Curriculum Vitae

Personal information

Maja Lovrek Romcevic

Work experience

1. Employer: AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
   - Start date: 02/2012
   - End date: Present
   - Position: Head of Medicines Authorisation Division
   - Activities: Organisation and oversight of authorisation procedures of human medicinal products in the Republic of Croatia, including validation of applications, regulatory support and coordination, assessment of quality, safety and efficacy of medicinal products in national, decentralised, mutual recognition and centralised procedures as well as national and European scientific advice procedures.
   - Country: Croatia
2. Employer: Worldwide Clinical Trials d.o.o.
   - Start date: 04/2010
   - End date: 02/2012
   - Position: Regulatory Affairs Manager
   - Activities: Preparation, coordination and management of Clinical Trial Applications submissions to the Regulatory Authorities and Ethics Committees on the territory of Central and Eastern Europe. Review and expert recommendations for all relevant documents included in the applications in order to assure compliance with current guidelines and local regulations. Communication with Sponsors, project managers and CRAs. Providing expert regulatory advice and education of employees on local regulations.
   - Country: Croatia
3. Employer: AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
   - Start date: 01/2008
   - End date: 04/2010
   - Position: Expert Secretary to the Central Ethics Committee
   - Activities: Organisation of the work of the Central Ethics Committee, including: preparation of documentation for the assessment, organisation of meetings, keeping the minutes of the meeting, preparation of the opinions and giving advice to the applicants.
   - Country: Croatia
4. Employer: AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
   - Start date: 11/2005
   - End date: 01/2008
   - Position: Pharmacovigilance Associate
   - Activities: Assessment of SUSARs, Annual Safety Reports and preparation of Agency's reports on safety of medicinal products in clinical trials for the Central Ethics Committee and Ministry of Health and Social Welfare. Organisation and participation in the pharmacovigilance education of healthcare professionals and pharmaceutical industry representatives.
   - Country: Croatia
5. Employer: AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
   - Start date: 10/2004
   - End date: 11/2005
   - Position: Central Registration Office Associate
   - Activities: Regulatory affairs - medicinal products authorisation procedures.
   - Country: Croatia
6. Employer: PRIMA PHARME PHARMACIES
   - Start date: 04/2003
   - End date: 09/2004
   - Position: Community pharmacist
   - Activities:
   - Country: Croatia

Education and training

1. Subject:
   - Start date:
   - End date: 03/2003
   - Qualification: MPharm
   - Organisation: Faculty of Pharmacy and Biochemistry, University of Zagreb
   - Country: Croatia

Additional information

Publications

ORIGINAL PAPERS:

Škrnjug I, Uzeirbegović S, Lovrek Romčević M, Tomić S, Meyer H, Conrad C. Mutual recognition in the European system: A blueprint for increasing access to medicines? Regulatory Toxicology and Pharmacology. 2019;106:270-277.

Vitezić D, Lovrek M, Tomić S. Centralized National Ethical Review of Clinical Trials in Croatia. CMJ. 2009;50:111-6.

POSTER PRESENTATIONS:

Arapovic Dzakula S., Juricic Nahal D., Lovrek Romcevic M., Tomic S., *Interchangeability of biosimilars from a regulatory standpoint: Croatian experience (2018 - 2020),* 15th Congress of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Athens, Greece 2022, Eur J Clin Pharmacol 78, 1–163 (2022). https://doi.org/10.1007/s00228-022-03333-y

Perina Lakoš G., Uzeirbegović S., Lovrek Romčević M., *HALMED's experience in MR/DC procedures for the period from 1.7.2013 to 1.7.2018*, Sixth Croatian Congress on Pharmacy, Dubrovnik, Croatia 2019

Lovrek M., Juričić V., Ilić Martinac A., Tomić S., *Import of a medicinal product that does not have a marketing authorization in the Republic of Croatia according to a doctor's prescription,* Fourth Croatian Congress on Pharmacy, Opatija, Croatia 2010

