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HTA 2.0 Europe – Teaming Up for Value

30-31 October, Rome, Italy

James Anderson, Director, European Partnership, GSK, Brentford, Middlesex, UK

James Anderson has worked at GSK for the last 10 years improving the way we develop and commercialise our products by working in partnership with stakeholders. Working collaboratively, he addresses significant health policy issues, often conducting pilots. James led GSK's engagement with EU payers, politicians and HTA agencies, which delivered the first multi-country parallel advice process and is currently working to improve patient access via Medicines Adaptive Pathways to Patients (MAPPs, or adaptive licensing).

James participates in MIT's NEWDIGS programme, leads much of GSK and EFPIA's MAPPs advocacy and helps drive GSK's EMA pilots.

James also leads on Antimicrobial Resistance, launching the ground-breaking >€650m IMI AMR project with the EU Commission and working with Chatham House, Brookings and UK Government programmes and is the Vice-Chair of the Healthcare Taskforce to the OECD. James Anderson has a MBA from Harvard Business School and a Molecular Biology degree from Cambridge.

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Luciana Ballini, Head of Regional Observatory for Innovation, Regional Agency for Health and Social Care – Emilia-Romagna, Bologna, Italy

Luciana Ballini graduated in Sociology at the London School of Economics and has a Master in Methods of clinical and epidemiological research. She leads the research unit named Regional Observatory for Innovation within the Regional Agency for Health and Social Care (ASSR), which provides scientific and technical advice to the regional health authority on matters inherent to health policy. The main function of her unit is to provide support to the regional health authority and the local health trusts in the evaluation, adoption, diffusion and appropriate clinical use of innovative health technologies and interventions.

As coordinator of the HTA production unit she has expertise in Evidence Based Medicine methodology, including critical appraisal and synthesis of biomedical research, systematic review and meta-analysis, quality assessment of studies and grading of evidence, identification and prioritization of research gaps. With her team she has worked at developing methods and tools for context analysis and consideration of organizational and social consequences of new technologies' adoption.

She has experience in design, execution and management of research projects aimed at the evaluation of health technologies and interventions. She has been responsible for the monitoring of the regional Health Services Research program and supports the regional health trusts in evaluating the impact of complex healthcare interventions. Moreover she has a long-standing commitment to the research on determinants of effective local implementation of clinical practice guidelines and innovative health technologies/interventions. She dedicates part of her activity to research in methodology, particularly for the evaluation of diagnostic tests, assessment and presentation of the quality of evidence, managing scientific uncertainty, communication with policy makers and uptake of HTA results in decision making processes.

She is editor of the Cochrane Collaboration Review group named Effective Practice and Organization of Care (EPOC) and responsible for the EPOC Italian Satellite, targeted at the use of systematic reviews to identify research gaps and inform health services research agenda.
Besides the institutional membership to INAHTA, HTAi and G-I-N, she is member of the Normalization Process Theory group, based at Southampton University, of the Italian Cochrane Network, of the Prognostic Studies Method Group and Qualitative Research Method Group of the Cochrane Collaboration. She is on the Editorial Board of Implementation Science and acts as peer-reviewer for several scientific journals.

Luciana Ballini has been nominated Chair of the EUnetHTA Plenary Assembly for 2014-2016 and has been leading ASSR's participation in EUnetHTA Joint Action 1 and 2.

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Bert Boer, Executive Board member, National Health Care Institute(Zorginstituut Nederland – ZIN), Diemen, Netherlands

Bert Boer is a member of the Executive Board of *Zorginstituut Nederland* [National Health Care Institute]. The institute's main task is to advise the Minister of Health on matters relating to the package of insured health care. This includes general matters such as the insurance system and the criteria for compiling the package. Its "core-business", however, is the concrete assessment of forms of care for facilitating decision-making on inclusion in the insured package. Until the system was revised in 2006, this assessment (which includes Assessments and Appraisals) focused mainly on medicines, but nowadays it relates to the entire health care package.

One aspect of the Health Care Institute's activities is consulting existing research and, where necessary commissioning research to substantiate its package advice. This involves making use of – and employing – Health Technology Assessment.
Alongside its package management task, the Health Care Institute is home to, and responsible for, the Quality Institute.

Bert Boer trained as a GP and spent 12 years as a practising GP. He joined CVZ (the predecessor of the Health Care Institute) as a medical advisor in 1988. By the end of the nineteen-nineties, his work experience in using HTA in package management resulted in his own research into the use of HTA in policy-forming, with particular reference to the factors that determine whether HTA is or is not used. He obtained a doctoral degree on this subject in 2002.

Since March 2014 Bert is an appointed professor with the Institute of Policy and Management of Health Care (BMG) of the University of Rotterdam, whereby his teaching and research remit is: Policy and Research for Management of the Basic Package of Health Care.

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Paul Cornes, Clinical Outcomes Group, Bristol Oncology Centre, Bristol, United Kingdom

Paul Cornes is an Oncologist from Bristol, U.K. He has been co-steering the European School of Oncology's Working Party on Access to Innovation in Cancer Treatment.

