



News Across Central & Eastern Europe

ISPOR Central & Eastern Europe Network Newsletter

Volume 1 Issue 2 December 2013

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LETTERS FROM THE EDITORS



John Yfantopoulos, PhD
Co Editor, News Across CEE

Dear Colleagues,

Welcome to the 2nd issue of ISPOR Central & Eastern Europe (CEE) Network e-newsletter: *News Across Central & Eastern Europe!*

Since the publication of the Newsletter back in June 2013 a lot has happened in ISPOR CEE community. On November 2-6, 2013 ISPOR held 16th Annual European Congress in Dublin, Ireland. The congress, which gathered over 3800 attendees, was a great experience for the members of ISPOR CEE Network.

The visibility of the Network was unprecedented with many informative and relevant to current CEE health care trends Forums presentations, multiple ISPOR Regional Chapters and CEE Network meetings. ISPOR CEE Network Chair, Dr. Zoltan Kalo opened the 1st ISPOR CEE Network Reception and together with ISPOR President (2013-2014), Dr. William H. Crown welcomed over 100 participants from the CEE region.

The importance of what is happening in health care in the CEE region was demonstrated through participation of ISPOR CEE Chapters in 5 Forums presentations. Speakers representing experts in pharmacoeconomics (health economics) and patient health outcomes from the CEE countries, discussed topics, such as: "Pricing and Reimbursement Process for Medical Devices in CEE" and "The Use of Pharmacoeconomic Principles in Local

Drug Policy Decisions in Poland, Russia, and Ukraine." As part of a new initiative, Forums presenters were asked to summarize the discussed country-specific issues and contribute a brief article to the *News Across CEE* and develop a paper for *Value in Health Regional Issues* (ViHRI) focusing on Central & Eastern Europe, Western Asia and Africa (CEEWAA). We encourage you to read Forums-based articles on: "Risk-Sharing in Pharmaceutical Pricing and Reimbursement Decisions," which appear in this Newsletter.

One of the most significant accomplishments of ISPOR CEE Network in 2013 was the publication of [ViHRI Volume 2 Issue 2 \(September 2013\)](#). The issue provided a great opportunity for authors to publish their research on topics such as: The Process of Privatization of Health Care Provision in Poland and Capacity Building for HTA Implementation in Middle-Income Countries: The Case of Hungary. We hope that you will not only read the articles published in this issue but will in fact consider submitting a manuscript to this new ISPOR scientific journal.

In addition to engaging in many ISPOR activities, the Network established 3 working committees: Education, Publication, and Research Committees. These committees focus on collaborative scientific research initiatives, publication and communication of scientific results and education and training

programs. The Research Committee held its 1st meeting in Dublin, during which a plan for regional research collaboration and topics were discussed. The outcome of this meeting is summarized in this issue.

The year 2013 was very successful for ISPOR CEE Network and there is still a lot to be accomplished. With platforms such as the ViHRI (CEEWAA), *News Across CEE*, and working committees, ISPOR members from CEE can contribute to improving the effectiveness, efficiency and fairness in resource allocation in health care decisions in their countries. In this issue, you will find out about the start of the Romanian HTA system and many successful educational initiatives led by the ISPOR CEE Chapters. We encourage you to keep checking [ISPOR CEE Network](#) website for collaboration opportunities in the CEE region.

With kindest regards,

John Yfantopoulos, PhD, Professor, Health Economics, University of Athens, Athens, Greece

Dusan Djuric, MD, PhD, Assistant Professor, Head of Department for Research and Balneo-Climatology, Institute for Rehabilitation, Belgrade, Serbia

Andras Inotai, PharmD, PhD, Senior Pharmacoeconomist, Syreon Research Institute, University Lecturer, Eötvös Loránd University, Budapest, Hungary



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HEALTH CARE SYSTEM & POLICY

The Growing Importance of Health Economics Outcomes Research in Drug Development

By Vera Madzarevic PhD¹, Dusan Djuric MD, PhD²

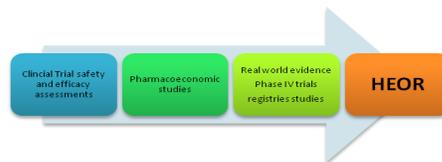
¹Director R&D and Head of Training and Education, Global Research Pharma Canada (GRPC), The Clinical Research Institute of America, Toronto, Canada

²Assistant Professor & Head, Department for Research and Balneo-Climatology Institute for Rehabilitation, Belgrade, Serbia

The clinical trial process has evolved into a very complex, time consuming and characteristically costly endeavor in the pursuit of new therapeutic products that will ultimately improve patients' lives. Pharmacoeconomic studies used to be conducted as add-on studies to phase III clinical trials to provide for important marketing data that ultimately will drive important decisions for the positioning of the product in a predetermined market. Originally, pharmacoeconomic studies, in the clinical research context, allowed us to measure the potential economic impact that new drugs will have in the market, allowing pharmaceutical companies decide on pricing as well as payers' make the decision of incorporating a new product into their formularies. Pharmacoeconomic data used not to be a submission requirement in the US, and was not always entertained by payers as it should have been since it does not necessarily reflect the real human impact but the projected economic one. Many European countries in the early '90s initially had the requirement of pharmacoeconomic data for the premarket assessment of a new drug. Presently, the EU region established the requirement of submission of premarket pharmacoeconomic data. Conversely, the FDA also established the requirement of further demonstrating the economic and human impact of a new drug and therefore those studies are incorporated as part of premarket development in the US.

