

PERSONAL INFORMATION **Fatima Ventura**WORK EXPERIENCE

- November 2020- Present **Representative of Infarmed**
General Health Directorate (Portugal)
Representative of Infarmed at the Portuguese NITAG for COVID-19 vaccines: input from regulatory perspectives and status of COVID-19 vaccines and contribution to advice on national recommendations for COVID-19 vaccination
- March 2019- Present **CHMP representative (alternate)**
European Medicines Agency (EMA) - Patients' and Consumer's Working Party (PCWP) (Netherlands)
Liason between CHMP and PCWP
- March 2017- Present **Head of Unit, Medicines Evaluation Department/Scientific Evaluation Unit**
INFARMED National Authority of Medicines and Health Products I.P. (Portugal)
- June 2016- Present **CHMP representative (member)**
European Medicines Agency (EMA) - Healthcare Professional's Working Party (HCPWP) (Netherlands)
Liason between CHMP and HCPWP
- March 2016- Present **CHMP Alternate Member (PT)**
European Medicines Agency (EMA) - Committee for Medicinal Products for Human Use (CHMP) (United Kingdom)
Alternate member from Portugal. Quality assessor in Biological, Biotechnology and Chemical Human Medicines.
- March 2016- Present **Quality Assessor**
INFARMED National Authority of Medicines and Health Products I.P. (Portugal)
Internal quality assessor in Biological, Biotechnology and Chemical Human Medicines under the National, Decentralized, Mutual Recognition, and Centralized Procedures, including Marketing Authorisation Applications, Variations and Renovations; Clinical Trials and Variations to Clinical Trials of Experimental Medicinal Products; BSE/TSE issues in the context of medical devices
- April 2007-February 2016 **Assistant Professor**
Department of Biochemistry and Human Biology, Faculty of Pharmacy, University of Lisbon (Portugal)
 - Teaching Biochemistry
 - Supervision of Degree and Post-Graduated Students (Master and PhD)
- July 2010- Present **Member of the Human Medicines Evaluation Committee (CAM)**
INFARMED National Authority of Medicines and Health Products, IP (Portugal)
 - External quality assessor in Chemical and Biological Human Medicines under the National, Decentralized and Mutual Recognition Procedures, including Marketing Authorisation Applications, Variations and Renovations; Clinical Trials and Variations to Clinical Trials of Experimental Medicinal Products; BSE/TSE issues in the context of medical devices
- July 2007- Present **Researcher**
Research Institute for Medicines (iMed.Ulisboa) Metabolism & Genetics Group, Faculty of Pharmacy, University of Lisbon (Portugal)

- Research in the areas of Molecular and Biochemical Bases of Inborn Errors of Metabolism; Energy Metabolism; Heterologous Expression of Human Proteins involved in lipid metabolism

September 2004-July 2010

Quality Assessor

INFARMED National Authority of Medicines and Health Products, IP (Portugal)

- External quality assessor in Chemical and Biological Human Medicines under the National, Decentralized, Mutual Recognition procedures, including Marketing Authorisation Applications, variations and renovations; Clinical trials and variations of clinical trials of experimental medicinal products; BSE/TSE issues in the context of medical devices

April 2002-March 2007

College / university teaching professional

Department of Biochemistry and Human Biology, Faculty of Pharmacy, University of Lisbon (Portugal)

- Teaching Biochemistry
- Supervision of degree and post-graduated students (Master and PhD)

April 2002-July 2007

Researcher

Molecular Pathogenesis Center Unit of Molecular Biology & Experimental Biopathology Molecular and Biochemical Bases of Inborn Errors of Metabolism, Faculty of Pharmacy, University of Lisbon (Portugal)

- Research in the Biochemical and Molecular Bases of Inborn Errors of Metabolism; Energy metabolism; Heterologous expression of human proteins involved in lipid metabolism

January 2001-April 2002

Coordinator at the Technical-Scientific Evaluation Operational Unit of the Human Medicines Evaluation Department

INFARMED National Authority of Medicines and Health Products, IP (Portugal)

- Management and coordination

2000- 2001

INFARMED's Representative at the Analysis Commission for the Acquisition of Blood Derived Products (2000)