He has been a UK National Health Service cancer clinical trial lead, and for more than a decade lectured on the biennial London TPI course on clinical trial designs and on improving the effectiveness of clinical trials. He is participating in the Wolfson Institute Cochrane Group at Bath. He was involved in the United Kingdom Health Technology Assessment of Erythropoietins for cancer at NICE (National Institute for Health and Clinical Excellence).

He helped to organise the Cambridge Blue-Sky Future Cancer meeting with the Centre for the Study of Financial Innovation and is a paper reviewer on anaemia and economics issues for several English language medical journals.

Paul Cornes encourages that health economics should be embraced as part of routine medical practice. He has taught clinical and cost effective care to physicians, pharmacists and nurses in countries as different as the USA, Russia and China. He has given the American Society of Hematology Annual Meeting "spotlight lecture" – on cost effectiveness.

Katelijne De Nys, President of the Reimbursement Commission of Medicines, Brussels, Belgium

Katelijne De Nys is a radiation oncologist with a PhD in pharmacology, and she also obtained a diploma in Pharmaceutical Medicine. She is the head of the Clinical Trial Center of the university hospitals of Leuven, President of the Reimbursement Commission of Belgium, and professor in pharmacology at the university of Leuven.

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Andrew Dillon, Chief Executive, National Institute for Health and Care Excellence (NICE), London, United Kingdom

Andrew Dillon joined the UK National Health Service in 1975 after graduating from the University of Manchester. He held a number of senior management positions in the National Health Service, including General Manager of the Royal Free Hospital and Chief Executive of St George's Hospital, both academic medical centres in London, before joining the National Institute for Health and Care Excellence as its founding Chief Executive in 1999.

Paloma Casado Durandez, Deputy Director of Quality and Cohesion, Ministry of Health, Madrid, Spain

Paloma Casado Durandez is a specialist in Laboratory Medicine, Master in Heath Services Management, with 20 years of experience in quality management systems and health management services. Her experience includes several years in leading the implementation of health quality systems (Hospital Mancha Centro in Ciudad Real and Hospital Clinico San Carlos in Madrid) in laboratory medicine and other clinical services, and also in some hospitals as medical director (Hospital Central de la Cruz Roja and Hospital del Henares in Madrid.

Currently, as Deputy Director of Quality and Cohesion of the Spanish Ministry of Health, Paloma Casado Durandez is leading at national level, the definition and implementation of the Spanish health strategies and the Spanish national HTA network, among other responsibilities.

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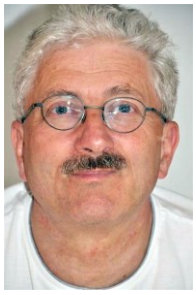
Wolfgang Ecker, Chair of Working Group on Clinical Investigation and Evaluation (Medical device legislation), European Commission; Head of Department III/3, Pharmaceuticals and Medical Devices, Blood, Tissue and Transplantation, Federal Ministry of Health, Vienna, Austria



Wolfgang Ecker is Dr. med. univ. graduated from Vienna University and has 4 years of practical training at several Viennese hospitals. He worked at the Austrian Health Ministry since 1985, starting in the areas of medical radiation protection, radiopharmaceuticals, medical devices, clinical trials of pharmaceuticals.

He initiated the Competence Mall Initiative (CMI) with Austrian Life Science Clusters; is a lecturer at several Universities of Applied Sciences in Austria and will, until the end of the International Medical Device Regulators Forum (GHTF), be a member of the EU-team in Study Group 5.

Member EU Council WP on Pharmaceuticals and Medical Devices; Member of Standing Committee for Medicinal Products for Human Use. Since December 2008, he is the Chairman of EU WG on Clinical Investigation and Evaluation (CIE).

Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA)

Hans-Georg Eichler is the Senior Medical Officer at the European Medicines Agency where he is responsible for coordinating activities between the Agency's scientific committees and giving advice on scientific and public health issues.
Prior to joining the European Medicines Agency, he was at the Medical University of Vienna in Austria for 15 years. He was vice-rector for Research and International Relations since 2003, and professor and chair of the Department of Clinical Pharmacology since 1992.

His other previous positions include president of the Vienna School of Clinical Research and co-chair of the Committee on Reimbursement of Drugs of the Austrian Social Security Association.

His industry experience includes time spent at Ciba-Geigy Research Labs, U.K., and Outcomes Research at Merck & Co., in New Jersey.

In 2011, he was the Robert E. Wilhelm fellow at the Massachusetts Institute of Technology's Center for International Studies, participating in a joint research project under the MIT's NEWDIGS initiative.

Hans-Georg Eichler graduated with an M.D. from Vienna University Medical School and a Master of Science degree in Toxicology from the University of Surrey in Guildford, U.K. He trained in internal medicine and clinical pharmacology at the Vienna University Hospital as well as at Stanford University.

