Navigating Joint HTA, Procurement, and Fair Pricing — Evidence-Based Insights and Practical Recommendations

27-28 March 2019
Airport Hotel Okecie
Warsaw, Poland

Program and Schedule of Events

WI-FI NETWORK: Airport Hotel Business
PASSWORD: 1234567890

#ISPORWarsaw
www.ispor.org
Navigating Joint HTA, Procurement, and Fair Pricing — Evidence-Based Insights and Practical Recommendations

ISPOR Warsaw 2019 provides opportunities to engage in discussions with key health economics and outcomes research (HEOR) stakeholders and leaders in Europe and beyond. The attendees will bring multi-stakeholder perspectives from industry, policy making, regulation, medical profession, research, academia and relevant national medical/health economics societies. The event will provide educational and information-sharing options to include educational symposia, meetings of the ISPOR CEE Consortium and ISPOR Chapters from the region, exhibition and a conference to address health-policy issues of joint HTA, and procurement and pricing in the European region.

ISPOR events provide a forum for the discussion and dissemination of information surrounding the science of HEOR. The events bring together experts and stakeholders in the HEOR field to share innovative research methods and health policy developments, to learn from each other, explore business opportunities and network.

Thank you to the ISPOR Warsaw 2019 Regional Conference Advisors

Marcin Czech, MD, PhD, MBA, Head, Department of Pharmacoeconomics, Institute of Mother and Child, and Business School, Warsaw University of Technology, Warsaw, Poland and Former Undersecretary of State/Vice Minister, Polish Ministry of Health, Poland

Rok Hren, PhD, MSc, Assistant Professor, University of Ljubljana, Slovenia

Roman Ilyk, PhD, DSci, Deputy Minister of Health, Ministry of Health of Ukraine, Ukraine

George Khachatryan, MD, Director, Department of Methodological Support of Comprehensive HTA, Federal State Budgetary Institution, Center of Healthcare Quality Assessment and Control, Ministry of Health of the Russian Federation, Russia

Joanna Lis, MSc, MBA, PhD, Head of Market Access, Sanofi, Professor, Department of Pharmacoeconomics, Medical University of Warsaw, Poland

Bertalan Németh, MSc, Senior Health Economist, Syreon Research Institute, Hungary

Maciej Niewada, MD, PhD, Professor, Department of Experimental and Clinical Pharmacology, Medical University of Warsaw, Poland

Vitaly Omelyanovsky, MD, PhD, DSc, General Director, Department of Comprehensive Health Technology Assessment, FSBI Center of Expertise and Quality Control of Medicines, Ministry of Health of the Russian Federation, Russia

Guenka Ivanova Petrova, MPharm, MEcon, PhD, DSc, Health Data Analyst, Diabetes Registry, Medical University of Sofia, Bulgaria

Oresta Piniazhko, PhD, Director of HTA Department SEC, Ministry of Health of Ukraine, Ukraine

Dinko Vitezić, MD, PhD, President, Croatian Society for Clinical Pharmacology and Therapeutics, Croatia

Olha Zaliska, PhD, Dsci, Professor, Department of Management and Economy of Pharmacy, Medicine Technology and Pharmacoeconomics, Postgraduate Faculty, Danylo Halytsky Lviv National Medical University, Ukraine

ISPOR Warsaw 2019 Thanks Our Supporting Institutions

Comenius University in Bratislava, Faculty of Pharmacy, Bratislava, Slovakia

Danylo Halytsky Lviv National Medical University, Department of Management and Economy of Pharmacy, Drug Technology and Pharmacoeconomics, Lviv, Ukraine

Halmed, Agency for Medicinal Products and Medical Devices of Croatia, Zagreb, Croatia

HDF—Croatian Pharmacological Society, Zagreb, Croatia

Kozminski University (Akademia Leona Koźmińskiego), Warsaw, Poland

Ministry of Health of Ukraine, Kiev, Ukraine

Polskie Towarzystwo Ekonomiki Zdrowia (Polish Society for Health Economics), Warsaw, Poland

Poznan University of Medical Sciences, Department of Pharmacoeconomics and Social Pharmacy, Poznan, Poland

University of Ljubljana, Faculty of Economics, Ljubljana, Slovenia
Agenda at a Glance

Day 1  Wednesday, 27 March 2019

8:00-19:00  Registration

9:00-10:30  ISPOR Poland Chapter Meeting  Prior RSVP is required.

