

Curriculum Vitae

Personal information **João Simões**

Work experience

06/2020 - Present

*Senior Officer - Unit for Interinstitutional and Health System Projects
INFARMED – National Authority of Medicines and Health Products, I.P.
Portugal*

- Management of processes regarding the integrated availability of medicines in the national market, particularly with regard to shortages and marketing cessations. Analysis of the inherent risk of product shortages, classification of impact levels, identification of therapeutic alternatives, investigation of market supply and verification/identification of mitigation strategies.

- Articulation with the different interested entities in the circuit of medicine, such as marketing authorization holders, wholesalers, hospitals and pharmacies. Evaluation of existing supply and marketing information/data for the identification of signals and fragilities that may anticipate potential risks of shortages of medicines. Coordination with other units within INFARMED, I.P. in the context of medicine availability management.

- Oversee the correct use of Infarmed's availability databases and ensure the maintenance of up-to-date information.

- Dissemination of both internal and/or external information regarding availability of process-related data.

06/2019 – 06/2020

*Regulatory Affairs
Portugal*

- Management of proprietary and client-licensed Market Authorizations.

- Regular support to other departments.

- Competencies centered on business development/maintenance and monitoring/follow-up of regulatory processes with clients and/or Authorities.

- Medical devices.

Education and training

10/2020 – 12/2020– Coimbra, Portugal

*13th Postgraduate Course in Pharmacy and Medical Law
Faculty of Law, University of Coimbra, Portugal
Non-degree education*

Part I - Medical Law

Pharmacy, medicine and society

Compounded medicines

Gene therapy

Generic medicines. Biotechnological derived medicines and advanced therapies

Veterinary medicines

Medicine safety; European medicine policies

European Union law and medicine; Animal experimentation

Human experimentation and clinical trials of medicines

Pharmacovigilance

Medical devices, cosmetics, and dietary supplements

Pharmaceutical product patents

Competition law and the pharmaceutical industry;

Pharmaceutical research: conflicts of interest, recruitment, and populations. Ethical dilemmas in drug innovation.

The specific case of personal health data in pharmaceutical research under the GDPR

Economic evaluation of medicines and authorizations for innovative medicines by INFARMED, I.P.

Economic Aspects of the pharmaceutical industry

Part II - Pharmacy Law

Deontology, pharmaceutical ethics, and disciplinary responsibility. Civil liability of the pharmaceutical industry and pharmacists. Criminal liability of the pharmaceutical industry and pharmacists. Labor relations in pharmacy

Legal aspects of the relationship between pharmaceutical industry and community pharmacy with the public and healthcare professionals: drug advertising and support for medical education

The duty of information in pharmaceutical activity: medical prescriptions. Ownership, opening, transfer/takeover and operation of the community pharmacy

Part III - New Technologies

Artificial intelligence, robotics, and health: legal challenges

Nanotechnology

New challenges in pharmacy and medicine

07/2019
Medicine Registration in Brazil
Vita - Regulatory Affairs Consulting
Coimbra, Portugal
Non-degree education

Current overview of the National Health Surveillance Agency (ANVISA)
Key differences between MA processes: European Union | Brazil
Documentation required for granting and renewing medicine registration - RDC No. 200, of December 26, 2017
Challenges and opportunities in the Brazilian market

2013 – 2018
Master's Degree in Pharmaceutical Sciences
Faculty of Pharmacy, University of Coimbra, Portugal
Thesis on "Open Access: a game changer in innovation | Academy, translational research, and unmet therapeutic needs"

Additional information

Publications

Projects

2023 - Present
Collaborator on Joint Action of Shortages – Coordination and Harmonisation of the Existing Systems against Shortages of Medicines (CHESSMEN)

Management (led by Infarmed) of WP2 - Communication, dissemination and exploitation
Collaboration on WP5 – Identifying the root causes of observed shortages of medicines
Collaboration on WP7 - Digital Information Exchange for Monitoring and reporting medicine shortages
Collaboration on WP8 – Reducing the likelihood of medicines shortages via preventive and mitigation measures

2023 - Present
Subject Matter Expert -European Shortage Monitoring Platform
Collaborator as SME on the development of ESMP

Memberships

Other Relevant Information