HTA REIMBURSEMENT IN THE CEE REGION:
- Experiences Of Cost Containment Measures In Poland And The South Central European Region

Health Economics in the context of health care system – experiences from Serbia, Bosnia & Hercegovina and Croatia

**Agenda**

**Serbia**

**Bosnia & Hercegovina**

**Croatia**

Health Technology Assessment (HTA)

**SERBIA**

State of Affairs

**Current State of Affairs**

Government can intervene, override and stipulate price of medicines

- Ministry of Trade, Tourism and Services
  - Proposes new pricing
- Ministry of Health
  - Evaluates and passes on for Government Decision
- Government
  - Passes legislature on revised pricing
- Medicines Pricing Revised

Serbia - State of Affairs

Introduction of a new technology

- New Drug / Medical Device
  - Ministry of Health
    - Evaluates and passes on for Government Decision
  - Government
    - Passes legislature on revised pricing
- Serbian Health Insurance Office (RZZO)
  - Patient pays full price or % that is not reimbursed
- Medicines and Medical Devices Agency of Serbia (ALIMS)
  - Approves? Yes
  - Negotiate Pricing
  - Government can intervene, override and stipulate price of medicines
  - Price Stipulated
- Medicines
  - Pricing Revised

- Patient pays full price or % that is not reimbursed
- Government can intervene, override and stipulate price of medicines
Current State of Affairs

Pro's
- Evidence Based Medicine and Health Technology Assessment are acknowledged as very important future factors.
- Health Economic training is established within academic institutions. Draft guidelines within reimbursement process (May 2011).

Con's
- Insufficient resources to handle intro to Health Technology Assessment.

Pricing
- Lack of innovation stimulation;

Reimbursement
- Lack of transparency and Evidence Based Medicine use;
- Insufficient resources to handle intro to Health Technology Assessment.

Assessment
- HTA not required.

Serbian Health Insurance Office (RZZO)

October 07, 2009 -
European Health forum awarded Director of National Insurance Office Svetlana Vukajlovic a special award for the achieved results in the reform of medicines financing.

"With the financing reform, it has been achieved that the List of Medicines that are provided by/charged to the national insurance office according to the number and type of medicine does not trail behind other European countries, whose citizens give more funds for health insurance than the citizens in Serbia."

"With measures of forming lower price medicines, prices of original medicines and their generic parallels are identical, which makes Serbian Healthcare system unique in Europe."

Serbian RZZO Introduces Expanded List as Value of Drug Reimbursement Rises 24% in 2009 - Published: 3/25/2010

The Serbian national health insurance has expanded its drug list with the addition of 250 new generics in March; the value of drug reimbursement provided by the insurer rose by 24% year-on-year in 2009.

The Serbian pharmaceutical market is growing dynamically, and the policy enunciated by the country’s health insurance provider specifies generic substitution wherever possible, so that it can be seen as a welcoming market for generics producers, and a more challenging market for innovative drug makers.

The market is expected to reach 930 million euros ($1.21 billion) in 2011 in wholesale prices, or around 1.1 billion euros in retail prices, according to Momir Mistic, the head of the Serbian Chamber of Commerce’s group of drug wholesalers, who cover 85 percent of the market.

The state owes 9.5 billion dinars (€95 mil/$120 mil) to wholesalers who then owe about as much to manufacturers, he said.

Growth will continue even with a “chronic” lack of liquidity in the Serbian health-care system as bills for drugs delivered are paid with an average delay of 90 days to 120 days.

Serbian NIF (RZZO) signed agreement to receive 10% discount on all drugs (both generic and brand) reimbursed (on a positive list) from Pharma (estimated 5 mil euro) in 2011.

– Feb 28, 2011

These savings will be used to improve patient care & introduce new innovative therapies to a positive list. Most likely, savings will be applied towards branded Oncology products, branded antibiotics and other products.

