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Up-scaling the global univocal identification of medicines

UNICOM KNOWLEDGE TRANSFER WEBINAR HALMED (Croatia): Progress of refactoring the HeAL system

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- Introduction: Croatian Agency for Medicinal Products and Medical Devices (HALMED)
- HeAL the IT system for core business processes
- Process of refactoring the HeAL system
- Redesign of User interface related to Packaged Medicinal Product
- RMS
- OMS
- SMS
- Challenges and our approach
- Next steps
- Q&A



Introduction

- HALMED is Croatian competent authority in the field of human medicines and medical devices
 - Established on 1 October 2003
 - Location: Zagreb (3 different locations)
 - 236 employees
 - 8.161 medicines in the registry:
 - 6.027 authorised nationally (2.305 active)
 - 2.134 authorised through MRP/DCP procedures (1.678 active)







Main activities:

- Marketing authorisation procedures (H)
- Issuance of manufacturing/importation authorisations
- Issuance of authorisations related to distribution of medicinal products

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- Quality control (OMCL)
- Pharmacovigilance
- Rational pharmacotherapy
- Pharmacoeconomics
- Medical devices
- Scientific advice
- GMP and GVP inspections

Veterinary medicinal products:

- issuance of manufacturing / importation and wholesale authorisations
- GMP and GDP inspections
- quality control.

Introduction

- Our own IT infrastructure (servers, storage systems, network equipment, etc.)
- Located in two separate data centres:
 - primary location is within the Agency facilities
 - secondary location is within rental facilities
- 12 employees in IT department + external contractors and service providers
- Custom software solutions for core business processes



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HeAL - the IT system for core business processes

- Custom developed IS for core business processes:
 - NRL Case management application for marketing authorization procedures
 - tracking of all procedural phases
 - tracking of deadlines and tasks completed by assessors
 - supporting the Committee for Medicinal Products processes
 - business reporting
 - PhV Application used for processing pharmacovigilance tasks
 - > **PKL** Application used for:
 - Inspectorate activities related to planning and executing medicinal products sampling
 - ✓ Quality control of medicinal products (H and V) in the official medicines control laboratory (OMCL)
 - Filing incoming samples, sample analysis and analysis task assignment
 - Reagent management and management of standards
 - Reporting of results and filing outgoing documents



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HeAL - Central IT system for core business processes



ISO IDMP standards compliance: process of refactoring the HeAL system

- Analysis of ISO IDMP data model
- Assessment of required data described in EU ISO IDMP implementation guide prepared by EMA
- Analysis of FHIR messages

ISO IDMP and

EU IDMP IG

Business

processes analysis

Assesšment

DB & UI

system

- Analysis of all the processes in the organization that use medicines data
- Analysis of external stakeholder's datasets required
- Defining master data set
- Assessment of current IT system with medicines registry
- Detecting gaps in current data model against ISO IDMP data model and EU IDMP Implementation Guide
- of current IT Identify needed changes
 - Design the data model
 - User interface redesign (UI mock-ups)
 - Detection of new RMS lists that should be introduced
- refactoring Testing of the data model and UI reconstruction on different medicines (especially those with complex packaging and composition)
 - Database refactoring and UI redesign implementation
 - Introduction of new SPOR RMS lists related to database refactoring
- Data cleansing / mapping / migration
 - Preparing FHIR messages for SPOR PMS



HALMED Project timeline

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	2020	2021	2022	2023	2024
1 Decemb	Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec	Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec	Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec J	an Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec	31 May 2024 Jan Feb Mar Apr May
	Year 1	Year 2	Year 3	Year 4	Year 5
ISO IDMP, EU IG & FHIR analysis, gaps identification					
Business processes analysis			-		
Defining master data set					
Replacing EUTCT with RMS lists (except Substances)					
New RMS lists: ATC-H, Variation Classification (UI & DB)					
Data cleansing & mapping related to new RMS lists					
DB and UI refactoring: Packaged Medicinal Product (PMP)					
PMP: introduction of related RMS lists					
PMP: data migration and cleansing					
DB and UI refactoring: Pharmaceutical Product					
DB and UI refactoring: Therapeutic Indication					
Therapeutic Indication: introduction of related RMS lists					
DB and UI: the rest of attributes required by EU IG					
Introduction of the rest of RMS lists (listed in EU IG)					
Data cleansing and mapping (related to RMS lists)					
Establishing connection with OMS					
ORG: data cleaning and linking with OMS ORG & LOC IDs					
DB and UI refactoring, data migration: Substances					
Substances – cleaning & mapping data with EUTCT terms					
Switching from EUTCT Substances codebook to SMS					
Establishing connection with PMS					