11:15-12:45  ISPOR Ukraine Chapter Meeting  Prior RSVP is required.

12:00-19:00  Exhibits

13:00-15:00  ISPOR CEE Consortium Meeting  By invitation only. Prior RSVP is required.

15:30-16:30  Educational Symposium: Improving Patient Access to Innovative Cancer Therapies: The Role of Managed Entry Agreements

16:30-16:45  Coffee break

16:45-17:45  Educational Symposium: The Implementation of Sustainable Biosimilar Policies to Increase Access to Biological Medicines in CEE Countries

17:45-18:00  Coffee break

18:00-19:00  Educational Symposium: Multi-Disciplinary Approaches to Address the Unmet Need in Schizophrenia

19:00-20:00  Welcome Reception

Day 2  Thursday, 28 March 2019

8:00-17:30  Registration and Exhibits

8:30-9:00  Refreshments and Networking

9:00-9:15  Welcome and Opening remarks

9:15-10:30  Session 1: Aligning Evidence Requirements for Drug Authorization and Coverage — Central and Eastern European (CEE) Countries Insights

10:30-11:00  Coffee break

11:00-12:30  Session 2: Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

12:30-13:30  Lunch

13:30-15:00  Session 3: Medical Device Assessment and Procurement — Fair and Efficient Access in Countries with Limited Health Budgets

15:00-15:15  Coffee break


16:45-17:00  Closing Remarks
Day 1  
Wednesday, 27 March 2019

9:00-10:30  
**ISPOR POLAND CHAPTER MEETING**  Prior RSVP is required.
The meeting will focus on presentations discussing “HTA and reimbursement hot topics in Poland - experience sharing.”

11:15-12:45  
**ISPOR UKRAINE CHAPTER MEETING**  Prior RSVP is required.
The program includes updates on the national drug policy and HTA implementation in Ukraine, capacity building in HEOR/HTA, bioequivalence and priority disease models, among other discussion topics.

Delegate Notes:
Day 1
Wednesday, 27 March 2019

13:00-15:00

**ISPOR CEE CONSORTIUM MEETING** By invitation only. Prior RSVP is required.
ISPOR Regional Chapter leadership representatives and members from the ISPOR CEE Consortium will meet to discuss education and research projects of the Consortium, and provide updates on the Chapters’ regional activities. ISPOR 2019 Top 10 HEOR Trends and Patient Engagement in HTA in the CEE Region will also be discussed.
EDUCATIONAL SYMPOSIUM: IMPROVING PATIENT ACCESS TO INNOVATIVE CANCER THERAPIES: THE ROLE OF MANAGED ENTRY AGREEMENTS

In recent years, innovative cancer therapies have demonstrated the potential to dramatically reduce the global cancer burden and improve patient outcomes. However, delivering these therapies to patients remains challenging in many countries; governments, payers, and industry face pressure to ensure timely access and budget predictability while maintaining incentives for future innovation.

Flexible access agreements such as managed entry agreements (MEAs) have been identified as mechanisms to address these challenges and expedite access to innovative cancer therapies by allowing pharmaceutical companies and payers to share risks associated with the introduction of new medicines.

This MSD-sponsored Educational Symposium will include a panel discussion on how MEAs and multi-year multi-indication agreements can be leveraged to address emerging challenges in the oncology landscape and accelerate patient access to innovative cancer therapies.

Moderator: Magdalena Władysiuk, MD, Vice President, HTA Consulting, Poland

Speakers: Luka Vončina, MSc, PhD, Managing Director, Freyr Consulting, Croatia; Tim Wilsdon, MSc, Vice President, Charles River Associates, United Kingdom; Denis Vujicic, Managing Director, MSD, Poland; Stanimir Hasardzhiev, MD, Secretary General, Patient Access Partnership, Board Member, European Patients’ Forum, Secretary General, CEE4Health, and Chairperson, National Patients’ Organization, Bulgaria; Francis Arickx, Head of the Directorate Pharmaceutical Policy, National Institute for Health and Disability Insurance (RIZIV-INAMI), Belgium

Sponsored by: Merck Sharp & Dohme (MSD)

