCALE	VALUE	DISABLED	DOMA	STD_TEF	ABREV	CODE	ABREV_CHNM
SPOR Only	10000075259	en	Intrapulmonary use	CURRENT	Vet				
SPOR Only	10000075553	en	In drinking water use	CURRENT	Vet				
SPOR Only	100000143556	en	Nail use	NULLIFIED	Human				
SPOR Only	10000075251	en	Conjunctival use	NON_CURRENT	Human				
SPOR Only	10000075252	en	Transmucosal use	NON_CURRENT	Human				
Gimed only	69549160670a11e2a630b5b5f09c4d	pt_PT	EC - Uso intramedular (medula óssea)	0		0		804	
Gimed only	69549160670a11e2a630b5b5f09c4d	en_GB	EC - Intramedullar (bone marrow) use	0		0		804	
SPOR Only	10000075247	en	Interstitial use	PROVISIONAL	Human				
SPOR Only	100000170847	en	Coarse spray	PROVISIONAL	Human				
SPOR Only	200000012510	en	instillation	PROVISIONAL	Human				
SPOR Only	200000010603	en	Intrapataminal use	CURRENT	Human				
SPOR Only	10000075275	en	Buccal use	CURRENT	Human				
SPOR Only	10000075275	pt	Uso bucal	CURRENT	Human				
SPOR Only	10000075554	en	Submucosal use	CURRENT	Human				
SPOR Only	10000075554	pt	Via submucosa	CURRENT	Human				
SPOR Only	100000155948	en	Intraportal use	CURRENT	Human				
SPOR Only	100000155948	pt	Via intraportal	CURRENT	Human				
SPOR Only	100000156091	en	Intracholangiopancreatic use	CURRENT	Human				
SPOR Only	100000156091	pt	Via intracolangiopancreática	CURRENT	Human				
Gimed only	697cb2d0670a11e2a8d68d49ddb15	en_GB	EC - Infiltration use	0		0		824	
Gimed only	697cb2d0670a11e2a8d68d49ddb15	pt_PT	EC - Infiltração	0		0		824	
Match	17B22EA8015E2481E050A8C034290	en_GB	Infiltration	0		1		135	Infiltra
Match	17B22EA8015E2481E050A8C034290	pt_PT	Infiltração	0		1		135	Infiltra

Figure 1. Routes and Methods of Administration: screenshot of the mapping table.

Match?	VALUE	Lista	GUID	LOI	VALUE	DOMAI	DISA	STD_	CD
Gimed Only	Dropper	Dispositivos Adm	73f9ea50670211e2b937ed4a77fd41	en_GB	Dropper		0	0	045
Gimed Only	Conta-gotas	Dispositivos Adm	73f9ea50670211e2b937ed4a77fd41	pt_PT	Conta-gotas		0	0	045
Gimed Only	Kit for perfusion	Dispositivos Adm	73fa1160670211e2b93ce3c53b0f8e	en_GB	Kit for perfusion		0	0	047
Gimed Only	Conjunto para perfusão	Dispositivos Adm	73fa1160670211e2b93ce3c53b0f8e	pt_PT	Conjunto para perfusão		0	0	047
SPOR Only	Lid	Closure	200000010647	en	Lid	Human & V	CURRENT		
SPOR Only	Valve	Closure	100000166980	en	Valve Válvula	Human & V	CURRENT		
SPOR Only	Oral applicator	Administration De	100000173982	en	Oral applicator Aplicador oral	Human & V	CURRENT		
SPOR Only	Pen	Administration De	200000005068	en	Pen Caneta	Human & V	CURRENT		
SPOR Only	Administration system	Administration De	10000075664	en	Administration system	Human & V	CURRENT		
SPOR Only	Sistema de administração	Administration De	10000075664	pt	Sistema de administração	Human & V	CURRENT		
SPOR Only	Needle-free injector	Administration De	100000116196	en	Needle-free injector	Human & V	CURRENT		
SPOR Only	Injetor sem seringa	Administration De	100000116196	pt	Injetor sem seringa	Human & V	CURRENT		
SPOR Only	Dose dispenser	Administration De	100000173983	en	Dose dispenser	Human & V	CURRENT		
SPOR Only	Dispensador de dose	Administration De	100000173983	pt	Dispensador de dose	Human & V	CURRENT		
Gimed Only	Pipette applicator VET	Dispositivos Adm	73efd830670211e2b798a1830b0d7	en_GB	Pipette applicator VET		1	0	030
Gimed Only	Fecho com pipeta VET	Dispositivos Adm	73efd830670211e2b798a1830b0d7	pt_PT	Fecho com pipeta VET		1	0	030
Match	Pipette applicator	Dispositivos Adm	73f92700670211e2b905cc685d4ec	en_GB	Pipette applicator		0	1	044
Match	Fecho com pipeta	Dispositivos Adm	73f92700670211e2b905cc685d4ec	pt_PT	Fecho com pipeta		0	1	044
Match	Needle applicator	Dispositivos Adm	73f72b30670211e2b8a5c161f67f69f	en_GB	Needle applicator		0	0	039
Gimed Only	Aplicador com agulha	Dispositivos Adm	73f72b30670211e2b8a5c161f67f69f	pt_PT	Aplicador com agulha		0	0	039
SPOR Only	Fecho com agulha	Closure	10000073535	pt	Fecho com agulha	Human & V	CURRENT		

Figure 2. Packaging: screenshot of the mapping table.

