HTA GUIDELINES IN CENTRAL AND EASTERN EUROPE (CEE): DEVELOPMENT, IMPLEMENTATION AND POLICY IMPLICATIONS

Speakers:

Croatia - Mirjana Huić, MD, MSc, Assistant Director
Department for Development, Research and HTA
Agency for Quality and Accreditation in Health

Bosnia and Herzegovina - Tarik Čatić, MSc.Pharm.,
ISPOR Bosnia&Herzegovina President

Greece - Prof. John Yfantopoulos PhD , ISPOR Greece President

Moderator:

Serbia - Vladimir Zah, PhD(c), ISPOR Serbia President

Republic of Croatia
● Population of 4.4 million
● GDP per capita 12.000 US$

Croatian Health care system
• A social health insurance, financed from several sources
• A major part is financed according to a national health insurance model
• The agreement and payment of the mandatory health insurance is conducted through the Croatian Institute for Health Insurance (HZZO)
• Total spending on health (2005-09):10%-14% GDP
• Per capita spending on health: 1200 US$
• HZZO budget for 2009: 20 billion HRK (~2.7 billion €)
• HZZO expenditure on prescription drugs: 18.9% of total health expenditure
• Special Fund for very expensive drugs: 400.000.000,00 HRK (53 million €)

Decision making process
Ministry of Health and Social Welfare (MOH):
1) health policy, planning and evaluation, including the drafting of legislation, regulation of standards for health services and training;
2) public health program, including monitoring and surveillance of health status, health promotion, food and drug safety, and environmental sanitation;
3) regulation of capital investments in health care providers in public ownership

Agency for Medicinal Products and Medical Devices (HALMED):
1) marketing authorization of drugs
2) regulation of medical devices

Croatian Health Insurance Institute (HZZO):
1) managing the Health Insurance Fund and contracting health care services
2) key role in the definition of basic health services covered under statutory insurance
3) the establishment of performance standards and price setting for services covered by the HZZO
   - pricing and reimbursement decision on drugs and medical devices

Croatian Framework for HTA
• 2006, Strategy of the development of the Croatian Health care system 2006-2011
• 2007, Act on Quality of Health Care: The Agency for Quality and Accreditation in Health (as legal, public, independent, non-profit institution), should provide the procedure for and database on HTA
Health technologies: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities
• December 2009, Ordinance regarding reimbursement on drugs
• October 2010, Plan and program of measures for insurance, improvement, promotion, and monitoring of health care quality

Health Technology Assessment (HTA) Guideline in Croatia

Mirjana Huić, MD, MSc
Assistant Director
Department for Development, Research and HTA
Agency for Quality and Accreditation in Health
Zagreb, Croatia

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### Annual HTA budget and permanent staff in HTA Agencies or Units in some European countries:

<table>
<thead>
<tr>
<th>Country</th>
<th>Since</th>
<th>Annual HTA budget (US $ million)</th>
<th>Population served (million)</th>
<th>Permanent staff in HTA Department</th>
<th>Consultants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finland</td>
<td>1995</td>
<td>2.0</td>
<td>5.1</td>
<td>18</td>
<td>65</td>
</tr>
<tr>
<td>Latvia</td>
<td>1995</td>
<td>0.05</td>
<td>2.3</td>
<td>8</td>
<td>variable</td>
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<tr>
<td>Denmark</td>
<td>1997</td>
<td>3.8</td>
<td>5.4</td>
<td>15</td>
<td>variable</td>
</tr>
<tr>
<td>Norway</td>
<td>2003</td>
<td>4.0</td>
<td>4.5</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td>Croatia</td>
<td>2007</td>
<td>0.4</td>
<td>4.4</td>
<td>1 (out of three planned in 2009)</td>
<td>1 on contract (from September 2010)</td>
</tr>
</tbody>
</table>


International collaboration and support were established:
- Membership in international society, HTAI (November 2009)
- Agency’s appointment (by Croatian Ministry of Health) and participation in EUnetHTA Joint Action as a EUnetHTA Partner (March 2010)

