Pharmaceutical Association of Serbia
Pharmacoeconomics Section

SFUS
Pharmaceutical Association of Serbia

Savez farmaceutskih udruženja Srbije
Sekcija za farmakoekonomiju

Central and Eastern European Society
CEESTAHC
of Technology Assessment in Health Care

UNIVERZITET U BEOGRADU
Farmaceutski fakultet

PRIVREDNA KOMORA SRBIJE
1857

The Fifth International Conference
CHALLENGES FOR EFFICIENT HEALTH CARE IN CENTRAL AND EASTERN EUROPE

Peta međunarodna konferencija
IZAZOVI ZA EFIKASNO ZDRAVSTVO CENTRALNE I ISTOČNE EVROPE

9th and 10th of October 2015
Belgrade, hotel Metropol

9. i 10. oktobar 2015. godine
Beograd, hotel Metropol

Pharmacoeconomics Section
Pharmaceutical Association of Serbia

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The Pharmacoeconomics Section of the Pharmaceutical Association of Serbia (SFE SFUS) is organizing its Fifth International Conference with the topic: **"CHALLENGES FOR EFFICIENT HEALTH CARE IN CENTRAL AND EASTERN EUROPE",** which will take place in Belgrade on the 9th and 10th of October 2015 *(http://www.farmakoekonomija.org and* http://www.farmacija.org/*)*.

Central and Eastern European healthcare providers face a wide range of unique and difficult challenges which must be addressed in order to meet the ever growing demands and expectations of their services. From healthcare financing, a perception of insufficient evidence to base decision making, through to difficult questions such as special diseases and the role of pharmaceuticals, this conference aims to address these specific challenges and provide solutions which will enable participants to improve the health of the populations they serve.

In 2014 Serbia formalized the role of pharmacoeconomics in their reimbursement process, as demonstrated during previous conferences, this vital first step is only a small part in the puzzle of addressing these challenges. Conference participants will have the opportunity to participate in workshops on Budget Impact, Cost Effectiveness Analysis and Central Tendering; to help increase their skills in these areas, as well as have the opportunity to meet leading experts from the region and international stage who have dedicated their lives to solving these challenges.

Participants of the Conference will have the opportunity to meet experts from London School of Economics, University of Liverpool Management School (United Kingdom), Karolinska Institute (Sweden) as well as the experts from the Netherlands, Poland, Germany, Switzerland, Croatia and Serbia and exchange their experience and opinions.

The conference is organized in cooperation with Central and Eastern European Society of Technology Assessment in Health Care (CEESTAHC) who associate professionals in the field of HTA analyses and assessment of quality of clinical studies and supported by Chamber of Commerce and Industry of Serbia and University of Belgrade - Faculty of Pharmacy.

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

PHARMACOECONOMICS SECTION OF PHARMACEUTICAL ASSOCIATION OF SERBIA

Sekcija za farmakoekonomiju
Savez farmaceutskih udruženja Srbije

Peta međunarodna konferencija

IZAZOVI ZA EFIKASNO ZDRAVSTVO CENTRALNE I ISTOČNE EVROPE

9. i 10. oktobar 2015. godine
Beograd, hotel Metropol

Sekcija za farmakoekonomiju Saveza farmaceutskih udruženja Srbije (SFE SFUS) organizuje Petu međunarodnu konferenciju sa temom: **„IZAZOVI ZA EFIKASNO ZDRAVSTVO CENTRALNE I ISTOČNE EVROPE"** koja će biti održana 9. i 10. oktobra 2015. godine, u Beogradu *(http://www.farmakoekonomija.org i http://www.farmacija.org/)*.

Pružaoci zdravstvene zaštite u Centralnoj i Istočnoj Evropi se suočavaju sa širokim spektrom jedinstvenih i teških izazova koji se moraju rešiti da bi se zadovoljile rastuće potrebe i očekivanja od zdravstvenih usluga i tehnologija. Finansiranje zdravstvene zaštite, nedostatak dokaza kao problem prilikom donošenja odluka i druga važna pitanja kao što su specijalne bolesti i uloga lekova u njihovoj terapiji biće teme ove konferencije. Njen cilj je da odgovori na ove specifične probleme i pruži rešenja koja će omogućiti učesnicima u zdravstvenom sistemu da doprinesu poboljšanju zdravlja stanovništva.

Uloga farmakoekonomije u procesu refundacije lekova u Srbiji tokom 2014. godine postaje formalna, ovo je važan prvi korak i samo mali deo u „slagalici" rešavanja izazova za efikasnu zdravstvenu zaštitu. Zato je jedan od ciljeva ove konferencije unapređenje znanja i veština iz oblasti analize uticaja na budžet i analize isplativosti kroz radionice koje će voditi stručnjaci sa velikim iskustvom, kako iz regiona tako i iz Evrope.

Učesnici konferencije će imati priliku da upoznaju eksperte sa Fakulteta za ekonomiju i političke nauke u Londonu, Fakulteta za menadžment Univerziteta u Liverpulu (Velika Britanija), sa Instituta Karolinska (Švedska), eksperte iz Nemačke, Holandije, Poljske, Švajcarske, Hrvatske i Srbije i razmene svoja iskustva i mišljenja.

Konferencija se organizuje u saradnji sa Udruženjem CEESTAHC (vodeće udruženje za medicinu zasnovanu na dokazima i procenu zdravstvenih tehnologija za Centralnu i Istočnu Evropu) i uz podršku od strane Privredne komore Srbije i Farmaceutskog fakulteta Univerziteta u Beogradu.

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

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Dipl. ph. spec. Danka Sladoje

Dipl. ph. spec. Milena Đipalo

Dipl. ph. spec. Marija Živković

Mr sc. Alessandra Ferrario

FRIDAY 9th October 2015

08.30-09.30 Registration of participants & Welcome coffee

09.30-10.00 **Introduction speech**
Tanja Novakovic MSc Pharm, President of Pharmacoeconomics Section, Serbia, Representative of Chamber of Commerce and Industry of Serbia / Prof. dr Zorica Vujic, Dean of Faculty of Pharmacy

PANEL I Challenges in Health Financing

10.00-10.30 **Using HTA for making legitimate reimbursement decisions in health care**
Wija Oortwijn PhD, Partner at ECORYS NL Rotterdam, The Netherlands

10.30-10.50 **HTA as advisory tool for investors – MedInvest Scanner databases**
Krzysztof Landa MD, President at MedInvest Scanner Ltd M.I.S., Poland

10.50-11.10 **Financing of orphan drugs**
Vanesa Benkovic MSc, Senior HTA and health research consultant, Croatia

11.10-11.30 **Central and Eastern Europe - Diversity to tame, Market Access potential to unveil**
Norbert Wilk, Arcana Institute, Poland

11.30-11.45 **Discussion**

11.45-12.00 *Coffee networking break*

PANEL II Transferring Evidence

12.00-12.20 **Managed Entry Agreements in China: Current Status and Lessons for Central and Eastern Europe**
Angela Yu MSc, London School of Economics, UK

12.20-12.40 **Real world evidence for real world challenges**
Mark Parker MSc, Health Economics Unit, University of Liverpool Management School, UK

12.40-13.00 **Patient registries as a tool for improvement in the quality of treatment and for appropriate planning and allocation of resources**
Tanja Novakovic MSc Pharm, President of Pharmacoeconomics Section, Serbia

13.00-13.20 **Pharmaceutical Policy in MICs – Challenges and Priorities**
Timothy Johnston, Program Leader for Inclusive Growth and Human Development, Southeast Europe, Europe and Central Asia Region, World Bank

13.20-13.35 **Discussion**

13.35-14.55 *Lunch break*

13.35-13.55 Novartis Sponsored Lecture
Pragmatic Reimbursement Decision Making Framework – A Key for Resolving Reimbursement Impasse in Serbia
Dávid Dankó PhD, Managing Director at Ideas & Solutions, Hungary

PANEL III Special diseases and Pharmaceuticals

14.55-15.15 **Western European markets for biosimilar drugs: worth differentiation?**
Livio Garattini, Mario Negri Institute, Milan, Italy

15.15-15.35 **Access to innovation – where is Serbia today?**
Bojan Trkulja MD, Managing Director at INOVIA, Serbia

15.35-15.55 **Challenges associated with high prices of new cancer medicines; potential ways forward for CEE countries based on HTA principles**
Prof. dr Brian Godman PhD, Strathclyde Institute of Pharmacy and Biomedical Sciences, Glasgow, UK; Karolinska Institute, Sweden

15.55-16.15 **Why are Orphan Drugs different? – Achieving sustainable access for orphan drugs**
Dr. Günter Harms, Market Access and Public Affairs Director, Shire, Germany

16.15-16.35 **Targeted therapies in oncology – a Serbian pharmacoeconomic perspective**
Jovan Mihajlovic, MSc Pharm, Unit of Pharmacoepidemiology & Pharmacoeconomics, Department of Pharmacy, University of Groningen, The Netherlands

16.35-16.50 **Discussion**

16.50-17.10 **Test**

SATURDAY 10th October 2015

08.30-09.00 **Registration of participants**

09.00-09.30 Novartis Sponsored Lecture
How public private partnerships can address challenges in patient access
Stephan Korte

09.30-10.00 **Improving Polish HTA guidelines to better serve the decision-maker**
Jakub Adamski, Arcana Institute, Poland

10.00-10.20 **HTA: Effectively capturing the patients voice**
Alan Haycox, MSc, Health Economics Unit, University of Liverpool Management School, UK

10.20-10.30 *Coffee networking break*

10.30-13.00 **WORKSHOP I: BUDGET IMPACT ANALYSIS**
Vanesa Benkovic MSc, Senior HTA and health research consultant, Croatia

13.00-14.00 *Lunch break*

14.00-14.20 Abbvie Sponsored Lecture
Croatian perspective cost effectiveness analysis of HCV "Interferon free" therapy
Neven Lovrinov, MSc Pharm, Terminal d.o.o., Croatia

14.20-17.00 **WORKSHOP II: WAR GAMING – COST EFFECTIVENESS ANALYSIS AND CENTRAL TENDERING**
Mark Parker, MSc, Health Economics Unit, University of Liverpool Management School, UK
Examples: 1. Chronic hepatitis C therapy; 2. Rheumatoid arthritis

17.00-17.20 **Conclusions and closing of the conference**

Petak, 9. oktobar 2015. godine

08.30-09.30 **Registracija učesnika i kafa dobrodošlice**

09.30-10.00 **Uvodna reč**
Mr sc. Tanja Novaković, predsednica Sekcije za farmakoekonomiju SFUS, Srbija,
Predstavnik Privredne komore Srbije / Prof. dr Zorica Vujić, dekan Farmaceutskog fakulteta

PANEL I Izazovi u finansiranju zdravstva

10.00-10.30 **Upotreba izveštaja procene zdravstvenih tehnologija (HTA) za donošenje opravdanih odluka za refundaciju u zdravstvu**
Dr sc. Wija Oortwijn, partner, ECORYS NL Roterdam, Holandija

10.30-10.50 **Procena zdravstvenih tehnologija kao koristan alat za investitore - baza podataka MedInvest Scanner**
Dr Krzysztof Landa, predsednik, MedInvest Scanner Ltd M.I.S, Poljska

10.50-11.10 **Finansiranje lekova za retke bolesti**
Mr sc. Vanesa Benković, konsultant za procenu zdravstvenih tehnologija i istraživanja u zdravstvu, Hrvatska

11.10-11.30 **Centralna i Istočna Evropa – Ukrotiti različitosti, potencijal za otkrivanje pristupa tržištu**
Norbert Wilk, Arcana Institut, Poljska

11.30-11.45 **Diskusija**

11.45-12.00 *Kafe pauza*

PANEL II Transfer dokaza

12.00-12.20 **Posebni ugovori za pristup tržištu u Kini: Trenutni status i lekcije za Centralnu i Istočnu Evropu**
Mr sc. Angela Yu, istraživač Fakulteta za ekonomiju i političke nauke u Londonu, Velika Britanija

12.20-12.40 **Realni dokazi za stvarne izazove**
Mr sc. Mark Parker, Odsek za zdravstvenu ekonomiju, Fakultet za menadžment, Univerzitet u Liverpulu, Velika Britanija

