

ORATEURS / ORADORES / SPEAKERS

MARIA DO CÉU MACHADO

Maria do Céu Machado is President of INFARMED (Portuguese Medicines Agency), Full Professor at the Faculty of Medicine of the University of Lisbon, Member of the National Council for Ethics and Life Sciences, Vice-President of the Portuguese Academy of Medicine, Vice-President of the European Federation of the Academies of Medicine. She was High Commissioner for Health (2006-2011), Clinical director of Centro Hospitalar Lisboa Norte (2013-2014) e Hospital Fernando Fonseca (2005-2006). Head of the Department of Pediatrics - Hospital Santa Maria, President of the General Council –Évora University (2010-2012), President of the National Committee for Children and Adolescent Health. She published 160 papers, 4 books and 663 scientific lectures/presentations.

Awarded with the Merit Order Grand Official by the President of the Portuguese Republic (2010) and Gold Medal by the Minister of Health (2012).



YVES JUILLET

Dr. Yves Juillet is currently Secretary General of the Foundation of the French Academy of Medicine. He is also Senior Vice-President Industrie Santé. He is a Member of the Académie Nationale de Médecine and Honorary President of the French Académie Nationale de Pharmacie (2013). Medical Doctor (University of Paris 1975), he is a specialist in internal medicine, cardiology and pharmacology.

He is the author of 150 publications in cardiology, pharmacology, regulatory and pharmacovigilance.

He was Senior Advisor to the president of LEEM (the Association of Pharmaceutical Companies in France), Director of Public Affairs of Aventis, Director of Pharmaceutical and Public Affairs of Hoechst Marion Roussel, Inspector General of Roussel Uclaf, Vice President for Licensing, Medical and Regulatory Affairs of the Jouveinal Group, Deputy Managing Director and Director of Scientific and Technical Affairs of SNIP (French Manufacturers Association). Dr. Juillet was a Member of the official Registration Committee (AMM), Transparency and Post Marketing Committees of the French Health Ministry, where he represented Industry. He was Chair of the EFPIA Scientific Technical and Regulatory Policy Committee (1991-2002). He was also the Chairman of the IFPMA Regulatory Policy and Technical Standards Committee (2004-2011). During 1996-2006 he was Member of the ICH Steering Committee representing European industry and used to be the Co-Chair of the ICH Global Cooperation Group. He was President of the Board of DIA (2012-2013), first President of DIA coming from Europe and was a member of the DIA Advisory Council for Europe, Middle East and Africa, DIA Member since 1990 and DIA Honorary Fellow.



MARIE-PAULE SERRE

Marie-Paule Serre has a University background in law and graduated from the National School of Public Administration. She started her professional pathway as head of department at the Medicine Directorate of the French Ministry of Health, and acted as head of unit of regional and local financial policies at the French Home Office. After 12 years in Government bodies, she joined the pharmaceutical industry, in charge of Market Access and Public Affairs at Pierre Fabre Laboratories for 6 years, and was member of the board of directors at Bouchara Recordati during the next 6 years. In the meantime, she was a member of the board of Leem (pharmaceutical industry association) and chairperson of its legal and fiscal committee. In 2006, she was appointed as a University professor at Pierre et Marie Curie-Sorbonne University, and chaired the Health Marketing Master department for 10 years. Her teaching specialization was the interactions between the healthcare systems and the regulation of health products. Currently, she gives courses in various executive programs, and is a consultant on related topics. She is a member of the Ethic Committee of Leem and member of the board of a non-profit organization managing social and medical services for precarious persons. She is a member of the French Academy of Pharmacy since 2014. She was granted the distinctions of Chevalier de la Légion d'honneur and Officier dans l'Ordre National du Mérite.