A new perspective had to be incorporated to measure the impact of new therapeutic compounds in which all aspects including the human one and real world data are assessed. Health Economics Outcomes Research (HEOR) provides for that perspec-

tive, where pharmaceutical manufacturers gather critical information in addition to safety and efficacy data in clinical trials to further demonstrate the clinical and economic impact to health professionals, regulators, decision-makers, patients and ultimate payers. HEOR allows us to incorporate real-world data into the analysis of the usefulness of the therapeutic product demonstrating its real value. There are many aspects into Health Economics Outcomes Research, as is clinical safety and efficacy data in clinical trials, real-world data in post marketing and registry studies, pre and post marketing patient quality of life assessments, cost comparison of treatment protocols in the real world, budget impact, and cost-effectiveness models. Essentially HEOR incorporates real world evidence (RWE) into the analysis of the impact of a therapeutic product into the market, as well as it brings a breath of reality to the clinical trial process. In our opinion, HEOR should play key role in the decision making process during clinical development as well as for marketing of therapeutic products. We need to demonstrate that a therapeutic product is indeed useful in treating indicated conditions as well as improving quality of life in a cost acceptable manner.



Reviewer: Dragomir Marisavljevic, PhD, Professor, Institute for Hematology, Beograd, Serbia



HEALTH CARE SYSTEM & POLICY (continued)

These articles are based on ISPOR CEE Forums presented at ISPOR 16th Annual European Congress.

The Use of Risk-Sharing in Pharmaceutical Reimbursement Decisions in the Czech Republic

By: Jana Skoupá, MD, MBA, Researcher, Medical Data Center, 1st Medical Faculty, Charles University Prague, Czech Republic;

Jan Švihovec, MD, DrSc, Professor, Department of Pharmacology, 2nd Medical Faculty, Charles University Prague, Czech Republic

In 2008 a new pricing and reimbursement system for pharmaceuticals has been introduced.

The manufacturer's price cannot exceed an average of three lowest prices in 19 European Union (EU) member states, maximum reimbursement is set at the level of the lowest price for a given substance in the EU. For high-costs medicines, in absence of a relevant comparator or unclear effectiveness in real-life setting, a temporary reimbursement for maximum of 3 years can be granted. Products applying for temporary reimbursement must fulfill criteria of "highly innovative products", can be used only in defined specialized medical facilities/centers and a registry must be set-up to capture parameters of efficacy, safety, quality of life and cost-effectiveness. No explicit willingness to pay threshold is applied.

The law considers a product cost-

effective if the calculated incremental cost-effectiveness ratio (ICER) is comparable to other reimbursed interventions¹. Starting in May 2013 the regulatory body (State Institute for Drug Control) considers 40 000 € per QALY as a threshold for cost-effectiveness. This is based on the WHO recommendation and corresponds to 3times GDP level per capita in the Czech Republic². If the threshold is exceeded, the marketing authorization holder should initiate discussions with insurance funds and agree on confidential discounts, rebates or other cost-containment measures; however it has to be stressed that no legal background for risk-sharing is currently in place.

If risk-sharing is applied, non-health outcome schemes are preferred. Utilization capping is currently the preferred scheme, which is applied to several oncology medications. Budget caps do not include only number of treated patients but reimbursed cycles as well (e.g. pemetrexed in 1st line of lung cancer and several hematologic malignancies). Some health-outcome based schemes are currently under discussion, however not yet in place.

Payers show high interest to introduce and enlarge risk sharing in the Czech Republic and manufacturers usually support these activities which enable faster market entry. Several limitations have to be overcome as currently only limited expertise is available. Issues concerning legal barriers, financing and appropriate information systems have to be solved before a well-functioning system is im-

plemented. In our opinion non-health outcomes based schemes will be preferred also in the future due to their simplicity.

References:

Act on Public Health Insurance (Act No. 48/1997 Coll.)

http://www.who.int/choice/costs/CER_thresholds/en/

Are Risk-Sharing Agreements Applicable in Turkey?

