

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

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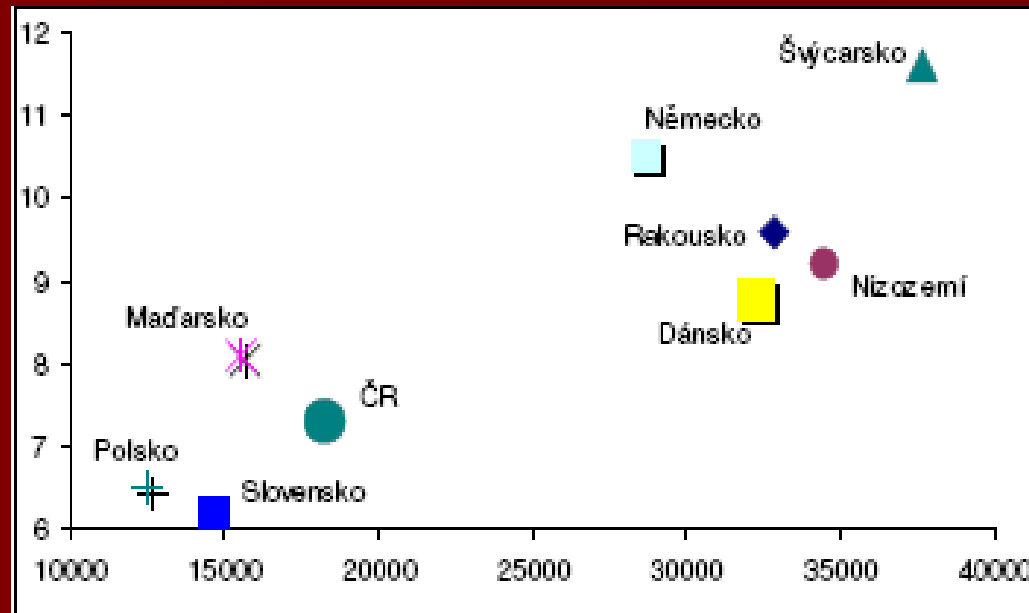
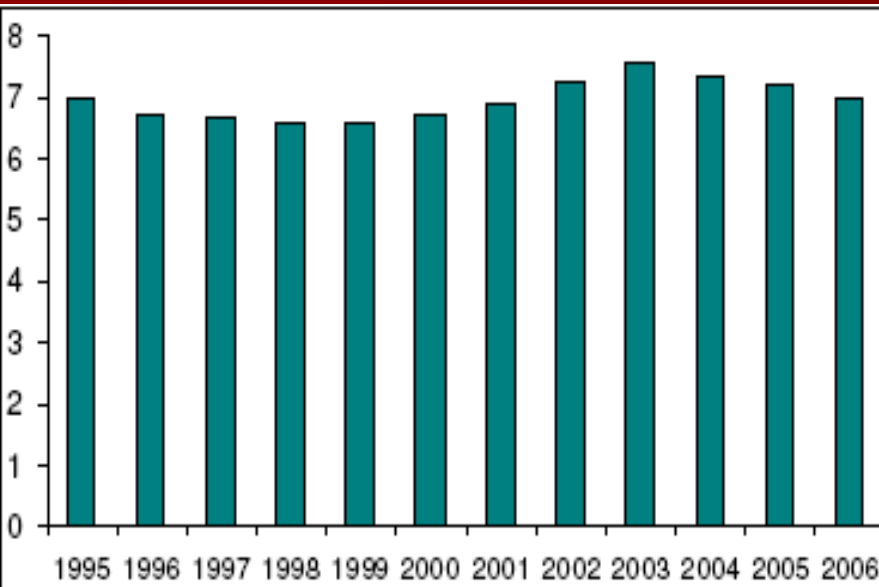
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# Outline

