

Flora Giorgio, Deputy Head of Unit, B6 Medical Devices and HTA, DG SANTE, European Commission, Brussels, Belgium

Flora Giorgio is the deputy head of Unit "Medical devices and HTA" at the European Commission in DG Health (SANTE). Flora and her team were responsible for preparation of the new EU HTA Regulation which was adopted in December 2021, after three years of negotiations with Member States. Previously in the field of HTA, they were responsible for developing an EU initiative on Strengthening EU cooperation on HTA, providing the Secretariat to the HTA Network, set up by Article 15 of the Directive 2011/24/EU on "the application of patients' rights in cross-border healthcare", and oversees the activities of the Joint Action EUnetHTA. Flora is a pharmacist by training.

In her presentation "New EU HTA Regulation: Why it matters for national/regional HTA bodies and different stakeholders?" Flora will present the major issues related to this new legal framework, like four areas and key principles of joint HTA work: Joint clinical assessment; Joint scientific consultations; Emerging health technologies and Voluntary cooperation. Why HTA Regulation matters for national/regional HTA bodies and different stakeholders, and implementation timeline will be discussed further.

Panel 1: Why health technology assessment (HTA) is important for supporting the evidence-based decision making on health technologies?

The main objective of this Panel is to share views and to stimulate a discussion with different stakeholders, like HTA bodies, patient organisations, health professionals and decision makers on importance of HTA for supporting the evidence-based decision making on health technologies. The importance of the new EU Regulation on HTA, appropriate stakeholders' involvement and three years preparation period until its mandatory application in January 2025, will be discussed as well.

Panelist



Claudia Wild, Chief Executive Officer, Austrian Institute for HTA (AIHTA), Vienna, Austria

Claudia Wild is Chief Executive Officer (CEO) of Austrian Institute for HTA (AIHTA) since 2020. Before she has been Director of the LBI-HTA since its establishment in 2006. From 1989-2006 she worked as a Senior Researcher at the Institute of Technology Assessment at the Austrian Academy of Sciences

and helped developing the research field Health Technology Assessment in Austria. She studied communications and psychology at the University of Vienna and political sciences at the Ohio University in Athens/Ohio/USA and completed her studies with a Graduation at the University of Vienna as Doctor of Philosophy in 1985. In 2009, she habilitated in social medicine (Medical University Graz) on the topic of "resource allocation in health-care systems".

In her presentation "HTA in Austria: National and international view", Claudia will stress the AIHTAs role at national level (how HTA is used in Austrian decision making) and international level, especially in EUnetHTA and recent collaborative activities in the COVID-19 pandemic. Preparedness for this new Regulation on HTA will be discussed as well.



François Houÿez, Information & Access to Therapies Director & Health Policy Advisor, EURORDIS, Paris, France

François Houÿez has worked as a patient advocate since the early 1990s (HIV/AIDS, Act Up -Paris and EATG) and joined EURORDIS in May 2003. He now works as Information & Access to Therapies Director & Health Policy Advisor. He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA). He also represents EURORDIS at the Health Technology Assessment Network, and in CIOMS Working Group XI on Patient Involvement in the Development and Safe Use of Medicines. François supervises EURORDIS's programme for Community Advisory Boards (EuroCAB) and the European Network of Rare Diseases Help Lines. He pioneered patient advocacy with the European Medicines Agency as part of the first patients' delegation that engaged dialogue with the Agency back in 1996 and has continuously been involved in the agency activities during the last 26 years. François is also a patient.

In his presentation "Appropriate patient involvement in HTA: the view from EURORDIS", Francois will point the importance of patient involvement in HTA, in joint clinical assessments and joint scientific advices within EUnetHTA and after mandatory application of Regulation on HTA in January 2025.



Mirjana Huić, International HTA expert, HTA/EBM Center, Zagreb, Croatia

Mirjana Huic is a medical doctor and specialist in clinical pharmacology and toxicology. Since 2009 she is working as HTA specialist and educator at national and international level, first as the Assistant Director for Development, Research and HTA in Croatian Agency for Quality and Accreditation in Health Care and Social Welfare and in 2019 as a Head of HTA Department at Croatian Ministry of Health. In this period, Dr Huic and her team were responsible for establishing a transparent, evidencebased HTA process in Croatia and for production of HTAs on the whole range of health technologies at national level. Since 2010 Dr Huic actively participated in different EUnetHTA JAs scientific work and production of European collaborative HTA reports on the whole range of health technologies, some with appropriate patient involvement. From January 2020 she is working as HTA independent specialist in HTA/EBM Center, conducting HTAs at international level.

In her presentation "HTA in Croatia: Past, present and the future" she will point out how Croatia has been strengthening HTA capacities for systematic and sustainable HTA work at the national level and sustainable HTA collaboration at the EU level. Some examples will be presented as well.



