



## Curriculum Vitae

Personal information Ewa Balkowiec Iskra

### Work experience

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Central Hospital of the Medical University of Warsaw

- Start date: 2000
- End date: 2001
- Position: Postgraduate Clinical Intern
- Activities:
- Country: Poland

Medical University of Warsaw, Department of Experimental and Clinical Pharmacology

- Start date: 2001
- End date: 2004
- Position: Assistant Professor
- Activities:
- Country: Poland

Department of Experimental and Clinical Pharmacology Medical University of Warsaw

- Start date: 2004
- End date:
- Position: Associate Professor
- Activities:
- Country: Poland

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

- Start date: 2006
- End date:
- Position: External Expert
- Activities:
- Country: Poland

Institute of Psychiatry and Neurology

- Start date: 2007
- End date: 2009
- Position: Physician
- Activities:
- Country: Poland

Department of Integrative Biosciences Oregon Health & Science University, Portland

- Start date: 2008
- End date: 2009
- Position: Visiting Scientist
- Activities:

- Country: United States
- Chair of Psychiatry, Nowowiejski Hospital
- Start date: 2012
- End date: 2017
- Position: Physician
- Activities:
- Country: Poland
- Department of Experimental and Clinical Pharmacology Medical University of Warsaw
- Start date: 2013
- End date:
- Position: Head of Pain Laboratory
- Activities:
- Country: Poland
- The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Start date: 2013
- End date:
- Position: Member of Medicinal Products Committee
- Activities:
- Country: Poland
- European Medicines Agency
- Start date: 2014
- End date:
- Position: External Expert
- Activities:
- Country: Netherlands
- European Medicines Agency
- Start date: 2016
- End date:
- Position: Observer, Pharmacokinetic Working Party
- Activities:
- Country: Netherlands
- European Medicines Agency
- Start date: 2016
- End date: 102022
- Position: Observer, Central Nervous System Working Party
- Activities:
- Country: Netherlands
- Polish Academy of Science
- Start date: 2016
- End date: 092019
- Position: Member of Therapy and Science of Medicines Committee
- Activities:
- Country: Poland
- Polish Academy of Science
- Start date: 2016
- End date: 092019
- Position: Member of Science of Physiology and Pharmacology Committee

- Activities:
  - Country: Poland
- Medical University of Warsaw
- Start date: 2017
  - End date: 122020
  - Position: Rector's Plenipotentiary, High School Partnership and Patronage Program
  - Activities:
  - Country: Poland
- European Medicines Agency
- Start date: 062017
  - End date:
  - Position: Member of Committee for Medicinal Products for Human Use (CHMP)
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 122017
  - End date:
  - Position: Member of Scientific Advice Working Party (SAWP)
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 032018
  - End date: 032021
  - Position: Co\_opted Member of Committee on Herbal Medicinal Products (HMPC)
  - Activities:
  - Country: Netherlands
- Iskra Healthcare Ewa Bałkowiec\_Iskra
- Start date: 062007
  - End date:
  - Position: Owner
  - Activities: General medical practice activities
  - Country: Poland
- The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Start date: 062021
  - End date:
  - Position: Chair of Medicinal Products Committee
  - Activities:
  - Country: Poland
- European Medicines Agency
- Start date: 032022
  - End date:
  - Position: Member of the Emergency Task Force (ETF) for the therapeutic response to the COVID\_19 pandemic
  - Activities:
  - Country: Netherlands
- Nowowiejski Hospital

- Start date: 072022
  - End date:
  - Position: Psychiatrist (hospital outpatient clinic)
  - Activities:
  - Country: Poland
- European Medicines Agency
- Start date: 102022
  - End date:
  - Position: Member, Central Nervous System Working Party
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 102022
  - End date:
  - Position: Vice-Chair, Central Nervous System Working Party
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 122022
  - End date:
  - Position: Member, Immunisation and Vaccine Monitoring Advisory Board (IVMAB)
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 052024
  - End date:
  - Position: Member, Patients and Consumers Working Party
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 042025
  - End date:
  - Position: Chair, Central Nervous System Working Party
  - Activities:
  - Country: Netherlands
- European Medicines Agency
- Start date: 052025
  - End date:
  - Position: Vice-Chair, Scientific Advice Working Party
  - Activities:
  - Country: Netherlands

