



Curriculum Vitae

Personal information **John Joseph Borg**

Work experience

1. Medicines Authority
 - Start date: 112004
 - End date:
 - Position: Director Post_Licensing
 - Activities: 20 years in regulatory affairs, including assessment of non_clinical and clinical parts of MAA and Paediatric Investigation Plans for small chemical entities and recombinant biotherapeutics.
 - Country: Malta
2. Tor Vergata
 - Start date: 102007
 - End date:
 - Position: Visiting Professor
 - Activities: Clinical Pharmacology
 - Country: Italy
3. La Sapienza (Rome)
 - Start date: 022013
 - End date: 062017
 - Position: Visiting Senior Lecturer
 - Activities: Pharmaceutical Regulatory Affairs
 - Country: Italy
4. Lectus Therapeutics Ltd
 - Start date: 072003
 - End date: 072004
 - Position: Head of electrophysiology
 - Activities: High throughput screening and electrophysiology
 - Country: United Kingdom
5. Elborg Pharmaceuticals
 - Start date: 1998
 - End date: 2004
 - Position: Director
 - Activities: Sourcing and Supply of Retail Pharmacy
 - Country: Malta
6. European Commission
 - Start date: 2008
 - End date:
 - Position: H2020 Evaluator/FP7
 - Activities:
 - Country: Malta
7. European Medicines Agency
 - Start date: 112004
 - End date:
 - Position: CHMP Member
 - Activities: Rapporteur for numerous Centralised procedures (Pre_ and Post Authorization) CHMP/PRAC Rapporteurships experience/ BWP peer review of SAWP procedures experience; Non_clinical and clinical documentation requirements to support European Clinical Trial Applications and Marketing Authorisation Applications (MAA) as well as Paediatric Investigation Plans
8. European Medicines Agency
 - Start date: 012014
 - End date:
 - Position: PRAC Member
 - Activities: Pharmacovigilance Risk Assessment _ PRAC member Assessing and monitoring the safety of human medicines.
9. European Medicines Agency
 - Start date: 022007
 - End date:
 - Position: PDCO member
 - Activities:
10. European Medicines Agency
 - Start date: 022012
 - End date:
 - Position: CHMP member at CAT
 - Activities:
11. European Medicines Agency
 - Start date: 062013
 - End date:
 - Position: EMA Management Board Member
 - Activities:

Education and training

1. Subject: University of Bristol
 - Start date: 2000
 - End date: 2004
 - Qualification: PhD
 - Organisation: Ion channels/pre_clinical drug discovery/electrophysiology
 - Country: United Kingdom
2. Subject: University of Malta
 - Start date: 1998
 - End date: 1999
 - Qualification: MSc Agric.Vet.Pharm
 - Organisation: Veterinary Pharmacy
 - Country: Malta
3. Subject: University of Malta
 - Start date: 1994
 - End date: 1998
 - Qualification: BPharm Hons
 - Organisation: Pharmacy
 - Country: Malta