Institute for the Financial and Information Technologies Management of the Health Ministry (IGIF), Health Ministry (Portugal)

- Consultant

2000- 2001

Alternate Portuguese Member at the Biologics Working Party (BWP)

The European Agency for the Evaluation of Medicinal Products (EMA) (United Kingdom)

- Expert

2000- 2000

Portuguese member at the Tradenames Ad-Hoc Review Group of the Committee for Proprietary Medicinal Products (CPMP)

The European Agency for the Evaluation of Medicinal Products (EMA) (United Kingdom)

- Expert

October 1998-March 1999

College / university teaching professional

Instituto Superior de Ciências da Saúde Sul (Portugal)

- Teaching Cell Biology to Pharmaceutical Sciences students

April 1998-August 2001 **Regulatory Affairs at the Medicines Department**
INFARMED National Authority of Medicines and Health Products, IP (Portugal)

- Managements

- All aspects of National, Mutual Recognition and Decentralized Procedures (Present at the monthly meetings of CPMP at EMEA, London)

October 1997-April 1998 **Regulatory Affairs**
SDC Pharma, Lda (Portugal)

- Regulatory Affairs - preparation and submission of marketing authorisation applications of human medicines at INFARMED

EDUCATION AND TRAINING

October 1993-November 1998 **PhD in Pharmacy (Biochemistry)**
Faculty of Pharmacy, University of Lisbon (Portugal)

1993- 1997 **PhD Scholarship from the National Institute for Scientific and Technologic Research**
Metabolism and Genetics Center, Faculty of Pharmacy, University of Lisbon (Portugal)

1994- 1996 **PhD Scholarship from the National Institute for Scientific and Technologic Research**
Academical Medical Centre, University of Amsterdam (Netherlands)

1991- 1993 **Research Fellowship from the National Institute for Scientific Research in the Metabolism and Genetics Center**
Metabolism and Genetics Center, Faculty of Pharmacy, University of Lisbon (Portugal)

1985- 1991 **Degree in Pharmaceutical Sciences (Clinical Chemistry)**
Faculty of Pharmacy, University of Lisbon (Portugal)

November 2018-November 2018 **EU NTC - Quality Assessment training for Clinical Trials**
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (Germany)

November 2018- **Workshop on quality support to accelerated access schemes (i.e. PRIME, Breakthrough Therapies) (webinar)**
European Medicines Agency (United Kingdom)

September 2018- **EMA training on ‘European Legislation on Advanced Therapies’ (webinar)**
European Medicines Agency (United Kingdom)

July 2018- **European Drug Regulation and Advanced Therapies**
Faculty of Pharmacy, University of Porto ()

June 2018- **EU Network Regulatory Awareness Session on Medical devices (webinar)**
European Medicines Agency (United Kingdom)

June 2018- **BSWP webinar training session ‘Basics in Survival Analysis’ (webinar e online)**
European Medicines Agency (United Kingdom)

May 2018-	EMA webinar on regulatory science strategy (webinar) European Medicines Agency (United Kingdom)
March 2018-	EU Network Regulatory awareness session on New Developments in the field of ATMPs (webinar) ()
November 2017-December 2017	The risks of corruption and their prevention INFARMED National Authority for Medicines and Health Products, I.P. (Portugal)
November 2017-	Cibersecurity INFARMED National Authority for Medicines and Health Products, I.P. (Portugal)
October 2017-October 2017	Course on Ethical, Transparency and Corruption Prevention in Public Administration INFARMED National Authority for Medicines and Health Products rodutos de Saúde, I.P. (Portugal)
September 2017-December 2017	Certificate in Public Management (FORGEP) National Institute of Administration - General Department for Qualification of Employers of Public Administration (Portugal)
September 2017-	EU Network Regulatory Awareness Session Navigating through Biosimilar Development (webinar) European Medicines Agency (United Kingdom)
September 2017-	Expert meeting on Adeno Associated Virus (AAV) gene therapy medicinal products (webinar) European Medicines Agency (United Kingdom)
June 2017-June 2017	Quality Working Party training for quality assessors (webinar) EU-NTC/European Medicines Agency (United Kingdom)
June 2017-	EU network regulatory awareness session on Early Access (webinar) European Medicines Agency (United Kingdom)
April 2017-	Orphan Medicines Designation and development in Rare Diseases (webinar) European Medicines Agency (United Kingdom)
March 2017-	Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) joint workshop on personalised medicines European Medicines Agency (United Kingdom)
December 2016-	EMA Workshop on Adaptive pathways (webinar) European Medicines Agency (United Kingdom)
December 2016-	Assessors training on viral safety evaluation of biotechnological medicinal products (webinar) European Medicines Agency (United Kingdom)
November 2016-November 2016	EU-NTC: EU and International Assessor training on Biosimilars EU-NTC/European Medicines Agency (United Kingdom)