Jasna Karačić, President, Croatian Association for the Promotion of Patients' Rights, Split, Croatia

Jasna Karacic is the Head of the Health Diplomacy Unit of International chair in bioethics (Former UNESCO chair). She has a Ph.D. in health diplomacy and patient rights. She served as a diplomat during the Croatian Presidency of the Council of the European Union 2020, delegated from the Ministry of Health. Due to the effort made for the engaging scientific rule in person-centered medicine elected a Patient Ombudsman by the International Council of the Patient Ombudsman© on general assembly. She is a counselor for the hospital managers regarding health policy, and she contributes significantly to health diplomacy scientific research. She holds consultative status with the United Nations and she got the Rector's Award for Achievements at the UNESCO level for human rights in medicine. She is assigned "Young Leader" for health crisis management in 2021 and serves as national coordinator for a worldwide association of women forensic experts.



Ivan Buljan, Department for Research in Biomedicine and Health & Center for Evidence-based Medicine, University of Split School of Medicine, Split, Croatia

Ivan Buljan is a postdoctoral researcher at the University of Split School of Medicine and part of the Centre for Evidence-based Medicine. He is teaching statistics and research methodology, and his research interests cover health communication, evidence-based medicine, and research integrity.

In the presentation: How can the Center for EBM help in conducting high-quality studies relevant for health care system? Ivan will describe the structure of the Center, recent projects relevant to the health care system, and the potential role of the Center in narrowing the gap between research and practice.

Mira Armour, B Sc Econ Co-founder, Executive Director Mijelom CRO, Croatia, mira@mijelom.hr



Mira is a highly motivated and passionate expert patient advocate committed to improving outcomes for people affected by multiple myeloma, a rare blood cancer. Moved by personal experience with supporting a close relative with myeloma Mira has taken an active role in Croatian, European and global blood cancer patient advocacy communities since 2006. Mira is a Co-founder and Executive director of MijelomCRO, a non-profit patient association registered in 2011. She was part of two

working groups drafting the Croatian National Cancer Control Plan for 2020-2030, is a member of a steering committee of INSIGHT MM, a global observational study of 4200 MM patients, former treasurer of a European multiple myeloma patients association and on a number of MM patient advisory boards. She is interested in advancing early diagnosis, pricing and reimbursement and has organized and moderated two regional meetings on barriers to access to approved therapies and clinical trials in Croatia and Southeast Europe. Mira attends hematology meetings and congresses; she is part of EHA Patient Advocacy Track since 2014 and at ASH. She believes that providing quality information for patients is key to their better quality of life and better outcomes.

In her presentation **What are the barriers to availability of clinical studies in Croatia?** Mira will talk of reasons why it is important to have studies available from multiple myeloma patient's perspective, share findings on MM clinical trials in Croatia and the region and outline key barriers as well as ways for creating possibilities for access to clinical trials/studies, and why it is important for all stakeholders to work together with patients.



Ljubo Znaor was born in Split, Croatia. He has finished University of Padua Medical School, Italy, and achieved his PhD degree in Universty of Split, Croatia. Since 2004 he works in Eye Clinic, University Hospital of Split, at first as a resident, and after as an ophthalmologist. His major point of interest is vitreoretinal surgery and medical retina. During his residency he started to attend regularly and collaborate with the Department of Ophthalmology of the Rudolftiftung Hospital of Vienna, Austria under the mentorship of prof. Susanne Binder. Now he also teaches at the Medical School of the University of Split, Croatia. Actually he is a Head of the Department of Ophthalmology of the University of Split School of Medicine and of the Department for Science of the University Hospital of Split.

In his presentation Ljubo will talk of Clinical research in hospital asset is a valuable and powerfull mean that often can be neglected. It offers to the hospital many oportunities and challanges. Generally it brings excellence and revenue diversification but it has to be gradually implemented as a new service to the public.



Assoc.prof.Kresimir Dolic, MD,PhD.

Born on July 4, 1979 in Split. Graduated from the Faculty of Medicine, University of Split in 2004. From 2006. to 2012. completed resideny in radiology at the University hospital Split. From June 2010 to June 2011 I was on a research fellowship at the Buffalo Neuroimaging Analysis Center in the USA engaged in research of possible vascular etiology of multiple sclerosis, which was also topic of my PhD dissertion defended in 2013. Since 2012 I have been working as a radiologist at the Clinical department of diagnostic and interventional radiology at University hospital Split. In 2015 I obtained the scientific-teaching title of assistant professor and from December 2021 associate professor at he Faculty of Medicine, University of Split.

Since 2016 I have been the Head of the Radiology department at University hospital Split and from March 2019 deputy of the Hospital CEO. In 2017. I obtained European diploma in Neuroradiology and also passed Croatian subspecialty exam in Neuroradiology.

Since July 2020 I have been the president of the Assembly of the Croatian Medical Chamber and secretary of the Croatian Society of Radiology since 2021. Lecturer at the Faculty of medicine and Health studies in Split and Mostar. Author and co-author of 50 scientific and professional publications and several textbooks.