**What is the role of HE in decision making process? Czech perspective**

Tomáš Doležal  
Center for Pharmacoeconomics and Outcomes Research  
3rd faculty of Medicine, Charles University, Prague

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**Agenda**

- Introduction and basic principles
- Legislation and HE?
- Current methodology and guidelines?
- Appraisal body/institution – quality of evaluation?
- Willingness to pay threshold?
- Are not CE drugs rejected?

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**HTA and cost containment tools in CEE**

<table>
<thead>
<tr>
<th>Country</th>
<th>HE data required</th>
<th>International reference pricing</th>
<th>HTA agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Czech Republic</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Slovakia</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Hungary</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Poland</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

**Actual tools for regulations / Czech Republic**

- **International referencing**
  - Ex-factory prices regulated (basket)
  - Reimbursement level (lowest EU price)
- **Therapeutic referencing (>300 groups)**
- **Cost-effectiveness and budget impact**
- **Prescription regulations/restrictions**
  - Indication limitation
  - Only for selected speciality
- **Prescription limits**
  - for GPs, outpatient care, hospitals
- **Special budgets (limits) for expensive drugs**

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**Requirements for pharmacoeconomic data in Czech Republic**

- Pharmacoeconomic criteria should be taken into account during reimbursement process
  - Analysis of cost-effectiveness
  - Budget-impact analysis
- Mandatory for new drugs not categorized into reference groups
- For higher reimbursement level within reference group
- Changes in prescription conditions
- Revision of reimbursement level and conditions every year

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**Requirement for PE studies**

- **Cost-effectiveness analysis**
  - Wrong legislation definition (“cost-saving”)
  - No available methodology and detailed rules
  - CEA, CUA, CBA, CMA?
  - Sources for drug costs/resource use?
- **Budget-impact analysis**
  - Basis for PE evaluation
  - No available methodology
  - Shortage of relevant epidemiology and cost sources
PE analyses - current requirements

- **costs**
  - Outside the RG
  - Bonification for HE (30%)
  - Second reimbursement level

- **benefits**
  - Basic reference level
  - 2nd and further generic drugs
  - 1st generic drug

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**PE guidelines published by Czech Pharmacoeconomic Society**

- March 2009 – new edition
- Check-list

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target of analysis</td>
<td>Question-based correctly</td>
</tr>
<tr>
<td>Perspective</td>
<td>Payer, society, patient, institution</td>
</tr>
<tr>
<td>Target population</td>
<td>Clear definition (SPC, study, register)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Type of analysis CMA, CEA, CUA, BIA</td>
</tr>
<tr>
<td>Source data</td>
<td>RCT, observation study, retrospective data collection, vs. placebo, comparator</td>
</tr>
<tr>
<td>Source and costs calculation</td>
<td>Literature, health insurance funds, panel of experts etc.</td>
</tr>
<tr>
<td>Type of benefits</td>
<td>QALY, LYG, events, complications, and the like</td>
</tr>
<tr>
<td>Time horizon</td>
<td>Adequacy</td>
</tr>
<tr>
<td>Separate expression of costs and benefits</td>
<td>Stated, costs categorization</td>
</tr>
<tr>
<td>Incremental analysis</td>
<td>Yes/no, right/wrong</td>
</tr>
<tr>
<td>Sensitivity analysis</td>
<td>Yes/no, which one</td>
</tr>
<tr>
<td>Discounting</td>
<td>Yes/no, which one</td>
</tr>
</tbody>
</table>

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**WTP thresholds**

- Czech Republic: Not provided
- Slovakia: 18 000 – 26 500 EUR
- Hungary: Not provided
- Poland: Not provided

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**Where is WTP for CZ?**

- Increase in willingness to pay (WTP) as grounds of cost effectiveness
  - A: 5-15,000 GBP/QALY
  - B: 25-35,000 GBP/QALY

**Willingness to pay in Czech Republic?**

- GDP/capita...2007: ...
- 13 784 EUR/capita
- ...41 352 EUR/DALY (QALY)
Hemodialysis model of WTP

- Life expectancy without HD = 0.637 years/333 EUR with HD = 3.547 years/123,584 EUR

ICER: 42,404 EUR/LYG

<table>
<thead>
<tr>
<th>Disease</th>
<th>Comparator</th>
<th>ICER</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natalizumab MS</td>
<td>IFNβ</td>
<td>555 709</td>
<td>T vs. SUR</td>
</tr>
<tr>
<td>Sitagliptin JANUMA</td>
<td>DM 2 type</td>
<td>Normal</td>
<td>Dominant</td>
</tr>
<tr>
<td>Omalizumab XOLAIR</td>
<td>Persistent refractory AB</td>
<td>BSC</td>
<td>740 184/QALY</td>
</tr>
<tr>
<td>Nilotinib TASIGNA</td>
<td>CML</td>
<td>Dasatinib</td>
<td>937 485/QALY</td>
</tr>
<tr>
<td>Trabectedin YONDELIS</td>
<td>2. choice sarcoma</td>
<td>BSC</td>
<td>867 962/LYG</td>
</tr>
<tr>
<td>Sunitinib SUTENT</td>
<td>1. Choice RCC</td>
<td>IFN</td>
<td>566 148/rok bez progrese</td>
</tr>
<tr>
<td>Sorafenib NEXAVAR</td>
<td>HCC</td>
<td>BCS</td>
<td>1 301 015/LYG</td>
</tr>
<tr>
<td>Lenalidomid REVLIMID</td>
<td>MM</td>
<td>bortezomb</td>
<td>177 331/měsíc bez progrese</td>
</tr>
</tbody>
</table>

Types of PE analyses

- CEA: 23.8%
- CUA: 28.6%
- CMA: 47.6%

Sensitivity analysis

- Ne: 37.5%
- Ano: 62.5%

16 hodnocených analýz
21 potvrzených typů analýz (%)

Three main components for using pharmacoeconomics in decision making process

- Individuals capable of conducting the analyses
- A receptive audience among decision- and policy-makers
- A body of methodology appropriate to the task

HTA is not a decision

Assessment Appraisal/ Standardised procedure:
Effectiveness, safety, CE
Value for money

Decision

Budget impact
Payers
Social value

Singer ME. Pharmacoeconomics May 2008
Major principles of reimbursement in Czech Republic

External reference:
The lowest retail price in 27 EU countries

Internal reference:
>300 therapeutic groups/clusters/

HTA/health economy

Currently cost-containment dominates cost-effectiveness

Future prospects
- ↑ the role of HTA in assessment
- International referencing → value based pricing
- ↑ the impact of health economy
- Show long term benefits/value in chronic diseases
- Outcome-based reimbursement/risk sharing schemes
- Educate the staff properly
- European collaboration network – EUnetHTA, INAHTA

Thank you for attention!