November 2016-November 2016	Workshop on scientific and regulatory challenges of genetically modified cell-based cancer immunotherapy products (webinar) European Medicines Agency (United Kingdom)
April 2016-	Orphan designation training for newcomers (webinar) European Medicines Agency (United Kingdom)
February 2014-February 2014	VI SPB Clinical Biochemistry Workshop & V SPDM Post-Graduate Training Course - Peroxisomes and Mitochondria: Players in Cellular Metabolism Faculty of Pharmacy, University of Lisbon (Portugal)
April 2011-April 2011	Training for Advanced Therapy Medicinal Products Assessors European Medicines Agency (EMA) (United Kingdom)
October 2010-October 2010	9th Short Course of the Portuguese Biophysical Society Protein Folding, Misfolding and Disease Biophysics Portuguese Society (Portugal)
June 2009-June 2009	Gene Silencing using RNA interference: lectures and hands-on Life and Health Sciences Research Institute, School of Health Sciences, University of Minho (Portugal)
May 2009-May 2009	Integrated Approaches for the Study of Mitochondrial Dynamics Center for Neurosciences and Cell Biology, University of Coimbra (Portugal)
May 2009-May 2009	International Courses on Toxicology 2009 Mitochondria Between Life and Death Center for Neurosciences and Cell Biology, University of Coimbra (Portugal)
March 2009-March 2009	International Workshop Protein Folding Diseases: From Metabolic Disorders to Neurodegeneration ITQB (Portugal)
March 2007-March 2007	Crystallography of Proteins Faculty of Sciences and Technology, Nova University of Lisbon, Department of Chemistry (Portugal)
March 2010-March 2010	Masterclass on Systems Approaches to Membrane Proteins Institute for Membranes and Systems Biology and the Astbury Centre, University of Leeds (United Kingdom)
June 2006-June 2006	1st International Workshop on Expression, Structure and Function of Membrane Proteins (Italy)
November 2005-November 2005	Post-Graduate Course of Inborn Errors of Metabolism From the Biochemical and Molecular Bases to Clinics, Diagnosis, and Therapeutic Approaches: Mitochondrial Fatty Acid Beta-oxidation Disorders Portuguese Society of Metabolic Disorders, Faculty of Pharmacy, University of Lisbon (Portugal)
September 2005-September 2005	1st ESF and MAX-INF2 Course on Membrane Proteins: The Rocky Road from Gene to Structure ITQB (Portugal)

