

## PERSONAL INFORMATION

**Jolanta Gulbinovic**

## WORK EXPERIENCE

July 2014–Present

**Head of unit for collaboration with EMA and international relationship**

State Medicines Control Agency (Lithuania)

Drug safety evaluation, safety surveillance, risk assessment and risk management

September 2016–Present

**Professor**

Vilnius University (Lithuania)

Lecturing medical students in basic and clinical pharmacology, Drug utilisation, drug safety, risk minimisation research

September 2008–October 2011

**Deputy director for educational and scientific affairs**

Vilnius University Hospital Santariškių Klinikos (Lithuania)

Coordination of work of residents (trainees) at hospital; coordination of biomedical research (including clinical trials) at hospital, and formation of drug policy at hospital

February 2005–August 2008

**Clinical assessor**

Medical Product Agency (Sweden)

Postmarketing safety surveillance and PSUR assessment of the drugs, e.g. Remicade, Humira, Pegasys, Pegintron, Lucentis, Rapamune, Everolimus, Crizivan, Fuzeon, Propecia. Assessment of Risk management plans, e.g. Lenalidomide, Thalidomide, Lucentis, Cimzia, Humira. Participation in pharmacovigilance inspection (Humira).

April 1998–February 2005

**Clinical pharmacologist**

Vilnius University Hospital Santariškių klinikos (Lithuania)

Hospital drug policy, preparation of guidelines on rational antibiotic use, drug utilisation studies at hospital

## EDUCATION AND TRAINING

September 1982–June 1988

**Medical doctor**

Vilnius University (Lithuania)

Medical doctor

September 1993–June 1994

**Pediatrician**

Vilnius University Children's Hospital (Lithuania)

Pediatrician

September 1998–April 1999

**Clinical pharmacology**

Katrolinska Institutet, Huddinge University Hospital (Sweden)