12.40-13.00 **Registri pacijenata kao alat za poboljšanje kvaliteta zdravstvene zaštite i adekvatnog planiranja i raspodele resursa**
Mr sc. Tanja Novaković, predsednica Sekcije za farmakoekonomiju SFUS, Srbija

13.00-13.20 **Politika lekova u zemljama srednjeg nivoa razvoja**
Timothy Johnston, lider programa za rast i ljudski razvoj, Jugoistočna Evropa, Evropa i centralna Azija, Svetska banka

13.20-13.35 **Diskusija**

13.35-14.55 *Ručak*

14.35-14.55 Novartis sponzorisano predavanje
Okvir za pragmatično donošenje odluka za refundaciju u Srbiji – ključ za izlazak iz ćorsokaka
Dr sc. Dávid Dankó, direktor, Ideas & Solutions, Mađarska

PANEL III Specijalne bolesti i lekovi

14.55-15.15 **Tržište biosimilara Zapadne Evrope: da li vredi razlika?**
Livio Garattini, Mario Negri Institute, Milano, Italija

15.15-15.35 **Dostupnost inovacija - gde je Srbija danas?**
Dr Bojan Trkulja, direktor, INOVIA, Srbija

15.35-15.55 **Izazovi visokih cena novih onkoloških lekova: mogući pravci razvoja u zemljama centralne i istočne Evrope na osnovu principa procene zdravstvenih tehnologija**
Dr sc. Brian Godman, Institut za farmaciju i biomedicinske nauke Strathclyde, Glazgov, Velika Britanija, Karolinska Institut, Švedska

15.55-16.15 **Zašto su lekovi za retke bolest drugačiji? - Dostupnost lekova za retke bolesti**
Dr Günter Harms, direktor za pristup tržištu i odnose sa javnošcu, Shire, Nemačka

16.15-16.35 **Ciljana terapija u onkologiji - farmakoekonomska perspektiva Srbije**
Mr sc. Jovan Mihajlović, Institut za farmakoepidemiologiju i farmakoekonomiju, Odsek za farmaciju Univerziteta u Groningenu, Holandija

16.35-16.50 **Diskusija**

16.50-17.10 **Test**

SUBOTA, 10. oktobar 2015. godine

08.30-09.00 **Registracija učesnika**

09.00-09.30 Novartis sponzorisano predavanje
Kako saradnja javnog i privatnog sektora može odgovoriti na izazove u pristupu lekova pacijentima
Stephan Korte

09.30-10.00 **Unapređenje Poljskog HTA vodiča kako bi što bolje "služio" donosiocima odluka**
Jakub Adamski, Arcana Institut, Poljska

10.00-10.20 **HTA: Efikasno slušanje glasa pacijenata**
mr sc. Alan Haycox, Odsek za zdravstvenu ekonomiju, Fakultet za menažment, Univerzitet u Liverpulu, Velika Britanija

10.20-10.30 *Kafe pauza*

10.30-13.00 **RADIONICA I: ANALIZA UTICAJA NA BUDŽET (BIA)**
mr sc. Vanesa Benković, konsultant za procenu zdravstvenih tehnologija i istraživanja u zdravstvu, Hrvatska

13.00-14.00 *Ručak*

14.00-14.20 Abbvie sponzorisano predavanje
Analiza isplativosti HCV "interferon free" terapije iz Hrvatske perspektive
mr.ph. Neven Lovrinov, Terimanl d.o.o., Hrvatska

14.20-17.00 **RADIONICA II: RATNE IGRE - ANALIZA ISPLATIVOSTI (CEA) I CENTRALNA JAVNA NABAVKA**
mr sc. Mark Parker, Odsek za zdravstvenu ekonomiju, Fakultet za menažment, Univerzitet u Liverpulu, Velika Britanija, Primeri: 1. terapija za hronični hepatitis C, 2. terapija za reumatoidni artritis

17.00-17.20 **Zaključci i zatvaranje konferencije**

PANEL I Challenges in Health Financing

Using HTA for making legitimate reimbursement decisions in health care

Wija Oortwijn

Health Technology Assessment (HTA) must be tailored to the needs and requirements of health care systems in specific countries to be most useful as an aid to decision-making.The aim of the presentation is to obtain insight into methods and processes that can support timely decisions on reimbursement of health technologies, especially in Brazil, Serbia, Slovakia and Taiwan.

The use of HTA in reimbursement decisions is still in its early stages with varying levels of HTA implementation. Overall, the HTA processes adopted are new and as yet not very robust and transparent, leading to less predictability for relevant stakeholders. The funding for HTA is often not substantial and sustainable. In addition, countries often have poor availability of local data. Countries frequently use information (outputs) as well as methods/procedures from HTA in industrialized countries. With the exception of Brazil, it was found limited experience and expertise (i.e. capacity) and headcount to conduct HTA, especially with regard to economic evaluations (including modelling) and assessment of social, legal and ethical issues.

In Serbia HTA is less well developed compared to the other countries, while Brazil is rapidly developing effective HTA with clear links to the health needs of the country. However, the processes in Brazil are not yet fully developed in terms of transparency and inclusiveness. HTA in Slovakia and Taiwan are in an intermediate position. Increased collaboration across countries can support shared evidence generation (assessment) regarding health technology. It may also lead to increased capacity to undertake assessments. This leads to a bigger scope and impact of the work of evidence producers and simplifies evidence production. However, there is no one size that fits all. It would be good to investigate if and how countries follow HTA decisions in other countries and how to make best use of it to ensure fitness for purpose.

HTA as advisory tool for investors - MedInvest Scanner databases

Krzysztof Łanda

Nowadays most of medical device manufacturers around the world are participating in chaise for innovations. Innovations can not only change the medical practice and improve quality of patients care but also become a huge business success for the inventors. There is a big noise on the market and most of the producers describes their products as innovative. Unfortunately only a few of them deserves this definition. By Health Technology Assessment it is possible to substantially improve the process of selecting the most promising medical technologies. It is especially important for potential investors to undertake appropriate research which can inform about the true value of technologies of interest. HTA combined with different methodologies used in investment decision making can be a great tool aiming to decrease investment

risk. Consultancy MedInvest Scanner offers an access to database of disruptive non-drug medical technologies which debut on world markets. Those innovations are also ranked according to HTA and EBM criteria informing about their investment attractiveness.

Financing of orphan drugs

Vanesa Benkovic

There are approximately 7,000 different types of rare diseases and approximately 50% of the affected are children. Alongside with rapid progress of genomic medicine more and more benefits emerge for rare disease patients.

Although the EU has prioritized rare diseases and regulatory incentives are supporting faster access, budgetary constraints challenge financing and affordability in most countries.

About 15 years after implementation of EU and US orphan legislations, more than 100 ODs have been approved and represent 3-4% of the pharmaceutical budget. Recent publications predict that orphan drugs expenditure, would plateau between 4% and 5% of total pharmaceutical expenditure until 2020. Many factors impact financing the ODs such as: country own GDP spent on health care, availability of an alternative drug treatment, status of national plan for rare diseases, treatment length, administration route, impact on overall survival and QoL.

Pricing and affordability of orphan drugs are unique because R&D costs need to be recouped from small populations and there are usually few alternatives available.The rareness of the condition means the company can't spread the R&D cost over large patient populations.

Many questions rise around the issue of financing and then costing of ODs: What are the criteria that should be used to assess the value of an orphan drug? What does a drug offer to mitigate the condition and meet the unmet need? Does it help lower overall societal health care costs and improve quality of life?

Due to different pricing and reimbursement policies prices vary across countries and present a very inventive landscape especially in CEE, mostly refered to as the *black box*.

Additional challenge represent current limitations of conventional HTA models, without taking into account specificities of OD such as disease severity, equity, burden to patient and families, availability of other therapies and the age of patients. Therefore a multi criteria decision analysis model should be used whenever possible to include mentioned variables and not only budget impact and cost-effectiveness.

Given continuous budgetary constraints, countries should continue implementing national plans allowing access to orphan drugs and go toward more transparency in reimbursement as well as collaboration between stakeholders (patient organizations, payers, centers of excellence).

Central and Eastern Europe - Diversity to tame, Market Access potential to unveil

Norbert Wilk, Arcana Institute, Poland

Key points:

- Regional diversities in approaches to public funding decision making
- Comparative measures to enable informed allocation of company strategic efforts
- Analysis of public funding decision making practice as a tool to identify risks and opportunities and to provide unbeatable arguments to CEE decision makers

Central and Eastern Europe is a region of some twenty countries but 380 million people, including Russia and Turkey. Since the fall of communism CEE countries are clearly engaging on a path towards strong economic growth. Due to various geopolitical and macroeconomic reasons the pace may be even hastened in the coming years.

Differences among the CEE countries are also reflected in their various approaches to granting public funding for drugs. The range is dramatic, from no HTA and no submission approach up to extensive HTA requirements imposed by law and a EUR25,000 official submission fee. With such diversity the question arises if the public funding decisions in these countries are of similarly good quality? Are they appropriately addressing the issues that the decision makers are required to address by law? How can the informational needs of those decision makers be so different?

Apart from the differences, these countries share a feature that may have the largest impact on their decision making approach – a post-communist legacy of dialectical materialism. In its most extreme form it is not the content-related issues that drive the decision but the other implicit criteria. Some call it lack of predictability.

So, what matters… more? How the case performs on the official criteria or how attractive is the unofficial offer?

To answer such questions and learn the real impact of evidence we developed an approach called Decision Making Practice Analysis. In regard to reimbursement decisions it relies on thorough analysis of all available documentation of the decision making processes.

If the requirement for equal treatment of every human and legal entity is universal, which seems to be the case in the civilized world, then it results in the need for coherency in public funding decision making for drugs in a given country. This means that based on previous decisions in similar cases we may predict what the decision should be in our case. We can also communicate to the decision maker the arguments drawn on the basis of cases supporting the decision positive to us. In this way we shoot two birds with one stone. At a business micro level we greatly improve our chances for such positive resolution in a given case. But at a country level we also increase coherency of the public funding decision making practice because the decision maker would be more prone to make officially justifiable decisions.

The Decision Making Practice Analysis is particularly important and applicable to CEE countries as the before mentioned legacy can still be seen in public funding decision making processes even in the countries with the most formally developed HTA.

PANEL II Transferring Evidence

Managed Entry Agreements in China: Current Status, and Lessons for Central and Eastern Europe

Angela Yu

Against the background of growing country health care spending, the increasing availability of potentially lifesaving highcost drugs represents several risks to payers: the risk of funding a costly technology without sufficient evidence to assess effectiveness, the risk of not providing access to technologies which can extend life and/or significantly improve quality of life, and the risk of discouraging future investment in the local life-sciences sector.

Managed Entry Agreements (MEA), or formal arrangements between payers and manufacturers with the aim of sharing the financial risk due to uncertainty surrounding the introduction of new technologies have gained increasing interest in the health policy domain. In recent years, subnational government payers in China have begun to experiment with formal MEA's, the earliest of which came to fruition in the port city of Qingdao, Shandong province in 2011. Following successful implementation in Qingdao, and the announcement by the central government to allocate resources to offer financial protection against critical illnesses, many other regions have begun to explore MEA's.

This talk focuses on the Chinese experience of MEA's so far, while shedding light on institutional structures which enabled MEA implementation. Relevant lessons are drawn for CEE countries in maximizing the value of health spend, the role of HTA in resource allocation, and perspectives on collaborating with manufacturers.

Real World Evidence for Real World Challenges

Mark Parker

Randomised controlled trials represent the gold standard in defining clinical evidence for treatments. These trials are designed to minimise the various biases and other problems which accompany an assessment of clinical benefit. However, such trials are limited in time and place, extremely expensive to conduct and the real world is infinitely more complicated than is represented by the trials. Recent advancements in technology have resulted in an explosion of available evidence collected in real world settings, from hospital and general practice, to specific patient registries collecting a wealth of data on a range of treatments and practices. While this evidence is vital to support our knowledge of healthcare delivery, the ability to analyse it is still in its infancy. This lecture is intended to demonstrate both the problems and solutions to the challenges which surround evidence based medicine based on real world data.

Patient registries as a tool for improvement in the quality of treatment and for appropriate planning and allocation of resources

Tanja Novakovic

From the perspective of health economist the main aim of a clinical register is to collect data concerning effectiveness (with respect to clinically significant endpoints) and the most important cost-generating events. Such a register should be properly designed to provide credible and useful information in relation to possible reservations and doubts concerning the effectiveness.