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Sebastian Gaiser, Director, Health Economics & Reimbursement, Europe, Middle East, Africa and Canada, St. Jude Medical, Zaventem, Belgium

Sebastian Gaiser is the Director of Health Economics & Reimbursement for Europe, Middle East and Africa, and leads all reimbursement activities in those geographies. He is responsible for securing adequate coverage for all St. Jude Medical product lines. He and his team are working closely with hospitals, payers, HTA agencies and governments to ensure market access. He joined St. Jude Medical in 2012 after more than 5 years at Heraeus where he was charged with different leadership roles as Head of Health Economics, Head of Sales and Licensing Coating and Chief Compliance Officer.

Sebastian Gaiser is leading different task forces and working groups within Eucomed, an industry association representing the medical technology industry in Europe. He has a Master in Economics from the University of Koeln, Germany.

Dominique Giorgi, Chair, Economic Committee for Healthcare Products, Ministry for Health and Solidarity , Paris, France

Dominique Giorgi is the Chair of the Pricing Committee for medicines and health devices, in Paris, France.
His previous positions counts former deputy head, Paris hospitals (Assistance Publique, hôpitaux de Paris); former member of the audit service, Ministry of Health and Social Affairs; former assistant director, social security department, Ministry of Health and Social Affairs.

He has a Master from Institut d'Etudes Politiques de Paris and alumni of the National School of Administration (Ecole Nationale d'Administration – ENA). Publication by Dominique Giorgi: *"La politique du médicament » (1997) Clefs-Montchrétien, Paris"*

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Wim Goettsch, Advisor, International Affairs and Academia, National Health Care Institute (Zorginstituut Nederland – ZIN), Diemen, Netherlands

Wim Goettsch is currently the Project Leader of work package 5 of the European Network of HTA (EUnetHTA) Joint Action 2 (2012-2015) where ZIN participates. In this work package, rapid joint assessments of relative effectiveness of pharmaceuticals are piloted between more than 25 HTA organisations around Europe. These pilots are based on the methodology that was developed in a similar work package in EUnetHTA JA1 (2010-2012) of which he was also the Project Leader. Until the beginning of 2013, Dr. Goettsch was the Deputy Secretary of the Medicinal Products Reimbursement Committee at Dutch National Health Care Institute (ZIN, formerly known as CVZ).

The Dutch Medicinal Products Reimbursement Committee (currently known as the Scientific Advisory Board) assists the National Health Care Institute in the advice to the Dutch Minister of Health on whether new drugs need to be included in the basic insurance package. The Secretary and the Deputy Secretary were responsible for the coordination of the committees work. Currently, he is also Advisor of International Affairs and Academia for the National Health Care Institute. Since 2013 he is also Director in the Board of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

He has an MsC in environmental toxicology, a PhD in immunology and an advanced education in (pharmaco)- epidemiology and pharmaco-economics. Before joining the National Health Care Institute, he worked as a research manager for the PHARMO Institute and was responsible for coordination of numerous pharmacoepidemiological and outcomes studies for international offices of pharmaceutical companies such as AstraZeneca, Novartis, Pfizer and GSK.
Wim Goettsch has more than 50 publications in peer-reviewed international journals. He also worked as a senior epidemiologist in the field of antimicrobial resistance for the National Institute for Public Health and the Environment in the Netherlands and was involved in the initiation of the European Antimicrobial Resistance Surveillance Network (EARS-Net) that is now coordinated by the ECDC.

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Marlene Gyldmark, Head of the Health Technology Assessment Group (MORSE), Global Pricing and Market Access, Pharmaceutical Division, F. Hoffmann-La Roche Ltd, Basel, Switzerland

Marlene Gyldmark holds an MSc in Economics, University of Copenhagen, Denmark, and an MPhil in Health Economics, University of York, UK.

She joined Roche Global Headquarter in the Global Pricing and Market Access group November 2000.

Current responsibilities at Roche include heading a team of statisticians, health economic modellers and epidemiologists responsible for payer and HTA evidence generation.

Previous work experiences include e.g. Health Economic Manager at Pfizer Denmark, International Health Economic and Strategic Pricing Manager Novo Nordisk International, Denmark, Lecturer in economics at Royal Danish University of Pharmacy, Copenhagen, Denmark, Research Scientist at DSI - Institute for Health Service Research and Development, where Marlene also participated in a number of EU concerted action projects on e.g. willingness to pay for health, economics of intensive care, socio-economic costs of AIDS and the HARMET project on standardizing methods for economic evaluation, and Health Economist at the Tanzanian Ministry of Health, Dar es Salaam, Tanzania.

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Jean-Luc Harousseau, Chairman of the Board, French National Authority for Health (Haute Autorité de Santé – HAS), Paris, France

Jean-Luc Harousseau is Professor of Hematology at the University of Nantes in France. He has been Chairman of the French National Authority for Health (HAS) since February 2011 and Chair of its Economic and Public Health Evaluation Committee since February 2014. He headed the Department of Clinical Haematology in Nantes teaching Hospital for 24 years and was Director of the Cancer Center René Gauducheau in Nantes from October 2008 to January 2011.