By: Mete Saylan, MD, Senior Market Access Manager, Novartis Pharma Turkey, Istanbul, Turkey

Despite slow economic growth in the last few years, Turkey remains to be the biggest pharmaceutical market in the region. Ageing population and universal health coverage are the main drivers of health expenditure increase in Turkey. Keeping equity of access to health services continues to be an important goal of health policy makers in Turkey. However, trying to increase access to health care at no cost for citizens and maintaining governmental pharmaceutical expenditure in a flat manner is the biggest internal conflict that Turkish payers are facing today.

The state and university hospitals are the major service providers and the Social Security Institution is the main purchaser. Social insurance contribution rates and premium levels are determined by the central government. Sources of finance for Social Security Institution can be the
Continued on pg. 5...



HEALTH CARE SYSTEM & POLICY (continued)

government (as an employer), employers and the employee (taxes and premiums) or the beneficiary (out of pocket payments)¹. The pricing procedure of pharmaceuticals is handled by the Ministry of Health, whereas the reimbursement list and the rules and regulations governing the products listed therein are handled by Social Security Institution. Since 2004, International Reference Pricing scheme is used to determine maximum ex-factory prices of human medicinal products. Reductions in reference country prices are continuously updated and reflected in the ex-factory prices in Turkish currency. Upon first generic entry, price of both original and generic are reduced to 60% of the reference price. Mandatory institutional discount is applied within a broad range (0-41%) depending on age, generic status, price level, disease severity and priority. Internal reference pricing band (with $\pm 10\%$ reimbursement band applied for the therapeutic equivalent product) is an additional fund raising method for innovative high cost medicines.

Although there is no regulation that allows the implementation of risk sharing agreements; manufacturers and payers agree on some schemes that minimize the risk for payer also ensuring access to high cost medicines. These schemes may be recognized as initial steps for risk sharing agreements. They can be categorized under financial (e.g. exemptions from institutional discount, price increase or reference pricing using the actual exchange rate for some critical products), patient based (e.g. early access pathway for limited number of patients) and health services schemes (e.g. manufacturer undertakes administration and home care

cost of medicines, cost/burden of markers for diagnostic or treatment response tests). Some of these practices are already defined in the Health Implementation Guide².

Price/volume agreements may be the preferred scheme for Turkish payers because it will provide access to larger population while giving the payer the possibility to stay within their pre-determined pharmaceutical budget. Delays in review period of new medicine and very few innovative drugs in the market compared to total number of medicine approved by EMA or FDA are other challenges for Turkish payer³. Performance linked reimbursement after marketing authorization may be a helpful solution for minimizing long review periods and reducing uncertainties. Implementation of risk sharing schemes is inevitable considering the transformation in the Turkish health care system (large coverage and equity in access), the particularities (very low drug prices and very high institutional discounts) in pricing of reimbursed medicines and sustainability of the system. From the perspective of manufacturers operating in Turkey, risk sharing agreements (i.e. special price agreements) may be utilized as a practice to optimize international reference pricing, to capture real life benefits of a product in a large population and to operate in a more stable pricing and reimbursement environment. Patient is the party to benefit the most from implementation of risk sharing schemes by obtaining equal chance of access to effective and innovative medicine on time while preventing catastrophic health expenditures. Risk sharing agreements may affect many other

stakeholders (Ministry of Health, Ministry of Finance, Ministry of Economy and the Undersecretary of Treasury, distribution channels, physicians, regional hospital managements) depending on its type and scope. Involvement of all affected parties and their agreement are the key points for successful execution.

There are still important legal and structural obstacles for the implementation of real risk sharing schemes for the benefit of patients. For all stakeholders, the first aim should be amendments in laws and regulations, followed by pilot practices which may help to understand the structural gaps in health and reimbursement system.

References:

1. Mollahaliloğlu S et al. (2007). *Human resources in health and policy dialogue workshop*. Ankara, Sağlık Bakanlığı Hıfzıssıhha Mektebi Müdürlüğü.
2. http://www.sgk.gov.tr/wps/portal/tr/mevzuat/yururlukteki_mevzuat/tebligler/
3. http://aifd.org.tr/pdf/hastlarin_yenilikci_ilaclara_erisimi_en.PDF

For articles on: “Risk-Sharing Policy in Pharmaceutical Pricing in Croatia,” “Update on Drug Reimbursement and Risk-Sharing Schemes in Romania” and “Current Practice for Medicines Reimbursement Agreements in Bulgaria” please access [here](#).

More articles on ISPOR CEE Forums topics will be published in News Across CEE, June 2014 issue!



Announcements:

ISPOR CEE Network

established 3 Working Committees:

- **Education**
- **Publication**
- **Research**

The role of these Committees is to facilitate the development of Network's various initiatives and activities, such as:

- promotion of ISPOR educational programs in the region (Education Committee)
- preparation of *News Across CEE* Newsletter and articles submitted to ViHRI (Publication Committee)
- development of country-specific health care systems roadmaps for ISPOR and development of ISPOR CEE Forum topics.