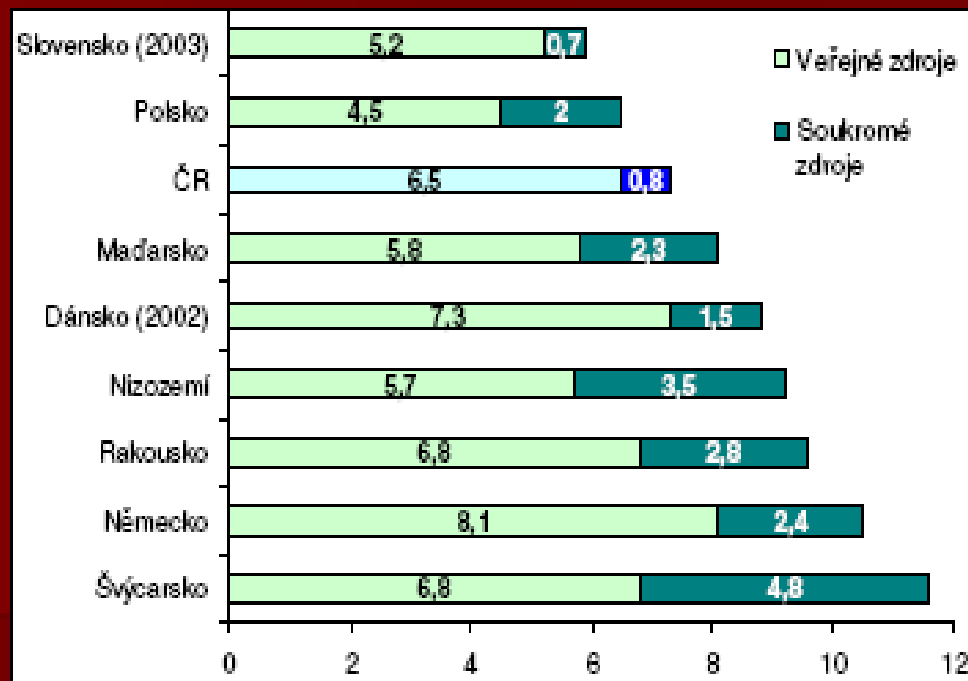
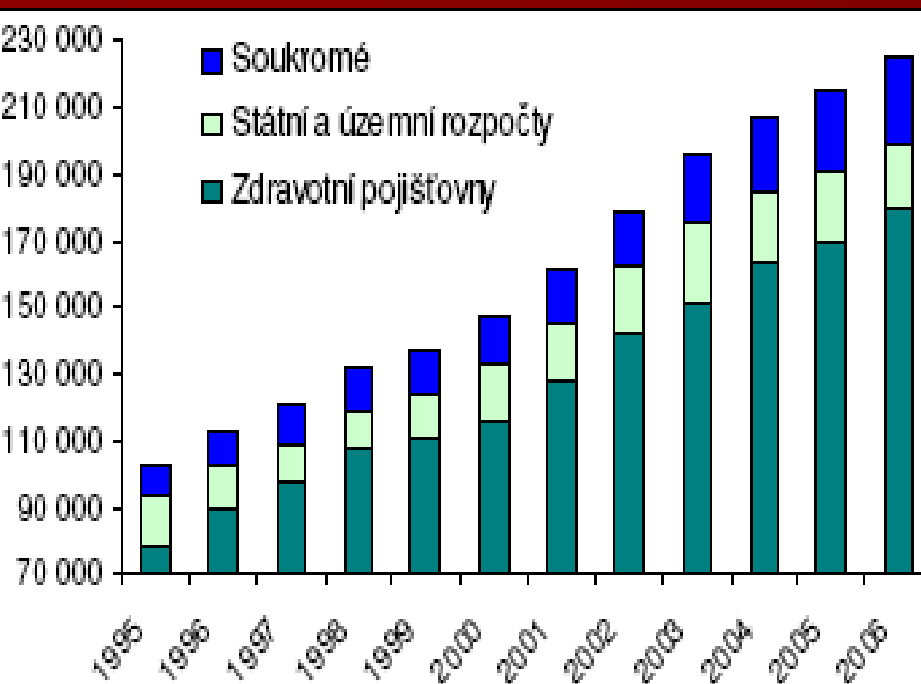
- Basic facts about healthcare in Czech Republic
- Pricing and reimbursement rules
- Legislation change 2008
- Pharmacoeconomics
- HTA

# Health Care expenditure/GDP



- 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 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