ANA PAULA MARTINS

Ana Paula Martins is the President of the Portuguese Pharmaceutical Society since 2016. She graduated in Pharmaceutical Sciences by University of Lisbon Faculty of Pharmacy in 1990. She also holds a Master Degree in Epidemiology by the New University of Lisbon Faculty of Medical Sciences (1995) and a PhD in Clinical Pharmacy by the University of Lisbon Faculty of Pharmacy (2005), where she is currently Assistant Professor at the Department of Social Pharmacy. Her activity as researcher is presently done under iMED.UL [University of Lisbon Medicines Research Institute] in the fields of Pharmacoepidemiology and Social Pharmacy. Previously, she was Institutional Relations Director for ANF (Portuguese National Association of Pharmacies) (2014-2015), External Affairs and Market Access Direct at MSD Portugal (2006-2014), Director of the Centre for Pharmacoepidemiology Studies of ANF (1994-2006) and Secretary General of the Portuguese Pharmaceutical Society (1989-1992). In the public service, Ana Paula Martins was Advisor to the Minister of Education and to the Minister of Parliamentary Affairs Attached to the Prime-Minister (1992-1994), where she held responsibility over the National Program to Fight Drug Addiction and the Schools Health Promotion Program. Since March 2015, by appointment of the Portuguese Parliament, she is an alternate member at the National Council for Bioethics.



PROGRAMME / PROGRAMA / PROGRAMME



Académie nationale
de Pharmacie

REUNIÃO À LISBONNE

16 février 2018
Ordre des Pharmaciens du Portugal

REUNIÃO EM LISBOA

16 fevereiro 2018
Ordem dos Farmacêuticos

MEETING IN LISBON

February 16th, 2018
Portuguese Pharmaceutical Society

15:30

OUVERTURE

ABERTURA

OPENING

Agostinho Franklim Marques

Rui Santos Ivo

Agnès Artiges

Yves Juillet

16:00 – 17:00

LES NOUVEAUX ENJEUX DE LA SÉCURITÉ ET DU RISQUE DES MÉDICAMENTS

AS NOVAS QUESTÕES DA SEGURANÇA E RISCO DOS MEDICAMENTOS

THE NEW QUESTIONS ON THE SAFETY AND RISK OF MEDICINES

Rui Santos Ivo (modérateur | moderador | moderator)

Agnès Artiges (modérateur | moderador | moderator)

Véronique Lamarque-Garnier

Francisco Batel Marques

17:00 – 18:00

LES DÉFIS DU SYSTÈME EUROPÉEN AU SUJET DE L'ÉVALUATION ET SUPERVISION DES MÉDICAMENTS

OS DESAFIOS DO SISTEMA EUROPEU NA AVALIAÇÃO E SUPERVISÃO DOS MEDICAMENTOS

THE CHALLENGES OF THE EUROPEAN SYSTEM FOR THE EVALUATION AND SUPERVISION OF MEDICINES

José Aranda da Silva (modérateur | moderador | moderator)

Jean-Loup Parier (modérateur | moderador | moderator)

Georges France

Bruno Sepodes

18:00 – 19:00

LES BESOINS DES SYSTÈMES DE SANTÉ: DE L'EFFICACITÉ A L'EFFECTIVITÉ

AS NECESSIDADES DOS SISTEMAS DE SAÚDE: DA EFICÁCIA À EFECTIVIDADE

THE NEEDS OF THE HEALTH SYSTEMS: FROM EFFICACY TO EFFECTIVITY

Maria do Céu Machado (modérateur | moderador | moderator)

Yves Juillet (modérateur | moderador | moderator)

Marie Paule Serre

Ana Paula Martins

19:00

CLÔTURE

ENCERRAMENTO

CLOSING

Ana Paula Martins

Jean-Loup Parier

Vincent Brignol

José Aranda da Siva

Apoio:

INSTITUT
FRANÇAIS
Portugal

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RUI SANTOS IVO

Rui Santos Ivo is currently Vice-President of INFARMED – National Authority of Medicines and Health Products, I.P., since January 2016. Member of the Management Board of the EMA since March 2016. He is also an Invited Assistant Professor of Medicines Regulation, at the University of Lisbon Faculty of Pharmacy, where he is a member of the School Council. Previously he was President (2014/2016) and Vice-President (2011/2014) of the Central Administration of the Health System (ACSS,IP) at the Ministry of Health, in Portugal. In 1993 he joined INFARMED, where he held various responsibilities, namely vice-president (1994-2000) and President (2002-2005). In 2000 and 2002 he worked as Administrator at the Directorate of the European Medicines Agency (EMA), and in 2006 and 2008 he worked for the European Commission as Administrator at the Pharmaceuticals Unit, Directorate General for Enterprise and Industry, in Brussels.

He was a member of the Management Board of the EMA (2002/2005) and the first Chairman of the European Union Heads of Medicines Agencies Management Group (2004-2005).

