

Practical aspects of working electronically in the Network

Croatian experience

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7 May 2013

Summary

- Introduction
- Implementation of EU Telematics in HALMED
- The Croatian extranet portal development
- Connection with CESP
- Conclusion

Introduction

- Since 2006 HALMED's employees participate in EU Telematics meetings at EMA
- Participation is sponsored through EU pre-accession programmes
- Our role is transforming from observers to active participants
- Several EU telematics systems have already been successfully implemented in HALMED

HALMED's participation in EU telematics

- Fully implemented EU telematics systems:
 - EudraLink
 - EudraNet
 - EudraVigilance
 - EURS (European Review System)
 - EUTCT

EudraVigilance

- Project started in 2008 - system was set up and tested
- 2009 – system was made operational
- 2010 – Croatia was granted to use EMA gateway infrastructure despite not being a member state
- April 2010 – HALMED announced that it is ready for electronic reporting
- 64 companies registered for electronic reporting with HALMED, 15 are actively sending reports
- More than 20 000 ICSRs received monthly

EURS (European Review System)

- System that enables NCAs and EMA to receive, validate, store and make available for review marketing authorisation applications submitted in eCTD, NeeS format
- HALMED implemented the EURS system in 2010
- Beside the technical part of implementation, the internal business process needed to be organized
- In June 2010 HALMED announced its readiness to work with electronic formats of documentation

EUTCT

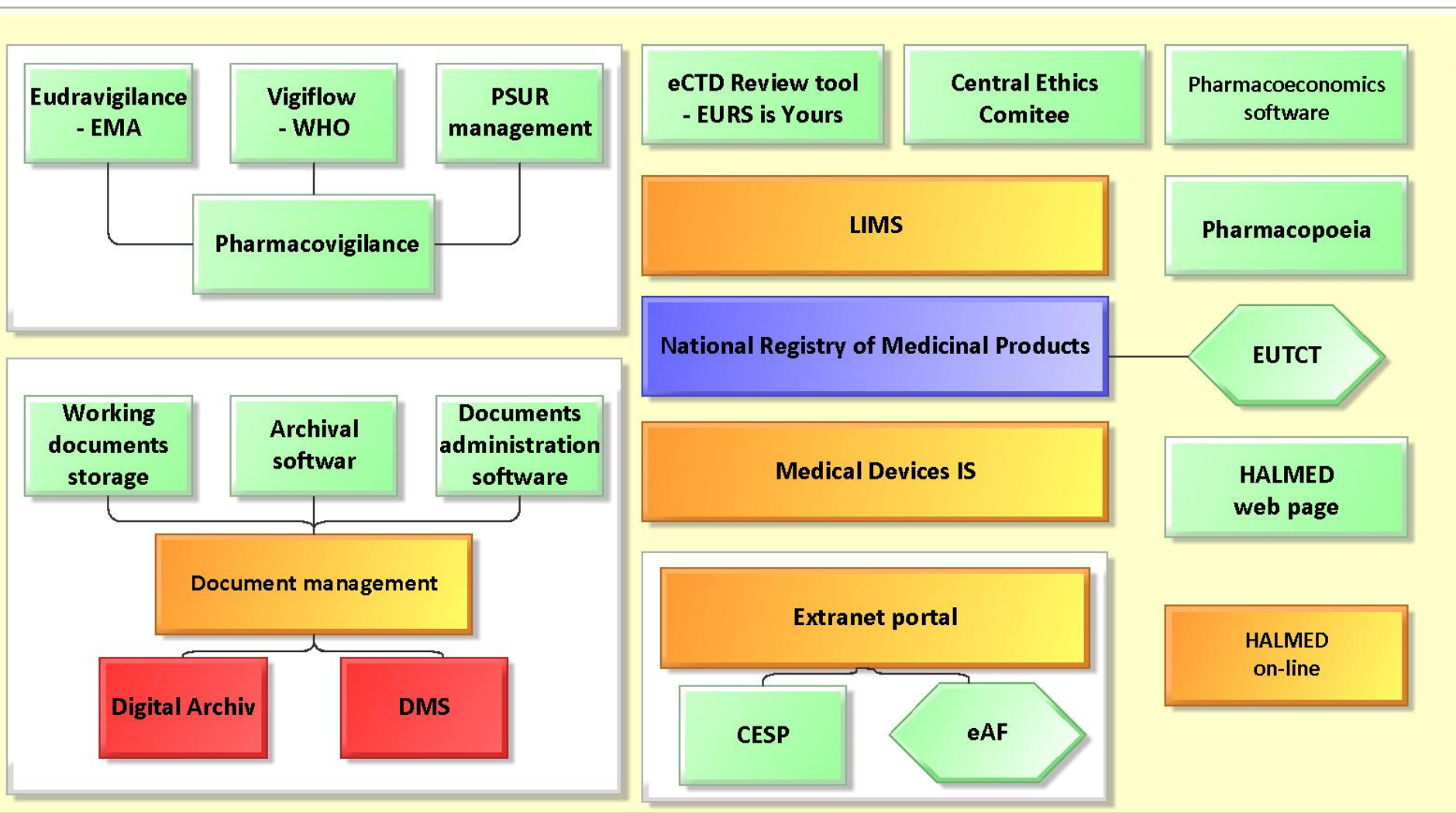
- In 2011 HALMED recreated NRL (National Registry of Medicinal Products)
- “Internal” lists were replaced with EUTCT lists
- EUTCT lists have been used in HALMED ever since

