

PERSONAL INFORMATION

Grzegorz Cessak



The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products,  
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<https://www.facebook.com/gcessak>  
<https://twitter.com/GCessak>

Sex: Male |

Nationality: Polish

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

WORK EXPERIENCE

- 1.02.2022 – Present **Member of the Medical Council of the Prime Minister of Poland**
  
- 19.09.2021- 18.09.2024 **Member of the Committee for Medicinal Products for Human Use of the European Medicines Agency Management Board**  
European Medicines Agency
  
- 1.12.2020 - Present **Member of the COVID-19 Crisis Management of the Prime Minister’s Office**
  
- 18.06.2020 - Present **Member of Steering Board on joint procurement agreement Covid-19 vaccines**  
European Commission  
Health Sector
  
- 22.03.2012 - Present **Member of Coordination Group of Budget and Work Programme European Medicines Agency Management Board**  
European Medicines Agency  
Health Sector
  
- 1.01.2010 – Present **Member of European Medicines Agency Management Board**  
European Medicines Agency  
Health Sector
  
- 6.10.2016 – 10.2019 **Vice Chair of European Medicines Agency Management Board**  
European Medicines Agency  
Health Sector
  
- 1.07.2009 - Present **President of The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Health Sector

**Main tasks of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:**

- 1) representative of the Office in outside relations;
- 2) in scope of medical devices:
  - decision making in scope of the medical devices;
  - administration of the registry of medical devices and marketing authorisation holder responsible for their marketing and use;
  - administration of the Medical Incident Registry;
  - entry into the Central Clinical Trails Index;
  - monitoring of medical devices manufactured and marketed for sale and use in Poland;
  - control of clinical trails;
  - medical incidents assessment;
- 3) in scope of medicinal products:
  - preparatory activities for decisions of the competent minister for health issues regarding marketing of medicinal products, including veterinary medicinal products;
  - administration of the Registry of Medicinal Products Authorised for Marketing in Poland;
  - preparation of procedures for entry of medicinal products or future medicinal products to the Central - Clinical Trails Index and the administration of the Central Clinical Trails Index;
  - collecting of reports on adverse reactions and information about effects of medicinal products or future medicinal products, and monitoring of the safety of medicinal products use and the administration of the Central Index of adverse reactions of medicinal products authorised for marketing;
  - preparation and publishing of the Polish Pharmacopeia;
  - control of compliance of clinical trials of medicinal products or future medicinal products with the Good Clinical Practice requirements;
  - administration of the safety monitoring of medicinal products use control system;
- 4) in scope of biocides:
  - accepting of authorisation application, temporary application or registry entries;
  - administration of the registry and the registry files;
  - determination of the framework formula including joint parameter for biocidal products with the same use, destined for the same kind of users;
  - consent for clinical and development trails during which a biocidal product or active substance can be released to the environment.

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. Simultaneously as a member of the European Medicines Agency Management Board I was personally involved into creation of number of politics enforcing pharmacovigilance effectiveness with Pan-European social campagne among them.

01.10.2008 – 1.07.2009

**Co-coordinator of the medicinal products unit.**

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

01.06. 2008 – 31.12.2008

**Head of Herbal Medicinal, Homeopathic and Pharmacopoeia Products**

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

10.2006 – 02.2007

**Expert of Office for Registration of Medicinal Products, Medical Devices and Biocides for the Parliamentary Health Subcommittee and Commission in the framework of the amendment of the Pharmaceutical Law.**

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

- 01.08.2006 **Head of Post-authorization Variations and Registration Department, harmonization procedure coordinator,**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- 20.01.2006 **Head of coordination working group for tasks related to post-authorization variations for medicinal products,**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- 1.04.2004 – 31.07.2006 **Head of Post-authorization Variations Department**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- 1.10.2002 – 31.03.2004 **Post-authorization Variations – Specialist**  
The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products  
Health Sector
- 5.04.2001- 30.11.2002 **Specialist on monitoring of drug consumption and destination import, monitoring of drug consumption and destination import**  
Medicinal Products Institute in Warsaw,  
Health Sector

