europass Curriculum vitae

PERSONAL INFORMATION

Dinah Duarte

WORK EXPERIENCE

April 1999–Present

Non-clinical Assessor at Scientific Evaluation Unit , Directorate for the Evaluation of Medicinal Products - Portuguese Medicines Agency, INFARMED, I.P.

Portuguese Medicines Agency, INFARMED, I.P. – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P (Portugal)

- Head of Scientific Evaluation Unit , Directorate for the Evaluation of Medicinal Products
- COMP member from Portugal, at European Medicines Agency (EMA), since 2015
- COMP Representative in the Steering Group of ENCePP (European Network of Centres for Pharmacoepidemiology & Pharmacovigilance), since 2015
- CHMP alternate member from Portugal, at European Medicines Agency (EMA), 2012-2015
- CHMP Representative in the EMA's group "Human Scientific Committees Working Party With Healthcare Professionals Organisations (HCPWP) ", 2013-2015
- Expert member at the European Medicines Agency (EMA), since 2001

EDUCATION AND TRAINING

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Master of Science Degree

Faculty of Pharmacy, University of Lisbon (Portugal)

MSc

Master of Science Degree in "Regulation and Evaluation of Medicines and Health Products", by the Faculty of Pharmacy, University of Lisbon. Master thesis dissertation developed on the Pharmacotoxicology field and entitle "Non-clinical development of medicines for pediatric use: Relevance of pre-clinic studies in juvenile animals as a model for Human development", with the maximum grade of "Excellent".

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Regulatory Affairs Specialist

Portuguese Pharmaceutical Society (Ordem dos Farmacêuticos), Lisbon (Portugal)

Speciality Title in "Regulatory Affairs" – Specialist nº 76 of the Board of Specialists in Regulatory Affairs

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Hospital Pharmacy Specialist

Portuguese Pharmaceutical Society (Ordem dos Farmacêuticos), Lisbon (Portugal)

Speciality Title in "Hospital Pharmacy" – Specialist nº 378 of the Board of Specialists in Hospital Pharmacy

ADDITIONAL INFORMATION

Expertise

Scientific research

Human medicines evaluation; Pharmacology; Pediatric medicines; Orphan medicines; Regulatory Sciences and Medicines information.

Research and analysis in Regulatory Sciences (Pharmacotoxicology and Paediatrics fields), namely about the relevance of pre-clinic studies in juvenile animals as a model for Human development.

Publications

Books

- Duarte D Medicamentos pediátricos: Regulamentação = Inovação terapêutica? (Paediatric medicines: Regulation = Therapeutic Innovation?). Cap. 11, Direito e os Medicamentos: Vigilância Sanitária (Chapter 11, Law and Drugs: Health Surveillance), Direito do Consumidor e Regulamentação das Práticas Químico-Farmacêuticas. Sociedade Interamericana de Vigilância Sanitária (SIVS), Brasil, September 2011

- Duarte D, Martins J Comercialização de Medicamentos, Rotulagem e Folheto Informativo (Medicines labelling and Package Leaflet), Deontologia e Legislação Farmacêutica, Lidel – Edições Técnicas, Portugal (in press)

Peer Reviewed Articles

- Sheean M, Sepodes B, Duarte D, et al. Nonclinical data supporting orphan medicinal product designations: lessons from rare neurological conditions, Drug Discovery Today vol. 23, Issue 1, 26-48, January 2018

- Kurz X. Duarte D, et al. Strengthening standards and collaboration to support medicines evaluation: Ten years of the European Network of Centres for Pharmacoepidemiology and Parmacovigilance (ENCePP), Pharmacoepidemiology and Drug Safety, 2018

- Duarte D. Use of Juvenile Animal Studies to Support Oncology Medicine Development in Children, Reproductive Toxicology, vol 56, 43rd Annual Conference of the European Teratology Society, 97-104, 15 August 2015
- Duarte D, Silva Lima B. Juvenile animal studies in the development of paediatric medicines: Experience from European medicines and Paediatric Investigation Plans, Birth Defects Research (Part B), vol 92, number 4, 353-358, August 2011
- Duarte D., Fonseca H., Better Medicines in Pediatrics, Acta Pediátrica Portuguesa, vol. 39, nº 1, p. 17-22, Jan-Feb 2008
- Duarte, D., Developing Medicines for Children – Learning from ten years of American PaediatricRegulation, Rev. Lusófona de Ciências e Tec. de Saúde Ano 5, nº1, p.11-23, June 2008
- Duarte D., Medicines for Children – The present reality in the European Union, Rev. Lusófona de Ciências e Tec. de Saúde, Ano 3, nº1, p.9-18, June 2006

Peer Reviewed Abstract

- Duarte D., Silva-Lima B. Nonclinical safety evaluation of anticancer medicines for paediatric population: A role for juvenile animal studies? Reprod Toxicol. September 2011, volume 32, Issue 2, 164:179.
- Duarte D., Silva-Lima B. Juvenile animal studies for the nonclinical safety evaluation of the therapeutic monoclonal antibodies for the paediatric population: Revision of approved medicines in Europe for the last 15 years, Reprod Toxicol. September 2010, volume 20, Issue 2, 220:342.
- Duarte D., Silva-Lima B. On the need for juvenile animal studies in paediatric drugs development: Experience from Paediatric Investigation Plans, Reprod Toxicol. September 2009: 28:126.
- Duarte, D., Contribution to accelerate the Study Phase in the process of Pharmacotherapeutic Follow up in Pediatrics, Rev. Lusófona de Ciências e Tec. de Saúde, Ano 3, nº1, Suplemento I, p. 123, Junho/2006 (Best Poster Award)

Projects

Grants

HOME/2012/ISEC/AG/FINEC/4000003871 – FAKESHARE

Two-year European project of cooperation and intelligence approved by the European Commission, in the framework of the “Prevention of and fight against crime” program. FAKESHARE is finalized to protect the health of citizens from the dangers deriving from the illegal trade of medicines on the web.

National Coordinator of the Portuguese Hub from EATRIS-ERIC: European infrastructure for translational medicine - European Research Infrastructure Consortium, since 2018.

Memberships

Membership of professional / scientific societies

- Member of the Scientific Committee of *Orphanet* Portugal (The portal for rare diseases and orphan drugs), since 2018.

- Member of the Portuguese scientific Evaluation Board of Medicines (Comissão de Avaliação de Medicamentos – CAM) of the Portuguese National Authority of Medicines and Health Products - INFARMED, I.P.
- Member of the Portuguese Pharmacopeia Commission (Comissão da Farmacopeia Portuguesa – CFP) of the Portuguese National Authority of Medicines and Health Products - INFARMED, I.P., 2013-2014.
- Member of the Coordinating Committee for the Treatment of Lysosomal Storage Disorders (Comissão da Comissão Coordenadora do Tratamento das Doenças Lisossomais de Sobrecarga - CCTDLS), of the National Institute of Public Health (INSA), Ministry of Health, since 2013-2016.
- Full membership for Portuguese Pharmaceutical Society (Ordem dos Farmacêuticos)
- Member of the European Teratology Society – ETS
- Member of the European Society of Clinical Pharmacy – ESCP
- Member of the European Society for Paediatric Research – ESPR

- Member of the Portuguese Pediatrics Society (Sociedade Portuguesa de Pediatria) – SPP
- Member of the Board of Specialists in Regulatory Affairs - Portuguese Pharmaceutical Society
- Member of the Board of Specialists in Hospital Pharmacy - Portuguese Pharmaceutical Society
- Member of the Portuguese Society of Hospital Pharmacists – APFH

Other Relevant Information