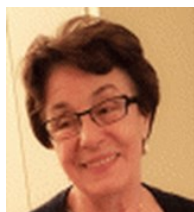
Rui Santos Ivo graduated in Pharmaceutical Sciences by the University of Lisbon in 1987. Specialist in Hospital Pharmacy (1992) and Pharmaceutical Regulation by the Portuguese Pharmaceutical Society (1997). Post graduate education on Health Law and Pharmaceutical Legislation (University of Lisbon Faculty of Law and National School of Public Health), Pharmaceutical Medicine (University of Basel), Regulation (London School of Economics and Political Science) and Health Management (Portuguese Catholic University (2000) and AESE (2015)).

Almofariz Prize, Personality of the Year in the Pharmaceutical Sector (2004), European Correspondent Member, Académie Nationale de Pharmacie, France (2014) and Medal (gold) for distinguished Services, Ministry of Health (2015).



AGNÈS ARTIGES

Dr. Agnès Artiges graduated in Pharmacy and has a Doctorate in Pharmacy as well as a Degree and Doctorate in Law the latter, for the University of Paris. Dr. A. Artiges was Assistant and Assistant Instructor in the Toxicology Laboratory of the Faculty of Pharmacy of Bordeaux before joining the French Ministry of Health in 1971. During her career with the Ministry, she has held the posts of Head of the French Pharmacopeia, Head of the Registration Authority for Medicinal Products for Human Use and Head of the Sub-directorate of Scientific and Technical Affairs. In addition, Dr. A. Artiges was Chairperson of the European Pharmacopeia Commission from November 1989 to November 1992, and a Member of the Quality Working Party of the Committee for Proprietary Medicinal Products (CPMP) of the EC (Chairman of this Working Party from December 1991 to March 1993). Dr. A. Artiges left the French Ministry of Health in April 1993 to take up the post of Director of the European Pharmacopeia (Council of Europe). In 1996, Director of the European Directorate for the Quality of Medicines and Health Care (Council of Europe). Member of the French "Académie nationale de Pharmacie" in 1990, she is currently "Secrétaire Perpétuelle" (Executive Director) since 2011.



VERONIQUE LAMARQUE-GARNIER

Véronique Lamarque-Garnier is medical doctor, PhD in pharmacology. After starting her career at the hospital in clinical pharmacology and pharmacovigilance, she held various medical positions in the pharmaceutical industry, both in France and at the International, focusing on risk management and Pharmacovigilance. In September 2011, she created "Eval'Santé", a consulting company in strategy and organization dedicated to the evaluation and risk management of pharmaceutical Products. She is a teacher in professional Masters, a board member of the French Society of Pharmacology and Therapeutics and a permanent member of the National Academy of Pharmacy.



FRANCISCO BATEL MARQUES

Francisco Batel Marques has a Pharmaceutical Sciences degree from the University of Coimbra since 1985 and holds a PhD from the Welsh School of Pharmacy, Cardiff, UK since 1994. He is an Associate Professor in the School of Pharmacy, University of Coimbra, Portugal. He is also the Director of the Centre for Health Technology Assessment and Drug Research of AIBILI, Coimbra, Portugal and Coordinator of the Coimbra Pharmacovigilance Centre. Formerly he was Director of the Division of Health Economics, INFARMED (Portuguese Medicines Regulatory Agency). He has authored over 40 full text publications in international peer-reviewed scientific journals.



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JOSÉ ARANDA DA SILVA

José Aranda da Silva is a Doctor Honoris Causa (University of Porto, 2017), and graduated in Pharmacy in 1972. Until 2001 he was Colonel of the Portuguese Army – Health Service.