Vitezić D., Lovrek M., Tomić S., *Oncology Clinical Trials in Croatia,* 16th World Congress of Basic and Clinical Pharmacology, Copenhagen, Denmark 2010

Vitezić D., Lovrek M., Tomić S., Lovreček D., *Clinical Trials in Croatia: Economical Impact,* First Croatian Congress on Pharmacoeconomics and Outcomes Research with International Participation, Rijeka, Croatia 2010

Mirosevic N, Jankovic I, Lovrek M, Krnic D, Macolic Sarinic V, **Tomic S**, Duggan C, Bates I. Risk factors for developing serious adverse drug reactions. 7thISoP Annual Meeting, Bournemouth, 21-24 October, 2007. Drug Safety 30 (10): 939, 2007.

Macolic Sarinic V, Mirosevic N, Lovrek M, Krnic D, Jankovic I, **Tomic S**. Evidence of clinically significant cyclosporine-fluvastatin interaction. 8th Congress of the European Association for Clinical Pharmacology and Therapeutics, Amsterdam, September, 2007. Basic & Clin Pharmacol Toxicol 101 (1): P169

D. Vitezić, M. Lovrek, S. Tomic, *Centralized Model of Clinical Trials Review: Croatian Central Ethics Committee,* 9th Congress of the European Association for Clinical Pharmacology and Therapeutics, 12-15 July 2009, Edinburgh, Basic & Clinical Pharmacology and toxicology, 105 (Suppl. 1): 57

V. Macolić Šarinić, S. Tomić, M. Lovrek, N. Mirošević, *Impact of Pharmacovigilance Workshops for Healthcare Professionals on the Number and Quality of ADR Reports in Croatia*, poster, Sixth ISoP (International Society of Pharmacovigilance) Annual Meeting, Liége, Belgium 2006

V. Macolić Šarinić, S. Tomić, M. Lovrek, N. Mirošević, D. Krnić, A. Ilić, *Pharmacovigilance in Croatia*, poster, Twenty-ninth Annual Meeting of Representatives of the National Centres participating in the WHO Programme for International Drug Monitoring, Liége, Belgium 2006

V. Macolić Šarinić, S. Tomić, M. Lovrek, N. Mirošević, D. Krnić, A. Ilić, *Pharmacovigilance in the Republic of Croatia*, poster, Fourth Croatian Congress of Internists With International Participation, Opatija, Croatia 2006

Lovrek M., Tomić S., *Role of the Pharmacist in Adverse Reaction Reporting*, poster, Third Croatian Congress on Pharmacy, Cavtat, Croatia 2005

Medić-Šarić M., Lovrek M., Mornar A., Kovačić M., *Continuing Education of Pharmacists: Osteoporosis*, poster, FIP 2002 Pharmacy and Pharmaceutical Science World Congress 2002, 62nd Congress of FIP. Nice, France, 2002

Lovrek M., Medić-Šarić M., *Osteoporosis on the Internet – Click of a Mouse Away*, poster, Second Croatian Congress on Pharmacy, Cavtat, Croatia 2001

Projects

01/2021 – 07/2022

EU Twinning project Support to the Institute for Medicines and Medical Devices of Montenegro (CInMED), MN 16 IPA HE 01 20

Component Leader 3 *Authorisation and Inspection Systems for Medicines and Clinical Trials in Montenegro improved.*

12/2019 – 05/2024

EU UNICOM PROJECT (Up-scaling the global univocal identification of medicines)

Responsible for project implementation within HALMED's Medicines Authorisation Division.

09/2013 – 09/2014

EU IPA CROATIA 2009 Preparations for eCTD and implementation of digital archival information system

Involved in analysis and redesign of existing business processes, proposal of strategic plan and new organisation of HALMED during the project.

Memberships

Croatian Pharmaceutical Society - Member of the Executive Board of the Section for Pharmaceutical Regulation

Croatian Society of Clinical Pharmacology and Therapeutics

Croatian Pharmacological Society

Other Relevant Information

2017 - Croatian Pharmaceutical Society diploma for the work and affirmation of the pharmaceutical profession