## Education and training

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1. Subject: Medical University of Warsaw
  - Start date: 1994
  - End date: 2000
  - Qualification: M.D.
  - Organisation:
  - Country: Poland
2. Subject: Medical University of Warsaw, Department of Experimental and Clinical Pharmacology
  - Start date: 2000
  - End date: 2004

- Qualification: Ph.D. (Pharmacology)
  - Organisation:
  - Country: Poland
3. Subject: Medical University of Warsaw, Department of Experimental and Clinical Pharmacology
- Start date: 2011
  - End date:
  - Qualification: D.Sc. (Pharmacology)
  - Organisation:
  - Country: Poland
4. Subject: Graduate School of Economy and Innovation, Lublin
- Start date: 2010
  - End date: 2012
  - Qualification: Postgraduate Studies, Research Project Management
  - Organisation:
  - Country: Poland
5. Subject: Department of Psychiatry, Medical University of Warsaw, Nowowiejski Hospital, Warsaw
- Start date: 2012
  - End date: 2017
  - Qualification: Specialization in Psychiatry
  - Organisation:
  - Country: Poland

## Additional information

### Publications

Guizzaro L, **Bałkowiec-Iskra E**, Haberkamp M, Mol P, Moreau A, Mueller-Berghaus J, Philadelphia D, Balabanov P, Garcia J, Thirstrup S, Sepodes B. Balancing benefit and risk in early Alzheimer's disease: the European Medicines Agency (EMA) assessment of lecanemab and donanemab. *The Lancet Regional Health - Europe* 2026;63:101644

Kas MJH, Penninx BWJH, Knudsen GM, Cuthbert B, Falkai P, Sachs GS, Ressler KJ, **Bałkowiec-Iskra E**, Butlen-Ducuing F, Leboyer M, Marston H, Luthman J, Mantua V. Precision psychiatry roadmap: towards a biology-informed framework for mental disorders. *Mol Psychiatry*, 2025 Aug;30(8):3846-3855.

Fidahic M, Lozo Vukovac E, **Bałkowiec-Iskra E**, Krnic D, Andric A, Margan Koletic Z, Puljak L. Signals from randomized clinical trials predicting hepatotoxicity of flupirtine: systematic review. *Eur J Clin Pharmacol*, 2025.

Fuggle N, Laslop A, Rizzoli R, Al-Daghri N, Alokail M, **Bałkowiec-Iskra E**, Beaudart C, Bruyère O, Botto-van Bemden A, Burlet N, Cavalier E, Cerreta F, Chandran M, Cherubini A, da Silva Rosa M, Conaghan P, Cortet B, Cruz Jentoft A, Curtis E, D'Amelio P, Dawson-Hughes B, Dennison E, Hilgsmann M, Kaufman J, Maggi S, Matijevic R, McCloskey E, Messina D, Pinto D, Prieto Yerro M, Radermecker R, Rolland Y, Torre C, Veronese N, Kanis J, Cooper C, Reginster J, Harvey N. Treatment of Osteoporosis and Osteoarthritis in the Oldest Old. *Drugs*. 2025;85(3):343-360

Curtis E, Rosa M, McEvoy C, Ticinesi A, Torre C, Al-Daghri N, Alokail M, **Bałkowiec-Iskra E**, Bruyère O, Burlet N, Cavalier E, Cerreta F, Clark P, Cherubini A, Cooper C, D'Amelio P, Fuggle N, Gregson C, Halbout P, Kanis J, Kaufman J, Laslop A, Maggi S, Maier A, Matijevic R, McCloskey E, Ormarsdóttir S, Yerro C, Radermecker R, Rolland Y, Singer A, Veronese N, Rizzoli R, Reginster J, Harvey N. Impact of dementia and mild cognitive impairment on bone health in older people. *Aging Clinical and Experimental Research*. 2025;37(1):1-22

