

Under the auspices of:

Ministero della Salute


Ministero dello Sviluppo Economico


Agenzia Italiana del Fisco
AIFA

ISTITUTO
SUPERIORE
DI SANITÀ



SECOND WORKSHOP ON DRUG PRICING

SCIENTIFIC BOARD

Prof. Pier Luigi Canonico
Prof. Armando Genazzani
Prof. Claudio Jommi

ROME
APRIL 28th | 29th 2016

VOI Donna Camilla Savelli Hotel
via Garibaldi 27



OBJECTIVE

Organising a multi-stakeholders working table dealing with current and future issues related to drugs pricing, focusing on the assessment and the appraisal of innovativeness.

TOPICS



DEFINITION OF INNOVATION, INCREMENTAL INNOVATION AND ADDED THERAPEUTIC VALUE

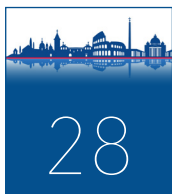


NEW SCENARIOS IN DRUG PRICING AND REIMBURSEMENT IN ITALY



COMBO-THERAPIES





APRIL 28th, 2016

14.30 Registration

15.00 Introduction
Pier Luigi Canonico
Armando Genazzani
Claudio Jommi

SESSION I **INNOVATION AND ADDED THERAPEUTIC VALUE**

Chairpersons: **Armando Genazzani**
Claudio Jommi

15.15 The European framework on added therapeutic value and the effects on P&R decisions
Philippe Van Wilder

15.45 Added therapeutic value: towards minimum clinical benefit?
Alberto Sobrero

16.15 Multiple decision criteria analysis: the results of the ISPOR Taskforce
Maarten J. IJzerman

16.45 *Coffee break*

17.00 Innovation besides added therapeutic value
Francesca Patarnello

17.30 Funding innovative drugs: what solutions?
Paolo Bonaretti

18.00 Discussion





APRIL 29th, 2016

09.30 *Lecture*
The challenge of sustainability
Nello Martini

SESSION II **NEW SCENARIOS IN DRUG PRICING AND REIMBURSEMENT IN ITALY**

Chairperson: **Pier Luigi Canonico**

10.00 Innovation, pricing and reimbursement: the Italian experience
Agnese Cangini

10.30 Combo-therapies challenges: management and technical
options for their management
Giovanni Giuliani

11.00 *Coffee Break*

11.15 AIFA registries: future role and management issues
National perspective
Entela Xoxi
Regional application
Alessandra Mecozzi

12.00 Alternative Pricing Models for Innovative Drugs
Guido Didoni

12.30 Discussion

13.00 Market Access Award prize-giving ceremony
Pier Luigi Canonico
Antonio Gaudio
Armando Genazzani
Claudio Jommi
Walter Ricciardi

13.30 Conclusions



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PIER LUIGI CANONICO

*PROFESSOR OF PHARMACOLOGY,
PIEMONTE ORIENTALE UNIVERSITY*

Pier Luigi Canonico, MD and Specialist in Endocrinology and Metabolic Diseases, became Full Professor of Pharmacology at the Faculty of Medicine and Surgery at the University of Pavia in 1990; in 1999 he moved as Professor of Pharmacology and Pharmacotherapy at the Faculty of Pharmacy of the Università del Piemonte Orientale University in Novara. He was Chairman of the Department of Chemical, Nutritional, Pharmaceutical and Pharmacological Sciences (DISCAFF) from 2000 to 2008, Vice Dean of the Faculty from 2008 to 2009 and Dean from 2009 to 2011, Member of the Board of Directors of the University (2000-2001); actually he is also Member of the Senato Accademico (since 2002). From 2012 Prof. Canonico is Chairman and Dean of the Department of Pharmaceutical Sciences. He was the CEIMS Director from 2012 to 2013, and CEIMS Member of the Board since 2014.

Professor Canonico is member of several national and international scientific societies: among these, the Italian Society of Pharmacology (Councilor for 10 years and President from 2011 to 2013) and the Italian Society of Neuropsychopharmacology (member of the Council since 2006). Among his extra-academic assignments, Member of the Commissione Unica del Farmaco (CUF) (Commission for Drug Approval and Reimbursement) of the Italian Ministry of Health (2001-2003), Vice-president of the Ethical Committee of the Institute for Neurological Research Casimiro Mondino (2006-2010), Member of the Scientific Group for Innovative Pharmacology (Biological Drugs) of the Presidenza del Consiglio dei Ministri (2008-2010), Member of the Regional Committee for the Organization of the Regional Network for Pain Therapy (Regione Piemonte). He is a Member of the Scientific Board of CeSBio and ISPOR Italy Rome Chapter Director.