Additional information

Publications

Mifsud Buhagiar L, Micallef B, Borg JJ, Vella H, Serracino Inglott A, LaFerla G. Regulatory sciences and translational pharmacogenetics: amitriptyline as a case in point. *Drug Metab Pers Ther*. 2019 Borg JJ, Melchiorri D, Sepodes B, Caramella CM, Tomino C, Micallef B, Serracino Inglott A, Nistico R. Optimising bench science to withstand regulatory scrutiny. *Pharmacol Res*. 2019 Jan;139:491_493 Cilia M, Ruiz S, Richardson P, Salmonson T, Serracino_Inglott A, Wirth F, Borg JJ. Quality Issues Identified During the Evaluation of Biosimilars by the European Medicines Agency's Committee for Medicinal Products for Human Use. *AAPS PharmSciTech*. 2017 Oct 12. Tanti A, Camilleri M, Borg AA, Micallef B, Flores G, Serracino_Inglott A, Borg JJ. Opinions of Maltese doctors and pharmacists on medication errors. *Int J Risk Saf Med*. 2017;29(1_2):81_99. Chetcuti M, Serracino_Inglott A, Flores G, Borg JJ. Pharmaceutical issues during the review of European Marketing Authorisation Applications in Malta. *Pharm Dev Technol*. 2017 Aug 7:1_12. Refalo N, Chetcuti D, Tanti A, Serracino_Inglott A, Borg JJ. Changing paradigms in bioequivalence trials submitted to the EMA for evaluation _ A clinical and regulatory perspective. *Saudi Pharm J*. 2017 Feb;25(2):280_289. Filippatos GS, de Graeff P, Bax JJ, Borg JJ, Cleland JG, Dargie HJ, Flather M, Ford I, Friede T, Greenberg B, Henon_Goburdhun C, Holcomb R, Horst B, Lekakis J, Mueller_Velten G, Papavassiliou AG, Prasad K, Rosano GM, Severin T, Sherman W, Stough WG, Swedberg K, Tavazzi L, Tousoulis D, Vardas P, Ruschitzka F, Anker SD. Independent academic Data Monitoring Committees for clinical trials in cardiovascular and cardiometabolic diseases. *Eur J Heart Fail*. 2017 Apr;19(4):449_456. Tanti A, Micallef B, Serracino_Inglott A, Borg JJ. A review of the National pharmacovigilance system in Malta _ implementing and operating a pharmacovigilance management system. *Expert Opin Drug Saf*. 2017 Jan;16(1):65_76. Borg JJ. A Rapid, Cost_Effective Pre_Clinical Method to Screen for Pro_ or Antiarrhythmic Effects of Substances in an Isolated Heart Preparation. *Sci Pharm*. 2015 Apr 13;83(2):339_52. doi: 10.3797/scipharm.1503_03. eCollection 2015. Borg JJ, Anker SD, Rosano G, Serracino_Inglott A, Strasser F. Multimodal management as requirement for the clinical use of anticachexia drugs _ a regulatory and a clinical perspective. *Curr Opin Support Palliat Care*. 2015 Dec;9(4):333_45. doi: 10.1097/SPC.000000000000176. Borg JJ, Tanti A, Kouvelas D, Lungu C, Pirozynski M, Serracino_Inglott A, Aislaitner G. European Union pharmacovigilance capabilities: potential for the new legislation. *Ther Adv Drug Saf*. 2015 Aug;6(4):120_40. doi:10.1177/2042098615591802. Review. Borg JJ, Tomasi P, Pani L, Aislaitner G, Pirozynski M, Leufkens H, Melchiorri D. Licensing of Generic Medicines: Are There Any Challenges Left? A Pharmaceutical Regulatory Perspective. *Sci Pharm*. 2014 May 22;82(4):847_56. doi: 10.3797/scipharm.1312_10. eCollection 2014 Dec. Tanti A, Serracino_Inglott A, Borg JJ. Designing a national combined reporting form for adverse drug reactions and medication errors. *East Mediterr Health J*. 2015 Jun 9;21(4):246_55. PubMed PMID: 26077519. Borg JJ, Laslop A, Pani L, Maciulaitis R, Melchiorri D. Reflections on Decisions Made on the Well_Established Use of Medicinal Products by EU Regulators and the ECJ. *Sci Pharm*. 2014 Mar 24;82(3):541_54. doi: 10.3797/scipharm.1402_14. Micallef B, Attard E, Serracino_Inglott A, Borg JJ. Could EU herbal monographs contribute to Malta's treatment armamentarium? *Phytomedicine*. 2015 Mar 15;22(3):400_5. doi: 10.1016/j.phymed.2015.01.005. Salmikangas P, Menezes_Ferreira M, Reischl I, Tsiptsoglou A, Kyselovic J, Borg JJ, Ruiz S, Flory E, Trouvin JH, Celis P, Ancans J, Timon M, Pante G, Sladowski D, Lipnik_Stangelj M, Schneider CK. Manufacturing, characterization and control of cell_based medicinal products: challenging paradigms toward commercial use. *Regen Med*. 2015;10(1):65_78. Borg JJ. Teaching pharmacy in Malta '1676 _ 1990s' Part II. *Pharm Hist (Lond)*. 2014 Sep;44(3):68_73. Borg JJ. Teaching pharmacy in Malta 1676_1990s: Part I. *Pharm Hist (Lond)*. 