

PERSONAL INFORMATION **Bruno Sepodes**WORK EXPERIENCE

- 2013- Present **Member of the Committee for Advanced Therapies (CAT)**
European Medicines Agency (Netherlands)
CAT member nominated by the Committee for Medicinal Products for Human Use (CHMP)
- 2012- Present **Member of the Committee for Medicinal Products for Human Use (CHMP)**
European Medicines Agency (Netherlands)
Vice-Chairperson, since October 2018
Member nominated for PORTUGAL (PT)
- September 2008-October 2020 **Member of the Committee of Orphan Medicinal Products (COMP)**
European Medicines Agency (Netherlands)
Chairperson, from September 2012 to September 2018.
From 2008 to 2012 - Member nominated by the European Commission under EMA recommendation.
From 2018 to 2020 - Member nominated by the European Commission under EMA recommendation.
- March 2003- Present **Full Professor (Pharmacological Sciences)**
University of Lisbon - Faculty of Pharmacy (Portugal)
Member of the Scientific Council and Vice-President of the School Council.
President of the Ethics Committee of Research involving Human Beings of the School of Pharmacy (since 2018)
- Responsible for the courses of Pharmacotherapy of the Integrated Master of Pharmaceutical Sciences, and several other courses in Pharmacology, Therapeutics and Regulatory Science. Research interests are developed in the non-clinical translational research and Regulatory Sciences.
- 2005- Present **Senior Assessor**
INFARMED I.P. (Portugal)
Senior Assessor for the Portuguese National Authority for Medicines and Health Products.
- 2010- Present **Member of the Evaluation Board of Medicines**
INFARMED I.P. (Portugal)
- 2011- Present **Non-clinical and Pharmaceutical (Quality) Expert**
Portuguese National Authority for Animal Health (Direção Geral de Veterinária, DGV) (Portugal)
- 2012- Present **Member of the Scientific Coordination Board**
European Medicines Agency (Netherlands)
From 2012 to 2018, given the Chairmanship of the Committee of Orphan Medicinal Products. From 2018 onwards, as Vice-Chairperson of the Committee of Human Medicinal Products.
- 2011- 2012 **Member of the Patients and Consumers Working Party**
European Medicines Agency (United Kingdom)
Representative of the Committee of Orphan Medicinal Products at the PCWP.
- 2005- Present **Portuguese National Formulary of Medicines Working Group**
INFARMED I.P. and Ministry of Health (Portugal)

EDUCATION AND TRAINING

- 2020- **Master of Public Health (MPH)**
Johns Hopkins University (Bloomberg School of Public Health) (United States)
- 2014- **Habilitation**
University of Lisbon (Portugal)
Pharmacology and Pharmacotherapy
- 2008- **PhD**
University of Lisbon (Portugal)
Doctorate in Pharmacy (Pharmacology)
- 2006- **MSc**
University of Lisbon (Portugal)
Master of Science in Regulation and Evaluation of Medicines and Health Products
- 1995- 2001 **PharmD**
University of Lisbon (School of Pharmacy) (Portugal)
Pharmaceutical Sciences and Pharmacy degree with a 5 years curriculum and 6 months internship in pharmacy (community and hospital pharmacy).

ADDITIONAL INFORMATION

- Expertise** MAJOR RESEARCH INTERESTS:
Pharmacology of inflammation;
Ischemia-reperfusion injury and solid organ transplantation;
Human and Veterinary medicinal products evaluation;
Pharmacodynamics and non-clinical pharmacokinetics;
Pharmacology in laboratory and target animals;
General and special toxicology;
Non-clinical drug development;
Rare Diseases and Orphan Drugs Development;
Public Health
- Publications** Selection of published full papers in peer reviewed indexed journals:
- 1: Carvalho M, Sepodes B, Martins AP. Regulatory and Scientific Advancements in Gene Therapy: State-of-the-Art of Clinical Applications and of the Supporting European Regulatory Framework. *Front Med (Lausanne)*. 2017 Oct 26;4:182. doi: 10.3389/fmed.2017.00182. eCollection 2017. Review. PubMed PMID: 29124055; PubMed Central PMCID: PMC5662580.
 - 2: Ecker A, Mariz S, Naumann-Winter F, Norga K, Barisic I, Girard T, Tomasi P, Mentzer D, Sepodes B. Comparative analysis of the scope of European Union paediatric investigation plans with corresponding orphan designations. *Arch Dis Child*. 2018 May;103(5):427-430. doi: 10.1136/archdischild-2017-313352. Epub 2017 Oct 31. PubMed PMID: 29089318.
 - 3: Fregonese L, Greene L, Hofer M, Magrelli A, Naumann-Winter F, Larsson K, Sheean M, Stoyanova-Beninska V, Tsigkos S, Westermark K, Sepodes B. Demonstrating significant benefit of orphan medicines: analysis of 15 years of experience in Europe. *Drug Discov Today*. 2018 Jan;23(1):90-100. doi: 10.1016/j.drudis.2017.09.010. Epub 2017 Oct 9. Review. PubMed PMID: 29024805.
 - 4: Sheean ME, Stoyanova-Beninska V, Capovilla G, Duarte D, Hofer MP, Hoffmann M,