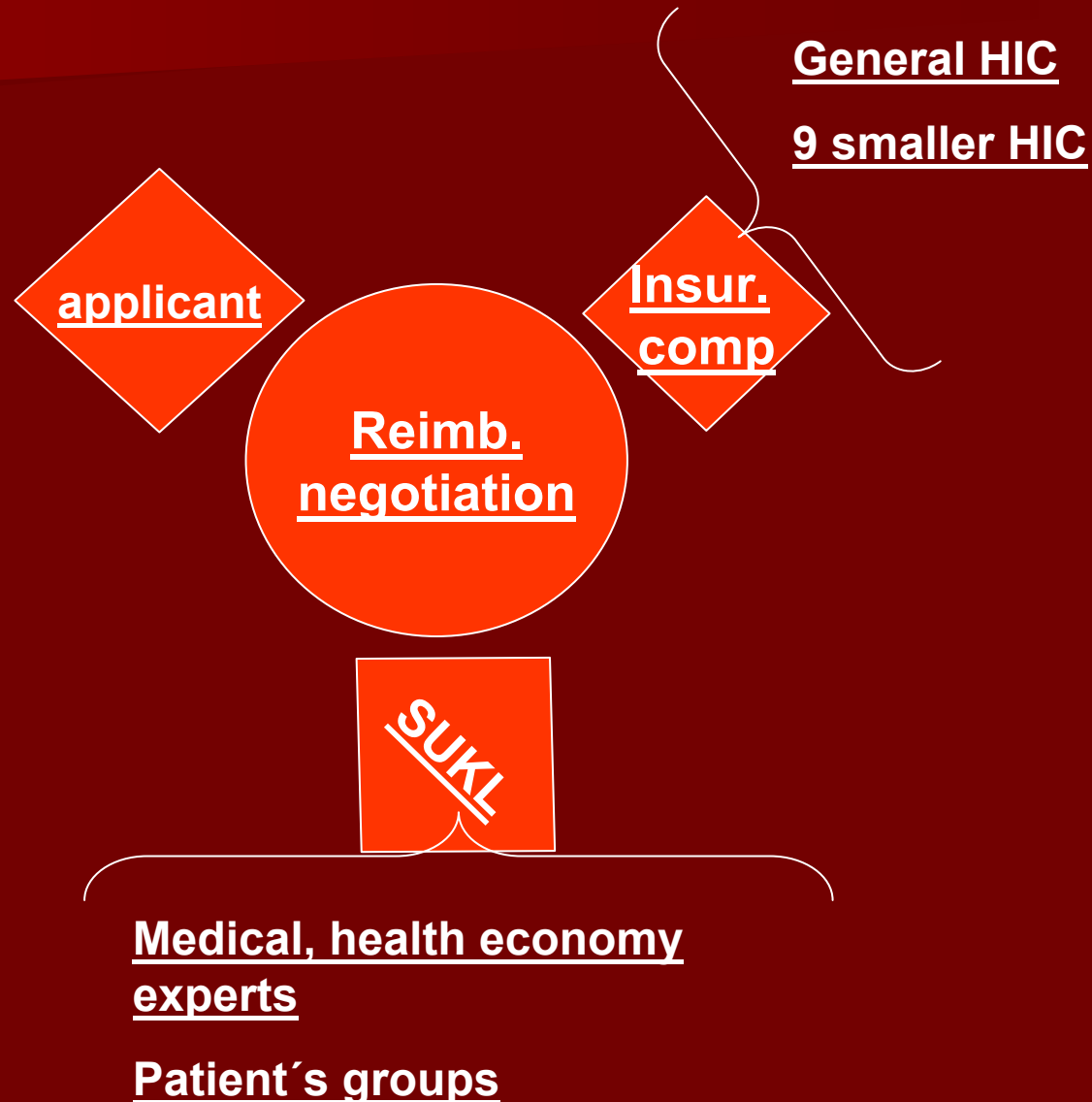
-Categorisation  
Committee

- Reimbursement  
proces

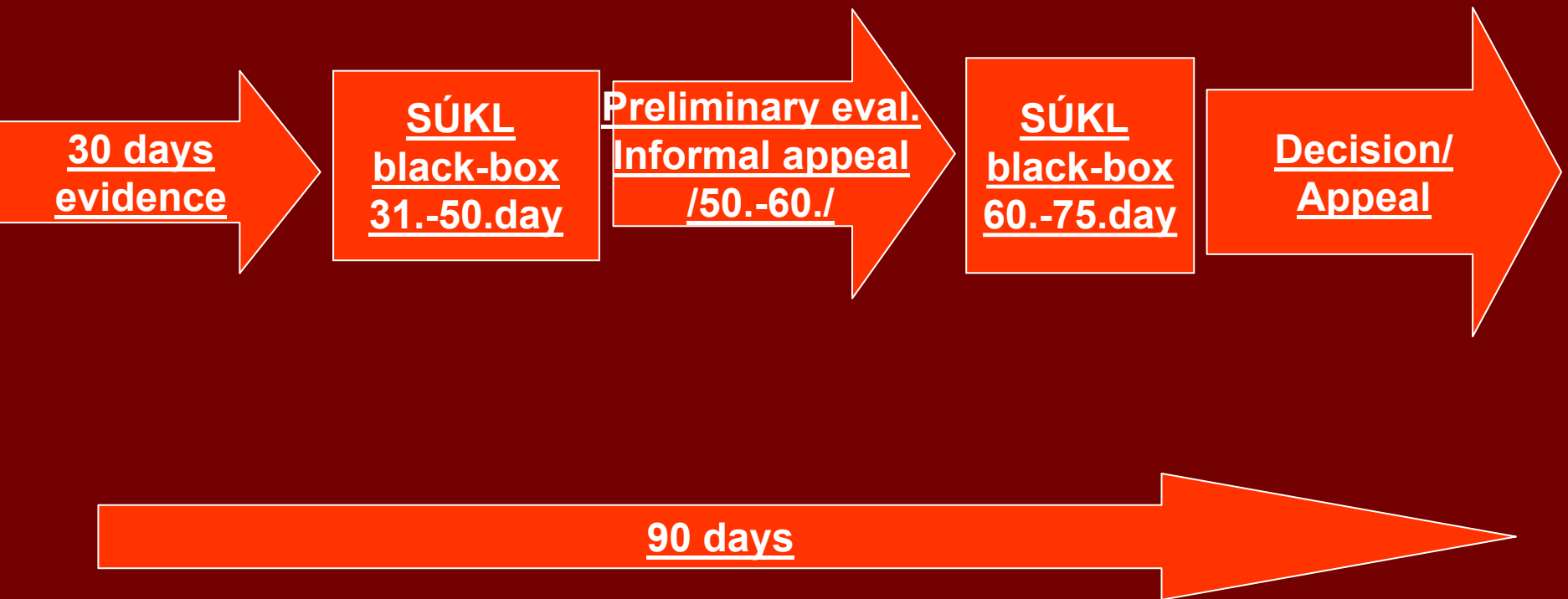
## State Institute for Drug Control

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graph LR; A["Ministry of finance  
