

WORKSHOP

SEVENTH WORKSHOP ON DRUGS PRICING

SCIENTIFIC BOARD
Pier Luigi Canonico, Claudio Jommi

ROME
14TH | 15TH SEPTEMBER 2021

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ISPOR

Italy-Rome Chapter



UNIVERSITÀ DEL PIEMONTE ORIENTALE

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WORKSHOP

OBJECTIVE

The workshop, now in its seventh edition, is a multistakeholder working table to discuss issues related to the assessment, appraisal and pricing of medicines from a national and international perspective.

The 7th Edition addresses the following topics:

- Managing Drugs Appraisal Process
- Therapeutic Innovation
- Value-Based Pricing for Pharmaceuticals

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SCIENTIFIC PROGRAM

September 14th 2021

13:30 Registration

14:00 Introduction
Pier Luigi Canonico, Claudio Jommi



Session I – MANAGING DRUG APPRAISAL PROCESS

Chairperson: **Pier Luigi Canonico**

14:15 The German Experience
Eva Susanne Dietrich
Discussant: **Valentino Confalone**

15.00 *Question time*

15.45 *Coffee Break*



Session II – THERAPEUTIC INNOVATION

Chairperson: **Pier Luigi Canonico**

16:15 Current experience and future prospects
Patrizia Popoli

16:45 Pros and cons of innovativeness appraisal process
Dario Scapola

17:15 Discussion: Is any revision of the therapeutic innovation criteria expected/needed?
Valentino Confalone, Carlotta Galeone, Patrizia Popoli, Dario Scapola

18:15 *Question time*

18:45 *Conclusions*

September 15th 2021



Session III – VALUE BASED PRICING (VBP)

Chairperson: **Claudio Jommi**

09:00 Is there a wide consensus on VBP for pharmaceuticals?

Claudio Jommi

09:30 The UK experience: relying on cost-effectiveness

Andrew Walker

10:00 VBP for pharmaceuticals in Italy:

- The view of the AIFA's CTS/CPR

Mauro Biffoni

10:30 *Coffee Break*

11:00 Discussion - How to get a consensus on a VBP framework?

Antonio Addis, Luigi Boano, Francesco Damele, Antonio Gaudio, Francesco Saverio Mennini, Francesca Patarnello, Anna Ponzianelli, Pierluigi Russo, Geremia Seclì

12:30 Question time

13:30 Conclusions

SCIENTIFIC BOARD



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.



Claudio Jommi

PROFESSOR OF PRACTICE OF HEALTH POLICY,
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.

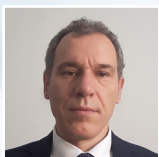
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Antonio Addis

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.



Mauro Biffoni

DIRECTOR OF THE DEPARTMENT OF ONCOLOGY AND MOLECULAR MEDICINE (OMM)
OF THE ISTITUTO SUPERIORE DI SANITÀ (ISS)

Mauro Biffoni, graduated in medicine at the University "La Sapienza" in Rome, then obtained a specialization in pharmacology and clinical pathology at the same University. He began his career as a researcher at "Cesare Serono" Research Institute and later became Contract Professor of Pharmacology, University of Rome "Tor Vergata" in the meantime occupying the role of Substantive consultant (Medical Director), "G.B. Grassi" Hospital (ASL Roma D), Section of Clinical Pathology. In 2004 he joined the Istituto Superiore di Sanità (ISS) as Research Director at Department of Hematology Oncology and Molecular Medicine and since 2017 he has been Director of the Department of Oncology and Molecular Medicine (OMM) of the Istituto Superiore di Sanità (ISS). As permanent delegate of ISS President he is member of the Technical and Scientific Committee (CTS) and since 2018 of the Prices and Reimbursement Committee (CPR) of the Italian Drug Agency (AIFA), since 2020 is member of the Committee for the evaluation of the admissibility of phase 1 clinical trials.

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Luigi Boano

EXECUTIVE VICE PRESIDENT FEDERCHIMICA ASSOBIOTEC

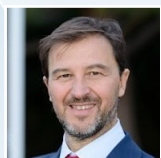
Luigi Boano is currently Managing Director and Oncology General Manager at Novartis Farma. In this position, he is responsible for the management and development of the overall performance of the Business Unit, the current portfolio and the products under development, through the coordination of the Marketing, Sales, Market Access, Finance and Medical functions. He currently manages a staff of around 300 employees, with a revenue of over 500 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 member of Farmindustria.