Prof. Canonico research includes several areas in the field of neuropsychopharmacology, neuroendocrinology, neurobiology, cancer therapy, pharmacogenetics/genomics and issues concerning biotechnology drugs. He is the author of over 200 publications on international journals.



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ARMANDO GENAZZANI

*PROFESSOR OF PHARMACOLOGY,
PIEMONTE ORIENTALE UNIVERSITY*

Graduated in Medicine and Surgery at the University of Catania in 1992. He then spent several years in Oxford, Zurich and Cambridge, working mainly on Ca²⁺-signalling and signal transduction in health and disease. In Cambridge, he was appointed University Lecturer at the Department of pharmacology and Official Fellow of Clare Hall.

Since 2003 he is Professor of Pharmacology at the Piemonte Orientale University, and was appointed full professor in 2011. His research still focuses on the role of signal transduction in health and disease, including Alzheimer's disease and oncological diseases, as well as on pharmacogenetics. He has authored over 130 publications on international journals.

He also also grown an interest in scientific, regulatory and market access-related issues in the pharmaceutical sector. In this area, along with Professor Canonico and Professor Jommi, organizes a Master in "Regulatory Disciplines and Market Access" at the Department of Pharmaceutical Sciences at Novara, is an expert since 2013 of the WHO "International non-proprietary names committee" and has been vice-chair for biologicals at the 62nd consultation, and is a member of the "Commissione Tecnico-Scientifica" of the Italian Medicines Agency since 2005.

From 2013 to 2015 is was an elected member of the board of the Italian Society of Pharmacology.



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CLAUDIO JOMMI

*ASSOCIATE PROFESSOR OF MANAGEMENT AT THE DEPARTMENT OF
PHARMACEUTICAL SCIENCES, PIEMONTE ORIENTALE UNIVERSITY*

Claudio Jommi is Associate Professor of Management at the Department of Pharmaceutical Sciences, University of Novara. He is also Director of the Pharmaceutical Observatory at Cergas (Centre for Research on Health and Social Care Management), Bocconi University, and Professor at Bocconi School of Management, Public Management and Policy Department, where he Coordinates the Specialisation in Pharmaceuticals and Medical Technologies, Master in International Health Management Economics and Policy (Mihmep). He is President of the Italian Health Economics Association.

He has been visiting professor at Essec Business School, Cergy (Paris), at the Herivan K. Haub School of Business, St Joseph University, Philadelphia (USA), at the Andrija School of Public Health, Zagreb and the University of Claude Bernard Lyon 1 (European Market Access University Diploma).

His research activity is focused on Pharmaceutical Economics, Policy and Management, Health Technology Assessment and Decision Making in Health Care.

He has published in many international and national journals, including Drug Design Development and Therapy, European Journal of Health Economics, Health Policy, International Journal of Health Planning and Management, Journal of Medical Marketing, Pharmacoeconomics, PLOS Neglected Diseases, Public Money and Management.



FACULTY



PAOLO BONARETTI

ASTER GENERAL MANAGER

Since 1992 to the present, General Director of ASTER S. Cons. p. A. (the Consortium including Emilia-Romagna regional administration, the Universities located in the regional territory, CNR, ENEA, working in collaboration with the industrial associations).

Since September 2015 to the present President of E35 Foundation, the Foundation for the International Planning of the Chamber of Commerce of Reggio Emilia, Italy.

Since May 2013 Councillor for the Industrial Policies of the Cabinet of the Ministry of Economic Development, and since 2008 to 2010 Member of the Panel of Experts of Industrial Policy of the Ministry.

Since 2015 Coordinator of the Pharmaceutical Working Table of the Ministry of Economic Development, and of its related Working Groups.

Coordinator of the S3 - Smart Specialization Strategy "Food, Health and Quality of Life" Working Group of the Italian Premiership

Since January 2014 Deputy President of Ecolabel Ecoaudit Committee of the Ministry of Environment and President of the EMAS Section.

Since February 2015 to date Referent for Enterprise Europe Network Italy for relations with national Institutions. Since 2011 to 2014, official spokesman of SAG - Steering Advisory Group (Italy) of Enterprise Europe Network, and since the end of 2009 appointment as the Italian representative for the year 2010 within the SAG of the Enterprise Europe Network.

