



Department  
of  
Health Economics  
**HUNHTA**



## Corvinus Health Policy and Health Economics Conference Series 2015/3

Department of Health Economics, Corvinus University of Budapest  
Health Research Group Central European University, Budapest

*in cooperation with:*

Health and Health Care Economics Section of the Hungarian  
Economic Association

Health Economics Study Circle, Corvinus University of Budapest

# RATIONALIZING THE INTRODUCTION AND USE OF PHARMACEUTICAL PRODUCTS: the role of Managed Entry Agreements in Central European countries

keynote speaker: Prof. Niek Klazinga

# INVITATION



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**RATIONALIZING THE INTRODUCTION AND USE OF  
PHARMACEUTICAL PRODUCTS:  
The role of Managed Entry Agreements in  
Central European countries**

**Corvinus University of Budapest**

**April 27, 2015**

**Room E3005, 14:00-16:30**  
Budapest, Fővám tér 8.

**Background**

Health care budgets are under a continuous pressure, and with the increasing availability of potentially life-saving, quality of life improving drugs and the increasing patients' demands, means that producers searching for coverage from public funds need to show the additional benefit and the real value for money. To appraise the clinical and cost effectiveness of a new drug, countries adopt a widely used tool – health technology assessment (HTA). However, this is frequently not enough due to the limited data available at the registration, which is insufficiently accurate to predict to a certain degree the real life budget impact or cost – effectiveness. Thus, delays in access to market occur.

Against this background, bilateral contractual arrangements between payers and manufacturers, aiming to share the financial burden of the reimbursement decision. These agreements can take different shapes, including price-volume agreements (PVAs), discounts, dose caps, budget caps, outcome guarantees, coverage with evidence development (CED), and disease management programmes. Throughout the years, all these schemes were described by different names - risk-sharing agreements (RSAs), performance-based agreements (PBAs), patient access schemes (PAS), etc.. Klemp et al [1], summarized recently all these arrangements under the concept of “managed entry agreements (MEAs)”. According to Klemp, a “*A Managed Entry Agreement is an arrangement*

*between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize effective their use, or limit their budget impact.”*

One particular important aspect of MEAs, is their potential to provide a faster access to market [2], wider coverage and deal with the uncertainty regarding its clinical benefit and cost-effectiveness. Nevertheless, for a MAE to provide its real benefit, some hindering elements need to be overcome: the provider push-back, the good informational systems [3, 4], the competence to measure the adequate outcome and actual use [5], the lack of transparency and knowledge around these mechanisms [6]. Last, but not least, it is crucial to develop sharp and objective decision-making for data collection criteria and reimbursement decisions [4, 7].

In this light, MEA have received increased attention across Europe and several forms have been implemented in many countries. With the tradition among EU countries to benchmarking each other it is safe to assume, that the number and variety of MEAs will increase in the next years, and have the potential to become a strong element in reimbursement decisions aside HTA.

### **Conference chairperson:**

**Prof. László Gulácsi**, head, Department of Health Economics Corvinus University of Budapest

### **Scientific programme committee:**

**Petra Baji**, Ph.D., assistant professor, Department of Health Economics, Corvinus University of Budapest

**Olga Löblová**, Ph.D. candidate, Department of Public Policy, Central European University (CEU), Budapest

**Valentin Brodszky**, Ph.D., associate professor, Department of Health Economics, Corvinus University of Budapest

**Márta Péntek**, Ph.D., habil, associate professor, Department of Health Economics, Corvinus University of Budapest

**Prof. László Gulácsi**, Ph.D., head, Department of Health Economics, Corvinus University of Budapest

## **Programme**

### **Moderator**

**Prof. László Gulácsi**, head, Department of Health Economics, Corvinus University of Budapest

#### **14.00-14.10 Opening**

**László Szakadát**, Ph.D., Dean, Faculty of Economics, Corvinus University of Budapest

**Olga Löblová**, Ph.D. candidate, Department of Public Policy, Central European University, Health Research Group

#### **14.10-14.30**

**Rationalizing the introduction and use of pharmaceutical products; the role of MEA's in Central European Countries**

**Prof. Niek Klazinga**, Professor of Social Medicine at the Academic Medical Centre, University of Amsterdam; OECD Senior Policy Advisor, OECD Paris, Doctor Honoris Causa Corvinus University of Budapest