Refactoring of the HeAL system

	As is (Dec 2019)	Status (March 2023)	To be
Data model refactoring and user interface redesign	Data model built on Reference Data Model (RDM v3.0) published by EMA	 The HeAL data model gap analysis vs ISO IDMP completed Packaged Medicinal Product: DB refactoring completed and implemented to production UI redesign: currently on development & testing PhP – DB & UI refactoring: Initial analysis completed and documented Therapeutic indication: FRS for refactoring DB & UI on review 	The HeAL data model comply with ISO IDMP standards UI redesign completed Data migrated
Referential lists (RMS)	EUTCT referential lists synchronized daily with internal NRL codebooks: 6 EUTCT lists with no custom- added terms 12 EUTCT lists, with additional user-added terms 15 EUTCT lists replaced with RMS lists	 Last 2 EUTCT lists (except Substances) are replaced with corresponding RMS lists: Packaging / Routes and Methods of Administration 2 Internal codebooks replaced with RMS lists: Anatomical Therapeutic Chemical classification system – Human Variation Classification 8 New RMS lists introduced (on production environment): Domain / Units of Presentation / Container Category / Material / Shelf Life Type / Medical Device Legislative Category / EU Procedural Authority Role / Substance Type 27 RMS lists + EUTCT Substances list – daily synchronized with internal codebooks Data cleaning / mapping / replacing – work in progress 	All RMS codebooks listed in EU IG introduced to the HeAL system (i.e. 53 RMS codebooks) Cleansing of the legacy data completed
Organisations (OMS)	Internal Organisations repository (sync with other HALMED systems)	Connection with OMS established Cleaning and mapping internal organisations with OMS ORG IDs and LOC IDs	OMS data synchronized with internal Organisations repository
Substances (SMS)	EUTCT list Substances in use	EUTCT list Substances in use	Switch from EUTCT Substances codebook to SMS
PMS			Connection & daily synchronisation with PMS established

Medicines registry data model refactoring

- Data model built on Reference Data Model (RDM v3.0) published by EMA
- the HeAL data model vs. ISO IDMP data model and EU IG major gaps:
 - Packaged Medicinal Product - Manufactured Item should be introduced in data model
 - Pharmaceutical product and Ingredient need some adjustments





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Transition strategy: Packaged Medicinal Product

- Database reconstructed: added new tables and established new relations in database for entities and attributes related to:
 - Manufactured Item
 - Package Item (Container)
 - > Device
- UI reconstruction (tab "Packaging"):
 - enable input of more Packaged Medicinal Products
 - enable input of more Package Items
 - enable input of Devices
 - enable input of Manufactured Items



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Example: *Qlaira*

Place weekday sticker strip her

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Qlaira



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Packaged Medicinal Product (PMP) - user interface and level of information before refactoring

Pregl	led lijeka	Osnovni p	oodaci	Dodatni po	odaci	Sastav	Pakiranja	Predmeti	Dokumenti	FollowUp mjere	Napomene							
C	Novi zapis																	
Kro	ovni lijek	c	Qlaira			A	ГК	G03	AB08 (dienogest i	estradiol)	Nositelj odobrenja	Bayer d.o.o.	Bro	oj odobrenja	н	R-H-182628999 ⊘		
Na	ziv lijeka	c	Qlaira film	iom obložene	e tablete	P	ut primjene	Kro	z usta		Vrsta postupka	EU, RUP	Šifr	a postupka	N	L/H/1230/001/R/002		5
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Packaged Medicinal Product (PMP) - user interface and level of information after refactoring



Novi vanjski spremnik Novi spremnik Nova proizvedena jedinka Novi medicinski proizvod

			Package	d Medic	inal Product			Contain	er	Shelf Life / Storage			Manufac	tured Item			Medical	Device		
Uredi		BO pakiranja	Registracijski status	Status na tržištu	Opis pakiranja	Veličina ^(j) pakiranja	(j) Spremnik	Dodatni opis spremnika	Komponente spremnika	Rok valjanosti i uvjeti čuvanja	jedinica prezentacije	Količina proizvedene jedinke	Proizvedeni farmaceutski oblik	() Opis proizvedene jedinke	Sastav	Kombinacija (i lijek/medicinski proizvod) Tip medicinskog proizvoda	Zaštićeni naziv () medicinskog proizvoda	Količina () medicinskog proizvoda) Briši
- 1	Vanjski spremnik	HR-H- 182628999-01	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 1 x 28 tablets film coated tablets.	28 tableta	Kutija			<u>dodaj rok</u> <u>valjanosti i uvjete</u> <u>čuvanja</u>										
- × /	Spremnik						Blister													
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnožuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	5	Filmom obložena tableta	srednjecrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	17	Filmom obložena tableta	svjetložuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnocrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	bijela tableta	Prikaži sastav					
- 1	Vanjski spremnik	HR-H- 182628999-02	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. ³ x 28 tablets film coated tablets.	84 tableta	Kutija			pregledaj rokove valjanosti i uvjete čuvanja							Place wee	kday sticker strip here / 論時上	e當的種貼	*
-1	Spremnik						Blister													*



PMP: Top-level packaging item



Pregled lijeka	Osnovni podaci	Dodatni podaci	Sastav	Pakiranja	Predmeti	Dokumenti	FollowUp mjere	Napomene					
Krovni lijek	Qlaira		1	ATK		G03AB08 (dien	ogest i estradiol)		Nositelj odobrenja	Bayer d.o.o.	Broj odobrenja	HR-H-182628999 🚱	
Naziv lijeka	Qlaira filmo	m obložene tablete		Put primje	ene	Kroz usta			Vrsta postupka	EU, RUP	Šifra postupka	NL/H/1230/001/R/002	5
Status lijeka	Važeće			Jačina		tamnožuta tab srednjecrvena t svijetložuta tab tamnocrvena t	ileta: 3 mg; tableta: 2 mg + 2 mg; ileta: 2 mg + 3 mg: ableta: 1 mg		Format dokumentacije	eCTD	Klasa lijeka	UP/I-530-09/17-02/850	PIL SPC LAB

New top-level package Item (outer-most packaging)

Novi vanjski spremnik Novi spremnik Nova proizvedena jedinka Novi medicinski proizvod

