

## PERSONAL INFORMATION Ewa Balkowiec Iskra

WORK EXPERIENCE

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- 2000- 2001 **Postgraduate Clinical Intern**  
Central Hospital of the Medical University of Warsaw (Poland)
- 2001- 2004 **Assistant Professor**  
Medical University of Warsaw, Department of Experimental and Clinical Pharmacology (Poland)
- 2004- Present **Associate Professor**  
Department of Experimental and Clinical Pharmacology Medical University of Warsaw (Poland)
- 2006- Present **External Expert**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Poland)
- 2007- 2009 **Physician**  
Institute of Psychiatry and Neurology (Poland)
- 2008- 2009 **Visiting Scientist**  
Department of Integrative Biosciences Oregon Health & Science University, Portland (United States)
- 2012- 2017 **Physician**  
Chair of Psychiatry, Nowowiejski Hospital (Poland)
- 2013- Present **Head of Pain Laboratory**  
Department of Experimental and Clinical Pharmacology Medical University of Warsaw (Poland)
- 2013- Present **Member of Medicinal Products Committee**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Poland)
- 2014- Present **External Expert**  
European Medicines Agency (Netherlands)
- 2016- Present **Observer, Pharmacokinetic Working Party**  
European Medicines Agency (Netherlands)
- 2016-October 2022 **Observer, Central Nervous System Working Party**  
European Medicines Agency (Netherlands)

- 2016-September 2019 **Member of Therapy and Science of Medicines Committee**  
Polish Academy of Science (Poland)
- 2016-September 2019 **Member of Science of Physiology and Pharmacology Committee**  
Polish Academy of Science (Poland)
- 2017-December 2020 **Rectors Plenipotentiary, High School Partnership and Patronage Program**  
Medical University of Warsaw (Poland)
- June 2017- Present **Member of Committee for Medicinal Products for Human Use (CHMP)**  
European Medicines Agency (Netherlands)
- December 2017- Present **Member of Scientific Advice Working Party (SAWP)**  
European Medicines Agency (Netherlands)
- March 2018-March 2021 **Co-opted Member of Committee on Herbal Medicinal Products (HMPC)**  
European Medicines Agency (Netherlands)
- June 2007- Present **Owner**  
Iskra Healthcare Ewa Bakowiec-Iskra (Poland)  
General medical practice activities
- June 2021- Present **Chair of Medicinal Products Committee**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Poland)
- March 2022- Present **Member of the Emergency Task Force (ETF) for the therapeutic response to the COVID-19 pandemic**  
European Medicines Agency (Netherlands)
- July 2022- Present **Psychiatrist (hospital outpatient clinic)**  
Nowowiejski Hospital (Poland)
- October 2022- Present **Member, Central Nervous System Working Party**  
European Medicines Agency (Netherlands)
- October 2022- Present **Vice-Chair, Central Nervous System Working Party**  
European Medicines Agency (Netherlands)

## EDUCATION AND TRAINING

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- 1994- 2000 **M.D.**  
Medical University of Warsaw (Poland)
- 2000- 2004 **Ph.D. (Pharmacology)**  
Medical University of Warsaw, Department of Experimental and Clinical Pharmacology (Poland)
- 2011- **D.Sc. (Pharmacology)**  
Medical University of Warsaw, Department of Experimental and Clinical Pharmacology

(Poland)

2010- 2012 **Postgraduate Studies, Research Project Management**  
Graduate School of Economy and Innovation, Lublin (Poland)

2012- 2017 **Specialization in Psychiatry**  
Department of Psychiatry, Medical University of Warsaw, Nowowiejski Hospital, Warsaw (Poland)

## ADDITIONAL INFORMATION

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**Expertise** Psychiatry, pharmacology, toxicology, neurology, neuroscience, bioequivalence

