Pharmaceutical Association of Serbia
Pharmacoeconomics Section

SFUS
Pharmaceutical Association of Serbia

Savez farmaceutskih udruženja Srbije
Sekcija za farmakoekonomiju

Treća međunarodna konferencija

POLITIKA CENA I REFUNDACIJE U EVROPI: VEZA SA PROCENOM ZDRAVSTVENIH TEHNOLOGIJA

Third International Conference

PRICING AND REIMBURSEMENT POLICIES ACROSS EUROPE: ITS RELATION TO HEALTH TECHNOLOGY ASSESSMENT

24. maj 2013. Hotel M, Beograd, SRBIJA

May 24th, 2013, Hotel M, Belgrade, SERBIA

Pharmacoeconomics Section
Pharmaceutical Association of Serbia

Third International Conference

PRICING AND REIMBURSEMENT POLICIES ACROSS EUROPE: ITS RELATION TO HEALTH TECHNOLOGY ASSESSMENT

24th May, 2013
Hotel M, Belgrade, SERBIA

Pharmacoeconomics Section of the Pharmaceutical Association of Serbia (SFE SFUS) is organising the Third International Conference with the topic: "PRICING AND REIMBURSEMENT POLICIES ACROSS EUROPE : ITS RELATION TO HEALTH TECHNOLOGY ASSESSMENT", which will take place in Belgrade on 24th May 2013. (http://www.farmacija.org).

The purpose of the Conference is to present characteristics of pricing and reimbursement policies in health care in Europe and in Serbia and to emphasize the importance of using Health Technology Assessment (HTA) in these processes. The aim is also based on experience of developed and developing countries to improve Serbian health care system enabling patients' availability to health care technologies selected on HTA principles. An important objective of the Conference is to improve the skills and expertise of participants especially in the area of pharmacoeconomics modeling by using uncertainty in costeffectiveness models.

Conference program will be proactive and it will represent a unique event in Serbia and the region. For the first time Conference is organized in cooperation with Central and Eastern European Society of Technology Assessment in Health Care (CEESTACH) who associate professionals in the field of HTA analyses and assessment of quality of clinical studies.

Participants of the Conference will have, for the first time, the opportunity to meet experts from Health Economics Unit, University of Liverpool Management School (United Kingdom) as well as the experts from Poland, Hungary, Croatia, Slovakia and exchange their experience and opinions.

We look forward to welcoming you in person at the Third International Conference, organized by

PHARMACOECONOMICS SECTION OF PHARMACEUTICAL ASSOCIATION OF SERBIA!

Sekcija za farmakoekonomiju
Savez farmaceutskih udruženja Srbije

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POLITIKA CENA I REFUNDACIJE U EVROPI: VEZA SA PROCENOM ZDRAVSTVENIH TEHNOLOGIJA

24. maj 2013.
Hotel M, Beograd, SRBIJA

Sekcija za farmakoekonomiju Saveza farmaceutskih udruženja Srbije (SFE SFUS) organizuje Treću međunarodnu konferenciju sa temom: „POLITIKA CENA I REFUNDACIJE U EVROPI – VEZA SA PROCENOM ZDRAVSTVENIH TEHNOLOGIJA“ koja će biti održana 24. maja 2013. godine, u Beogradu.(http://www.farmacija.org/).

Po svom sadržaju konferencija će predstavljati jedinstven stručni skup u Srbiji i u regionu. Konferencija se prvi put organizuje u saradnji sa Udruženjem CEESTACH (vodeće udruženje za medicinu zasnovanu na dokazima i procenu zdravstvenih tehnologija za Centralnu i Istočnu Evropu).

Cilj konferencije je da se predstave osobenosti refundacije i formiranja cena u zdravstvenim sistemima Evrope i Srbije i da se istakne značaj primene Procene zdravstvenih tehnologija u ovim procesima. Cilj je takođe da se na osnovu iskustava razvijenih zemalja i zemalja u razvoju unapredi zdravstveni sistem Srbije na način da se omogući pacijentima dostupnost zdravstvenim tehnologijama izabranim na osnovu kriterijuma koje nalaže Procena zdravstvenih tehnologija. Važan cilj konferencije je unapređenje veština i znanja naročito u oblasti farmakoekonomskog modelovanja i neizvesnosti u “cost-effectiveness” modelima.