		I	Packageo	d Medici	nal Product			Contain	er	Shelf Life / Storage			Manufact	tured Item			Medical	Device		
Uredi		BO pakiranja	Registracijski status	i Status na tržištu	Opis pakiranja	Veličina ⁽ⁱ⁾ pakiranja	() Spremnik	Dodatni opis spremnika	Komponente spremnika	Rok valjanosti i uvjeti čuvanja	jedinica prezentacije	Količina proizvedene jedinke	Proizvedeni farmaceutski oblik	() Opis proizvedene jedinke	Sastav	Kombinacija lijek/medicinski proizvod) Tip medicinskog proizvoda	Zaštićeni naziv medicinskog proizvoda	Količina () medicinskog proizvoda	Briši
- 1	Vanjski spremnik	<u>HR-H-</u> <u>182628999-01</u>	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 1 x 28 tablets film coated tablets.	28 tableta	Kutija			<u>dodaj rok</u> valjanosti i uvjete <u>čuvanja</u>										
~ /	Spremnik						Blister													1
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnožuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	5	Filmom obložena tableta	srednjecrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	17	Filmom obložena tableta	svjetložuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnocrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	bijela tableta	Prikaži sastav					1
- 1	Vanjski spremnik	HR-H- 182628999-02	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. ³ x 28 tablets film coated tablets.	84 tableta	Kutija			pregledaj rokove valjanosti i uvjete čuvanja										
- /	Spremnik						Blister													



Pop-up New top-level package Item (outer packaging) UN/COM

Veličina pakiranja			×
Veličina pakiranja	28	Tableta	\$
		Spremi	Odustani

Śifra	(RMS)	20000003529	
Naziv	(HR)		¢
Nazi	v (EN)	Cardboard	¢

		Hrvatski				
		Prozirni PVC/Alu obloženih table 5 srednje crven tablete i 2 bijel	iminij blister u karto ta poredanih sljede ih tableta, 17 svjetlo e tablete	nskoj kutiji. 1 x 28 f ćim redom: 1 tamno o žutih tableta, 2 taj	ilmom) žute tablete, mno crvene	
Opis	s pakiranja	Engleski			0	
		Transparent PV tablets film-coa contains in the tablets, 17 light tablets	C/Aluminium blister ited tablets. Each wa following order: 2 da t yellow tablets, 2 da	in a cardboard wal allet (28 film-coated ark yellow tablets, 5 ark red tablets and 3	let. 1 x 28 I tablets) i medium red 2 white	
Vrsta	spremnika	Kutija			•	
Količina	spremnika	1	Spremnik		• 1	
Dodatni opis	spremnika					
ableta						
vođeči +						•
rođači + OMS šifra subjekta	Naziv pro	izvođača	OMS šifra lokacije	Adresa		Brisi
vodači + OMS šifra subjekta V ORG-100023528	Naziv proi Bayer W und Co.	izvođača /eimar GmbH KG.	OMS šifra lokacije LOC-100032674	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Briši Î
ableta wodači + OMS šifra subjekta ORG-100023528 zrijali +	Naziv pro Bayer W und Co.	izvođača /eimar GmbH KG.	OMS šifra lokacije LOC-100032674	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Brisi T
tableta izvođači +	Naziv pro Bayer W und Co.	izvođača /eimar GmbH KG.	OMS šifra lokacije LOC-100032674	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Briši T
ableta wodaći + OMS šifra subjekta ORG-100023528 erijali + D Naziv (HR)	Naziv proi Bayer W und Co.	izvođača /eimar GmbH .KG. 15)	OMS šifra lokacije LOC-100032674 Naziv (RMS)	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Briši Briši
ableta vođeći + OMS šifra subjekta ORG-100023528 prijeli + Naziv (HR)	Naziv proi Bayer W und Co. Sifra (RM 2000000	izvođača /eimar GmbH KG. 15)	OMS šifra lokacije LOC-100032674 Naziv (RMS) Cardboard	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Brisi Brisi Erisi
ableta vođači + OMS šifra subjekta ORG-100023528 erijali + Naziv (HR)	Naziv proi Bayer W und Co. Šifra (RM 2000000	izvođača /eimar GmbH KG. 45) 003529	OMS šifra lokacije LOC-100032674 Naziv (RMS) Cardboard	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Briši Briši
tableta izvođači +	Naziv proi Bayer W und Co. Šifra (RM 2000000	izvođača /eimar GmbH KG. AS) D03529	OMS šifra lokacije LOC-100032674 Naziv (RMS) Cardboard	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka	Briši Briši
tableta zvodači + OMS šifra subjekta ORG-100023528 terijali + D Naziv (HR) B Maziv (HR)	Naziv proi Bayer W und Co. Sifra (RM Sifra (RM	kzvođača /eimar GmbH .KG. 003529 50 Naziv (R	OMS šifra lokacije LOC-100032674 Naziv (RMS) Cardboard	Adresa Doebereinerstr 99427 Weimar	asse 20, , Njemačka Proizvođači komponen	Briši atte Briši

roizvođač			×	
Šifra subjekta	ORG-100001442			
Naziv proizvođača	Pliva Croatia Limited			
Šifra lokacije	LOC-100003105			
Adresa	Prilaz Baruna Filipovica 25, Zagreb		¢	
Opis			11.	
		Spremi	Odustani	