Conclusion:

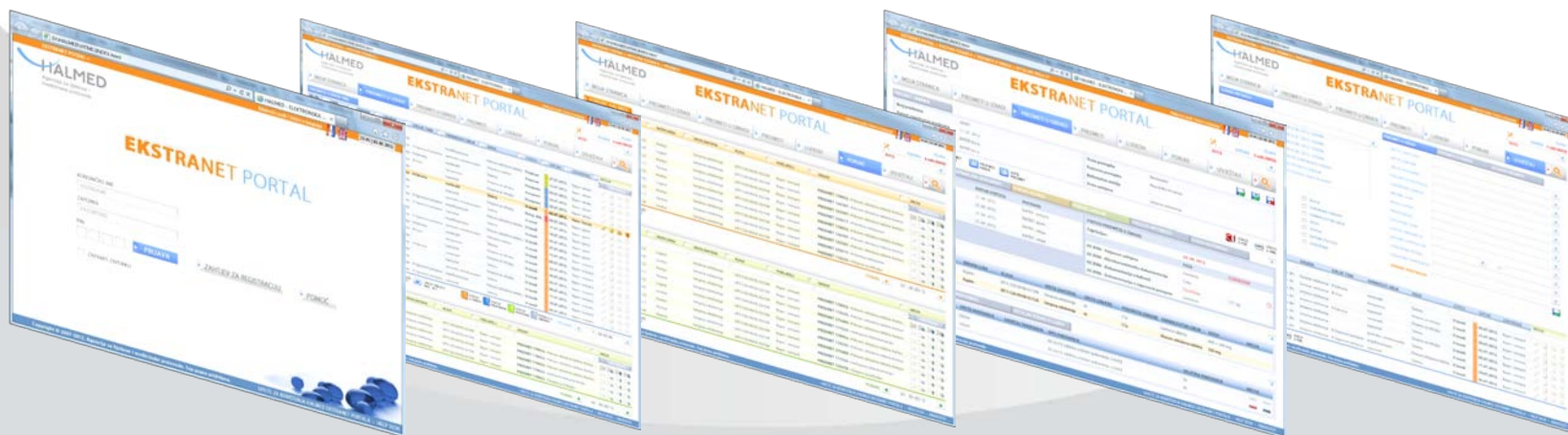
- Cooperation with EMA and participation in EU telematics has been very successful so far



HALMED IS



EKSTRANET PORTAL



EKSTRANET PORTAL

- HALMED decided to build extranet portal as a tool for increasing efficiency, transparency and interactive work with the industry
- Through the portal, HALMED will receive medicinal products applications from both national and European marketing authorization holders, and allow marketing authorisation holders to track their cases submitted to Croatian Agency

EKSTRANET PORTAL

Benefits

- Extranet portal will be a web portal for:
 - submitting case applications and medicinal products dossiers in electronic formats
 - direct communication and interactive work of industry representatives with the Agency's employees through messages and document exchange
 - direct communication between stakeholders and their representatives
 - automatic notification of users on certain procedure changes
 - tracking the progress of applications