In his previous position, he was a member of the Scientific Advisory Board of the French National Cancer Institute and President of the Clinical Research in Oncology National Committee from October 2008 to January 2011.

He was a founding member of the Groupe Ouest-Est Leucémies Aigues et Maladies du Sang and of the Intergroupe Français du Myélome and President of this internationally renowned cooperative group from June 2009 to January 2011. Professor Harousseau is a member of the European Haematology Association, the European Group for Blood and Marrow Transplantation, the American Society of Hematology and the American Society of Clinical Oncology.

He was member of the Scientific Advisory Board for the Multiple Myeloma Research Foundation and the International Myeloma Foundation. His research interest areas concern the therapy of acute myeloid leukaemia and multiple myeloma.

Jean-Luc Harousseau received the 2005 Waldenström Award and the 2009 Robert Kyle Award for his scientific contribution in the field of Multiple Myeloma. Professor Harousseau has contributed to more than 500 peer-reviewed publications.

François Houÿez, Chair, EUnetHTA Stakeholder Forum; Director, Treatment Information and Access, Health Policy Advisor, the European Rare Diseases Organisation (EURORDIS), Paris, France

François Houÿez is working at the European Organisation for Rare Diseases EURORDIS. He is always been working as a patient advocate since the early 90s. He joined EURORDIS in May 2003, and is now Director of Treatment Information and Access, Policy Advisor. He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA). François Houÿez co-chairs the stakeholders' forum of the EUnetHTA Joint Action 2.

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Mirjana Huic, Assistant Director, Department for Development, Research and Health Technology Assessment, Agency for Quality and Accreditation in Health Care and Social Welfare, Zagreb, Croatia

Mirjana Huic is a medical doctor, specialist in clinical pharmacology and toxicology. Since 2009, as the Assistant Director in Croatian Agency for Quality and Accreditation in Health Care and Social Welfare and Head of Department for Development, Research and HTA, she is responsible for establishing a transparent, evidence-based HTA process in Croatia. She is appointed as representative of Croatia for EUnetHTA Joint Action Plenary Assembly and actively participates in different JAs WPs scientific work and production of collaborative HTA reports. Dr Huic is a former Chair of the EUnetHTA Plenary Assembly (2012-2014) and current Co-chair of ISPOR HTA Roundtable Europe.

She represents Croatia in the HTA Network. From 1992 to 2006 she worked as a clinician and clinical trials investigator at Zagreb University Hospital Center and Zagreb University School of Medicine.

In 2006-2011, she worked as Editor for Evidence-Based Medicine, in the Croatian Medical Journal (CMJ) and in 2008-2009 she was the Director of the Institute for Clinical Medical Research, University Hospital "Sestre milosrdnice", Zagreb, Croatia. She participated in different national and international projects; she is author or co-author of 22 scientific articles, different book chapters, international and national HTA reports.

Mirjana Huic is a member of the Croatian Society of Clinical Pharmacology and Therapeutics, European Forum for Good Clinical Practice (EFGCP), Council of Science Editors, HTAi, ISPOR, ISPOR HTA Roundtable Europe, and ISPOR HTA Council.

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Haralampos Karanikas, Senior Researcher, National and Kapodistrian University of Athens, Athens Greece

Haralampos Karanikas holds a PhD in the field of Temporal Text Mining at University of Manchester on health data. The case study was related to Intelligent Monitoring Competition (e-Competitive Intelligence) in the field of biomedicine. He also holds a MSc in Computer Science from UMIST (University of Manchester Institute of Science and Technology) with a thesis on the development of a database system to support center for people with disabilities in the city of Manchester and a B.Sc. degree in Physics from the Aristotle University of Thessalonica, Greece.
He is actively involved in Information Management as a focal research area.

His research work has informed the formation of research proposals related to text mining in collaboration with leading European Universities, research institutes and industrial partners. His work aims at advancing the ways data mining algorithms are used in order to analyse natural language text in an attempt to discover structure and implicit meanings "hidden" within the text or data. His research interests include document/data warehouse, eHealth, ontology construction, data mining, big data and business intelligence.

He has been involved in many research projects. From September 2010 till March 2012 he was special IT advisor of the General Secretary, Ministry of Health, scientific responsible for the implementation of ESY.net (National health BI system), member of the Greek DRGs implementation team and member of the Central Committee of the Ministry to monitor the IT systems of the NHS. From March 2012 till April 2013 Haralampos Karanikas was board member of the Greek Health Procurement Committee (E.P.Y.), an independent agency with administrative and financial autonomy, reporting directly to the Minister of Health. E.P.Y. is responsible for strategic and operational planning of the procurement system in the Health Sector.