In December 2011, I was appointed member of the Scientific Committee of Bologna Metropolitan Strategic Plan and Manager of the Innovation and Development Board.

Since 2004 to the present President of SPINNER - consortium for the promotion of innovation and research Executive roles in CRS4 srl, I TECH OFF, the Incubator and Consortium for a new hi-tech companies' entrepreneurs, and DEMOCENTER. Expert auditor of the European Commission - DG Research, and tutor of the Ministry of University and Research for the National Operational Programme of Scientific and Technological Research.

Since 2008 to 2013 Member of the Advisory Board of the TTVenture - Fondamenta SGR fund, the first private equity fund in Italy.



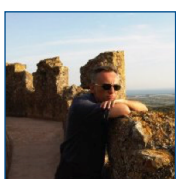
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AGNESE CANGINI

HEALTH ECONOMIST ITALIAN MEDICINES AGENCY (AIFA)

Graduated at University Cattolica del Sacro Cuore in Economy and Management of Health Authorities and Services, Doc. Cangini is a Health Economy at AIFA.



GUIDO DIDONI

VALUE MARKET ACCESS DIRECTOR, MSD

He graduated in Chemical and Pharmaceutical Technology in 1990. He has a strong experience in health economics, outcome research and market access field as health economist manager (2001-2003 Pfizer), outcome research manager (2004-2009 Pfizer), HE & OR Director (Bristol-Myers Squibb 2009-2012). He is the HTA&OR Lead for Merck Italia since 2012 and the Value Health & Regional Access Director for MSD since 2014.



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GIOVANNI GIULIANI

*PAYER EVIDENCE LEADER
ROCHE ITALIA*

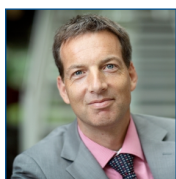
Doc. Giuliani graduated in Economics at Bocconi University (Milan) in 1995 and completed his education in Health Economics during a 2 year research fellowship at CESAV - Center for Health Economics at Mario Negri institute in Bergamo has attended several specialized courses about management skills, communication, presentations, leadership.

He's working in Market Access field since 1999 at Roche, both in Italian and West Europe context, as Pricing Project Manager (F. Hoffmann-La Roche Ltd., Basel), Pricing and Health Economics Oncology/Hematology group coordinator, Regional Strategic Pricing Lead Western Europe, Strategic Pricing and Reimbursement manager. His current position is Payer Evidence Leader (Roche Italy).

During last years he attended several national and international conferences as speaker about HTAs, Innovative Pricing schemes and Market Access and published several papers on National and International journals (Health Policy, Journal of HTA, ClinicoEconomics, Journal of Virology, etc.) about Pharmacoeconomics and Health policies and collaborated on publications about pricing systems, distribution of pharmaceuticals and generics uptake in Europe.



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MAARTEN J. IJZERMAN

*PHD, PROFESSOR, HEALTH TECHNOLOGY & SERVICES RESEARCH
UNIVERSITY OF TWENTE (NL)*

Maarten J. IJzerman is a full professor of clinical epidemiology & HTA at the University of Twente. He is the dean of Health and Biomedical Technology in the School for Science and Technology, responsible for the academic programs in Technical Medicine, Biomedical Engineering and Health Sciences.

Maarten and his team work on methods to evaluate the benefits of diagnostic and imaging technologies for personalized medicine and on the application of outcomes research to evaluate stakeholders' value and the health economic impact of medical technologies in development. Maarten has been actively involved in the initiation of early Health Technology Assessment, Multi-Criteria Decision Analysis and Patient Preference research in ISPOR. More recently he was involved in several initiatives to develop emerging good practices for applying Simulation Modelling in Healthcare Delivery research. Maarten IJzerman has more than 130 peer-reviewed articles in the intersection of engineering, medicine and outcomes research.

Maarten IJzerman serves on numerous national and international committees, including the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). In 2014 and 2015 he served as the chair of the Dutch pharmacoeconomic guidelines committee of Zorginstituut Nederland.



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NELLO MARTINI

*RESEARCH & DEVELOPMENT DIRECTOR
NATIONAL ACADEMY OF MEDICINE*

Degree in Pharmacy and specialized in Clinical Pharmacology.
From 1973 to April 1998 directed the pharmacy of the Policlinico Borgo-Rome in Verona.

From May 1998 to June 2004 he was General Director of Drugs and Medical Devices of the Ministry of Health.

Later held the position of General Director of the Italian Drugs Agency (AIFA) until June 2008, and was a member of the Board of Directors of the EMA.