Required: PharmacoEconomic analysis.
But will be specified what kind...
BOSNIA & HERCEGOVINA
State of Affairs

Health Technology Reimbursement in the CEE Region
Situation in Bosnia and Herzegovina
Tarik Catic, MScPharm
ISPOR Bosnia&Herzegovina President
ISPOR 16th Annual International Meeting
May 21-25, 2011
Hilton Baltimore, Baltimore, MD, USA

Bosnia and Herzegovina
General data
Location: Western part of Balkan Peninsula
Surface: 51,129 km²
Total inhabitants: 3.9 million
Capital: Sarajevo
GDP per capita: 3.120 €
Total Health Expenditure: 10% GDP

Administrative Organization
General Framework Agreement for Peace (Dayton Peace Agreement) from 1995
State level
Entity level
Cantonal /regional level
10 Cantons 4 Regions
Bosnia and Herzegovina
Health Sector Governance

- Ministry of Civil Affairs of Bosnia and Herzegovina is in charge for the overall coordination of health issues at the state level
- Agency for Medicines and Medical Devices of Bosnia and Herzegovina
- Ministry of Health of Entity governments responsible for health and social sector (organization and financing)

"3 Health Care Systems"

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**Bosnia and Herzegovina**

**Health Sector Governance**

- Bismarck Model – solidarity system
- Financing through Health Insurance Funds
- Managed by insured persons
- No private Health Insurance introduced in practice
- New legal framework exists

Health expenditure:
- 10% of GDP (public expenditure 7.3% + private 2.6%)
- Higher than average in CEE

Health inequalities:
17% - 35% of population not covered by HI (in different parts of country)

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**Bosnia and Herzegovina**

**Health Sector Governance**

- Decission Sector and Herzegovina
- Herzegovina Cantonal Expenditure:

<table>
<thead>
<tr>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>$613,543,207</td>
<td>$604,644,769</td>
<td>$741,079,223</td>
</tr>
<tr>
<td><strong>Pharmaceuticals</strong></td>
<td><strong>Pharmaceuticals</strong></td>
<td><strong>Pharmaceuticals</strong></td>
</tr>
<tr>
<td>$130,314,171</td>
<td>$154,028,410</td>
<td>$170,042,847</td>
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<tr>
<td><strong>Total Expenditure</strong></td>
<td><strong>Total Expenditure</strong></td>
<td><strong>Total Expenditure</strong></td>
</tr>
<tr>
<td>$15,429,429</td>
<td>$17,663,974</td>
<td>$23,571,038</td>
</tr>
</tbody>
</table>

*Data published by Health Insurance Funds

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**Bosnia and Herzegovina**

**Health Decision Process (pharmaceuticals)**

Federal HIF (Primary Health Care)
- Essential medicines list
- obligatory for all HIFs
- 100% reimbursement level
- Other medicines
- Reimbursement level 25%, 50% or 75% depending on HIF budget
- HIF Board of Experts
- Reimbursement Approval
- Tender pricing or Tender

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**Bosnia and Herzegovina**

**Health Decision Process (Reimbursement of pharmaceuticals)**
Bosnia and Herzegovina

Health Decision Process (Reimbursement of pharmaceuticals)

- Republic of Srpska HIF
  - Citostatics and other “expensive” drugs
  - Referral pricing or Tender

Bosnia and Herzegovina - Conclusion

- Systematic approach to HTA is not introduced
- Preliminary results of Survey on HTA conducted by ISPOR BH among Health Insurance Funds and Ministries of Health indicate that HTA and Pharmacoeconomic analyses are/should be implemented in reimbursement decisions in future
- Positive movement in Federation of BH
  - New Law on Health Care (2010) predicts establishment of HTA board appointed by Ministry of Health
- Lack of educated experts in HTA field
- Need for more transparent reimbursement decision making process
- Need for cooperation with other countries in region
- HTA Agency as independent organization on state level could help in HTA implementation