#### **14:30 – 14:50**

**Managed Entry Agreements in Europe – Where do we stand? West vs. East**

**Alexandru Rotar**, M.D., Ph.D. Researcher student at the Academic Medical Centre, University of Amsterdam

#### **14.50 – 15.05**

**MEA in a political science perspective**

**Olga Löblová**, Ph.D. candidate, Central European University, Budapest

#### **15.05-15.20**

**MEA - Hungarian experiences**

**Varga Péter**, MD, Head of Analysis, Medical Expertise and Controlling Head-department

**Balogh Illés Gyula**, MD

National Health Insurance Fund Administration, Budapest

#### **15.20 – 15.35**

**MEA - Policy implications in Hungary**

**Prof. Imre Boncz**, director, Institute for Health Insurance, University of Pécs; visiting professor, Corvinus University of Budapest

#### **15:35 – 16:30**

**Discussion**

#### **16.30**

**Take home message & Closing**

**Prof. Niek Klazinga**

**Prof. László Gulácsi**

## **Professor Niek S. Klazinga**

Niek Klazinga (1957) holds a medical degree from Groningen State University (1984) and a Ph.D. from the Erasmus University Rotterdam (1996; quality management of medical specialist care in The Netherlands).



He is a Professor of Social Medicine at the Academic Medical Centre of the University of Amsterdam in The Netherlands, since 1999

From January 2007 till January 2011 Prof. Klazinga had on request of the Dutch Ministry for Health and Welfare been working at the OECD in Paris. In this capacity he has been coordinating the Health Care Quality Indicator work of the OECD. Off January 2011 he was directly employed by the OECD as senior policy advisor and lead of the work on Quality of Care. He is at present still combining his work at the OECD in Paris with his professorship in Amsterdam.

Professor Klazinga is a regular temporary adviser to WHO and the EU.

Between 2005 and 2011 he was president of the Dutch Public Health Federation (NPHF) and between 2005-2009 chairman of the College on Social Medicine (CSG), the Dutch national body responsible for specialty training in the domain of social medicine. Presently he is a member of advisory committees of the Canadian Institute for Health Information (Toronto), the Department of Health in London and the Irish Ministry of Health as well as a member of the board of trustees of a large teaching hospital in The Netherlands (Isala, Zwolle) and mental health care institute (Arkin, Amsterdam).

Niek Klazinga co(authored) 200 articles in peer-reviewed journals on the functioning and quality of health care services and health systems. His present research activities concentrate on public health and health services research, more specifically on the development and use of quality indicators, quality systems in health care and health system performance.

To date (March 2015) he has successfully supervised the completion of 30 PhD thesis and is in the process of supervising another 8.

February 2008 he obtained a visiting-professorship at the faculty of economics at the Corvinus University in Budapest.

The Senate of the Corvinus University of Budapest, in its meeting of June 25th 2012 awarded him with the title of DOCTOR HONORIS CAUSA in appreciation of his academic achievements in the field of health services research and pioneering work on quality of care and public health.

## **Olga Löblová**

PhD candidate at the Doctoral School of Political Science, Public Policy and International Relations -- Public Policy track, at Central European University, Budapest.

Student chair of the multidisciplinary CEU Health Research Group.

Academic Background: MA in European Interdisciplinary Studies from the College of Europe, Natolin (2009-2010 Darwin Promotion), MA and Master Recherche in Political Science from Sciences Po Paris (2009; Politiques et sociétés en Europe), exchange in Political Science at University of Mannheim (2006-7).

Professional Background: visiting professor, European Political and Administrative Studies Department, College of Europe, Bruges; visiting lecturer at Sciences Po Paris, collège universitaire de Dijon (2014), health policy consultant since 2011 (Daniel J Edelman, Brussels/London; independent), intern at Novartis AG, Brussels (2012), foreign correspondent from Paris for business daily E15, Prague (2008-2009).

Fields of interest: EU health policy, national health policy, health care priority-setting, welfare state, Central and Eastern European politics.



## **Alexandru M. Rotar**

Ph.D. Researcher in International Comparison in Health Technology Assessment and Quality of Care at the Amsterdam Medical Center – University of Amsterdam, The Netherlands.