Cerreta F, **Bałkowiec-Iskra E**, Cupelli A, Sepodes B, Rönnemaa E, Rosa M, Mayrhofer S, Trauffer M, Torre C, Berntgen M, Vucic K, Bahri P, Koch A, Herdeiro M, Mirosevic Skvrce N, Pallos J, Laslop A. Medicines for an aging population: The EMA perspective and policies. *Journal of the American Geriatrics Society*. 2024;72(9):2921-2927

Almeida D, Rodrigues A, Guerreiro J, **Bałkowiec-Iskra E**, Stichele R, Sepodes B, Torre C. COVID-19 pandemic and the consumption of self-care products for pediculosis capitis in Portugal: an interrupted time-series analysis. *Parasitology Research*. 2024;123(6):1-7

Buchholz S, Di Meco E, **Bałkowiec-Iskra E**, Sepodes B, Cavaleri M. Generating clinical evidence for treatment and prevention options for long COVID. *Nature Medicine*. 2024;30(8):2109-2110

Butlen-Ducuing F, Haberkamp M, Aislaitner G, **Bałkowiec-Iskra E**, Mattila T, Doucet M, Kollb-Sielecka M, Balabanov P, Leuchs AK, Elferink A. [The new European Medicines Agency guideline on antidepressants: a guide for researchers and drug developers](#). *Eur Psychiatry*. 2023 Dec 15;67(1):e2. doi: 10.1192/j.eurpsy.2023.2479.

Denkinger M, Knol W, Cherubini A, Simonds A, Lionis C, Lacombe D, Petelos E, McCarthy M, Ouvrard P, Van Kerrebroeck P, Szymański P, Cupelli A, Laslop A, Koch A, Sepodes B, Torre C, Rönnemaa E, **Bałkowiec-Iskra E**, Herdeiro MT, Rosa MM, Trauffer M, Mirošević Skvrce N, Mayrhofer S, Berntgen M, Silva I, Cerreta F. [Inclusion of functional measures and frailty in the development and evaluation of medicines for older adults](#). *Lancet Healthy Longev*. 2023 Dec;4(12):e724-e729. doi: 10.1016/S2666-7568(23)00208-8

Butlen-Ducuing F, McCulloch DE, Haberkamp M, Mattila T, **Bałkowiec-Iskra E**, Aislaitner G, Balabanov P, Lundberg J, Stenbæk DS, Elferink A, Knudsen GM, Thirstrup S. The therapeutic potential of psychedelics: the European regulatory perspective *Lancet*, 2023; 4:401(10378):714\_716.

Butlen-Ducuing F, **Bałkowiec-Iskra E**, Dalla C, Slattery D, Ferretti MT, Kokras N, Balabanov P, De Vries C, Mellino S, Santuccioni Chadha A. Implications of sex-related differences in central nervous system disorders for drug research and development *Nat Rev Drug Discov*, 2021; 20: 881\_882.

Lis K, Grygorowicz T, Cudna A, Szymkowski DE, **Bałkowiec-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.

**Bałkowiec-Iskra E**, Mirowska – Guzel D, Wielgoś 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, Dąbrowska M, Sejbuk-Rozbicka K, Zaremba A, Mirowska-Guzel D, **Bałkowiec-Iskra E**. Therapeutic equivalence of antipsychotics and antidepressants – a systematic review. *Pharmacological Reports*, 2016; 68: 217\_223.

Kuzawinska O, Lis K, Cessak G, Mirowska-Guzel D, **Bałkowiec-Iskra E**. Targeting of calcitonin gene-related peptide action as a new strategy for migraine treatment. *Neurol Neurochir Pol*, 2016; 50:463\_467.