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Kristian Kidholm, Head of the HTA-Unit at Odense University Hospital, Odense, Denmark

Kristian Kidholm holds Ph.D. in health economics and is head of the HTA unit at Odense University Hospital and research manager of CIMT – Center for Innovative Medical Technologies.
For the last five years he has been doing assessments of telemedicine applications in Denmark and other EU countries by use of MAST (Model for Assessment of Telemedicine).
He is a work package leader for evaluation in several EU projects on telemedicine in which MAST is being used as the framework for assessment of outcomes of telemedicine, e.g. the Renewing Health project and the United4Health project.

Kristian Kidholm has also participated in the development of the mini-HTA approach in Denmark and participates in the AdHopHTA projects that develop guidelines and toolkits for hospital based HTA.

Finn Boerlum Kristensen, Director, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Professor, Health Services Research and HTA, University of Southern Denmark, Odense, Denmark

Finn Boerlum Kristensen is Head of the Coordinating Secretariat of the European network for Health Technology Assessment, EUnetHTA (www.eunethta.eu), in the Danish Health and Medicines Authority (DHMA), Copenhagen, since 2006. Chairman of the EUnetHTA Executive Committee since 2010. Adjunct professor in health services research and health technology assessment at University of Southern Denmark since 1999.

Formerly Head of Danish Centre for Health Technology Assessment (DACEHTA) from its establishment in DHMA, 1997-2009. University graduate in medicine. PhD in Epidemiology. Primary care physician and specialist in Public Health.

Chairman International Network of Agencies for Health Technology Assessment (INAHTA) 2003-06. Board Director, International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2011-13. Chairman, ISPOR HTA Council from 2013.

Editor of Health Technology Assessment Handbook (English, translated), 2007 and chief editor of three peer reviewed publication series from DACEHTA 1998-2009.

Finn Boerlum Kristensen has also authored numerous scientific publications on HTA, health services research, epidemiology and policy analysis.

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Stefan Lange, Deputy Director, Institute for Quality and Efficiency in Health Care, IQWiG, Cologne, Germany

Stefan Lange completed his medical studies at the Heinrich-Heine-University in Düsseldorf in 1989 and received his MD in 1994. From 1989-1993 he was initially in practical training at the Ferdinand-Sauerbruch-Clinic in Wuppertal, then assumed the position of intern/resident physician. In 1993 he joined the department of medical computer sciences, biometrics and epidemiology at the Ruhr-University in Bochum and was appointed to the position of research assistant in 1995. He was awarded the certificate of Biometrics in Medicine with the title of "Qualified Statistician" by the German Association for Medical Computer Sciences, Biometry and Epidemiology (GMDS) in 1999.

In 2003 he received his PhD (second thesis, the Habilitationsschrift) at the Ruhr University and received the venia legendi (right to teach) in Medical Biometry and Clinical Epidemiology. He joined the Institute for Quality and Efficiency in Health Care in 2004 and headed the department of Non-Medical Interventions until 2007.

Since 2005, Stefan Lange has held the position of Deputy Director of IQWiG.

Jörg Lauterberg, EUnetHTA coordinator, Department of Health Care Quality, International Affairs, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany

Jörg Lauterberg has an academic education in psychology, sociology, and medicine at the universities of Bonn, Vienna, Lübeck and Hamburg. He has done scientific work in the fields of Gerontology and Geriatrics and clinical work as MD in a tertiary academic hospital.

From 1998 – 2008, Jörg Lauterberg was Deputy Head of the medical department of the federal association of local health insurance funds (AOK-Bundesverband). From 2007 -2012, he was the manager / treasurer of the German coalition on patient safety and from 2009-10 the Deputy Head of the Institute for patient safety (University of Bonn).
Since 2012, Jörg Lauterberg has been the coordinator at IQWiG for the EUnetHTA Joint Action 2.

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Leslie Levin, Vice President, Evidence Development and Standards Health Quality Ontario, Toronto, Canada

Leslie Levin is the Chief Scientific Officer of Excellence in Clinical Innovation and Technology Evaluation (EXCITE) program at MaRS, which provides single harmonized trials and evidence-based assessments of new health technologies through a collaboration between industry, government, payers, regulators, academia and the broader health system in the pre-market space. This is regarded as a disruptive application of evidence with compared to more traditional Health Technology Assessment (HTA)
He is a senior consultant in Medical Oncology at the Princess Margaret Hospital, Toronto and is a Professor of Medicine at the University of Toronto.

Until recently and for the past 12 years, he was the Vice President of Health Quality Ontario's (HQO's) Evidence Development and Standards (EDS) division which provides evidence for policy development to the Ministry of Health and Long-Term care

He created the Ontario Health Technology Advisory Committee (OHTAC), which advises HQO and the Ministry of Health and Long-Term Care on adoption of non-drug health technologies and broader health systems changes including disease conditions and health states such as Aging in the Community and End of Life Care. This advice is anchored by evidence based analyses produced by EDS which Dr Levin had a previous leadership role in

Leslie Levin is a Professor in the Department of Medicine, University of Toronto and is a senior consultant at Princess Margaret Hospital. He is the recipient of the Excellence through Evidence award from the Canadian Health Services Research Foundation, the 2014 Canadian Agency for Drugs and Technologies in Health (CADTH) Anniversary Medal, and the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Distinguished Service Award 2014.