- July 2005-July 2005 **Post-Graduate Course of Inborn Errors of Metabolism From the Biochemical and Molecular Bases to Clinics, Diagnosis, and Therapeutic Approaches: Organic Acidurias**
Portuguese Society of Metabolic Disorders, Faculty of Pharmacy, University of Lisbon (Portugal)
- May 2005-May 2005 **Post-Graduate Course of Inborn Errors of Metabolism From the Biochemical and Molecular Bases to Clinics, Diagnosis, and Therapeutic Approaches: Defect of Urea Cycle**
Portuguese Society of Metabolic Disorders, Faculty of Pharmacy, University of Lisbon (Portugal)
- May 2005-May 2005 **Second Meeting of the COST Working Group Principles of Membrane Protein Folding and Stability**
IST (Portugal)
- April 2005-April 2005 **Post-Graduate Course of Inborn Errors of Metabolism From the Biochemical and Molecular Bases to Clinics, Diagnosis, and Therapeutic Approaches: Defect of Pyruvate Dehydrogenase**
Portuguese Society of Metabolic Disorders, Faculty of Pharmacy, University of Lisbon ()
- June 2003-June 2003 **International Symposium on Stem Cells and Regenerative**
Faculty of Pharmacy, University of Lisbon ()
- October 2000-October 2000 **Pharmacogenetics and Pharmacogenomics**
Institute Pasteur (France)
- September 2000-September 2000 **IBC's 9th Annual International Conference - Protecting and Exploiting - Utilising biotechnological patents to the full**
IBC (Denmark)
- May 2000-May 2000 **Human TSEs and Plasma Derived Medicinal Products**
The European Agency for the Evaluation of Medicinal Products (EMA) (United Kingdom)
- April 2000-April 2000 **First International Conference on Gene Technology & Skin Gene Therapy**
University of Essen (Germany)
- November 1999-November 1999 **Meeting on the use of pharmacogenetics in drug development**
Agencia Española del Medicamento (Spain)
- October 1999-October 1999 **Development and Clinical Progress of DNA Vaccines**
Paul-Ehrlich-Institut and NIBSC - Paul-Ehrlich-Institut (Germany)
- October 1999-October 1999 **6th Annual EAPPI EPFA - Regulatory Affairs Symposium - Quality & Safety of Plasma Products**
European Association of the Plasma Products Industry (EAPPI) and European Plasma Fractionation Association (EPFA) (France)
- April 1999-April 1999 **Introduction to European Regulatory Affairs**
IIR (United Kingdom)
- February 1999-February 1999 **TSE Perception vs. Reality**
Cambridge Healthtech Institute (United States)

February 1999-February 1999	Blood Safety & Screening Cambridge Healthtech Institute (United States)
October 1998-October 1998	2nd European Course of Pre-Clinical Assessors (Portugal)
May 1998-May 1998	Methodologies in Pharmacovigilance INFARMED (Portugal)
October 1992-October 1992	High Performance Liquid Chromatography Professional Course Faculty of Sciences and Technology, Nova University of Lisbon, Department of Chemistry, Costa da Caparica, Portugal & Toxicology Institute, University of Tübingen , Germany (Portugal)

