

WEBINAR

SIXTH WORKSHOP ON DRUG PRICING

SCIENTIFIC BOARD

Pier Luigi Canonico, Armando Genazzani, Claudio Jommi

ON AIR LIVE
OCTOBER 7th | 8th, 2020

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OBJECTIVE

Realizing a multi-stakeholder working table to discuss about issues related to the pricing of drugs.
This 6th Edition will be focused on the following key topics:

- How the pricing scenario will change after the Covid-19 Pandemic
- Decision-making processes and relationship between HTA authorities and stakeholders for pharmaceuticals policies
- New reimbursement mechanisms

SCIENTIFIC PROGRAM

WEDNESDAY, OCTOBER 7TH, 2020

14:30 Registration

15:00 Introduction
Pier Luigi Canonico
Armando Genazzani
Claudio Jommi



Session I – HOW THE PRICING SCENARIO WILL CHANGE AFTER THE COVID-19 PANDEMIC

Chairperson: **Armando Genazzani**

15:15 The Clinical Trials Experience for the COVID emergency in Italy
Patrizia Popoli

15:45 Drug Pricing after the Covid-19 pandemic
Giovanna Scroccaro

16:15 What Should We Expect from the Future?
• Regulatory Aspects
Paola Minghetti
• Organizational and Management Implications
Filippo de Braud
• Strategic Challenges on Product Development
Sergio Scaccabarozzi

17:15 Pause

17:30

Discussion

Filippo de Braud
Barbara Grassi
Paola Minghetti
Patrizia Popoli
Giuseppe Recchia
Sergio Scaccabarozzi
Giovanna Scroccaro
Enrico Zanalda

18:15

Conclusions

THURSDAY, OCTOBER 8TH, 2020



Session II – DECISION-MAKING PROCESSES AND RELATIONSHIPS BETWEEN HTA AUTHORITIES AND STAKEHOLDERS FOR PHARMACEUTICAL POLICIES

Chairperson: **Claudio Jommi**

09:00

How to actively involve Stakeholders in the decision-making processes
Antonio Addis

09:30

Discussion: How to improve and handle process and relationship between HTA authorities and stakeholders
Antonio Addis
Massimo Di Maio
Massimo Galli
Antonio Gaudio
Massimo Riccaboni
Michele Uda
Leonardo Vingiani

10:30

Conclusions

10:45

Pause



Session III – NEW REIMBURSEMENT MECHANISMS

Chairperson: **Pier Luigi Canonico**

11:00

Analysis of four-years of evolution of MEAs and comparison with other Countries
Fulvio Luccini

11:20

Case History: Delayed payment
Americo Cicchetti

11:40

Case History: CAR-T experience and the payment at results
Giovanni Alquati
Luigi Boano

12:00

Discussion: New Reimbursement Models
Giovanni Alquati
Luigi Boano
Americo Cicchetti
Fulvio Luccini
Marika Russo

12:45

Question Time

13:15

Conclusions

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Pier Luigi Canonico

PROFESSOR OF PHARMACOLOGY
UNIVERSITÀ DEL PIEMONTE ORIENTALE

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 and chairman of Department of Pharmaceutical Sciences from 2011 to 2019.

Member of the Board of Directors of the University (2000-2001), actually he is also Member of the Senato Accademico (2002-2019). He was the CEIMS Director from 2012 to 2013, and CEIMS Member of the Board since 2014.

Professor Canonico is a 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 and vice-president since 2015). 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 the President of ISPOR Italy Rome Chapter.

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 in international journals.



Armando Genazzani

DIRECTOR OF PHARMACEUTICAL SCIENCES DEPARTMENT AND PROFESSOR OF PHARMACOLOGY
UNIVERSITÀ DEL PIEMONTE ORIENTALE

Armando Genazzani graduated in Medicine and Surgery at the University of Catania. 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 Università del Piemonte Orientale, and was appointed full professor in 2011 and Director Of Pharmaceutical Sciences Department in 2019. His research still focuses on the role of signal transduction in health and disease, including Alzheimer's disease and oncological disorders, as well as on pharmacogenetics. He has authored over 150 publications on international journals.