Currently holds the position of Director of Research and Development of the National Academy of Medicine.

He carried out training courses in France and in the United States and is author of over 150 publications including books and scientific articles.



ALESSANDRA MECOZZI

*REGIONAL DIRECTION OF HEALTH AND SOCIAL POLICIES
ROME*

Graduated at La Sapienza University (Rome) in Pharmacy in 1984, specialisation in Hospital Pharmacy, she is the Director of Prosthetic Assistance Office and Direction of Health and Medico-social Integration for Lazio Region.

She is a Member of Regional Commission for Appropriateness Prescriptions, a Member of Regional Commission for DPC Distribution Agreement, a Member of HIV Regional Working Group, a Member of HCV Regional Working Group, a Member of Haemophilia Regional Working Group and a Member of Lazio Region PTOR Commission.



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FRANCESCA PATARNELLO

VALUE ACCESS & POLICY DIRECTOR
AMGEN

Francesca Patarnello is, since June 2014, Value & Access Director for Amgen, the first company in the world in the field of biotechnology. Comes from GlaxoSmithKline where was Payers and Evidence Solution Director.

Degree in Statistics and Economics, began his career in Farmitalia Carlo Erba, passing successively from Fidia to Glaxo Wellcome (now GlaxoSmithKline). Before moving to the Market Access, plays a number of roles in medical science, including HTA Director and Scientific Director and Quality. Member of several working groups, is currently on the Board of the Research center CesBio of Bocconi University and Piemonte Orientale University for Assobiotech and sits on the Board of Directors of SIHTA (Society of Health Technology Assessment).

He also held a series of academics positions at the University of Bologna, Catania, Novara, Padova and Verona, and is co-author of numerous publications regarding innovation of drugs, on HTA and on market access.



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ALBERTO SOBRERO

*HEAD OF THE MEDICAL ONCOLOGY UNIT, OSPEDALE SAN MARTINO
GENOVA*

Alberto Sobrero has been the Head of the Medical Oncology Unit at Ospedale San Martino in Genova, Italy, since 2001. Before this, he was Associate Professor in Medical Oncology at the University of Florence and Udine.

After receiving his medical degree from the University of Genova in 1978, Prof. Sobrero took up the position of postdoctoral Associate in Medical Oncology at Yale University, Connecticut, USA. In 1983, he became Associate Research Scientist in Medical Oncology at Yale. Before returning to Genova in 1985, he completed a residency in Internal Medicine at the Yale Affiliated Norwalk Hospital.

From 2002 to 2006, Professor Sobrero has been the Chairman of the Protocol Review Committee of the European Organisation for Research and Treatment of Cancer (EORTC) and has been part of the faculty of the ASCO-FECS Clinical Research courses at Flims for 7 years. He has served on the editorial board of the Journal of Clinical Oncology 2004-2006, has been part of the Scientific Committee of ASCO (2007-2008), the Educational Committee of ESMO (2008-2014, Chair of the GI committee 2012-2016) and is the chairman of the ESMO Nominating Committee.

His main research interests include gastrointestinal cancer treatment and design and interpretation of clinical trials in oncology and he is an active member of the Task Force of ESMO for the Evaluation of the Clinical Benefit of new agents.



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PHILIPPE VAN WILDER

*CONSULTANT IN ACCESS TO HEALTH CARE, SMART&BI,
ZAVENTEM (B)*

Graduated in Pharmacist with Industrial Pharmacist specialization, is Doctor in Pharmaceutical Sciences and has collected several professional qualifications in Regression Analysis Economie de la Santé and in statistics applied to clinical research.

He has an extensive pricing & reimbursement experience from the payer perspective in Belgium (Head of Pharmaceutical Reimbursement Department, Internal expert RIZIV/INAMI National Health Insurance Agency 2002 -2009; Pricing & Reimbursement, Market Access Director Europe, TiGenix NV 2010-2012; Director Study & Strategy Department, Independent Sickness Fund, MLOZ, Mutualités Libres / Onafhankelijke Ziekenfondsen, Brussels, 2012 - 2014) and a 4 year EU networking on pricing & reimbursement, involving regular contacts with EU member states and EC staff.

He was a member of 2005-08 European High Level Pharmaceutical Forum working groups on Pricing and Relative Effectiveness. Doc. Van Wilder's focus is on relative effectiveness and cost-effectiveness of innovative medicinal products, on alignment of administrative reimbursement criteria to HTA-outcome and political and legal objectives and He Has development of first 'risk-sharing' pharmaceutical contract between payer and pharmaceutical company in Belgium.