In well organized health care systems, patient registries are part of a society. Law strictly controls data collection, maintenance and use of the data. The main objective of patient registry in such systems is to improve the quality of care and to put a patient in the centre of the system. Registries have exceptional practical value for all stakeholders in the health system: the service provider and the payer (in terms of improving health care, as a decision making tool and the means of making payment and financing therapy, monitoring of epidemiology), academia and clinicians (for clinical outcomes research and translating medical research into practice), patients (who are becoming more aware of how they can contribute to better treatment outcomes) and pharmaceutical companies (as a unique platform for outcomes research, safety and effectiveness studies, pricing analysis and providing earlier access of a therapy).The presentation will show the role of patient registries in informing decision making and propose potential future prospects of use of patient data in Serbia.

Novartis Sponsored Lecture

Pragmatic Reimbursement Decision Making Framework – A Key for Resolving Reimbursement Impasse in Serbia

Dávid Dankó

In times of austerity and constrained public budgets, investments in health systems should continue. Evidence suggests significant reductions in healthcare/pharmaceutical budgets risk creating new inefficiencies, undermining access to and quality of care, and damaging health outcomes. However, the need for investing in patient access to innovative medicines must be balanced with the need for budgetary/fiscal consolidation. This clearly requires adoption and implementation of more efficient, consistent, transparent, sustainable and depoliticized reimbursement decision making process.

In view of limited pharmaceutical budgets and the low level of HTA resources and capabilities, pharmaceutical assessment system in Serbia should be balanced and resource conscious, while offering higher process transparency and facilitating patient access to value-added and/or cost-saving new medicines. It should look beyond budget impact and facilitate more rational decision-making.

Proposed Framework can help with consistent and transparent decision making on P&R of medicines, allocate resources efficiently (within a given budget), prioritize scarce healthcare expenditure according to consistent rules, understand the "value" that a medicine brings to the healthcare system, and align health spending decisions with societal preferences and patient needs.

Having in mind the recommendations arising from EU Transparency Directive, according to which NHIF must ensure that principles of accountability, transparency and good governance are applied throughout the reimbursement policy and process, proposed Framework is taking into account available resources and capabilities and is supposed to facilitate access to new "value-added" pharmaceuticals while ensuring the transparency of decision-making process and stability/sustainability of the pharmaceutical budget.

PANEL III Special diseases and Pharmaceuticals

Access to innovation – Where is Serbia today?

Bojan Trkulja

Innovative medicines provide significant value to both patients and society – saving and prolonging lives, halting and/or slowing disease progression, reducing side effects, improving quality of life and preventing unnecessary hospitalizations and other more expensive procedures are some of the mechanisms through which innovation has transformed healthcare in the last 50 years. Unfortunately, Serbia is starting to significantly lag behind the region in terms of access to innovative medicines in the last five years.

In order to capture the real life data, INOVIA association commissioned IMS Health to benchmark Serbia to three official reference countries – Croatia, Slovenia and Italy – plus Bulgaria, as a country with very similar economic and demographic data. Results showed not only that Serbia adopted fewest number of new innovative medicines (that garnered marketing authorization in EU after January 1 2007) compared to the region, but that the difference is bigger than anticipated, with Serbian patients having access to 9 times less new medicines than the average in the peer countries.

More importantly, survey revealed important learnings about the root of the problem, pointing out to the possible short-term solutions that would allow Serbia to catch-up even without significantly increasing healthcare funding.

Challenges associated with high prices of new cancer medicines; potential ways forward for CEE countries based on HTA principles

Brian Godman

Prices of new cancer medicines have increased ten-fold during the past decade, and this will continue with companies typically seeking orphan status for new medicines. Currently often little association between health gain and requested prices, e.g. of the 12 drugs approved by the FDA for cancer in 2012, 9 were priced at more than US$10,000/ month with only 3 prolonging survival, two by less than 2 months. Of 7 targeted therapies for renal cell cancer, all were associated with minimal or no improvement on overall survival times, at a cost of US$70,000 to US$140,000 annually. This coupled with increasing prevalence of patients with cancer is putting real pressure

on healthcare systems. These challenges are resulting in a re-thinking of approaches including greater questioning over requested prices and the development of essential medicine list of oncology drugs. These issues will be discussed and debated during the presentation.

Why are Orphan Drugs different? – Achieving sustainable access for orphan drugs

Günter Harms

Since 2000, the European Union has prioritized rare diseases as one of the public health areas which require strongsupport, with the creation of the EU Regulation on Orphan Medicinal Products (or OMPs). This is recognizing that due to their rarity, patients with a rare disease have not benefited from medical innovation to the same extent as patients with more common diseases. In addition, regulatory and economic incentives are required to ensure that patients suffering from rare conditions can in fact benefit from advances in medical innovation.

Research and development of OMPs is complex and time-consuming, due to the specificities of rare diseases, such as the small number of patients and the heterogeneity of the conditions – one rare disease can have a wide array of different symptoms and impact with varying severity. The scarcity of "centres of excellence", initially limited scientific knowledge and the lack of alternative treatment, can all influence the medicine development.

Because of the complexities associated with rare diseases, some EU Member States have amended their HTA systems to support access to OMPs. However, in many cases, conventional HTA systems are not adapted and therefore the assessment fails when applied to OMPs.

There is a recognized need for a concerted effort to establish a proper system of care for rare disease patients. Following the Council Recommendationon European action in the field of rare diseases in June 2009, Member State national plans have reached different stages of advancement. A maintained focus on rare diseases should be a health policy priority, and countries must continue adopting national plans to allow access to rare diseases.

Targeted therapies in oncology – a Serbian pharmacoeconomic perspective

Jovan Mihajlovic

Targeted cancer therapies (TCTs) bring clinically important gains in survival in one of the most challenging therapeutic areas, yet, this is followed by considerable increase in healthcare expenditures. The aim of the presentation will be to identify differences in the recommendations for TCTs in three distinctive European healthcare systems: the Serbian, Scottish and Dutch, and to examine the role of pharmacoeconomic (PE) assessment in such recommendations.

A list of currently approved TCTs cited from the European Medicines Agency (EMA) was cross-referenced with the drug reimbursement reports issued by National Health Insurance Fund (NHIF) for Serbia, Scottish Medicines Consortium (SMC) for Scotland and National Health Institute (ZiNL) for the Netherlands. The key variables were gathered from the reports: drug indication, registration status, reimbursement status and outcome of the PE evaluation.

There were 41 TCTs approved for 70 cancer indications by EMA. Out of total number of TCTs' indications (TCT/i), for 20 of them therapy is reimbursed in Serbia, for 25 of them therapy is still without the decision from NHIF. Therapy for 25 remaining indications are not registered in Serbia. None of submissions neither PE analyses were publically available.

Reimbursement statuses of TCTs significantly differ in three examined healthcare systems. Level of PE application within TCTs' evaluation procedures seem to largely affect final reimbursement decisions. More precise pharmacoeconomic guidelines are still to be designed for TCTs' reimbursement in Serbia. Guidelines must account for specific epidemic and economic conditions of the country and could build on the experiences of Scotland and the Netherlands.

Novartis Sponsored Lecture

How public private partnerships can address challenges in patient access

Europe's partnership for Health was founded back in 2008 by EU and Pharmaceutical Industry and has currently more than 60 ongoing projects under the umbrella of the IMI (innovative medicine initiative) program. By facilitating and leveraging collaboration between healthcare researchers including universities, pharmaceutical companies, patient organisations and medicines regulators, the main objective of the "Innovative Medicine Initiative" is to improve health by speeding up the development of, and patient access to, the next generation of medicines, particularly in areas where there is an unmet medical or social need. The focus of IMI's Strategic Research Agenda for 2014-2024 is on delivering the right prevention and treatment for the right patient at the right time. Health priorities in the IMI Strategic Research Agenda 2014 are rare/orphan diseases, cancer, vaccines, ageing associated diseases, immune mediated diseases, respiratory diseases, psychiatric diseases, neurodegenerative diseases, cardiovascular diseases, osteoarthritis and antimicrobial resistance.

Improving Polish HTA guidelines to better serve the decision-maker

Jakub Adamski, Arcana Institute, Poland

Health technology assessment aims at enabling better decision-making with regard to spending public funds on healthcare through informing the authorities about important characteristics of interventions and possible consequences of future decisions. However, to achieve that goal it is instrumental that the HTA dossier submitted for assessment as well as the appraisal criteria reflect the needs of said decision-maker.

For that reason, requirements to be met by reimbursement applications vary significantly from country to country – they reflect (or at least should reflect) not only organisational capabilities but more importantly the preferences and values of the decision maker. The requirements may vary from simply budget impact analyses (Croatia), through presenting /cost-effectiveness/cost-utility analyses (Hungary) to RCT systematic reviews (Poland). Appraisal results also vary as countries may put different value to factors like innovativeness (France) or indications (UK).

In Poland, under the 2011 legislation all pharmaceuticals which have an active substance not yet reimbursed have to provide a comprehensive HTA dossier, including clinical, economic and budget impact analyses. These are assessed by the Agency for Health Technology Assessment and Tariff System and appraised by its President who advises the Minister of Health on financing healthcare services from public funds. HTA dossiers have to comply with minimum requirements set out by the Minister of Health in 2012. The current HTA guidelines were published in 2010.

From 2012 more than 300 recommendations on reimbursement of pharmaceuticals were issued by the President of the HTA Agency. However, as Institute Arcana's research shows the appraisal of HTA dossiers done in recommendations has limited impact on final decisions issued by the Minister of Health due to his "other considerations". This brings an important question, whether data provided in the HTA dossier is as useful for the decision-taker as expected when the regulations were drafted? Shouldn't they better reflect the crux of the decision to be taken? And what information is really necessary to take the final decision?

Recent presentation of the Institute Arcana on a conference in Cracow sparked a very important discussion on future of minimum requirements and HTA guidelines. As the Ministry of Health is actively partaking in the process, there is a chance for change.

WORKSHOP I:
BUDGET IMPACT ANALYSIS

Vanesa Benkovic

Abbvie Sponsored Lecture

Croatian perspective cost effectiveness analysis of HCV "Interferon free" therapy

Neven Lovrinov

New generation of oral HCV treatment demonstrates high effectiveness rate with SVR(sustained viral response) over 95% both in treatment experienced and naive patients with HCV genotype 1 and 4. Treatment duration is 12 weeks in most of the patients and administration route oral which leads to high compliance rates. Since new generation of treatment caries incremental costs of medicines compared to current standard, we conducted cost effectiveness analysis to determine patient groups that can be treated at cost effective ratio (Shepherd 2007; Hartwell 2011).

In treatment naïve patients ombitasvir, paritaprevir, ritonavir and dasabuvir combined with or without ribavirin (depending on genotype 1a/1b), compared to dual treatment,can achieve additional QALY with 113.113 kn (≈14.786 Eur) incremental cost(ICER). Cost per QUALY gained in treatment experienced patients with genotype 1 HCV varies between 20,512 kn (≈2.681 Eur) and 30.256 kn (≈3.955 Eur) depending if compared to triple treatment including boceprevir or telaprevir. Treatment experienced patient with HCV genotype 4, who do not have treatment alternative can be treated with ombitasvir, paritaprevir and ritonavir combined with ribavirin at 73.761 kn (≈9.641 Eur) per QALY gained.

Probabilistic and deterministic sensitivity analysis confirms robustness of results.

At proposed threshold of highly cost effective (<1 x GDP) and cost effective (<3 x GDP), treatment of naive patients with genotype 1 represents cost effective strategy and highly cost effective in treatment experience patients regardless of HCV genotype 1 or 4.

WORKSHOP II:
WAR GAMING – COST EFFECTIVENESS ANALYSIS AND CENTRAL TENDERING (example of chronic hepatitis C therapy)

Mark Parker

Applying Budget Impact and Cost Effectiveness Analysis (BIA and CEA) is an ever more important practice in healthcare decision making. National regulatory agencies such as the National Institute for Health and Clinical Excellence in England and Wales and the Pharmaceutical Benefits Advisory Committee in Australia, as well as managed care organizations in the United States, have required for several years that companies submit estimates of both the cost-effectiveness and the likely impact of the new health-care interventions on national, regional, or local health plan budgets.