Bernard Merkel, former senior policy analyst, DG SANCO, European Commission

Bernard Merkel recently retired from the European Commission where he held positions such as Head of the Health Strategy and Health Systems Unit and Head of Unit for Policy Analysis & Development and International Questions in the Health and Consumers Directorate General (DG Sanco).

During his years in the Commission he was responsible for the EU's first overall health strategy, "Together for Health", which was published in 2007.

He was seconded to the EU delegated in Washington for several years responsible for bilateral EU-US relations on Health, consumer affairs and food safety.

Bernard Merkel developed the first EU public health programmes, and several EU healthcare initiatives, including the Directive on Cross-border Healthcare, actions on patient safety, healthcare quality, pharmaceuticals, health technology assessment, the health workforce, and health investment.

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Raf Mertens, Director General, Belgian Health Care Knowledge Centre (KCE), Brussels, Belgium

Raf Mertens graduated as a medical doctor at the K.U.Leuven in 1981. During the next 4 years, he practiced in Kivu, Congo. From 1985 to 1997 he was in charge of the national programme for nosocomial infections surveillance and epidemiology at the Scientific Institute of Public Health in Brussels. Meanwhile, he obtained a diploma in medical and social hygiene (1986, K.U.Leuven) and in epidemiology (1989, London school of Hygiene and Tropical Medicine) and got his recognition as a specialist in health data management. For 4 years, he was the coordinator of the European HELICS programme for the harmonization of nosocomial infections registration networks.

In 1997, he became in charge of healthcare data analysis and feedback and the development of (hospital) quality of care improvement programmes at the Christian Sickness Fund. From 2001, he was also actively involved in the development of the Intermutualistic Agency, treating the pooled data of all Belgian Sickness Funds. He was vice-president of the National Council for Quality Improvement and member of the Belgian Healthcare Knowledge Centre (KCE) Board. From 2006 to 2009 he was heading the R&D department of the Christian Sickness Fund.

As of December 2009, Raf Mertens is general director of KCE.

François Meyer, Advisor to the President, International Affairs, French National Authority for Health (Haute Autorité de Santé – HAS), Paris, France

François Meyer is currently Advisor to the President of the French National Authority for Health (HAS, Haute Autorité de Santé), with a particular focus on International Affairs. He is a member of the board of HTAi, the international professional society for HTA, and INAHTA, the international network for HTA agencies.

He joined HAS in 2005 with the responsibility of setting up the Health Technology Assessment (HTA) Division. In this role, he oversaw the grouping of the 5 major health technology domains (pharmaceuticals, medical devices, interventional and diagnostic procedures, and public health actions and programs) under one roof, and led HAS's expanding role of economic analysis in the field of HTA in France.

Prior to joining HAS, he worked for 5 years at the French Health Products Agency, initially as Deputy Director of the Regulatory Division and then as Director of the Drugs and Devices HTA Division. Before this position, he worked for 5 years in the R&D Division of a pharmaceutical company.

François Meyer earned his MD degree from the University of Montpellier Medical School in France. He served for more than 10 years the teaching hospitals of Montpellier as a practicing physician. Dr. Meyer is qualified in endocrinology and metabolic disorders and internal medicine.

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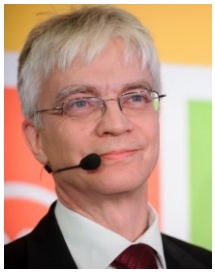
HTA 2.0 Europe – Teaming Up for Value

30-31 October, Rome, Italy

Tapani Piha, Head of Unit, e-Health and Health Technology Assessment, DG Health and Consumers, European Commission



Tapani Piha works as Head of Unit since 2004, having joined the European Commission in 2001. First he managed the Health Law and International Unit, then the Human Resources Unit, and moved to eHealth & Health Technology Assessment in September 2012. The Unit works on eHealth, Health Technology Assessment, data handling and protection in healthcare, expert advice for EU health systems, and coordinates health research and nano policies.
A physician and specialist in community medicine and public health by training, he started his career in epidemiological and intervention research on health behaviours and cardiovascular disease.

He held positions at the Finnish Ministry of Health working on health promotion and tobacco control. He coordinated Finland's EU policies in health in 1995-2001, based first in Helsinki and later in Brussels.
At the WHO Regional Office for Europe, Copenhagen, in 1989-94 he was responsible for the Action Plan for a Tobacco-free Europe.

Tapani Piha is particularly interested in European integration as a unique process; the impact and effectiveness of health and other interventions; health and economy. His interest in information and communication technologies started in the 1970s.