Magrelli A, Mariz S, Tsigkos S, Shaili E, Polsinelli B, Ricciardi M, Bonelli M, Balabanov P, Larsson K, Sepodes B. Nonclinical data supporting orphan medicinal product designations: lessons from rare neurological conditions. *Drug Discov Today*. 2018 Jan;23(1):26-48. doi: 10.1016/j.drudis.2017.09.015. Epub 2017 Oct 4. Review. PubMed PMID: 28987289.

5: Mateus V, Rocha J, Alves P, Mota-Filipe H, Sepodes B, Pinto R. Thiadiazolidinone-8 Ameliorates Inflammation Associated with Experimental Colitis in Mice. *Pharmacology*. 2018;101(1-2):35-42. doi: 10.1159/000471808. Epub 2017 Sep 30. PubMed PMID: 28965119.

6: Aartsma-Rus A, Straub V, Hemmings R, Haas M, Schlosser-Weber G, Stoyanova-Beninska V, Mercuri E, Muntoni F, Sepodes B, Vroom E, Balabanov P. Development of Exon Skipping Therapies for Duchenne Muscular Dystrophy: A Critical Review and a Perspective on the Outstanding Issues. *Nucleic Acid Ther*. 2017 Oct;27(5):251-259. doi: 10.1089/nat.2017.0682. Epub 2017 Aug 10. PubMed PMID: 28796573; PubMed Central PMCID: PMC5649120.

7: Tsigkos S, Hofer MP, Sheean ME, Mariz S, Larsson K, Naumann-Winter F, Fregonese L, Sepodes B. Establishing rarity in the context of orphan medicinal product designation in the European Union. *Drug Discov Today*. 2018 Mar;23(3):681-686. doi: 10.1016/j.drudis.2017.06.003. Epub 2017 Jun 21. Review. PubMed PMID: 28647377.

8: Farkas AM, Mariz S, Stoyanova-Beninska V, Celis P, Vamvakas S, Larsson K, Sepodes B. Advanced Therapy Medicinal Products for Rare Diseases: State of Play of Incentives Supporting Development in Europe. *Front Med (Lausanne)*. 2017 May 16;4:53. doi: 10.3389/fmed.2017.00053. eCollection 2017. PubMed PMID: 28560211; PubMed Central PMCID: PMC5432638.

9: Direito R, Lima A, Rocha J, Ferreira RB, Mota J, Rebelo P, Fernandes A, Pinto R, Alves P, Bronze R, Sepodes B, Figueira ME. Dyospiros kaki phenolics inhibit colitis and colon cancer cell proliferation, but not gelatinase activities. *J Nutr Biochem*. 2017 Aug;46:100-108. doi: 10.1016/j.jnutbio.2017.03.002. Epub 2017 Mar 30. PubMed PMID: 28494341.

10: Polsinelli B, Tsigkos S, Naumann-Winter F, Mariz S, Sepodes B. Evolving prevalence of haematological malignancies in orphan designation procedures in the European Union. *Orphanet J Rare Dis*. 2017 Jan 21;12(1):17. doi: 10.1186/s13023-017-0567-7. PubMed PMID: 28109318; PubMed Central PMCID: PMC5251220.