Clinical Pharmacology, Pharmacokinetics, Pharmacogenetics, Drug information

## ADDITIONAL INFORMATION

**Expertise**

Drug safety, risk assessment and management, safety signal management

## Publications

- Bochenek T, Abilova V, Alkan A, Asanin B, de Miguel Beriain I, Besovic Z, Vella Bonanno P, Bucsics A, Davidescu M, De Weerd E, Duborija-Kovacevic N, Furst J, Gaga M, Gailite E, Gulbinovic J, Gürpınar EU, Hankó B, Hargaden V, Hotvedt TA, Hoxha I, Huys I, Inotai A, Jakupi A, Jenzer H, Joppi R, Laius O, Lenormand MC, Makridaki D, Malaj A, Margus K, Marković-Peković V, Miljković N, de Miranda JL, Primožič S, Rajinac D, Schwartz DG, Šebesta R, Simoens S, Slaby J, Sović-Brkičić L, Tesar T, Tzimis L, Warmańska E, Godman B. Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries. *Front Pharmacol.* 2018 Jan 18;8:942.
- Kawalec P, Tesar T, Vostalova L, Draganic P, Manova M, Savova A, Petrova G, Rugaja Z, Männik A, Sowada C, Stawowczyk E, Harsanyi A, Inotai A, Turcu-Stiolica A, Gulbinovic J, Pilc A. Pharmaceutical Regulation in Central and Eastern European Countries: A Current Review. *Front Pharmacol.* 2017 Dec 18;8:892.
- Brinkman DJ, Tichelaar J, Mokkink LB, Christiaens T, Likic R, Maciulaitis R, Costa J, Sanz EJ, Maxwell SR, Richir MC, van Agtmael MA; Education Working Group of the European Association for Clinical Pharmacology and Therapeutics (EACPT) and its affiliated Network of Teachers in pharmacotherapy (NOTIP). Key Learning Outcomes for Clinical Pharmacology and Therapeutics Education in Europe: A Modified Delphi Study. *Clin Pharmacol Ther.* 2017 Dec 5.
- Vella Bonanno P, Ermisch M, Godman B, Martin AP, Van Den Bergh J, Bezmelnitsyna L, Bucsics A, Arickx F, Bybau A, Bochenek T, van de Castele M, Diogene E, Eriksson I, Furst J, Gad M, Greičiūtė-Kuprijanov I, van der Graaff M, Gulbinovic J, Jones J, Joppi R, Kalaba M, Laius O, Langner I, Mardare I, Markovic-Pekovic V, Magnusson E, Melien O, Meshkov DO, Petrova GI, Selke G, Sermet C, Simoens S, Schuurman A, Ramos R, Rodrigues J, Zara C, Zebedin-Brandl E, Haycox A. Adaptive Pathways: Possible Next Steps for Payers in Preparation for Their Potential Implementation. *Front Pharmacol.* 2017 Aug 23;8:497.
- Lisauskienė I, Garuolienė K, Gulbinovič J. Utilization of cardiovascular medicines and cardiovascular mortality in Lithuania, Sweden and Norway in 2003-2012. *Medicina (Kaunas).* 2017;53(4):259-267.
- Wild C, Grössmann N, Bonanno PV, Bucsics A, Furst J, Garuoliene K, Godman B, Gulbinovič J, Jones J, Pomorski MK, Emprechtlinger R. Utilisation of the ESMO-MCBS in practice of HTA. *Ann Oncol.* 2016 Nov;27(11):2134-2136.
- Ermisch M, Bucsics A, Vella Bonanno P, Arickx F, Bybau A, Bochenek T., van de Castele M., Diogene E., Furst J, Garuolienė K, van der Graaff M, Gulbinovič J, Haycox A, Jones J, Joppi R, Laius O, Langner I, Martin AP, Markovic-Pekovic V, McCullagh L, Magnusson E, Nielsen E, Selke G, Sermet C, Simoens S, Sauermann R, Schuurman A, Ramos R, Vlahovic-Palcevski V, Zara C, Godman B. Payers' views of the changes arising through the possible adoption of Adaptive Pathways. *Front Pharmacol.* 2016 Sep 28;7:305.
- Garuolienė K, Godman B, Gulbinovič J, Schiffrers K, Wettermark B. Differences in utilization rates between commercial and administrative databases: implications for future health-economic and cross-national studies. *Expert Rev Pharmacoecon Outcomes Res.* 2016 Apr;16(2):149-52.
- Matuszewicz W, Godman B, Pedersen HB, Furst J, Gulbinovič J, Mack A, Selke G, Timoney A, Warmańska E, Malmström RE. Improving the managed introduction of new medicines: sharing experiences to aid authorities across Europe. *Expert Rev Pharmacoecon Outcomes Res.* 2015 Oct;15(5):755-8.
- Godman B, Malmström RE, Diogene E, Gray A, Jayathissa S, Timoney A, Acurcio F, Alkan A, Brzezinska A, Bucsics A, Campbell SM, Czczot J, de Bruyn W, Eriksson I, Yusof FA, Finlayson AE, Furst J, Garuoliene K, Guerra Júnior A, Gulbinovič J, Jan S, Joppi R, Kalaba M, Magnisson E, McCullagh L, Miikkulainen K, Ofierska-Sujkowska G, Pedersen HB, Selke G, Sermet C, Spillane S, Supian A, Truter I, Vlahović-Palčevski V, Vien LE, Vural EH, Wale J, Władysiuk M, Zeng W, Gustafsson LL. Are new models needed to optimize the utilization of new medicines to sustain healthcare systems? *Expert Rev Clin Pharmacol.* 2015 Jan;8(1):77-94.
- Garuoliene K, Godman B, Gulbinovič J, Wettermark B, Haycox A. European countries with small populations can obtain low prices for drugs:Lithuania as a case history. *Expert Rev Pharmacoecon Outcomes Res.* 2011 Jun;11(3):343-9.
- Committee for Advanced Therapies (CAT); CAT Scientific Secretariat, Schneider CK, Salmikangas P, Jilma B, Flamion B, Todorova LR, Paphitou A, Haunerova I, Maimets T, Trouvin JH, Flory E, Tsiftoglou A, Sarkadi B, Gudmundsson K, O'Donovan M, Migliaccio G, Ancāns J, Maciulaitis R, Robert JL, Samuel A, Ovelgönne JH, Hystad M, Fal AM, Lima BS, Moraru AS, Turcáni P, Zorec R, Ruiz S, Akerblom L, Narayanan G, Kent A, Bignami F, Dickson JG, Niederwieser D, Figuerola-Santos MA, Reischl IG, Beuneu C, Georgiev R, Vassiliou M, Pychova A, Clausen M, Methuen T, Lucas S, Schüssler-Lenz M, Kokkas V, Buzás Z, MacAleenan N, Galli MC, Linē A, Gulbinovic J, Berchem G, Fraczek M, Menezes-Ferreira M, Vilceanu N, Hrubisko M, Marinko P, Timón M, Cheng W, Crosbie GA, Meade N, di Paola ML, VandenDriessche T, Ljungman P, D'Apote L, Oliver-Diaz O, Büttel I, Celis

P. Challenges with advanced therapy medicinal products and how to meet them. *Nat Rev Drug Discov.* 2010 Mar;9(3):195-201.

