

Professor Siniša Tomić, PhD

POSITION

Head of Croatian Agency for Medicinal Products and Medical Devices (HALMED)

WORK EXPERIENCE

Full Professor for Postgraduate (Doctoral) studies

The Faculty of Medicine, University of Rijeka [6/2020]

- **Business or sector:** Health Education

Professor for Pharmacy Programme

The Faculty of Medicine, University of Split [6/2011]

- **Business or sector:** Health Education

Head of Agency (re-elected)

Croatian Agency for Medicinal Products and Medical Devices (HALMED) [12/2019 – Current]

City: Zagreb

Country: Croatia

- **Business or sector:** Health

- preparing and monitoring implementation of annual work plans and financial plans, preparation of internal acts, strategic planning, policy planning, staff education and recruitment
- Co-chair the BEMA (Benchmarking of the European Medicines Agencies) Steering Group
- Member of the European Medicines Agency (EMA) Management Board
- Member of the Heads of Medicines Agencies

Head of Agency

Croatian Agency for Medicinal Products and Medical Devices (HALMED) [12/2015 – 11/2019]

City: Zagreb

Country: Croatia

- **Business or sector:** Health

- preparing and monitoring implementation of annual work plans and financial plans, preparation of internal acts, strategic planning, policy planning, staff education and recruitment
- Co-chair the BEMA (Benchmarking of the European Medicines Agencies) Steering Group
- Member of the European Medicines Agency (EMA) Management Board
- Member of the Heads of Medicines Agencies

Advisor for European Affairs

Croatian Agency form Medicinal Products and Medical Devices (HALMED) [12/2011 – 11/2015]

City: Zagreb

Country: Croatia

- **Business or sector:** Health

- participating in international projects, preparation of web and promotional material, communication with external stakeholders

Head of Agency

Croatian Agency form Medicinal Products and Medical Devices (HALMED) [12/2003 – 11/2011]

City: Zagreb

Country: Croatia

- **Business or sector:** Health

- preparing and monitoring implementation of annual work plans and financial plans, preparation of internal acts, strategic planning, policy planning, staff education and recruitment
- BC Project Leader for Twinning Light Project "Strengthening of expert capacity of EU legislation on medicines in HALMED HR/2007/IB/SO/01 TL

Ad interim Head of Agency

Croatian Agency form Medicinal Products and Medical Devices (HALMED) [10/2003 – 12/2003]

City: Zagreb

Country: Croatia

- **Business or sector:** Health

- preparing and monitoring implementation of annual work plans and financial plans, preparation of internal acts, strategic planning, policy planning, staff education and recruitment

Expert Assistant for Business Development

JGL Ltd [7/2001 – 9/2003]

City: Rijeka

Country: Croatia

- **Business or sector:** Pharmaceutical Industry

- participation in strategic and international marketing activities of the company, development of international markets

Advisor

Ministry for European Integration [6/1999 – 6/2001]

City: Zagreb

Country: Croatia

- **Business or sector:** European and International Affairs

- tasks related to preparation of Croatia to EU accession, preparation of sectorial policies (Health, Science, Local/Regional administration)

EDUCATION AND TRAINING

NLP Practitioner Certificate

Miroras d.o.o [2017]

Address: Zagreb (Croatia)

Certificate in General Management Programme

IEDC – Bled School of Management [2010 – 2011]

Address: Bled (Slovenia)

Postdoctoral Fellow

Department of Medicine, McGill University Health Centre [1997 – 1999]

Address: Montréal, Québec (Canada)

Molecular oncology research

Certificate in International Trade

Concordia University [1998]

Address: Montréal, Québec (Canada)

International Law, International Finance, International Marketing, Accounting, Communication Skills

Doctor rerum naturalium

Faculty of Biology and Pharmacy Friedrich Schiller University of Jena [1993 – 1996]

Address: Jena (Germany)

Biochemistry, Microbiology, Clinical Chemistry

Postgraduate fellow

Max-Planck-Gesellschaft zur Förderung der Wissenschaften, e.V. [1993 – 1996]

Address: Jena (Germany)

Research in molecular and cellular biology

Master of Science

Faculty of Science, University of Zagreb [1991 – 1993]

Address: Zagreb (Croatia)

Biochemistry

Bachelor of Science

Faculty of Pharmacy and Biochemistry, University of Zagreb [1985 – 1990]

Address: Zagreb (Croatia)

Medical Biochemistry

LANGUAGE SKILLS

Mother tongue(s):

Croatian

English

LISTENING: C2 READING: C2 UNDERSTANDING: C2

SPOKEN PRODUCTION: C2

SPOKEN INTERACTION: C2

Certificate of Proficiency in English, McGill University, Montréal (1997)

French

LISTENING: C2 READING: C2 UNDERSTANDING: C2

SPOKEN PRODUCTION: C2

SPOKEN INTERACTION: C2

Diplôme approfondi de langue française (DALF), Ministère de l'Éducation nationale (1999)

German

LISTENING: C2 READING: C2 UNDERSTANDING: C2

SPOKEN PRODUCTION: C2

SPOKEN INTERACTION: C2

Italian

LISTENING: C1 READING: C1 UNDERSTANDING: C1

SPOKEN PRODUCTION: C1

SPOKEN INTERACTION: C1

Certificato di lingua e cultura italiana, Istituto Italiano, Florence (2010)

PUBLICATIONS

Benković G, Bojić M, Maleš Ž, **Tomić S**. Screening of flavonoid aglycons, metabolism mediated by the human liver cytochromes P450. *Acta Pharm* 2019; 69:541-62.