Delegate Notes:
16:45-17:45
EDUCATIONAL SYMPOSIUM: THE IMPLEMENTATION OF SUSTAINABLE BIOSIMILAR POLICIES TO INCREASE ACCESS TO BIOLOGICAL MEDICINES IN CEE COUNTRIES

In many countries, high-priced original biological medicines are unavailable or reimbursement is restricted. The main value proposition of biosimilar medicines in these countries is not only to save money, but to increase patient access to treatment. To increase access for patients, there is a need — especially in CEE countries — for sustainable pricing and demand-side policies on biosimilar medicines that would go beyond a sole short-term objective of cost savings to the healthcare budgets. In this workshop, panel members will discuss the implementation of sustainable biosimilar policies from the academic, payer, regulatory, and industry perspectives.

Speakers: Rok Hren, PhD, MSc, Assistant Professor, University of Ljubljana, Slovenia; András Inotai, Principal Researcher, Head of Pharmaceutical Policy Department — Syreon Research Institute, Hungary; Marcin Czech, PhD, MD, MBA, Head, Department of Pharmacoconomics, Institute of Mother and Child, and Business School, Warsaw University of Technology, Warsaw, Poland, and former Deputy Minister of Health and Undersecretary of State, Poland; Maarten Van Baelen, Market Access Director, Medicines for Europe, Belgium; Tomáš Tesař, PhD, PharmD, MBA, Member, Reimbursement Committee, Union Health Insurance Fund, Slovakia

Sponsored by: Medicines for Europe

Delegate Notes:
18:00-19:00 EDUCATIONAL SYMPOSIUM: MULTI-DISCIPLINARY APPROACHES TO ADDRESS THE UNMET NEED IN SCHIZOPHRENIA

The symposium will provide an overview on the public health importance of mental disorders, with special focus on clinical, economic, and societal burden of schizophrenia. The clinical overview will highlight the current unmet medical need for schizophrenic patients with negative symptoms. Multidisciplinary HTA approaches — including the economic modelling framework — to evaluate therapeutic options in schizophrenia will be presented.

Speakers: Zoltán Kaló, PhD, Eötvös Loránd University, Hungary; István Bitter, PhD, DSc, Semmelweis University, Hungary; Bertalan Németh, Syreon Research Institute, Hungary

Sponsored by: Gedeon Richter plc.

Delegate Notes:
Day 2 Thursday, 28 March 2019

9:00-9:15
WELCOME
Speaker: Nancy S. Berg, Chief Executive Officer and Executive Director, ISPOR, Lawrenceville, NJ, USA
OPENING REMARKS
Speaker: Zbigniew J. Krol, MD, PhD, Undersecretary of State, Deputy Minister of Health, Ministry of Health, Poland

9:15-10:30
SESSION 1: ALIGNING EVIDENCE REQUIREMENTS FOR DRUG AUTHORIZATION AND COVERAGE — CENTRAL AND EASTERN EUROPEAN (CEE) COUNTRIES INSIGHTS

This session will focus on the benefits and challenges of scientific advice offered jointly or in parallel by the European Medicines Agency and HTA bodies in Europe, and advancements of the European network for Health Technology Assessment (EUnetHTA) early dialogue program, while exploring the CEE countries’ perspectives on the experiences.
Moderator: Finn Berlum Kristensen, MD, PhD, Managing Director, Science & Policy Consultancy, Professor in Health Services Research and HTA at Department of Public Health Research Unit of User Perspectives, University of Southern Denmark, and External Lecturer at Copenhagen Business School, Department of Strategy and Innovation, Denmark
Panelists: Tomáš Tesař, PharmD, PhD, MBA, Member, Reimbursement Committee, Union Health Insurance Fund, Slovakia; Zbigniew J. Krol, MD, PhD, Undersecretary of State, Deputy Minister of Health, Ministry of Health, Poland; Maggie Galbraith, Project Manager, Haute Autorité de Santé, France; Pero Draganić, MD, PhD, Principal Advisor for Distribution of Medicines and Pharmacoeconomics, Croatian Agency for Medicinal Products and Medical Devices (HALMED), Croatia; Francis Atrickx, Head of the Directorate Pharmaceutical Policy, National Institute for Health and Disability Insurance (RIZIV-INAMI), Belgium

Delegate Notes:
11:00-12:30  HEALTH DATA, HEALTH DATA, AND MORE HEALTH DATA: FROM QUANTITY TO QUALITY THROUGH COOPERATION

The session’s objective is to share experiences and approaches to a more comprehensive, effective, and sustainable use of health data in healthcare systems in and across European countries.