PMP: Adding new Container



Pregled lijeka	a Osnovni po	odaci Dodati	ni podaci	Sastav	Pakiranja	Predmeti	Dokumenti	FollowUp	o mjere	Napomene										
Krovni lijek	Qla	aira		i.	ATK		G03AB08 (di	ienogest i estra	diol)	Nositelj	odobrenja		Bayer d.o.o.	Broj o	dobrenja	HR-H-182	628999 📀			
Naziv lijeka	Ql	aira filmom oblož	ene tablete		Put primjen	2	Kroz usta			Vrsta po	stupka		EU, RUP	Šīfra p	ostupka	NL/H/1230	/001/R/002			5
Status lijeka	Va	žeće			Jačina		tamnožuta t srednjecrver svijetložuta t tamnocrven	tableta: 3 mg; na tableta: 2 mg tableta: 2 mg + a tableta: 1 mg	g + 2 mg; - 3 mg: 9	Format	dokumenta	cije	eCTD	Klasa I	ijeka	UP/I-530-0	9/17-02/850		PIL	SPC LAB
Novi vanjski s	New (zvedena jedink	a Novi med	dicinski proizvod															
			Package	d Medic	inal Product			Contain	er	Shelf Life / Storage			Manufac	tured Item			Medical	Device		
Uredi	/	BO pakiranja	Registracijski status	i Status na tržištu	Opis pakiranja	Veličina pakiranja) (j Spremnik	i Dodatni opis spremnika	Komponente spremnika	Rok valjanosti i uvjeti čuvanja	(i) Jedinica prezentacije	Količina proizvedene jedinke	Proizvedeni farmaceutski oblik	() Opis proizvedene jedinke	Sastav	Kombinacija lijek/medicinski proizvod) (j Tip medicinskog proizvoda	Zaštićeni naziv medicinskog proizvoda	Količina (medicinskog proizvoda	Briši
- 1	Vanjski spremnik	<u>HR-H-</u> 182628999-01	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 1 x 2 tablets film conted tabl	28 tableta	Kutija			<u>dodaj rok</u> valjanosti i uvjete čuvanja										
- 1	Spremnik				tublets jiin touteu tub	rix.	Blister													÷.
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnožuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	5	Filmom obložena tableta	srednjecrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	17	Filmom obložena tableta	svjetložuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnocrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	bijela tableta	Prikaži sastav					1
- 1	Vanjski spremnik	<u>HR-H-</u> 182628999-02	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 3 x 28 tablets film coated table	84 tableta	Kutija			pregledaj rokove valjanosti i uvjete čuvanja										
-1	Spremnik						Blister													



Pop-up: New Container

	Vrsta sp	vremnika	Blister				¢ (j			
	Količina sp	premnika	1		Bliste	r	¢ (j)		
	Dodatni opis sp	oremnika					())	Ac	ddin
Proizvo	odači +								Komp	onente
	OMS šifra subjekta	Naziv pr	roizvođača	OMS šifra loka	cije A	dresa		Briši		
1	ORG-100023528	Bayer V und Co	Weimar GmbH o. KG.	LOC-100032	2674 D 9	oebereinerstrasse 9427 Weimar, Nje	20, mačka			
Materij	Šifra (RMS)	Naziv (H	R)	Na	uziv (EN))		Briši	Mate	rijali kom
/	20000003200			A	luminiu	m		1		Šifra (R
/	20000003222			P	olyViny	Chloride		×.	/	200000
Iterna	ativni materijali 🛛 🕂								Alter	mativni m
	Šifra (RMS)	Naziv (H	R)	Na	ziv (EN)			Briši		Šifra (R
/								1	1	
								•		
ompor	nente spremnika +									

Adding container's components

		Komp	onente				×
	Briši			Šifra (RMS)	10000073563		
	*			Naziv (HR)	Bočica		¢
				Naziv (EN)	Vial		\$
	Briši	Mater	rijali komponente 🕇				
			Šifra (RMS)	Naziv (HR)		Naziv (EN)	Briši
	X	1	20000003204			Glass type I	Î
		Alter	nativni materijal kompone	ente 🕂			
	Briši		Šifra (RMS)	Naziv (HR)		Naziv (EN)	Briši
	a	1					Î
	•					Spremi Odu	ustani
rijali	Briši						
				_			



PMP: Shelf life and Special precautions for storage

Pregled lijeka	Osnovni podaci	Dodatni podaci	Sastav	Pakiranja	Predmeti	Dokumenti	FollowUp mjere	Napomene	_				
Krovni lijek	Qlaira		4	ATK		G03AB08 (diend	ogest i estradiol)		Nositelj odobrenja	Bayer d.o.o.	Broj odobrenja	HR-H-182628999 ⊘	
Naziv lijeka	Qlaira filmo	om obložene tablete		Put primje	ne	Kroz usta			Vrsta postupka	EU, RUP	Šīfra postupka	NL/H/1230/001/R/002	5
Status lijeka	Važeće			Jačina		tamnožuta tabl srednjecrvena ta svijetložuta tabl tamnocrvena ta	eta: 3 mg; ableta: 2 mg + 2 mg; eta: 2 mg + 3 mg: ibleta: 1 mg		Format dokumentacije	eCTD	Klasa lijeka	UP/I-530-09/17-02/850	PIL SPC LAB
Novi vanjski sprem	nik Novi spremnik	Nova proizvedena jedinka	Novi medici	nski proizvod		I							