He has 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, he organizes a Master in "Regulatory Affairs and Market Access" at the Department of Pharmaceutical Sciences in Novara, was an expert between 2014-2018 of the WHO "International non-proprietary names (INN) Committee", was a member of the WHO "Essential Medicines List" Committee in 2019 and is a member since 2015 of the "Commissione Tecnico-Scientifica" of the Italian Medicines Agency.

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Claudio Jommi

PROFESSOR OF PRACTICE GOVERNMENT
HEALTH AND NOT FOR PROFIT DIVISION SDA BOCCONI SCHOOL OF MANAGEMENT

Claudio Jommi is Professor of Practice at SDA Bocconi School of Management (Government, Health and Not for Profit Division). He is also Member of the Executive Committee, Director of the Health Policy Area and Scientific Coordinator of the Pharmaceutical Observatory at Cergas (Centre for Research on Health and Social Care Management), SDA Bocconi and Director of the Master in International Health Management Economics and Policy (Mihmep) at SDA Bocconi School of Management. He was Associate Professor of Management at the Department of Pharmaceutical Sciences, University of Novara and visiting professor at Essec Business School, Cergy (Paris), at the Herivan K. Haub School of Business, St Joseph University, Philadelphia (US), at the Andrija School of Public Health, Zagreb and the University of Claude Bernard Lyon 1 (European Market Access University Diploma) (Paris). He was the President of the Italian Health Economics Association (2014-2017).

His research activity is focused on Market Access for Medicines and other Medical Technologies, Pharmaceutical Economics, Policy and Management, Health Technology Assessment and Decision Making in Health Care.

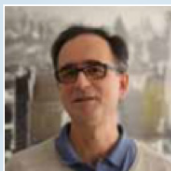
He has had his work published in many international and national journals, including Drug Design Development and Therapy, Frontiers in Pharmacology, European Journal of Health Economics, Health Policy, International Journal of Health Planning and Management, Journal of Medical Marketing, Pharmacoeconomics, PLOS and PLOS Neglected Diseases, Public Money and Management, Social Science and Medicine, Value in Health.

He is also the Editor in Chief of the Journal Global and Regional Health Technology Assessment.

He systematically participate in international Conferences, such as ISPOR, iHEA (International Health Economics Association) and EUHEA (European Health Economics Association).

He joined international Advisory Boards supporting the Pharmaceutical Companies on Economic Evidence for Market Access purposes.

FACULTY



Antonio Addis

DEPARTMENT OF EPIDEMIOLOGY
REGIONAL HEALTH SERVICE, REGIONE LAZIO

PhD in pharmacological research (Istituto "Mario Negri" Milano, Italy) and research experience at international (Division of Clinical Pharmacology, Hospital for Sick Children; University of Toronto, Canada 1995-1997) and national (Centre for the Evaluation of Effectiveness and Health Care- CeVEAS, Modena) level. Head of the Office for Drug Information at Ministry of Health, and then of the Italian Medicine Agency-AIFA (2002-2009); National Expert at the European Medicine Agency-EMA in London (2009-2011). Coordinator for the Governance of Research at the Regional Social and Health Agency of Emilia Romagna Region (2012-2015); Delegate for the Ministry of Health and Italian Medicine Agency at the Committee for Medicinal Products for Human Use (CHMP), the World Health Organization (WHO). Principal Investigator for Project supported by European Commission. Currently working as researcher for the Department of Epidemiology of Lazio Region. Member of the Regional Medicine Committee (CoReFa) of Lazio Region. Member of the Ethical Committee of paediatric Hospital Bambino Gesù. Since 2012 Member of the Scientific Committee (CTS) of the Italian Medicine Agency.



Giovanni Alquati

EXECUTIVE DIRECTOR MARKET ACCESS & REIMBURSEMENT
GILEAD SCIENCES

Giovanni Alquati is a Chemical Engineer and MBA at SDA Bocconi with an skilled commercial and financial experience within different pharmaceutical and commercial biopharmaceutical companies, with a diverse and broad set of functional expertise across Operations, Finance, Sales and Marketing organizations.

