



## Corvinus Health Policy and Health Economics Conference Series 2015/5

Organiser:

Department of Health Economics, Corvinus University of Budapest

Co-organisers:

Health Economics Study Circle, Corvinus University of Budapest

Health and Health Care Economics Section of the Hungarian  
Economic Association

**Focus on biological and biosimilar  
drugs in Europe:  
pricing, reimbursement and access  
issues**

# INVITATION



**Corvinus Health Policy and Health Economics Conference Series 2015/5**

*organized by*

Department of Health Economics, Corvinus University of Budapest

*co-organisers*

Health Economics Study Circle, Corvinus University of Budapest

Health and Health Care Economics Section of the Hungarian Economic Association

**Focus on biological and biosimilar drugs in Europe:  
pricing, reimbursement and access issues**

**Corvinus University of Budapest**

**20 October, 2015**

**Room 3001, 15:30-17:45**

Budapest, Fővám tér 8<sup>1</sup>

## **Background**

Biological drugs revolutionized the treatment of chronic inflammatory diseases in rheumatology, gastroenterology and dermatology, as well as of oncology diseases. This conference aims to provide an update on the main clinical and health economic issues related to biological drugs with special focus on biosimilars.

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<sup>1</sup> Map:

<https://maps.google.com/maps?q=Budapest,+F%C5%91v%C3%A1m+t%C3%A9r+8,+Magyarorsz%C3%A1g&hl=hu&ie=UTF8&sl=37.0625,-95.677068&sspn=61.19447,89.560547&oq=f%C5%91v%C3%A1m+t%C3%A9r+8&hnear=Budapest,+IX.+ker%C3%BClet,+F%C5%91v%C3%A1m+t%C3%A9r+8,+1093+Magyarorsz%C3%A1g&t=m&z=17>

## Conference chairperson:

**Prof. Márta Péntek**, Corvinus University of Budapest, Department of Health Economics; President of the Health and Health Care Economics Section of the Hungarian Economic Association

## Scientific programme committee:

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

**Prof. Márta Péntek**, Department of Health Economics Corvinus University of Budapest; President of the Health and Health Care Economics Section of the Hungarian Economic Association

## Programme

**15:30 – 15:35 Opening**

**Prof. Márta Péntek**

**15:35 – 16:15**

**NICE<sup>2</sup> approach to biological and biosimilar drugs**

**Paul Cornes**

Clinical Outcomes Group, Bristol, United Kingdom

*Abstract:*

- *Introduction to biological – biosimilar drugs and QALYs*
- *NICE decision making*
- *Transferability of NICE decision to other countries*
- *Practicing physicians' perspective*

**16:15 – 16:40**

**Biosimilars at the interface of science, medicine and economics**

**Uwe Gudat**

Head of Safety Biosimilars, Merck Serono, Aubonne, Switzerland

*Abstract:*

- *Benefitting the patient by enhancing access to medicines*
- *A long history of “comparable biologics”*
- *Biologic product identity: a heterogeneous “blend” of molecular species*
- *Totality of evidence: minimizing residual uncertainty, maximizing safety*
- *Benefit vs. risk at the population and personal level*
- *Understanding is the key to acceptance*

**16:40 – 17:05**

**Biotechnology revolution: The industry perspective.**

**Mike Muenzberg**

Global Medical Director of Biosimilar Unit, Merck Serono, Aubonne, Switzerland

*Abstract:*

- *Manufacturer's challenges and manufacturing costs,*
- *Why expensive diversity in approach in different countries*
- *Challenges in the 2<sup>nd</sup> wave of biosimilars*
- *Access issues & Eligibility*

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<sup>2</sup> National Institute for Health and Care Excellence

**17:05 – 17:15**

**Issues of biological therapies in Central and Eastern Europe**

**Zsombor Zrubka**

Ph.D. student, Corvinus University of Budapest

Head of Specialty Business Unit, Sandoz

**17:15 – 17:45 Discussion**

**Invited discutant:**

**Ágnes Mészáros Pharm.D., Ph.D., habil**

associate professor University Pharmacy Department of Pharmacy Administration

Faculty of Pharmacy Semmelweis University; honorary professor Department of

Health Economics, Faculty of Economics, Corvinus University of Budapest

**17:45 Closing**

**Relevant recent publications, Department of Health Economics, Corvinus University**

Brodzky V, Rencz F, Péntek , Baji P, Lakatos PL, Gulácsi L, A budget impact model for biosimilar infliximab in Crohn's disease in Bulgaria, the Czech Republic, Hungary, Poland, Romania and Slovakia. *Expert Rev Pharmacoecon Outcomes Res.* 2015 Jul 10:1-7. IF: 1,669.