Valentino Confalone

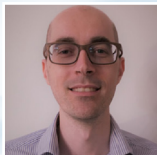
GENERAL MANAGER AT GILEAD SCIENCES ITALY AND MEMBER OF FARMINDUSTRIA BOARD

Valentino Confalone is the General Manager at Gilead Sciences in Italy, where he works closely with a wide range of stakeholders in the healthcare system to address market access issues. He has negotiated a number of deals with Italian authorities with the implementation of innovative Management Entry Agreements. As Chairman of the Advance Therapy Medical Products group of the Italian trade association Farmindustria, he is working on the development of a Value Framework for advanced therapies currently under discussion with the Italian authorities. Before coming to Gilead, he was Head of Europe Dompé Biotech and he held various positions at Bristol Myers Squibb (BMS), both at national and international level, including General Manager Portugal, Oncology Market Access Lead Europe and Business Unit Director Virology France. In his role of Market Access Lead Oncology he developed the access and pricing strategies for the first immune-oncology treatments ipilimumab and nivolumab for the treatment of advanced melanoma.

Confalone started his career in the pharma industry with Schering-Plough in Spain.

He holds a degree in Economics from the University Federico II of Naples, a Master's Degree in International Relations, and a Master in Business Administration from IESE Business School in Barcelona.

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Francesco Damele

VALUE & ACCESS HEAD AT SANOFI

Francesco Damele is the Value & Access Head at Sanofi Italy, where he is responsible for successful implementation of the market access strategy for the whole portfolio, medicines and vaccines; through meaningful partnerships with national relevant HTA organizations and experts, payers and stakeholders. He negotiated several products with the National Authority with the implementation of innovative contracting. Before Sanofi, he worked in Janssen across different positions in Business Operations and Market Access. He holds a degree in Political Economics from the "Università Commerciale Luigi Bocconi" of Milan.



Eva Susanne Dietrich

INSTITUTE FOR EVIDENCE-BASED POSITIONING IN THE HEALTH CARE SECTOR
C/O UNIVERSITY OF BONN

Eva Susanne Dietrich is a pharmacist, had a Doctorate in the field of pharmacoeconomics and since 2012 is Honorary Professor, appointed by the Chancellor of Rheinische Friedrich-Wilhelms-University, Bonn, Germany. She served as a deputy member of the Federal Joint Committee (G-BA) which specifies for almost 90 percent of the German population the services in medical care that are reimbursed. In parallel, she led the Department of Drugs, Remedies and Aids at the German National Association of Statutory Health Insurance Physicians (KBV) which concludes contracts with health insurance funds and other parties of the health care sector on the part of the 140,000 office-based physicians and psychotherapists in Germany. In the time after, she organized a scientific institute for one of the largest health insurance funds in Germany and was responsible for the Management Division Health Sciences. In 2018 she founded the Institute for Evidence-Based Positioning in the Health Care Sector, Bonn/Lörrach focusing on strategy consulting (positioning new drugs and digital applications from the perspective of decision makers and evidence-based medicine AMNOG process: creation of AMNOG dossiers, further education and employee coaching in health policy structures and decision-making), digital applications (support in the fast track application process) and evidence and information mapping (health care, health economics and market access).

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Carlotta Galeone

RESEARCHER AT BICOCCA-APPLIED STATISTICS CENTER (B-ASC)
UNIVERSITY OF MILAN - BICOCCA

Carlotta Galeone (PhD, ScD) is a senior biostatistician and epidemiologist. After 15 years of experience in observational studies at Mario Negri Institute in Milan, Department of Epidemiology, and at the University of Milan, she currently collaborates with Bicocca-Applied Statistics Center (B-ASC) at the University of Milan-Bicocca. She is working on various projects on data analyses of Real World Data. She collaborated with Prof. Jommi to identify the key drivers of innovativeness appraisal for medicines by analyzing the Italian experience after the adoption of the new ranking system. She is an expert in the GRADE system application for drug innovativeness evaluation.



Antonio Gaudioso

PRESIDENT AT CITTADINANZATTIVA

Antonio graduated in Political Science and is President of Cittadinanzattiva.

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

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 a board member of the Foundation for Active Citizenship (Fondaca) and a board member of the Fondazione Scuola Nazionale Servizi.

He is a member of the General Council of the Ania Consumer Foundation.