For information on the Committees Chairs, see page 9.

****Are you interested in becoming a Chapter member and engaging with the Committees'?**

Please email:

ceenet@ispor.org

HEALTH POLICY NEWS FROM CEE REGION

The Start of the Romanian HTA System

By: Ruxandra Cernea, MSc, Market Access Officer, Roche Romania, Bucharest, Romania;
Paul Radu, MD, PhD, Market Access Manager, Roche Romania, Bucharest, Romania

On June 10th, 2013 the reimbursement system in Romania has changed when the new HTA legislation (MoH order 724/2013) was set in place. The key role is played by the new HTA Unit created within the Ministry of Health, the Specialty Commissions within the MoH (the two are doing the assessment) and the National Commission for the coordination of the Specialty Commissions, which does the appraisal of the assessed files, in order to establish the reimbursement conditions.

HTA system implies the evaluation of molecules that have not yet received a reimbursement status. Through this process multiple types of drugs will be evaluated: new innovative molecules, old molecules that have new indications according to SmPC and biosimilars. HTA evaluation is made according to a score card with a total of 10 points. The threshold for the positive reimbursement decision has been set at 6 points on the scorecard.

The points are given to a molecule as follows:

1. HAS (from France) positive opinion – max. 1 point, depending on the degree of the therapeutic benefit
2. NICE/SMC/AWMSG (from England/Scotland/Wales) positive opinion – max. 1 point (depending on the existence or not of restrictions for reimbursement),
3. Number of EU countries (max. 26) where the submitted drug is reimbursed – max. 2 points,
4. Relative efficacy/effectiveness – max. 2 points,
5. Relative safety – max. 2 points
6. Relative patient-reported-outcomes (PRO) – max. 2 points.

The first wave of dossiers was submitted in June and July 2013, followed by new submissions every 15

days of each month, arriving at over 180 dossiers by the end of November (because the last update of the list was done in 2008). By December 2013, most of the dossiers submitted within the first round have been evaluated by the HTA Unit (167 HTA dossiers) and the MoH has made public results for these submitted dossiers, which include both new molecules and new indications. There has been an acceptance rate (score above 6 points) of about 80%, up to this point. In the following months, the new reimbursement list will be updated and published in the Official Gazette.

The new HTA process is an important step in the reform of the Romanian health care system and it is part of a greater process that involves also the definition of the basic benefit package, readjustment of basic state-funded health care insurance, the introduction of the private (complementary/supplementary) insurance and other important changes.

Pricing and Reimbursement for Medicinal Products in Bulgaria

Information provided by [ISPOR Bulgaria Chapter](#)

New Regulations for pricing and reimbursement for medicinal products came into force in the beginning of May 2013. It continues the line of amendments in the national legal framework that started at the end of 2012.

The amendments came as a result of the heavy pressure to lower the prices of the medicinal products. A new body currently responsible for medicines prices and reimbursement is the National Council for Pricing and Reimbursement of the Medicinal Products (Council) established by the Council of Ministers. The Council is the final pricing & reimbursement decision maker. Bulgaria does not have an institutional HTA agency such as e.g. NICE or IQWiG to assess new medicines. However, structure and capacity for HTA is in place and budget impact, cost-effectiveness and affordability are taken into account for coverage.



Contribute your original paper to *Value in Health Regional Issues* (ViHRI)!

Are you writing a manuscript on health policy analysis, original health care research, or other health related topics focusing on CEE?

ViHRI welcomes health policy analysis and original health care researches on the following topics:

- * Economic Study
- * Clinical Outcomes Study
- * Patient-Reported Outcomes (PRO)
- * Preference-Based Outcomes Study
- * Health Policy Study
- * Research on Methods
- * Conceptual Papers

Note: Submission and editorial review process of ViHRI is year-round!

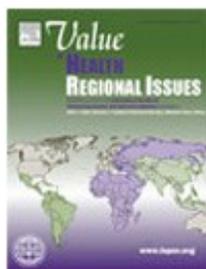
**Submit your manuscript (s) for consideration to the upcoming ViHRI focusing on CEEWAA.

[Submit Manuscript ▶](#)

For author's guidelines please see [Manuscript Submission Instructions](#) or visit [Value in Health Regional Issues](#) for more information on the journal.

OUTCOMES RESEARCH

Value in Health Regional Issues (ViHRI) Volume 2 Issue 2 Focusing on Central & Eastern Europe, Western Asia and Africa (CEEWAA)



Published!