Brodzky V, Baji P, Balogh O, Pentek M: Budget impact analysis of biosimilar infliximab (CT-P13) for the treatment of rheumatoid arthritis in six Central and Eastern European countries. *European Journal Of Health Economics* 15:(1) pp. 65-71. IF: 1,774

Gulácsi L, Brodzky V, Baji P, HoUng Kim, Su Yeon Kim, Yu Young Cho, PéntekM, Biosimilars for the management of rheumatoid arthritis: economic considerations. *Expert Rev. Clin. Immunol.* 2015. 11(S1), S43–S52 (2015) IF: 2,484

Gulácsi, L., Rencz, F., Péntek, M., Brodzky, V., Lopert, R., Hever, N. V., Baji, P. Transferability of results of cost utility analyses for biologicals in inflammatory conditions for Central and Eastern European countries. *Eur J Health Econ.* 2014, 15 Suppl 1, S27-34. IF: 1,913

Gulácsi, L., Rotar, A. M., Niewada, M., Loblova, O., Rencz, F., Petrova, G., Boncz, I., Klazinga, N. S. Health technology assessment in Poland, the Czech Republic, Hungary, Romania and Bulgaria. *Eur J Health Econ.* 2014, 15 Suppl 1, 13-25. IF: 1,913

Baji P, Gulácsi L, Lovász BD, Golovics PA., Brodzky V, Péntek M, Rencz F, Lakatos P. Treatment preferences of originator versus biosimilar drugs in Crohn's disease; discrete choice experiment among gastroenterologists. *Scandinavian Journal of Gastroenterology.* 2015 June 10: 1-6. (doi: 10.3109/00365521.2015.1054422) Early Online. IF: 2,361

Baji P, Gulácsi L, Golovics PA., Lovász BD, Péntek M, Brodzky V, Rencz F, Lakatos P. Perceived risks contra benefits of using biosimilar drugs in ulcerative colitis; discrete choice experiment among gastroenterologists. Submitted to *Digestive and Liver disease* (IF=2,963), 2015. October

Baji, P., Péntek, M., Czirják, L., Szeé8kanecz, Z., Nagy, G., Gulácsi, L., Brodzky, V. Efficacy and safety of infliximab-biosimilar compared to other biological drugs in rheumatoid arthritis: a mixed treatment comparison. *Eur J Health Econ.* 2014, 15 Suppl 1, 53-64. IF: 1,774

Baji, P., Péntek, M., Szanto, S., Geher, P., Gulacsi, L., Balogh, O., Brodzky, V. Comparative efficacy and safety of biosimilar infliximab and other biological treatments in ankylosing spondylitis: systematic literature review and meta-analysis. *Eur J Health Econ.* 2014, 15 Suppl 1, 45-52. IF: 1,774

## Paul Cornes

Clinical Outcomes Group  
9 Royal Victoria Park, Bristol, BS10 6TD, UK  
Email: paul.cornes@yahoo.co.uk  
Phone: +44 117 904 2603



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### CV

Paul Cornes is an Oncologist from Bristol, UK, where biosimilars and generics are routine practice.

He is part of the steering group for the European School of Oncology Working Party on the Access to Innovation in Cancer Treatment. He encourages physicians that health economics is to be embraced as part of routine medical practice.

We live in an era of both unprecedented medical advances in targeted treatments and international economic troubles. Physicians, hospitals and nations now have to make difficult choices to offer the best care to patients when budgets are under such strain. Paul teaches that we have to move forward from “Evidence Based Medicine” EBM to adopt “Value Based Medicine” VBM if innovation is to be affordable.