EDUCATION AND TRAINING

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- 2020 Training “ developmental diagnosis based on the Reiss Motivations Profile
- 2016 Ph. D. Regulatory and clinical aspects of psychotropic medicinal products bioequivalence
- 9-11.09.2010 Emotional Intelligence  
Academy of Quick Learning - Poland
- 24.06.2010 Management control  
Institute of Accounting and Taxation  
The practical aspects of the Public Finance Act implementation
- 14.12.2009 Decision-making procedures in the European Union in scope of written and co-decision procedures voting, so-called comitology  
European Centre for Training and Administrative (ECSA)
- 08.03.2008 Clinical trials – risks and benefits  
Ministry of Health
- 05 – 08.11.2007 Strengthening of anticorruption activities in Poland  
EU-Twinning Project for the managerial staff of the Ministry of Health and other subordinated bodies
- 07 – 09.06.2004 European Regulatory Procedures  
Training by an advisor of the German Agency for Registration of Medicinal Products - Prof. Rolf Bass
- 01-04.2004 Pharmaceutical system and legislation in the EU  
Training by advisors of the Spanish Agency for medicinal Products and Medical Devices

- 2001 MA in Pharmacy, Specialization: Industrial technology  
Medical Academy in Warsaw
  
- 06.1999 Internship in Pharmaceutical Enterprise  
Polfa Warszawa, Poland  
Good Manufacturing Practice - Industrial technology
  
- 07.1998 Pharmacy internship  
Poland

PERSONAL SKILLS

Mother tongue(s) Polish

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	Proficient	Proficient	Proficient	Proficient	Proficient

Organisational / managerial skills Leadership currently responsible for a team of four hundred people

Job-related skills High managerial skills, work organization of diverse work groups, inter-agency, public administration and industry cooperation, as well as international cooperation.

Project Leader for harmonization of medicinal products documentation. The key aim of this project was adjustment of all existing medicinal products documentations to the Acquis Cmmunautaire requirements.

Other skills Social goals oriented on organizational skills  
Choir and Chair member of the Association Sacral Music Musica Sacra®  
Choir Varsovie Regii Cantores  
President of the Polish – Mongolian Association  
CrossFit Level 2 Trainer  
Yacht Skipper

Driving licence B

ADDITIONAL INFORMATION

Publications

1. Cessak G., Bałkowiec-Iskra E., The knowledge and opinion of pharmacists on the safety and effectiveness of generic products - the results of the survey, Almanach, vol.15 n.1, 2020; 58-71
  
2. Cessak G., Fordymacka A., Maciejczyk A. Marketing authorization and monitoring of vaccine safety in Poland and the European Union - Medycyna Praktyczna 3 (31) July-September 2019
  
3. 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.
4. 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>
  5. 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.
  6. Cessak G., Rokita K., Bałkowiec-Iskra E. Therapeutical and biological equivalence of psychotropic drugs. *Advances in Psychiatry and Neurology*, 2015; 24: 8-17
  7. 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.
  8. Bałkowiec-Iskra E., Cessak G. Erectile dysfunction. *Postgraduate Medicine*, 2015; 10 (11-12): 12-18.
  9. Cessak G., Sejbuk-Rozbicka K., Kuzawińska O., Bałkowiec-Iskra E., Pharmacists' opinion survey on the safety of over-the-counter medicinal products, *Almanach*, Vol.9 n.1, 2014; 47-61
  10. 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.
  11. Rokita K., Cessak G., Bałkowiec-Iskra E. At-risk mental state. *Postgraduate Psychiatry*, 2014, 11:34-38.
  12. 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
  13. Cessak G. Bioequivalence - one of the basic conditions for the marketing authorization of medicinal products generic. *Therapy* 2013; 2: 3-6.
  14. Bałkowiec-Iskra E., Ryszewska-Pokrasiewicz B., Cessak G. Role of pharmacotherapy and psychotherapy in the treatment of depression. *Postgraduate Psychiatry*, 2013; 12: 41-45.
  15. Cessak G. Mechanisms responsible for the occurrence of the placebo effect. *Almanach*, 2013; 8: 50-53.
  16. 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.
  17. Cessak G. Bioterrorism - Biological Weapons in: *Disaster Medicine - Educational Resources – Training*. Medical University of Warsaw, Warsaw, 2011
  18. Cessak G. Accidental contact with toxic warfare agents in : *Disaster Medicine -*