11: Figueira ME, Oliveira M, Direito R, Rocha J, Alves P, Serra AT, Duarte C, Bronze R, Fernandes A, Brites D, Freitas M, Fernandes E, Sepodes B. Protective effects of a blueberry extract in acute inflammation and collagen-induced arthritis in the rat. *Biomed Pharmacother*. 2016 Oct;83:1191-1202. doi: 10.1016/j.biopha.2016.08.040. Epub 2016 Aug 20. PubMed PMID: 27551767.

12: Sepodes B. Regulation Of Orphan Medicinal Products In Europe: History Trends And Challenges. *Clin Ther*. 2016 Oct 6;38(10S):e7-e8. doi: 10.1016/j.clinthera.2016.07.101. PubMed PMID: 27673673.

- 13: Mateus V, Rocha J, Alves P, Mota-Filipe H, Sepodes B, Pinto RM. Anti-Inflammatory Effect of Erythropoietin in the TNBS-induced Colitis. *Basic Clin Pharmacol Toxicol*. 2017 Feb;120(2):138-145. doi: 10.1111/bcpt.12663. Epub 2016 Nov 23. PubMed PMID: 27579991.
- 14: Straub V, Balabanov P, Bushby K, Ensini M, Goemans N, De Luca A, Pereda A, Hemmings R, Campion G, Kaye E, Arechavala-Gomez A, Goyenville A, Niks E, Veldhuizen O, Furlong P, Stoyanova-Beninska V, Wood MJ, Johnson A, Mercuri E, Muntoni F, Sepodes B, Haas M, Vroom E, Aartsma-Rus A. Stakeholder cooperation to overcome challenges in orphan medicine development: the example of Duchenne muscular dystrophy. *Lancet Neurol*. 2016 Jul;15(8):882-890. doi: 10.1016/S1474-4422(16)30035-7. Review. PubMed PMID: 27302365.
- 15: Mariz S, Reese JH, Westermark K, Greene L, Goto T, Hoshino T, Llinares-Garcia J, Sepodes B. Worldwide collaboration for orphan drug designation. *Nat Rev Drug Discov*. 2016 Jun 1;15(6):440-1. doi: 10.1038/nrd.2016.80. PubMed PMID: 27245396.
- 16: Morel T, Lhoir A, Picavet E, Mariz S, Sepodes B, Llinares J, Cassiman D. Regulatory watch: The orphan drug pipeline in Europe. *Nat Rev Drug Discov*. 2016 Jun 1;15(6):376. doi: 10.1038/nrd.2016.96. PubMed PMID: 27245390.
- 17: Sousa M, Machado V, Costa R, Figueira ME, Sepodes B, Barata P, Ribeiro L, Soares R. Red Raspberry Phenols Inhibit Angiogenesis: A Morphological and Subcellular Analysis Upon Human Endothelial Cells. *J Cell Biochem*. 2016 Jul;117(7):1604-12. doi: 10.1002/jcb.25452. Epub 2016 Mar 16. PubMed PMID: 26590362.
- 18: Tsigkos S, Mariz S, Llinares J, Fregonese L, Aarum S, Naumann-Winter F, Westermark K, Sepodes B. Erratum to: Establishing medical plausibility in the context of orphan medicines designation in the European Union. *Orphanet J Rare Dis*. 2015 Oct 6;10:129. doi: 10.1186/s13023-015-0309-7. PubMed PMID: 26444545; PubMed Central PMCID: PMC4596420.
- 19: Cardoso FL, Herz J, Fernandes A, Rocha J, Sepodes B, Brito MA, McGavern DB, Brites D. Systemic inflammation in early neonatal mice induces transient and lasting neurodegenerative effects. *J Neuroinflammation*. 2015 Apr 29;12:82. doi: 10.1186/s12974-015-0299-3. PubMed PMID: 25924675; PubMed Central PMCID: PMC4440597.
- 20: Silva S, Sepodes B, Rocha J, Direito R, Fernandes A, Brites D, Freitas M, Fernandes E, Bronze MR, Figueira ME. Protective effects of hydroxytyrosol-supplemented refined olive oil in animal models of acute inflammation and rheumatoid arthritis. *J Nutr Biochem*. 2015 Apr;26(4):360-8. doi: 10.1016/j.jnutbio.2014.11.011. Epub 2014 Dec 30. PubMed PMID: 25620693.
- 21: Tsigkos S, Mariz S, Llinares J, Fregonese L, Aarum S, Naumann-Winter F, Westermark K, Sepodes B. Establishing medical plausibility in the context of orphan medicines designation in the European Union. *Orphanet J Rare Dis*. 2014 Dec 5;9:175. doi: 10.1186/s13023-014-0175-8. Erratum in: *Orphanet J Rare Dis*. 2015;10:129. Frauke, Naumann-Winter [corrected to Naumann-Winter, Frauke]. PubMed

PMID: 25475155; PubMed Central PMCID: PMC4264401.