- Godman B, Wettermark B, Vlahovic-Palcevski V, Schwabe U, Gulbinovic J et al. The impact of reforms to enhance the quality and efficiency of statin prescribing across 20 European countries. *Basic Clin Pharmacol Toxicol*, 2009; 107:35-35 Suppl. 1
- Godman B, Vlahovic-Palcevski V, Laius O, Bennett K, Gulbinovic J et al. Trends in consumption and expenditure of proton pump inhibitors (PPIs) in 20 European countries. *Basic Clin Pharmacol Toxicol*, 2009; 107:37-37 Suppl. 1
- R. Kviliute, A. Paskevicius, J. Gulbinovic, R. Stulpinas, L. Griskevicius. Nonfatal *Trichoderma citrinoviride* pneumonia in an acute myeloid leukemia patient. *Ann Hematol*, 2008; 87:501-502,
- U. Dumpis, J. Gulbinovic, J. Struwe, Å. Lagergren, L. Griskevicius and U. Bergman. Differences in antibiotic prescribing in three university hospitals in the Baltic region revealed by a simple protocol for quality assessment of therapeutic indications. *Int J Clin Pharmacol Ther*, 2007; 45: 568-577.
- Vlahovic-Palcevski V, Dumpis U, Mitt P, Gulbinovic J, Struwe J, Palcevski G, Stimac D, Lagergren A, Bergman U. Benchmarking antimicrobial drug use at university hospitals in five European countries. *Clin Microbiol Infect*, 2007;13: 277-283.
- Struwe J, Dumpis U, Gulbinovic J, Lagergren A, Bergman U. Healthcare associated infections in university hospitals in Latvia, Lithuania and Sweden: a simple protocol for quality assessment. *Euro Surveill*, 2006;11: 167-171.
- J. Gulbinovič, K.-E. Myrbäck, J. Bytautienė, B. Wettermark, J. Struwe, U. Bergman. Inversed relation between antibacterial resistance and antibiotic pressure: a comparison between university hospitals in Vilnius, Lithuania and Huddinge, Sweden. *Microbial Drug Resistance*, 2001; 7: 383-389.
- R. A. Kiivet, V. Biba, D. Enache, V. Foltan, J. Gulbinovic, N. Oltvanyi, A. Orazem, M. Popova, L. Stika. Changes in the use of antibacterial drugs in the countries of central and eastern Europe. *Eur J Clin Pharmacol*, 1995; 48: 311-316.
- Lissauskienė I, Garuolienė K, Gulbinovič J. Trends and pattern of the utilization of cardiovascular medicines in Lithuania in 2003–2012 // *Acta medica Lituanica*. - 2014. Vol. 21. No. 3. P. 143–150.
- Griškevičius L., Gulbinovič J., Trociukas I., Balsys J.. Neprognozuojama ciklofosfamido ir 4-hidroksiciklofosfamido farmakokinetika vartojant įprastinę ciklofosfamido dozę [Unpredictable pharmacokinetics of cyclophosphamide and 4-hydroxycyclophosphamide using standard dose of cyclophosphamide] // *Laboratorinė medicina*.- 2001, Nr. 4 (12), p. 21-28.
- Gulbinovič J.. Bakterinio meningito gydymas [The treatment of bacterial meningitis] // *Neurologijos seminarai*.- 2001, Nr. 3(13).- p. 15-20.
- Gulbinovič J., Griškevičius L.. Citochromo P450 reikšmė vaistų metabolizmui [The role of cytochrome P450 in drug metabolism]. // *Laboratorinė medicina*.- 2000.- Nr. 4(8), p. 45-49.
- Griškevičius L., Gulbinovič J.. Lietuvos gyventojų debrizokvino ir S-mefenitoino hidroksilinimo polimorfizmas [Debrizoquine and S-mephenytoin hydroxylation polymorphism in Lithuanian population]. // *Medicina*.- 2000.- T. 36. - Nr. 2.- p. 131-136.
- Ručinskas K., Gulbinovič J., Storpirstytė-Dranenkienė A., Ivaškevičienė L., Sirvydis V.. Perioperacinės infekcijos profilaktika antibiotikais. Cefazolinas ir cefuroksimas [Antibiotics for the prophylaxis of peri-operative infections. Cefazolin vs. Cefuroxime]. // *Medicina*.- 1999.T- 35, pr.7, P.- 197-200.
- Gulbinovič J., Griškevičius L.. Changes of drug use for bronchial obstruction in childre's hospital in 1993 and 1995. *Acta medica Lithuanica*.- 1996.- Nr. 4.-P. 12-17.
- Gulbinovič J., Ramanauskas J.. Vaistų suvartojimo Lietuvoje analizė [Analysis of drug utilisation in Lithuania]. *Acta medica Lithuanica*.- 1994.- Nr. 1.- p.83-89.
- A.Ambrozaitis, J. Gulbinovič, A. Marcinkutė. Infekcijos ir antiinfekciniai vaistai [Infections and antiinfective drugs].- Vilnius: UAB „Vaistų žinios“, 2004.
- J. Gulbinovič. Bakterinės infekcijos ir antibakteriniai vaistai (mokomoji knyga) [Bacterial infections and antibacterial drugs].- Vilnius: UAB „Vaistų žinios“, 2001.- 304 p.
- J. Gulbinovič. Infekcinių ligų antimikrobinio gydymo principai (Infekcinių ligų vadovas. Sudarytojas A. Ambrozaitis).- Vilnius: UAB „Vaistų žinios“, 2010.- 86-96 p.

#### Projects

1. Phenotyping and genotyping (CYP 2D6, CYP2C19) of Lithuanian population (1998-1999).
2. Benchmarking of antibiotic use and antimicrobial resistance in university hospitals in Lithuania and Sweden.

**Memberships** PRAC member  
Member of Association of Clinical Pharmacology of Lithuania  
Member of Executive Committee of the European Association of Clinical Pharmacology and Therapeutics (EACPT)  
Member of Council of European Drug Utilisation Group (EuroDurg)  
Member of Piperska Group

**Other Relevant Information** 1993 - defended the PhD theses