### WP8: Strategy and Business Model Development

- Two meetings were organized: 1) a one day meeting with international experts for main HTA users (January 2010), and 2) HTA symposium during the 1st Croatian congress on pharmacoconomics and outcome research with international participation (April 2010)

### December 2010, organized by the Technical Assistance Information Exchange Instrument of the European Commission (TAIEX) in co-operation with our HTA Department: 2 days Workshop - “Health Technology Assessment; main principles, HTA process and report”

### Romanian Guideline for Health Technology Assessment

#### Process and Report, issue date: July 2010 (still on international peer-review process)

- HTA Department and multidisciplinary HTA Working Group (appointed by Agency for this purpose)
- **Table of Contents**
  - I Introduction and legal framework
  - II HTA process
    - 1 Topics suggestion and selection process
    - 2 Scope prepared
    - 3 Assessment process
    - 4 Appraisal process
    - 5 HTA Report
  - 6 Guide for Croatian new economic analysis
- **Appendix I: BIBLIOGRAPHY OF RECOMMENDED HTA GUIDELINES AND METHODOLOGY**
- **Appendix II: A Code of Practice for Declaring and Dealing with Conflicts of Interest in HTA process**
- **Appendix III: Authorship**
- **Appendix IV: Selected Data Sources on Croatian Population Health, Healthcare Resource Use and Costs**

### Croatian Guideline for Health Technology Assessment

#### 1 Topics suggestion and selection process

- **Topics suggested and requirements:** Croatian Ministry of Health, Croatian Institute for Health Insurance, private health insurance company, industry, health professionals’ societies, clinical and public health professionals, patients’ societies, hospitals directors and policy teams, as well as Agency staff through HTA Topic Proposal Form
- Agency HTA staff review: to ensure they are appropriate, to check whether they are already included in its work, then filtered according to selection criteria and check list:
  - a) burden of disease (population affected, morbidity, mortality)
  - b) resource impact (i.e. the cost impact on Croatian Institute for Health Insurance or the public sector)
  - c) policy importance (i.e. whether the topic falls within a government priority area)
  - d) whether there is inappropriate variation in practice across the country
- **Topics approved and prioritized quarterly by the HTA Advisory Committee**

### 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 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 HTAs from other countries), final decision about HTA process. Assessment phase, will be done according Algorithm for HTA process (Assessment phase).

1. Already published core HTA and/or HTAs from other countries (Yes or No)
   - If Yes, HTA will be critically appraised for quality by [blank HTA checklist for the appraisal of HTA Reports; further analysis will be done according "EUnetHTA Adaptation Toolkit with new health economic analysis" according the part of this guideline - Guide for Croatian new health economic analysis.
   - If No, 2. Already published Systematic Reviews (SR) on clinical effectiveness and safety (Cochrane database of SR, DARE databases) and SR of economic analyses (Yes or No)
   - If Yes, SR will be critically appraised and new clinical trials will be added if necessary; with new health economic analysis according the part of this guideline - Guide for Croatian new health economic analysis.
   - If No, 3. New SR on clinical effectiveness and safety (with protocol) (will be based on Cochrane Handbook for Systematic Reviews or the CRD guidance for systematic reviews), with new health economic analysis according the part of this guideline - Guide for Croatian new health economic analysis.

5 HTA Report

- Four main types of HTA report: 1) full HTA report on English language, 2) Summary of full English report translated to Croatian language, 3) short Advice to the Minister of Health, and 4) short Advice to the HZZO in Croatian language and for all other different HTA users.
- Full HTA Report: Title, Authors, Conflict of interest declare, Executive Summary, Introduction with scope, Current use of the technology (Implementation level), Description and technical characteristics of technology and comparator, Clinical systematic review with Effectiveness and Safety, Economic analysis with systematic review of economic studies and primary economic evaluation, Ethical aspects, Organizational aspects, Social aspects, Legal aspects, adding Accuracy as a new domain for diagnostic and screening techniques, Discussion with summary of results, study limitations, generalizability of findings, knowledge gaps, and Conclusion. References, Appendices (as literature search strategy, large tables and figures...)
- Quality assessment: internal review, international peer-review (including clinicians, methodologist, and economist)
- The Final report: published in English on Agency’s web site and subsequently in print
- The Summary of English report: translated to Croatian language and posted on the web site, printed, as well as short Advice

Conclusion

- The way for establishing a transparent, scientific, independent, evidence-based HTA process in Croatia not an easy and quick process
- Importance of support and commitment of government institutions, adequate legal framework and funding, educated permanent staff, national and international cooperation and collaboration (network)

Thank you for your attention!