Učesnici konferencije će, prvi put, imati priliku da čuju širom sveta poznate eksperte sa katedre za zdravstvenu ekonomiju Univerziteta u Liverpulu Management School (Velika Britanija) i eksperte iz Poljske, Mađarske, Hrvatske, Slovačke i razmene svoja iskustva i mišljenja.

Velika nam je čast da Vas pozovemo na
Treću međunarodnu konferenciju
SEKCIJE ZA FARMAKOEKONOMIJU
SAVEZA FARMACEUTSKIH UDRUŽENJA SRBIJE!

Honorary Committee

Prof. dr Ivanka Miletic

Prof. dr Guenka Petrova

Prof. dr Zorica Vujic

Prof. dr Darko Ivanovic

Prof. dr Nada Kovacevic

Prof. dr Ljiljana Tasic

Scientific Committee

Alan Haycox

Krzysztof Landa

Tanja Novakovic

Danka Stefanovic

Danka Tesic

Organizing Committee

Gordana Simic

Dubravka Urosev

Goran Medic

Magdalena Wladysiuk

Anna Tabor

Počasni odbor

Prof. dr Ivanka Miletić

Prof. dr Guenka Petrova

Prof. dr Zorica Vujić

Prof. dr Darko Ivanović

Prof. dr Nada Kovačević

Prof. dr Ljiljana Tasić

Naučni odbor

Alan Haycox

Krzysztof Landa

Tanja Novaković

Danka Stefanović

Danka Tešić

Organizacioni odbor

Gordana Simić

Dubravka Urošev

Goran Medić

Magdalena Wladysiuk

Anna Tabor

08.00-09.00 Registration

09.00-09.10 **Opening ceremony**
MSc. Pharm Tanja Novakovic, President of the Pharmacoeconomics Section, Galenika a.d., Serbia

PANEL I – Pricing/Reimbursement

Moderators: Tanja Novakovic, Danka Stefanovic

09.10-09.35 **Drug Pricing in Republic of Serbia**
Radica Vavan, BA Economics, Ministry of Trade and Telecomunication, Republic of Serbia

09.35-10.00 **Reimbursement of medicines in Serbia with regards to the consumption in 2012**
Dragana Baltazarevic, MD, Vesna Zivkovic, B Pharm spec, Republic Fund for Health Insurance, Republic of Serbia

10.00-10.25 **Assessing the value of medicines in middle-income countries**
David Danko, PhD, Corvinus University of Budapest, Hungary

10.25-10.50 **HTA Principles Inclusion in New European Member States and Cost/QALY Threshold in New Legislation and its Impact on Access to Innovative Medicines in Slovakia**
Pharm Dr. Dominik Tomek, MPH, PhD, Faculty of Medicine, Slovak Medical University and Faculty of Pharmacy, Comenius University, Bratislava, Slovakia

10.50-11.00 Questions and discussion

11.00-11.30 *Coffee networking break*

11.30-12.00 **Pharmaceutical Pricing and Reimbursement Policies in Croatia**
Martina Bogut, MSc, Ministry of Health, Republic of Croatia

12.00-12.30 **Pricing and reimbursement – tools and their impacts on markets in selected countries**
Magdalena Wladysiuk, M.D., HTA Consulting president and CEESTACH president, Poland

12.30-13.00 **Pricing policy and reimbursement of innovative drugs in Serbia**
Bojan Trkulja, M.D., INOVIA

13.00-13.10 Questions and discussion

13.10-14.10 *Lunch break*

PANEL II - Health Technology Assessment

Moderators: Tanja Novakovic, Danka Stefanovic

14.10-14.40 **Development of Health Technology Appraisal in England – lessons for Serbia**
Alan Haycox, BA MA PhD, Health Economics Unit, University of Liverpool Management School, United Kingdom

14.40-15.10 **HTA in Pricing and Risk sharing – needs and practice in middle income countries**
Krzysztof Landa, M.D., CEO HTA Audit, Poland

15.10-15.20 Questions and discussion

15.20-15.50 *Coffee networking break*

WORKSHOP

15.50-18.00 **The Role of Uncertainty in Cost-effectiveness Modeling**
Mr Mark Parker, BA Economics and Computer Science, MSc Health Economics, Health Economics Unit, University of Liverpool Management School, United Kingdom

18.00-18.10 **Final test, Evaluation and Closing of the Conference**

08.00-09.00 Registracija učesnika

09.00-09.10 **Otvaranje konferencije**
Mr sc. farm. Tanja Novaković, predsednica Sekcije za farmakoekonomiju SFUS, Galenika a.d.