		I	Packaged	d Medici	nal Product			Containe	er	Shelf Life / Storage			Manufact	tured Item			Medical	Device		
Uredi		BO pakiranja	Registracijski status	i Status na tržištu	Opis pakiranja	Veličina ⁽ⁱ⁾ pakiranja	(j) Spremnik	Dodatni opis spremnika	Komponente spremnika	Rok valjanosti i uvjeti čuvanja	iedinica prezentacije	Količina proizvedene jedinke) Proizvedeni ⁽ⁱ⁾ farmaceutski oblik	(i) Opis proizvedene jedinke	Sastav	Kombinacija 🛈 lijek/medicinski proizvod	i) Tip medicinskog proizvoda	Zaštićeni naziv ⁽ⁱ⁾ medicinskog proizvoda	Količina (medicinskog proizvoda) Briši
-1	Vanjski spremnik	HR-H- 182628999-01	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 1 x 28 tablets film coated tablets.	28 tableta	Kutija			<u>dodaj rok</u> <u>valjanosti i uvjete</u> <u>čuvanja</u>										*
~ /	Spremnik						Blister													1
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnožuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	5	Filmom obložena tableta	srednjecrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	17	Filmom obložena tableta	svjetložuta tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	tamnocrvena tableta	Prikaži sastav					
1	Proizvedena jedinka										tableta	2	Filmom obložena tableta	bijela tableta	Prikaži sastav					1
- 1	Vanjski spremnik	HR-H- 182628999-02	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. ³ x 28 tablets film coated tablets.	84 tableta	Kutija			pregledaj rokove valjanosti i uvjete čuvanja										
-1	Spremnik						Blister													1



Pop-up: Shelf life and Special precautions for storage

Rok valja	nosti i uvjeti čuvanja				×
+					
Jredi	Rok valjanosti (vrsta)		Rok valjanosti - vremenski period (broj)	Uvjeti čuvanja	Briši
-	Shelf life of the medicinal proc as packaged for sale	duct	3 year	Do not store above 25 °C Store in the original package in order to protect from moisture	Î
Rok valjar	nosti i uvjeti čuvanja				×
	Rok valjanosti (vrsta)	She	If life of the medicinal pro	oduct as packaged for sale	¢
Rok v	aljanosti - vremenski period (broj)	3	year		¢
Uvjeti čuv	vanja 🕂				
Do not sto	ore above 25 °C				×
Store in th	e original package				×
in order to	protect from moisture				×
				Spremi	Odustani

Uvjeti	čuvanja				×		
+							
Uredi	Šifra (RMS)		Uvjeti čuvanja		Briši		
	10000073410)	Do not store above 25 °C		Î		
1	10000073421	L	Store in the original package		Ê		
1	10000073427		in order to protect from moistur	e	Î		
Tražilio	a uvjeta čuva	nja					×
Odaberi	Šifra (RMS)	Naziv	/ (HR)	Naziv (EN)		Označi
	Q	Q		Q			
÷	10000073410	Ne ču	uvati na temperaturi iznad 25°C	Do not	store abov	∕e 25°C	~
<i>></i>	10000073421	Čuva	ti u originalnom pakiranju	Store in	n the origir	nal package	✓
→	10000073422	Sprei	mnik čuvati čvrsto zatvoren	Keep tł	ne containe	er tightly closed	
\rightarrow	10000073423	Sprer pakir	mnik čuvati u vanjskom anju	Keep tł	ne containe	er in the outer carton	
\rightarrow	10000073427	radi :	zaštite od vlage	in orde	r to protec	t from moisture	~

Dodaj označeno

×

PMP: Manufactured Items



Pregled lijeka	a Osnovni	podaci Dodat	ni podaci	Sastav	Pakiranja	Predmeti	Dokumenti	FollowUp	mjere N	lapomene										
Krovni lijek		Qlaira		1	ATK		G03AB08 (die	enogest i estra	diol)	Nositelj (odobrenja		Bayer d.o.o.	Broj od	lobrenja	HR-H-182	628999 📀			
Naziv lijeka		Qlaira filmom oblož	iene tablete		Put primjen	e	Kroz usta			Vrsta po	stupka		EU, RUP	Šifra po	ostupka	NL/H/1230	/001/R/002			5
Status lijeka	Ņ	New M	anufac	tured	Jačina Item		tamnožuta t srednjecrven svijetložuta t tamnocrvena	ableta: 3 mg; a tableta: 2 mg ableta: 2 mg + a tableta: 1 mg	g + 2 mg; 3 mg: 1	Formatio	dokumenta	ije	eCTD	Klasa li	jeka	UP/I-530-0	9/17-02/850		PIL	SPC LAB
Novi vanjski s	premnik Novi	premnik Nova proi	zvedena jedink	a Novi met	dicinski proizvod															
			Package	ed Medic	cinal Product			Contain	er	Shelf Life Storage			Manufac	tured Item			Medica	l Device		
Uredi		BO pakiranja	Registracijsk status	i Status na tržištu	Opis pakiranja	(i) Veličina pakiranja) (j Spremnik	Dodatni opis spremnika	Komponente spremnika	Rok valjanosti i uvjeti čuvanja	() Jedinica prezentacije	Količina proizvedene jedinke	Proizvedeni farmaceutski oblik	() Opis proizvedene jedinke	Sastav	Kombinacija lijek/medicinski proizvod) (i Tip medicinskog proizvoda	Zaštićeni naziv medicinskog proizvoda	Količina (medicinskog proizvoda	Briši
- 1	Vanjski spremni	HR-1/- 187628999-01	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 1 x 2 tablets film coated tab	28 tableta	Kutija			<u>dodaj rok</u> valjanosti i uvjete <u>čuvanja</u>										
~ /	Spremnik						Blister													
-	Proizvedena jedin	ta									tableta	2	Filmom obložena tableta	tamnožuta tableta	Prikaži sastav					1
1	Proizvedena jedin	ta									tableta	5	Filmom obložena tableta	srednjecrvena tableta	Prikaži sastav					
1	Proizvedena jedin	ka									tableta	17	Filmom obložena tableta	svjetložuta tableta	Prikaži sastav					
1	Proizvedena jedin	ia i									tableta	2	Filmom obložena tableta	tamnocrvena tableta	Prikaži sastav					
1	Proizvedena jedin	ta									tableta	2	Filmom obložena tableta	bijela tableta	Prikaži sastav					
- 1	Vanjski spremnil	HR-H- 182628999-02	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 3 x 2 tablets film coated tabl	g 84 tableta ets.	Kutija			pregledaj rokove valjanosti i uvjete čuvanja										
-1	Spremnik						Blister													



