CONFERENCE PROGRAMME

HTA 2.0 Europe – Teaming Up for Value

30-31 October, Rome, Italy

Day 1: 30 October	Session	Speakers
8:00-9:00	*Registration*	
9:00 – 9:15	**Welcome and introduction:** ***"What is HTA 2.0 Europe"***	**Julia Chamova,** Director of Operations, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark
9:15 – 11:00	**Opening plenary: HTA, regulation and policy making – synergy in focus** *Individual presentations*	**Hon. Beatrice Lorenzin,** Minister of Health, Ministry of Health, Rome, Italy, (TBC) **Andrzej Rys,** Director for Health Systems and Products, DG Health and Consumers, European Commission **Finn Børlum Kristensen,** Director, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark and Professor, Health Services Research & Health Technology Assessment, University of Southern Denmark, Odense, Denmark **Guido Rasi,** Executive Director, European Medicines Agency (EMA) **Wolfgang Ecker,** Chair of Working Group on Clinical Investigation and Evaluation (Medical device legislation), European Commission and Head of Department III/3, Pharmaceuticals and Medical Devices, Blood, Tissue and Transplantation, Federal Ministry of Health, Vienna, Austria
11:00 – 11:45	***Networking Coffee Break (Interaction at the EUnetHTA Activity Stations and FP7 HTA Projects Area)***	

Session description

Cooperation and exchange of information between HTA organisations in Europe and globally has taken place for quite some time. However, recently European HTA witnessed a significant increase in the level of organisation, intensity and coherence of joint efforts such as producing HTA information together, engaging with the HTA process stakeholders, and establishing working relationship with the regulators. Efforts are made to develop sustainable strategic interaction with policymakers on matters regarding assessment and access to health technologies. Both the European Commission and individual EU Member States have been instrumental in supporting these efforts which the European HTA organisations themselves initiated more than a decade ago.

This session will bring you up-to-date on the key objectives, achievements and trends in the European HTA cooperation efforts from the point of view of the national healthcare system of the EU Member State, the European Commission and the European regulatory bodies.

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11:45 – 13:30	**Panel discussion: European cooperation on HTA – how does it make a difference at national/ regional level?** *Presentation, Q&A and interactive discussion*	**Moderator: Leslie Levin,** Vice President, Evidence Development and Standards Health Quality Ontario, Toronto, Canada **Speaker:** **Luciana Ballini,** Head of Regional Observatory for Innovation, Regional Agency for Health and Social Care – Emilia-Romagna, Bologna, Italy **Panel A:** **Luciana Ballini,** Head of Regional Observatory for Innovation, Regional Agency for Health and Social Care – Emilia-Romagna, Bologna, Italy **Wim Goettsch,** Advisor International Affairs and Academia, National Health Care Institute (Zorginstituut Nederland – ZIN), Diemen, Netherlands **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 **Jörg Lauterberg,** Department of Health Care Quality, International Affairs, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany **Panel B:** **Andrew Dillon,** Chief Executive, National Institute for Health and Care Excellence (NICE), London, United Kingdom **Jean-Luc Harousseau,** Chairman of the Board, French National Authority for Health (Haute Autorité de Santé – HAS), Paris, France **Raf Mertens,** Director General, Belgian Health Care Knowledge Centre (KCE), Brussels, Belgium **Mairin Ryan,** Acting Deputy CEO and Director of Health Technology Assessment, Health Information and Quality Authority (HIQA), Dublin, Ireland **Stefan Lange,** Deputy Director, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany

Session description

Next year EUnetHTA will celebrate its 10th anniversary of working together on developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries. What (and concretely how) is done in EUnetHTA: A) to support sharing of information and collaborative assessments B) to close the gap between regulatory and HTA requirements and C) to improve methodological standards, quality and transparency of HTA information?

What are the national/regional HTA production needs in the European countries that can be met via European cooperation on HTA? What is done to facilitate the use of EUnetHTA tools and products in the European countries? This session will clarify and discuss EUnetHTA efforts (scientific tools, processes, achievements) bringing added value to national/regional HTA production processes.

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13:30 – 15:00	***Networking Lunch (Interaction at the EUnetHTA Activity Stations and FP7 HTA Projects Area)***	
15:00 – 16:45	**Panel discussion: Getting an effective technology from the lab to the patient in Europe – challenges and opportunities** *Q&A and interactive discussion*	**Moderator: François Houÿez**, Chair, EUnetHTA Stakeholder Forum and Director, Treatment Information and Access, Health Policy Advisor, The European Rare Diseases Organisation (EURORDIS), Paris, France **Panel:** **Wolfgang Ecker**, Chair of Working Group on Clinical Investigation and Evaluation (Medical device legislation), European Commission and Head of Department III/3, Pharmaceuticals and Medical Devices, Blood, Tissue and Transplantation, Federal Ministry of Health, Vienna, Austria **Hans-Georg Eichler**, Senior Medical Officer, European Medicines Agency (EMA) **Sebastian Gaiser**, Director, Health Economics & Reimbursement, Europe, Middle East, Africa and Canada, St. Jude Medical, Zaventem, Belgium **James Anderson**, Director European Partnerships, GSK, Brentford, Middlesex, UK **Finn Børlum Kristensen**, Director, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark and Professor, Health Services Research & Health Technology Assessment, University of Southern Denmark, Odense, Denmark **Francois Meyer**, Advisor to the President, International Affairs, French National Authority for Health (Haute Autorité de Santé – HAS), Paris, France
17:00 – 19:00	***Networking Reception***	