Educational Resources – Training. Medical University of Warsaw, Warsaw, 2011

19. Cessak G., Transparency of the procedure in the registration process of medicinal products, Vol.5 n.3, 2010; 29-30
20. Sławiński J., Cessak G. Systematical Drug Use – Main Therapy Elements. Postgraduate Medicine, 2008; 08: 4-7.
21. Cessak. G., HARMONIZATION OF DOCUMENTATION 5 MONTHS BEFORE THE END OF THE TRANSITION PERIOD, Almanach, Vol.3 n3, 2008, 68-69

- 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, URPLWMI PB, GIF, Kościelisko;
- 18-20.10.2010 - Chairman of the Program Committee of the Conference of Industrial Pharmacy Forum organized by the Polish Pharmaceutical Society, URPLWMI PB, 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;

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 2<sup>nd</sup> 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;
- 20-22.10.2014 Industrial Pharmacy Forum in Lodz;
- 23-24.10.2014 10th Health Market Forum in Warsaw;
- 24.11.2014 Public Health Congress 2014 in Warsaw;
- 7-11.04.2015 Forum BioKorea & Medicine 2015, Korea;
- 15-17.06.2015 The Forum on Health Cooperation and Development between China and CEE Countries in Prague;
- 2-4.09.2015 Baltic States Regulators Forum in Vilnius;
- 27-29.09.2015 Conference 50 years of pharmaceutical law regulations- achievements and prospects for the future in Brussels;
- 19.01.2016 Conference "Early access to oncological innovative medicines - proposals for system solutions" organized by Institute of Management in Health Care in Warsaw;
- 12.05.2016 Day of Polish Pharmacy in Warsaw;
- 18-19.05.2016 Industrial Pharmacy Forum in Lodz;
- 31.05.2016 International Clinical Research Day in Warsaw;
- 27.11-03.12.2016 18<sup>th</sup> International Conference on Regulators of Medicinal Products, WHO in RPA;
- 10-14.04.2017 Forum BioKorea & Medicine 2017, Korea;
- 11.05.2017 Day of Polish Pharmacy in Warsaw;
- 25.05.2017 International Day of Clinical Research in Warsaw;
- 25-31.07.2017 8<sup>th</sup> conference on integrated traditional medicines in Ulan Bator;
- 7.12.2017 Public Health Congress 2017 in Warsaw;
- 5.03.2018 The III International Conference on Personalized Medicine in Warsaw;
- 8.03.2018 Warsaw Days of Health Promotion in Warsaw;
- 24.05.2018 International Day of Clinical Research in Warsaw;
- 24-26.10.2018 Industrial Pharmacy Forum in Lodz;
- 13.11.2018 3rd Asia and Pacific Day in Warsaw;
- 16.04.2019 XX European Immunization Week in Warsaw;
- 12.05.2019 XV Mongolia Development Forum: "Health system, perspective and opportunities";
- 4.12.2019 ABM conference "New opportunities for the development of medical sciences and



health sciences – Where are we? Where are we heading?”.

05.2020-02.2021 Participation in the Program Council of the Patient Organization Development Academy project PACIENCI.PRO

20.04.2021 workshops for journalists from the Quo vadis medicina series: “ Vaccinations as a chance for life” Journalists for Health Association – Registration of vaccinations against Covid -19

24.02.2021 Press conference on discussions between the Polish Anti-Doping Agency, the Polish Olympic Committee and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

19.05.2021 Conference “Clinical Trials- together we can do more on the International Day of Clinical Trials

7-9.09.2021 30<sup>th</sup> Economic Forum, Karpacz

28.09.2021 National Pharmacist Day – “ A new dimension of the pharmacist profession – how to take advantage of the opportunities and overcome the the upcoming challenges?”