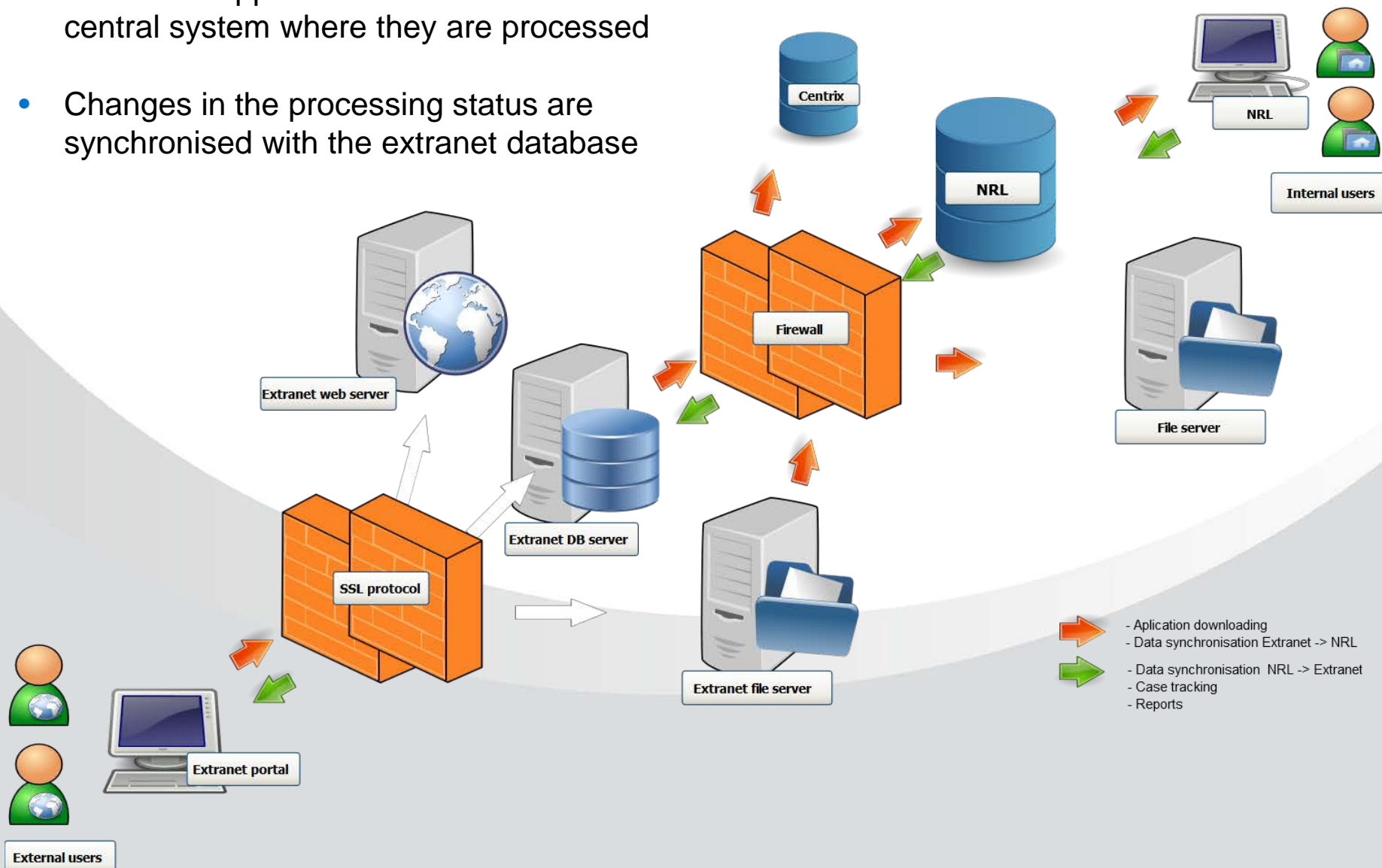
EKSTRANET PORTAL

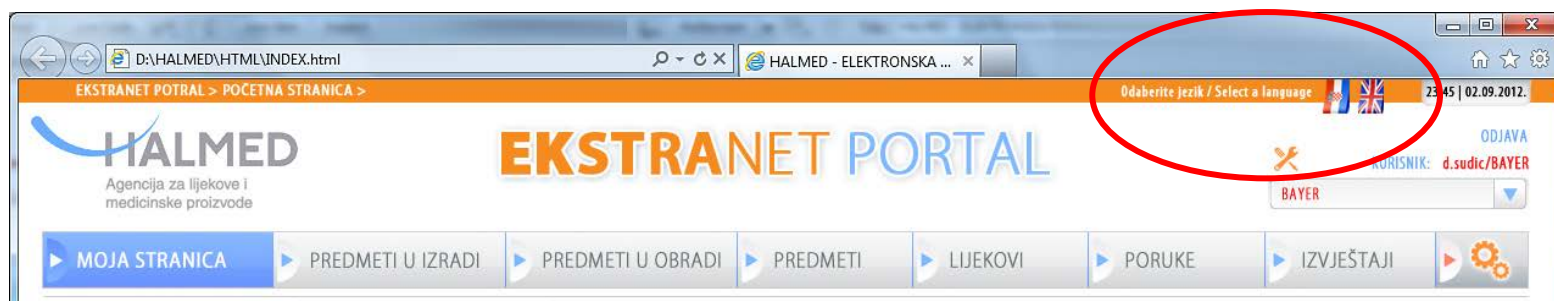
How we started:

- By analysing existing problems in internal business processes
- By analysing existing problems in current practice with electronic submissions
- By analysing existing approaches and solutions from the Irish agency
- Held workshops for applicants as future users of the portal
- By consulting with software developers



- Submitted applications are loaded into our central system where they are processed
- Changes in the processing status are synchronised with the extranet database





Functionalities:

- **My Page** – every user defines which contents are going to be displayed
- **Applications in Draft** – applications currently in draft
- **Applications under Assessment** – all applications sent to the Agency and under assessment
- **Applications** – search and display of complete applications
- **Medicinal Products** – search and display of medicinal products
- **Messages** – display of messages
- **Reports** – page for creating reports regarding the application processing and medicinal products
- **Administration** – page for local administrators and portal administrators

All portal pages will be in Croatian or English.

- EMA's EU Electronic Application Forms (eAF) are used for:
 - registration
 - renewal
 - variation of marketing authorisation
- HALMED designed intelligent PDF forms for:
 - transferral of a marketing authorisation
 - withdrawal of a marketing authorisation
 - upgrading existing dossiers
 - homeopathic products
- All forms will be in Croatian or English

APPLICATION FORM

SUMMARY OF THE DOSSIER

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for human use submitted to (a) the European Medicines Agency under the centralised procedure or (b) a Member State (as well as Iceland, Liechtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure.

Usually a separate application form for each strength and pharmaceutical form is required.
For centralised procedures a combined application form is acceptable (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name

Pharmaceutical Form:

Strength:

Active Substance(s):

Applicant details:
Name

Person authorised for communication*, on behalf of the Applicant:
Title
First name
Surname

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate.
It is hereby confirmed that fees will be paid/have been paid according to the national/Community rules**.

On behalf of the applicant
Title
First name
Surname
Function

1.4.B Article 16a Traditional use registration for herbal medicinal product
Note: Complete application
Refer to Notice to Applicants, Volume 2A, Chapter 1

4 ways

Creating a new application:

1. By filling out an empty form
2. By editing a form pre-filled with downloaded medicinal product data
3. By editing a form pre-filled with downloaded data from an existing case
4. By importing an XML file from the user's system

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DECLARATION AND SIGNATURE

Product (invented) name

Pharmaceutical Form:

Strength:

Active Substance(s):

Add Active Substance(s)

Populate data

Applicant details:

Name

Person authorised for communication*, on behalf of the Applicant:

Title

First name

Surname

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate.
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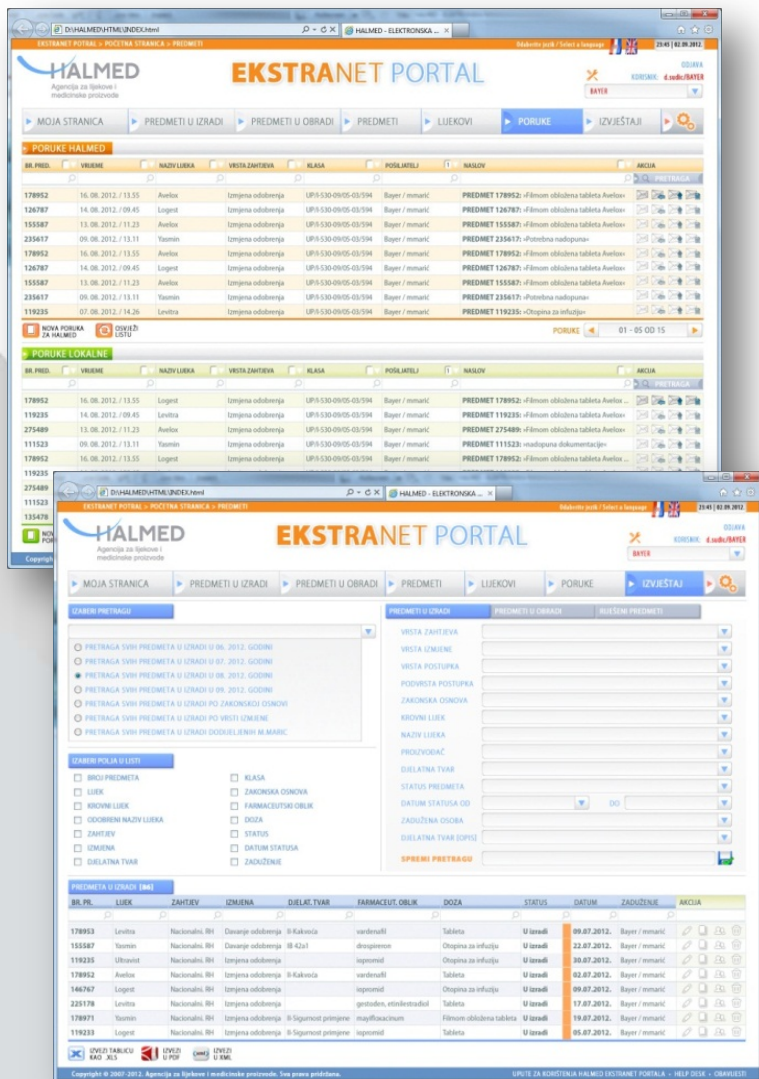
- Filled out application can be edited, updated, corrected, even deleted until submission
- Multiple user roles:
 - user who fills the application
 - user who verifies the application
 - user who approves the submission
- Only the user authorised for approving the application can submit it
 - The user must re-enter username and password

The screenshot displays the HALMED EKSTRANET PORTAL interface. The top navigation bar includes links for 'MOJA STRANICA', 'PREDMETI U IZRADI', 'PREDMETI U OBRADI', 'SVI PREDMETI', 'PORUKE', and 'IZVJEŠTAJI'. Below the navigation bar is a table of applications with columns for BR. PR., LIJEK, ZAHTEV, IZMJENA, DIELAT TVAR, FARMACEUT. OBLIK, DOZA, STATUS, DATUM, ZADUŽENJE, and AKCIJA. The table lists various applications for drugs like Avelox, Logest, Levitra, Yasmin, Ultravist, and others, with their respective statuses (e.g., Potpisan, U izradi, Provjeren). At the bottom, there is a section for 'PORUKE LOKALNE' (Local Messages) showing messages for application 178952.

- The “Application Tracking” list displays the application processing phase
- Figure: the case is in the Clock Stop status; 12 out of 45 days for providing additional documentation have already passed
- Exchange of working documents is supported by the portal
- Submitted documents can be edited until HALMED’s internal user checks them in
- When internal users request updates or changes, working documents are unlocked to edit

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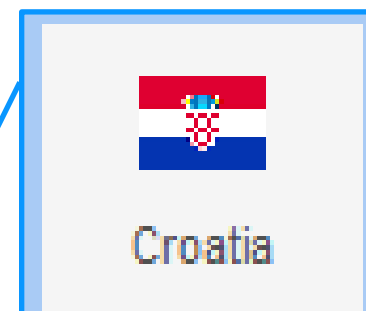
STATUSI PREDMETA U IZRADI	DATUM STATUSA	POSTAVIO	STATUSI PREDMETA U OBRADI	DATUM STATUSA	POSTAVIO
U izradi	21. 09. 2012.	BAYER \ mmaric	Zaprimljen	29. 09. 2012.	
Provjeren	23. 09. 2012.	BAYER \ ajuric	FAZA		
Potpisan	27. 09. 2012.	BAYER \ istipic	OCJENA - Valjanost zahtjeva	Završeno	
Poslan / u najavi	27. 09. 2012.	BAYER \ istipic	OCJENA - Klinička/neklinička dokumentacija	Ceka	
			OCJENA - Dokumentacija o kakvoći	ClockStop	12 / 30
			OCJENA - Dokumentacija o sigurnosti primjene	Završeno	



- Communication by messages is available during the whole process
- Each message corresponds to a specific application
- Two types of messages: local and HALMED messages
 - Local messages for communication between users
 - HALMED messages for communication between the users and the Agency employees
- „Reports“ page for searching and displaying the statistics
- Additional features:
 - Printing all data in PDF format
 - Exporting all lists into xls format
 - Exporting each application into XML format



- Transport mechanism for sending electronic documentation from MAH to NCA
- Benefits:
 - Saving time
 - Interoperability
 - Consistency with other EU Agencies