In the last decade in Gilead Sciences he is reporting directly to the country G.M. and member of the senior leadership team for the Italian organization.

Responsible for leading the Italian Affiliate in the coordination of all pricing matters, health economics and outcomes research including development of evidence and value-based pricing and market access schemes, providing negotiation and decision support for optimal market access launch, including championing, coordinating, guiding and delivering the submission and P.&R. dossier.

FACULTY



Luigi Boano

MANAGING DIRECTOR AND GENERAL MANAGER
NOVARTIS ONCOLOGY

Luigi Boano is currently Managing Director and Oncology General Manager at Novartis Farma. In this position, he is responsible for the management and development of the overall performance of the Business Unit, the current portfolio and the products under development, through the coordination of the Marketing, Sales, Market Access, Finance and Medical functions. He currently manages a staff of around 300 employees, with a revenue of over 400 million €.

He has an extensive experience (over 25 years) in sales & marketing management positions within the pharmaceutical industry (Merk Sharp&Dome, Sandoz, Novartis).

He received his University degree in Pharmacy from Turin University and holds a MBA from Bocconi University.

He also attended several top management courses in the main US Universities: Marketing Excellence Program at Stanford University; One-X at Columbia University; Business Leadership Program, Business Finance and Executive Forum V at Harvard University.

He is vice-president of Assobiotech and member of Farmindustria.



Americo Cicchetti

FULL PROFESSOR OF BUSINESS ORGANIZATION AT THE FACULTY OF ECONOMICS, UNIVERSITÀ CATTOLICA DEL SACRO CUORE AND DIRECTOR OF ALTEMS (ADVANCED SCHOOL OF ECONOMICS AND MANAGEMENT OF HEALTH SYSTEMS)

Americo Cicchetti is Professor of Healthcare Management at Università Cattolica del Sacro Cuore, Faculty of Economics, Rome. He is Director of the Advanced School of Health Economics and Management (ALTEMS).

Chief of Research, Health Technology Assessment Unit and Biomedical Engineering "A. Gemelli" University Hospital – IRCCS Rome, Italy.

Visiting Researcher at the Center of Medical Education and Healthcare of Thomas Jefferson University, Philadelphia (USA)

Member of the Scientific Advisory Board of the European Health Management Association [EHMA].

Member of the Price & Reimbursement Committee of the Italian National Drug Agency (AIFA) from 2009-2015.

Member of the Scientific Board of Agenas, National Agency for Regional Healthcare Services, Italy (2015-2019).

Member of the Technical Advisory Group the National Programme for HTA of Medical Devices of the Italian Ministry of Health (2017-).

He served as Director of the Health Technology Assessment international (2005-2008) and then member of the Executive Committee (from 2010 to 2018) as Treasurer and Secretary.

He chairs the HTAi's Hospital Based HTA interest sub group and the International Scientific Program Committee for the Annual Meeting of Health Technology Assessment International (Rome 2017).

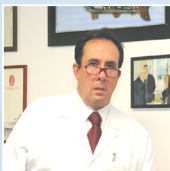
Member of the International Scientific Program Committee of the XVI HTAi Annual Meeting (Cologne 2019) and of the XVII HTAi Annual Meeting (Beijing 2020, transformed in webinar).

Founder and Past President of the Italian Society of Health Technology Assessment. Chairman of the Health Policy forum of SIHTA.

Member of EUNetHTA Joint Action 3, Leader of the Associate Partner Università Cattolica del Sacro Cuore.

He has collaborated with the European Observatory on Health Care Systems (WHO Ueuropa, Copenhagen) and he is the author of 5 monographs and over 100 articles in national and international journal.