2014 Jun;44(2):24_6. Borg JJ, Serracino_Inglott A, Azzopardi LM, Schneider CK. Comment on: "EU's new pharmacovigilance legislation: considerations for biosimilars". *Drug Saf*. 2014 Feb;37(2):123_4. doi: 10.1007/s40264_013_0128_5. Melchiorri D, Pani L, Gasparini P, Cossu G, Ancans J, Borg JJ, Drai C, Fiedor P, Flory E, Hudson I, Leufkens HG, Müller_Berghaus J, Narayanan G, Neugebauer B, Pokrotnieks J, Robert JL, Salmonson T, Schneider CK. Regulatory evaluation of Glybera in Europe _ two committees, one mission. *Nat Rev Drug Discov*. 2013 Sep;12(9):719. Tanti A, Camilleri M, Bonanno PV, Borg JJ. Medication errors through a national pharmacovigilance database approach: A study for Malta. *Int J Risk Saf Med*. 2013 Jan 1;25(1):17_27. - Corresponding author Schneider CK, Borg JJ, Ehmann F, Ekman N, Heinonen E, Ho K, Ruiz S, van der Stappen T, Thorpe R, Tiitso K, Tsiptsoglou A, Vleminckx C, Waxenecker G, Welin M, Weise M, and Trouvin JH "Biosimilars - clinical complications without comparability exercise" *Nature Biotech* August 2012. Borg JJ, Aislaitner G, Pirozynski M, Mifsud S. The authors' reply. *Drug Saf*. 2011 Jun 1;34(6):530_1 Corresponding author Borg JJ, Aislaitner G, Pirozynski M, Mifsud S, "Strengthening and rationalising pharmacovigilance in the European Union. Where is Europe heading to?" *Drug Saf*. 2011 Mar 1;34(3):187_97. Corresponding author Pirozynski M & Borg JJ., "Chapter 17: Occupational and drug induced disorders" in *Interstitial lung diseases (USA)*, Baughman & Du Bois eds., Springer published. Corresponding author Borg JJ, Robert JL, Wade G, Aislaitner G, Pirozynski M, Abadie E, Salmonson T, Vella Bonanno P., "Where is industry getting it wrong? A review of quality concerns raised at Day 120 by the Committee for Medicinal Products for Human use during European Centralised Marketing Authorisation submissions for chemical entity medicinal products." *J Pharm Pharmacol Sci*. 2009;12(2):181_98. Corresponding author Borg JJ, Hancox JC, Zhang H, Spencer CI, Li H, Kozlowski RZ. Differential pharmacology of the cardiac anionic background current I(AB). *Eur J Pharmacol*. 2007 Aug 27;569(3):163_70. Spencer CI, Borg JJ, Kozlowski RZ, Sham JS. Differential effects of extracellular cesium on early afterdepolarizations in ventricular myocytes and arrhythmogenesis in isolated hearts of rats and guinea pigs. *Pflugers Arch*. 2004 Aug;448(5):478_89. Yuill KH, Borg JJ, Ridley JM, Milnes JT, Witchel HJ, Paul AA, Kozlowski RZ, Hancox JC. Potent inhibition of human cardiac potassium (HERG) channels by the anti_estrogen agent clomiphene_without QT interval prolongation. *Biochem Biophys Res Commun*. 2004 May 28;318(2):556_61. Culliford SJ, Borg JJ, O'Brien MJ, Kozlowski RZ. Differential effects of pyrethroids on volume_sensitive anion and organic osmolyte pathways. *Clin Exp Pharmacol Physiol*. 2004 Mar;31(3):134_44. Borg JJ, Hancox JC, Hogg DS, James AF, Kozlowski RZ. Actions of the anti_oestrogen agent clomiphene on outward K+ currents in rat ventricular myocytes. *Clin Exp Pharmacol Physiol*. 2004 Jan_Feb;31(1_2):86_95. Corresponding author Borg JJ, Yuill KH, Hancox JC, Spencer IC, Kozlowski RZ. Inhibitory effects of the antiestrogen agent clomiphene on cardiac sarcolemmal anionic and cationic currents. *J Pharmacol Exp Ther*. 2002 Oct;303(1):282_92. Corresponding author Borg JJ, Hancox JC, Spencer CI, Kozlowski RZ. Tefluthrin modulates a novel anionic background conductance (I(AB)) in guinea_pig ventricular myocytes. *Biochem Biophys Res Commun*. 2002 Mar 22;292(1):208_15. Corresponding author Spencer CI, Yuill KH, Borg JJ, Hancox JC, Kozlowski RZ. Actions of pyrethroid insecticides on sodium currents, action potentials, and contractile rhythm in isolated mammalian ventricular myocytes and perfused hearts. *J Pharmacol Exp Ther*. 2001 Sep;298(3):1067_82. Erratum in: *J Pharmacol Exp Ther* 2001 Oct;299(1):399. Borg JJ, Hancox JC, Meaden GM, Spencer CI and Kozlowski RZ (2001) A simple computational method to quantify arrhythmias based upon contractile variability. *Anal Pharmacol*. 1: 101_114. Corresponding author Mulvaney AW, Spencer CI, Culliford S, Borg JJ, Davies SG, Kozlowski RZ. Cardiac chloride channels: physiology, pharmacology and approaches for identifying novel modulators of activity. *Drug Discov Today*. 2000 Nov 1;5(11):492_505. Presenter of Abstracts and during conferences Numerous

