CORVINUS UNIVERSITY of BUDAPEST

Department of Health Economics HUNHTA

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[1]

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.

[1] Map: https://maps.google.com/maps?q=Budapest,+F%C5%91v%C3%A1m+t%C3%A9r+8,+Magyarorsz%C3%A1g&hl=hu&ie=UTF8&sll=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[2] 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 2nd wave of biosimilars*
- *Access issues & Eligibility*

[2] 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

Brodszky 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.

Brodszky 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, Brodszky 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., Brodszky, 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., Brodszky 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, Brodszky 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., Brodszky, 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., Brodszky, 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
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Phone: +44 117 904 2603

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.

Uwe Gudat

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

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

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mike.muenzberg@merckgroup.com |

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.

Zsombor Zrubka M.D., MBA

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zsombor.zrubka@googlemail.com

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

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Faculty of Pharmacy – Semmelweis University
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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
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Department of Health Economics
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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

WORKPLACE

1989 – to present: senior consultant rheumatologist, Flór Ferenc County Hospital, Department of Rheumatology (part-time since 2008); Address: Semmelweis tér 1, Kistracsa, 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

PUBLICATIONS

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

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=