This important trend has been followed closely by Central and Eastern European Countries, with Serbia for example making both CEA and BIA a compulsory part of their submission process in April of 2014.

Despite the efforts to standardise both BIA and CEA in highly developed nations, local health care, epidemiology, information availability and available local skills reflect a very different environment for submissions within Central and Eastern European Countries.

This presents the unique challenge of greater evidence synthesis requirements for similar quality submissions, while at the same time a lack of local skills and ability to pay for the education to acquire them makes even the simplest submission a difficult task.

Attendees to the Workshop day, on the 10th of October 2015, Hotel Metropol, Belgrade, Serbia will have the opportunity to meet highly experienced practitioners of both BIA and CEA, who have worked extensively on constructing such submissions both for the developed markets and regionally. Providing unique insight into the means used to address these problems and learn the important skills required to construct a good submission for the region, as well as the common mistakes which plague such submissions currently.

This will culminate at the end of the day, when participants engage in a competitive war game, putting their acquired knowledge and skill to the test in a simulated patient population in Serbia. This simulation combines the recent advent of Central Tendering in Serbia, with skills and models for the Rheumatoid Arthritis therapy and for thechronic hepatitis C therapy (HCV) to travel into a plausible future where HCV is cured in Serbia.

PANEL I Izazovi u finansiranju zdravstva

Upotreba HTA kod donošenja legitimne odluke o refundaciji u zdravstvu

Wija Oortwijn

Procena zdravstvenih tehnologija (HTA) mora da bude prilagođena potrebama i zahtevima zdravstvenih sistema zemalja, kako bi maksimalno koristila kao pomoć prilikom donošenja odluka. Cilj prezentacije je da se dobije uvid u metode i procese koji mogu da podrže blagovremeno donošenje odluka o refundaciji zdravstvenih tehnologija, posebno u Brazilu, Srbiji, Slovačkoj i Tajvanu.

Upotreba HTA u donošenju odluka o refundiranju je još uvek u ranoj fazi sa različitim nivoima implementacije HTA. Sve u svemu, usvojeni HTA procesi su novi i mada još nisu veoma robustni i transparentni, što dovodi do manje predvidljivosti za relevantne učesnike u zdravstvenom sistemu. Sredstva za HTA su u ovim zemljama često beznačajna i u većini slučajeva je mala dostupnost lokalnim podacima. U njima se često koriste informacije (rezultati), kao i metode/procedure iz HTA izveštaja iz razvijenih zemalja. Sa izuzetkom Brazila, utvrđeno je ograničeno iskustvo i stručnost (tj. kapacitet) i broj zaposlenih stručnjaka koji rade HTA, posebno u pogledu ekonomske evaluacije (uključujući modeliranje) i procenu socijalnih, pravnih i etičkih pitanja.

U Srbiji je HTA manje razvijena u poređenju sa drugim zemljama, dok se u Brazilu ubrzano razvija efikasna HTA sa jasnim vezama sa zdravstvenim potrebama zemlje. Međutim, procesi u Brazilu još uvek nisu u potpunosti razvijene u smislu transparentnosti i uključenosti. HTA u Slovačkoj i Tajvanu je srednje razvijen. Povećana saradnja između zemalja može da podrži razmenu dokaza (procena) u vezi zdravstvene tehnologije. To takođe može dovesti do povećanog kapaciteta za izvođenje procene. Ovo dovodi do većeg obima rada I pojednostavljuje stvaranje dokaza. Međutim, nepostoji univerzalna veličina koja odgovara svima. Bilo bi dobro istražiti da li I kako zemlje prate HTA odluke u drugim zemljama I kako najbolje iskoristiti iskustva drugih zemalja da se osigura maksimalna efikasnost.

Procena zdravstvenih tehnologija kao koristan alat za investitore – baza podataka MedInvest Scanner

Krzysztof Łanda

Danas većina proizvođača medicinskih sredstava širom sveta učestvuje u trci za inovacije. Inovacije ne moraju samo da promene medicinsku praksu i poboljšaju kvalitet nege pacijenata, već takođe postaju ogroman poslovni uspeh za pronalazače. Puno je uzburkana javnost na tržištu gde većina proizvođača svoje proizvode karateriše kao inovativne. Nažalost samo njih nekoliko zaslužuje taj epitet. Procenom zdravstvenih tehnologija moguće je značajno poboljšati

proces izbora zdravstvenih tehnologija koje najviše obećavaju. Naročito je važno, za potencijalne pronalazače da izvrše odgovarajuće istraživanje koje može da pokaže pravu vrednost tehnologije koja se ispituje. HTA zajedno sa različitim metodologijama koje se koriste u odlučivanju, mogu biti značajan alat u cilju smanjenja rizika ulaganja. MedInvest Scanner nudi mogućnost pristupa bazi podataka ne-lek medicinskih tehnologija koje debituju na svetskom tržištu. Ove inovacije su rangirane prema HTA i EBM (medicina zasnovana na dokazima) kriterijumima koji pružaju podatke o njihovim investicionim privlačnostima.

Finansiranje lekova za retke bolesti

Vanesa Benković

Postoji oko 7.000 različitih vrsta retkih bolesti i oko 50% obolelih su deca. Uporedo sa brzim napretkom genomske medicine postiže se sve više koristi za pacijente obolele od retkih bolesti.

Iako je EU stavila kao prioritet retke bolesti i regulatornim podsticajem podržava bržu dostupnost lekova za njihovo lečenje, u većini zemalja ograničenja u budžetu predstavljaju izazov za finanasiranje i pristupačnost.

Oko 15 godina nakon implementacije orfan lekova u zakonodavstvo EU i SAD, više od 100 orfan lekova su odobreni i predstavljaju 3-4% budžeta za lekove. Noviji radovi predviđaju da će potrošnja za orfan lekove dostići plato između 4% i 5% ukupne potrošnje za lekove do 2020. godine. Mnogi faktori utiču na finansiranje orfan lekova kao što su: koliko od bruto domaćeg proizvoda država izdvaja na zdravstvenu zaštitu, dužina lečenja, administracija, uticaj na ukupno preživljavanje i kvalitet života.

Cene i dostupnost lekova za retke bolesti su jedinstveni, jer troškove istraživanja i razvoja (R&D) treba nadoknaditi iz male populacije, a tu je obično malo alternativa na raspolaganju. Retkost stanja znači da kompanija ne može da širi R&D troškove oko velike populacije pacijenata. Javlja se mnogo pitanja oko finansiranja i koštanja lekova za retke boldest: Koji su kriterijumi koji treba da se koriste za procenu vrednosti orfan lekova? Šta lek "nudi" za ublažavanje stanja i za zadovoljenje nezadovoljenjih potreba? Da li doprinosi smanjenju ukupnih društvenih troškova zdravstvene zaštite i poboljšanju kvaliteta života?

Zbog različitih načina određivanja cena i politike refundacije cene variraju od zemlje do zemlje, što predstavlja inventivni krajolik, naročito u zemljama Srednje i Istočne Evrope, koje su uglavnom označene kao *crna kutija*.

Dodatni izazov predstavlja trenutno ograničenje konvencionalnih modela procene zdravstvenih tehnologija, bez uzimanja u obzir specifičnosti orfan lekova poput težine bolesti, pravičnosti, opterećenja pacijenta i porodice, dostupnost drugih terapija i starost pacijenta. Zbog toga treba da se koriste različiti kriterijumi u analizi kad god je to moguće, a ne samo uticaj na budžet i isplativost.

Imajući u vidu stalna budžetska ograničenja, zemlje treba da nastave sa sprovođenjem nacionalnih planova koji omogućavaju pristup orfan lekovima i da idu ka većoj transparentnosti u njihovoj refundaciji, kao i saradnji između zainteresovanih strana (organizacije pacijenata, platioca, centara izvrsnosti).

Centralna i Istočna Evropa – Ukrotiti različitosti, potencijal za otkrivanje Pristupa tržištu

Nobert Wilk, Arcana Institut, Poljska

Ključne tačke:

- Regionalne razlike u pristupu u odlučivanju o javnom finansiranju
- Uporedne mere kako bi se omogućila informisana alokacija strateških napora kompanije
- Analiza prakse odlučivanja javnog finansiranja kao sredstvo da se identifikuju rizici i mogućnosti i da se obezbedi nepobedivi argumenti donosiocima odluka Centralne i Istočne Evrope

Centralna i Istočna Evropa je region od nekih 20 zemalja i 380 miliona ljudi, uključujući Rusiju i Tursku. Od pada komunizma Centralna i Istočna Evropa se jasno angažuje na putu ka jačem ekonomskom rastu. Zbog različitih geopolitičkih i makroekonomskih razloga tempo rasta u narednim godinama može biti čak i brži.

Razlike među zemljama ovog regiona se takođe odražavaju na njihovim različitim pristupima javnog finansiranja lekova. Opseg je dramatično širok, od ne postojanja HTA i bez njenog podnošenja do izuzetno velikih HTA zahteva nametnutih zakonom gde je zvanična naknada za podnošenje ovog zahteva 25 000€. Sa takvim razlikama, postavlja se pitanje da li su odluke o javnom finansiranju u ovim zemljama slično dobrog kvaliteta? Da li je adekvatno rešavanje pitanja koje zahtevaju donosioci odluka upućivanje na zakon? Zašto su ovim donosiocima odluka potrebne toliko različite informacije?

Osim razlika, ove zemlje imaju funkciju koja može da ima najveći uticaj na njihovo odlučivanje u pristupa donošenju odluka – post-komunističkog nasleđa dijalektičkog materijalizma. U njihovoj najekstremnijoj formi to nije pitanje sadržaja koje dovodi donosioce odluka do donošenja odluke ali i druge implicitne kriterijume. Neki to nazivaju nedostatak predvidivosti. Dakle, ono što je važno...više? Kako se slučaj izvodi prema zvaničnim kriterijumima a koliko je primamljiva nezvanična ponuda? Da bi odgovorili na ova pitanja i shvatili pravi uticaj dokaza, razvili smo pristup koji se zove Analiza prakse donošenja odluke. U pogledu odluka o refundiranju, ona se zasniva na temeljnoj analizi svih dostupnih dokumenata o procesu donošenja odluka.

Ako je uslov za podjednaku terapiju svake osobe i pravnog lica univerzalan, što bi trebalo da je slučaj u civilizovanom svetu, onda to vodi ka potrebi za koherenciju u donošenju odluka kod javnog finansiranja lekova u datoj zemlji. To znači da na osnovu prethodnih odluka u sličnim slučajevima možemo predvideti kakva će se odluka doneti u našem slučaju. Možemo takođe komunicirati sa donosiocima odluka o argumentima izvedene na osnovu slučajeva koji podržavaju odluku koja je pozitivna po nas. Na ovaj način jednim potezom rešavamo dva pitanja. Na mikro nivou znatno poboljšavamo šanse za ovakva pozitivna rešenja u datom slučaju. Ali i na nivou zemlje takođe se povećava koherentnost javnog finansiranja, jer će donosilac odluke biti više sklon da zvanično opravda odluke.

Analiza prakse donošenja odluke je posebno važna i primenljiva na zemlje Centralne i Istočne Evrope, kao što je prethodno spomenuto nasleđe se još uvek može videti u slučaju javnog donošenja odluka u procesu finansiranja čak i u zemljama sa formalno veoma razvijenom HTA.

PANEL II Transfer dokaza

Posebni ugovori za pristup tržištu u Kini: Trenutni status i lekcije za Centralnu i Istočnu Evropu

Angela Yu

Nasuprot sve većim izdvajanjima za zdravstvenu zaštitu, povećanje dostupnosti skupih lekova koji potencijalno mogu da spasu život nosi sa sobom nekoliko rizika za platioce: rizik od ulaganja u skupu zdravstvenu tehnologiju bez dovoljno dokaza da se proceni efikasnost, rizik od nemogućnosti da se obezbedi tehnologija koja bi produžila život i/ili značajno popravila kvalitet života i smanjila rizik za buduća ulaganja u lokalni sektor koji se bavi naukom.