22: Rocha J, Figueira ME, Barateiro A, Fernandes A, Brites D, Pinto R, Freitas M, Fernandes E, Mota-Filipe H, Sepodes B. Inhibition of glycogen synthase kinase-3 attenuates organ injury and dysfunction associated with liver ischemia-reperfusion and thermal injury in the rat. *Shock*. 2015 Apr;43(4):369-78. doi: 10.1097/SHK.000000000000298. PubMed PMID: 25394244.

23: Figueira ME, Camara MB, Direito R, Rocha J, Serra AT, Duarte CM, Fernandes A, Freitas M, Fernandes E, Marques MC, Bronze MR, Sepodes B. Chemical characterization of a red raspberry fruit extract and evaluation of its pharmacological effects in experimental models of acute inflammation and collagen-induced arthritis. *Food Funct*. 2014 Dec;5(12):3241-51. doi: 10.1039/c4fo00376d. PubMed PMID: 25322288.

24: Rocha J, Eduardo-Figueira M, Barateiro A, Fernandes A, Brites D, Bronze R, Duarte CM, Serra AT, Pinto R, Freitas M, Fernandes E, Silva-Lima B, Mota-Filipe H, Sepodes B. Anti-inflammatory effect of rosmarinic acid and an extract of *Rosmarinus officinalis* in rat models of local and systemic inflammation. *Basic Clin Pharmacol Toxicol*. 2015 May;116(5):398-413. doi: 10.1111/bcpt.12335. Epub 2014 Nov 6. PubMed PMID: 25287116.

25: Rocha J, Eduardo-Figueira M, Barateiro A, Fernandes A, Brites D, Pinto R, Freitas M, Fernandes E, Mota-Filipe H, Sepodes B. Erythropoietin reduces acute lung injury and multiple organ failure/dysfunction associated to a scald-burn inflammatory injury in the rat. *Inflammation*. 2015 Feb;38(1):312-26. doi: 10.1007/s10753-014-0035-7. PubMed PMID: 25270658.

26: Ratilal BO, Arroja MM, Rocha JP, Fernandes AM, Barateiro AP, Brites DM, Pinto RM, Sepodes BM, Mota-Filipe HD. Neuroprotective effects of erythropoietin pretreatment in a rodent model of transient middle cerebral artery occlusion. *J Neurosurg*. 2014 Jul;121(1):55-62. doi: 10.3171/2014.2.JNS132197. Epub 2014 Apr 4. PubMed PMID: 24702327.

27: Tsigkos S, Llinares J, Mariz S, Aarum S, Fregonese L, Dembowska-Baginska B, Elbers R, Evers P, Foltanova T, Lhoir A, Correa-Nunes A, O'Connor D, Voordouw A, Westermark K, Sepodes B. Use of biomarkers in the context of orphan medicines designation in the European Union. *Orphanet J Rare Dis*. 2014 Jan 27;9:13. doi: 10.1186/1750-1172-9-13. PubMed PMID: 24461084; PubMed Central PMCID: PMC3907589.

28: Vaquer G, Riviere F, Mavris M, Bignami F, Llinares-Garcia J, Westermark K, Sepodes B. Animal models for metabolic, neuromuscular and ophthalmological rare diseases. *Nat Rev Drug Discov*. 2013 Apr;12(4):287-305. doi: 10.1038/nrd3831. Epub 2013 Mar 15. Review. PubMed PMID: 23493083.

29: Serra AT, Rocha J, Sepodes B, Matias AA, Feliciano RP, de Carvalho A, Bronze MR, Duarte CM, Figueira ME. Evaluation of cardiovascular protective effect of different apple varieties - Correlation of response with composition. *Food Chem*. 2012 Dec 15;135(4):2378-86. doi: 10.1016/j.foodchem.2012.07.067. Epub 2012 Jul 20. PubMed PMID: 22980816.