FACULTY



Filippo de Braud

FULL PROFESSOR OF MEDICAL ONCOLOGY DIRECTOR OF SCHOOL OF SPECIALIZATION IN MEDICAL ONCOLOGY –
UNIVERSITÀ DEGLI STUDI DI MILANO, ITALY DIRECTOR OF MEDICAL ONCOLOGY AND HEMATOLOGY DEPARTMENT
AND DIVISION - ISTITUTO NAZIONALE DEI TUMORI - MILAN, ITALY

Filippo de Braud, MD, is currently Full Professor of Medical Oncology and Director of the School of Specialization in Medical Oncology, Università degli Studi di Milano, Italy, Director of Medical Oncology and Hematology Department, Director of Medical Oncology Division of the Istituto Nazionale dei Tumori, Milan, where his principal area of expertise is clinical research in oncology.

In 1984, Prof. de Braud received his medical degree in medicine from the University of Milan and continued his training in oncology at various institutions, including the Royal Free Hospital School of Medicine, London, UK, the Wayne State University, Detroit, MI, USA., and the Institute Gustave Roussy, Paris, FR. He has held clinical posts at the European Institute of Oncology, where he was appointed Deputy Director of the Medical Oncology Division in 1994, later becoming Director of Division of Clinical Pharmacology and New Drugs Development since August 2011 when he was appointed as Chief of Division of Medical Oncology at National Cancer Institute, Milan.

He leads researchers in new drugs development (Phase I and early Phase II studies) and teaches medical oncology as full professor at Università degli Studi di Milano.

Since 2000, he has been appointed Scientific Advisor and Member of Committee at Italian Medicine Agency AIFA, Ministry of Health, and several Pharmaceutical Companies.

Prof. de Braud is the author or coauthor of over 530 publications in medical oncology.



Massimo Di Maio

DIRECTOR OF MEDICAL ONCOLOGY AT OSPEDALE MAURIZIANO AND ASSOCIATE PROFESSOR OF MEDICAL ONCOLOGY,
DEPARTMENT OF ONCOLOGY AT UNIVERSITÀ DI TORINO, TORINO

Massimo Di Maio is associate professor of Medical Oncology at Department of Oncology, University of Turin, Italy, since 2014, and director of Medical Oncology at Mauriziano Hospital, Turin, since 2016. In 1999, he obtained degree cum laude in Medicine and Surgery at the University of Napoli "Federico II", Italy. Four years later, in 2003, he graduated from the Specialty School in Oncology at the same University.

From 2000 to 2006 and from 2008 to 2014 he worked at the Clinical Trials Unit of the National Cancer Institute "G.Pascale" Foundation, in Naples, Italy, where he was involved in the planning, conducting and analysis of clinical trials.

His main areas of interest are:

- methodology of clinical trials in oncology,
- conduction of meta-analyses based on individual patients' data
- patient-reported outcomes in clinical research and in clinical practice.

Prof Di Maio has been invited as speaker at many national and international meetings and has authored nearly 300 publications in international peer-reviewed journals (H-Index August 2020: 41 according to Scopus, 38 according to Web of Science).

Additionally, Prof. Di Maio is an active member of the Associazione Italiana di Oncologia Medica (Italian Society of Medical Oncology, AIOM) and the European Society of Medical Oncology (ESMO).

Between 2009 and 2013, Prof. Di Maio acted as national coordinator of the AIOM Young Oncologists Working Group. Between 2013 and 2017, he was councilor (member of the National Board) of AIOM. Since October 2019, he is AIOM National Secretary.

FACULTY



Massimo Galli

FULL PROFESSOR OF INFECTIOUS DISEASES AT THE UNIVERSITÀ DEGLI STUDI DI MILANO AND DIRECTOR OF THE III DIVISIONE OF INFECTIOUS DISEASES AT OSPEDALE L. SACCO, MILANO

Massimo Galli is Full Professor of Infectious Diseases and Director of the Department of Biomedical and Clinical Sciences Luigi Sacco of the University of Milan. Since November 2008 is Director of the University Unit (III divisione) of Infectious Diseases at the L.Sacco Hospital in Milan. He has been director of the postgraduate Schools in Infectious Diseases and in tropical medicine and of the PHD in infectious diseases (2006-2012) of the university of Milan.

