

PERSONAL INFORMATION

Grzegorz Cessak

WORK EXPERIENCE

January 2009–Present

President

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

- 1) representative of the Office in outside relations,
- 2) Management of medical devices,
- 3) Management of medicinal products,
- 4) Management of biocides,

As the Head of National Competent Authority I established multilevel relations with international partners in every one of them the topic of safety of pharmacotherapy surveillance is pivotal.

January 2002–June 2009

Employe

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

- Head of Herbal Medicinal, Homeopathic and Pharmacopoeia Products
- Co-coordinator of the medicinal products unit
- expert of Office for Registration of Medicinal Products, Medical Devices and Biocides for the Polish Parliament Health Subcommittee and Commission in the framework of the amendment of the Pharmaceutical Law.
- Head of coordination workgroup for tasks related to variations for medicinal products
- Head of Variations and Registration Department, harmonization procedure coordinator
- Head Variations Department
- Variations Department – Specialist

April 2001–November 2002

Spacialist

Medicinal Products Institute in Warsaw (Poland)

Specialist on monitoring of drug consumption and destination import, monitoring of drug consumption and destination import

EDUCATION AND TRAINING

1996–2001

MA in Pharmacy

Medical Academy in Warsaw (Poland)

Specialization: Industrial technology

–2016

Ph. D. in Pharmacy

Medical Academy in Warsaw (Poland)

Ph. D. Regulatory and clinical aspects of psychotropic medicinal products bioequivalence

ADDITIONAL INFORMATION

Expertise**Publications**

1. 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.

2. Kuzawińska 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. Polish Neurology and Neurosurgery, 2016; <http://dx.doi.org/10.1016/j.pjnns.2016.07.012>
3. Bałkowiec-Iskra E., Cessak G., Kuzawińska O., Sejbuk-Rozbicka K., Rokita K., Mirowska-Guzel D. Regulatory and clinical aspects of psychotropic medicinal products bioequivalence. European Neuropsychopharmacology, 2015; 25: 1027-1034.
4. Cessak G., Rokita K., Bałkowiec-Iskra E. Therapeutical and biological equivalence of psychotropic drugs. Advances in Psychiatry and Neurology, 2015; 24: 8-17
5. Kuzawińska O., Lis K., Cessak G., Bałkowiec-Iskra E. The role of the CGRP in the pathogenesis and treatment of migraine. Pharmacotherapy in Psychiatry and Neurology, 2015; 31: 127-140.
6. Bałkowiec-Iskra E., Cessak G. Erectile dysfunction. Postgraduate Medicine, 2015; 10 (11-12): 12-18.
7. 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.
8. Rokita K., Cessak G., Bałkowiec-Iskra E. At-risk mental state. Postgraduate Psychiatry, 2014, 11:34-38.
9. Bałkowiec-Iskra E., Cessak G., Krynska Ł., Łoza B Wojnar M. Venous thromboembolism as an adverse effect of antipsychotic treatment. Polish Psychiatry, 2014; 48: 997-1014
10. Cessak G. Bioequivalence - one of the basic conditions for the marketing authorization of medicinal products generic. Therapy 2013; 2: 3-6.
11. Bałkowiec-Iskra E., Ryszewska-Pokrasiewicz B., Cessak G. Role of pharmacotherapy and psychotherapy in the treatment of depression. Postgraduate Psychiatry, 2013; 12: 41-45.
12. Cessak G. Mechanisms responsible for the occurrence of the placebo effect. Almanach, 2013; 8: 50-53.
13. Krasny M., Zadurska M. Cessak G., Fiedor P. Analysis of effect of non-steroidal anti-inflammatory drugs on teeth and oral tissues during orthodontic treatment. Report based on literature review. Acta Poloniae Pharmaceutica, 2013; 70:573-577.
14. Cessak G. Bioterrorism - Biological Weapons in: Disaster Medicine - Educational Resources – Training. Medical University of Warsaw, Warsaw, 2011
15. Cessak G. Accidental contact with toxic warfare agents in : Disaster Medicine - Educational Resources – Training. Medical University of Warsaw, Warsaw, 2011
16. Splawiński J., Cessak G. Systematical Drug Use – Main Therapy Elements. Postgraduate Medicine, 2008; 08: 4-7.

Projects

Lectures:

- 2004 – 2008 – over 30 lectures and seminars on medicinal products marketing authorisation with the specification of post-authorization variations and harmonization and the amended Pharmaceutical Law;
- 22.11.2005 – lecture with representatives from the Registration Agency EU;
"Experiences of a new EU Member State in bringing old systems in-line with EU regulations", London;
- 01-04.10.2009 - Chairman of the Program Committee of the Conference of Industrial Pharmacy Forum organized by the Polish Pharmaceutical Society, URPLW MiPB, GIF, Kościelisko;
- 18-20.10.2010 - Chairman of the Program Committee of the Conference of Industrial Pharmacy Forum organized by the Polish Pharmaceutical Society, URPLW MiPB, GIF, Lodz;
- 12.09.2010 - lecture on the 1st International Anti-Corruption Conference: "Transparency in the proceeding of medicinal products marketing authorisation", Warsaw;
- 06/01/2010 Club Doctor - Warsaw Medical Society;
- Since 2010 Present lectures campaign Press "Drug Safety" organized by the Office;
- 16.04.2010 Polfarmed Association in Warsaw;
- 26.05.2010 Conference "Golden Scalpel" in Warsaw;
- 27.05.2010 The conference is organized by the Polish Pharmaceutical Society in Warsaw;
- 11-12.06.2010 Conference of the Polish Herbal Committee in Żerków;