Education is the single most important weapon against cancer. Paul has taught cost effective care in Countries as diverse as the USA, Russia, Saudi Arabia, China and Japan and has been the American Society of Hematology Annual Spotlight Lecturer for cost control. He gives the health economics lectures for his EORTC group. He organised the first ever cost-effectiveness conference in Turkey, and at the first teaching programme on cost-control for Oncologists in Japan. He gave 2 key invited lectures on the importance of “VBM” at the recent 18th ECCO – 40th ESMO European Cancer Congress in Vienna, 2015

He has a special interest in delivering innovation in cancer treatment in middle-income countries. With the Malaysian Ministry of Health he has run workshops on cost-effective care to redesign their National Cancer Reimbursement Programme. You can also see him as a key speaker in the special day on cost control at the 18th ECCO – 40th ESMO European Cancer Congress in Vienna, 2015.

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## **Uwe Gudat**

Merck Serono  
Head of Safety Biosimilars  
Zone Industrielle de l'Ourietta  
Aubonne. CH-1170. Switzerland  
Email: uwe.Gudat@merckgroup.com



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Dr. Uwe Gudat is Head of Safety, Biosimilars at the Merck Serono Biosimilar Unit.

Dr. Gudat is licensed in internal medicine with diabetology as a sub specialty. He studied in Marburg, Germany, and received his post-graduate training under Michael Berger in Düsseldorf, Germany. He joined the pharmaceutical industry in 1995 and has held positions at Eli Lilly & Company, Actelion, and Novartis as medical director, leading global clinical development and in-licensing teams, as well as guiding clinical trial methodology and clinical safety evaluations.

Dr Gudat joined Merck Serono in 2009 and has been Head of Safety Biosimilars since Oct 2012.

## **Mike Muenzberg**

Ares Trading S.A.  
Aubonne Business Center-Building Z  
Z.I. de l'Ouriettaz  
CH-1170 Aubonne  
mike.muenzberg@merckgroup.com |



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Dr. Mike Muenzberg is Global Medical Director at Merck Seronos Biosimilar Unit. He was born in Austria and educated in Austria, Canada and Sweden.

Dr. Muenzberg is licensed as Doctor of Nuclear Medicine and has more than 15 years experience in Pharmaceutical Industry, working as local as well as global Medical Manager/Director for Serono, Novartis, Amgen, Roche and Sandoz International Biopharmaceuticals.

Since 2014 Dr. Muenzberg holds his position as Global Medical Director Biosimilars at Merck Seronos Biosimilar Unit, responsible for Merck Seronos pipeline Biosimilars.

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## Zsombor Zrubka M.D., MBA

Contact: cell phone: +36-30-202-9415;  
E-mail:  
zsombor.zrubka@googlemail.com



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### PROFESSIONAL EXPERIENCE

- 1997-1998 Resident in psychiatry  
National Institute of Psychiatry and Neurology
- 1998-2000 Child psychiatrist  
Vadaskert Clinic of Child and Adolescent Psychiatry
- 2000-2002 Sales representative  
Janssen-Cilag, division of Johnson & Johnson Ltd.
- 2002-2006 Product Manager  
Pfizer Hungary
- 2006-2008 Brand Manager, Zeldox European Brand Team (EBT)  
Pfizer Germany
- 2008-2009 Senior Brand Manager Zeldox, Neuroscience European Brand Team  
Pfizer UK
- 2009-2010 Medical Team Leader Psychiatry / Zeldox - Specialty Care Business Unit  
Europe / Australia New Zealand  
Employer: Pfizer Hungary, team location: Paris, France
- 2010 Head of Marketing Business Unit 1  
Pfizer Hungary
- 2010-2011 Business Development Manager  
Egis Pharmaceuticals Plc.
- 2011 – 2013 International Biotechnology Business Unit Manager – Autoimmune Portfolio  
Egis Pharmaceuticals Plc.
- 2013 – 2014 International Biotechnology and Oncology Business Unit Egis Manager  
Pharmaceuticals Plc.
- 2014 – 2015 International Biotechnology and Oncology Marketing Team Leader  
Egis Pharmaceuticals Plc.
- 2015 – Head of Specialty Business Unit  
Sandoz Hungary Plc.