In 2006 he was responsible for the Cittadinanzattiva programme with UNDP (United Nations Agency for Human Development) in Colombia.

He was, among others, a member of the jury of the Premio Areté (initiative of Confindustria/Il Sole 24 ore) on responsible communication and the Sodalitas Social Award on similar issues promoted by Assolombarda; member of the "group of interest on patient and citizen" of HTAI (International Association of Health Tec. Asses.); member of the Committee of Guarantors, upon appointment of the Presidency of the Council of Ministers, of the Commissariat for Emergency Health in Calabria; Member of the Commission of the Ministry of Health on the appropriateness of pharmaceutical prescriptions; member of the Board of the European Charter of Patient's rights.

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Francesco Saverio Mennini

PROFESSOR FOR HEALTH ECONOMICS AT UNIVERSITY OF ROME "TOR VERGATA" AND PRESIDENT OF SITHA

Prof. Francesco Saverio Mennini, is presently Professor for Health Economics and Economics at University of Rome "Tor Vergata" (both at the Faculty of Economics and Faculty of Medicine). He is also Visiting Professor to the Institute of Leadership and Management in Health, Kingston University, London, UK (Health Economics and Management). Prof. Mennini is Research Director of Economic Evaluation and HTA (EEHTA) research area within CEIS (Faculty of Economics, University of Rome "Tor Vergata"). Within EEHTA CEIS, Prof Mennini is the scientific coordinator of the Observatories on the Social Costs of eye diseases; multiple sclerosis; mental illness; oncological diseases. Prof Mennini is a member, as an expert in Health Economics, of two commissions within the Superior Health Council (Ministry of Health). Prof Mennini is Co-Coordinator of the Working Group on Large Medical Equipment and PNRR within the Superior Health Council (Ministry of Health). Prof Mennini is a member, as an expert in Health Economics, of the Working group on Medical Device within Ministry of Health. Prof Mennini is a consultant, as a Health Economist, to the Deputy Minister of Health. Prof Mennini is President of Italian Society for Health Technology Assessment (SIHTA). His main contributions have dealt with welfare policies, health system analysis, Health Technology Assessment (HTA), pharmacoconomics, pharmaceutical economics and waste, fraud and corruption and Health (author of more than 100 papers in indexed journals).

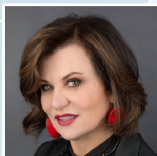


Francesca Patarnello

VP MARKET ACCESS & GOVERNMENT AFFAIRS AT ASTRAZENECA

Francesca Patarnello is, since March 2017, Vice President Market Access & Government Affairs, AstraZeneca Italia. Degree in Statistics and Economics, began his career in Farmitalia Carlo Erba, passing successively from Fidia to GlaxoSmithKline. Before AstraZeneca she spent three years as Value and Access Director in Amgen, working to make accessible to patients the innovative pipeline. Before moving to the Market Access, she plays a number of roles in medical science, including HTA Director and Scientific Director and Quality. Member of several working groups, Francesca currently sits on the Assolombarda General Council and working groups, and she is author of numerous publications regarding innovation of drugs, on HTA and on market access.

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Anna Ponzianelli

INSTITUTIONAL AFFAIR HEAD AT NOVARTIS

Anna Ponzianelli is a biologist with a PhD in pharmacology and boasts a career, build up in the Pharma environment with deep commercial, technical and strategic understanding in pharmaceutical management, with a strong strategic and technical know-how about regulations, governance, strategies, decision making process, RWE and MEA and Value Based Pricing. She led more than one hundred P&R negotiation several of them positively concluded thanks to content-based interactions with AIFA General Directors, HTA Office and CTS/CPR and also MoH and ISS both for cronicity and ATMP (Gene and CAR T).

Throughout her career, Anna has worked in different Therapeutics Areas managed (Ophtha, Derma, NS, MS, Inflammation, Rare Diseases, Immunology and Transplantation, BPCO and Respiratory, CV and Diabetes).

Since 2014 she is Vice President of SIARV – Public Affairs (Italian Society of Regulatory, Access & Pharmacovigilance Activities) and since 2017 she teaches at “Master II Level in Market Access” (Altems – Università Cattolica del Sacro Cuore di Roma).

Actually, she is a Directing Member of SIHTA and she holds the position of Institutional Affair Head at Novartis, with the responsibility for the Institutional Relation Management and Access strategy.