CROATIA

State of Affairs

Institutionalization of the Agency for Quality and Accreditation in Health

- 2007, Act on Quality of Health Care: The Agency for Quality and Accreditation in Health (as legal, public, independent, non-profit institution) responsible for HTA process and report and database on HTA
- Health technologies: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities
- Three departments: 1) Department for Quality and Education, 2) Department for Accreditation in Health, and 3) Department for Development, Research and HTA
- Formal HTA activities actually began in October 2009

Croatian Guideline for Health Technology Assessment Process and Reporting (with international peer-review process)

- HTA Department and multidisciplinary HTA Working Group (appointed by Agency for this purpose)
- Table of Contents
  1. Introduction and legal framework
  2. HTA process
  3. Topics suggestion and selection process
  4. Scope prepared
  5. Assessment process
  6. Appraisal process
  7. HTA Report
  8. Guide for Croatian primary economic analysis

www.farmakoekonomika.ba
1 Introduction and legal framework

- Croatian HTA reports as recommendation, with aims to support policymakers at national level, particularly Croatian MoH, and HZZO, in making evidence-informed decisions on the strategic planning, investment, management and the implementation of technologies in health care, on funding (reimbursement) and coverage of health technologies, as well on hospital level on request from hospitals directors and policy teams.
- Health technologies: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities.
- HTA process should have main parts: Topics suggestion and selection process, Definition of Scope for HTA, Assessment process, Appraisal process, and Report preparing and publishing.
- In the beginning, part of HTA process, Appraisal process, will be defined later in new version of Guideline after future changes in legal framework.
- A Single Technology Assessment (STA): a single technology for a single indication.
- A Multiple Technology Assessment (MTA): more than one technology, or one technology for more than one indication.

2 Scope prepared

- The Agency develops a final scope that describes the boundaries of the assessment and the issues that will be investigated.
- Objectives and research questions are defined for each approved topic, with the assistance of HTA Advisory Committee members and clinical experts, as necessary, according to the so-called PICO structure (Population/patients with the disease of interest; Intervention(s), i.e. the technology under assessment; Comparison(s), which should serve as reference or gold standard; Outcomes which encompass the endpoints for assessing effectiveness, safety, and economics).

3 Assessment process

A “pre-assessment” of the existing evidence on each selected topic is prepared by HTA Department staff (including existing Core HTA and/or HTA from other countries), final decision about HTA process, Assessment phase, will be done according Algorithm; Algorithm for HTA process (Assessment phase):

1. Already published Core HTA and/or HTA from other countries (Yes or No)
2. If Yes, HTA will be critically appraised for quality by INHTA checklist for the appraisal of HTA Reports; further education will be done according EUnetHTA Adaptation Toolkit.
3. STATA, MTAMTA Assessment phase, received core HTA, evaluation and SR of economic analyses (Yes or No)
4. If Yes, will be done according Algorithm; Algorithm for HTA process (Assessment phase), will be based on (will be based on Cochrane Handbook for Systematic Reviews, with protocol) and SR of economic analyses (with protocol) will be done according Algorithm; Algorithm for HTA process (Assessment phase), with new health economic analyses according the part of this guideline - Guide for Croatian primary health economic analysis.

4 Appraisal process defined in the future after necessary changes in HTA legal framework.

- Members of the HTA Pharmaceutical, and Devices and Systems Advisory Committees, appointed by the Agency, in the beginning will serve as part of the assessment team up to and including the protocol phase, but not beyond this phase (In the future they will serve in Appraisal process).