*Moderator: Katarzyna Kolasa, PhD, Head of Department of Health Economics and Healthcare Management, Kozminski University, Poland*

*Panelists: Wim Goettsch, PhD, Associate Professor of HTA, WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University, Netherlands; Guenka Petrova, MPharm, MEcon, PhD, DSc, Analysis of the Health Data, Diabetes Registry, Bulgaria; Jose Valverde, MD, Policy & Programme Officer, Unit eHealth, Well-being and Aging, DG-CNECT, European Commission; Janusz Cieszynski, Deputy Minister of Health for Digitalization of the Medical Sector, Ministry of Health, Poland; Alexander Berler, PhD, MSc, Director, Consulting Services, Gnomon Informatics SA, Greece*

*Delegate Notes:*
SESSION 3: MEDICAL DEVICE ASSESSMENT AND PROCUREMENT — FAIR AND EFFICIENT ACCESS IN COUNTRIES WITH LIMITED HEALTH BUDGETS

The session will provide an update on international efforts in advancing methodology and approaches to medical device assessment, present several European countries experiences, and discuss the issue of medical device assessment and procurement in the context of the healthcare systems working within restricted budgets.

Moderator: Ernesto Nogueira, MBA, Managing Director, ValueConnected, Netherlands

Lecturers: Rok Hren, PhD, MSc, Assistant Professor, University of Ljubljana, Slovenia; Claudia Wild, DPhil, Director, LBG — Ludwig Boltzmann Institute for HTA, Austria; Bence Takács, PhD, Health Economist, Division for Health Technology Assessment, Directorate General for Medicine Authorization and Methodology, OGYEI, Hungary; Richard Charter, MSc, Market Access & Value Based Healthcare Lead Medication Delivery Systems — Europe, Switzerland

Delegate Notes:
SESSION 4: HOW FAR CAN WE GO? FINDING COMMON WAY IN CLINICAL EVALUATION, DATA GENERATION, AND JOINT PROCUREMENT AND PRICING NEGOTIATIONS — SWOT ANALYSIS

In the context of the complexity of finding an effective balance to support the cost of coverage and the decision-making process, session participants will discuss strengths, weaknesses, opportunities, and threats of a joint approach to value assessment, procurement, and price negotiations that impact access to health technologies in Europe.

**Moderator:** Joanna Lis, MSc, MBA, PhD, Head of Market Access, Sanofi, Professor, Department of Pharmacoeconomics, Medical University of Warsaw, Poland

**Lecturers:** Iga Lipska, MD, PhD, Plenipotentiary of the National Health Fund, President of Hospital-based HTA, Poland; Marcin Czech, MD, PhD, MBA, Head, Department of Pharmacoeconomics, Institute of Mother and Child, and Business School, Warsaw University of Technology, Poland and Former Undersecretary of State/Vice Minister, Polish Ministry of Health, Poland; Stanimir Hasardzhiev, MD, Secretary General, Patient Access Partnership, Board Member — European Patients’ Forum, Secretary General, CEE Health Chairperson, National Patients’ Organization, Bulgaria; Andrzej Rys, MD, Director, Health Systems, Medical Products and Innovation DG SANTE, European Commission

*Delegate Notes:*
Key Information

RECORDING & PRESS INFORMATION
ISPOR supports the promotion of research presented at ISPOR conferences, while safeguarding sensitive information, data, and research findings that are not yet available to the public. Due to the sensitive nature of data and particularly the preliminary, unpublished research findings, all filming and recording of scientific sessions is prohibited during the conference, without the express written consent of ISPOR. By participating in the discussions, conference registrants agree that ISPOR may electronically copy, videotape, or audiotape their attendance at and involvement in any program. Registration and attendance at ISPOR Warsaw 2019 constitutes an agreement by the registrant to ISPOR’s use and distribution (both now and in the future) of their image or voice in photographs, videotapes, electronic reproductions, and audiotapes of such events and activities. ISPOR will strictly enforce its rights as the exclusive licensee of all publication and reproduction rights to each presentation, and no presentation, in whole or in part, may be reproduced without approval from ISPOR.