Match?	ID	Language	CODE	VALUE	Match String	DISABLED	ANO	SPOR ID	SPOR L	SPOR	SPOR	SPOR Stat
Gimed Only	8c8cd4b069b11e28cd5e6764e2e1bfff	en_GB	L04AB	Tumor necrosis factor alpha (TNF- $\alpha$ )	L04AB - Tumor nei		0	2020		#N/D		
SPOR Only	100000096864	en	L04AB	Tumor necrosis factor alpha (TNF- $\alpha$ )	CURRENT	100000000012						
Gimed Only	d8a5dc80696811e2948b9b4f5b2569e	en_GB	R06AX27	desloratadine	R06AX27 - deslora		0	2020		#N/D		
SPOR Only	100000098334	en	R06A X27	desloratadine	CURRENT	100000000012						
Gimed Only	23585dd0672911e2a0a1889b350dc8	en_GB	S01EA	Sympathomimetics in glaucoma therapy	S01EA - Sympatho		0	2020		#N/D		
SPOR Only	100000098489	en	S01EA	Sympathomimetics in glaucoma therapy	CURRENT	100000000012						
Gimed Only	00ac06a06a0911e28d35b94aef50dc2	en_GB	V09IX07	fluorocholine (18F)	V09IX07 - fluoroch		0	2020		#N/D		
SPOR Only	100000116289	en	V09IX07	fluorocholine (18F)	CURRENT	100000000012						
SPOR Only	200000012481	en	B06AX02	betibeglogene autotemcel	CURRENT	100000000012						
SPOR Only	200000010632	en	L01XC37	polatuzumab vedotin	CURRENT	100000000012						
SPOR Only	200000012517	en	L01XC38	isatuximab	CURRENT	100000000012						
SPOR Only	200000013641	en	L01XC39	belantamab mafodotin	CURRENT	100000000012						
SPOR Only	200000015177	en	L04AA45	figotnib	CURRENT	100000000012						
SPOR Only	200000013491	en	R07AX32	ivacaftor, tezacaftor and elexacaftor	CURRENT	100000000012						
Match	8E429E08262DF464E050A8C03429	en_GB	J05AR21	dolutegravir and rilpivirine	J05AR21 - dolutegi		0	2020	200000003480	en	J05AR21	dolutegravi NULLIFIED
Match	2ae87160672a11e2821cd1b4f64402e	en_GB	A	ALIMENTARY TRACT AND METABOLIC - ALIMENTARY			0	2020	100000093554	en	A	ALIMENTA CURRENT
Match	2ae8e690672a11e28225fa56aba3f71	en_GB	A01	STOMATOLOGICAL PREPARATION: A01 - STOMATOLOGICAL			0	2020	100000093555	en	A01	STOMATO CURRENT
Match	2ae87160672a11e2821189cab209d2	en_GB	A01A	STOMATOLOGICAL PREPARATION: A01A - STOMATOLOGICAL			0	2020	100000093556	en	A01A	STOMATO CURRENT
Match	2ae89870672a11e282211bc64c22b8c	en_GB	A01AA	Caries prophylactic agents	A01AA - Caries prc		0	2020	100000093557	en	A01AA	Caries proj CURRENT

Figure 3. ATC: screenshot of the mapping table.

Priority, inclusion and exclusion of lists for mapping and translations will be under continuous scrutiny depending on project needs for the xBorder prescription pilot.

The knowledge achieved with mapping activities includes a better knowledge of the various categories of lists that exist in SPOR, their relationship with national lists, and with corresponding fields in national databases. Although at an initial stage, the mapping activities, have already identified some potential issues such as the existence of SPOR lists that are currently stored as unstructured data.

### 3.3.4 OMS mapping and data cleansing

OMS mapping and data cleansing will begin when the RMS activities are concluded, currently estimated for the second quarter 2021.

### 3.3.5 SMS mapping and data cleansing

SMS / PMS activities planning is currently under review.

### 3.3.6 Gap analysis

In the Gap analysis phase, we will compare Informed's current data model against the ISO IDMP model and define the activities needed to reach the final model.

The Gap analysis model will follow the same order used for the data mapping and cleansing activities:

1. RMS;
2. OMS;
3. SMS & PMS.

The Gap analysis for RMS begun in November and is ongoing, expected to be concluded before the end of the first quarter 2021.

Gap analysis timeline for the next phases (OMS, SMS & PMS) is currently being reviewed.

## 4 Summary and outlook

Unfortunately, the COVID-19 pandemic had a strong negative impact in the first year of the project.

From planned activities, the ones that could be ensured were ongoing data mapping and cleansing of RMS lists, with three lists concluded, and start of RMS gap analysis expected to be concluded before the end of the first quarter 2021.

Mitigation measures were put in place that should have a positive effect on the project in 2021: review of project plan, consider the lessons learned shared by the other Unicom partners, anticipation of procurement procedures, reinforce business experts and develop team capacities.

Experience in first year has led to a better understanding that IDMP/SPOR has a profound direct impact on INFARMED business processes besides being a technological project. It is necessary to secure a bigger involvement of business experts and their education and training about IDMP/SPOR.

Work to increase experience and knowledge about IDMP/SPOR, already started, is expected to develop significantly in early 2021.

Gap analysis for RMS is ongoing and should be shortly followed by OMS gap analysis.

Data mapping and cleansing activities will create a significant search for human resources. The search for software to speedup these activities is ongoing.