- Maximal prices"] --> C["State Institute for  
Drug Control"]; B["Ministry of health  
-Categorisation  
Committee  
- Reimbursement  
proces"] --> C;
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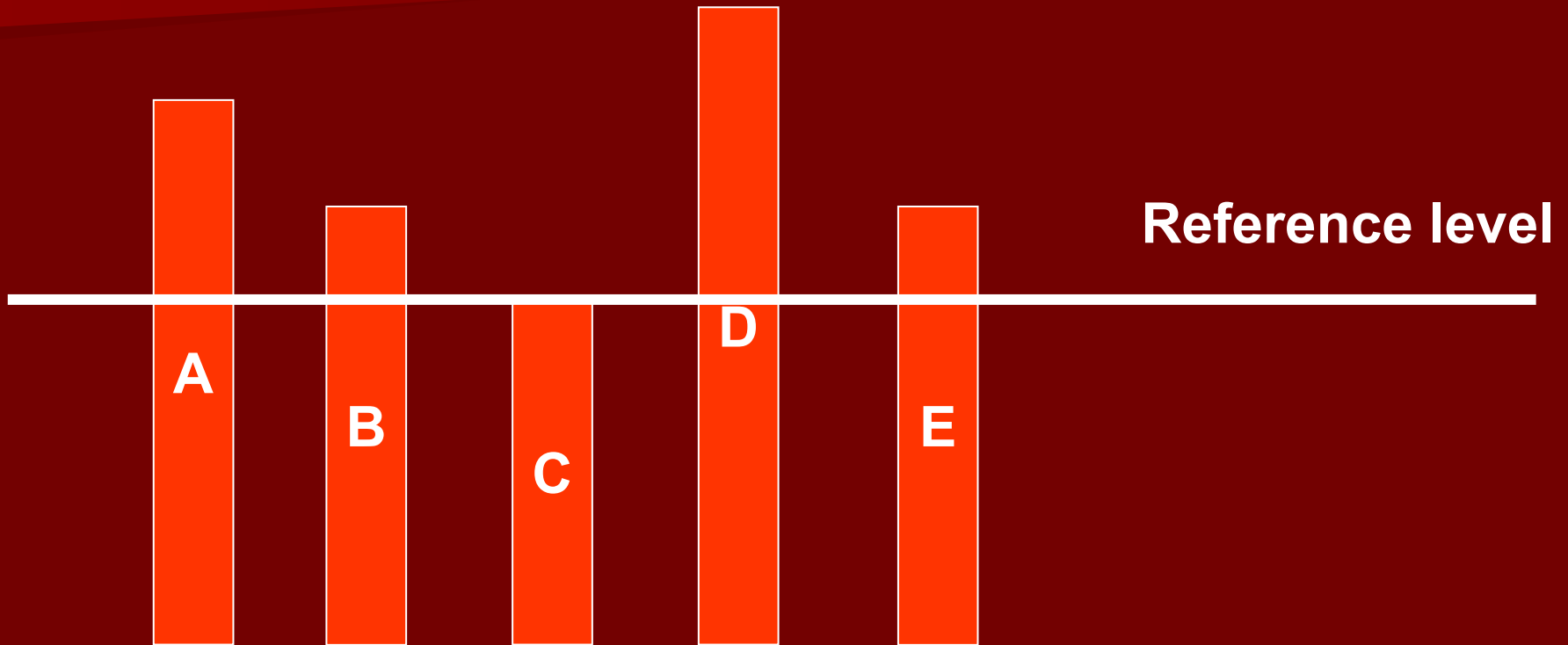
# Reimbursement negotiation