This issue features 23 articles (54 articles submitted) from 15 different countries and includes economic analyses and patient-reported outcomes on various disease areas, such as cardiovascular diseases, diabetes, cancer, and psychiatric conditions, as well as clinical outcomes studies and health policy analyses. Articles from the CEE region discuss topics, such as: The Process of Privatization of Health Care Provision in Poland and Dossier System as a Practical Tool for Compiling Reimbursement Lists and Economic Burden of Cardiovascular Diseases in the Russian Federation. *To access the issue, please go to [ViHRI Volume 2 Issue 2 \(CEEWAA\)](#).*

ISPOR Good Practices for Outcomes Research

ISPOR Good Practices for Outcomes Research Reports, which represent guidelines on key outcomes research method or the use of outcomes research in health care decision making, provide an important research tool for researchers, decision makers, educators, payers, students and patients in the CEE region. There is a growing interest in translating the reports and currently thanks to [ISPOR Bosnia-Herzegovina](#) and [ISPOR Russia Chapters](#) they are available in Russian and Bosnian languages and more translations are being developed. *To view translated reports, visit [ISPOR Good Practices for Outcomes Research Reports](#).*

ISPOR Global Health Care System Road Maps

ISPOR Regional Chapters in Central & Eastern Europe are participating in ISPOR Global Health Care Systems Road Maps initiative by developing

an overview of their country-specific health care delivery systems focusing on reimbursement and pricing approval processes for pharmaceuticals, medical devices and diagnostics. Health care system overview is being finalized for: Bosnia-Herzegovina, Bulgaria, Hungary, Russia and Turkey! Additional for Greece and Italy are in process. *To view country-specific information check [ISPOR Global Health Care Systems Road Maps](#).*

ISPOR Pharmacoeconomic Guidelines Around the World

Country-specific economic evaluation guidelines or recommendations are being developed/or updated by experts in the CEE region. For instance, pharmacoeconomic recommendations are being updated for the Russian Federation, whereas, pharmacoeconomic guidelines have just recently been updated for the Slovak Republic. *To view the country-specific economic evaluation guidelines or recommendations check [ISPOR Pharmacoeconomic Guidelines](#).*

ISPOR Books

ISPOR CEE Regional Chapters are contributing to a wide promotion of ISPOR books by translating them into different languages spoken in the CEE region. [ISPOR Health Care Cost, Quality and Outcomes: ISPOR Book of Terms](#) is currently available in Bosnian, Bulgarian, Serbian, Polish, Slovakian, Turkish, Russian and more languages, such as Romanian, Greek, and Macedonian are being developed. [The Therapeutic and Diagnostic Devise Outcomes Research](#) book is currently being translated into Bosnian, Serbian and Polish. *For more information on specific translations, visit [ISPOR Publications](#).*

****If you would like to submit a health care system road map or have your country's PE guidelines published on ISPOR website, email ceenet@ispor.org**



ISPOR CEE NETWORK

ISPOR Dublin: An Opportunity for Visibility and Networking

400 Attendees from CEE

Exactly a year after the establishment, [ISPOR Central & Eastern Europe Network \(CEE\)](#) succeeded in marking its presence at ISPOR 16th Annual European Congress, Dublin, Ireland. The congress was a great experience for the members of ISPOR CEE Network. The visibility of the Network was unprecedented with 400 attendees from Central & Eastern Europe, 5 informative and relevant to current CEE health care trends Forums presentations, multiple ISPOR Regional Chapters and CEE Network Committee meetings.



Chapter Representatives at ISPOR CEE Network Executive Committee Meeting



CEE Forum: Pricing & Reimbursement in CEE Region



ISPOR CEE Network Research Committee Meeting



ISPOR President Dr. Crown (2nd from right) with Chapter Representatives at the CEE Network Reception



Members of ViHRI CEEWAA Editorial & Editorial Advisory Board

ISPOR CEE Network Forum Presentations

The importance of what is happening in health care in the CEE region was reflected through the participation of CEE Regional Chapters in excellent Forums presentations. Speakers representing experts in pharmacoeconomics (health economics) and patient health outcomes from the CEE countries, discussed the following topics:

- [Pricing and Reimbursement Process for Medical Devices in Central & Eastern Europe](#)
- [Patient Data and Patient Registries in Central & Eastern Europe](#)
- [New Health Care Reforms and HTA Status in Russia, Ukraine, Belarus, Kazakhstan, Armenia](#)
- [The Use of Risk-Sharing in Pharmaceutical Pricing and Reimbursement Decisions in CEE](#)
- [The Use of PE Principles in Local Drug Policy Decisions in Poland, Russia, and Ukraine](#)

Presentations were not only well attended but generated many questions from the audience, which proved increasing interest in current health policies in the CEE region.

ISPOR CEE Network Research Committee Meeting

In addition to annual ISPOR CEE Network Executive Committee meeting, a separate meeting was held for the members of the newly formed [ISPOR CEE Network Research Committee](#). The meeting was moderated by the Research Committee Chair, Dr. Lyubov Krasnova. The focus of the discussion was on developing collaborative scientific research initiatives. Participants, who represented various ISPOR CEE Chapters, agreed that research topics for regional collaboration should include: health care systems under crisis (Horizon 2020 priority), benefit of innovative medicines in CEE, impact of parallel trade in CEE and evaluation of generic and biosimilar drug policies in CEE. For full summary of the program, please visit ISPOR CEE Network website.

