

PERSONAL INFORMATION **Zeljana Margan Koletic**

WORK EXPERIENCE

-
- April 2019- Present **Head of Pharmacovigilance and Rational Pharmacotherapy Department**
Agency for Medicinal Products and Medical Devices of Croatia (HALMED) (Croatia)
- November 2017-March 2019 **Principal Coordinator for Safety assessment of Medicines**
Agency for Medicinal Products and Medical Devices of Croatia (HALMED) (Croatia)
Coordinating assessment activities of 10 assessors in the department (planning, assignment of assessors, controlling of execution)PRAC Rapporteur for several medicinal products as Alternate Member of Pharmacovigilance Risk Assessment Committee (PRAC) at European Medicines Agency (EMA) and contributor to the revision of Good Pharmacovigilance Practices (GVPs)Member and representative of Pharmacovigilance Department in HALMED's Committee for Medicinal ProductsMember of HALMED's Medicinal Products' Safety CommitteeMember of HALMED's OTC Working Group responsible development and publishing of guidelines for OTC medicinal productsMentor of Junior assessors
- October 2016-October 2017 **Senior Associate - Specialist for Pharmacovigilance and Rational Pharmacotherapy**
Agency for Medicinal Products and Medical Devices of Croatia (HALMED) (Croatia)
PRAC Rapporteur for several medicinal products as Alternate Member of Pharmacovigilance Risk Assessment Committee (PRAC) at European Medicines Agency (EMA) and contributor to the revision of Good Pharmacovigilance Practices (GVPs)Member and representative of Pharmacovigilance Department in HALMED's Committee for Medicinal ProductsLead assessor and/or peer reviewer of Periodic Safety Update reports (PSURs) in PSUR Single Assessment (PSUSA) proceduresLeading assessment/approvals of Safety variations and/or Renewals for medicinal productsConducting assessment and approvals of educational materials for medicinal productsConducting assessment of safety documentation during Referral procedures for medicinal productsInvolved in the assessment of Post-Authorisation Safety Study (PASS) for medicinal products
- February 2014-September 2016 **Senior Associate for Pharmacovigilance and Rational Pharmacotherapy**
Agency for Medicinal Products and Medical Devices of Croatia (HALMED) (Croatia)
- March 2013-January 2014 **Associate for Pharmacovigilance and Rational Pharmacotherapy**
Agency for Medicinal Products and Medical Devices of Croatia (HALMED) (Croatia)
- June 2011-March 2013 **Community Pharmacist**
ZU Ljekarne Zeus (Croatia)
Reporting of adverse drug reactions; patient consultation about correct and safe use of medicines; implementation of risk minimisation measures; informing of national competent authority about detected irregularities
- June 2010-May 2011 **Pharmacist Trainee**
ZU Ljekarne Kuhari (Croatia)

EDUCATION AND TRAINING

- December 2018- Present **PhD candidate**
School of Medicine, University of Split (Croatia)
- August 2015-November 2019 **University Master of Clinical Pharmacy**
Faculty of Pharmacy and Biochemistry, University of Zagreb (Croatia)
- June 2011- Present **State professional exam/Licence for independent work**
Ministry of Health and Croatian Chamber of Pharmacists (Croatia)
- September 2004-April 2010 **MPharm**
Faculty of Pharmacy and Biochemistry, University of Zagreb (Croatia)

ADDITIONAL INFORMATION

- Expertise** Pharmacovigilance
Risk management
Clinical pharmacy
- Publications** Margan Koletic Z, Dosenovic S, Puljak L. Efficacy and safety of modified-release paracetamol for acute and chronic pain: a systematic review protocol. *BMJ Open* 2019;0:e029728. doi:10.1136/bmjopen-2019-029728
Mirosevic Skvrce N, Margan Koletic Z, Krnic D, Prpic S, Gvozdanovic K, Mucalo I, Vladimir-Kneevi S, Boina N, Marusic S, Mudnic I, Klarica M, Tomic S. Ten Years Of Experience In Graduate And Postgraduate Education In Pharmacovigilance (ISOP 2018 abstract)
Signals from randomized clinical trials predicting hepatotoxicity of flupirtine: a systematic review (PROSPERO database registration number: CRD42018085123) (review ongoing)
New restrictions in valproate use and obligation of conducting pregnancy prevention programme (PharmaBiz, 2018 Apr, 32:40-42)
Use of quinolones and fluoroquinolones potentially associated with lasting and debilitating ADRs (PharmaBiz, 2018 Mar, 31:74-75)
Ineffectiveness of existing risk minimisation measures for valproate (PharmaBiz, 2017 Nov, 29:12-14)
Medication errors document (SCOPE project, 2016/2017)
Carnovale C, Gentili M, Maticena M, Dimov Di Giusti M, Krnic D, Dolinic B, Kolaric D, Margan Koletic Z, Macolic Sarinic V, Culjak M, Fortino I, Merlino L, Clementi E, Radice S. A retrospective review of paediatric adverse drug reactions reported in Lombardy and Croatia from 2005 to 2013. *Expert Opin Drug Saf.* 2016 Dec;15(sup2):35-43.
Lesicar M, Gvozdanovic K, Dimov Di Giusti M, Krnic D, Dolinic B, Margan Koletic Z, Macolic Sarinic V
Prescribing Medication Errors: 2nd Generation Sulfonylureas (Conference Paper in Drug Safety, January 2013)
- Projects** DigitalHealthEurope Twinning project - Strengthening the capacity for the analysis of electronic healthcare data (SCAN) - part of the project team (2019-)
EU funded Coordination and Support Action on Strengthening Training of Academia in Regulatory Science (CSA STARS) (under H2020) - representative of HALMED (associate partner) (2019-)
Operation of Pharmacovigilance in the EU (EU PVOP) Training Curriculum (TC) - National Competent Authority lead for Adverse Drug Reactions reporting area (2017-)
Web-Recognizing Adverse Drug Reactions (WEB-RADR) project - testing the Clinical Documentation tool (ClinDoc) developed by LAREB (2015)
The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) - lead for Topic 1a "Medication

errors" within Work Package 4 (2013 - 2017)

Memberships

EMA's Pharmacovigilance Risk Assessment Committee (PRAC)PRAC Subgroup -
Pharmacovigilance Inspectors Working GroupCroatian Chamber of PharmacistsCroatian
Pharmaceutical SocietyMedicinal Products' Safety Committee (HALMED)Committee for Medicinal
Products (HALMED)

Other Relevant Information