publications of abstracts at conferences of the British Pharmacology society, British Physiology society, PACE and the Drug Information Association

Projects

Co_Lead WP2 H2020 Project STARS _ Strengthening Academia in Regulatory Sciences Rapporteur for the European centralised application process and arbitration Olanzapine Apotex – Marketing Authorisation Application Dextropropoxyphene _ Article 31 referral of Directive 2001/83/EC Dexamethasone Alapis – Article 29 referral of Directive 2001/83/EC Cymbalta – Article 9 referral of Regulation 726/2004/EC Loraxine Vitabalans _ _ Article 29 referral of Directive 2001/83/EC Raxone – _ Marketing Authorisation Application Capecitabine SUN _ Marketing Authorisation Application Voriconazole Accord _ Marketing Authorisation Application Imatinib Medac _ Marketing Authorisation Application Atosiban SUN _ Marketing Authorisation Application Envarsus _ Marketing Authorisation Application Busulfan 6 mg/ml concentrate for solution for infusion (busulfan), _ Marketing Authorisation Application Zalviso_Grunenthal GmbH (Sufentanil Sublingual Microtablet system) _ Marketing Authorisation Application Aripiprazole Sandoz _ Marketing Authorisation Application Aripiprazole Zentiva _ Marketing Authorisation Application Aripiprazole Accord _ Marketing Authorisation Application Duloxetine Mylan _ Marketing Authorisation Application Duloxetine Sandoz _ Marketing Authorisation Application Pemetrexed _ Marketing Authorisation Application Lopinavir/Ritonavir Mylan Generics (UK) Ltd _ Marketing Authorisation Application Darunavir Mylan _ Marketing Authorisation Application BreTuo Spiromax Aerivio Spiromax _ Marketing Authorisation Application BreTuo Spiromax changed name to Airexar Spiromax _ Marketing Authorisation Application Tenofovir disoproxil Zentiva _ Marketing Authorisation Application Emtricitabin Tenofovir Krka _ Marketing Authorisation Application Lacosamide Accord _ Marketing Authorisation Application Darunavir Krka _ Marketing Authorisation Application Ritonavir Mylan Limited _ Marketing Authorisation Application Emtricitabine/Tenofovir Disproxil Krka dd _ Marketing Authorisation Application Efavirenz/Emtricitabine/Tenofovir _ Marketing Authorisation Application Darunavir Krka d.d. _ Marketing Authorisation Application Febuxostat Krka _ Marketing Authorisation Application Aprepitant _ Marketing Authorisation Application

Memberships

Registered Pharmacist Malta Editorial Board member_ Pharmaceutical Regulatory Affairs

Other Relevant Information