5 HTA Reports

- Several types of HTA report:
  Full HTA report (STA, MTA) in English language and Summary of full English report translated to Croatian language, Short Advice to the Ministry of Health and Short Advice to the HZZO in Croatian language.
  Short Advice to Hospitals, Short Advice to health professionals, and Short Advice to patients, written in lay language.
- Quality assessment: internal review, international peer-review (including clinicians, methodologist, and economist).
- The Final reports: published on Agency’s web site and subsequently in print.
- Update of each HTA Report: every 2 years, or before (when there is significant new evidence that is likely to change the recommendations).
### Future Croatian HTA perspective

**At national level**
- First pilot STA, further permanent STAs and MTAs process and reports; Further educational activities for HTA users, HTA doers, and promotion of HTA

**At international level**
According to EU Cross-Border Health Care Directive, with Article 15 on Cooperation on health technology assessment - prepared for participation and contribution to the cooperation and exchange of objective, reliable, timely, transparent and transferable information among Member States within a voluntary network (in accordance with the legislation of the Member States where they are established) connecting national authorities or bodies responsible for health technology assessment designated by the Member States

- Importance of support and commitment of government institutions, adequate legal framework and funding, educated permanent staff, national and international cooperation and collaboration (network)

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**Learning Process**

**It is important to look at others’ experiences!**

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**5. International Reference Pricing – 2008 West Europe**

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**Learning Process**

Different Options to Regulate Drug / Medical Device prices through:

- 1. Rate of Return (RoR) Regulation
- 2. Price Setting
- 3. Value-based pricing
- 4. Controlling use (price-volume tradeoffs)
- 5. International price referencing
Learning Process
Risk sharing as part of the value based pricing strategy

Health Technology Assessment (HTA)

Health Technology Assessment (HTA)

Health Technology and Decision making

“To be useful to decision makers, HTA must be tailored to the decision nodes of the health-care system and the needs and interests of decision makers at each of these nodes.”

The Greek Healthcare System

Overview 1

The Greek health system presents the features of the Southern European Model based on the mixture of both Bismarck and Beveridge elements. Following the European taxonomy of health systems, Greece presents a mixture of “public contract and public integrated” models.

Overview 2

Highly fragmented it is characterized by the co-existence of three subsystems:

- ESY - National Health Service
- Compulsory social insurance
- Voluntary private insurance

The Ministry of Health and Social Solidarity (YYKA);
overall responsibility for national health policy, together with;

ESY - National Health Service

FUNDING comes from:
- general taxation
- social insurance premiums
- private expenditure (primarily patient out-of-pocket payments)

MAJOR REFORMS IN THE PHARMACEUTICAL SECTOR

1997 Introduction of Positive List (Article 20)
2006 Pharmaceutical Care Reform Legislative Act 3457/2006
2010 The Greek Memorandum
2011 Introduction of New Pharmaceutical reforms aiming at cost containment

Pharmaceutical Policy
The Regulatory Framework

- Ministry of Health and Social Solidarity
  - Overall Planning
  - Implementing Reforms
  - Administrative Structure

- EOF National Organization of Medicines
  - Functions under the MoH
    - Marketing Authorization
      - National, Central, Decentralized, Mutual Recognition

- Ministry of Development
  - Pricing Committee
  - Issuing price bulletin
GDP per capita

More Expenditure does not lead to better health

Exponential increase of Pharmaceutical expenditure in Greece

Relative retail pharmaceutical prices EU

Oversupply of Physicians in Greece generate higher Pharmaceutical Expenditure
The Greek Memorandum

• In May 2010, the IMF and the euro zone states agreed a 110.0 billion euro (US$156.5 billion) rescue package for Greece over three years.
• In response to the rescue package, Greece announced its fourth austerity package designed to reduce the government deficit by 11.0% of GDP by 2013, from 13.6% of GDP in 2009 to under 3.0% of GDP by 2014.

A reform of the healthcare sector is urgently needed.

• Public expenditure on health accounted for 5.9 percent of GDP in 2008.
• Public per capita expenditure grew at a real average rate of growth of 5.4 percent in 2004-08.
• A large set of measures are needed to stabilise or even reduce the public health spending-to-GDP ratio to around 6 percent, while improving the quality of care provision through substantial gains in productivity and significant cuts in waste and corruption.