He is Past President of the Italian Infectious and Tropical Diseases Society (SIMIT) and president of Italian Group for Study on cryoglobulinemias (ALCRI/GISC) and belongs or belonged to several committees of the Italian Ministry of Health.

The main topics he dealt with are the infection of the human immunodeficiency virus, with particular reference to clinical, immunological, therapeutic and side effects of antiretroviral therapy and the study of cryoglobulinemias. More recently he authored more than 25 papers on SRS-CoV-2 and COVID-19.

He is the author of over 530 peer-reviewed international journals, for a H index = 53. He is also the author of several chapters of scientific treatises.



Antonio Gaudioso

SECRETARY GENERAL OF CITTADINANZATTIVA

Antonio graduated in Political Science and is Secretary General of Cittadinanzattiva.

He has been working for 20 years to promote and protect the rights of citizens and consumers, in Italy and in Europe.

The fields in which Cittadinanzattiva is particularly active are health, with the Tribunal for Patients' Rights, consumer and users' rights, with the Citizens' Advocates, education and training, with the School for active citizenship, justice, with Justice for Citizens' Rights, European citizenship, with Active Citizenship Network and Corporate Social Responsibility

He took part to the writing of the European Patients' rights Chart and he is engaged in the process of adoption of the first law about pain.

He is one of the founder of Forum Diseguaglianze Diversità whose aim is to study new public strategies and community actions to reduce inequalities and social discrimination.

He is Senior Advisor to the World Bank on the "connect for climate" campaign on climate change and a member of the National Council of Consumers and Users (CNCU) of the Ministry of Economic Development.

He is Vice President of the Health City Institute, member of the foundation for the personalized medicine, he is a spokesperson of the scientific technical committee about vaccines of ECDC (European Centre for disease prevention and control), member of the scientific foundation Italia in Salute and member of the Scientific committee for Fondazione Cannavò.

From January 2020, member of the Advisory Board of the National Institute of Health in order to support the Strategic Committee coordinator of SNLG (Guideline National System).

In May 2020, he was appointed by Minister of Health, as member of LEA committee (essential levels of assistance).

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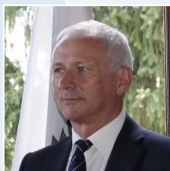
Barbara Grassi

MEDICAL AND SCIENTIFIC DIRECTOR
GSK ITALY

Barbara was appointed as VP, Medical and Scientific Director for GSK Italy in January 2019. Barbara trained as a physician at San Raffaele Hospital in Milan and then as a psychiatrist. She also took an MBA in 2011.

She worked at San Raffaele Hospital in Milan and then at San Paolo Hospital in Milan, dealing at the same time with medical care of severe mental illnesses and clinical research for those illnesses in the field of neuropsychology, neurophysiology and neuropharmacology.

In 1999 she started her career in the pharmaceutical industry by joining GlaxoWellcome in Verona as Head of Investigational and Experimental Medicine for schizophrenia and bipolar disorder. From 2001-2004 she moved to Novartis as the Neuroscience Therapeutic Area physician with full accountability for clinical research and medical affairs related activity. In 2004 she joined back GSK as Head of Clinical Operations and subsequently took on several local roles encompassing medical affairs, medical information and patient advocacy. In 2012 she took on her first above-country role, i.e. Head of Clinical Operations for all GSK Europe and in 2014 she took the accountability of GSK clinical operations on a global scale. She was the Country Lead for TransCelerate in Italy from 2013-2017.



Fulvio Luccini

MANAGING DIRECTOR MA PROVIDER ITALIA, MILAN

Fulvio has 40 years of experience in the pharma industry with growing responsibility in sales, marketing and access.

From 2000 to 2008 served as BU transplant and immunology director and from 2008 to 2012 acted as director of the Specialty division of Novartis.

In 2012 established the national and regional patient access organization at Novartis and has managed it since then, in this period has acquired expertise in advanced therapies as well. He was a member of the Novartis Italy Leadership team since 2000 and of the Novartis Patient access Global Leadership Team.