PANEL I - Cene/Refundacija

Moderatori: Tanja Novaković, Danka Stefanović

09.10-09.35 **Formiranje cena lekova u Republici Srbiji**
Dipl. ecc. Radica Vavan, Ministarstvo trgovine i telekomunikacija, Republika Srbija

09.35-10.00 **Refundacija i potrošnja lekova u Srbiji u 2012. godini**
Dr Dragana Baltazarević , mr ph spec. Vesna Živković, Republički fond za zdravstveno osiguranje Srbije, Republika Srbija

10.00-10.25 **Procena vrednosti lekova u zemljama sa srednjim nivoom razvoja**
Dr sc. David Danko, Corvinus Universitet u Budimpešti, Mađarska

10.25-10.50 **Principi PZT u novim članicama Evropske Unije "cost / QALY threshold" u novom zakonodavstvu i njihov uticaj na dostupnost inovativnih lekova u Slovačkoj**
Prof. dr Dominik Tomek, Medicinski fakultet, Comenius Univerzitet, Bratislava, Slovačka

10.50-11.00 Diskusija

11.00-11.30 *Kafe pauza*

11.30-12.00 **Politika formiranja cena i refundacije lekova u Hrvatskoj**
Mr sc. Martina Bogut, Ministarstvo zdravlja, Republika Hrvatska

12.00-12.30 **Cena i refundacija - prikaz instrumenata i njihov uticaj na tržištima u izabranim zemljama**
Dr Magdalena Wladysiuk, HTA Consulting i predsednica CEESTACH, Poljska

12.30-13.00 **Određivanje cena i refundacija inovativnih lekova u Srbiji**
Dr Bojan Trkulja, INOVIA

13.00-13.10 Diskusija

13.10-14.10 *Pauza za ručak*

PANEL II – Procena zdravstvenih tehnologija

Moderatori: Tanja Novaković, Danka Stefanović

14.10-14.40 **Razvoj Procene zdravstvenih tehnologija u Engleskoj - pouke za Srbiju**
Prof. dr Alan Haycox, Univerzitet u Liverpulu, Management School, Health Economics Unit, Velika Britanija

14.40-15.10 **Procena zdravstvenih tehnologija u određivanju cena i u "risk sharing" – potrebe i praksa u zemljama sa srednjim nivoom razvoja**
Dr Krzysztof Landa, HTA Audit, Poljska

15.10-15.20 Diskusija

15.20-15.50 *Kafe pauza*

KRATAK KURS

15.50-18.00 **Uloga neizvesnosti u "cost-effectiveness" modelima**
Mr sc. Mark Parker, Univerzitet u Liverpulu, Management School, Health Economics Unit, Velika Britanija

18.00-18.10 **Evaluacije konferencije i zatvaranje konferencije**

Radica Vavan

Radica Vavan is a senior advisor for regulation of drug prices at the Ministry of Foreign and Internal Trade and Telecommunications, Republic of Serbia. She holds this position since 2003. She has a degree in economics. She has participated in proposing several decrees on drug prices in Serbia (about 60 decrees concerning drug pricing); proposed economic policy for drug prices; proposed criteria for setting up and determination of maximum prices for prescription drugs for human use.

In 2011 she worked as a Consultant - Lecturer on the project „Drafting decrees with criteria for setting maximum prices of medicines" as a part of Consulting Services: „Technical assistance in delivering training, capacity building and skills transfer services to Agency for Medicines and Medical Devices of Montenegro (CALIMS)".