From evidence to recommendation

Policy Design and Implementation

Objectives:
• Successful Health Reforms
• Improve Population’s Health
• New legislation
• Health Reforms (Primary, Secondary, Tertiary)
• Public Health
• Restructuring Pharmaceutical Sector

Pharmaceutical Reforms
• Development of National drug policies
• Sustainable Pharmaceutical sector – Business Plans, Procedures, Audit …
• Access to Medicines
• Regulatory Framework
• Alleviate shortages in hospital primary care
• Support the Pharmaceutical Industry
• Training Programmes
Main Conclusions

- Economic Crisis: Need to Control Expenditure
- Relative low Pharmaceutical Prices
- Ineffectiveness of List to Control Expenditures
- Excess Supply of Doctors contributes to Pharma expenditures: Lack of Prescribing Control

The authorities plan:
- to save between EUR 2 and 3 billion in the coming years.
- Introduce e-prescribing to all social security funds by end 2010
- an updated price list and a “positive list” of reimbursed medicines based on new reference prices are due to be launched by end-2010
- Overall, the government should aim at reducing pharma spending to the EU average of 1 percent of GDP.

FINANCING HEALTH TECHNOLOGY IN POLAND: COST-CONTAINMENT MEASURES

Prof. Karina Jahnz-Różyk
Dr Joanna Lis
POLSKIE TOWARZYSTWO FARMAOEKONOMICZNE

CHARACTERIZING HEALTH CARE SYSTEMS

IN TERMS OF THE SIZE OF PHARMACEUTICAL MARKET, POLAND OCCUPIES THE SIXTH POSITION IN EUROPE.

IN TERMS OF MARKET SIZE PER CAPITA, POLAND OCCUPIES ONE OF THE LAST PLACES IN EUROPE. MARKET IN SLOVAKIA AND HUNGARY IS BIGGER THAN IN POLAND BY 47% AND 60%.
Poland has one of the lowest average prices of medicines in Europe, emerging 55% below the average. It is caused by the large share of generics and poor availability of innovative medicines.

There are 591 innovative medicines in Poland, most of which have been on the market for a long time. Their average price is 54% below the European average.

Poland has one of the lowest average prices of medicines in Europe, emerging 55% below the average. It is caused by the large share of generics and poor availability of innovative medicines.

The average price of generic and innovative drugs, EURO, not producer prices.

The average price of original drug, EURO, not producer prices.

Prices of generic drugs in Poland are also one of the cheapest in EU and lower than the average of 40%.

The price of generic drug, EURO, not producer prices.

Poland has the highest level of co-payment for the patient, 67%, in total spending on health care compared to other European countries. The level of patients co-payment for the reimbursed medicines is 32%

The level of patient’s co-payment in total spending on health care in selected countries.

Cost-Containment measures

Price Control $ Volume Control = Spending Control
COST-CONTAINMENT MEASURES ARE ALL OVER EUROPE

Ireland
Norway
Sweden
Finland
Denmark
Netherlands
Estonia
Latvia
Lithuania

Price cuts, mandatory rebates 2010
Price freeze 2010
Introduction of IRP 2010
Changes planned in 2011/2012

• Paybacks,
• Limits on sponsorships,
• Extension of TRP,
• Value Based Pricing

Hungary 2011: since Jan ↑ Combo RP since Jul:
↑ tax 12 → 18% and ↑ rep fee 5 → 10 M HUF
Rebind PV agr. -10%

UK
Netherlands
Germany
Poland
Czech
France
Belgium
Austria
Hungary
Slovakia
Bulgaria
Portugal
Spain
Switzerland
Slovenia
Greece
Bosnia
Croatia
Serbia
Albania
Romania
Italy

Source: INFARMA Poland

NEW REIMBURSEMENT BILL IN POLAND

Reimbursement decisions
Applicant's obligations:
Continuity of supplies,
Prohibition of trade marketing,
Risk-sharing instruments,
Course of issuing the reimbursement decision,
Transitional and final regulations

Impact on access to innovation
• Drug spend freeze on 17% of total health budget
• Retail margins based on cluster limit, not price
• Risk-sharing mechanisms (?)