**Bałkowiec-Iskra E.**, Cessak G., Sejbuk – Rozbicka K., Kuzawinska O., Rokita K., Mirowska – Guzel D. Regulatory and clinical aspects of psychotropic drugs bioequivalence. *European Neuropsychopharmacology* 2015, 25: 1027\_1034.

Cessak G., Rokita K, **Bałkowiec-Iskra E**. Bioequivalence and therapeutic equivalence of psychotropic drugs *Advances Psychiatry Neurology*, 2015; 24: 8\_17

Kuzawinska O., Cudna A., Lis K., **Bałkowiec-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., Kuzawińska O., Lis K., Wojnar M., Bałkowiec-Iskra E. „TNF inhibitors – mechanisms of action, approved and off\_label indications". Pharmacological Reports, 2014; 66: 836\_844.

Lis K., Kuzawińska O., Bałkowiec-Iskra E. „Tumor necrosis factor inhibitors – State of Knowledge". Archives of Medical Science, 2014; 6: 1175\_1185.

Bałkowiec-Iskra E., Cessak G., Krynska Ł., Łoza B Wojnar M.. Venous thromboembolism as an adverse effect of antipsychotic treatment. Psychiatria Polska 2014; 48: 997-1014.

Mirowska-Guzel D., Bałkowiec-Iskra E. The role of monoamine oxidase in humans and its metabolism. Psychiatric Annals, 2014, 44: 495\_501. Bałkowiec-Iskra E, Vermehren\_Schmaedick A, Bałkowiec A. Tumor necrosis factor\_α increases brain\_derived neurotrophic factor expression in trigeminal ganglion neurons in an activity\_dependent manner. Neuroscience. 2011;180:322\_33. Bałkowiec-Iskra E. The role of immune system in inflammatory pain pathophysiology Pol Merkur Lekarski. 2010, 174:395\_399. Tarsa L, Bałkowiec-Iskra E, Kratochvil FJ 3rd, Jenkins VK, McLean A, Brown AL, Smith JA, Baumgartner JC, Bałkowiec A. Tooth pulp inflammation increases brain\_derived neurotrophic factor expression in rodent trigeminal ganglion neurons. Neuroscience, 2010; 167:1205\_1215. Kurkowska-Jastrzębska I. Bałkowiec-Iskra E. Ciesielska A. Joniec I. Cudna A. Zaremba MM. Członkowski A. Członkowska 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. Bałkowiec A , Bałkowiec-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. Bałkowiec-Iskra E, Kurkowska-Jastrzębska I, Joniec I, Ciesielska A, Członkowski A, Członkowski 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 Bałkowiec-Iskra E, Kurkowska-Jastrzębska I, Joniec I, Ciesielska A, Przybyłowski A, Członkowska A, Członkowski A. MPTP induced central dopamine depletion exacerbates EAE in C57Bl mice. Inflamm.Res, 2007; 56(8):311\_317. Kurkowska-Jastrzębska Iwona, Ewa Bałkowiec-Iskra, Ilona Joniec, Tomasz Litwin, Andrzej Członkowski, Anna Członkowska. 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. Bałkowiec-Iskra E. Influence of dopaminergic system injury on experimental autoimmune encephalomyelitis progression. Ph.D. thesis. Medical University of Warsaw, 2004. Bałkowiec-Iskra E., Kurkowska-Jastrzębska I, Joniec I, Członkowska A, Członkowski 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. Bałkowiec-Iskra E. Gryśka K. Izycki D. Jakobiński 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. Bałkowiec-Iskra E. Czajka A. Switaj T. Stokłosa T. Giermasz A. Jakobiński 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. Bałkowiec E. Stokłosa T. Giermasz A. Malejczyk M. Jakobiński 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. Bałkowiec E. Sieberth E. Marczak M. Dąbrowska A. Giermasz A. Czajka A. Jakobiński 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)