Posebni ugovori za pristup tržištu (MEA), ili formalni sporazumi između platioca i proizvođača sa ciljem podele finansijskog rizika zbog neizvesnosti koja prati uvođenje novih tehnologija, su stekli sve veći interes u polju zdravstvene politike. Poslednjih godina, podnacionalni Vladini platioci u Kini su započeli eksperiment sa formalnim MEA, od kojih je najraniji urodio plodom u gradu Qingdao, provinicija Shandong 2011. Nakon uspešne implementacije u Qingdao i saopštenja Vlade da se mogu izdvojiti sredstva za zaštitu od teških bolesti, mnoge druge provincije su počele da istražuju MEA.

Ovo predavanje je fokusirano na dosadašnje iskustvo Kine sa MEA, i rasvetljavanje institucionalnih struktura koje su omogućile implementaciju MEA. Relevantne lekcije su date za zemlje Centralne i Istočne Evrope u cilju maksimiziranja vrednosti zdravstvene potrošnje, uloge HTA u raspodeli resursa i perspektivi saradnje sa proizvođačima.

Realni dokazi za stvarne izazove

Mark Parker

Randomizovane kontrolisane studije predstavljaju zlatni standard u definisanju kliničkih dokaza lečenja. Ove studije su dizajnirane da minimiziraju različite vrste pristrasnosti i druge probleme koji prate procenu kliničkog benefita. Međutim, ovakve studije su ograničene vremenom i prostorom, dosta je skupo da se realizuju i realan život je mnogo komplikovaniji od onog predstavljenog u studiji. Trenutna tehnološka dostignuća su dovela do eksplozije dostupnih dokaza koji su prikupljeni iz realnog života, iz bolnica i opšte prakse, i specifičnih registara pacijenata koji sadrže mnoštvo podataka o nizu terapija i primera iz prakse. Iako su ovi podaci značajni za podršku znanja o pružanju zdravstvene zaštite, sposobnost obrade ovih podataka je još uvek u povoju. Cilj ovog predavanja je da pokaže i probleme i rešenja izazova koji prate medicinu zasnovanu na dokazima, bazirane na podacima iz realnog života.

Registri pacijenata kao alat za poboljšanje kvaliteta zdravstvene zaštite i adekvatnog planiranja i raspodeleresursa

Tanja Novaković

Iz perspektive zdravstvene ekonomije glavni cilj registara pacijenata je da prikuplja podatke o efektivnosti terapije (u smislu klinički značajnih ishoda) i najvažnijih događaja koji generišu ili štede troškove u realnom vremenu kroz koje prolazi pacijent. Takav registar treba da bude pravilno dizajniran da pruži pouzdane i korisne informacije u vezi sa mogućom rezervisanošću i sumnjom u efektivnost terapije.

U dobro organizovanom sistemima zdravstvene zaštite, registri pacijenata su deo društva gde je prikupljanje podataka, održavanje i korišćenje podataka strogo kontrolisano zakonom. Glavni cilj registara u ovakvim sistemima je poboljšanje kvaliteta zdravstvene zaštite pacijenata i pacijent jeste u središtu sistema. Registri imaju izuzetnu praktičnu vrednost za sve činioce u zdravstvenom sistemu: pružaoca i platioca usluga (u smislu unapređenja zdravstvene zaštite, alata prilikom donošenja odluka i sredstava za plaćanje i finansiranje terapija, praćenja epidemiologije), akademije i kliničara (za istraživanje kliničkih ishoda terapija i mogućnosti za prevođenje medicinskih istraživanja u praksu), pacijenata (koji postaju svesniji kako sami mogu doprineti boljim ishodima lečenja) i farmaceutskih kompanija (kao jedinstvene platforme za istraživanje ishoda, za studije bezbednosti, efektivnosti, određivanja cena i mogućnost ranijeg pristupa terapiji). Prezentacija će predstaviti ulogu registara pacijenata u informisanju donosioca odluka i predložiće potencijalne buduće perspektive korišćenja podataka iz registara pacijenata u Srbiji.

Novartis sponzorisano predavanje

Okvir za pragmatično donošenje odluka za refundaciju u Srbiji – ključ zaizlazak iz ćorsokaka

Dávid Dankó

U doba štednje i ograničenih javnih budžeta, ulaganje u zdravstvene sisteme bi trebalo nastaviti. Dokazi potvrđuju da značajne redukcije u budžetima zdravstvene zaštite ili budžetima za lekove dovode do rizika od stvaranja novih neefekisnosti, do podrivanja pristupa i kvaliteta zdravstvene nege, kao i do narušavanja zdravstvenih ishoda. Međutim, potreba za ulaganjem u pristup inovativnih lekova pacijentima mora bi izbalansirana sa potrebom za budžetskom/fiskalnom konsolidacijom. Ovo jasno zahteva usvajanje i implementaciju efikasnog, doslednog, transparentnog, održivog i depolitizovanog procesa donošenja odluka o refundaciji.

S obzirom na ograničen budžet za lekove i nizak nivo HTA resursa i mogućnosti, sistem za procenu lekova u Srbiji treba da bude uravnotežen i u skladu sa resursima, dok se pruža veća transparentnost procesa i pacijentima olakšava pristup novim lekovima sa dodatnom vrednošću i/ili lekovima koji smanjuju troškove.

Predloženi okvir (Framework) može biti od pomoći u konzistentnom i transparentnom donošenju odluka o cenama i refundaciji lekova; može pomoći u efikasnoj raspodeli sredstava (u okviru budžeta); postaviti prioritete u zdravstvenim troškova prema konzistentnim pravilima;

dati razumevanje vrednosti koju lek donosi zdravstvenom sistemu; i uskladiti odluke o finansiranju u zdravstvu u skladu sa preferencama društva i potrebama pacijenata.

Imajući u vidu preporuke potekle iz Evropske direktive o transparentnosti (EU Transparency Directive), prema kojoj RFZO mora da obezbediti da su principi odgovornosti, transparentnosti i dobrog upravljana primenjeni kroz politiku i proces refundacije, predloženi okvir u obzir uzima dostupne resurse i mogućnosti, i trebalo bi da olakša pristup novim lekovima sa dodatnom vrednošću, dok obezbeđuje transparentnost procesa donošenja odluka i stabilnost/održivost budžeta za lekove.

PANEL III Specijalne bolesti i lekovi

Dostupnost inovacija - gde je Srbija danas?

Bojan Trkulja

Inovativni lekovi imaju značajnu vrednost kako za pacijente tako i za društvo – čuvaju i produžavaju život, doprinose zdravlju i/ili usporavanju napredovanja bolesti, smanjuju neželjene efekte, poboljšavaju kvalitet života i preveniraju nepotrebnu hospitalizaciju i na druge načine, mnoge skupe procedure su samo neki od mehanizama kroz koje su inovacije transformisale zdravstvenu zaštitu u poslednjih 50 godina. Nažalost, Srbija počinje značajno da zaostaje za regionom u pogledu inovativnih lekova, u poslednjih pet godina.

Da bi se prikupili podaci iz stvarnog života, udruženje INOVIA je naručilo od IMS Health da benchmark Srbiju sa tri zvanične referentne zemlje – Hrvatska, Slovenija i Italija – plus Bugarska, kao zemlja sa veoma sličnim ekonomskim i demografskim podacima. Rezultati su pokazali ne samo da je Srbija usvojila najmanji broj novih inovativnih lekova (koji su dobili dozvolu u EU nakon 01. januara 2007.) u poređenju sa regionom, već je razlika veća nego što se očekivalo, sa pacijentima u Srbiji kojima je dostupno do 9 puta manje novih lekova nego što je prosek u poredbenim zemljama.

Još značajnije, istraživanje je otkrilo važna saznanja o korenu problema, ističući moguća kratkoročna rešenja koja će omogućiti Srbiji nadoknadu bez značajnog povećanja zdravstvenog finansiranja.

Izazovi povezani sa visokim cenama novih lekova protiv kancera; mogući načini napretka u zemljama Centralne i Istočne Evrope na osnovama HTA principa

Brian Godman

Cene novih onkoloških lekova su porasle desetostruko tokom poslednje dekade, sa tendencijom daljeg rasta, budući da kompanije traže orfan status za nove lekove. Često postoji mala veza između zdravstvene dobiti i tražene cene, npr. od 12 lekova protiv kancera koji su

dobili dozvolu od strane FDA tokom 2012. godine, 9 je koštalo više od 10.000$/mesečno od kojih su samo 3 leka produžila preživljavanje, 2 manje od 2 meseca. Od 7 ciljanih terapija protiv kancera bubrega, sve su bile povezane sa minimalnim ili nikakvim poboljšanjem sveukupnog vremena preživljavanja, a koštale su između 70.000$ i 140.000$ godišnje. Ovo je povezano sa povećanjem prevalence pacijenata koji imaju rak i stvaraju povećani pritisak na zdravstveni sistem. Ovi izazovi su za rezultat imali preispitivanje pristupa obrade zahteva za dobijanje cena lekova i razvoja esencijalne liste onkoloških lekova.

Zašto su lekovi za retke bolest drugačiji? – Dostupnost lekova za retke bolesti

Günter Harms

Od 2000. godine EU je retke bolesti, stavila kao prioritet, pri čemu je doneta EU Regulativa o Orfan lekovima (ili OMP). Ovom regulativom oni su prepoznati budući da su u pitanju retke bolesti, pacijenti sa retkim bolestima nemaju u istom obimu benefit od medicinskih inovacija kao pacijenti oboleli od opštih bolesti. Pored toga, potrebne su regulatorne i ekonomske inicijative kao bi se osiguralo da pacijenti oboleli od retkih bolesti mogu imati koristi od napretka u medicinskim inovacijama.

Istraživanje i razvoj orfan lekova je složen i dugotrajan proces zbog specifičnosti retkih bolesti, kao što je mali broj pacijenata i heterogenost uslova – jedna retka bolest može da ima široku lepezu različitih simptoma i na pacijenta može uticati sa različitim stepenom težine. Nedostatak centara za procenu ovakvih lekova, u početku ograničeno znanje i nedostatak alternativnih terapija, sveukupno utiče na razvoj ovakvih lekova.

Zbog kompleksnosti retkih bolesti, neke zemlje članice EU su izmenile svoj HTA sistem kako bi podržale orfan lekove. Međutim, u mnogo slučajeva, konvencionalni HTA sistemi nisu prilagođeni i zato HTA procena orfan leka ne može da se sprovede.

Postoji prepoznata potreba za zajedničkim naporom kako bi se uspostavio odgovarajući sistem za zaštitu pacijenata obolelih od retkih bolesti. U skladu sa preporukama Saveta o evropskoj akciji u polju retkih bolesti u junu 2009, nacionalni planovi zemalja članica su dostigli različite nivoe napredovanja. Konstantan fokus na retke bolesti treba da bude prioritet zdravstvene politike i zemlje moraju da nastave sa usvajanjem nacionalnih planova kako bi omogućili pristup terapiji retkih bolesti.

Ciljana (target) terapija u onkologiji - farmakoekonomska perspektiva Srbije

Jovan Mihajlović

Ciljane antikancerske terapije (TCT) daju značajne kliničke rezultate kod preživljavanja pacijenata u jednoj od najizazovnijih terapijskih oblasti, ipak, praćene su značajnim povećanjem troškova u zdravstvu. Cilj ovog predavanja je da se identifikuju razlike u preporukama za TCT u tri karakteristična evropska zdravstvena sistema: srpski, škotski i holandski, i da se ispita uloga farmakoekonomskih procena u takvim preporukama.

Lista TCT koji su trenutno odobreni u Evropskoj agenciji za lekove (EMA) je upoređena sa izveštajem o refundaciji lekova Republičkog fonda za zdravstveno osiguranje (RFZO) u Srbiji, Škotskog medicinskog konzorcijuma (SMC) u Škotskoj i Nacionalnog instituta za zdravstvo (ZiNL) u Holandiji. Iz izveštaja su prikupljene ključne varijable: indikacija, registracioni status, status vezan za refundaciju i ishod farmakoekonomske evaluacije.

