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

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SHORT BIO

Arian Rajh holds a PhD in archival science since 2010. He was born in Zagreb in 1980. He is the Head of Document, Records, and Project Management Department at the Croatian Agency for Medicinal Products and Medical Devices. The University of Zagreb appointed him an assistant professor in 2012, and an associate professor in 2018. During his work in the Agency and at the Faculty of Humanities and Social Sciences at Zagreb University, he was managing or participating in projects related to software development, implementation, and customisation of various systems (case management systems, review applications, enterprise content management systems, archives management systems, digital archives). Also, he was involved in teaching and archives management consulting. He published scientific and professional articles in various journals, conference proceedings, and books (Bulletin d'archives, InFuture proceedings, CJILS, IARIA proceedings, ICA proceedings, IJDLDC, IGI Global books).

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

INTRODUCTION

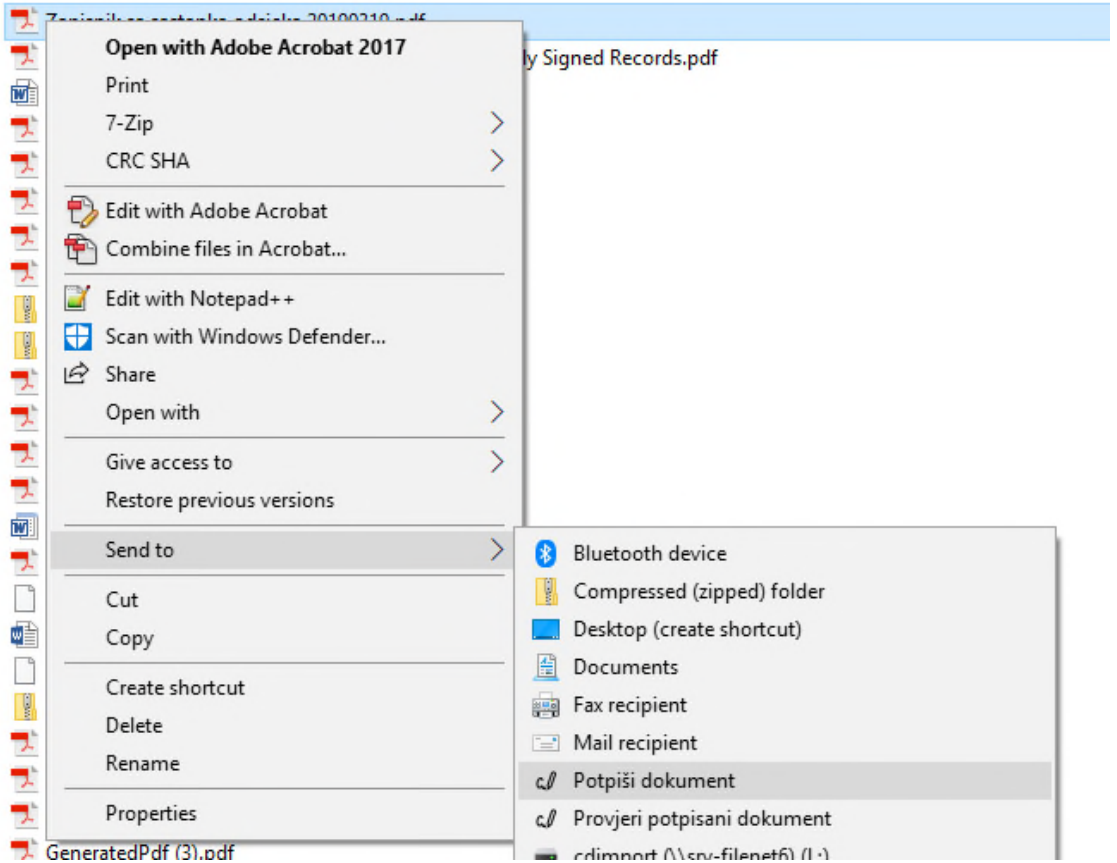
- HALMED
  - The Agency for Medicinal Products and Medical Devices
  - National Competent Authority for the regulation of medicinal products and medical devices of the Republic of Croatia
  - Established in October 2003, however, the function of regulation of medicines in Croatia is much older
  - Units
    - 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

Questions:

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