Towards Establishing an EU Real-World Evidence Generation Action Plan for Better Healthcare Systems & Patient Outcomes

NATIONAL, EUROPEAN & INTERNATIONAL PERSPECTIVES

Virtual Event
@RWE4Decisions

*Moderated by **Jacki Davis***

Wednesday, 24 November (14h00-16h30 CET)

RWE4Decisions

14.00 – 14.20	**KEYNOTES**

Welcome – How real-world evidence can contribute to better healthcare decision-making
Frank Vandenbroucke, Belgian Deputy Prime Minister and Minister for Social Affairs and Public Health

Next steps in realising an evidence generation action plan: Council Conclusions on Access to Medicines (EU Portuguese Presidency)
Rui Santos Ivo, President, National Authority of Medicines and Health Products (INFARMED)

14.20 – 15.00	**RWE4DECISIONS LEARNINGS – REAL-WORLD EVIDENCE IN OUTCOMES-BASED MANAGED ENTRY AGREEMENTS**

Karen Facey, Visiting Senior Research Fellow, Usher Institute, University of Edinburgh
Nicole Mittmann, Chief Scientist and Vice-President of Evidence Standards, Canadian Agency for Drugs and Technologies in Health (CADTH), Canada
Hervé Nabarette, Deputy Director for Public Affairs, AFM-Téléthon
Anna Nachtnebel, Senior HTA Expert, Austrian Social Insurances
Karen Coulton, Global Head of Payer Engagement, AstraZeneca

15.00 – 15.30	**REAL-WORLD EVIDENCE FRAMEWORKS IN CROSS BORDER COLLABORATION INITIATIVES**

Beneluxa Initiative

Aldo Golja, Senior Policy Advisor on Drug Pricing and Reimbursement, Ministry of Health, Welfare and Sports, The Netherlands

Nordic Pharmaceuticals Forum and FINOSE

Flemming Sonne, CEO, Amgros, Denmark
Tuomas Oravilahti, Pharmacoeconomist, Finnish Medicines Agency (FIMEA), Finland

15.30 – 16.25	**BUILDING BLOCKS FOR ESTABLISHING AN EU REAL-WORLD EVIDENCE GENERATION ACTION PLAN**

A discussion moderated by Jacki Davis

Regulators' perspective

Peter Arlett, Head of Data Analytics and Methods Taskforce, European Medicines Agency (EMA)

Pharmaceutical industry's perspective

Alexander Natz, Secretary-General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

HTA bodies' perspective

Judith Fernandez, Coordinator – RWE unit, HTA division, Haute Autorité de Santé (HAS)

Payers' perspective

Diane Kleinermans, President of the Commission of Drugs Reimbursement, Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)

Patients' perspective

Yann Le Cam, Chief Executive Officer, EURORDIS – Rare Disease Europe

European Commission's perspective

Flora Giorgio, Deputy Head of Unit, Unit for Medical Devices and Health Technology Assessment, DG SANTE, European Commission

16.25 – 16.30	**CONCLUDING REMARKS & NEXT STEPS**

Jo De Cock, former CEO of the Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)

About the RWE4Decisions initiative

RWE4Decisions is a multi-stakeholder group, which has developed stakeholder actions that will better enable the use of real-world evidence in HTA/payer decisions about highly innovative technologies. The work has been commissioned by the Belgian National Institute of Health and Disability Insurance (INAMI-RIZIV) and contributors include HTA bodies and payers, regulatory agencies, patient groups, clinicians, industry and academic experts/researchers. FIPRA has facilitated the multi-stakeholder discussions with sponsorship by the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Astra Zeneca, Gilead, Novartis, Roche and Takeda.