### EDUCATION AND TRAINING

- 1997 Medical Doctor at Semmelweis University, Budapest
- 1996-1997 Two semesters at Faculty in Biomedical Engineering, Budapest Technical University
- 2005 MBA at Oxford Brookes University – Omegaglen
- 2009 Pfizer Advanced Leadership Program (Pfizer UK)
- 2015 PhD Student at Corvinus University

### SCIENTIFIC WORKS, PUBLICATIONS

- 2003 Diploma in Management Studies - Project Report: Effective sales force management (FF optimization techniques)



2005 MBA Diploma: Improving promotional effectiveness of a premium pharmaceutical brand (promotional ROI, brand equity management)

2005 Invited speaker & workshop leader on pharmaceutical brand building - Pirula Katedra Workshop, Hungary

2006 Speaker at Jacob-Fleming VI. International Pharmaceutical Branding Conference in Barcelona – Neuroscience of Branding

2014 Speaker at Informa Life Sciences Biosimilars Congress in Berlin – Experiences

2015 Scientific poster accepted for the European Workshop for Rheumatology Research (EWRR) in Budapest: Authorized Manufacturing Changes of Therapeutic Monoclonal Antibodies in EPAR Documents

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## **Ágnes Mészáros Ph.D., habil**

Contact

Department of Pharmacy Administration  
Faculty of Pharmacy – Semmelweis University  
H-1092, Hógyes Endre u. 7-9.

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Dr Agnes Meszaros qualified as a pharmacist in 1997 at the Semmelweis Medical University; since then she was working and teaching at the Faculty of Pharmacy. As Chevening scholar she was studying at the University of York and obtained an MSc degree in Health Economics. Her research interest focuses on the field of pharmacoeconomics, quality of life studies, adherence evaluation of chronic patients and clinical pharmacy/pharmaceutical care. She is the founder member of the Hungarian Health Economics Association, and member of several national and international organisations.

## **Márta Péntek M.D., Ph.D., habil**

### **CONTACT**

Corvinus University of Budapest,  
Department of Health Economics  
Fővám tér 8, 1093 Budapest, Hungary  
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### **QUALIFICATIONS**

Medical Doctor, Semmelweis University Medical School, 1989  
Rheumatology and Physiatry, specialisation - Semmelweis University, 1997  
Ph.D. - Semmelweis University 2008, thesis: „Health status and disease burden of rheumatoid arthritis patients in Hungary” (Supervisor: Prof. László Gulácsi)  
Habilitation – University of Pécs, 2013

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### **WORKPLACE**

1989 – to present: senior consultant rheumatologist, Flór Ferenc County Hospital, Department of Rheumatology (part-time since 2008); Address: Semmelweis tér 1, Kistracska, H-2143 Hungary  
and  
2009 – to present: associate professor, Corvinus University of Budapest, Department of Health Economics; Address: Fővám tér 8, Budapest, H-2143 Hungary

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### **LANGUAGE**

English, Portuguese, Hungarian

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### **PUBLICATIONS**

Scientific papers: 77 (IF: 68.7)  
Independent citations: 266  
Hirsch index: 13

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### **LIST OF PUBLICATIONS**

[https://vm.mtmt.hu//search/slist.php?inited=1&co\\_on=&ty\\_on=1&la\\_on=&LanguageID=&abs\\_on=&sp\\_on=&st\\_on=&url\\_on=1&cite\\_type=2&orderby=3D1a&Scientific=1&Independent=&top10=&lang=1&location=mtmt&debug=&stn=1&AuthorID=10002852&DocumentID=&tipus=&besorolas=&jelleg=](https://vm.mtmt.hu//search/slist.php?inited=1&co_on=&ty_on=1&la_on=&LanguageID=&abs_on=&sp_on=&st_on=&url_on=1&cite_type=2&orderby=3D1a&Scientific=1&Independent=&top10=&lang=1&location=mtmt&debug=&stn=1&AuthorID=10002852&DocumentID=&tipus=&besorolas=&jelleg=)