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Paola Minghetti

PROFESSOR OF PHARMACEUTICAL TECHNOLOGY AND LEGISLATION
UNIVERSITÀ DEGLI STUDI DI MILANO

Paola Minghetti, graduate in Pharmacy and Industrial Pharmacy, PhD in Pharmaceutical Sciences, is full professor of Pharmaceutical Technology and Legislation at Università degli Studi di Milano. She is an expert of the Italian Pharmacopoeia and member of a team appointed by EDQM for the creation of the monograph "Pharmaceutical Dosage Forms". She is member of the AIFA evaluation and authorization Secretariat since 2012. The research is mainly related to transdermal and buccal drug delivery systems. to the doctrinal elaboration regards the national and UE legislation related to the production and the commercialization of medicaments, medical devices, and health products.



Patrizia Popoli

HEAD, NATIONAL CENTER FOR DRUG RESEARCH AND EVALUATION
ISTITUTO SUPERIORE DI SANITÀ, ROMA

Patrizia Popoli obtained a degree in Medicine and Surgery at the Università degli Studi in Perugia. She majored in neurological clinic at the Università degli Studi in Perugia. Currently, she is the Director of the National Center for Drug Research and Evaluation at Istituto Superiore di Sanità, and member of the Committee for the evaluation of admission to Phase I clinical trials (ISS), of the Ethic Committee of ISS and of the Coordinating Center of Ethic Committees (Italian Drug Agency, AIFA).

She has been for many years permanent substitute of the President of Istituto Superiore di Sanità in the Scientific and Technical Committee of AIFA and is currently President of this Committee.

In the field of experimental research, her activity has been focused on Central Nervous System Pharmacology.

She is a member of scientific societies and author of several publications. Furthermore, she performs numerous regulatory activities in the pharmaceutical sector.

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Giuseppe Recchia

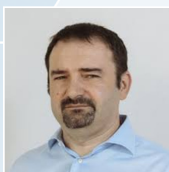
CO-FOUNDER AND CEO, DAVINCI DIGITAL THERAPEUTICS
VICE PRESIDENT, SMITH KLINE FOUNDATION

Graduated in Medicine at Padua University, Research Fellow at Downstate Medical Centre in Brooklyn, NY (1983-84). Specialist in General Surgery and Pharmacology.

Medical Director in GSK Italy (1993-2018).

Vice President of Smith Kline Foundation since 2018.

In Jan 2019, co-founder of daVinci Digital Therapeutics, a Digital Biotech Company committed to research, develop and delivery evidence-based, prescription Digital Therapeutics to treat chronic diseases and substance use disorders.



Massimo Riccaboni

PROFESSOR OF ECONOMICS AND DIRECTOR OF AXES RESEARCH UNIT AT IMT, LUCCA

Massimo Riccaboni is Full Professor of Economics at IMT School for Advanced Studies Lucca. He is the Director of AXES research unit and the head of the PhD track in Economics Networks and Business Analytics at IMT Lucca. He is visiting professor at the Dept. of Managerial Economics, Strategy and Innovation at K.U.Leuven.

He has published, among the others, in Science, PNAS, Nature Reviews, Journal of the European Economic Association, Management Science, Research Policy, Economic Letters, International Journal of Industrial Organization, R&D Management, Health Affairs, Marketing Letters, Health Policy, Small Business Economics, Scientometrics, Physical Review E, New Journal of Physics, Journal of Economic Dynamics and Control, World Economics, Nature Scientific Data, Nature Scientific Reports.

He is an author of the EU reports on "Innovation and Industrial Leadership: Lessons from Pharmaceuticals", "Innovation and Competitiveness in European Biotechnology" and on "Medical Devices Competitiveness and Impact on Public Health Expenditure".

He has been a member of the AIFA's Committee for Prices and Reimbursement (CPR) from 2015 until 2018.