30: Brachkova MI, Marques P, Rocha J, Sepodes B, Duarte MA, Pinto JF. Alginate films containing *Lactobacillus plantarum* as wound dressing for prevention of burn infection. *J Hosp Infect.* 2011 Dec;79(4):375-7. doi: 10.1016/j.jhin.2011.09.003. Epub 2011 Oct 13. PubMed PMID: 22000853.

31: Committee for Orphan Medicinal Products and the European Medicines, Westermark K, Holm BB, Soderholm M, Llinares-Garcia J, Riviere F, Aarum S, Butlen-Ducuing F, Tsigkos S, Wilk-Kachlicka A, N'Diamoi C, Borvendeg J, Lyons D, Sepodes B, Bloechl-Daum B, Lhoir A, Todorova M, Kkolos I, Kubackova K, Bosch-Traberg H, Tillmann V, Saano V, Heron E, Elbers R, Siouti M, Eggenhofer J, Salmon P, Clementi M, Krievins D, Matuleviciene A, Metz H, Vincenti AC, Voordouw A, Dembowska-Baginska B, Nunes AC, Saleh FM, Foltanova T, Mozina M, Torrent i Farnell J, Beerman B, Mariz S, Evers MP, Greene L, Thorsteinsson S, Gramstad L, Mavris M, Bignami F, Lorence A, Belorgey C. European regulation on orphan medicinal products: 10 years of experience and future perspectives. *Nat Rev Drug Discov.* 2011 May;10(5):341-9. doi: 10.1038/nrd3445. Review. PubMed PMID: 21532564.

32: Kapoor A, Shintani Y, Collino M, Osuchowski MF, Busch D, Patel NS, Sepodes B, Castiglia S, Fantozzi R, Bishop-Bailey D, Mota-Filipe H, Yaqoob MM, Suzuki K, Bahrami S, Desvergne B, Mitchell JA, Thiernemann C. Protective role of peroxisome proliferator-activated receptor- α in septic shock. *Am J Respir Crit Care Med.* 2010 Dec 15;182(12):1506-15. doi: 10.1164/rccm.201002-0240OC. Epub 2010 Aug 6. PubMed PMID: 20693380.

33: da Silva G, Tanica M, Rocha J, Serrano R, Gomes ET, Sepodes B, Silva O. In vivo anti-inflammatory effect and toxicological screening of *Maytenus heterophylla* and *Maytenus senegalensis* extracts. *Hum Exp Toxicol.* 2011 Jul;30(7):693-700. doi: 10.1177/0960327110379242. Epub 2010 Jul 29. PubMed PMID: 20670987.

34: Maio R, Sepodes B, Patel NS, Thiernemann C, Mota-Filipe H, Costa P. Erythropoietin preserves the integrity and quality of organs for transplantation after cardiac death. *Shock.* 2011 Feb;35(2):126-33. doi: 10.1097/SHK.0b013e3181e83236. PubMed PMID: 20523268.

35: Rauter AP, Martins A, Borges C, Mota-Filipe H, Pinto R, Sepodes B, Justino J. Antihyperglycaemic and protective effects of flavonoids on streptozotocin-induced diabetic rats. *Phytother Res.* 2010 Jun;24 Suppl 2:S133-8. doi: 10.1002/ptr.3017. Erratum in: *Phytother Res.* 2010 Jun;24 Suppl 2:S233-4. PubMed PMID: 20309949.

36: Milsom AB, Patel NS, Mazzon E, Tripatara P, Storey A, Mota-Filipe H, Sepodes B, Webb AJ, Cuzzocrea S, Hobbs AJ, Thiernemann C, Ahluwalia A. Role for endothelial nitric oxide synthase in nitrite-induced protection against renal ischemia-reperfusion injury in mice. *Nitric Oxide.* 2010 Feb 15;22(2):141-8. doi: 10.1016/j.niox.2009.10.010. Epub 2009 Nov 3. PubMed PMID: 19892029.