Session description

EU citizens want the best possible health care now and in the future, and they hope that resources will be allocated according to need, in a fair way, no matter what the economic climate. The challenges in meeting this demand are many. However, regulators and HTA agencies explore feasible and sustainable ways to overcome them while ensuring appropriate involvement of technology producers and scientific expertise. Taking stock of more than three years of cooperation between the European Medicines Agency and EUnetHTA and bringing into picture recent developments in streamlining requirements for assessing medical technologies (medical devices) in Europe, the panel will discuss opportunities and concrete actions to align the requirements from "regulators" and HTAs towards the technologies coming to the market.

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Day 2: 31 October	Session	Speakers
9:00 – 10:45	**Plenary: Innovative tools for HTA – today and tomorrow** *Individual presentations*	**Chair: Alric Ruether,** Head, Department of Health Care Quality, International Affairs, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany **Topics and Speakers:** 1. HTA in and for hospitals – AdHopHTA project. **Laura Sampietro-Colom**, Deputy Director for Innovation, Evaluation of Innovation and New Technologies Hospital Clinic, Barcelona, Spain 2. Patient Registries & HTA – PARENT Joint Action. **Haralampos Karanikas**, Senior Researcher, National and Kapodistrian University of Athens, Athens Greece 3. HTA Core Model® & MCDA in regional decision making – experiences from Lombardia, Italy. **Michele Tringali**, Deputy Officer, HTA Programme, Direzione Generale Salute, Regione Lombardia, Milan, Italy 4. HTA Core Model® & assessment of e-health technology – MAST project. **Kristian Kidholm**, Head, HTA-Unit at Odense University Hospital, Odense, Denmark 5. HTA Core Model® as a value assessment framework – perspective of a global healthcare company. **Marlene Gyldmark**, Head of the Health Technology Assessment Group (MORSE), Global Pricing and Market Access, Pharmaceutical Division, F. Hoffmann-La Roche Ltd, Basel, Switzerland 6. Outputs of joint work in EUnetHTA applied in HTA agencies. **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 **Session description** Interaction, collaboration, working across silos of any kind, i.e., organisational, geographical, intellectual; building and linking networks as platforms for connectivity and interactivity in any environment including decentralized systems of operation within a country or a sector – these are just a few characteristics of the "2.0" approaches applicable to HTA. This session will provide a few examples of how cooperation and networking relevant to HTA across European projects, joint actions, national and regional initiatives as well as cooperation with stakeholders can be sources of bringing added value to participants of such cooperation and to a healthcare system as a whole.
10:45 – 11:30	***Networking Coffee Break (Interaction at the EUnetHTA Activity Stations and FP7 HTA Projects Area)***	

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11:30 – 13:00	**Roundtable: HTA in Europe – from strategy to action: what's next?** *Q&A and interactive discussion*	**Moderator: Bernard Merkel,** former senior policy analyst, DG SANCO, European Commission **Discussants:** **Bert Boer,** Executive Board member, National Health Care Institute(Zorginstituut Nederland – ZIN), Diemen, Netherlands **Paul Cornes,** Clinical Outcomes Group, Bristol Oncology Centre, Bristol, United Kingdom **Katelijne De Nys,** President, Reimbursement Commission of Medicines, Brussels, Belgium **Dominique Giorgi,** Chair, Economic Committee for Healthcare Products, Ministry for Health and Solidarity, Paris, France **Juergen Schulze,** President and CEO, Sysmex EMEA, Norderstedt, Germany; Chairman of the Board, MedTech Europe; President, European Diagnostic Manufacturers Association (EDMA) **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

Session description

Broadening of the concept of value beyond clinical and economic evaluation, methodological readiness to take into account new modes of healthcare management and delivery (e-health and m-health), increased transparency and use of real world evidence are just a few requests to those who perform HTA.

What can and should the European cooperation on HTA do to help meet the new requirements and how can the challenges in building a broad value concept be overcome? When are HTAs needed by those who make decisions, who should make the HTAs, how will they best fit into decision-making processes – and do these processes need to be organised differently? Multi-stakeholder perspectives from the health technology assessors, payers, policy makers, technology producers and users will be explored in this round table discussion.

13:00 – 13:30	**Conference Summation and Closing**	**Speakers:** **Paloma Casado Durandez,** Deputy Director of Quality and Cohesion, Ministry of Health, Madrid, Spain **Finn Børlum Kristensen,** Director, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark and Professor, Health Services Research & Health Technology Assessment, University of Southern Denmark, Odense, Denmark **Tapani Piha,** Head of Unit, e-Health and Health Technology Assessment, DG Health and Consumers, European Commission

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