14.06.2010 Conference at the Medical University of Lublin;
12-14.09.2010 PTFarm XXI Scientific Congress in Warsaw;
15.09.2010 Scientific Congress of the Society of Orthopaedics and Traumatology;
18-20.10.2010 Conference of the Museum of the City of Lodz "Pharma Industry" in Lodz;
17.12.2010 Conference on Innovation 2010, Media Center Foksal;
28.03.2011 Debate "Innovation in pharmaceuticals" House of Journalists in Warsaw;
13.05.2011 Days of Polish Pharmacy Conference;
15.09.2011 Conference "Forum Military Pharmacy and Medicine in Celestynow;
12-14.10.2011 Conference of the Pharmaceutical Society of horse by PTFarm in Lodz;
7-8.11.2011 Conference in Poznan, Minister of Health;
12/05/2011 Conference organized by the Lawyers Legal Allan & Overy;
25-26.05.2012 Assembly Herb in Żerków;
18.10.2012 Day of Polish – Korean Pharmacy, Warsaw;
26.10.2012 Workshop on Registration of Medicinal Products in the European Union, China;
29.10.2012 Workshop on Registration of Medicinal Products in the European Union, Korea;
14.03.2013 European Conference of Health report 2012 Ministry of Health in Warsaw;
16-17.05.2013 Medical University of Warsaw in Warsaw - "Clinical Trials";
22.05.2013 Business Conference Between Poland and Korea;
23-25.05.2013 Polish Pharmacological Society Congress in Warsaw;
29.10.2012 Workshop on Registration of Medicinal Products in the European Union, Korea;
14.03.2013 European Conference of Health report 2012 Ministry of Health in Warsaw;
16-17.05.2013 Medical University of Warsaw in Warsaw - "Clinical Trials";
22.05.2013 Business Conference Between Poland and Korea;
29.10.2012 Workshop on Registration of Medicinal Products in the European Union, Korea;
14.03.2013 European Conference of Health report 2012 Ministry of Health in Warsaw;
16-17.05.2013 Medical University of Warsaw in Warsaw - "Clinical Trials";
22.05.2013 Business Conference Between Poland and Korea;
23-25.05.2013 Polish Pharmacological Society Congress in Warsaw;
5.06.2013 Meeting between the URPL and the Ministry of Food and Drug Safety of Korea, Korea;
12.09.2013 Forum BioKorea, Korea;
24.09.2013 Round Table meeting of the Pharmaceutical Sector in Warsaw;
22.10.2013 2nd Polish – Korean Business & Technology Cooperation Forum (the official visit of the President of the Republic of Poland in Korea);
30.01.2014 Healthy Ageing Congress in Warsaw;
02.04.2014 Cancer Day in Warsaw;
15.04.2014 Conference "Vaccinate the urge vaccination" in Warsaw;
25.04.2014 Conference organized by the Ministry of Health in Warsaw;
16/05/2014 Day of Polish Pharmacy in Warsaw;
20.05.2014 International Day of Clinical Research - "Clinical trials-benefits and opportunities" in Warsaw;
29.05.2014 Forum BioKorea & Medicine 2014, Korea.

Memberships

1st of January 2010- Present Member of EMA Management Board
22nd of March 2012- Present Member of Coordination Group of Budget and Work Programme

Other Relevant Information

Emotional Intelligence- Training by the Academy of Quick Learning
Management control - the practical aspects of the Public Finance Act implementation- Training by the

Institute of Accounting and Taxation

Decision-making procedures in the European Union in scope of written and co-decision procedures voting, so-called comitology- Training by the European Centre for Training and Administrative (ECSA)

Clinical trials – risks and benefits- Training by the Ministry of Health

Strengthening of anticorruption activities in Poland- Training organized in the framework of EU-Twinning Project for the managerial staff of the Ministry of Health and other subordinated bodies. The training has been prepared by Inspectors of the German Police Force and the Ministry of the Interior and Administration.

European Regulatory Procedures- Training in the framework of the PHARE TWINNING on medicinal products, between Poland and Germany. Training by an advisor of the German Agency for Registration of Medicinal Products - Prof. Rolf Bass.

Pharmaceutical system and legislation in the EU- Training in the framework of PHARE TWINNING PROJECT on medicinal products, between Poland and Spain. Training by advisors of the Spanish Agency for medicinal Products and Medical Devices.

Internship in Pharmaceutical Enterprise Polfa Warszawa

GMP course (Good Manufacturing Practice- Industrial technology

Pharmacy internship- Pharmacy