Co-Creating Real-World Evidence Excellence for Decision-Making: Meeting Regulatory and HTA/Payer Needs

Thursday, 22 April 2021 | 16:30 – 18:00 CET |Online

Agenda

16h30	Welcoming remarks & Opening Statement

Jo De Cock, CEO of RIZIV/INAMI

16h40	Introduction to EMA's Guideline on registry-based studies, DARWIN and Big Data Stakeholder Implementation Forum

Dr Xavier Kurz, Senior pharmacoepidemiologist and head of data analytics, European Medicines Agency

17h00	Panel interventions from HTA/Payer community

Moderated by Dr Karen Facey, Evidence Based Health Policy Consultant

- **Dr Roisin Adams,** Head of HTA Strategy and External Engagement, National Centre for Pharmacoeconomics (**NCPE) -** *Ireland*
- **Dr Antje Behring,** Acting Head of Drug Department, Federal Joint Committee **(G-BA) -** *Germany*
- **Dr Pier Paolo Olimpieri,** Data Analyst Coordinator, Monitoring Registries Office, Italian Medicines Agency **(AIFA) -** *Italy*
- **Piia Rannanheimo,** Pharmacoeconomist, Finnish Medicines Agency **(FIMEA) –** *Finland*
- **Cláudia Furtado,** Head of Health Technology Assessment, Pricing and Reimbursement Division (DATS) and the Information and Strategic Planning Division **(INFARMED) –** *Portugal*

17h30	Panel discussion and Q&A with the audience

17h55	Closing remarks

Jo De Cock, CEO of RIZIV/INAMI

18h00	Meeting close

Speaker Biographies

Jo De Cock
CEO, INAMI - RIZIV

Jo De Cock has been CEO of the Belgian National Institute of Health and Disability Insurance (INAMI- RIZIV) since 1995. Prior to this, he was a Deputy Director and Counsellor for social affairs in the office of the Belgian Prime Minister (1985-1993) and later filled the position of adjunct general administrator of the National Social Security Office (1993-1995). Under Jo De Cock's thought leadership as CEO, INAMI-RIZIV conveyed a series of roundtables bringing together different stakeholders to consider the use of real-world evidence to ensure short term affordability, long-term sustainability and patient access in 2018 and 2019. This resulted in several papers including on 'The use of real world data throughout an innovative medicine's lifecycle', 'Outcomes based pricing and reimbursement of innovative medicines with budgetary limitations' and 'TRUST4RD: Tool for Reducing Uncertainties in the evidence generation for specialised Treatments for Rare Diseases' (published in Orphanet). Since its creation in 2019, Jo De Cock is closely involved in the International Horizon Scanning Initiative (IHSI), an independent entity legally registered at RIZIV/INAMI and a spin-off of the BeNeLuxA initiative which aims to provide data to payer organisations and decision-makers to drive better medicinal products pricing.

Dr. Xavier Kurz
Senior pharmacoepidemiologist and head of Data Analytics, European Medicines Agency (EMA)

Dr. Xavier Kurz is senior pharmacoepidemiologist and head of the Data Analytics team within the Analysis and Methods Task Force at the European Medicines Agency (EMA). Dr. Kurz graduated in 1982 as a Medical Doctor at the University of Liege, Belgium. He specialised in Tropical Medicine and worked for several years in public health projects in Africa and Asia. He obtained a MSc (1991) and a PhD (1997) in Epidemiology and Biostatistics at McGill University, Montreal, Canada. He then joined the Department of Pharmacology of the University of Liege and the Belgian Centre for Pharmacovigilance (Ministry of Health) as scientific expert. He joined the European Medicines Agency (EMA) on 1st September 2005.

Dr. Karen Facey (moderator)
Evidence Based Health Policy Consultant

Dr. Karen Facey worked as a senior statistician in the pharmaceutical sector and UK medicines regulation, before becoming the founding Chief Executive of the first national HTA agency in Scotland. Since 2003, Dr Facey has been an independent consultant on health policy, HTA and patient involvement. She has served as Non-Executive Director on Scottish health boards and now leads research part-time on appraisal of rare disease treatments in the IMPACT HTA project as Principal Investigator at the University of Edinburgh. She is passionate about holistic HTA to determine value and use of health service data to improve patient care. Dr Facey has facilitated the development of the RWE4Decisions multi-stakeholder initiative and is the lead co-author of the paper on 'Real-World Evidence to Support Payer/HTA Decisions about Highly Innovative Technologies in the EU – Actions for Stakeholders', commissioned by the Belgian payer INAMI-RIZIV.

