

# 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.