Pop-up: New Manufactured Item

ova j	oroizvedena je	dinka								×	
			Jedinica prezentacije	a Tablet					¢	•	
		Količina	proizvedene jedinke	2	counta	able unit(s)			¢	0	
		Proizvede	ni farmaceutski oblil	Film-coate	d tablet				\$	0	
				Hrvatski							
				Tamno žut	e tablete						
		Opis	proizvedene jedinke	Engleski						0	
				Dark yello	w tablets						
										-	
asta	/ proizvedene jedir	nke 🕂									> Next pa
lredi	Uloga sastojka (Substance role)	Proizvođači	Tip tvari (Substance type)	Tvar (Substance)	Jačina po jedinici prezenta	cije Koncentracija	Referentna tvar	Jačina po jedinici prezentacije	Koncentracija	Briši	
/	Active	Prikaži proizvođače	Chemical	Dienogest	= 2 mg / 1 tablet		Dienogest	= 1 mg / 1 tablet		Ê	
	Active	Prikaži proizvođače	Chemical	Estradiol valerate	= 2 mg / 1 tablet		Estradiol valerate	= 3 mg / 1 tablet		Ê	
	Excipient	Prikaži proizvođače	Chemical	Lactose monohydrate	= 1 mg / 1 tablet					Ê	
	Excipient	Prikaži proizvođače	Chemical	Maize starch	= 1 mg / 1 tablet					Ê	
/	Excipient	Prikaži proizvođače	Chemical	Pregelatinized maize starch	= 1 mg / 1 tablet					Ê	
	Excipient	Prikaži proizvođače	Chemical	Povidone K25 (E1201)	= 1 mg / 1 tablet					Ê	
/	Excipient	Prikaži proizvođače	Chemical	Magnesium stearate (E572)	= 1 mg / 1 tablet					Ê	
1	Excipient	Prikaži proizvođače	Chemical	Hypromellose type 2910	= 1 mg / 1 tablet					Ê	
/	Excipient	Prikaži proizvođače	Chemical	Macrogol 6000 Talc (E553b)	= 1 mg / 1 tablet					Ê	
	Excipient	Prikaži proizvođače	Chemical	Talc (E553b)	= 1 mg / 1 tablet					Ê	
/	Excipient	Prikaži proizvođače	Chemical	Titanium dioxide (E171)	= 1 mg / 1 tablet					Ê	
	Excipient	Prikaži proizvođače	Chemical	Iron oxide yellow (E172)	= 1 mg / 1 tablet					Ê	
Proi	zvođači proizved	lene jedinke 🕂									
	OMS šifra subj	ekta Naziv proizvođ	lača		OMS šifra loka	acije Adresa				Briši	

Manufactured item composition

Dodavanje tvari

Jačina

Operator količine

Količina





PMP: Adding new Device



Pregled lijek	a Osnovni	podaci Doda	atni podaci	Sastav	Pakiranja	Predmeti	Dokumenti	FollowUp	mjere Na	apomene										
Krovni lijek		Qlaira			ATK		G03AB08 (di	enogest i estra	diol)	Nositelj (odobrenja		Bayer d.o.o.	Broj o	dobrenja	HR-H-182	628999 📀			
Naziv lijeka		Qlaira filmom oblo	žene tablete		Put primjene		Kroz usta			Vrsta po	stupka		EU, RUP	Šifra p	ostupka	NL/H/1230	/001/R/002			5
Status lijeka		/ažeće		Now	Jačina Modical [)ovico	tamnožuta t srednjecrven svijetložuta t tamnocrven	ableta: 3 mg; la tableta: 2 mg ableta: 2 mg + a tableta: 1 mg	g + 2 mg; ·3 mg:)	Formatio	dokumenta	cije	eCTD	Klasa I	jeka	UP/I-530-0	9/17-02/850		PIL	SPC LAB
				New		evice	1													
Novi vanjski :	premnik Novi	spremnik Nova pro	oizvedena jedink	a Novi me	dicinski proizvod															
			Package	d Medic	inal Product			Contain	er	Shelf Life / Storage			Manufac	tured Item			Medical	Device		
Uredi		BO pakiranja	Registracijsk status	i Status na tržištu	Opis pakiranja	Veličina pakiranja) (j Spremnik	i Dodatni opis spremnika	Komponente spremnika	Rok valjanosti i uvjeti čuvanja	Jedinica prezentacije	Količina proizvedene jedinke) Proizvedeni (i) farmaceutski oblik	() Opis proizvedene jedinke	Sastav	Kombinacija (lijek/medicinski proizvod) (i Tip medicinskog proizvoda	Zaštićeni naziv medicinskog proizvoda) Količina (medicinskog proizvoda	Briši
- 1	Vanjski spremni	k <u>HR-H-</u> <u>182628999-01</u>	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 1 x 21 tablets film coated table	28 tableta	Kutija			<u>dodaj rok</u> <u>valjanosti i uvjete</u> <u>čuvanja</u>										*
	Spremnik				,		Blister													
1	Proizvedena jedin	ka									tableta	2	Filmom obložena tableta	tamnožuta tableta	Prikaži sastav					1
1	Proizvedena jedin	ka									tableta	5	Filmom obložena tableta	srednjecrvena tableta	Prikaži sastav					
1	Proizvedena jedin	ka									tableta	17	Filmom obložena tableta	svjetložuta tableta	Prikaži sastav					÷.
1	Proizvedena jedin	ka									tableta	2	Filmom obložena tableta	tamnocrvena tableta	Prikaži sastav					
-	Proizvedena jedin	ia									tableta	2	Filmom obložena tableta	bijela tableta	Prikaži sastav					1
- 1	Vanjski spremni	HR-H- 182628999-02	Važeće	nepoznato	Transparent PVC/ Aluminium blister in a cardboard wallet. 3 x 28 tablets film coated table	84 tableta	Kutija			pregledaj rokove valjanosti i uvjete čuvanja										
-1	Spremnik						Blister													