# Overview of reimbursement process in Czech Republic



# Reference reimbursement system

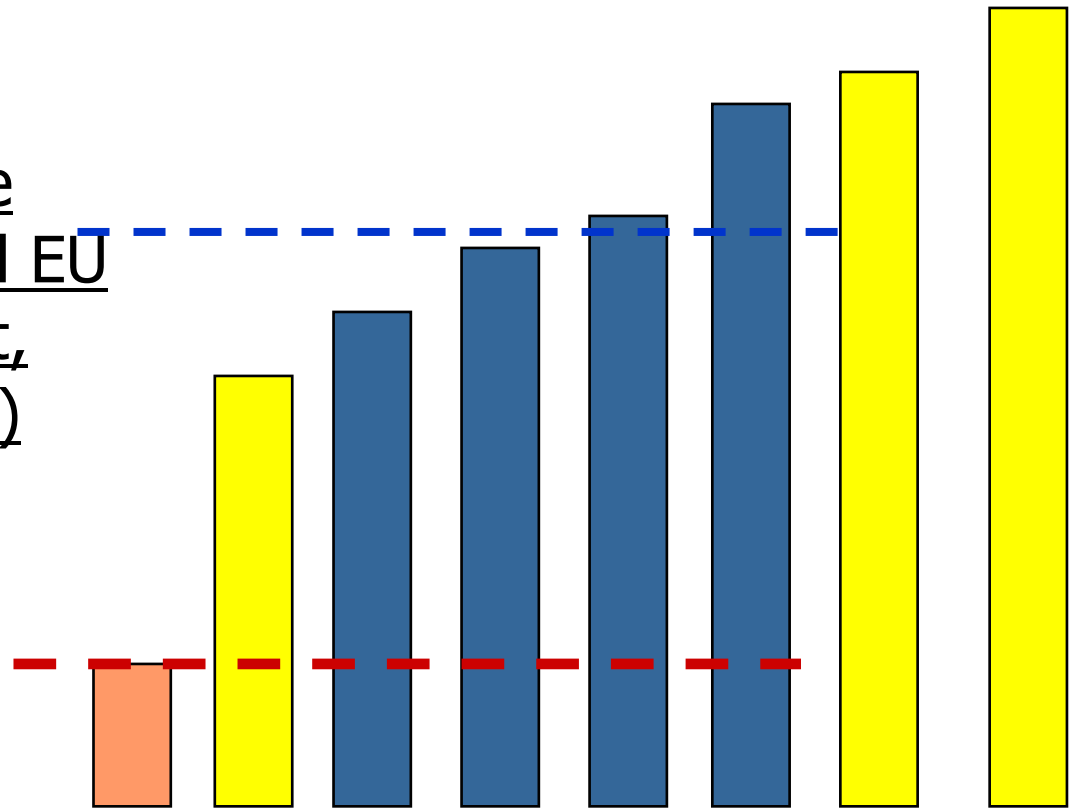


- 111 reference groups (i.e. statins, SSRI, atypical antipsychotics)