He is Associate Editor to 'Frontiers in Pharmacology', a member of the Belgian Statistical Society (since 1994) and a member of the International Society for Pharmaco-economics and Outcomes Research (ISPOR) since 2003.



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ENTELA XOXI

CO-ORDINATOR AIFA REGISTERS

Doc. Xoxi has a Bachelor's degree Honours (Doctor in Pharmacy), Pharmacology and Toxicology, PhD in Pharmacology and Toxicology, Master's degree, Pharmaceutics and Drug Design and a Master's degree in Health Technology Assessment. She is skilled in post-marketing data collection design and application of Managed Entry Agreements. Currently, is the Co-ordinator of AIFA's Registries and member of Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP).



DATE AND VENUE

Thursday, 28th April 2016 | h. 14.30-18.30

Friday, 29th April 2016 | h. 09.30 - 14.00

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BY TRAIN: From Termini, take the express bus line “H” from the Piazza dei Cinquecento and get off at Trastevere/Ministero della Pubblica Istruzione (the 5th stop). From here you catch another bus, the 125 and alight at the 4th stop, which is Garibaldi/Panieri. The Hotel Donna Camilla Savelli Rome is located at number 27 via Garibaldi, only 100 metres from the bus stop.

BY PLANE: From Leonardo Da Vinci International Airport - Take the train heading for the Trastevere Railway Station. Once you get off take tram number 8 from the tram stop heading for Piazza Argentina and get off at Trastevere/Ministero Pubblica Istruzione. From here, follow the directions as given above.

BY CAR: From the GRA (Grande Raccordo Anulare) - Take the first exit for Aurelia and follow signposts for the city centre. After 2.5km, turn right on to via Aurelia Antica and continue for 4km. Straight ahead on to via di San Pancrazio and take a right on to via Giacinto Carini, about 100m down.

Take the second left on to via Fratelli Bonnet and after 100m, a further right turn on to via Calandrelli. Take a left 150m down on to via Nicola Fabrizi - the end of this street finds you on via Garibaldi. Turn right to find number 27.

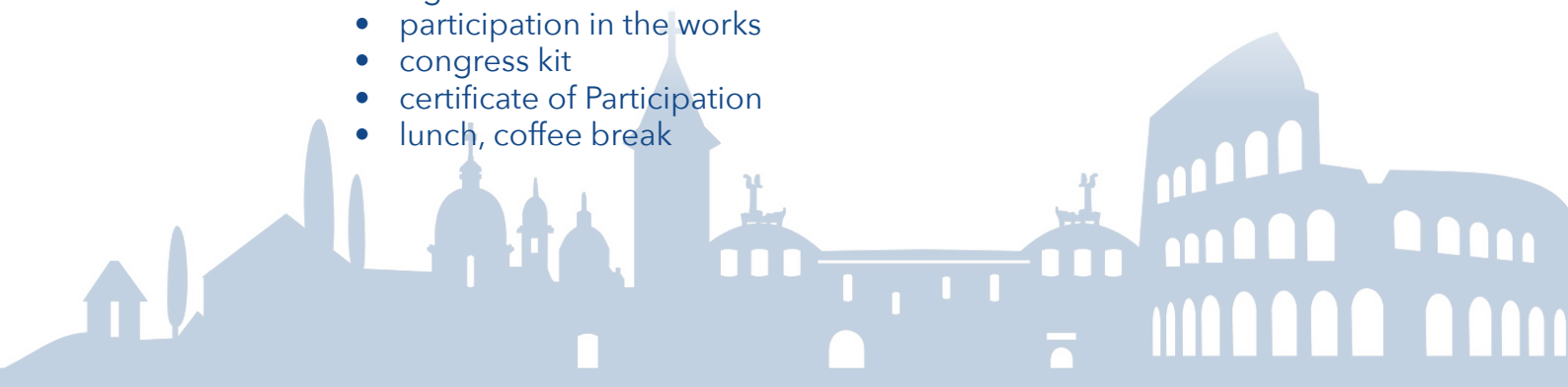
MEMBERSHIP

Registration fee 1.150,00 € + VAT

To participate you must register at the Organizing Secretariat, by returning the completed registration form (downloadable by the specific link in the menu on left) and making the payment of the amount, in the manner specified on the same.

The registration fee includes:

- participation in the works
- congress kit
- certificate of Participation
- lunch, coffee break



ROME, APRIL 28th | 29th 2016

NOTE

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