THE USE OF ELECTRONIC SIGNATURE IN PROCESSES AND APPLICATIONS OF THE CROATIAN AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

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• Introduction
• Processes with electronic signatures in HALMED
• The solution implemented in HALMED
• Further work
• Conclusion
INTRODUCTION

• HALMED
  • The Agency for Medicinal Products and Medical Devices
  • National Competent Authority for the regulation of medicinal products and medical devices of the Republic of Croatia
  • Established in October 2003, however, the function of regulation of medicines in Croatia is much older
• Units
  • Directorate, Official Medicines Control Laboratory, Medicines Authorization, Safe Use Division, Division for Legal, Financial, IT and General Affairs
  • 230 employees
INTRODUCTION

• Electronic signature is “data in electronic form which is attached to or logically associated with other data in electronic form and which issued by the signatory to sign” – eIDAS
  • Electronic signatures
  • Advanced Electronic Signatures (AES)
  • Qualified Electronic Signatures (QES)
PROCESSES WITH ELECTRONIC SIGNATURES IN HALMED

- PDF files in MS Windows environment and within HALMED’s Digital Archival Information System (DAIS built on IBM FileNet platform - ISO 14721:2012 compatible)
- Signing with internal and external certificates
- Ongoing digital transformation of HALMED’s processes
THE SOLUTION IMPLEMENTED IN HALMED

- IT solution provided by Ericsson Nikola Tesla company
- Based on EU CEF eSignature building block and standards
  - ETSI EN 319 142 PDF Advanced Electronic Signature Profiles (PAdES)
  - ETSI TS 119 612 v2.1.1 Electronic Signatures and Infrastructures (ESI), Trusted Lists
  - RFC 5280 and X509 standard, RFC 7292 and PKCS#12/Personal Exchange File (PFX)
FURTHER WORK

• Integration of signing functionality in all DAIS modules
• Business process reengineering for HALMED’s main business processes
• Equipping HALMED’s representatives with legally valid certificates
• Preparation of Marketing Authorization Holders (mainly the local pharma industry) for the new practice
• Digitalization of HALMED’s support processes
• Archiving of electronically signed records
CONCLUSION

• The solution implemented in HALMED is based on the CEF eSignature building block, it is compatible with EU practice, and it works with various certificates.

• Further digital transformation of the marketing authorization process needed.

• Other core and support processes will follow:
  • Establishing the generic process of signing electronic records is not sufficient for the successful functioning of a paperless organization – the complete digital transformation of selected business processes should be performed!
THANK YOU

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