Drug Pricing in Republic of Serbia

Radica Vavan, BA Economics, Ministry of Trade and Telecomunication, Republic of Serbia

The presentation consists of medicines pricing policy in the Republic of Serbia in the period 2004-2013., methods used for establishing medicines pricing, and a detailed description of criteria for establishing medicine pricing. The elements of making the decision on the highest medicines pricing are provided with the total number of medicines and the medicine status (generic or original), as well as average parity of prices when refered to average prices in the reference countries in April of 2013. The effects of the prices revision in the last five years are explained, on the bases of medicines pricing changes in the reference countries, the changes in exchange rate based on the currency in reference countries, as well as the effects of the policy of the gradually eliminating disparities in drugs prices.

Dragana Baltezarević, MD, spec

Dragana Baltezarević is currently employed at the Department of drug policy and pharmacoeconomics at the Republic Fund of Health Insurance (RFZO) in Belgrade, Serbia.

She is a medical doctor. She had been working at the pharmaceutical company 'Hemofarm-STADA' for more then five years, as a Medical representative, Product (SBU) manager and Medical advisor at the central Portfolio Service and as a consultant/licenced trainer for DRG system: ''Serbia Health Project - AF'' at the Ministry of Health - Republic of Serbia. Meanwhile, she's finished specialization in Pharmacy (pharmacoeconomics, and pharmaceutical legislative).

At the Department of drug policy and pharmacoeconomics at the Republic Fund of Health Insurance, she is responsible for reimbursement List: for pharmaceutical reimbursement strategy, drug application processing, monitoringof drugs consumption.Also, she is a member of the Committee for the therapy of ulcerative colitis and M.Crohn:Humira (adalimumab) & Remicade (infliksimab) as well as of ATC subcommittees.

Reimbursement of medicines in Serbia with regards to the consumption in 2012

Dragana Baltezarević, MD; Vesna Zivkovic, B Pharm spec., Republic Fund of Health Insurance, Republic of Serbia

The Serbian healthcare system is based on the principles of equality and solidarity. Citizens pay health insurance contributions as a percentage of their income and financial capacity, while healthcare services are used according to their needs. Rights and obligations of the Republic Fund of Health Insurance (RFHI) are governed by the Law on Health Insurance and the Articles of Association of the RFHI. The Serbian Reimbursement List is an integral part of the Rulebook which is published in the Official Gazette. The Reimbursement List includes the medicines that are prescribed and dispensed under the mandatory health insurance scheme, as well as the conditions under which such medicines are available to insured persons.

The general criteria for the Reimbursement list are: the financial plan of the Republic Fund of Health Insurance (published in the Official Gazette), pharmacotherapeutic aspects and pharmacoeconomic aspects. The Central Experts' Committee for medicines determines which medicines will be included in the Reimbursement list on the basis of the opinion and recommendations of the Experts' ATC Subcommittees and the Committee for pharmacoeconomics. These committees consist of the most eminent experts in pharmacy and medicine.

The Reimbursement List has ensured: monitoring of the use of medicines, reliable planning, more rational use of medicines, development of guidelines and parameters (restrictions) in prescribing and precisely targeting diseases. In addition the Reimbursement list enabled: prices reductions, cost control and measures for establishing lower prices for medicines, the adoption of the economic principles during evaluation and decision-making regarding the reimbursement of medicines, as well as the development of the capitation formula and the establishment of the Committees for approving the use of medicines.

In 2013. the plan is to include even more new medicines within fixed RFHI budget. It is also planned to ensure faster updating of the Reimbursement List, more precise planning (risk sharing agreements, volume cap agreements, the most expensive INNs - based on a GDP, adding new reference countries, defining sustainable funding of medicines). Simultaneously RFHI plans to introduce DRG system and to become a member of the EURIPID project.

Bojan Trkulja

Bojan Trkulja, director of the Association of Manufacturers of innovative medicines INOVIA in Belgrade, Serbia from 1st December 2010. He was born in 1971 in Belgrade, where he completed his elementary, high school and medical university. After a successful internship and passing the state exam, he worked in the office of F. Hoffmann - La Roche in Belgrade, from December 1999. Over the last 11 years he held a variety of positions, from associate through the Medical Product Manager, Compliance Officer and Market Access Manager.

Bojan Trkulja is happily married.