Conference attendees must gain approval from a speaker prior to quoting or publishing that individual’s scientific results. Members of the press must identify themselves as such before questioning speakers and congress attendees if using the information in a professional capacity. More detailed information on ISPOR's Press Pass, Legal, and Embargo Policies are available on ISPOR’s News & Press page at the ISPOR website (www.ispor.org).

For further questions on these policies, please contact: Betsy Lane (blane@ispor.org), Director and Chief Marketing & Communications Officer.

CONFERENCE PROGRAM DISCLAIMER
Please be advised that while the conference program is designed to provide accurate information regarding the subject matter covered, the views, opinions, and recommendations expressed are those of the authors and speakers, not of ISPOR — the professional society for health economics and outcomes research, and thus ISPOR does not guarantee the accuracy of the information disseminated. If professional advice is desired, please consult a competent professional.

ANTITRUST COMPLIANCE
It is the undeviating policy of ISPOR to comply strictly with the letter and spirit of all local and U.S. Federal, State, and applicable international trade regulations and antitrust laws. Any activities of ISPOR or ISPOR-related actions of its officers, Executive Committee Members, or members that violate these regulations and laws are detrimental to the interests of ISPOR and are unequivocally contrary to ISPOR policy.

SAFETY AND RESPONSIBILITY POLICY
ISPOR is committed to providing a safe, productive, and welcoming environment for all participants and staff. All participants, including, but not limited to, attendees, speakers, volunteers, exhibitors, ISPOR staff, service providers, and others, are expected to abide by this Safety and Responsibility Policy as noted on our website under Attendee Information—Key Information.

ISPOR in Action in Europe Grow with us!

Through its regional groups engagement and contribution, meetings, region-specific events and publications, ISPOR provides a wide array of resources and tools to help all healthcare stakeholders in the European region apply the best scientific methodologies to health economics and outcomes research to improve decision making for health.

ISPOR Regional Consortium, Regional and Student Chapters
• 26 Regional Chapters in Europe (23 in CEE region)
• Over 3500 ISPOR members (35.5% are located in Europe; 5.65% are in CEE region)
• 22 Student Chapters

Publications
• Value in Health Regional Issues publishes scientific, peer-reviewed research specific to the region
• News Across EMEA (Europe, Middle East and Africa) newsletter features health policy, regional initiatives, and Chapters members-reported news

Get Involved
• Contribute to scientific program during ISPOR conferences
• Attend ISPOR CEE Consortium meetings and network at global receptions during ISPOR events
• Become a member of a Regional or Student Chapter in your local area

For questions about ISPOR in Europe, please contact EMEA@ispor.org
Thank You to Our Supporters

PTEZ
Polskie Towarzystwo Ekonomiki Zdrowia

KOZMINSKI UNIVERSITY

University of Ljubljana

HALMED

HRVATSKO DRUŠTVO FARMAKOLOGA CROATIAN PHARMACOLOGICAL SOCIETY

ОХОРОНИ ЗДОРОВ’Я УКРАЇНИ

SYMPOSIUM HOSTS

biosimilar medicines

RG

MSD

EXHIBITORS

decisioneyes

Vienna School of Clinical Research
ISPOR 2019 Conferences

**ISPOR 2019**
May 18-22, 2019
New Orleans, LA, USA
Register by April 9, 2019 and SAVE!

**ISPOR Europe 2019**
2-6 November 2019
Copenhagen, Denmark
Abstract Submission Closes: 12 June 2019
Abstract Acceptance Notification: 1 August 2019
Register by 24 September 2019 and SAVE!

**ISPOR Scientific Summit 2019**
October 11, 2019
Baltimore, MD, USA

**ISPOR Latin America 2019**
12-14 September 2019
Bogotá, Colombia
Abstract Acceptance Notification: 1 May 2019
Register by 30 July 2019 and SAVE!

FOR MORE INFORMATION AND TO REGISTER: [www.ispor.org](http://www.ispor.org)
Mark your calendar!

**ISPOR 2020 Conferences**

**ISPOR 2020**
May 16-20, 2020
Orlando, FL, USA

**ISPOR Asia Pacific 2020**
12-15 September 2020
Seoul, South Korea

**ISPOR Europe 2020**
14-18 November 2020
Milan, Italy

#ISPORWarsaw

WI-FI NETWORK:
Airport Hotel Business

PASSWORD:
1234567890

www.ispor.org