Dr. Roisin Adams

Head of HTA Strategy and External Engagement, National Centre for Pharmacoeconomics (NCPE)

Dr. Roisin Adams is Head of HTA Strategy and External Engagement for the National Centre for Pharmacoeconomics (NCPE). Dr. Adams led the HTA team for a number of years before being seconded to the HSE to lead a new unit tasked with overseeing and managing high-cost drugs in acute hospitals. Dr. Adams co- chairs the HTA domain of the BeNeLuxA initiative and oversees the EUNetHTA work of the NCPE. She also is a Director on the Board of the International Horizon Scanning Initiative. She has been awarded a number of grants from the Health Research Board to examine health preferences in Ireland, the most recent examines patient preferences in HTA. Her areas of interest include methods for preference elicitation, combining different data for evidence synthesis and reimbursement mechanisms for high cost drugs. She has held advisory positions for Department of Health, the Health Information and Quality Authority and policy direction at EU level.

Dr. Antje Behring

Acting Head of Drug Department, German Federal Joint Committee (G-BA)

Dr. Antje Behring is head of the Pharmaceuticals Department in the Federal Joint Committee (G-BA). In the G-BA she has been involved in the early benefit assessment procedure for new drugs from the very beginning. Before joining the G-BA in 2011, she worked as a consulting pharmacist for a German health insurance company. She completed her pharmaceutical studies and her doctorate at the Ludwig-Maximilians-University Munich. Before studying pharmacy, she worked as a physiotherapist.

Dr. Pier Paolo Olimpieri

Data Analyst Coordinator, Monitoring Registries Office, Italian Medicines Agency (AIFA)

Dr. Pier Paolo Olimpieri is a Data Analyst Coordinator at the Monitoring Registries Office of the Italian Medicines Agency (AIFA).

Previously to his role at AIFA, Dr. Olimpieri worked as a Postdoctoral Researcher in the Physics Department of "Sapienza" University of Rome under the supervision of prof. Anna Tramontano, developing machine learning algorithms for the prediction of the antibody-antigen recognition mode and automatic antibody humanization techniques.

Piia Rannanheimo
Pharmacoeconomist, Finnish Medicines Agency (FIMEA)

Piia Rannanheimo is a pharmacoeconomist at the Finnish Medicines Agency (FIMEA). She joined FIMEA's HTA-team in 2010. With a background in Pharmaceutical Sciences, Rannanheimo has contributed to numerous national, Nordic and European HTAs and worked as a visiting researcher at CADTH and Center for Health Economics at University of York. She also serves as an expert for the Council for Choices in Health Care in Finland. In addition, she is a member in several working groups led by the Ministry of Social Affairs and Health in Finland, covering rational use of medicines, HTA, RWD and medical product data management. Currently, she is working as a project manager for a project which aims to establish a national medicinal data repository. She is one of the co-authors of the RWE4Decisions paper on 'Real-World Evidence to Support Payer/HTA Decisions about Highly Innovative Technologies in the EU – Actions for Stakeholders', commissioned by INAMI/RIZIV.

Cláudia Furtado
Head of Health Technology Assessment, Pricing and Reimbursement Division (DATS) and the Information and Strategic Planning Division, INFARMED

Cláudia Furtado is the head of Health Technology Assessment, Pricing and Reimbursement Division (DATS) as well of the Information and Strategic Planning Division (DIPE) at INFARMED, the Portuguese National Authority of Medicines and Health Products. As head of DATS, she is responsible for HTA evaluation, pricing and reimbursement of medicines, medical devices and health products, and for managed entry agreements. As head of the DIPE, she oversees monitoring of health consumption and expenditure and the definition and evaluation of policy measures. In addition to her role at INFARMED, she is an assistant professor at the Portuguese National School of Public Health (Universidade NOVA de Lisboa).

Call for input for the next RWE4Decisions Newsletter (June)!

Do you have any news, policy development, upcoming events, calls for applications etc… related to real-world data/real-world evidence which you would like to see included in the next RWE4Decisions Newsletter?

Please send it to: secretariat@rwe4decisions.com

Looking for further information? Visit our website: https://rwe4decisions.com/