Pricing policy and reimbursement of innovative drugs in Serbia
Bojan Trkulja, M.D., INOVIA, Republic of Serbia

Pharmaceutical innovation brings undisputed value to society. Constant increase in life expectancy is clear evidence of the importance of innovative medicines. However, innovation is expensive and as a result it sometimes leads to criticism toward the price-forming in innovative pharmaceutical industry. Prolonged average life expectance is putting additional burden on payers as they are facing increasing imbalance between demand for medicines and ability to fund them. As a result, in an effort to limit the drug expenditure, governments are introducing different obstacles for reimbursement of innovative medicines. Unfortunately, even though such administrative measures are successful in limiting drug budgets, they are detrimental to patient's access to modern medicines, resulting in visible inequality between richer and poorer countries. In Serbia, problem is additionally expressed due to the poor recognition of value innovative drugs are bringing. As a result, number of innovative drugs that are reimbursed in Serbia is among lowest in Europe. Whether such policy toward innovative drugs have direct consequences on healthcare outcomes in Serbia is not known, but major HC indicators are deteriorating in the last decade. As a solution, innovative industry is proposing value based pricing system that would take into account legitimate needs of all stakeholders – payers, prescribers, patients and research based pharmaceutical companies.

Domenik Tomek

Domink Tomek is the current president of ISPOR Chapter Slovakia. He is teaching at the Faculty of Medicine, Slovak Medical University, and Faculty of Pharmacy, Comenius University, Bratislava, Slovakia. He is a founding member of the Slovak Society for Pharmacoeconomics where he pioneered and founded patient empowerment and patient education in Slovakia. Dr Tomek is a former member of the Drug committee of State lnstitute for Drug Control, of the Pricing Committee of Ministry of Finance and of the Reimbursement Committee of Ministry of Health. Dr Tomek has a doctor degree in clinical pharmacy, a PhD in the field of public health and degrees of postgraduate specializations in the management of public pharmacy, preparation of radiopharmaceuticals, revision pharmacy for health insurance, pharmacoeconomics and management of public health.

HTA Principles Inclusion in New European Member States and Cost/QALY Threshold in New Legislation and its Impact on Access to Innovative Medicines in Slovakia
Pharm Dr. Dominik Tomek, MPH, PhD, Faculty of Medicine, Slovak medical university and Faculty of Pharmacy, Comenius University, Bratislava, Slovakia

Health technology assessment (HTA) is an established method in the majority of old EU member states. Our effort was to make an overview of HTA in new EU member states to see how is HTA used and applied within this environment. The first objective was to compare the

role of threshold used in these countries and the second objective was to show an example of a country with threshold defined in primary legislation and to evaluate the impact of policy restrictions and assess their future impact on the access to new medicines.

HTA form and role differ in new EU member states, but some similarities were identified. The example of Slovakia shows that the drug policy is shifted more and more towards objective measures with the help of pharmacoeconomics or HTA, actually without scientific evaluation of the results. The new legislation is dramatically influencing the P&R approval of new, particularly high priced medicines and new indications. This will challenge payers, health care providers, industry and patients to find new ways to maintain the availability of innovative treatment.

Martina Bogut

Martina Bogut is an adviser at the Ministry of Health, Republic of Croatia from January 2013. She was born 1981 in Osijek. She was finished Faculty of Economics and additional training in accounting, information technology, human resources, project management and health economics. She is master of economics and currently extra attending specialist postgraduate studies in the field of organizations and management in health care at the Faculty of Economics and at the Faculty of Medicine in Zagreb. Martina Bogut worked in Croatian Institute for Health Insurance from 2003 to 2013. She held a variety of positions, including head of department for drugs and medical products.

Research area is health economics, analytics, pharmacoeconomics and health care management. She is a co-author on the several publications including "Comparing pharmaceutical pricing and reimbursement policies in Croatia to the European Union Member States", also she is contributing to the Croatian National Health Strategy 2012.-2020.

Pharmaceutical Pricing and Reimbursement Policies in Croatia
Martina Bogut, MSc, Ministry of Health, Republic of Croatia

The presentation presents information about Croatian pharmaceutical pricing and reimbursement policies. Croatian pharmaceutical system is similar to those in the EU Member States. In the final stage of the drafting are new ordinances which establish pricing and reimbursement regulation of medicines with the aims of maximising value for invested funds, increasing efficiency and transparency of the system. Key policies, like external and internal price referencing, which have increasingly been introduced in EU countries, are also applied in Croatia with main goal: to ensure access to medicines while containing public pharmaceutical expenditure. The presentation also includes new actions and measures on Croatian pharmaceutical market in period of last three years.