OECD Observer in Health Care Quality Indicators meetings – 2011, 2012, 2014

Lecturer in the NIHES Course 2014: International Comparison of Health Care Systems

London School of Economics Summit 2014 – Managed Entry Agreements

Founding member of ISPOR Chapter Romania



### **Academic background**

2011: Diploma Course in International Health and Policy Evaluation, International Institute of Social Studies, Erasmus University Rotterdam, the Netherlands

2010 – 2012: MSc. Health Economics, Policy and Law, Institute of Health Policy and Management, Erasmus University Rotterdam, The Netherlands

2010: Erasmus Summer Programme – Research Training in Medicine and Health Services

2009 – 2011: MSc. Oral – Dental Public Health, “Gr.T.Popa” University of Medicine and Pharmacy, Iasi, Romania

2003 – 2009: Faculty of Dental Medicine, “Gr.T.Popa” University of Medicine and Pharmacy, Iasi, Romania

### **Professional background**

2014 – Present: Market Access Manager Romania & Moldova – Sanofi Aventis

2011 – 2014: Market Access Specialist Romania- Abbott/AbbVie

### **Fields of interest**

Global public health, health system reform, medicine in management, health technology assessment, health care quality indicators, efficient resource allocation, social welfare

## **Péter Varga, MD**

**Head of Analysis, Medical Expertise and Controlling Department at the National Health Insurance Fund Administration (NHIFA) of Hungary.**



In the past few years, Dr Varga participated in the introduction of financing protocol system and implementation of itemized financing of high-value drugs and medical devices in Hungary. Currently, his responsibilities at NHIFA include tracking financial protocols and coordination of a 500-employee network across the whole country. He is a member of the Health Technology Assessment Committee of NHIFA and a delegation member of the Committee on Maintenance of Financial Codes, serves as an advisory board of the Minister of Human Capacities. Furthermore, he participates in training of health insurance specialists, and as well in academic research projects focusing on financial datasets related to medical expenditures.

### **Academic background:**

2011 Healthcare Management MSc, University of Szeged

2009 postgraduate degree in Public Administration specialized in financial and budget management, National University of Public Service

1997 Doctor of Medicine (MD) –Szent-Györgyi Albert Medical University, Szeged

### **Professional background:**

2008- Served several appointments (head of Analysis, Medical Expertise and Controlling Department head of Finance Department, head of Regional Health Insurance Fund of Central Hungary) at National Health Insurance Fund Administration of Hungary

2001- 2008 Sales manager in pharmaceutical industry, specialised to the fields of is primary care and central nervous system

1997-2001 Emergency doctor at the National Ambulance Service, responsibilities included general ambulance service, rescue helicopter service and emergency medicine seminars to first year medical students.



**Prof. Imre Boncz, M.D. Ph.D. habil, University of Pécs**



**Imre Boncz is the head of Department of Health-Economics, Policy & Management at the University of Pécs and the director for strategic affairs of the Coordinative Center for Medical and Health Sciences of the University of Pécs.**

After graduation in 1993 as a medical doctor from the University Medical School of Pécs, he started to work for the Faculty of Health Sciences of the same university with a research focus on health-economics, management and public health. After receiving a scholarship from the World Bank he completed a Master of Science programme at the Erasmus University Rotterdam, The Netherlands Institute for Health Sciences in 1996/1997. He defended his PhD in 2007 at the University of Pécs.

In 1999 he moved to the National Health Insurance Fund Administration (OEP) and was appointed the director of County “Vas” Health Insurance Fund in Szombathely. From 2001 Dr. Boncz was appointed the head of Department of Health Policy at the headquarter of the Hungarian National Health Insurance Fund Administration in Budapest. His responsibilities included the refinements of the financing and reimbursement system of health care services, coordination of health technology assessment activities, financial monitoring of the Hungarian National Public Health Programme and the management of the “named patients” drug system. He is an original member of the Hungarian Health-Economics Association (META) serving in the presidium of this society; member of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the International Health Economics Association (IHEA). He was elected to the Standing Scientific Committee of IHEA. He is a member of several other national and international bodies.

In recognition his professional work and commitment, he obtained several awards: Bas-relief „Saint Christopher“ for the social security (NHIFA, 2004), Diploma of merit of the Director General (NHIFA, 2001), Medallion „Saint Christopher“ for the social security (NHIFA, 2000), Diploma of merit of the Dean (Medical University of Pécs, Faculty of Health Sciences, 1999), Diploma of merit of the Rector (Medical University of Pécs, 1993, 1994)

His scientific reserach focuses on health-economics, health care financing and public health resulting in an extensive publication activity including 26 English publications, 100 published conference abstract in English, 150 English conference presentations, 98 Hungarian publications and 152 Hungarian conference presentations.

## References

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**A képzési idő: 2 félév**

**Létszám: 20 fő**

**Tandíj: 350 000 Ft/fő/félév**

**Kezdés: 2015. október**

**Jelentkezési határidő: 2015.**

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