He is an expert in Pharmaceutical Industry (1989), Hospital Pharmacy (1989) and Pharmaceutical Registration and Regulation (1998). José Aranda da Silva during 2000-2001 was Director of the Military Laboratory of Chemical and Pharmaceutical Products. He is also a Guest assistant lecture at the Faculty of Pharmacy of the University of Lisbon, Guest lecture in several masters and postgraduate courses. Since 2000 until 2005 he was Regent of the Clinical Pharmacy discipline at ISCTEM (Maputo). He was Regent of the Pharmacy Clinic discipline at the Faculty of Pharmacy of Lisbon, and between 1985 and 1990 Guest Assistant of the Faculty of Pharmacy of Lisbon. José Aranda da Silva is since 2009 Director of Revista Portuguesa de Farmacoterapia, and Consultant in health and medicines policy and regulation. He was President of the Portuguese Pharmaceutical Society (2001-2007), and from 1994 to 2000 he was Member of Management Board of the European Agency of Medicines Evaluation. From 1993 to 2000 he was President of the Management Board of INFARMED. From 1996 to 2000 he was Member of Consultative Council of the Action Programme of Essential Drugs (Genebra/WHO), and in 1991-1993 was Portuguese Delegate in the Committee of Proprietary Medicinal Products – CPMP – European Union. He is a member of a number of Scientific and Professional Societies and Associations, namely the International Pharmaceutical Federation, the National Academy of Pharmacy of France, among others. José Aranda da Silva published several books and is author and co-author of over 70 published papers. He has also been awarded in various occasions, namely the Medal of Military Merit 1st Class (1998), the "Almofariz" Prize Figure of the Year (2000) and Distinguished Service Gold Medal of the Ministry of Health (2012).



JEAN-LOUP PARIER

Jean-Loup Parier is a corresponding member of the Académie nationale de Pharmacie since 1989, international corresponding member (1991-2001) and a Full member since 2006. He was Session secretary since 2010. He performed duties of 4th département Président (Pharmaceutical and juridical sciences applied to industrial environment and drugs) from 2013 to 2016. He holds Pharmacy Diploma from 1968 and graduated as a Medical doctor in 1975, and completed his PhD in 1983. He performed various Hospital and University activities: interne des hôpitaux de Paris (pharmacy); hospital resident, hospital consultant (medicine); Medicine University Assistant (histology), CHU St-Antoine. He was a responsible pharmacist (1969-1970), a medical doctor for the french community (Tokyo), and held positions in the Research & Development (1976-2009) at Ipsen (Bottu, Bellon, France); RPR (Japan, Australia, USA); J&J (USA), Boehringer (France) and Regulatory Affairs at RPR (Australia 1993-1995), Responsible pharmacist at Boehringer (France 2001-2009). He is author of scientific publications and communications: 23 publications, 4 books (co-author), 17 communications, 3 scientific short movies.



GEORGES L. FRANCE

Georges France is Vice President and Global Quality Lead for the Local Operating Company at GSK Consumer Healthcare. Previously Georges was Global in-Country Quality Head at Novartis OTC and head of Quality Strategy for Novartis corporate. He worked at Pfizer as a Vice President of Global Quality Strategy and Global Affiliates Quality. In 2005, Georges became Vice President, Quality and Compliance in Europe, Middle East and Africa. Member of "L'Académie Française de Pharmacie", Georges holds a Doctorate in Pharmacy and a post-graduate degree in Pharmacology and completed the INSEAD Advanced Management Program. He was EPFIA topic leader in the Expert working Group for the ICH Q10-EWG (Pharmaceutical Quality System) guidelines as the ICH Q8, Q9 and Q10 Implementation Working Group (IWG). Today he is an EPFIA Expert for ICH Q12. Georges is a active member of ISPE, PDA & DIA and had a lot of opportunity to share about Quality System.



BRUNO SEPODES

Bruno Sepodes is a PharmD, holds a MSc in Regulatory Sciences and holds a PhD in Pharmacy by the University of Lisbon (Portugal). He is currently pursuing the Master of Public Health at the Bloomberg School of Public Health of the Johns Hopkins University (USA). Bruno Sepodes is an Assistant Professor at the School of Pharmacy of the University of Lisbon, lecturing several courses in Pharmacology and Pharmacotherapy and developing his research in Pharmacology and Translational Medicine. Presently Bruno Sepodes is the Chair of the Committee for Orphan Medicinal Products (COMP) and member of the Committee of Human Medicinal Products (CHMP) at the European Medicines Agency in London. Bruno Sepodes is an expert for the National Medicines Authority (INFARMED) and for the Veterinary General Directorate (DGV). Author and co-author of more than 70 scientific publications in international journals, and 90 scientific, presented to national and international scientific meetings. Bruno Sepodes was awarded the 2016 EURORDIS Black Pearl Leadership Award, an award that acknowledges the outstanding achievements and exceptional work of people making a difference for the rare disease community, attributed as a recognition of his commitment to involve patient advocates in all discussions and decisions related to orphan medicines.