Dávid Dankó

Dávid Dankó is research leader at the Institute of Management of the Corvinus University of Budapest, where he teaches pharmaceutical and medical device reimbursement, health care management and strategic management. He is also managing director of Ideas & Solutions, a strategic advisory firm which works together with leading pharmaceutical and medical device manufacturers on making new medicines accessible for patients, as well as local portfolio strategies and patient adherence management.

Dávid received his MSc degree in Economics at Corvinus in 2003, and a PhD degree in 2012 with his thesis on long-term resource management in the pharmaceutical industry. He has been the co-editor of a comprehensive textbook on reimbursement policy.

Between 2003 and 2008, he worked as a consultant specialized in health care and life sciences, working with local and multinational companies as well as the Hungarian government. His consulting and expert assignments were mainly focused on health care reform, strategy formulation and implementation, and business planning. Between 2008 and 2010, he worked on the payer side, as deputy head for the strategy, analysis and integration of the Department of Reimbursement at the Hungarian National Health Insurance Fund Administration. There he was primarily responsible for pharmaceutical and medical device reimbursement strategy, concept development, international co-operations, and the co-ordination of IT development as well as research and analysis activities.

Dávid Dankó is a lecturer at Vienna School of Clinical Research, Université Lyon 1 (EMAUD), Semmelweis University of Budapest, Eötvös Lorand University, and he a regular speaker at international workshops and conferences on pharmaceutical and medical device reimbursement.

Assessing the value of medicines in middle-income countries

David Danko, PhD, Corvinus University of Budapest, Hungary

In many middle-income countries, there is a visible gap between health technology assessment (HTA) and reimbursement decision-making processes. The nature of this gap can be basically twofold: either HTA is not used, or HTA and actual reimbursement decisions are only tangentially aligned. In this presentation, I set out to explore the potential reasons of this discrepancy, and I endeavour to give some recommendations on how HTA could come closer to reimbursement decision-makers (payers) and offer them effective support. I suggest a pragmatic, balanced framework for drug assessment, learning from the experiences of those middle-income countries which implemented HTA in the 2002-2010 periods.

Magdalena Wladysiuk

Magdalena Wladysiuk is a president and owner of HTA Consulting. She is the president of the Central & Eastern European Society of Technology Assessment in Health Care (CEESTACH).

She is a medical doctor with MBA in Technology Management. She is one of the authors of 100 HTA reports for industry and public health insurance and financial analyses developed since 2001 (some are in Polish and some are available in English and can be found on www.hta.pl/raports). From 2006 till 2008 she provided consultancy services for the Serbian Ministry of Health in respect to evidence based basic benefit package, design and feasibility study on different models of HTA Agency in Serbia and quality of best practice guidelines. In addition she was also involved in the Evidence Based Heath care (EBHC) development, HTA systemic implementation, in-depth training of Serbian HTA analysts and development of 3 country specific HTA reports.

Currently she closely works with MoH Poland counterparts and private sector, develops strategic planning, economic analysis, health promotion, standards, cost reduction and clinical/health information systems.

Magdalena Wladysiuk is involved in promotion of HTA in the region of CEE which resulted in international cooperation in education and HTA. She organized many national and international HTA workshops and conferences and she was a speaker at most of them.

Pricing and reimbursement – tools and their impacts on markets in selected countries
Magdalena Wladysiuk, M.D., HTA Consulting president and CEESTACH president, Poland

The presentation presents recent changes on pricing and reimbursement in Poland in comparison with selected countries for specific methods of pricing. In the first look we have present countries with revolutional changes in reimbursement systems. Taxonomy of main tools / criterias/ type of pathways will be presented. The role of HTA in pricing and reimbursement especially in Poland will be presented for some changes in 2011-2013. On-going or planned reforms in many countries focused not only decreasing of prices but also on optimisation the entry of new drugs with post launch activates. Additional measures to enhance the quality and efficiency of prescribing of existing drugs including generics versus originators and patented products at low prices. Few cases on price erosion of already existing drugs and price negotiations of new drugs will be presented.

