europass Curriculum vitae

PERSONAL INFORMATION

John Joseph Borg

WORK EXPERIENCE

June 2013–Present

EMA Management Board Member

European Medicines Agency (Netherlands)

November 2004–Present

Director Post-Licensing

Medicines Authority (Malta)

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.

November 2004–Present

CHMP Member

EMA (Malta)

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

February 2007–Present

PDCO member

EMA (Malta)

February 2012–Present

CHMP member at CAT

EMA (Malta)

October 2007–Present

Visiting Professor

Tor Vergata (Italy)

Clinical Pharmacology

February 2013–June 2017

Visiting Senior Lecturer

La Sapienza (Rome) (Italy)

Pharmaceutical Regulatory Affairs

July 2003–July 2004

Head of electrophysiology

Lectus Therapeutics Ltd (United Kingdom)

High throughput screening and electrophysiology

1998–2004

Director

Elborg Pharmaceuticals (Malta)

Sourcing and Supply of Retail Pharmacy

2008–Present

H2020 Evaluator/FP7

European Commission (Malta)

EDUCATION AND TRAINING

2000–2004

PhD

University of Bristol (United Kingdom)

Ion channels/pre-clinical drug discovery/electrophysiology

1998–1999 **MSc Agric.Vet.Pharm**

University of Malta (Malta)

Veterinary Pharmacy

1994–1998 **BPharm Hons**

University of Malta (Malta)

Pharmacy

ADDITIONAL INFORMATION

Expertise

Previous positions as Consultant (2000-2004)

• Developed proof-of-concept within the pre-clinical development of a lead compound for a start up venture capital funded biopharmaceutical company (2M GBP)

• Optimisation of non-clinical development plan (350K GBP)

• Evaluation and tackling of regulatory risks and hurdles

• Gap analyses in pre-clinical drug development

Area of Expertise

Regulatory and Managerial Achievements

• Direct hands on experience in policy formulation and medicines regulation (both at European and national level):

• Direct hands on experience in Budget Setting for the Medicines Authority and review of EMA budget at the EMA Management Board.

o Leading formulation and transposition of legislation and policy on pharmacovigilance, clinical trials, paediatric and advanced therapies into Maltese Legislation. Also lead the discussions for Malta on these directives at a European Level.

• 20 years in regulatory affairs, including assessment of non-clinical and clinical parts of Marketing Authorisation Applications and Paediatric Investigation Plans for small chemical entities and recombinant biotherapeutics; main therapeutic areas:

o Cardiovascular disorders

• Detailed knowledge of the European approval system including European Medicines Agency (EMEA), DCP and national procedures.

• > 20 CHMP/PRAC Rapporteurships / BWP peer review of SAWP procedures experience/SAWP procedures

• Experienced assessor (quality/pre clinical/Clinical)

• Non-clinical and clinical documentation requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisation Applications (MAA) as well as Paediatric Investigation Plans

• Cardiovascular Pharmacology

• Clinical drug development

• Paediatric Investigation Plans

• Advanced therapies

• Signal detection

Academia and Research

• DG Research FP7 CORDIS single stage call evaluator (2008- to date)

• DG Research FP7 Marie Curie evaluator (2010-2011)

• Researcher at University of Bristol in Ion channels (2000-2003)

• Research at the Malta Medicines Authority on Pharmaceutics and Drug Safety (2004-to date)

Medical Specialities

• Cardiovascular pharmacology

• Drug Discovery

• Bioequivalence

• Pharmacokinetics

• Ion channels

• Pharmacovigilance

• Pharmacy

Major Projects

As Regulator

• Set-up and maintenance of the Maltese Medicines Agency Post-licensing Directorate handling all variations/renewals/line extensions as well as Pharmacovigilance and advertising of medicinal products for human use. Inclusive of quality assurance of assessment of these procedures.

• Rapporteur/Co-rapporteur, non-clinical and clinical assessor for NCEs in the Centralised Procedure

• Review of quality, non-clinical clinical parts of MAA in national/DCP procedures 2008 to date

• Rapporteur for Paediatric Investigation Plans (PIP) at the EMA

• Set-up and maintenance of the Maltese Medicines Agency handling of clinical trials and scientific advice procedures submitted to the agency. Inclusive of quality assurance of assessment of these procedures

• Maltese Delegate to the European Council for the Paediatric regulation; Advanced therapies regulation and the pharmacovigilance directive and regulations. Also responsible for their national implementation.

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.0000000000000176.

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, Tsiftsoglou 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, Tsiftsoglou 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 Pharmaceut 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

Dextropoxyphene - 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
Emtricitabibe/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