Andrea Rappagliosi, Vice President, Market Access, Health Policy and Medical Affairs, Sanofi Pasteur MSD, Lyon, France; Co-Chair, HTA Task Force, European Federation of Pharmaceutical Industries and Associations (EFPIA), President Vaccines Europe

Andrea Rappagliosi, a lawyer by training, is the Vice President Market Access, Health Policy and Medical Affairs and member of the Executive Committee of Sanofi Pasteur MSD, a European joint-venture fully dedicated to vaccines and prevention. He is currently President of Vaccines Europe, the European Vaccine Manufacturers Association.

He is the co-Chair of the HTA Task Force of EFPIA, the European Association of the R&D pharmaceutical Industry and represents the healthcare Industry at the HTA Network.

In the last four years, Andrea was member of the EU Commission Social Responsibility in the Pharmaceutical Sector Steering Committee – Access to Medicines in Europe.

Andrea Rappagliosi has been a member of Active & Healthy Aging Steering Group EU commission / Member States that has launched in 2011 the European Innovation Partnership addressing the demographic challenge by 2020.

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Guido Rasi, Executive Director, European Medicines Agency (EMA)

Guido Rasi has been Executive Director of the European Medicines Agency since November 2011, and was a member of its Management Board in the three years prior to this.

He was Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008.
He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008.

From 2005 to 2008 he was Director of the Institute of Molecular Medicine of the National Research Council in Rome.
From 1990 to 2005 he worked at the Institute for Experimental Medicine of the National Research Council, Italy. He had a teaching and research experience at the University of California, Berkeley in 1999.
Professor Rasi holds a degree in medicine and surgery, with specialisations in internal medicine, allergology and clinical immunology from the University of Rome.

From 1978 to 1990, he worked as a physician in hospital, research and private practice. Guido Rasi is author of more than 100 scientific publications.

Alric Ruether, Head, Department of Health Care Quality, International Affairs, Institute for Quality and Efficiency in Health Care, (IQWiG), Cologne, Germany

Alric Ruether is a physician trained in Internal Medicine and Oncology. Based on his engagement in Evidence Based Medicine and Cochrane Collaboration he worked to establish and build the discipline of Health Technology Assessment in Germany. Alric is founder of the German Agency for HTA (DAHTA) at DIMDI, Federal Ministry of Health. In 2007 Alric joined the Institute of Quality and Efficiency in Health Care (IQWiG) heading the Dept. of Health Care Quality and being responsible for the international affairs of the institute.

Alric Ruether is engaged in worldwide HTA development since more than 10 years, i.e. HTAi since its founding, INAHTA (vice chair until 2006, chair of internal communications since 2005), EUnetHTA (chair of plenary 2010-12) or ISPOR (chair of HTA roundtable Europe since 2013).

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Máirín Ryan, Acting Deputy CEO and Director of Health Technology Assessment, Health Information and Quality Authority (HIQA), Dublin, Ireland

Máirín Ryan is the Director of Health Technology Assessment in the Health Information and Quality Authority (HIQA) and is an Assistant Professor in Pharmacoeconomics in the Department of Pharmacology and Therapeutics, Trinity College Dublin.

Prior to this position she was Chief I Pharmacist at the National Centre for Pharmacoeconomics where she worked since its inception in 1998, and was a senior clinical pharmacist in HIV medicine in St James's Hospital.

She holds a PhD from Trinity College, a Diploma in Health Economics from the University of York and a Diploma in Clinical Pharmacy from the University of Derby. Her research interests include: cost data generation in the Irish setting, determinants of health policy decision making in Ireland, and economic evaluation of HIV interventions in the African setting.

She was co-chair of the Contributed Research Review Committee of the ISPOR 10th Annual European Congress in Dublin 2007 and chair of the Local Organising Committee for the Health Technology Assessment International Annual Conference held in Dublin in June 2010.

Máirín Ryan and her team at HIQA are responsible for conducting assessments of health technologies including devices, diagnostics, procedures and public health programmes. The assessments help inform safe and effective health policy and health service decisions which are patient centred and deliver value. In addition the Directorate supports the development of HTA capacity and capability through the Irish health service and the incorporation of HTA methodologies into decision making.

Andrzej Rys, Director for Health Systems and Products, DG Health and Consumers, European Commission

Andrzej Rys is a medical doctor specialized in radiology and public health; he graduated from Jagiellonian University, Krakow (PL). In 1991, he established the School of Public Health at the Jagiellonian University. SPH's director till 1997. From 1997-1999, he was director of Krakow's city health department. From 1999-2002 he was deputy Minister of Health in Poland. Member of the Polish accession negotiators team. In 2003, he established and ran as a director, the Center for Innovation and Technology Transfer at Jagiellonian University. In 2006, Andrzej Rys joined the European Commission as the Director for Public Health and Risk Assessment in the Directorate-General for Health and Consumers in Luxembourg. In 2011, he was appointed Director for Health Systems and Products in the Directorate-General for Health and Consumers in Brussels.

