Lara Miletić

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Experience

Senior Associate for Pharmacovigilance and Rational Pharmacotherapy January 2022 – Present
Croatian Agency for Medicinal Products and Medical Devices (HALMED) *Zagreb, Croatia*

Associate for Pharmacovigilance and Rational Pharmacotherapy July 2019 – December 2021
Croatian Agency for Medicinal Products and Medical Devices (HALMED) *Zagreb, Croatia*

Pharmacist in public pharmacy September 2018 – June 2019
Ljekarne Filipović (Pharmacy Filipović) *Zagreb, Croatia*

Pharmacist intern in public pharmacy March 2018 – August 2018
Ljekarne Filipović (Pharmacy Filipović) *Zagreb, Croatia*

Education

London School of Hygiene and Tropical Medicine University of London, United Kingdom
Master of Epidemiology (Distance Learning) *October 2022 – Present*

Faculty of Pharmacy and Biochemistry University of Zagreb, Croatia
Master of Pharmacy *September 2013 – September 2018*

Competences

Experienced pharmacovigilance assessor responsible for a variety of pharmacovigilance procedures, in particular:

- Assessment of individual case safety reports (ICSRs)
- Safety signal detection, validation and evaluation
- Assessment of Periodic safety update reports (PSURs) in PSUR single assessment (PSUSA) procedures
- Assessment in safety-related referral procedures, i.e. procedures on EU level with aim of resolving concerns over the safety or benefit-risk balance of a medicine or a class of medicines
- Assessment of variations in the terms of marketing authorization granted by one of the following procedures: National Procedure (NP), Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP) and Centralised Procedure (CP)
- Assessment of risk management plan (RMP)
- Assessment of study protocols for post-authorization safety studies (PASS) with involvement of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC)
- Assessment of study protocols, informed consent form (ICF) and other documentation required for national approval of non-interventional studies initiated by marketing authorization holders (MAHs)
- Coordination and management of an EU4Health project Safety assessment cooperation and facilitated conduct of clinical trials (SAFE CT)
- Approval of direct healthcare professional communication (DHPC)

Soft skills

Creative, Communicative, Problem solving oriented, Open-minded, Eager to learn and improve

Personal interests

Hiking, Nature, Traveling