ISPOR CEE Network Reception

Over 100 members attended the 1st ISPOR CEE Network Reception held at the Convention Centre Dublin. ISPOR CEE Network Chair, Dr. Zoltan Kalo and ISPOR President Dr. William H. Crown, welcomed reception guests, who took the opportunity to network with colleagues from CEE and discuss ideas for regional collaboration.



**ISPOR CEE Network Working
Committees Chairs and
Chairs-Elect**

**Congrats to
CEE Network
Committee
Chairs**

Education Committee



**Olga Zaliska, PhD,
Dr.Sci (Pharm)**
ISPOR Ukraine
Chapter



**Dominik Tomek,
PharmD, MPH, PhD**
ISPOR Slovakia
Chapter

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**Imre Boncz, MD, MSc,
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**Prof. Karina Jahnz-
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ISPOR Poland
Chapter

Research Committee



**Liubov Krasnova,
PhD, MD**
ISPOR Russia Chapter



**Guenka Petrova,
MPharm, MEcon,
PhD, DSc**
ISPOR Bulgaria Chapter

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EDUCATION INITIATIVES

[ISPOR Bosnia-Herzegovina Chapter](#) has translated into Serbian language ISPOR Distance Learning Program (IDL) Modules, such as: Introduction to Pharmacoeconomics, Introduction to Outcomes Research and Cost of Illness/Cost Estimation. *Translated modules are available for free on [ISPOR DLP website](#).* In addition, the Chapter has translated ISPOR Good Practices for Outcomes Research reports, such as: Prospective Observational Clinical Studies Good Research Practices and Interpreting Indirect Treatment Comparisons for Decision-Making. *To view these reports, visit [ISPOR Good Practices for Outcomes Research website](#).*

[ISPOR Bulgaria Chapter](#) organized on February 13-15, 2013 in Velingrad a workshop focused on: "Pricing and Reimbursement of Medicines in EU" for regulatory institutions - Ministry of Health and National Health Insurance Fund and members of the Chapter. Invited speakers included: Prof. Jaime Espin and Dr. David Danko. The pricing and reimbursement of medicines in Spain, Portugal, and Hungary was presented.

On June 3-7, 2013 the Chapter and the Bulgarian Scientific Pharmaceutical Society organized an educational activity

focused on discussing the basic pharmacoeconomic methods, health care statistics, and epidemiology. In addition to Chapter members, the meeting was attended by health care professionals from various institutions.

On November 28 – 29, 2013 the Chapter also organized a meeting on: "Health Technology Assessment" in Sofia and Pravetz. The meeting was held under the patronage of the Chairman of the Parliamentary Committee on Health to the 42nd National Assembly, Bulgarian Parliament. Participants included: health authorities, the Association of Research-based Pharmaceutical Manufacturers in Bulgaria, Association of Bulgarian Generic Manufacturers, Associations of the Patients and Representatives of Professional Organizations. Invited speakers included Prof. Dominik Tomek and Dr. David Danko.

Members of [ISPOR Hungary Chapter](#) with the Eötvös Loránd University (Budapest), Faculty of Social Sciences, Institute of Economics are launching a two-year Master's Program (MSc) in health policy, planning and financing with specialization in health economics. The program, which will be taught in English, is co-directed by Dr. Zoltán Kaló and Zoltán Vokó. In addition to basic knowledge

taught at similar programs in Western Europe, students of this course will be able to apply their knowledge and specific analytical skills in context of middle-income countries. Application deadline is 30th April, 2014.

In June 2014 the Chapter in collaboration with the Eötvös Loránd University (ELTE) will also organize two summer university courses focused on: the application of (1) biostatistics and (2) economic modeling in the implementation of HTA in Central-Eastern European countries. Course leaders include: Dr. Zoltán Kaló (ELTE), Zoltán Vokó (ELTE). *For further information, please refer to the [ISPOR Hungary Chapter website](#).*



*Summer university courses at
Eötvös Loránd University*

[ISPOR Russia Chapter](#) organized and hosted the 15th International Congress on: "Equity, Quality, Cost-Effectiveness" on 16-17-December, 2013 in Moscow. The main topics included: evidence-based medicine, clinical and economic analysis, pricing of medicines, generics and biosimilars, interaction of pa-



EDUCATION INITIATIVES (continued)

ISPOR Russia Chapter President presents a special award to ISPOR and Dr. Marilyn Dix Smith for leadership and contribution to promoting pharmacoeconomics.