ADDITIONAL INFORMATION

Expertise	<p>COVID-19 vaccines and therapeutics</p> <p>Quality assessor (chemical, biotechnology products, advance therapy)</p> <p>Rare Diseases - Inborn Errors of Metabolism (expertise in energy and aminoacid metabolism related defects)</p> <p>Recombinant protein expression and engineering</p> <p>Chemical and Pharmacological Chaperones</p>
Publications	<p>20. Souto EB, Silva GF, Dias-Ferreira J, Zielinska A, Ventura F, Durazzo A, Lucarini M, Novellino E, Santini A. Nanopharmaceutics: Part I-Clinical Trials Legislation and Good Manufacturing Practices (GMP) of Nanotherapeutics in the EU. <i>Pharmaceutics</i>. 2020 Feb 11;12(2):146. doi: 10.3390/pharmaceutics12020146.</p> <p>19. Souto EB, Silva GF, Dias-Ferreira J, Zielinska A, Ventura F, Durazzo A, Lucarini M, Novellino E, Santini A. Nanopharmaceutics: Part I-Clinical Trials Legislation and Good Manufacturing Practices (GMP) of Nanotherapeutics in the EU. <i>Pharmaceutics</i>. 2020 Feb 11;12(2):146. doi: 10.3390/pharmaceutics12020146.</p> <p>18. Janeiro P, Jotta R, Ramos R, Florindo C, Ventura FV, Vilarinho L, Tavares de Almeida I, Gaspar A. Follow-up of fatty acid -oxidation disorders in expanded newborn screening era. <i>Eur J Pediatr</i>. 2019 Mar;178(3):387-394. doi: 10.1007/s00431-018-03315-2.</p> <p>17. Pelfrene E, Harvey Allchurch M, Ntamabyaliro N, Nambasa V, Ventura FV, Nagercoil N, Cavaleri M. The European Medicines Agency's scientific opinion on oral fexinidazole for human African trypanosomiasis. <i>PLoS Negl Trop Dis</i>. 2019 Jun 27;13(6):e0007381. doi: 10.1371/journal.pntd.0007381. doi: 10.1371/journal.pntd.0007381.</p> <p>16. Bonito CA, Nunes J, Leandro J, Louro F, Leandro P, Ventura FV, Guedes RC. Unveiling the Pathogenic Molecular Mechanisms of the Most Common Variant (p.K329E) in Medium Acyl-CoA Dehydrogenase Deficiency by in Vitro and in Silico Approaches. <i>Biochemistry</i>. 2016. 55(51):7086-7098. doi: 10.1021/acs.biochem.6b00759.</p> <p>15. Bonito CA, Leandro P, Guedes R, Ventura FV. Insights on Medium-chain acyl-CoA dehydrogenase structure by Molecular Dynamics simulations. <i>Chemical Biology & Drug Design</i>. 2016. doi: 10.1111/cbdd.12755.</p> <p>14. Houten SM, Violante S, Ventura FV, Wanders RJ. The Biochemistry and Physiology of Mitochondrial Fatty Acid ss-Oxidation and Its Genetic Disorders. <i>Annual Review Physiol</i>. 78:23-44, 2016. doi: 10.1146/annurev-physiol-021115-105045.</p> <p>13. Ventura FV, Leandro P, Luz A, Rivera IA, Silva MF, Ramos R, Rocha H, Lopes A, Fonseca H, Gaspar A, Diogo L, Martins E, Leao-Teles E, Vilarinho L, Tavares de Almeida I. Retrospective study of the medium-chain acyl-CoA dehydrogenase deficiency in Portugal. <i>Clinical Genetics</i>. 2014. doi: 10.1111/cge.12227.</p> <p>12. Violante S, Ijlst L, Te Brinke H, Koster J, Tavares de Almeida I, Wanders RJ, Ventura FV, Houten SM. Peroxisomes contribute to the acylcarnitine production when the carnitine shuttle is deficient. <i>Biochimica et Biophys Acta</i>. 1831(9):1467-74, 2013; doi: 10.1016/j.bbapip.2013.06.007.</p> <p>11. Violante S, Ijlst L, Ruiten J, Koster J, van Lenthe H, Duran M, de Almeida IT, Wanders RJ, Houten SM, Ventura FV. Substrate specificity of human carnitine acetyltransferase: Implications for</p>

fatty acid and branched-chain amino acid metabolism. *Biochimica et Biophysica Acta*. 1832(6):773-9, 2013; doi: 10.1016/j.bbadis.2013.02.012.

10. Violante S, IJlst L, Te Brinke H, Tavares de Almeida I, Wanders RJ, Ventura FV, Houten SM. Carnitine palmitoyltransferase 2 and carnitine/acylcarnitine translocase are involved in the mitochondrial synthesis and export of acylcarnitines. *FASEB J*. 27(5):2039-44, 2013; doi: 10.1096/fj.12-216689.

9. Violante S, IJlst L, van Lenthe H, Tavares de Almeida I, Wanders RJ, Ventura FV. Carnitine Palmitoyltransferase 2: New Insights on the Substrate Specificity and Implications for Acylcarnitine Profiling. *Biochimica et Biophysica Acta* 1802: 728-732, 2010. doi:10.1016/j.bbadis.2010.06.002.

8. Ventura FV, Tavares de Almeida I, Wanders RJA. Inhibition of adenine nucleotide transport in rat liver mitochondria by long-chain acyl-coenzyme A ss-oxidation intermediates. *Biochemical and Biophysical Research Communications* 352: 873-878, 2007. doi:10.1016/j.bbrc.2006.11.109.

7. Ventura FV, Ruiter J, IJlst L, Tavares de Almeida I, Wanders RJA. Differential inhibitory effect of long-chain acyl-CoA esters on succinate and glutamate transport into rat liver mitochondria and its possible implications for long-chain fatty acid oxidation defects. *Molecular Genetics and Metabolism* 86: 344-352, 2005. doi:10.1016/j.ymgme.2005.07.030.