**Publications** Lis K, Grygorowicz T, Cudna A, Szymkowski DE, Balkowiec-Iskra E.  
Inhibition of TNF reduces mechanical orofacial hyperalgesia induced by Complete Freund's Adjuvant by a TRPV1-dependent mechanism in mice. *Pharmacol Rep.* 2017; 69(6):1380-1385.  
Balkowiec-Iskra E, Mirowska - Guzel D, Wielgos M. Effect of antidepressants use in pregnancy on foetus development and adverse effects in newborns. *Ginekol Pol.* 2017;88(1):36-42.  
Cessak G, Rokita K, Dabrowska M, Sejbuk-Rozbicka K, Zaremba A, Mirowska-Guzel D, Balkowiec-Iskra E. Therapeutic equivalence of antipsychotics and antidepressants - a systematic review. *Pharmacological Reports*, 2016; 68: 217-223.  
Kuzawska O, Lis K, Cessak G, Mirowska-Guzel D, Balkowiec-Iskra E. Targeting of calcitonin gene-related peptide action as a new strategy for migraine treatment. *Neurol Neurochir Pol.* 2016; 50:463-467.  
Balkowiec-Iskra E., Cessak G., Sejbuk - Rozbicka K., Kuzawska O., Rokita K., Mirowska - Guzel D. Regulatory and clinical aspects of psychotropic drugs bioequivalence. *European Neuropsychopharmacology* 2015, 25: 1027-1034.  
Cessak G., Rokita K, Balkowiec-Iskra E. Bioequivalence and therapeutic equivalence of psychotropic drugs *Advances Psychiatry Neurology*, 2015; 24: 8-17  
Kuzawska O., Cudna A., Lis K., Balkowiec-Iskra E. "Gender differences in the neurochemical response of trigeminal ganglion neurons to peripheral inflammation in mice" *Acta Neurobiologiae Experimentalis* 2014, 74: 1-6  
Cessak G., Burda A., Kuzawska O., Lis K., Wojnar M., Balkowiec-Iskra E. „TNF inhibitors - mechanisms of action, approved and off-label indications". *Pharmacological Reports*, 2014; 66: 836-844.  
Lis K., Kuzawska O., Balkowiec-Iskra E. „Tumor necrosis factor inhibitors - State of Knowledge". *Archives of Medical Science*, 2014; 6: 1175-1185.  
Balkowiec-Iskra E., Cessak G., Krynska L., Loza B Wojnar M.. Venous thromboembolism as an adverse effect of antipsychotic treatment. *Psychiatria Polska* 2014; 48: 997-1014.  
Mirowska-Guzel D., Balkowiec-Iskra E. The role of monoamine oxidase in humans and its metabolism. *Psychiatric Annals*, 2014, 44: 495-501.  
Balkowiec-Iskra E, Vermehren-Schmaedick A, Balkowiec A. Tumor necrosis factor- increases brain-derived neurotrophic factor expression in trigeminal ganglion neurons in an activity-dependent manner. *Neuroscience*. 2011;180:322-33.  
Balkowiec-Iskra E.The role of immune system in inflammatory pain pathophysiology *Pol Merkur Lekarski*. 2010, 174:395-399.  
Tarsa L, Balkowiec-Iskra E, Kratochvil FJ 3rd, Jenkins VK, McLean A, Brown AL, Smith JA, Baumgartner JC, Balkowiec A. Tooth pulp inflammation increases brain-derived neurotrophic factor expression in rodent trigeminal ganglion neurons. *Neuroscience*, 2010; 167:1205-1215.  
Kurkowska-Jastrzebska I. Balkowiec-Iskra E. Ciesielska A. Joniec I. Cudna A. Zaremba MM. Czlonkowska A. Czlonkowska A. Decreased inflammation and augmented expression of trophic factors correlate with MOG-induced neuroprotection of the injured nigrostriatal system in the murine MPTP model of Parkinson's disease. *International Immunopharmacology*, 2009; 9:781-791.  
Balkowiec A , Balkowiec-Iskra E. "Novel Approaches to Studying Activity-Dependent Regulation of Neurotrophins and Neuropeptides in Sensory Pathways from Orofacial Tissues." In: A.Daskalaki (ed.) *Informatics in Oral Medicine: Advanced Techniques in Clinical and Diagnostic Technologies*. IGI-Global, 2009.

