

## OSOBNJE INFORMACIJE

Maja Lovrek Romčević

## ZVANJE

mr. pharm.

## TITULA

## RADNO ISKUSTVO

02.2012 -

Voditeljica Odjela za odobravanje lijekova

Agencija za lijekove i medicinske proizvode

04.2010 - 02.2012

Voditeljica regulatornih poslova

Worldwide Clinical Trials d.o.o.

01.2008 - 04.2010

Stručna tajnica Središnjeg etičkog povjerenstva

Agencija za lijekove i medicinske proizvode

09.2006 - 01.2008

Viši stručni suradnik za farmakovigilanciju

Agencija za lijekove i medicinske proizvode

11.2005 - 09.2006

Stručni suradnik za farmakovigilanciju

Agencija za lijekove i medicinske proizvode

10.2004 - 11.2005

Stručni suradnik u Središnjem registru

Agencija za lijekove i medicinske proizvode

04.2004 - 09.2004

Ljekarnik

Ljekarne Prima Pharme

04.2003 - 04.2004

Ljekarnik na stažu

Ljekarne Prima Pharme

OBRAZOVANJE I  
OSPOBLJAVANJE

09.1997 - 03.2003

mr. pharm.

Farmaceutsko-biokemijski fakultet

## OSOBNJE VJEŠTINE

Ostali jezici	RAZUMIJEVANJE		GOVOR		PISANJE
	Slušanje	Čitanje	Govorna interakcija	Govorna produkcija	
Engleski	C1/2: Iskusni korisnik	C1/2: Iskusni korisnik	C1/2: Iskusni korisnik	C1/2: Iskusni korisnik	C1/2: Iskusni korisnik
Njemački	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik
Talijanski	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik	B1/2: Samostalni korisnik

## DODATNE INFORMACIJE

### Izdanja

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

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.

## Prezentacije

### POSTERSKE PREZENTACIJE:

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., Iskustvo HALMED-a u europskim postupcima odobranja lijekova (MRP/DCP) u razdoblju od 01.07.2013. do 01.07.2018., Sixth Croatian Congress on Pharmacy, Dubrovnik, Croatia 2019

Lovrek M., Juričić V., Ilić Martinac A., Tomić S., Uvoz lijeka koji nema odobrenje za stavljanje u promet u Republici Hrvatskoj prema receptu liječnika, 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, Liège, 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, Liège, 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

### USMENE PREZENTACIJE:

Lovrek Romčević M., Tomić S., HALMED's past achievements and future challenges, 10th Croatian Congress of Pharmacology and 1st Croatian Congress of Clinical Pharmacology and Therapeutics with International Participation, Opatija, Croatia, 2022

Lovrek Romčević M., Borić Bilušić A., Davosir Klarić Ž., Ikić Komesar J., Ilić Martinac A., Mihalic V., Osrečki V., Uzeirbegović S., Koščak S., Srkoč Z., New

regulatory issues: questions and answers, 9th Croatian Congress of Pharmacology, Zagreb, Croatia 2019

Lovrek Romčević M., Croatian Journey to Joining the European Medicines Regulatory Network, Kosovo Congress on Pharmacy, Priština, Kosovo 2018

Lovrek Romčević M., Borić Bilušić A., Timelines, Clock stop, Responsibilities, 2-day Variation Workshop, Zagreb, Croatia 2017

Lovrek M., Ilić Martinac A., EU iskustvo, Pet godina ALMBIH, perspektive, Jahorina, Bosnia and Herzegovina 2015

Lovrek M., HALMED godinu dana nakon ulaska u EU: Odobravanje lijekova, Hrvatski trag u EU, Šibenik, Croatia 2014

Lovrek M., HALMED experience after EU Accession, 13th EGA Regulatory and Scientific Affairs Conference, London, UK 2014

Radionice o regulativi lijekova, Zagreb, Croatia 2013-2015

Lovrek M., Pre-accession challenges - HALMED perspective, EU 28: science, medicines, health – a regulatory system fit for the future, Dubrovnik, Croatia 2013

Lovrek M., Praktična pitanja i odgovori o odobravanju lijekova nakon ulaska u EU, S HALMED-om ukorak s EU, Zagreb, Croatia 2012

Lovrek M., Application of Clinical Trials Directive in Croatia, Clinical Trial Safety, ISOP, Belgrade, Serbia 2010

Vitezić D., Lovrek M., The Advantages of Centralized Ethical Review Process of Clinical Trials: Croatian Experiences, 4th Annual Clinical Site Partnerships in Central & Eastern Europe, Budapest, Hungary 2009

Mirošević N, Lovrek M, Krnić D, Ilić Martinac A, Arapović S, Macolić Šarinić V, Tomić S. Influence of workshops about the role of pharmacists in adverse drug reactions reporting and pharmacovigilance system in Croatia on pharmacists' contribution on drug safety, 37th European Symposium on Clinical Pharmacy, October 22-24, 2008, Dubrovnik, Pharm Care Models Ther Innov, ED-12

Vitezić D., Lovrek M., Roles and Responsibilities of the Central Ethics Committee in Croatia, 9th World Congress of Bioethics, "Ethics of Clinical Trials" Symposium, Rijeka, Croatia 2008

Seminar Pharmacovigilance in Croatia – Excellence through Collaboration, oral presentation, Lipovac, Croatia 2007

Training Course in Pharmacovigilance, oral presentation, Lipovac, Croatia 2007

Pharmacovigilance Workshop, oral presentation at Pharmacon 2007, Dubrovnik, Croatia 2007

Herbal Medicines, oral presentation at The University of Rijeka, School of Medicine, 2006

Adverse Drug Reactions of Herbal Medicines, oral presentation at the Croatian Pharmaceutical Society, Zagreb, Croatia 2006

Aseptic Meningitis following the immunization with MoPaRu combined vaccine, oral presentation at Twenty-ninth Annual Meeting of Representatives of the National Centres participating in the WHO Programme for International Drug Monitoring, Liège, Belgium 2006

Patient Safety Assurance for Unapproved Imported Medicines, oral presentation at Ninth Conference of Pharmacists, Opatija, Croatia 2006

Seminar on Periodic Safety Update Report, oral presentation, Trakošćan, Croatia 2006

Pharmacovigilance, oral presentation at The University of Rijeka, School of

Medicine, 2005 and 2006

Continuing Education of Pharmacists: Osteoporosis, different cities in Croatia,  
2001-2002

#### Priznanja i nagrade

2017. Diploma Hrvatskog farmaceutskog društva za rad i potvrđivanje pred  
javnošću farmaceutske struke

#### Članstva

Hrvatsko farmaceutsko društvo  
Hrvatsko društvo za kliničku farmakologiju i terapiju  
Hrvatsko društvo farmakologa