Impact on reimbursement process
• Improvement of transparency:
  predictable and timely (?)

Impact on drug prices and patient co-pay
• Fixed prices and margins
• New limit groups criteria: expanding jumbo Gx clusters, mkt share indicator
• New reimbursement level classification: no pay burden and length of treatment
• Risk-sharing mechanisms, timing & frequency
• Timelines and rules of reimbursement decisions
  1. 15 MTHs for approval
  2. 5 YR periods
  3. Impact of data exclusivity expiry on price erosion
  4. Gx entry price erosion criteria

Impact on commercial practices
• Ban on incentives aimed to increase reimbursement products sales

As a result of new regulations NHF will save in the next four years, more than 5 billion PLN on the cost of the reimbursement of medicines, therapeutic programs and chemotherapy

IMPACT OF PLANNED COST-CONTAINMENT MEASURES

NHF savings resulting from restricted budget of expenditures on drugs
Expenditures on reimbursement, therapeutic programs and chemotherapy after the introduction of reform

TOTAL 5,3 bln PLN

2011 2012 2013 2014 2015
11,8 11,8 11,8 11,8 11,8

MSE-Warsz: savings resulting from restricted budget of expenditures on drugs
Expenditures on reimbursement, therapeutic programs and chemotherapy after the introduction of reform

As a result of new regulations NHF will save in the next four years, more than 5 billion PLN on the cost of the reimbursement of medicines, therapeutic programs and chemotherapy

IMPACT OF NEW REIMBURSEMENT BILL
One of the effects of a new law will be to increase patients’ expenditures on reimbursed drugs by more than 3 billion PLN, and reduction of the profitability of generic companies.

### Scenario I – all manufacturers will bear the costs of reduction of drugs prices (unlikely option):

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Companies</td>
<td>-3.58</td>
<td></td>
</tr>
<tr>
<td>Innovative Companies</td>
<td>-1.68</td>
<td></td>
</tr>
<tr>
<td>Patients cost</td>
<td>0.00</td>
<td></td>
</tr>
</tbody>
</table>

TOTAL 5.3 bln PLN

### Scenario II – only some manufacturers will bear the costs of reduction of drugs prices (probable option):

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of Generic Companies will reduce costs</td>
<td>-1.79</td>
<td></td>
</tr>
<tr>
<td>20% of Innovative Companies will reduce costs</td>
<td>-0.42</td>
<td></td>
</tr>
<tr>
<td>Patients cost</td>
<td>3.05</td>
<td></td>
</tr>
</tbody>
</table>

Citation for IMS Poland

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Poland is an important player in the export market in Europe.

Price reduction due to the introduction of new pharmaceutical legislation will increase the phenomenon of parallel exports.

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Change of margins and average prices of drugs caused by the introduction of new law will lead to losses of warehouses at the level of 47 million PLN and pharmacies at the level of 91 million PLN.

<table>
<thead>
<tr>
<th></th>
<th>Wholesales prices</th>
<th>Retail prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Margins decrease</td>
<td>-5%</td>
<td>-10%</td>
</tr>
<tr>
<td>Warehouse value</td>
<td>1 074</td>
<td>913</td>
</tr>
<tr>
<td>Warehouse value after the new law</td>
<td>1 027</td>
<td>822</td>
</tr>
<tr>
<td>Change</td>
<td>-5%</td>
<td>-17%</td>
</tr>
</tbody>
</table>

Citation for IMS Poland

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What else can happen in Poland?

- INN prescribing
- Central / group purchasing
- Increasing restrictions on access to prescribers and promotional practices
- Emerging drug formularies, pressure on prescribers to control costs
- New payers will emerge as a result of evolution in insurance systems