RMS: referential lists in use

		C	0	N A
U	N	6	U	M

	Šiframici		Globalni		Subjekti	
e	🗄 Subjekti	+	Kategorije dokumenata Opisi dokumenata		Područno ustrojstvo	
	Tvari		RMS - ATK klasifikacije	Anatomical Therapeutic Chemical class	Pravni oblici sification system – Human	
			RMS - Domene	Domain		
	NRL		RMS - Države	Country		
	Sradičnji podaci o lijekovima		RMS - Farmaceutski oblici	Pharmaceutical Dose Form, Combined	term, Combined Pharmaceutical Dose Form, Combination Packag	e
	Središnji podači o lijekovima		RMS - Grupe farmaceutskih oblika	Dosage Form Category		
	Obrada predmeta	+	RMS - Jedinice mjere	Units of Measurement		
	<u>,</u>		RMS - Jedinice prezentacije	Units of Presentation		
	Case	+	RMS - Jezici	Language		
	Obavijesti	+	RMS - Kategorije pakiranja	Container Category		
			RMS - Mjesta izdavanja	Supply		
	Povjerenstvo	+	RMS - Načini izdavanja	Legal Status for the Supply		
	MF dokumenti	+	RMS - Operatori količine	Quantity Operator		
			RMS - Putevi primjene	Routes and Methods of Administration	n	
			RMS - Registracijski statusi lijeka	Regulatory Entitlement Status		
			RMS - Statusi lijeka na tržištu	Marketing Status		
2	Reagensoteka	+	RMS - Šifre izmjena	Variation Classification		
	Analiza		RMS - Uloge u EU postupcima	EU Procedural Authority Role		
	Andiiza	- T	RMS - Uvjeti čuvanja	Special Precaution for Storage		
	Standardoteka	+	RMS - Vrste pakiranja	Packaging		
			RMS - Vrste sastojaka	Ingredient Role		
	Uzorkoteka	+	RMS - Materijali	Material		
	ы і ·	,	RMS - Vrste kombiniranog pribora	iviedical Device Legislative. Category		
			RMS - Tip tvari	Substance type		
			RMS - Vrste roka valjanosti	Shelf Life Type		





- In case when RMS list term is not localized, users will choose English terms
- RMS and internal term versions are stored
- If SPOR version is increased, all term attributes are updated in internal codebook, except internal version.
- Internal version automatically increments in case when:
 - Croatian localization of term has changed
 - The term status changed from current or provisional to non-current or nullified
- Search engine enables searching and filtering data by either old or new term



RMS: Localized term versioning – indicators in UI (1/2) UN/COM

- On all opened applications and medicines that have old term, term is not changing before regulatory activities that are changing product information documents.
- Changed terms are indicated on status bar:

Pregled predmeta	Osnovni podaci	Sastav	Pakiranja	Izmjene	Zaprimljena do	okumentacija	Ocjene	Tijek obrade predmeta	U/I dokumenti	i I. serija	Nalog za fakturiranje	Nanomene	
												Sljedeći zapisi koje koristite dobili su nove verzije:	
E Spremi	🧭 Odustani	¶Status ي	oredmeta									Država proizvođača lijeka	
												Makedonija (ver. 1) CURRENT → Sjeverna Makedonija (ver. 2) CURRENT	
												Farmaceutski oblik lijeka	
Krovni lijek	Betadine			Klasa lijek	a	UP/I-530-09/	14-02/307	Naziv lijeka	B	Setadine 1% g	rgijača	 grgljača (ver. 1) CURRENT → Otopina za grgljanje (ver. 2) CURRENT 	
ATK klasifikacija	R02AA15,	povidon jo	dirani	Broj Odob	orenja	HR-H-81538	4810 📀	Nositelj od	obrenja 🥻	Alkaloid d.o.o			5
Jačina	1%			Podnosite	elj zahtjeva	Alkaloid d.o	.o.	Datum zap	rimanja 2	26.11.2020.			



