Reimbursement system and HTA in Slovakia

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2012
Economy outline Slovakia

- **Minimum wage 2012**
  - 327.20 € / 1 month
  - 1.88 € / 1 hour
- **Average wage 2011 (1.-3. Q)**
  - 765 € / 1 month
- **GDP 2008 per capita**
  - 15 886 €
Life expectancy and GDP and health spending

Source: OECD Health Data 2011; World Bank and national sources for non-OECD countries.

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Healthcare spendings: Incomes and Outcomes Projection Slovakia

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2/3 of patients believe, that they don't get the appropriate health care

Myslim/e si, že v súčasnej dobe vzhľadom na svoje ochorenie dostávam/e všetku potrebnú zdravotnú starostlivosť v dostatočnej kvalite a množstve

1. Ano
2. Nie
The most patients comply about access to health care and health insurance

1. dostupnosti (lieky, ošetrenie, diagnostika…)
2. kvality
3. schvalovania v zdravotnej poistovní
4. iné
5. nemám/e problémy
Reforms and the social impact

Poor households spend a significant share of net income on health

Total Mortality and Oncology spendings
Slovakia 1996-2004

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Stakeholders in Slovak Healthcare

- Healthcare Providers (HPs)
- Health Insurance Companies (HIC)
- Healthcare Surveillance Authority (HCSA)
- Healthcare Industry (Pharma)
- Healthcare Professionals (HPf)
- Ministry of Health (MoH)
- Parliament, Healthcare Committee (PHC)
- Patients, Citizens in general (P)
MoH tools in drug policy

- Committee for drug policy
- Committee for economics and pricing
- Committee for pharmacoeconomics and clinical outcomes
- Rules for including drug to list
- Rules for excluding drug out of list
- Generic substitution
- Degressive margin
- Databasis of reference pricing in EU c.-ies
CEE: Pharma as % of total HC Expenditures
(Source: OECD Health Data and Eurostat)

- still almost doubled, compared to “top” OECD countries (US, CAN, JAP, AUS, NZ)
- similar to “bottom line” OECD countries
Reimbursement and Co-Payment for Drugs (in mil.€, by Health Insurance Companies)

- 3 years of “flat market” in terms of reimbursement
- co-payment has increased by more than 50%
- co-payment ceiling for handicap and elderly population (30 vs. 45 € per quarter) too strict and inefficient (less than 0.2% affected)
Drug costs 2002-2010

- Reimbursed by the health insurances (EUR)
- Patient co-payments (EUR)
- Number of packages

• The patient co-payments represent almost 45%
• The costs of the health insurances almost doubled (48.116%) between 2002-2010
Drug consumption in ATC groups 2001-2008

Prehľad spotreby liekov v SR

DDD/1000/deň

A B C D G H J L M N P R S V

ATC klasifikácia

2001 2002 2003 2004 2005 2006 2007 2008
Timetable of Reimbursement process (until 2011)

- 2012: new categorization online system—any kind of application can be submitted at any time (that means also weekends and public holidays)
Therapeutical and societal evaluation of drugs

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<th>Spoločenská hodnota</th>
<th>Terapeutická hodnota</th>
<th>Veľmi vysoká Počet bodov</th>
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Bez úhrady

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Relevant criteria to set the level of reimbursement

- Mortality with new drug lowered by at least 20%
- Median survival with new drug better at least by 50%, if until now shorter then 2 years
- TTP, TTR with new drug better at least 50%, if until now shorter then 1 year (dead due to illness not considered)
- Less severe illness complications at least by 30%
- Serious improvement in quality of life
- Less serious adverse events at least by 30%
- Less serious drug interactions by at least 30%
QALY threshold according to the law Nr.363/2011 from september 13th 2011

• The drug can be reimbursed if:
  ▫ The ICER/QALY needed for the improvement is less or equal the sum of 24x the medium wage

• The drug can be reimbursed under condition if:
  ▫ The ICER/QALY is in the range of the sum 24x to 35x the medium wage
  ▫ If the drug is considered to treat a illness with prevalence less then 1:100 000

• The drug cant be reimbursed if:
  ▫ The ICER/QALY needed for the improvement is more then the sum of 35x the medium wage
  ▫ This doesnt apply if the drug is considered to treat a illness with prevalence less then 1:100 000
Cost effectiveness threshold

\[ \lambda_2 = 26,500 \text{ €} \]

\[ \lambda_1 = 18,000 \text{ €} \]

I. Dominant segment (neefektívny)

II. 

III. 

IV. 

\( \Delta C \) +

\( \Delta E \)

\( \Delta C \) -

\( \Delta E \) -
Assesments examples - june 2009

Applications in meeting 8.6.2009 – 12.9.2009, positive list from 1.10.2009

RoActemra® (tocilizumab, Roche)
Stelara ® (ustekinumab, Johnson)
NPLATE ® (romiplostin, Amgen)
Synflorix® (vaccine, GSK)
Arixtra ® (fondaparinux, GSK)
IDFlu ® (vaccine, SanofiAventis)
Assesments examples - september 2009


Mabthera® (rituximab, L01XC02, CLL, Roche)
Intelence ® (etravirin, J05AG04, AIDS, Johnson)
Prezista ® (darunavir, J05AE10, AIDS, Johnson)
Synflorix® (vaccine, GSK)
Noliterax ® (perindopril/indapamid, C09BA04, Servier)
Vidaza ® (azacitidin, L01BC07, MDS, Celgene)
Clobex shp ® (clobetasol, D07AB01, psoriáza, PEARs HC)
Assesments - data

ICER/QALY: 3002 €, 12 798 €, 14 160 €, - 2 639 €, - 1 801 €, - 37 988 €, - 60 €

Type: CEA, CEA, CEA, CEA, COI, CUA, CUA

Sensitivity 5%, 10%, 15%, 30%
HTA- SVK vs. EU

- 3 of 27 have not an HTA agency, incl. Slovakia (until 02/2010)
- Exemption are drugs – but this is a narrow system – direct medical costs covered by the insurance
- Direct non medical, indirect, intangible costs. ect. not included
- Services, hospitals, diagnostic procedures, CT, MRI ect. not included
HTA vs. PhE

- HTA currently in Slovakia present but not functional
- PhE established
  - Complex and detailed legislation
  - Incl. threshold ICER/QALY 18 000–26 500€
  - Standard and mandatory use of PhE in reimbursement procedures for DRUGS
  - Medical devices and medical food included but not the same standard as drugs
  - S_HTA for robotic surgery performed 2011
Bodies operating in HTA (in drug policy spec. in PhE) in Slovakia

- Slovak Society for Pharmacoeconomics (2004)
- Slovak Medical University, postgraduate certification degree in pharmacoeconomics (2005)
- Ministry of Health is responsible for formulation of rules and requirements into legislation (1998)
- The Committee for Pharmacoeconomics and Drug Policy was established in September 2005 as an advisory body of the Health Care Board of the Slovak National Parliament (till 2006)
- The Committee for Pharmacoeconomics and Clinical Outcomes as advisory group for MOH (2007)
- SLOVAHTA – Slovak Agency for Health Technology Assessment (02/2010)