

Practical aspects of working electronically in the Network

Croatian experience

Dubravka Sudić, M. Sc. Head of IT Department

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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

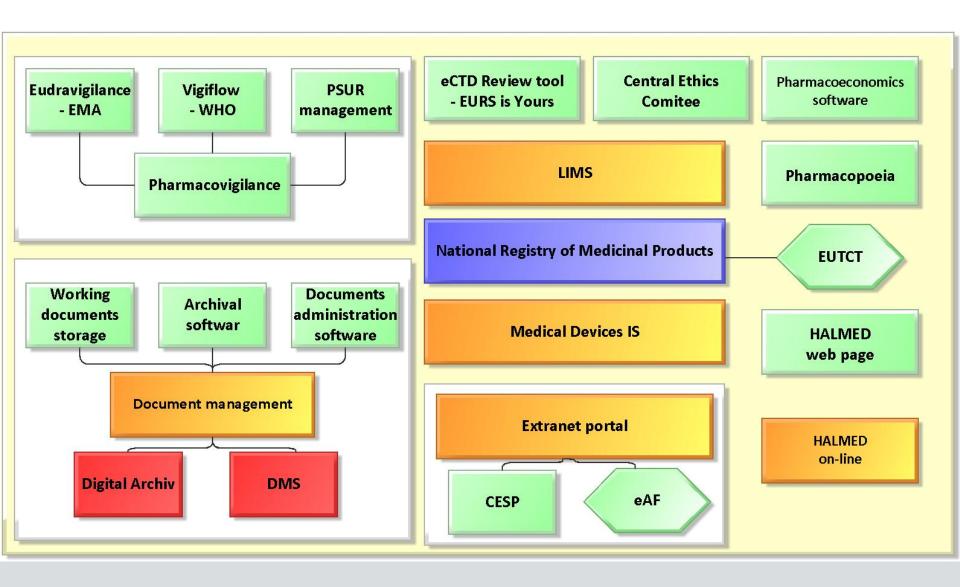
Conclusion:

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















- HALMED 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

- 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

Benefits



EKSTRANET PORTAL

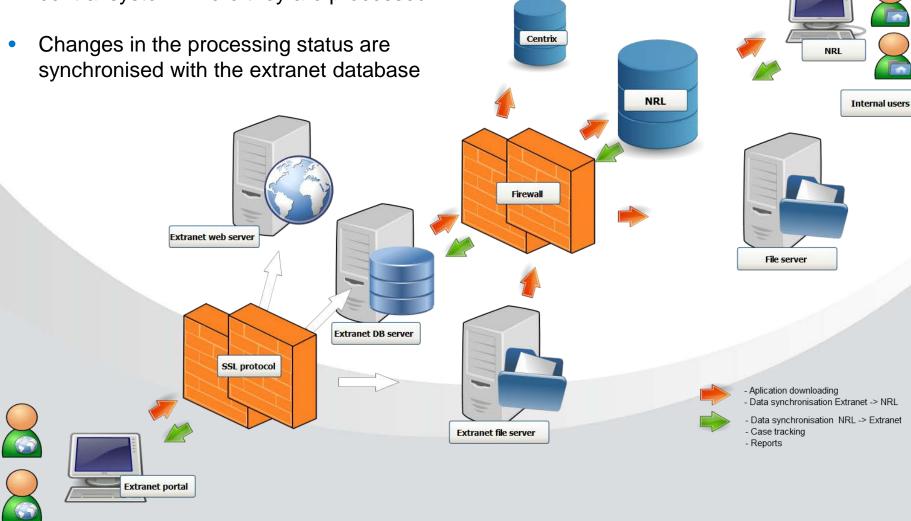
How we started:

- 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



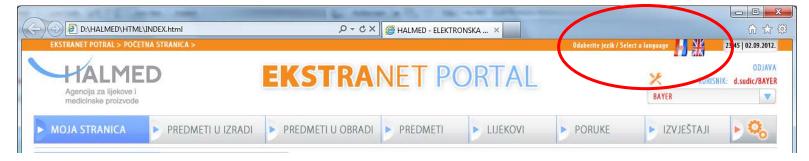


 Submitted applications are loaded into our central system where they are processed



External users





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.



EKSTRANET PORTAL

- 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

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- upgrading existing dossiers
- homeopathic products
- All forms will be in Croatian or English

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EKSTRANET PORTAL

4 ways

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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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- 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

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- 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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- 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





Common European Submission Platform



- Transport mechanism for sending electronic documentation from MAH to NCA
- Benefits:

Heads of Medicines Agencies

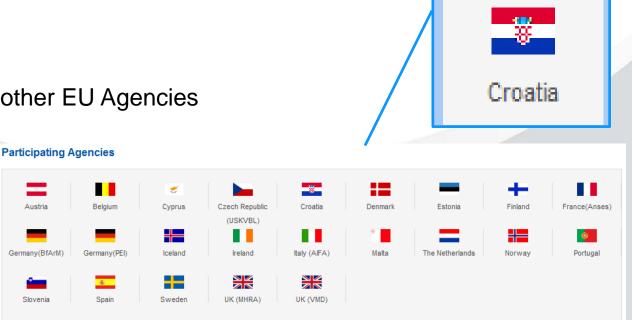
- Saving time
- Interoperability
- Consistency with other EU Agencies

20

Austria

Germany(BfArM)

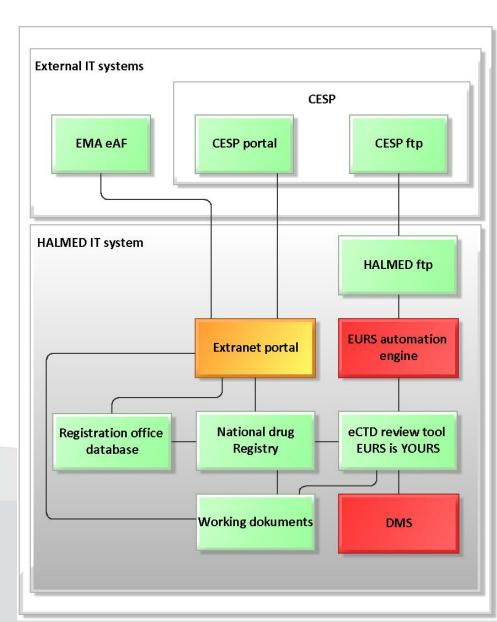
Slovenia





CESP – EXTRANET PORTAL

- Applications will be submitted through Extranet Portal
- Dossiers will be submitted through CESP portal
- Submitted dossiers are reposited 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!



dubravka.sudic@halmed.hr