ISPOR CEE Chapters in Dublin



ISPOR Greece Chapter



ISPOR Hungary Chapter



ISPOR Poland Chapter



ISPOR Ukraine Chapter

patient organizations, information about the application of new technologies, gerontopharmacology and pharmacogenetics, rare diseases, evaluation and standardization of medical technology. During the Congress attendees had the opportunity to attend workshops, forums, podium presentations and an award session. ISPOR has been acknowledged for its role and great contribution to the development of pharmacoeconomics and outcome research as well as educational initiatives and publications. **ISPOR Founding Executive Director, Dr. Marilyn Dix Smith** was awarded a memorable plaque: "For great merits and leadership in spreading the science of pharmacoeconomics throughout the world."

[ISPOR Russia St. Petersburg Chapter](#) and [ISPOR Russia HTA Chapter](#) are collaborating on translating ISPOR Distance Learning Program (IDL) Modules into Russian. Also, [ISPOR Russia Chapter](#) and [Russia St. Petersburg Chapter](#) are translat-

ing Good Practices for Outcomes Research reports, which will be of a great use to students and faculty of educational institutions in Russia.

The Russian Ministry of Health approved the first round of basic studies on health technology assessment (HTA). The goal is to further train physicians and other decision-makers on the use of safe and effective medical technologies that cater to the needs of patients and strive to achieve the best possible investment. These studies will be conducted by the [ISPOR Russia St. Petersburg Chapter](#) members/professors at the First St. Petersburg State Medical University named after I.P. Pavlov, as well as by the academia of other leading universities in St. Petersburg.

[ISPOR Serbia Chapter](#) in collaboration with the Institute for Rehabilitation will organize a course on Pharmacoeconomics titled: "Introduction to Health Economics / Why Use a Model, Types of Analyses and When

Use the Right One with Practical Example," which will be held on March 17th, 2014 in Selters Spa, Mladenovac (near Belgrade). The course is targeted towards: pharmacists, physicians, and dentists. This course is designed to promote and develop „Health Economics Outcomes Research (HEOR).“ Expected attendees include members of the Serbian Chamber of Health Care Institutions. The Chamber’s most important duties and responsibilities include participating in developing staff norms, work standards, and work standards of health care services. Program evaluation will be performed and participants knowledge will be assessed. Educational materials include: ISPOR Book of Terms. The course is free. Participants will receive 6 credits for attending the course.

[ISPOR Turkish SCP Chapter](#) has translated into Turkish the ISPOR Distance Learning Program (IDL) Module: Introduction to Outcomes Research. The module is available for free on

ISPOR CEE Regional Chapters

[ISPOR Republic of Macedonia](#), [ISPOR Bosnia & Herzegovina](#) and [ISPOR Serbia Chapters](#) together with the Section of Pharmacoeconomics and Outcomes

Research of the Croatian Society for Clinical Pharmacology and Therapeutics will held 1st Macedonian and 4th Adriatic Congress on Pharmacoeconomics and Out-

comes Research on April 24-27, 2014 in Ohrid, Republic of Macedonia. The Congress will focus on: "The Impact of Health

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ISPOR Regional Chapters in Central & Eastern Europe

[Belarus Chapter](#)

[Bosnia and Herzegovina Chapter](#)

[Bulgaria Chapter](#)

[Croatia Chapter](#)

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[Russia Far East Chapter](#)

[Russia St. Petersburg Chapter](#)

[Serbia Chapter](#)

[Slovakia Chapter](#)

[Turkish SCP Chapter](#)

[Ukraine Chapter](#)

ISPOR CEE Regional Chapters (continued)

Economic Assessments on Health Policy Decisions” and will discuss topics such as: health economics, health policies, pharmaceutical parallel trade, cost-effective use of medicines, HTA and personalized medicine. *For program details, please visit [ISPOR Republic of Macedonia Chapter website](#).*

[The ISPOR Hungary Chapter](#) will organize its 8th National Congress of Health Economics with international plenary session on: “Generic Drug Policies” in Budapest, on 18-19th June, 2014.

[ISPOR Poland Chapter](#) organized the XI International Conference of the Polish Pharmacoeconomics Society focused on: “Current Trends in Reimbursement and Pricing of Medicines in Europe,” held on 5-6 December, 2013 in Warsaw. Discussed topics included: current issues in pricing and reimbursement from the perspective of leading European HTA agencies and authorities. Members of [ISPOR Russia Chapter](#) were among the attendees and presenters, including the Chapter President Prof. Pavel Vorobiev. Dr. Andrey Vorobiev, the Chapter Secretary presented plans for creating students association within [ISPOR CEE Network](#). Students from Poland, Russia, Kazakhstan and

Ukraine were encouraged to participate in scientific research projects coordinated by the Network and publish the results of their research in Polish, Russian and international journals. Conference participants discussed the possibility and relevance of international epidemiological studies on the affordability of medicines. Monika Nowicka (from Poznan) demonstrated a poster presentation on the work carried out on a similar design, for some drugs in different European countries. Malwina Holownia (from Moscow) shared her experience on the comparative study of the drug supply system in Russia, UK and Germany, also performed in the course of her thesis and defended at the Warsaw Medical University. The idea of developing students’ movement within the CEE region was discussed and supported by Dr. Zoltan Kalo, Chair, ISPOR CEE Network.