Benković G, Rimac H, Maleš Ž, **Tomić S**, Lončar Z, Bojić M. Characterization of O-demethylations and Aromatic Hydroxylations Mediated by Cytochromes P450 in the Metabolism of Flavonoid Aglycons. *Croat Chem Acta* 2019, 92(1), 115-123. Doi:10.5562/cca3528

Škrnjug I, Uzeirbegović S, Romčević ML, **Tomić S**, Meyer H, Conrad C. Mutual recognition in the European system: A blueprint for increasing access to medicines? *Regul Toxicol Pharmacol*. 2019 May 7;106:270-277. doi: 10.1016/j.yrtph.2019.05.004. [Epub ahead of print]

Rusic D, Bozic J, Bukic J, Seselja-Perisin A, Leskur D, Modun D, **Tomić S**. Evaluation of accordance of antibiotics package size with recommended treatment duration of guidelines for sore throat and urinary tract infections. *Antimicrob Resist Infect Control*. 2019 Feb 11;8:30. doi: 10.1186/s13756-019-0495-5. eCollection 2019.

Zorić N, Kopjar N, Bobnjarić, I, Horvat I, **Tomić S**, Kosalec I. Antifungal activity of oleuropein against *Candida albicans* – the in vitro study. *Molecules*, 2016; 21: 1631-1631.

Zorić N, Kopjar N, Oršolić N, **Tomić S**, Kosalec I. Olive leaf extract activity against *Candida albicans* and *C. Dubliniensis* – the in vitro viability study. *Acta Pharm* 2016;66:411-21

Zulfikari S, Filipović Sučić A, Meštrović K, Perić Barbarić M, Mandarić V, Zorić N, **Tomić S**. Generic Medicines in Croatia - Regulatory aspects and statistics. *Coll Antropol* 2015;39:363-70

PRESENTATIONS

National Agency for Medicinal Products and Medical Devices (HALMED): Role at national and European level, 2018 Training Session, The European Pharmacopoeia, EDQM, Council of Europe, 24-25 May 2018, Zagreb

The impact of the New Medical Device Regulation, AESGP Conference with the Heads of Medicines Agencies, 26-27 February 2018, Lisbon

The Role of the National Competent Authority (NCA) in the Assessment of Medicinal Products in the National Procedure, European Association for Clinical Pharmacology and Therapeutics Meeting, October 6-9, 2016, Opatija

European trends and approaches of EU countries to informing patients ", International Pharmaceutical Regulatory Seminar, 5-7. February 2014, Ljubljana

Regulating Medical Devices in the Transition Period in Croatia, DIA EuroMeeting, 4-6 March 2013, Amsterdam

Medical device regulation in an EU candidate country – adjusting market access strategies in times of on-going reform and health system modernisation, Medical Device Leaders Forum, Next Level Pharma, 28-30 November 2012, Berlin

Crucial regulatory update from CEE countries including the Balkan States, Croatia and Bosnia, Informa Life Sciences' Medical device & IVD Regulations in Russia, CIS, CEE and Turkey, 9-10 October 2012, Budapest

Market Access: Regulatory Considerations when Entering the Russian and CEE Market, C5's EU Pharma Regulatory Law, Minimising Risks by Ensuring Compliance with Critical Evolving Regulatory Developments. 25-26 September 2012, Brussels

„Case Study: Assessing the Regulatory Environment in Croatia“, Informa Life Sciences Regulatory Affairs in Central & Eastern Europe, 25-26 April 2012, Budapest

„Experiences of the Croatian Regulatory Authority: Implementing CTD dossier, 1st Saudi International & Registration Workshop, 26-28 February 2012, Riyadh

„Filing Variations in a candidate country“, Filing Variations, Informa Life Sciences, 28-29, June 2011, Berlin

„Accession Preparation: Situation in Croatia“, Reinforcing patient safety in Europe, 14-15 June 2011, Zagreb

Full list of publications in Croatian bibliographic library:

<https://www.bib.irb.hr/pregled/profil/28534>

SCIENTIFIC PROJECT TEAM MEMBER

Biological active compounds, metabolites and QSAR

Excytotoxicity and neuroprotection in epilepsy and brain ischemia

CONFERENCES AND SEMINARS

Tumir H., Tomić S., Bošnjir J., Puntarić D.. Elements in Medicines for Oral Administration. International Congress of FIP 2012, Amsterdam, The Nedeerlands. October 2012.

Banovac M, Andric A, Macolic Sarinic V, Mirosevic Skvrce, Tomic S. One in Three Adverse Reactions Induced by Topical Antiglaucoma Medications is systemic: Analysis of Adverse Drug Reactions Spontaneously reported to Croatian agency for Medicinal Products and Medical Devices. Drug Saf;34:1014-1015.

Pusic P, Drcelic M, Kosalec I, Segvic Klaric M, Zubcic S, Tomic S. Mycological contamination of medicinal herbs from Croatian market. 2nd CESC 2010 Central European Summer Course on Mycology „Biology of pathogenic fungi“, July 5-9, 2010, Szeged

HONOURS AND AWARDS

Medal “Professor Julije Domac” Croatian Pharmaceutical Society

[2019]

Diploma of the Croatian Pharmaceutical Society for years of dedicated and successful work

[2009]

NETWORKS AND MEMBERSHIPS

Croatian Pharmaceutical Society

Croatian Society of Pharmacology