37: Tripatara P, Patel NS, Brancaleone V, Renshaw D, Rocha J, Sepodes B, Mota-Filipe H, Perretti M, Thiernemann C. Characterisation of cystathionine gamma-lyase/hydrogen sulphide pathway in ischaemia/reperfusion injury of the mouse kidney: an in vivo study. *Eur J Pharmacol.* 2009 Mar 15;606(1-3):205-9. doi:

10.1016/j.ejphar.2009.01.041. Epub 2009 Feb 5. PubMed PMID: 19374832.

38: Bignotto L, Rocha J, Sepodes B, Eduardo-Figueira M, Pinto R, Chaud M, de Carvalho J, Moreno H Jr, Mota-Filipe H. Anti-inflammatory effect of lycopene on carrageenan-induced paw oedema and hepatic ischaemia-reperfusion in the rat. *Br J Nutr.* 2009 Jul;102(1):126-33. doi: 10.1017/S0007114508137886. Epub 2009 Feb 10. PubMed PMID: 19203414.

39: Teixeira de Lemos E, Reis F, Baptista S, Pinto R, Sepodes B, Vala H, Rocha-Pereira P, Correia da Silva G, Teixeira N, Silva AS, Carvalho L, Teixeira F, Das UN. Exercise training decreases proinflammatory profile in Zucker diabetic (type 2) fatty rats. *Nutrition.* 2009 Mar;25(3):330-9. doi: 10.1016/j.nut.2008.08.014. Epub 2008 Dec 5. PubMed PMID: 19062255.

40: Brines M, Patel NS, Villa P, Brines C, Mennini T, De Paola M, Erbayraktar Z, Erbayraktar S, Sepodes B, Thiemermann C, Ghezzi P, Yamin M, Hand CC, Xie QW, Coleman T, Cerami A. Nonerythropoietic, tissue-protective peptides derived from the tertiary structure of erythropoietin. *Proc Natl Acad Sci U S A.* 2008 Aug 5;105(31):10925-30. doi: 10.1073/pnas.0805594105. Epub 2008 Aug 1. PubMed PMID: 18676614; PubMed Central PMCID: PMC2504825.

41: de Lemos ET, Reis F, Baptista S, Pinto R, Sepodes B, Vala H, Rocha-Pereira P, Silva AS, Teixeira F. Exercise training is associated with improved levels of C-reactive protein and adiponectin in ZDF (type 2) diabetic rats. *Med Sci Monit.* 2007 Aug;13(8):BR168-74. PubMed PMID: 17660720.

42: Maio R, Sepodes B, Figueiredo N, Pinto R, McDonald M, Thiemermann C, Costa P, Mota-Filipe H. Effects of diethyldithiocarbamate (DETC) on liver injury induced by ischemia-reperfusion in rats. *Transplant Proc.* 2007 Mar;39(2):365-8. PubMed PMID: 17362731.

43: Sepodes B, Maio R, Pinto R, Sharples E, Oliveira P, McDonald M, Yaqoob M, Thiemermann C, Mota-Filipe H. Recombinant human erythropoietin protects the liver from hepatic ischemia-reperfusion injury in the rat. *Transpl Int.* 2006 Nov;19(11):919-26. PubMed PMID: 17018128.

44: Murch O, Collin M, Sepodes B, Foster SJ, Mota-Filipe H, Thiemermann C. Lysophosphatidylcholine reduces the organ injury and dysfunction in rodent models of gram-negative and gram-positive shock. *Br J Pharmacol.* 2006 Jul;148(6):769-77. Epub 2006 Jun 5. PubMed PMID: 16751791; PubMed Central PMCID: PMC1617069.

45: Sepodes B, Maio R, Pinto R, Marques C, Mendes-do-Vale J, McDonald MC, Thiemermann C, Mota-Filipe H. Tempol, an intracellular free radical scavenger, reduces liver injury in hepatic ischemia-reperfusion in the rat. *Transplant Proc.* 2004 May;36(4):849-53. PubMed PMID: 15194291.

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Projects

Memberships

Member of the International Federation of Pharmacy (FIP) (Academic Section)

Member of the American Society of Pharmacology and Therapeutics (ASPET).

Member of the Portuguese Board of Pharmacists (Ordem dos Farmaceuticos, Portugal)

National and International Scientific Awards: 15

Most relevant award:

2018 - EURORDIS LEADERSHIP BLACK PEARL AWARD ON RARE DISEASES

Other Relevant Information