Curriculum Vitae

Personal information

Bruno Sepodes

Work experience

1. European Medicines Agency
   - Start date: 2024
   - End date:
   - Position: Chair of the Committee for Medicinal Products for Human Use (CHMP)
   - Activities:
   - Country: Netherlands
2. European Medicines Agency
   - Start date: 2013
   - End date: 2024
   - Position: Member of the Committee for Advanced Therapies (CAT)
   - Activities: CAT member nominated by the Committee for Medicinal Products for Human Use (CHMP)
   - Country: Netherlands
3. European Medicines Agency
   - Start date: 2012
   - End date: 2024
   - Position: Member of the Committee for Medicinal Products for Human Use (CHMP)
   - Activities: Vice_Chairperson, since October 2018 Member nominated for PORTUGAL (PT)
   - Country: Netherlands
4. European Medicines Agency
   - Start date: 2008
   - End date: 2020
   - Position: Member of the Committee of Orphan Medicinal Products (COMP)
   - Activities: 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.
   - Country: Netherlands
5. University of Lisbon _ Faculty of Pharmacy
   - Start date: 2003
   - End date:
   - Position: Full Professor (Pharmacological Sciences)
   - Activities: 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.
   - Country: Portugal
6. INFARMED I.P.
   - Start date: 2005
   - End date:
   - Position: Senior Assessor
   - Activities: Senior Assessor for the Portuguese National Authority for Medicines and Health Products.
   - Country: Portugal
7. INFARMED I.P.
   - Start date: 2010
   - End date:
   - Position: Member of the Evaluation Board of Medicines
   - Activities:
   - Country: Portugal
8. Portuguese National Authority for Animal Health (Direção Geral de Veterinária, DGV)
   - Start date: 2011
   - End date:
   - Position: Non_clinical and Pharmaceutical (Quality) Expert
   - Activities:
   - Country: Portugal
9. European Medicines Agency
   - Start date: 2012
   - End date:
   - Position: Member of the Scientific Coordination Board
   - Activities: 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.
   - Country: Netherlands
10. European Medicines Agency
    - Start date: 2011
    - End date: 2012
    - Position: Member of the Patients and Consumers Working Party
    - Activities: Representative of the Committee of Orphan Medicinal Products at the PCWP.
    - Country: United Kingdom
11. INFARMED I.P. and Ministry of Health
    - Start date: 2005

- End date:
- Position: Portuguese National Formulary of Medicines Working Group
- Activities: Co_Author of all editions published since 2005
- Country: Portugal

Education and training

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

Additional information

Publications

Author of more than 100 publications in Pharmacology, Translational Medicine and Regulatory Sciences, including 96 full papers, alongside with several published abstracts and book chapters. A selection of relevant co-authored full papers published in the last 10 years is presented below.

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Scopus Author ID: 6507271629