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Laura Sampietro-Colom, Deputy Director for Innovation, Evaluation of Innovation and New Technologies Hospital Clinic, Barcelona, Spain

Laura Sampietro-Colom is the Deputy Director of Innovation and Head of the Health Technology Assessment (HTA) Unit at the Hospital Clinic of Barcelona, a high-tech hospital and a reference for health care, research and medical training in Spain. She is currently the coordinator of the EU-funded research project AdHopHTA (FP7) on promoting the adoption of hospital-based HTA.

Prior to this, Dr Sampietro-Colom was the General Director of Information Systems, Projects and Evaluation of the Catalan Health Institute, the leading provider of public health services in the Region of Catalonia (8 Hospitals and 238 Primary Care Centres) and the Director of the Strategic Planning Unit of Health Services within the Planning and Evaluation Directorate of the Ministry of Health of Catalonia (Spain).

She has over 20 years of experience in evaluative research, specifically in HTA and was one of the founders of the Catalan Agency for Health Technology Assessment (nowadays AQuAS). She was the Founding member of the International Society for Health Technology Assessment (HTAi), serving on the Board of Directors since its foundation, including three years as Secretary of the Executive Committee, two years as Vice-President and two years as President. She is also the Vice-Chair of the HTAi-Policy Forum. Responsible for the development of one of the research lines of the first international project conducted by the International Network of Agencies for Health Technology Assessment (INAHTA), she has also worked in several EU HTA projects. She has been temporary adviser of the United Nations Agencies WHO and PAHO. She also advises on HTA strategies to public and private organisations worldwide. She also serves in the editorial board of the International Journal for Health Technology Assessment in Health Care.

She is a trained Medical Doctor; Board Certified Specialist in Preventive Medicine and Public Health (University of Barcelona) and holds a PhD in Medicine and Surgery by the Autonomous University of Barcelona, and a Master of Science in Public Health by the Rolling School of Public Health (Emory University, Atlanta, USA) as well as post graduate courses in Health Economics, Management of Health Care Institutions and Management of Innovation & Science.

During all these years, Laura Sampietro-Colom's work has focused on the development, identification, management and transfer of information to advise on the designing of strategies and policies in the areas of assessment, planning and access of medical devices, drugs, surgical procedures and other health care technologies as well as health care programs.

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Juergen Schulze, President and CEO, Sysmex EMEA, Norderstedt, Germany; Chairman of the Board, MedTech Europe; President, European Diagnostic Manufacturers Association (EDMA)

Jürgen Schulze became a board member of EDMA in 2003 and was elected as the Association's President in 2009. He is also on the board of the German National Association VDGH since 1997 and has been elected President from 2007 to 2009. He is a board member of the MedTech Europe Association and was elected as the Chairman of the board in 2013.

He is the CEO and President of SYSMEX Europe, Middle East & Africa after having held several other positions in SYSMEX since 1995. Prior to joining Sysmex, Jürgen Schulze has held several business functions in the IVD industry, mainly linked to Merck AG and Bayer Diagnostics, both in Europe and the USA.

Michele Tringali, Deputy Officer, HTA Program, Direzione Generale Salute, Regione Lombardia, Milan, Italy

Michele Tringali is deputy officer for the Lombardy program of Health Technology Assessment in Milano, where he leads the implementation of a MCDA approach to appraisal of medical devices and other health care technologies (http://vts-hta.asl.pavia.it).

He is director of an HTA structure at the ASL Pavia, a public health purchaser organisation. He coordinated an experimental programme on knowledge management (KM) in the health care and contributed to other Lombardy initiatives in education and applied research.

During year 2008 he worked for a national committee in AIFA, the Italian Agency for Drugs for the evaluation of proposals from the drug industry to a call for public incentives for pharmaceutical R&D and for new drug production. 2005-2007: seconded researcher at CEFASS (European Centre for Teaching and Learning in the Social and Health Care, then an antenna of the EIPA European Institute for the Public Administration of Maastricht, NL) with contribution to seminars on health care pathways and regional programs on e-Health. 2001-2004: staff for CEO at S. Maria della Misericordia hospital, Udine, for a project on knowledge management in health care, the development of EBM-EBN (evidence based medicine and nursing) groups and a learning program on bibliographic databases and critical appraisal of literature. 2001-2003 visiting scholar at the Lister Hill Center for Biomedical Communications of the National Library of Medicine (Bethesda - MD, USA) where he contributed to analysis and integration of a terminology for gastrointestinal endoscopy in English, Italian and French within the Unified Medical Language System (UMLS) and acquired experience on information extraction from biomedical texts using Natural Language Processing (SemRep).

During 1987-2001, Michele Tringali practiced Emergency Medicine and Gastroenterology at a community hospital in Aosta, Italy. Postgraduate Degree in Gastroenterology and Gastrointestinal Endoscopy (Ferrara University, 1994). Degree in Medicine and Surgery at Turin University (1985).

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