



Curriculum Vitae

Personal information **Zane Neikena**

Work experience

1. Employer: First Medical Aid station
 - Start date: 081983
 - End date: 052003
 - Position: physician
 - Activities: Intensive therapy, resuscitation
 - Country: Latvia
2. Employer: State Agency of Medicines
 - Start date: 052001
 - End date:
 - Position: Pharmacovigilance assessor, Deputy head of the ADR monitoring department, Editor of the drug bulletin Cito!
 - Activities: Pharmacovigilance assessments, Communication on pharmacovigilance issues to HCP_ preparation and editing articles.
 - Country: Latvia
3. Employer: State Agency of Medicines
 - Start date: 052004
 - End date: 062012
 - Position: PhVWP alternate delegate from Latvia
 - Activities: Activities defined in the mandate of PhVWP
 - Country: Latvia
4. Employer: State Agency of Medicines
 - Start date: 042015
 - End date: 102015
 - Position: PRAC alternate
 - Activities: The PRAC is one of seven committees at the European Medicines Agency (EMA). It is responsible for assessing and monitoring safety issues for human medicines. This includes the detection, assessment, minimisation and communication relating to the risk of adverse reactions, while taking the therapeutic effect of the medicine into account. It also has responsibility for the design and evaluation of post_ authorisation safety studies and pharmacovigilance audit.
 - Country: Latvia
5. Employer: State Agency of Medicines
 - Start date: 102015
 - End date:
 - Position: PRAC Delegate
 - Activities: The PRAC is one of seven committees at the European Medicines Agency (EMA). It is responsible for assessing and monitoring safety issues for human medicines. This includes the detection, assessment, minimisation and communication relating to the risk of adverse reactions, while taking the therapeutic effect of the medicine into account. It also has responsibility for the design and evaluation of post_ authorisation safety studies and pharmacovigilance audit.
 - Country: Latvia

Education and training

1. Subject: Riga Medical Institution
 - Start date: 091976
 - End date: 051984
 - Qualification: MD, Internal medicinal doctor, First Medical Aid Physician
 - Organisation:
 - Country: Latvia
2. Subject: AEMPS
 - Start date: 122016
 - End date: 122016
 - Qualification: pharmacovigilance assessor
 - Organisation: Post Authorisation Safety Study (PASS) assessment
 - Country: Spain
3. Subject: AEMPS
 - Start date: 102017
 - End date: 102017
 - Qualification: pharmacovigilance assessor
 - Organisation: Course on Advanced Pharmacoepidemiology with case studies
 - Country: Spain
4. Subject: EMA
 - Start date: 052004
 - End date: 012012
 - Qualification: pharmacovigilance assessor
 - Organisation: Pharmacovigilance assessors' trainings on case causality assessment, signal management, risk management, Periodic Safety Update Report (PSUR) assessment, Post Authorisation Safety Study (PASS) protocol assessment, risk - benefit assessment, riskminimisation and risk communication, assessment of effectiveness of riskminimisation.

- Country: United Kingdom
5. Subject: EMA
- Start date: 012012
 - End date: 042024
 - Qualification: pharmacovigilance assessor
 - Organisation: Annual EMA PRAC assessors trainings on Referrals, ATMPs, COVID _ 19 prophylaxis and treatment, signal management, Periodic Safety Update Report (PSUR) assessment, Post Authorisation Safety Studies (PASS), protocol assessment, Qualitative and qualitative research methods, Use of Real World Data (RWD) in pharmacovigilance, Serious cutaneous adverse reactions (SCARs), Drug induced liver injury (DILI), impact research on the effectiveness of riskminimisation measures, Signal assessment, EudraVigilance data analysis system (EVDAS) training etc.
 - Country: Netherlands
6. Subject: State Agency of Medicines Latvia
- Start date: 122017
 - End date: 122018
 - Qualification: pharmacovigilance assessor
 - Organisation: Medical statistics
 - Country: Latvia

Additional information

Publications

1) Editor and author of the articles of the brochure "Introduction to Pharmacovigilance" (Ievads farmakovigilancē, Zāļu valsts aģentūra, 2005, 128 pages, ISBN 9984_19_824_3, ES PHARE Twinning Project "Medicinal Products Market Surveillance and Pharmacovigilance. Strengthening of Pharmacovigilance Function of the Agency" November 2004 _ November 2005) 2) Z.Neikena, Predict the unpredictable. Most important aspects of pharmacovigilance of biological medicines, drug bulletin Cito! 2014/2 (57) 3) Z.Neikena, Safety of BCG vaccine SSI, drug bulletin Cito! 2006_2 (20) 4) Z.Neikena, Gentian violet potential carcinogenic substance, drug bulletin Cito! 2004_2 (8) 5) A number of other articles on pharmacovigilance issues in the drug bulletin Cito! and other medicinal journals in Latvia.

Impact of Risk Minimisation Measures on Valproate Use Among Women in Reproductive Age in Latvia between 2013 and 2020: A 7 - Year Nationwide Prescription Database Study, Original Research article, Published 12 October 2023, Drugs - Real World Outcomes, Ieva Rutkovska, Andis Seilis, Zane Neikena & Elita Poplavska.

Projects

Project team member of the PHARE Twinning Project "Medicinal Products Market Surveillance and Pharmacovigilance. Strengthening of Pharmacovigilance Function of the Agency" November 2004 – November 2005

Memberships

Other Relevant Information

PRAC representative in the EMA SCARs (Severe Cutaneous Adverse reactions) guidance development.