Conflict of interest: None

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
Bosnia and Herzegovina

Health Sector Governance

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

Legal Framework

State: Law on Drugs
Entity: Law on Health Care – Health Sector Organization
Law on Health Insurance – Health financing
Pricing system – In development on State level

Bosnia and Herzegovina

Health Sector Financing

Bismarck Model – solidarity system
Financing through Health Insurance Funds
Managed by insured persons
No private Health insurance introduced

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)

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
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<tbody>
<tr>
<td>%</td>
<td>%</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>FBiH</td>
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<td></td>
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<td>Pharmaceuticals</td>
<td>120,314,721</td>
<td>154,228,410</td>
<td>170,042,677</td>
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<tr>
<td>%</td>
<td>10.4</td>
<td>16.4</td>
<td>16.4</td>
</tr>
<tr>
<td>Total Expenditure</td>
<td>1,135,043,907</td>
<td>1,685,648,785</td>
<td>1,911,079,011</td>
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<tr>
<td>RS</td>
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<tr>
<td>Pharmaceuticals</td>
<td>10,622,974</td>
<td>23,571,628</td>
<td>24,987,762</td>
</tr>
<tr>
<td>%</td>
<td>4.1</td>
<td>5.1</td>
<td>5.1</td>
</tr>
<tr>
<td>Total Expenditure</td>
<td>203,886,463</td>
<td>232,395,636</td>
<td>240,519,019</td>
</tr>
</tbody>
</table>
Bosnia and Herzegovina
Health Decision Process (pharmaceuticals)

Marketing approval
(Agency for Medicines and Medical devices)

Reimbursement
(Health Insurance Funds)

Federation of Bosnia and Herzegovina
Republic of Srpska

HTA Policies in GREECE
John Yfantopoulos
Professor of Health Economics
University of Athens

www.farmakoekonomika.ba
The Greek Healthcare System

Health care model

- 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
- Highly fragmented it is characterized by the co-existence of three subsystems:
  - ESY - National Health Service
  - Compulsory social insurance
  - Voluntary private insurance

The Greek Healthcare System

Organizational chart of health care system

The Greek Healthcare System

Institutional Roles

National Level
- The Ministry of Health and Social Solidarity (YYKA) overall responsibility for national health policy, together with;
  - ESY - National Health Service
  - DYPE - Seven regional health authorities implement national policies at a regional level
- The Ministry is responsible for provision and financing of the National Health Service as well as health and social services for the poor, elderly and disabled;
- The Central Health Council (KESY) and Committees for AIDS, Drugs, Cancer, play an advisory role to the Minister
- Local Authorities (52 districts or prefectures) through the Ministry of Health, play a limited role in the administration of 128 NHS hospitals and around 200 rural Health centers

The Greek Healthcare System

Pharmaceutical Expenditure

- Pharmaceutical expenditures are relatively high in Greece. Both in absolute (total Pharma expenditure) and relative terms (share of GDP and share of total health expenditure)
- Pricing of pharmaceutical products is among the lowest in the European Member States
- Pharmaceutical expenditures increased very fast over the last two decades

The increase of Pharmaceutical expenditures in Greece is among the highest in the EU countries for the period 1991-2006

Source: OECD Health Data 2009

Cost Containment Policies

- Cost containment focused on Price controls without introducing measures to control over-prescribing behavior by physicians and specialists
- The reimbursement system does not provide any incentive to physicians to be cost conscious
- No control of prescriptions
Coverage of the Cost

Out of Pocket payments for Drugs

Thank you for your attention

Q&A Session