UNCOM **RMS:** Localized term versioning – indicators in UI (2/2)

- Old terms are indicated with red letters where they appear in UI and in drop down lists
- In marketing authorization case for new MP, only new terms will be listed on all term lists

Put primjene			_		
Farmaceutski oblik (lijeka) 🔺	grgijača (stara verzija)	~	/ 🖃		
	Granule za rektalnu suspenziju Granule za sirup Granule za suspenziju za injekciju Granule za uporabu u vodi za piće grgljača (stara verzija)	Drop-down list old term in red with explanatio	: letters on: "old	term"	^
	Implantacijska matrica Implantacijska pasta Implantacijska suspenzija Implantacijska tableta Implantacijski lanac				
	implantat Implantat u napunjenoj štrcaljki Impregnirana obloga Impregnirani jastučić				
	Impregnirani uložak Infuzija instant biljni čaj Intestinalni gel intramamarna emulzija				
	Intramamarna mast				×







- Internal Organizations repository
 - used for different business processes,
 - shared with other applications
 - Organizations versioning implemented
- OMS API connection established enabled linking of internal organization IDs with OMS IDs
- Data cleansing work in progress



OMS: Linking NRL organisations with OMS ORG and LOC IDs

Osnovni podaci Identifikatori Kontakt podaci Kontakt osoba Verzije podataka o subjektu SPOR Lokacije SPOR Organisation ID Naziv subjekta Država Subjekt: 402, Pliva Hrvatska d.o.o., Verzija: 1 Q Q Q X Natrag ORG-100001442 Pliva Hrvatska d.o.o. Croatia Obavijesti Location ID Aktivno Q (Svi) 💌 Pravni subjekt Pravni subjekt ili fizička osoba \checkmark LOC-100003105 SPOR Organisation ID ORG-100001442 Vrsta Naziv ORG-100001442 Pliva Hrvatska d.o.o. Poštanski broj \square Oda... Jezik Adresa Mjesto Q Q Q Puni naziv tvrtke ORG-100003349 Pliva Hrvatska d.o.o. Q Q Q Q Stručni savjet ORG-100004041 Pliva Hrvatska d.o.o. Stručni savjet - Plivacor 5 m Skraćeni naziv tvrtke PIIVALEINVATSKALO.0.0 \rightarrow en Prilaz Baruna Filipovica 25 Zagreb 10000 Stručni savjet Stručni avjet - Ibuprofen or Prilaz Baruna Filipovića 29 Zagreb 10000 \rightarrow h Alternativni naziv Stručni savjet Struini savjet - Azitromicin : Stručni savjet St učni savjet - Analgin/Alka \rightarrow h Prilaz Baruna Filipovića 25 Zagreb 10000 Pravni oblik Društvo s ograničenom odgovornošću \$ Stručni savjet Stručni savjet - Pliva (parace Nadređeni subjekt Stručni savjet Stručni savjet - acetilsalicilat LOC-100003107 Stručni savjet Stručni savjet - Acetilcistein \$ Država Hrvatska Stručni savjet Plivit D3 (kolekalciferol) - lin Oda Jezik Adresa Mjesto Poštanski broi OIB 44205501677 Punomoć Actavis Group PTC ehf. pund Q Q Q Q Stručni savi Stručni savjet-Paracetamol Prudnicka Cesta 54 Savski Marof 10291 \rightarrow en Brdovec ACTIVE SPOR status Teva GmbH za Pliva Hrvatsk Punomo Prudnička Cesta 54 Savski Marof Brdovec 10291 \rightarrow h Aktivno Aktivno Ì Brexit izuzeće Zahtjevi za izuzećem zbog Kreirala aplikacija NRL ili PKL Lokacija ubjekta ~ LOC-100006207 +

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- Currently in use EUTCT list Substances (List ID: 100000075825)
- Data cleansing in progress:
 - > 0,3% terms (175 out of 61.308) were custom added:
 - ✓ 129 (74%) deactivated (replaced with EUTCT terms)
 - ✓ 46 (26%) still active will be replaced with EUTCT terms during regulatory activities that are changing product information documents



Challenges and our approach

	Challenges	Our approach			
Data model refactoring and user interface redesign	Besides ISO IDMP system refactoring, the HeAL's functionalities are regularly upgraded due to the changes in regulatory and business process optimisation requirements. Managing those two projects and synchronising all the changes in IT system that is actively used is challenging	DB and UI refactoring of the HeAL IT system (in order to align with ISO IDMP) is divided into development phases that could be deployed to production independently and won't disturb regular system upgrades and business processes conducted in the HeAL IT system			
	EMA EU IG is expected to be updated and changes might impact existing deliverables	All changes in already finished DB and UI refactoring will require additional resources (time and financing)			
	Lack of ISO IDMP and FHIR experts	 Learning from each other: UNICOM knowledge sharing workshops Teaming with business experts and subject matter experts Regular workshops with vendor 			
Referential lists (RMS)	Internal codebooks with custom-added terms that should be mapped and/or replaced with RMS terms	Term versioning and notifying HeAL business users about the change, so that new term version could be used in regulatory activity that is changing product information documents.			
Organisations (OMS)	Data quality in OMS	Linking internal organisations with OMS ORG IDs and LOC IDs and taking OMS ORG data for organisations after verifying the information is correct			
Substances (SMS)	Although synchronized with EUTCT Substances codebook, internal codebook still have some custom-added terms	Custom-added terms will be mapped and/or replaced with substances from SMS during regulatory activity that is changing product information documents.			

Next steps



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Database and User interface	 Pharmaceutical Product reconstruction and preparation for PhPID introduction
RMS	 Introducing all RMS referential lists according to in EU IG requirements
Data	 Continue with data cleansing / mapping / migration
OMS	 Linking organisations data with OMS Organisation and Location IDs
SMS, PMS	 Prepare FHIR messages for synchronisation of substances data and for data exchange with PMS
National MP database (human)	 Participate in preparing Functional requirements specification for National MP database (e-lijekovi) Prepare services for daily synchronisation with National MP database