Alan Haycox

Dr Alan Haycox is a Reader in Health Economics at the University of Liverpool Management School, UK. He completed his education with a BA in Economics, and later obtained a MA in Regional Economics and a PhD in Health Economics at the University of Lancaster, UK.

Within the Management School, Dr Haycox is the Director of Liverpool Health Economics (LHE). LHE aims to improve the quality and cost-effectiveness of prescribing by working in collaboration with health services and the pharmaceutical industry to inform and support health

policy decision-making. Under his leadership, LHE has gained an international reputation as a leader in the field of pharmacoeconomics research.

Dr Haycox has extensive experience and expertise in health economic evaluations in a broad spectrum of disease groups and interventions. In addition to publishing over 100 peer reviewed papers in journals such as the BMJ and Pharmacoeconomics, Dr Haycox has authored a large number of Health Technology Assessment Monographs.

Dr Haycox is a member of the College of Experts who referee proposals submitted to the HTA Programme in the UK. He is also an expert advisor to the National Prescribing Centre (NPC) in England and the Scottish Medicines Consortium (SMC) in Scotland in addition to a wide range of national and international regulatory and funding authorities. He is a member of the NICE Technology Appraisal Committee which decides on the introduction of new drugs into the British National Health Service.

Development of Health Technology Appraisal in England – lessons for Serbia

Alan Haycox, BA MA PhD, Health Economics Unit, University of Liverpool Management School, United Kingdom

The presentation analyses the development of HTA in the UK and draws out potential messags that could provide a 'roadmap' for the development of HT in Serbia. The first part looks at the initial development of HTA in the UK as a research programme. Although successful in developing the evidence base on which decisions could be made no structures were in place to ensure that the evidence generated influenced decision making in practice. Thus following the election of a new government the National Institute of Clinical Excellence was established in 1999 to address the problem of uneven standards of care by developing national standards and guidance for healthcare provision. In 2002 a legal requirement was introduced which required local health services to provide funding to meet NICE guidance within three months of its' implementation. The presentation describes the structure and process of NICE evaluation and analyses its' performance to date and finishes with an analysis of the future challenges facing not only NICE but all HTA agencies throughout the world.

Krzysztof Landa

Krzysztof Landa is the CEO of HTA Audit, a company dealing with quality of HTA reports directed to authorities and public institutions in Poland and the President of Watch Health Care Foundation (www. WatchHealthCare.eu). From 2010 till 2011 he was President of the Central & Eastern European Society of Technology Assessment in Health Care (www.CEESTAHC.org). In 2006-2007 Dr Landa was the Director of Drug Policy Department in the Central Office of National Health Fund. In 2004 Krzysztof Landa was elected to the Board of Directors of Health Technology Assessment International (HTAi) and performed his duties till mid 2007. He was the Chairman of the LOC of the first HTAi Annual Meeting 2004, held in Krakow, Poland.

Dr Landa is a graduate of the University School of Medicine and received his management education at the Postgraduate School of Public Health of Jagiellonian University in Krakow.

Promotion of HTA in the region of CEE resulted in international cooperation in education and HTA. Dr Landa organized many national and international HTA workshops and conferences.

In years 2006 – 2008 Dr Landa provided consultancy for the Serbian Ministry of Health. He was team leader of the World Bank project aimed at introduction of HTA in Serbia, implementation of EBHC principles to the management of basic benefit package and designing a governmental HTA Agency.

HTA in Pricing and Risk sharing – needs and practice in middle income countries

Krzysztof Landa, M.D., CEO HTA Audit, Poland

Regulatory authorities, politicians, civil servants and decision makers who represent patients, the society and the state, have at their disposal various mechanisms to shape the pharmaceutical market. By using these mechanisms they can have a significant impact on the prices as well as on sales and the market structure. The pharmaceutical market in highly developed countries is therefore a regulated market, although the degree and scope of regulation is different in its specific segments.

The most important reasons making regulation of the health care services market necessary include: a high number of available health technologies, asymmetry of information, heterogeneity of the customers, difficult introduction of a new product onto the market, frequent absence of so-called "close substitutes", socially accepted system arrangements introduced years ago and other issues.