[ISPOR Russia HTA Chapter](#) established Center for Health Care Finance at the Scientific and Research Finance Institute of the Ministry of Finance. The Center will work on developing ways to increase efficiency in health care funding in Russia using such instruments as clinical and economic analysis and HTA.

ISPOR CEE MEMBERS



Tomas Dolezal, MD, PhD, Founder & Director, Institute of Health Economics and Technology Assessment (iHETA), Prague, Czech Republic became the newly elected President of [ISPOR Czech Chapter](#).



Andras Inotai, PharmD, PhD, Senior Pharmacoeconomist and Lecturer, Syreon Research Institute and Eötvös Loránd University, Budapest, Hungary was elected the new President of [ISPOR Hungary Chapter](#).



John Yfantopoulos, PhD, Professor, Health Economics, University of Athens, Athens, Greece became the newly elected President of [ISPOR Greece Chapter](#).



Vlad Zah, the Chair-Elect (2013-15) of ISPOR CEE Network and Past-President of ISPOR Serbia Chapter was interviewed on June 19th, 2013, during the 7th National Congress on Health Economics in Budapest, during which he discussed future initiatives of the Network. The interview can be read at, http://imeonline.hu/article/1933/vlad_angol.pdf.



Call for News!

News Across CEE

welcomes articles on policy updates, health care system changes, common trends and challenges in health care in the CEE region.

Articles and brief announcements may be submitted in the following categories:

- Health Care System & Policy
- Outcomes Research
- Education Initiatives
- ISPOR CEE Network Initiatives
- ISPOR CEE Regional Chapter Activities
- ISPOR CEE Members
- Letter to the Editors

Submit all news and comments to ceenet@ispor.org

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News Across Asia

For the latest health policy news and ISPOR activities in Asia look out for *News Across Asia's* next Winter 2014 issue in March 2014!

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ISPOR 19TH ANNUAL INTERNATIONAL MEETING



MAY 31– JUNE 4, 2014
Palais des Congrès de Montréal
Montréal, QC, Canada



The ISPOR Central & Eastern Europe Network will be actively present at the ISPOR 19th Annual International Meeting, May 31– June 4, 2014, the Palais des Congrès de Montréal, Montréal, QC, Canada. To register, please visit [ISPOR](http://ispor.org).

News Across Central & Eastern Europe

News Across CEE is the official newsletter of the ISPOR Central & Eastern Europe Network. It provides a platform for exchange of knowledge in CEE on the current health care systems and policies, outcomes research and education. **Contact ISPOR Central and Eastern Europe Network at ceenet@ispor.org to provide news.**

Tune in for our next June 2014 issue!

YouTube



ISPOR CEE Network on the Web



Translating Outcomes Research to Health Care Decisions

Interviews with key opinion leaders from ISPOR CEE Network at ISPOR 18th Annual International Meeting, New Orleans, LA, USA, May 2013



Vitaly Omelyanovskiy, MD, PhD, President of the ISPOR Russia HTA Chapter, discusses “Health Care in Russia: Policies and the Health Care System”: http://www.youtube.com/watch?v=EhideYvo_al&list=PLgL87tccouw2sMaV878MOELAQoF95jsba



Zoltán Kaló, MSc, MD, PhD, Chair (2013-2015) of ISPOR CEE Network Executive Committee, on “Health Care Challenges in Central & Eastern European Countries”: <http://www.youtube.com/watch?v=xYkZUtp1E1M&list=PLgL87tccouw2sMaV878MOELAQoF95jsba>



Vlad Zah, PhD (c), Chair-Elect (2013-15) of ISPOR CEE Network Executive Committee, talks about the “Serbian Health Care Challenges”: http://www.youtube.com/watch?feature=player_detailpage&v=pbEAa52UwaE

Coming Soon to YouTube

ISPOR interviews with key opinion leaders from the CEE region at ISPOR Congress in Dublin!



Josip Culig, MD, PhD, Professor, Institute of Public Health Dr.A. Štampar, Croatia



Sorin Paveliu, MD, PhD, Associate Professor, Titu Maiorescu University, Romania



Jana Skoupa, MD, MBA, Researcher, Charles University, Czech Republic



Imre Boncz, MD, MSc, PhD, Habil, Co-Editor, *ViHRI* (CEEWAA) and Professor & Director, University of Pecs, Hungary

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is a nonprofit, international, educational and scientific organization that strives to increase the efficiency, effectiveness, and fairness of health care resource use to improve health.