Balkowiec -Iskra E, Kurkowska-Jastrzebska I, Joniec I, Ciesielska A, Czlonkowska A, Czlonkowski A. Dopamine, seotonin and noradrenaline changes in striatum of C57Bl mice following myelin oligodendrocyte glycoproteins 35-55 and complete Freund adjuvant administration. *Acta Neurobiol. Exp*, 2007; 67(4):379-388

Balkowiec -Iskra E, Kurkowska-Jastrzebska I, Joniec I, Ciesielska A, Przybylkowski A, Czlonkowska A, Czlonkowski A. MPTP induced central dopamine depletion exacerbates EAE in C57Bl mice. *Inflamm.Res*, 2007; 56(8):311-317.

Kurkowska-Jastrzebska Iwona, Ewa Balkowiec -Iskra, Ilona Joniec, Tomasz Litwin, Andrzej Czlonkowski, Anna Czlonkowska. Immunization with MOG and CFA partially protects dopaminergic neurons from MPTP induced damage in mouse model of Parkinson's disease. *Neuroscience* 2005, 131:247-254.

Balkowiec -Iskra E. Influence of dopaminergic system injury on experimental autoimmune encephalomyelitis progression. Ph.D. thesis. Medical University of Warsaw, 2004.

Balkowiec-Iskra E., Kurkowska-Jastrzebska I, Joniec I, Czlonkowska A, Czlonkowski A. Post intoxicative therapeutic immunization with myelin oligodendrocyte glycoprotein (MOG 35-55) suppresses spontaneous regeneration of dopaminergic neurons injured with 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP). *Acta Neurobiol. Exp*, 2003, 63:109-115.

Lasek W. Mackiewicz A. Czajka A. Switaj T. Gol b J. Wiznerowicz M. Korczak-Kowalska G. Bakowiec-Iskra EZ. Gryska K. Izycki D. Jakobisiak M. Antitumor effects of the combination therapy with TNF-alpha gene-modified tumor cells and interleukin 12 in a melanoma model in mice. *Cancer Gene Therapy*, 2000; 7:1581-1590

Feleszko W. Mlynarczuk I. Balkowiec-Iskra EZ. Czajka A. Switaj T. Stoklosa T. Giermasz A. Jakobisiak M. Lovastatin potentiates antitumor activity and attenuates cardiotoxicity of doxorubicin in three tumor models in mice. *Clinical Cancer Research*, 2000; 6: 2044-52

Lasek W. Golab J. Maslinski W. Switaj T. Balkowiec EZ. Stoklosa T. Giermasz A. Malejczyk M. Jakobisiak M. Subtherapeutic doses of interleukin-15 augment the antitumor effect of interleukin-12 in a B16F10 melanoma model in mice. *European Cytokine Network*, 1999; 10: 345-56

Feleszko W. Balkowiec EZ. Sieberth E. Marczak M. Dabrowska A. Giermasz A. Czajka A. Jakobisiak M. Lovastatin and tumor necrosis factor-alpha exhibit potentiated antitumor effects against Ha-ras-transformed murine tumor via inhibition of tumor-induced angiogenesis. *International Journal of Cancer*, 1999; 81(4):560-567

#### Projects

#### Memberships

Polish Pharmacological Society

Polish Society for Clinical Pharmacology and Therapeutics

Warsaw Scientific Society

#### Other Relevant Information

Honours and awards

Scientific Award for studies on pathomechanisms of Parkinson's Disease

Polish Minister of Health (2006)

Scientific Award for studies on dopaminergic-immune interactions

Rector of the Medical University of Warsaw (2008)

Scientific Award for studies of neurodegeneration

Rector of the Medical University of Warsaw (2010)

Scientific Award for studies of neurotrophic factors in neurodegenerative diseases

Rector of the Medical University of Warsaw (2011)

Scientific Award for studies of inflammatory factors in trigeminal sensory function

Rector of the Medical University of Warsaw (2012)

Scientific Award for publication: "Regulatory and clinical aspects of psychotropic medicinal products bioequivalence"

Rector of the Medical University of Warsaw (2016)

Teaching Award for advancement of instruction in the Medical University of Warsaw  
Rector of the Medical University of Warsaw (2016)