6. Ventura FV, Costa CG, Ruiter JPN, Allers P, IJlst L, Tavares de Almeida I, Duran M, Jakobs C, Wanders RJA. Quantitative acylcarnitine profiling of [U-13C]palmitic acid ss-oxidation in human fibroblasts: an improved tool for the diagnosis of fatty acid oxidation defects. *Clinica Chimica Acta* 281: 1-17, 1999. doi:10.1016/S0009-8981(98)00188-0.

5. Ventura FV, Ruiter JPN, IJlst L, Tavares de Almeida I, Wanders RJA. Lactic acidosis in long-chain fatty acid ss-oxidation disorders. *Journal of Inherited Metabolic Disease* 21: 645-654, 1998. doi:10.1023/A:1005480516801.

4. Ventura FV, IJlst L, Ruiter JPN, Ofman R, Costa CG, Jakobs C, Duran M, Tavares de Almeida I, Bieber L, Wanders RJA. Carnitine palmitoyltransferase II specificity towards ss-oxidation intermediates: evidence for a reverse carnitine cycle in mitochondria. *European Journal of Biochemistry* 253: 614-618, 1998. doi:10.1046/j.1432-1327.1998.2530614.x.

3. Ventura FV, Costa CG, IJlst L, Dorland L, Duran M, Jakobs C, Tavares de Almeida I, Bieber L, Wanders RJA. Broad specificity of carnitine palmitoyltransferase II towards long-chain acyl-CoA ss-oxidation intermediates and its practical approach to the synthesis of various long-chain acylcarnitines. *Journal of Inherited Metabolic Disease* 20: 423-426, 1997. doi: 10.1023/A:1005315003913.

2. Ventura FV, Ruiter JPN, IJlst L, Tavares de Almeida I, Wanders RJA. Inhibitory effect of 3-hydroxy acyl-CoAs and other long-chain fatty acid ss-oxidation intermediates in mitochondrial oxidative phosphorylation. *Journal of Inherited Metabolic Disease* 19: 161-164, 1996. doi:10.1007/BF01799419.

1. Ventura FV, Ruiter JPN, IJlst L, Tavares de Almeida I, Wanders RJA. Inhibition of oxidative phosphorylation by palmitoyl-CoA in digitonin permeabilized fibroblasts: implications for long-chain fatty acid ss-oxidation disorders. *Biochimica et Biophysica Acta - Molecular Basis of Disease* 1272: 14-20, 1995. doi:10.1016/0925-4439(95)00064-B

Projects Since 1996 published 19 original communications, in the form of abstract, in Scientific Meetings Proceedings published in International Journals

Since 1992 presented/contributed for 24 oral communications (10 invited) at International (13) and Nacional (10) meetings

Since 1993 published 50 original communications, in the form of panel in various International (34) and Nacional (13) meetings

Memberships

- Understand to treat: Combining in vitro and in silico strategies to explore new therapeutic approaches to the most common mitochondrial fatty acid beta-oxidation disorder (mFAOD)" (PTDC/BIA-BQM/29570/2017) (Principal Investigator)
- Medium-chain Acyl-Coenzyme A Dehydrogenase Deficiency: Functional and Structural Characterization of Mutant Proteins (SPDM; 2010-2011) (Principal Investigator)
- Production of a Stable Form of Human Phenylalanine Hydroxylase: Towards the 3D Structure

Determination (PDTC/QUI/64023/2006; 2009-2012) (Team member)

- Inborn Errors of Metabolism: Aminoacidopathies and Organic Aciduria (PMCT/C/SAU/1540/92; 1992-1994) (Team member)

- Aminoacidopathies: detection and chemical characterization of the Inborn Errors of the Aminoacids' Metabolism (INIC; 1991-1993) (Team member)

Other Relevant Information

The Society for the Study of Inborn Errors of Metabolism (SSIEM) (1995- 1999; 2007-2009; 2013-) Ordem dos Farmaceuticos, Sociedade Farmaceutica Lusitana (Socio n.º L-8271- Seccao Regional de Lisboa) (since 1998)

Portuguese Society of Metabolic Disorders (since 2002)

Biochemistry Portuguese Society (since 2002)

Biophysics Portuguese Society (since 2010)