Trenutno je u EMA registrovano 41 TCT za 70 kancerskih indikacija. Od ukupnog broja TCT indikacija (TCT/i), u Srbiji se za 20 indikacija refundira terapija, a za 25 indikacija još uvek se čeka odluka RFZO o refundaciji terapije. Preostalih 25 indikacija ciljane antikancerske terapije (TCTi) nije odobreno u Srbiji. Nijedan od podnesaka niti farmakoekonomskih analiza nisu dostupni javnosti. Refundacioni statusi TCT se značajno razlikuju u ova tri ispitivana zdravstvena sistema. Nivo farmakoekonomske aplikacije unutar procedure za procenu TCT izgleda da u velikoj meri utiče na konačnu odluku o refundaciji. Precizniji farmakoekonomski vodiči treba tek da se naprave za TCT lekove u Srbiji. U vodičima mora da se obrati pažnja na specifične epidemiološke i ekonomske uslove zemlje i mogu se napraviti na osnovu iskustva iz Škotske i Holandije.

Novartis sponzorisano predavanje
Kako saradnja javnog i privatnog sektora može odgovoriti na izazove u pristupu lekova pacijentima

Evropsko partnerstvo za zdravlje (Europe's partnership for Health) osnovano je 2008. godine od strane Evropske Unije i farmaceutske industrije, i trenutno broji više od 60 aktivnih projekata u okviru IMI (Innovative Medicine Initiative) programa. Olakšavanjem i osnaživanjem saradnje među istraživačima u oblasti zdravstvene zaštite, uključući univerzitete, farmaceutske kompanije, udruženja pacijenata i regulatornih tela u oblasti zdravstva, glavni cilj programa "Innovative Medicine Initiative" jeste poboljšanje zdravlja kroz ubrzavanje razvoja budućih generacija lekova i njihovog pristupa pacijentima, posebno u oblastima gde postoji nezadovoljena medicinska ili socijalna potreba. Fokus Strateške istraživačke agende (Strategic Research Agenda) za period 2014-2024. u okviru IMI programa jeste pružanje prave prevencije i terapije za prave pacijente u pravom trenutku. Zdravstevni prioriteti Strateške istraživačke agende za 2014. godinu u okviru IMI programa jesu retke bolesti, kancer, vakcine, bolesti udružene sa starenjem, imunološki posredovane bolesti, respiratorne, psihijatrijske, neurodegenerativne, kardiovaskularne bolesti, osteartritis i rezistencija na antibiotike.

Unapređenje Poljskog HTA vodiča kako bi što bolje "služio" donosiocima odluka

Jakub Adamski, Arcana Institut, Poljska

Procena zdravstvenih tehnologija (HTA) ima za cilj da omogući što bolje donošenje odluka kod trošenja javnih sredstava za zadravstvenu zaštitu, a kroz informisanje nadležnih organa o važnim karakteristikama određenih intervencija i mogućim posledicama budućih odluka.

Međutim, da bi se postigao taj cilj jasno je da predat HTA izveštaj za procenu kao i kriterijumi za ocenjivanje odražavaju potrebe pomenutog donosioca odluka.

Zbog toga, uslovi koji treba da se ispune u procesu podnošenja zahteva za refundiranje zančajno variraju od zemlje do zemlje – odražavaju (ili bi barem trebalo da odražavaju) ne samo organizacione sposobnosti, već mnogo značajnije preferencije i vrednosti donosioca odluka. Uslovi mogu da variraju od jednostavne analize uticaja na budžet (Hrvatska), preko predstavljanje/analize isplativosti/analize odnosa troškova i korisnosti (Mađarska) do Sistematičnog pregleda randomizovanih kliničkih studija (Poljska). Procena rezultata takođe varir, jer svaka zemlja može da odredi različite faktore vrednosti kao što je inovativnost (Francuska) ili indikacije (Velika Britanija).

U Poljskoj, u skladu sa Regulativom 2011 za sve lekove koji imaju aktivnu supstancu koja se još uvek ne refundira mora da se dostavi sveobuhvatni HTA izveštaj, koji uključuje kliničku analizu, ekonomsku analizu i analizu uticaja na budžet. Ovi izveštaji se dalje procenjuju u Agenciji za procenu zdravstvenih tehnologija i tarifni sistem i procenjuje ih njihov Predsednik koji savetuje Ministra zdravlja u delu finansiranja zdravstvenog sistema iz javnog fonda. HTA izveštaji moraju da budu u skladu sa minimumom zahteva postavljenih od strane Ministra zdravlja 2012. godine. Trenutno važeći HTA vodič je objavljen 2010. godine.

Od 2012. godine Predsednik HTA je izdao više od 300 preporuka o refundiranju lekova. Međutim, istraživanje Instituta Arcana pokazuje da procena HTA izveštaja urađena prema preporukama ima ograničen uticaj na odluke o finansirnaju donete od strane Ministra zdravlja zbog njegovih "drugih faktora". Ovo donosi važno pitanje, da li su podaci dati u HTA izveštaju korisni za donosioce odluka kao što se očekuje kada se prave propisi? Zar ne bi trebalo da bolje odražava suštinu odluke koje treba preduzeti? I koje informacije su zaista potrebne kada se donosi konačna odluka?

Nedavno predstavljanje Instituta Arcane na konferenciji u Krakovu je izazvalo veoma važnu diskusiju o mogućim budućim minimalnim uslovima i HTA smernicama. Kako je Ministarstvo zdravlja aktivno učestvovalo u procesu, postoje šanse za promenu.

RADIONICA I:
ANALIZA UTICAJA NA BUDŽET (BIA)

mr sc. Vanesa Benković

Abbvie sponzorisano predavanje
Analiza isplativosti HCV "interferon free" terapije iz Hrvatske perspektive

Neven Lovrinov

Nova generacija oralnih lekova za lečenje HCV-a pokazala je veliku efikasnost za SVR (eng. sustained viral response) od preko 95%, kod prethodno neuspešno lečenih i kod prethodno nelečenih bolesnika sa genotipom 1 i 4 HCV-a. Lečenje traje kod većine bolesnika 12 nedelja, a primena lekova je isključivo oralna pa je i verovatnost pridržavanja režimu lečenja visoka. S obzirom da predložena kombinacija lekova nosi povećani trošak lekova u odnosu na dosadašnji standard terapije sproveli smo analizu isplativosti s ciljem određivanja podskupina bolesnika kod kojih lečenje novom generacijom lekova predstavlja isplativu strategiju (Shepherd 2007; Hartwell 2011).

Kod prethodno nelečenih bolesnika sa HCV-om genotipa 1, kombinacija ombitasvira, paritaprevira, ritonavira i dasabuvira sa ili bez ribavirina (zavisno od genotipa 1a/1b bolesti) u odnosu na dvojnu terapiju donosi dodatan QALY uz inkrementalan trošak (ICER) od 113.113 kn (≈14.786 Eur). Trošak po dodatnom QALY-u, kod bolesnika sa HCV genotipom 1 neuspešno lečenih dvojnom terapijom, uz novu generaciju lekova iznosi 20.512 kn (≈2.681 Eur) ili 30.256 kn (≈3.955 Eur) zavisno da li se upoređuje sa trojnom terapijom koja uključuje boceprevir ili telaprevir. Kod obolelih sa GT4 genotipom HCV-a koji nakon neuspeha prve linije lečenja nemaju terapijske alternative, lečenje ombitasvirom, paritaprevirom i ritonavirom u kombinaciji sa ribavirinom donosi dodatan QALY-a uz trošak od 73.761 kn (≈9.641 Eur).

Sprovedena probabilistička i deterministička analiza osetljivosti potvrdile su robustnost rezultata. Uz predloženu graničnu vrednost ICER (<1 x GDP) i graničnu vrednost ICER (<3 x GDP) lečenje prethodno nelečenih bolesnika sa genotipom 1 predstavlja isplativu strategiju dok primena nove terapije u prethodno lečenih bolesnika sa genotipom 1 i 4 predstavlja visoko isplativu strategiju.

RADIONICA II:
RATNE IGRE - ANALIZA ISPLATIVOSTI (CEA) I CENTRALNA JAVNA NABAVKA (primer terapija za hronični hepatitis C)

mr sc. Mark Parker

Primena analize uticaja na budžet i analize isplativost (BIA i CEA) u procesu donošenja odluka u zdravstvu postaje sve važnija. Nacionalne regulatorne agencije, kao što je Nacionalni institut za zdravlje i kliničku izvrsnost u Engleskoj i Velsu i slične institucije u Australiji i Sjedinjenim Američkim Državama, zahtevaju već nekoliko godina od kompanija da dostave procenu troškova i efektivnosti i najverovatniji uticaj novih terapija i zdravstvenih tehnologija na nacionalni, regionalni i lokalni zdravstveni budžet.

Ovaj važan trend su sledile zemlje Centralne i Istočne Evrope dok je Srbija u aprilu 2014. godine donela odluku da CEA i BIA budu obavezan deo dokumentacije koja se podnosi za refundaciju novih lekova.

Uprkos naporima da se u visoko razvijenim zemljama standardizuju BIA i CEA, zdravstvo pojedine zemlje, njena epidemiologija, dostupnost informacija i kapacitet znanja i veština predstavljaju veoma različito okruženje za aplikaciju dosijea za refundaciju u zemljama Centralne i Istočne Evrope.

Ovo predstavlja jedinstven izazov sinteze dokaza kao uslova za aplikaciju sličnog kvaliteta, dok u isto vreme nedostatak lokalnih veština i sposobnosti da se finansira obrazovanje čini čak i najjednostavnije aplikacije teškim zadatkom.

Učesnici radionica će 10. oktobra 2015. godine u hotelu Metropol, u Beogradu, imati priliku da se upoznaju sa veoma iskusnim ekspertima za BIA i CEA, koji su izradili brojne aplikacije za fondove zdravstvenih osiguranja za razvijena tržišta i za zemlje regiona. U okviru radionice imaćete jedinstveni uvid u alate koji se koriste za procenu terapija i priliku da steknete veštine potrebne za izradu aplikacije kao i da uočite greške koje se mogu sresti u sadašnjim aplikacijama.

U drugoj polovini dana prisutni će učestvovati u konkurencijskim ratnim igrama, koristeći stečeno znanje i veštine u simuliranoj populaciji pacijenata u Srbiji. Ova simulacija obuhvata od nedavno aktulenu centralnu javnu nabavku u Srbiji, model za terapijureumatoidnog artritisa i za terapiju hroničnog hepatitisa C (HCV) koja će dovesti do budućnosti u kojoj je HCV izlečen u Srbiji.

Wija Oortwijn

Wija Oortwijn studied health sciences and holds a PhD in Medicine. Dr. Oortwijn has more than 20 years of relevant professional experience in policy analysis with regard to health care, life sciences and public health. Examples include the ex ante evaluation of the Draft EC Regulation on Medicinal Products for Paediatric Use.

She led a project on the impact of HTA on prescribing patterns of diabetes and rheumatic arthritis drugs in Europe, the US, Canada and Australia and a project that assessed the impact of HTA in the process of pharmaceutical pricing and reimbursement in a selection of 10 middle-income countries. The outcomes of this research have been published in Health Policy. In addition, she developed an instrument to map the level of HTA at country level. This was applied to selected middle-income countries (Argentina, Brazil, India, Indonesia, Malaysia, Mexico and Russia) as well as to countries well-known for their comprehensive

HTA programs (Australia, Canada and United Kingdom). The instrument and the results of the application were published in the International Journal of Technology Assessment in Health Care. Finally, she conducted a study on methods and processes that can support timely decisions on reimbursement of health technologies, especially in Brazil, Serbia, Slovakia and Taiwan.

She has also coordinated and participated in different European collaboration networks focusing on HTA (Eurassess, HTA Europe, ECHAHI/ECHTA). She is also a founding Member of International Society for HTA (HTAi) and was involved in the organisation of several annual HTAi conferences. Furthermore, she is a member of the Editorial Board of the International Journal of Technology Assessment in Health Care.

Krzysztof Łanda

The Founder of Watch Health Care Foundation (www.WatchHealthCare.eu). The CEO of MedInvest Scanner Ltd. General partner in HTA Audit, a company dealing with quality of HTA (Health Technology Assessment) reports directed to authorities and public institutions in Poland; expert of BCC on health care system. From 2010 till 2011 he was President of Central & Eastern European Society of Technology Assessment in Health Care. 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.

Vanesa Benkovic

Senior consultant HTA, HE and Research, Croatian Society for Pharmacoeconomics and Health Economics, Zagreb, Croatia.