ResearcherID: A-4838-2014

Loop profile: 340113

1. Mandslay D, Almeida D, Marques A, Rocha J, Drafi F, Sepodes B, Torre C. Comparative Analysis of Post-Authorization Measures for Advanced Medicinal Products Authorized in the European Union and in the United States of America Between 2009 and 2023. Clin Pharmacol Ther. 2024 Aug 14.
2. Almeida D, Umuhire D, Gonzalez-Quevedo R, António A, Burgos JG, Verpillat P, Bere N, Sepodes B, Torre C. Leveraging patient experience data to guide medicines development, regulation, access decisions and clinical care in the EU. Front Med (Lausanne). 2024 May 23;11:1408636.
3. Buchholz S, Di Meco E, Bałkowiec-Iskra EZ, Sepodes B, Cavaleri M. Generating clinical evidence for treatment and prevention options for long COVID. Nat Med. 2024 Aug;30(8):2109-2110.
4. Cerreta F, Iskra EB, Cupelli A, Sepodes B, Rönnemaa E, Rosa MM, Mayrhofer S, Trauffler M, Torre C, Berntgen M, Vucic K, Bahri P, Koch A, Herdeiro MT, Mirošević Skvrce N, Pallos J, Laslop A. Medicines for an aging population: The EMA perspective and policies. J Am Geriatr Soc. 2024 Sep;72(9):2921-2927.
5. Duarte DM, da Silva Lima MB, Sepodes B. Trends from two decades of orphan designations in paediatric rare neuromuscular diseases. J Neurol Sci. 2024 May 15;460:122989.
6. Bouwman L, Sepodes B, Leufkens H, Torre C. Trends in orphan medicinal products approvals in the European Union between 2010-2022. Orphanet J Rare Dis. 2024 Feb 27;19(1):91.
7. Denkinger M, Knol W, Cherubini A, Simonds A, Lionis C, Lacombe D, Petelos E, McCarthy M, Ouvrard P, Van Kerrebroeck P, Szymański P, Cupelli A, Laslop A, Koch A, Sepodes B, Torre C, Rönnemaa E, Bałkowiec-Iskra E, Herdeiro MT, Rosa MM, Trauffler M, Mirošević Skvrce N, Mayrhofer S, Berntgen M, Silva I, Cerreta F. Inclusion of functional measures and frailty in the development and evaluation of medicines for older adults. Lancet Healthy Longev. 2023 Dec;4(12):e724-e729.
8. Teixeira MM, Borges FC, Ferreira PS, Rocha J, Sepodes B, Torre C. A review of patient-reported outcomes used for regulatory approval of oncology medicinal products in the European Union between 2017 and 2020. Front Med (Lausanne). 2022 Aug 12;9:968272.
9. Sepodes, B., Rocha, J., Batista, J., Figueira, M. E., Dráfi, F., & Torre, C. Implementation and Access to Pre-exposure Prophylaxis for Human Immunodeficiency Virus by Men Who Have Sex With Men in Europe. Frontiers in medicine, 2021, 8, 722247.
10. Amaral, R., Torre, C., Rocha, J., & Sepodes, B. Ebola outbreaks: A stress test of the preparedness of medicines regulatory systems for public health crises. *Drug Discovery Today*. 2021, S1359-6446(21)00329-9.
11. Duarte DM, Beatriz da Silva Lima M, Sepodes B. The translational value of animal models in orphan medicines designations for rare paediatric neurological diseases. Regul Toxicol Pharmacol. 2020

Dec;118:104810.

12. Eichler HG, Cavaleri M, Enzmann H, Scotti F, Sepodes B, Sweeney F, Vamvakas S, Rasi G. Clinical Trials for COVID-19: Can we Better Use the Short Window of Opportunity? Clin Pharmacol Ther. 2020 Oct;108(4):730-733.

13. Sheean ME, Malikova E, Duarte D, Capovilla G, Fregonese L, Hofer MP, Magrelli A, Mariz S, Mendez-Hermida F, Nistico R, Leest T, Sipsas NV, Tsigkos S, Vitezic D, Larsson K, Sepodes B, Stoyanova-Beninska V. Nonclinical data supporting orphan medicinal product designations in the area of rare infectious diseases. Drug Discov Today. 2020 Feb;25(2):274-291.

14. Eichler HG, Koenig F, Arlett P, Enzmann H, Humphreys A, Pétavy F, Schwarzer-Daum B, Sepodes B, Vamvakas S, Rasi G. Are Novel, Nonrandomized Analytic Methods Fit for Decision Making? The Need for Prospective, Controlled, and Transparent Validation. Clin Pharmacol Ther. 2020 Apr;107(4):773-779.

15. O'Connor DJ, Sheean ME, Hofer MP, Tsigkos S, Mariz S, Fregonese L, Larsson K, Hivert V, Westermark K, Naumann-Winter F, Stoyanova-Beninska V, Barišić I, Capovilla G, Magrelli A, Sepodes B. Defining orphan conditions in the context of the European orphan regulation: challenges and evolution. Nat Rev Drug Discov. 2019 Jul;18(7):479-480.

16. Carvalho M, Martins AP, Sepodes B. Hurdles in gene therapy regulatory approval: a retrospective analysis of European Marketing Authorization Applications. Drug Discov Today. 2019 Mar;24(3):823-828.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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 May16; 4:53.

24. 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.

25. Straub V, Balabanov P, Bushby K, Ensini M, Goemans N, De Luca A, Pereda A, Hemmings R, Campion G, Kaye E, Arechavala-Gomeza V, Goyenvalle 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.

26. 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.

27. 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.

28. 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.

29. Tsigkos S, Llinares J, Mariz S, Aarum S, Fregonese L, Dembowska-Baginska B, Elbers R, Evers P, Foltanova T, Lhoir A, Corrêa-Nunes A, O'Connor D, Voordouw A, Westermark K, Sepodes B. Use of biomarkers in the context of orphan medicinesdesignation in the European Union. Orphanet J Rare Dis. 2014 Jan 27;9:13.

30. Vaquer G, Rivière 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.

Projects

Memberships

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

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

Other Relevant Information