HALMED

Agency for Medicinal Products
and Medical Devices of Croatia

HALMED's accession to **PIC/S** and GMP inspections outside the EU

Second Russian GMP Conference 2017

Izabela Majić, Head of Inspectorate

izabela.majic@halmed.hr

September 2017

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Accession

- Agency established, October 2003
- Croatia entering EU, July 2013
  - ✓GMP & GVP inspection and GDP licensing became a legal responsibility of HALMED
- Application for PIC/S Accession, **05th September 2014**
  - ✓PIC/S secretariat confirms application as complete, 09th September 2014
- Application for MRA to Health Canada, **January 2015**
- Audit by PIC/S, JAP, MRA-FDA & HC, July 2015
- PIC/S accession letter, **04th November 2015**
- Accession to PIC Scheme January 2016
- EC-Canada MRA with Croatia effective, **April 2016**

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Accession/Agreement

- ✓ On 1 January 2016, Agency for Medicinal Products and Medical Devices of Croatia (HALMED) became the 48th PIC/S Participating Authorities:

  https://www.picscheme.org/en/members
- ✓ Croatia added to the list of regulatory authorities under the EC-Canada MRA, April 2016 : http://www.hc-sc.gc.ca/dhp-mps/compli-conform/int/mra-arm/update-miseajour/authorities-autorites-eng.php#Croatia
- ✓ EU and US regulators agree on mutual recognition of inspections of medicines manufacturers, march 2017

HALMED

Agency for Medicinal Products and Medical Devices of Croatia

Accession procedure

- General interest & commitment, eg. attend Seminars
- Written application to Secretary + supporting documents
- PIC/S Committee appoints Rapporteur to evaluate
- Applicant invited to Committee meeting to answer questions of Rapporteur and Committee
- PIC/S delegation undertakes assessment visit (Inspectorate's procedures; observe 3 or 4 inspections)
- Delegation report issued (to applicant & Committee)
- Committee decides on membership

PIC/S

HALMED

Agency for Medicinal Products and Medical Devices of Croatia

Useful documents

- Pharmaceutical Inspection Cooperation Scheme (PIC/S 1/95)
- Guidelines for Accession to PIC/S (PS/W 14/2011)
- Questionnaire for Competent Authorities (PS/W 1/2011)
- Audit Checklist (PS/W 1/2005)
- Recommendations on quality system requirements for pharmaceutical inspectorates (PI 002)
- Compilation of Community Procedures on Inspections and Exchange of Information http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Useful links

http://www.halmed.hr/

http://www.halmed.hr/en/O-HALMED-u/Zakoni-i-pravilnici/

http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html

This Ordinance transposes the following Directives into the legislation of the Republic of Croatia:

2. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States

Article 199

(1) When conducting an inspection, the pharmaceutical inspector and the Agency inspector shall have the right to:

- inspect business premises, facilities, installations, devices, equipment,

- inspect raw materials, active substances, excipients, intermediate products, medicinal products,

- inspect agreements, records and any other quality system documents or other business documents; if documents are supplied electronically, he may require to see them and have their printout,

- take copies of documents, subject to making the relevant note in the inspection report,

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Inspectors rights

Article 199

(1) When conducting an inspection, the pharmaceutical inspector and the Agency inspector shall have the right to:

- inspect business premises, facilities, installations, devices, equipment,

- inspect raw materials, active substances, excipients, intermediate products, medicinal products,

- inspect agreements, records and any other quality system documents or other business documents; if documents are supplied electronically, he may require to see them and have their printout,

- take copies of documents, subject to making the relevant note in the inspection report,

- take and use free data from official records and other databases related to persons, if necessary for inspection,

- remove medicinal products from the market if they do not comply with the provisions of this Act,

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Why PIC/S?

- ✓ International development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products
- ✓ Accession forced improvements – i.e. discipline
- ✓ Increased efficiency of the GMP Inspectorate
- ✓ Cost-saving measure notably in the field of Active Pharmaceutical Ingredients (APIs)
- ✓ Training (seminars, Joint Inspections, etc.)
- ✓ Involvement with developing international GMP guides and guidelines
- ✓ Facilitated MRA with EC
- ✓ Networking & personal contacts

PIC/S

HALMED

Agency for Medicinal Products and Medical Devices of Croatia

Benefits of PIC/S Membership for Industry

- ✓ Reduced duplication of inspections
- ✓ Cost savings
- ✓ Export facilitation
- ✓ Enhanced market access
- ✓ Some non-PIC/S Authorities accept GMP Certificates from PIC/S Participating Authorities
- ✓ Non-PIC/S Authorities and organisations have a greater confidence in medicines manufactured in countries where the Regulatory Authority is a PIC/S Participating Authority

PIC/S

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Liaison with other organisations

- ✓ The European Department for the Quality of Medicines (EDQM): Associated Partnership, since 2007
- ✓ UNICEF: Associated Partnership, since 2008
- ✓ WHO: Co-operation Agreement, since 2009
- ✓ HMA: Letter of Agreement, since 2016
- ✓ ICH
- ✓ European Commission (DG Health & Food Safety)
- ✓ ASEAN
- ✓ ICMRA
- ✓ OECD

PIC/S

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Quality system requirements for pharmaceuticals inspectorates

- ✓ Quality Manual
- ✓ Administrative Structure
- ✓ Organisation and Management
- ✓ Documentation and Change Control
- ✓ Records
- ✓ Inspection Procedures
- ✓ Inspection Resources
- ✓ Internal Audit

HALMED

Agency for Medicinal Products and Medical Devices of Croatia

Спасибо

"International development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products".