Vanesa Benkovic, graduated her masters study as manager in health and health services at Medical Faculty, University of Zagreb. She is currently finishing her PhD thesis on health inequalities at Faculty of Philosophy, Sociology Dpt. University of Zagreb. Vanesa graduated several educations in field of pharmacoeconomics, health economics and advanced modeling in HTA in France and Austria. She received Open Society scholarship at Global Health Economics project by European University of St. Petersburg, Russia. She teaches pharmacoeconomics and health economics at Faculty of Medicine, Faculty of Pharmacy University of Zagreb, and health statistics at European University of St. Petersburg GHE courses. Her field of work includes extensive list of health economic analysis for drugs, devices, technologies and cost of illness studies in Croatia, Slovenia and Bosnia and Herzegovina, as well as research methodology for various EU JA projects such as Urban health centers Europe and Cross border patient registries initiative (PARENT). She also designs and performs market and scientific research in health. Her latest engagements include health business intelligence for a World Bank project for Croatian Ministry of Health and strategic consultancy both for pharmaindustry and budget holders.

She publishes papers in area of research methodology, public health, pharmacoeconomics and health economics. Currently Vanesa is setting up business including IT applications for polypharmacy.

Norbert Wilk

Norbert Wilk, Arcana Institute's Consultancy Department Director. He was a deputy director for HTA and international cooperation of the Agency for Health Technology Assessment and Tariff System in Poland for 3 years. He is responsible for introducing a two-step system (assessment – appraisal) of preparing recommendations on financing health technologies in Poland which is evidence-based in compliance with EBM/HTA principles.

He was head of the Ministry of Health's Accreditation Office, where his work lead to issuing the first practice quality standards by way of regulation – for medical diagnostic laboratories. He also worked on updating reimbursement lists in the Reimbursement and Prices Unit of the Ministry of Health's Drug Policy and Pharmacy Department. He was a co-author of the first Polish HTA reports while working in the Standardisation Bureau of the Centre for Quality Monitoring in Health Care.

Angela Yu

Angela Yu graduated from Master's Health Policy, Planning and Financing, offered jointly by the London School of Economics and the London School of Hygiene and Tropical Medicine in 2015.

Prior to her Master's, Angela worked as Management Consultant in China for 5 years with the group IMS Health. In her work as a Consultant, she was charged with providing multi-national

biopharmaceutical companies, NGO's and industry associations with strategies which helped to maximize opportunities in Pricing and Market Access. During her time in China, she also participated in many independently commissioned policy-analysis and policy-shaping projects, which aimed to ensure the future of China's pricing and market access policies deliver sustainable growth for the nation, while meeting the needs of the Chinese population.

Mark Parker

Mark Parker is Senior Economic modeller for the University of Liverpool Health Economic Unit, Liverpool Cancer Trials Unit and Technical director of Evaluate Econ Ltd, UK. Early background was in software and electronic engineering (University of Manchester) and real time Digital Signal Processing, along with Radio Frequency 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. Mark enjoys a wide range of water, snow and motor sports.

Tanja Novakovic

Tanja Novakovic MSc Pharm is the president of the Pharmacoeconomics Section within the Pharmaceutical Association of Serbia (2006-to date). She is a founder of the ISPOR Serbian chapter and between 2007 and 2009 its vice president. Since 2001 she has been working in Galenika a.d., a pharmaceutical company, as a product manager for drugs for the central nervous system.

Tanja Novakovic is a graduate of the University of Belgrade, Faculty of Pharmacy finishing her postgraduate studies at the Faculty of Pharmacy at Ghent University in Belgium. She is the author of the "Handbook for pharmacoeconomic evaluations", the first such publication in the field of pharmacoeconomics in the Serbian language. Through the Pharmacoeconomics Section she is constantly increasing awareness of health economics, pharmacoeconomics and the importance of Health Technology Assessment. She is active in shaping healthcare policy, writing the first Guidelines for pharmacoeconomic evaluations for Serbia. She was also co-author in one of the three HTA reports first completed in Serbia, and was engaged to lead a group of experts to define all existing elements of basic benefit package in Serbia within the World Bank/Ministry of Health of Serbia projects.

Tanja has organized and presented in many national meetings and international conferences which have resulted in international cooperation in education and the developing of pharmacoeconomics and HTA in Serbia.

Dávid Dankó

Dávid Dankó is 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.

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 is happily married.

Brian Godman

Brian works with health authorities and health insurance companies across countries, including over 30 European countries and regions, to progress policies to enhance the quality and efficiency of care for both new and established medicines. This includes developing new models to optimise the managed entry of new medicines including those for oncology and orphan

diseases. This builds on a background in consultancy and the pharmaceutical industry. These activities have resulted in over 100 publications in recent years in peer reviewed journals, many of which are listed in Pub Med. Brian will use his combined experiences to debate key issues regarding new cancer medicines and potential ways forward.

Günter Harms

After graduating as a Pharmacist and PhD from the University of Kiel, Germany, Dr Harms moved into a management role within the Institute for Public Health Systems Research; a consulting firm and WHO collaborating centre. His responsibilities included health economics, pharmacoepidemiology and healthcare systems research. In 1996 he joined the pharmaceutical industry working in drug development and regulatory affairs at Ferring GmbH in Germany.

In 1999, Dr. Harms moved to a role with Novartis Pharma AG, initially in drug development. He subsequently took on strategic management positions in Novartis global headquarters in Basel, Switzerland and then within the US country organization. Returning from the US, as Director for Novartis Global Public Affairs, Dr. Harms was responsible for a broad portfolio of projects including market access, HTA, healthcare reform and cost containment issues. In 2009 - 2011 as Market Pricing Director for Novartis Pharma Dr. Harms was successively responsible for the implementation of Novartis pricing and reimbursement strategies in CEE, Turkey, Russia and CIS.

In 2011 Dr. Harms joined Shire Human Genetic Therapies and currently is Market Access & Public Affairs Director, responsible for Central and Eastern Europe for Shire.

Jovan Mihajlovic

Jovan Mihajlovic, a health economist, is a PhD fellow at the University of Groningen, the Netherlands and owner of a consulting company Mihajlović Health Analytics (MiHA). He is a graduated pharmacist completing the PhD thesis "Economic Evaluation ofTargetedCancer Therapies in Serbia". Jovan has an extensive experience within the pharmaceutical industry where he spent 7 years in the field of sales and marketing. Through MiHA he designed cost-effectiveness and budget impact models, conducted epidemiological/pharmaco-epidemiological studies, systematic reviews and network meta-analyses for academia and the industry in Serbia and the Netherlands. He published several studies in renowned medical journals and was speakerat numerous health economic and oncological professionals' meetings.

Jakub Adamski

Jakub Adamski, attorney-at-law. He specialises in advising on market access and financing healthcare technologies financed from public funds, in particular on reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices, as well as other healthcare system-related issues.

He worked at the Drug Policy and Pharmacy Department for 6 years.

As a chief expert he was responsible for inter alia reimbursement under the therapeutic and drug programmes, policy on orphan drugs and international cooperation on reimbursement of drugs. He is a former member of the Orphan Diseases Team (advisory body to the Minister of Health) and the European Union's Committee of Experts on Rare Diseases. He represented the Minister of Health in EU Council and European Commission working groups and Member States' networks on drug reimbursement.

He is a co-author of several publications on pharmaceutical pricing and healthcare policy.

Wija Oortwijn

Osnovne studije Wija Oortwijn je završila iz zdravstvenih nauka, a doktorat je uradila iz medicine. Dr Oortwijn ima više od 20 godina iskustva u pogledu analize politike zdravstvene zaštite, prirodnih nauka i javnom zdravlju. Primeri uključuju *ex ante* evaluaciju Nacrta EU Pravilnika o lekovima za pedijatrijusku upotrebu.

Wija vodi projekat o uticaju HTA na propisivanje lekova za dijabetes i reumatoidni artritis u Evropi, SAD, Kanadi i Australiji i projekat koji se bavi procenom uticaja HTA u procesu formiranja cena lekova i refundacije u 10 odabranih srednje razvijenih zemalja. Ishodi ovih istraživanja su objavljeni u stručnom časopisu *Health Policy*. Pored toga, razvila je instrument za mapiranje nivoa HTA na nivou države. Ovo je primenjeno na 10 odabranih srednje razvijenih zemalja (Argentina, Brazil, Indija, Indonezija, Malezija, Meksiko i Rusija) kao i na zemlje koje su dobro poznate po svojim sveobuhvatnim HTA programima (Austrija, Kanada i Velika Britanija). Instrument i rezultati su objavljeni u *International Journal of Technology Assessment in Health Care*. Konačno, Wija je sprovela studiju o metodama i procesima koji mogu da podrže pravovremene odluke o refundaciji zdravstvenih tehnologija, naročito u Brazilu, Srbiji, Slovačkoj i Tajvanu.

Takođe, koordinirala je i učestvovala u različitim Evropskim udruženjima koja su fokusirana na HTA (Eurassess, HTA Europe, ECHAHI/ECHTA). Osnivač je udruženja Member of International Society for HTA (HTAi) i bila je uključena u organizovanje nekoliko godišnjih HTAi konferencija. Osim toga, član je uređivačkog odbora *International Journal of Technology Assessment in Health Care*.

Krzysztof Landa

Krzysztof Landa je osnivač Watch Health Care Foundation (www.WatchHealthCare.eu). Izvršni direktor MedInvest Scanner Ltd. General partner HTA Audit, bavi se kvalitetom HTA (Procena zdravstvenih tehnologija) izveštaja koji su namenjeni vlasti i javnim ustanovama u Poljskoj, ekspert je BCC o sistemu zdravstvene zaštite. Od 2010.do 2011. godine bio je predsednik Udruženja CEESTAHC - vodećeg udruženja za medicinu zasnovanu na dokazima i procenu zdravstvenih tehnologija za centralnu i istočnu Evropu, a 2004. godine je izabran za člana borda direktora međunarodne organizacije za HTA – HTAi i na dužnosti je bio do 2007. godine.

Dr Landa je bio predsednik naučnog odbora Prvog godišnjeg HTAi sastanka u Krakovu, u Poljskoj. Diplomirao je na Medicinskom fakultetu, a postdiplomske studije iz menadžmenta završio je na Institutu za javno zdravlje Jagiellonian Univerziteta u Krakovu. Promocija HTA u CEE regionu rezultirala je međunarodnom saradnjom u edukaciji i HTA.Dr Landa je organizovao brojne nacionalne i međunarodne HTA kurseve i konferencije.Od 2006 do 2007. godine, dr Landa je bio direktor Odeljenja za lekove u Nacionalnom zdravstvenom fondu Poljske. Od 2006 do 2008. godine, bio je konsultant Ministarstva zdravlja Republike Srbije i vođa tima na projektu Svetske banke za uvođenje HTA u Srbiju, implementacija principa zdravstvene zaštite zasnovane na dokazima za definisanje paketa osnovnih zdravstvenih usluga i projektovanje HTA agencije.

Vanesa Benković

Vanesa Benković je magistrirala menadžment u zdravstvu na Medicinskom fakultetu u Zagrebu. Trenutno završava doktorsku disertaciju iz zdravstvenih nejednakosti na Odseku za sociologiju Filozofskog fakulteta u Zagrebu. Završila je niz edukacija iz oblasti farmakoekonomije, zdravstvene ekonomije i naprednog modelovanja procene zdravstvenih tehnologija u Francuskoj i Austriji. Dobitnica je stipendije Otvorenog društva za trogodišnji program Global Health Economics koji sprovodi European University of St.Petersburg, u saradnji sa LSE i MIT fakultetima. Predaje farmakoekonomiju, finansiranje i zdravstvenu ekonomiju na Medicinskom fakultetu i Fakultetu za farmaciju i biokemiju u Zagrebu, i zdravstvenu statistiku na kursu European University of St.Petersburg - GHE. Njeno područje rada uključuje iscrpnu listu zdravstveno ekonomskih analiza lekova, pomagala, tehnologija i studija tereta bolesti za Hrvatsku, Sloveniju i BiH, kao i niz istraživačkih metodologija za razne EU JA projekte kao što su Urban health centers *EuropeiCross border patient registries initiative (PARENT)*. Vanesa se takođe bavi dizajnom i sprovođenjem tržišnih i naučnih istraživanja u zdravstvu. Njeni nedavni angažmani uključuju poslove analitike zdravstvene poslovne inteligencije za projekat Ministarstva zdravlja HR finansiran od strane Svetske banke, strateška savetovanja za farmaceutsku industriju i zdravstvene upravne autoritete u regionu. Objavljuje radove iz područja metodologije, istraživanja, javnog zdravlja, farmakoekonomije i zdravstvene ekonomije. Trenutno radi na primeni IT rešenja na području polifarmacije i adherencije.

