Pricing and reimbursement in Czech Republic ...road to HTA?

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Outline

- Basic facts about healthcare in Czech Republic
- Pricing and reimbursement rules
- Legislation change 2008
- Pharmacoeconomics
- HTA
1. All citizens are covered by health care insurance (Health Care Insurance Law)

2. General health insurance system built on solidarity, equity and availability of health
Healthcare income/expenditure

- Drug expenditures = 22% of total healthcare budget
- Direct payments (out-of-pocket) still very low...........cca 10%
COST CONTAINMENT in CZECH REPUBLIC

- direct price regulation for reimbursed drugs (maximal ex-factory prices)
- reimbursement regulation (reference groups)
- prescription limits - for GP
  - for hospital
- special budgets (limits) for drugs
Pricing and reimbursement in Czech Republic 2008

- Jurisdiction moved to SÚKL
- Limit is 75 days and for joint procedure 165 days according to Transparency Directive
- The defined participants of pricing and reimbursement procedures are State Institute for Drug Control, applicant (pharma company in most cases) and health insurance companies
- Maximum ex-manufacturer prices are set according to reference price basket (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain).
Pricing and reimbursement in Czech Republic 2008 – cont.

- List of 111 reference groups year by year updated by Ministry of Health
- The basic reimbursement level for reference groups is calculated on the basis of cheapest retail price in all European Union countries
- Provisional reimbursement in highly innovative products
- Enter of first generic drug -20% in reimbursement levels
Major change in jurisdiction

Ministry of finance
- Maximal prices

Ministry of health
- Categorisation Committee
- Reimbursement process

State Institute for Drug Control
Reimbursement negotiation

- General HIC
- 9 smaller HIC

- applicant
- Insur. comp

- Reimb. negotiation

- SUKI

- Medical, health economy experts
- Patient’s groups
Overview of reimbursement process in Czech Republic

- 30 days evidence
- SÚKL black-box 31.-50.day
- Preliminary eval. /50.-60./
- SÚKL black-box 60.-75.day
- Decision/ Appeal

90 days
Reference reimbursement system

- 111 reference groups (i.e. statins, SSRI, atypical antipsychotics)
Pricing and reimbursement in CR

Maximum price:
Average price of the product in 8 defined EU countries (Est, Fr, It, Lit, Hu, Port, Gr, Sp)

Basic reimbursement:
The lowest price of the product in ALL EU countries
Bonus up to 30 %
Second price..?

Blue: prices in 8 defined EU countries of the product
Yellow prices of the product in other EU countries
Red: lowest price of all products of reference group with market share 3 % or more
Principles for drug reimbursement

- Efficacy and safety
- Severity of disease
- Cost-effectiveness
- Public interest
- Way of administration, formulation, compliance
- Replaceability with other drug
- Budget impact
- Therapeutic guidelines
Mechanism of reimbursement level setting

- Ex-factory
- VAT
- Margins

The lowest retail price in EU countries

Ex-factory in cheapest EU country

Czech margins and VAT = basis for reimbursement
Major principles of reimbursement in Czech Republic

External reference:
The lowest retail price in 27 EU countries

Internal reference:
111 therapeutic groups of interchangeable drugs

Decrease in reimbursement level
NEW MEDICINAL PRODUCT – REIMBURSEMENT APPLICATION

Can be included to reference group

No bonus

Basic reimbursement

MARKET SHARE

with bonus

Bonus up to 30%

BONIFICATION

No inovation

Individual judgement

No reference group

Highly inovative

Basic reimbursement

No inovation
Pharmacoeconomics is 4th hurdle

- quality
- efficacy
- safety
- Cost-effectiveness
- Budget-impact
Requierment 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
Czech Pharmacoeconomics Society

- Founded in 2005
- More than 150 active members
  (academia, pharma companies, CROs, health insurance comp, etc.)
- Working as a ISPOR chapter
- Organizing conferences (annual Czech-Slovak conference), education (seminars)
- Publishing Pharmacoeconomics Journal
- Developed Guidelines for PE studies in 2006
Pharmacoeconomic studies in Czech republic - evolution

Epidemiology
Cost of illness
Resource use

CEA
BIA
Modelling
Real-world data sources in Czech Republic

- **Patient databases and registries**
  - Very rare (anti-TNF drugs, biologic drugs in oncology)
  - Cost data missing

- **Insurance companies**
  - Not available for analysis, primary purpose is not PE evaluation but budget limits

- **Cross-sectional surveys in clinical practice**
  - Asthma, ankylosing spondylitis, type 2 diabetes

- **Expert panels**
  - Diabetic complications, venous thrombosis
Example - diabetes type 2 cost-of-illness

- Cross-sectional study in 500 type 2 diabetic patients
  - mean annual cost = 25 857 CZK/year
## CODE-2 methodology (international comparison)