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Marika Russo

MARKET ACCESS DIRECTOR EMEA ITALY AND GREECE
NOVARTIS GENE THERAPIES (GTX)

Marika Russo has been working in the market access field for more than five years and building experience in gene therapy as well as oncology at both European and local level. At present, she is Market Access Director at Novartis Gene Therapies (former Avexis) Italy and Greece for more than a year with focus on Zolgensma, first gene replacement therapy in SMA. In her previous role, she focused on oncology moving from onco-hematology to the lung cancer in four years at Takeda European headquarter where she worked as Associate Director Europe and Canada. Her expertise range from market access strategy, evidence generation and value demonstration, health economics, price, policies and reimbursement of ATMPs.



Sergio Scaccabarozzi

COUNTRY CLINICAL OPERATIONS TRANSFORMATION LEADER
ROCHE S.P.A.

Sergio Scaccabarozzi has been with Roche since 1989 and has currently the role of Country Clinical Operations Transformation Leader, supporting a historical transformation of the clinical operation way of working: from a classical hierarchical/matrix organization to a disease teams base organization, applying agile methodology. Sergio graduated in Medicine and Surgery from the University of Milan in 1984 and, subsequently, obtained a postgraduate diploma in general surgery. After a period of activity at the general surgery division of the San Raffaele Hospital in Milan, where he also dealt with aspects related to research, he began his work experience in the pharmaceutical sector. At first in Synthelabo, as Medical Manager, he followed clinical studies in pulmonology, neurology and metabolism; after this experience he began his professional career in clinical research at Roche. Before taking on his current role, Sergio gained extensive experience as a Research Physician in the infectious disease field, working on hepatitis and HIV infection. He then coordinated the group of Country Study Managers of all therapeutic areas and the start-up group in charge of the regulatory, ethical and administrative aspects of clinical trials. From 2019 to May 2020 he had the role of Country Head of Clinical Operations, coordinating a structure of about 90 people and responsible for the management of clinical trials from phase I to phase IV.

FACULTY



Giovanna Scroccaro

DIRECTOR OF THE PHARMACEUTICAL ORGANIC, PROSTHETIC AND MEDICAL DEVICES UNIT
REGIONE VENETO

Giovanna Scroccaro is graduated in Pharmacy at the University of Bologna, specialized in Applied Pharmacology at the University of Modena and in Clinical Pharmacology at the University of Milan and from 2012 she is the Director of the Pharmaceutical Organic, Prosthetic and Medical Devices Unit of Regione Veneto.

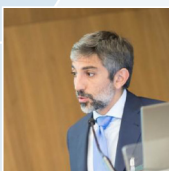
From 1998 to 2012 she was the Director of Hospital Hospice of the Integrated University Hospital of Verona and from 2012 to 2017 the Head of the Regional Drug Coordination (CRUF).

Since the beginning of her career, she has been a member of different regional and national committees, the most representative are: President of the Italian Society of Hospice Pharmacy (SIFO) from 2000 to 2007, Chairman of the Regional Medical Equipment Commission (CTRDM) from 2010 to present, Chairman of the Regional Drug Technical Commission (CTRF) from 2013 to present.

Since 2014, Giovanna Scroccaro has been the actual member of the Health Technical Committee, at the Ministry of Health, Department of Medical Devices and since 2015 she is a member of the National Cab - HTA at the Ministry of Health.

Since 2015 she is a member of the Committee Prices and Reimbursement (CPR) of the Italian Medicines Agency (AIFA), from 2016 she is a member of the Regional Coordination of the Venetian Hematology Network (CREV) and member of the Regional Coordination of the Veneto Network of Oncology (CROV).

From 2019 to present, she is the Chairman of the Committee Prices and Reimbursement (CPR) of the Italian Medicines Agency (AIFA).