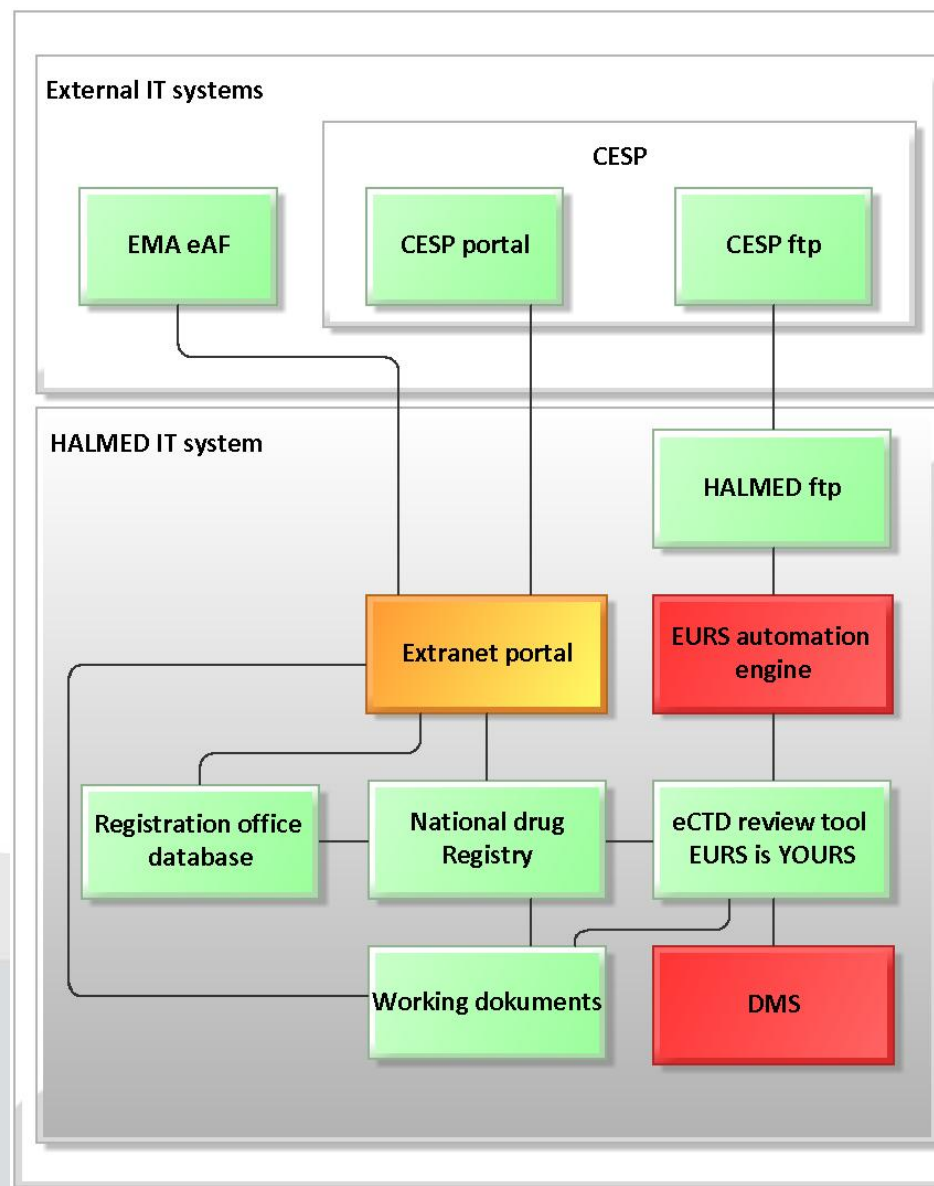


Participating Agencies



CESP – EXTRANET PORTAL

- Applications will be submitted through Extranet Portal
- Dossiers will be submitted through CESP portal
- Submitted dossiers are repositied on HALMED's FTP server
- Dossiers are automatically validated by EURS is Yours tool
- Dossiers are finally transferred to HALMED's DMS



Conclusion

- Many IT projects are initiated at HALMED
- EU telematics projects and HALMED's initiative enable HALMED:
 - To be fully interconnected with the network of European Medicines Agencies
 - To provide information to public and MAHs in a more efficient way
 - To increase the quality and speed of its services
- HALMED is prepared for all future challenges that will come with the EU membership



Thank you for your attention!

Hvala!

Q & A?

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