<table>
<thead>
<tr>
<th></th>
<th>Hosp.</th>
<th>Outpat</th>
<th>OAD</th>
<th>Other drugs</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Czech Republic</strong></td>
<td>633</td>
<td>70</td>
<td>41</td>
<td>291</td>
<td>1 034</td>
</tr>
<tr>
<td><strong>CODE-2 average</strong></td>
<td>1 333</td>
<td>603</td>
<td>103</td>
<td>476</td>
<td>2 834</td>
</tr>
<tr>
<td><strong>The least expensive (Spain)</strong></td>
<td>417</td>
<td>334</td>
<td>61</td>
<td>494</td>
<td>1 305</td>
</tr>
<tr>
<td><strong>The most expensive (Germany)</strong></td>
<td>2 173</td>
<td>388</td>
<td>119</td>
<td>896</td>
<td>3 576</td>
</tr>
</tbody>
</table>

EUR (2008)
Example - diabetes type 1/2 cost-effectiveness

**Adaptation of international models:**
- **CORE:** insulin analogues vs. Human insulins in type 1........... **dominant strategy**
- **CORE:** exenatide vs. Insulin analogue in type 2........... **464,441 CZK/QALY**
- **DiDACT:** rosiglitazone vs. Glibenclamide in type 2........... **152,811 CZK/QALY**
- **UKPDS:** ........... **dominant strategy**
Cost of refractory severe persistent asthma

Table 4: The average direct costs per patient and year

<table>
<thead>
<tr>
<th>Type of source</th>
<th>Costs/year (CZK)</th>
<th>Costs/year (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>hospitalization at standard bed</td>
<td>11 800</td>
<td>429</td>
</tr>
<tr>
<td>hospitalization at ICU</td>
<td>52 000</td>
<td>1 891</td>
</tr>
<tr>
<td>visits at Pulmonary disease dpt.</td>
<td>7 764</td>
<td>282</td>
</tr>
<tr>
<td>other visits at specialists</td>
<td>2 520</td>
<td>92</td>
</tr>
<tr>
<td>emergency visits</td>
<td>1 620</td>
<td>59</td>
</tr>
<tr>
<td>spa</td>
<td>8 060</td>
<td>293</td>
</tr>
<tr>
<td>Total</td>
<td>83 764</td>
<td>3 046</td>
</tr>
</tbody>
</table>

The cost of refractory persistent asthma in Czech Republic

- Hospitalization cost: 19%
- Out-patient cost: 61%
- Spa: 2%
- Antiasthmatic medication: 12%
- Other medication: 4%
- Productivity loss: 2%
Willingness to pay in Czech Republic?

Cost-Effectiveness Thresholds

Table 2 Theoretical values (in US$/DALY) for cost-effectiveness thresholds in several high-income countries, if thresholds were exclusively based on the “three times Gross Domestic Product (x3 GDP) per capita” approach proposed in the World Health Organization Report 2002 (WHO 2002). Values are based on Purchasing Power Parity-GDP per capita figures for 2000. (Source: The World Factbook 2001, accessed at http://www.bartleby.com/151/a64.html)

<table>
<thead>
<tr>
<th>Country</th>
<th>“x3 GDP threshold” (US$/DALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>108,600</td>
</tr>
<tr>
<td>Japan</td>
<td>74,700</td>
</tr>
<tr>
<td>Canada</td>
<td>74,400</td>
</tr>
<tr>
<td>France</td>
<td>73,200</td>
</tr>
<tr>
<td>Germany</td>
<td>70,200</td>
</tr>
<tr>
<td>Australia</td>
<td>69,600</td>
</tr>
<tr>
<td>UK</td>
<td>68,400</td>
</tr>
<tr>
<td>Italy</td>
<td>66,300</td>
</tr>
<tr>
<td>Spain</td>
<td>54,000</td>
</tr>
<tr>
<td>New Zealand</td>
<td>53,100</td>
</tr>
</tbody>
</table>

DALY, Disability Adjusted Life-Year.

Eichler...ViH 2004

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
# WTP – international comparisons

<table>
<thead>
<tr>
<th>Country</th>
<th>WTP (EUR/QALY)</th>
<th>Equivalent in USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>67,000</td>
<td>(100,000 USD)</td>
</tr>
<tr>
<td>UK (NICE)</td>
<td>38,000</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>35,000</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>56,000</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>80,000</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>cca 30-40,000</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** The Czech Republic values are approximate (cca 30-40,000 EUR/QALY).
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

Singer ME. Pharmacoeconomics May 2008
Health Technology Assessment

- It answers these questions by investigating four main factors:
  - whether the technology works (evidence)
  - for whom (target population)
  - at what cost (efficiency)
  - how it compares with the alternatives (comparative effectiveness)
- Health technology assessment (HTA) is the systematic evaluation of properties, effects or other impacts of health technology.

Currently no formal rules and institutions for HTA in Czech Republic……..only marginally at universities and SIDC
Currently cost-containment dominates cost-effectiveness
Thank you for attention!