Norbert Wilk

Direktor odseka za konsultacije Arcana Instituta. Tri godine je bio zamenik direktora za HTA i internacionalnu saradnju Agencije za procenu zdravstvenih tehnologija i tarifni sistem u Poljskoj. Odgovoran je za uvođenje dvostepenog sistema (procen – ocena) pripreme preporuka za finansiranje zdravstvenih tehnologija u Poljskoj koja je zasnovana na dokazima u skladu sa EBM/HTA principima.

Bio je šef Odseka za akreditaciju Ministarstva zdravlja, gde je njegov rad doveo do izdavanja prvih standarda kvaliteta u praksi kao deo propisa – za laboratorije za medicinsku dijagnostiku. Takođe, radio je na reviziji liste za refundaciju u Jedinici za refundaciju i cene, Odeljenja za lekove, Ministarstva zdravlja. Ko-autor je prvih HTA izveštaja za Poljsku dok je radio u Birou za standardizaciju Centra za praćenje kvaliteta u zdravstvenoj nezi.

Angela Yu

Angela Yu je 2015.godine završila Master studije iz Zdravstvene politike, planiranja i finansija na zajedničkom projektu Londonske škole za ekonomiju i Londonske škole higijene i tropske medicine.

Pre Master studija, Angela je radila pet godina u Kini kao konsultant u menadžmentu sa grupom IMS Health. Kao konsultant, bila je zadužena za multinacionalne kompanije za biofarmaciju, NVO i udruženja industrije, koje su pomogle da se povećaju mogućnosti za sprovođenje

politike cena i pristupa tržištu.Tokom rada u Kini, učestvovala je u mnogim projektima analize i kreiranja zdravstvene politike, koji imaju za cilj da se osigura budućnost politike cena i pristupa tržištu u Kini, kako bi se zadovoljile potrebe kineske populacije.

Mark Parker

Mark Parker je viši saradnik za ekonomsko modelovanje odseka za zdravstvenu ekonomiju Univerziteta u Liverpulu u Velikoj Britaniji i Jedinice za kliničke studije iz oblasti kancera u Liverpulu. Tehnički je direktor kompanije Evaluate Econ Ltd. Osnovno obrazovanje završio je iz oblasti softvera i elektronskog inženjerstva i realnog vremena "digitalna obrada signala", zajedno sa RF dizajnom, na Univerzitetu u Mančesteru. Magistarske studije iz zdravstvene ekonomije na Univerzitetu u Yorku završio je 2009.godine. Trenutno radi na doktorskoj tezi iz oblasti zdravstveno ekonomskog modelovanja na Univerizitetu u Liverpulu. Mark Parker je autor modela i poruka zasnovanih na dokazima za globalne dosijee za širok spektar bolesti i za HTA izveštaje koji se podnose NICE, SMC i CVZ, kao i analiza za interno donošenje odluka. U svojoj profesionalnoj karijeri radio je sa sledećim kompanijama: GSK (vakcine), Sanofi Aventis (dijabetes), Wirral Primary Care Trust (validacija podataka iz realnog života), CHAMPS (intervencije za regulisanje telesne težine) i Shire (biološka terapija u hroničnim stanjima). Mark Parker ima veliko iskustvo i stručnost u više terapijskih oblasti, populacionom modelovanju, ekonomiji, razvoju softvera, distributivnim sistemima i računarstvu, veštačkoj intelingenciji. Primenjujući stečene veštine i znanja razvio je argumente zasnovane na dokazima za procene zdravstvenih tehnologija. Navedene obuke, obrazovanje i iskustvo omogućili su primenu najsavremenijih svetskih tehnika za rešavanje složenih problema na metodički, transparentan i razumljiv način, sa osnovnim fokusom na transfer znanja.

Uživa u sportovima na vodi, snegu i vožnji motorom.

Tanja Novaković

Tanja Novaković je od osnivanja 2006. godine predsednica Sekcije za farmakoekonomiju Saveza farmaceutskih udruženja Srbije. Osnivač je udruženja ISPOR Srbija i od 2007 do 2009. godine bila je potpredsednica ISPOR Srbija.

Od 2001.godine radi u farmaceutskoj kompaniji, Galenika a.d., kao produkt menadžer za neuropsihijatrijske lekove. Tanja Novaković je diplomirala na Farmaceutskom fakultetu Univerziteta u Beogradu i završila poslediplomske studije na Farmaceutskom fakultetu Univerziteta u Gentu, u Belgiji. Ona je autor "Priručnika za farmakoekonomske evaluacije", prve takve publikacije iz oblasti farmakoekonomije u Srbiji. Kao predsednica Sekcije za farmakoekonomiju kroz aktivnosti Sekcije učestvuje u razvoju zdravstvene ekonomije, farmakoekonomije i procene zdravstvenih tehnologija.

Kao autor prvog Vodiča za farmakoekonomske evaluacije, Tanja Novaković učestvuje u kreiranju zdravstvene politike u Srbiji. Koautor je u jednom od prva tri HTA izveštaja za Srbiju. Takođe je bila angažovana da vodi grupu eksperata za definisanje postojećih elemenata paketa osnovnih zdravstvenih usluga u Srbiji (projekat Svetske banke i Ministarstva zdravlja Republike Srbije). Tanja Novaković je organizovala i bila predavač na mnogim nacionalnim skupovima i

međunarodnim konferencijama koje su rezultirale u međunarodnoj saradnji u oblasti obrazovanja i razvijanju farmakoekonomije i HTA u Srbiji.

Dávid Dankó

David Danko je generalni direktor konsultanske kompanije Ideas & Solutions, specijalizovane za oblast zdravstva gde sarađuje sa vodećim proizvođačima lekova i medicinskih sredstava na kreiranju uvođenja novih lekova na tržište, lokalnih portfolio strategija i pacijentovog pridržavanja terapije.

Nakon završenih studija u Švedskoj i Nemačkoj 2003. magistrirao ekonomiju na Corvinus Univerzitetu, a 2012. je odbranio doktorsku tezu i objavio udžbenik o politici refundacije lekova. U periodu od 2003. do 2008. radio je kao konsultant u oblasti zdravstvene zaštite sa lokalnim i multinacionalnim kompanijama kao i za Vladu Mađarske. Od 2008. do 2010. radio je kao zamenik šefa Odeljenja za refundaciju mađarskog nacionalnog zavoda za zdravstveno osiguranje gde je bio prvenstveno odgovoran za strategije refundacije lekova i medicinskih sredstava, koncept razvoja međunarodne saradnje i koordinacije IT razvoja, kao i za istraživačke i analitičke aktivnosti. David Danko je predavač na Fakultetu za klinička istraživanja u Beču, Univerzitetu u Lionu (EMAUD), Semmelweis Univerzitetu u Budimpešti, Eötvös Lorand Univerzitetu, redovan je predavač na međunarodnim radionicama i konferencijama iz oblasti refundacije lekova i medicinskih sredstava.

Bojan Trkulja

Bojan Trkulja je direktor Udruženja proizvođača inovativnih lekova – INOVIA, od 2010. godine. Rođen je 1971.u Beogradu, gde je završio osnovnu i srednju školu i Medicinski fakultet Univerziteta u Beogradu. Po obavljenom stažu i položenom državnom ispitu, od decembra 1999. godine radio je u predstavništvu kompanije „F. Hoffmann La Roche“ u Beogradu. Tokom narednih 11 godina radio je na različitim pozicijama, od stručnog saradnika, preko Medical i Product Manager-a, Compliance Officer-a i Market Access Manager-a.

Bojan je srećno oženjen.

Brian Godman

Brian radi na unapređenju politike za poboljšanje kvaliteta i efikasnosti novih i postojećih lekova, zajedno sa zdravstvenim vlastima i fondovima za zdravstveno osiguranje širom sveta, uključujući preko 30 zemalja u Evropi i regionu. Ovo podrazumeva razvoj novih modela za optimizaciju uvođenja novih lekova, uključujući onkološke i orfan lekove, a sve na osnovu iskustva stečenog radom u polju konsultacija i farmaceutske industrije. Iz ovakvog rada proisteklo je preko 100 publikovanih radova u stručnim časopisima u proteklim godinama, pri čemu je većina dostupna kroz Pub Med bazu. Brian će koristeći svoje iskustvo, govoriti o ključnim pitanjima vezanim za onkološke lekove i potencijalnim načinima unapređenja ove oblasti.

Günter Harms

Nakon završetka Farmaceutskog fakulteta i doktorata na Univerzitetu Kiel, u Nemačkoj, dr Harms prelazi u menadžment unutar Instituta za sistemska istraživanja javnog zdravlja; konsultanske firme i Centra za saradnju Svetske zdravstvene organizacije. Njegove nadležnostisu zdravstvena ekonomija, farmakoepidemiologija i sistemska istraživanja zdravstvene zaštite. 1996. godine prelazi u Ferring GmbH u Nemačkoj u deo za razvoj lekova i regulatornih poslova.

1999. godine, dr Harms prelazi u Novartis Pharma AG, prvo u odeljenje za razvoj lekova. Nakon toga dobija mesto u strateškom menadžmentu u Novartis global sa sedištem u Bazelu, u Švajcarskoj i nakon toga u SAD. Nakon povratka iz SAD, kao direktor Novartis globalnih odnosa sa javnošću, dr Harms je bio odgovoran za veliki broj projekata uključujući pristup tržištu, HTA, reforme zdravstvene zaštite i pitanja cena. 2009-2011 kao Direktor odseka za cene u Novartis-u, bio je odgovoran za implementaciju Novartis-ove strategije cena i sistema refundacije za zemlje centralne i ustočne Evrope, Tursku, Rusiju i CIS.

2011. dr Harms se pridružio Shire Human Genetic Therapies i trenutno je direktor pristupa tržištu i odnosa sa javnošću, odgovoran za Shire Centralne i Istočne Evrope.

Jovan Mihajlović

Jovan Mihajlović, ekonomista u zdravstvu, je doktorant Univerziteta u Groningenu, u Holandiji i vlasnik konsultantske kompanijeMihajlović HealthAnalytics (MiHA). On je diplomirani farmaceut i završava doktorsku disertaciju sa temom "Ekonomske studije target terapija raka u Srbiji". Jovan ima značajno iskustvo u farmaceutskoj industriji u kojoj je proveo 7 godina u oblasti prodaje i marketinga. Kroz svoju kompaniju MiHA je dizajnirao modele isplativosti i uticaja na budžet, sprovodio epidemiološke/farmakoepidemiološke studije, sistematske preglede literature i mrežne meta-analize za akademske institucije i industriju u Srbiji i Holandiji. Objavio je nekoliko studija u renomiranim medicinskim časopisima i bio govornik na brojnim farmakoekonomskim i onkološkimstručnim sastancima.

Jakub Adamski

Jakub Adamski, advokat. Specijalizovan je u savetovanju o pristupu tržištu i finansiranju zdravstvenih tehnologija koje su finasirane iz javnih fondova, naročito za lekove koji se refundiraju, namirnice za specijalnu nutritivnu upotrebu i medicinska sredstva, kao i za ostala pitanja vezana za sistem zadravstvene zaštite.

Radio je 6 godina u Odeljenju za politiku lekova i farmaciju. Kao glavni stručnjak bio je odgovoran, između ostalog, za refundiranje za terapiju i lekove, politiku orfan lekova i internacionalnu saradnju u vezi refundiranja lekova. Bivši je član Tima za orfan bolesti (savetodavno telo Ministarstva zdravlja) i European Union's Committee of Experts on Rare Diseases. Predstavlja Ministarstvo zdravlja u radnoj grupi EU Saveta i Evropske komisije i mreže Država članica za refundaciju lekova.

Ko-autor je nekoliko publikacija o cenama lekova i politici zdravstvene nege.

NOTE

- Program of the Conference is accredited by the decision of the Health Council of Serbia 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 kao Međunarodni kurs I kategorije, za ciljnu grupu farmaceute i lekare sa 7 bodova za slušaoce i 13 bodova za predavače.
- Zvaničan jezik konferencije je engleski.

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