Regulation of drug prices is aimed at rationalizing expenses and controlling costs in health care. The regulations used depend on historical issues (development of the health care system), the country's level of social development, priorities in health care, and the structure and characteristics of the industry and economy in a specific country. In practice, all methods of price or volume control are seldom used concomitantly. However, it is usual to apply methods at the same control level (e.g. at the level of introduction of technologies into a benefit package or price setting, or the control of volume or total pharmaceutical spending) in parallel.

Since the end of the 20th century the number of risk sharing schemes has been growing rapidly. Increasing interest in risk sharing is related to: increasing expenses on health care, higher legal requirements concerning clinical and economic evaluation of new drugs, growing social expectations with regard to progress in medicine, the necessity to ensure availability of modern health technologies in a situation of limited financial resources.

Risk sharing schemes (RSS) assume that a certain risk affects both parties: the regulatory authority (the payer) and the manufacturer. If all the risk is incurred by one party, risk sharing makes no sense. For example, if a marketing authorization holder is able to obtain reimbursement for a specific product without a RSS, he shouldn't consider such an agreement. On the other hand, if the regulatory authority or the payer consider no risk on their side, they will not be willing to negotiate a risk sharing agreement. In the simplest definition, the sense of risk sharing schemes is – risk sharing. The mechanisms specified in an appropriate agreement make each party take some of the risk carried by the other party. The final risk reduction may be different on either side (and that is why it is so important to determine the types of risk at the preparatory stage of negotiations or even earlier, at the time of developing a reimbursement or pricing strategy). If it was possible to quantify the risk on either side, the RSS could be expected to reduce the risk to a slight (e.g. 15%) or significant (e.g. 50%) degree.

Mark Parker

Mark Parker is Senior Economic modeller for the University of Liverpool Health Economic Unit http://www.liv.ac.uk/management/research/liverpool-healteconomics/, Liverpool Cancer Trials Unit (http://www.lctu.org.uk/) and Technical director of Evaluate Econ Ltd (http://lifecode.co/), UK. Early background was in software and electronic engineering (University of Manchester) and real time Digital Signal Processing, along with RF design. Completed the MSc in Health Economics at the University of York, UK (2009). Currently PhD submission pending in Health Economic Modelling at the University of Liverpool. These roles have mostly involved developing models and evidence based messages for a wide range of disease areas for global value dossiers and HTA submissions to NICE, SMC and CVZ, along with internal decision-making. Working with GSK (vaccines), Sanofi Aventis (Diabetes), Wirral Primary Care Trust (Real world data validation), CHAMPS (weight management interventions) and Shire (biological in a chronic condition). Experience in a vast range of disease areas and population modelling, with a strong educational background in economics, software development, distributed systems and computation, Artificial Intelligence (1st, BSc Economics and Computer Science, UoL). Applying these skills to develop evidence based value arguments for Health Technology Assessment. This training, education and experience provide the means to apply the world's most advanced techniques to solve complex problems in a methodical, transparent and comprehensible way, with a core focus on knowledge transfer. Enjoys a wide range of water, snow and motor sports.

The Role of Uncertainty in Cost-effectiveness Modeling

Mr Mark Parker, BA Economics and Computer Science, MSc Health Economics, Health Economics Unit, University of Liverpool Management School, United Kingdom

Workshop learning objectives

- To understand how and why probabilistic Sensitivity analysis is conducted
- To understand the role of probabilistic sensitivity analysis in the Health Technology Assessment decision making process.
- To establish the relationship between uncertainty, health economic modelling and the health technology decision rule.

NOTE

- Program of the Conference is accredited by the decision of the Health Council of Serbia (accreditation number B-147/13) as a First category International course, for pharmacists and physicians with 7 points for participants and 13 points for lectures.
- English is official language of the Conference.

OBAVEŠTENJE

- Program Konferencije akreditovan je Odlukom Zdravstvenog saveta Srbije (akreditacioni broj B-147/13) kao Međunarodni kurs I kategorije, za ciljnu grupu farmaceute i lekare sa 7 bodova za slušaoce i 13 bodova za predavače.
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