Michele Uda

GENERAL DIRECTOR OF ASSOGENERICI ASSOCIAZIONE NAZIONALE INDUSTRIE FARMACI GENERICI E BIOSIMILARI
AND ITALIAN BIOSIMILARS GROUP – IBG, MEMBER OF THE EXECUTIVE COMMITTEE OF MEDICINES FOR EUROPE AND
CHAIRMAN OF THE NAC (NATIONAL ASSOCIATION COMMITTEE OF MEDICINES FOR EUROPE)

Graduated in Political Science from the International University LUISS Guido Carli in Rome, with a specialization in International Economics, after an initial experience in one of the largest Italian trade unions, he has successfully completed a full time MBA in International Business and Economics at "Mib School of Management" of Trieste. He then continued his career in the retail consumer sector at Ferrero Italy as Assistant Brand Manager for the Italian multinational company's core business and, later, at Colgate Palmolive Italy as a market and industry sales analyst in the Household Care division. He stepped into the healthcare sector joining Johnson & Johnson Medical where he was responsible for direct management of sales and marketing for the breast care line in Italy's central and southern regions. From March 2007 he joined Assogenerici, the Italian Generic and Biosimilar Medicines Association, as "Pharmaceutical Economics & Policy Affairs Manager", assuming direct responsibility of the Centre for Economics and Policy Analysis of the association.

From April 2012 he has been appointed Director General of Assogenerici, keeping also the position as interim head of the Centre for Economics and Policy Analysis and the responsibility for international relations. Since 2014 is also managing IBG – Italian Biosimilars Group, the new industry body representing the biosimilar medicines industry within Assogenerici.

He is also member of the Executive Committee of Medicines for Europe (European Generic & Biosimilars Medicines Industry Association); appointed Chairman of the GMAC (Generic Market Access Committee of Medicines for Europe) in 2011, he is now Chairman of the NAC (National Association Committee of Medicines for Europe).

FACULTY



Leonardo Vingiani

ASSOBIOTEC DIRECTOR

Has a degree in law and a master in business administration and entrepreneurial development.

For ten years Managing Director of AISA, the Italian Association for Veterinary Medicines. Since 1999 is Managing Director of Assobiotech, the Italian Association for the Development of Biotechnology (www.assobiotech.it), representing more than 110 companies and science & technology parks operating in Italy and involved in various biotech-related fields – pharmaceuticals, diagnostics, agro-food, fine chemicals, environment, processing industry and equipment.

Invited as a speaker in many conventions and conferences, he represents the issues of biotechnologies and their impact on society. He is also the author of several articles on bioethics and the public acknowledgment of biotech. Represents Assobiotech in institutional relations and, in general, with all relevant interlocutors.



Enrico Zanalda

DIRECTOR OF MENTAL HEALTH DEPARTMENT OF ASL T03 & AOU SAN LUIGI GONZAGA. PRESIDENT OF ITALIAN SOCIETY OF PSYCHIATRY (SIP)

Enrico Zanalda was born in Turin on 02.05.1957 where he completed his training until obtaining a degree in Medicine and Surgery in 1982 and then specializing in Psychiatry, in 1986 at the University of Turin, city where he lives and works to this day.

For years he has been involved in the management of several scientific societies and is a founding member of the Academy of Psychiatry, Psychology and Law of Turin and a member of the Rotary Club Torino.

Since 2018 he has been President of the Italian Society of Psychiatry (SIP).

He immediately began teaching in the specialized schools in Psychiatry and Clinical Psychology of the University of Turin.

His passion for teaching continues to this day and since 2010 he has been directing the Course of Organization of Health Services of the degree course in Psychiatric Rehabilitation Technician of the University of Turin.

He has worked in the National Health Service since 1990 and since 2004 as Director of the Inter-company Mental Health Department of ASL T03.

He has been a Mental Health Consultant for the Piedmont Region at the Department of Health since 1996, and his collaboration continues in the field of the paths of patients who commit crimes.

Participates personally in the Technical Table on Mental Health Established by the Ministry of Health and represents the Piedmont Region within the Table of Coordination of Mental Health established by the Conference of the Regions for the monitoring of the Action Plan National Mental Health Department.

He has published over 200 scientific contributions in national and international journals and books, edited some editorial series and is editor of the journal Evidence Based Psychiatric Care, as well as author of the book on the protection of the mentally ill 1999 and co-author in 2010 of the Paths of social autonomy of patients with dual diagnosis.



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