Patrizia Popoli

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

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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Pierluigi Russo

DIRECTOR OF THE MONITORING REGISTRIES OFFICE AND INTERIM DIRECTOR OF THE ECONOMIC EVALUATIONS OFFICE, AIFA

Pierluigi Russo is a pharmacologist, expert in Pharmacoeconomics and Health Economics, with experience working on pharmaceutical regulation. Since 1998 he has been teaching in university courses, specialization schools and master's degrees, pertaining both to the Faculty of Medicine and Surgery, and to that of Economics, specifically related to the disciplines of Pharmacology, Regulatory Disciplines and Pharmacoeconomics. Since 2008 he has been a member of the editorial boards of several scientific journals in the field of Pharmacoeconomics and Health Technology Assessment. Since 2004 he has held several roles in AIFA including Manager in the supporting activity of the AIFA - Italian Regions Affairs, Director of Osmed Coordination Office and activities of HTA, Coordinator of Drug Strategies and Policies Area, Director of the Office for Health Technology Assessment in the Pharmaceutical Sector, Director of the Economic Evaluations Office and currently Director of the Monitoring Registers Office (Head of AIFA's Monitoring Registers). Since October 1st 2019, elected member to the Executive Committee of the EURIPID, the European project on monitoring of drug prices in Europe and since March 22nd 2021, Italian member to the Expert Group on Pharmaceuticals and Medical Devices, which operates within the OECD Health Committee.

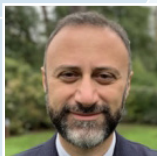


Dario Scapola

INTEGRATED ACCESS MANAGEMENT DIRECTOR AT ROCHE

Dario Scapola graduated in Economics from the University of Turin and began his career as specialist rep at Janssen - Cilag. His experience in pharmaceutical companies saw him Area Manager at Pfizer, Field Manager at Astrazeneca, BU Head HIV at GSK, Customer Operations & Healthcare Management Director again at Astrazeneca and again Payer Strategy PMO Director at Astrazeneca Global Marketing based in Brussels, and Payer Insight and Capability Regional Lead for CEEMEA at Astrazeneca Global Marketing based in London. In 2014 he was Head B.U. Biopharmaceuticals & Onco-Injectables at Sandoz (Novartis group) and from 2014 to 2015 he was Country President Portugal - Angola - Mozambique at Sandoz. In 2019 he joined Roche as Market Access Director and from 2020 he held the position of Integrated Access Management Director at Roche Group.

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Geremia Seclì

COORDINATOR OF THE VAM GROUP (EGUALIA)

Geremia Seclì has a degree in Business Economics from the University of Bari and a Master in Business Administration at Luiss-Guido Carli University in Rome, with a specific focus on economics, management and finance.

He began his working experience at Segix Italia and then he moved to Ebewe Pharma, where he was later appointed Head of Finance.

In 2010 he joined Sandoz (Novartis Group) as Sales Excellence Manager and in 2012 he moved to Medac Pharma with the title of Head of Finance and Administration. He is currently still in Medac Pharma with the role of Head of Operations, involved in the General Management of the Company.

Within Egualia, he is the Coordinator of the VAM Group (Value Added Medicines), the official representative body in Italy of companies that own or are interested in the development of Value Added Medicines (VAM).



Andrew Walker

DIRECTOR AT SALUS ALBA, GLASGOW

With 12 years of personal experience at SMC, including examples in all therapy areas, the depth and breadth of knowledge we have to draw upon in advising a pharmaceutical company will rarely be found elsewhere.

This allows Salus Alba to produce a bespoke approach to the specific issues raised by each new submission that draws from experience and precedent but combines with the latest trends in the way submissions are discussed.

Andrew's formal training is in economics and health economics to PhD level, including over 25 years of learning to apply the textbook principles in practice.

He acted as the economics reviewer on 144 different submissions, involving completing a checklist of questions, helping draft guidance, and attending committee meetings to brief members and answer questions.

During his time at SMC he studied the way members thought about the clinical data allowing him to predict which endpoints will provoke positive and negative reactions.

The way committees make decisions sometimes cuts across therapy areas and the most appropriate analogue for your submission might be in an area you had not previously considered.

We can help you understand what lessons you should learn from precedents and case studies, going beyond simply whether they were 'yes' or 'no' decisions.

Andrew's most recent experience is working with companies to solve problems they face and understanding the pragmatic nature of the solutions they need to address issues when they have limited time and resources.



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