# 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

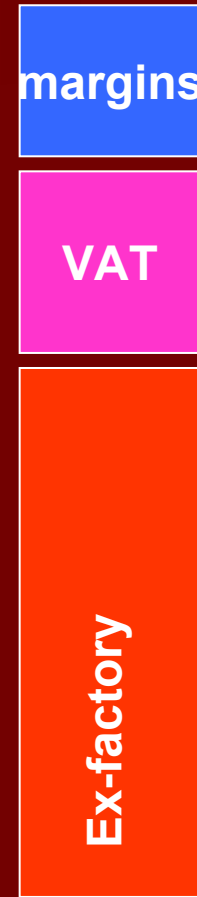
# Mechanism of reimbursement level setting



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 reference group**

MARKET SHARE

BONIFICATI ON

**No bonus**

**with bonus**

**No inovation**

**Highly inovative**

**Basic reim-bursement**

**Bonus up to 30 %**

**Individual judgement**

# Pharmacoeconomics is 4th hurdle



**quality**



**efficacy**



**safety**



**Cost-effectiveness**



**Budget-impact**

# Requierement 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 ?

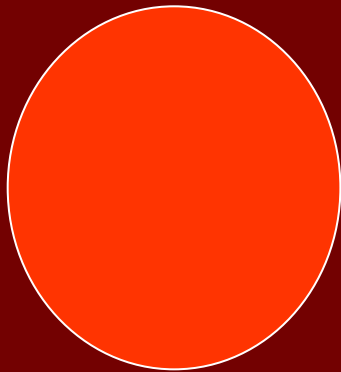
## ■ Budget-impact analysis

- Basis for PE evaluation
- No available methodology
- Shortage of relevant epidemiology and cost sources

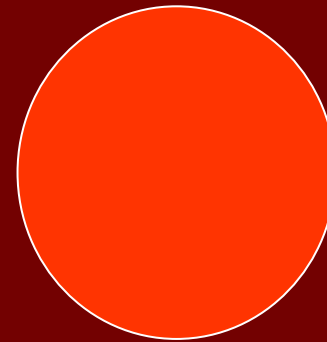
# Czech Pharmacoeconomics Society

- 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**

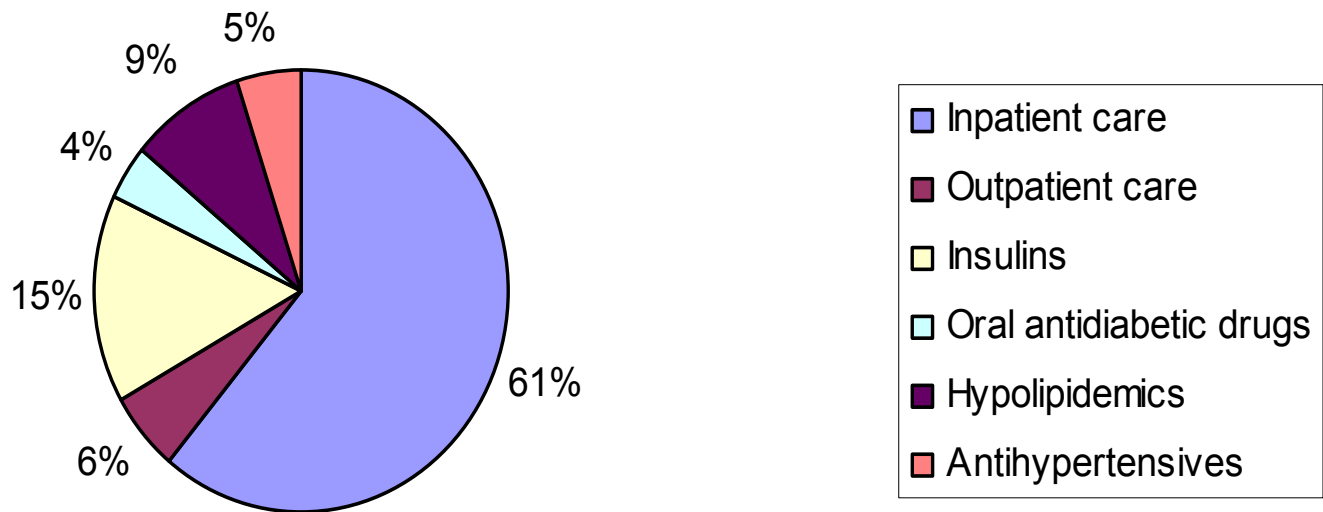


**CEA**  
**BIA**  
**Modelling**

# 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)

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

EUR (2008)

# Example - diabetes type 1/2 cost-effectiveness

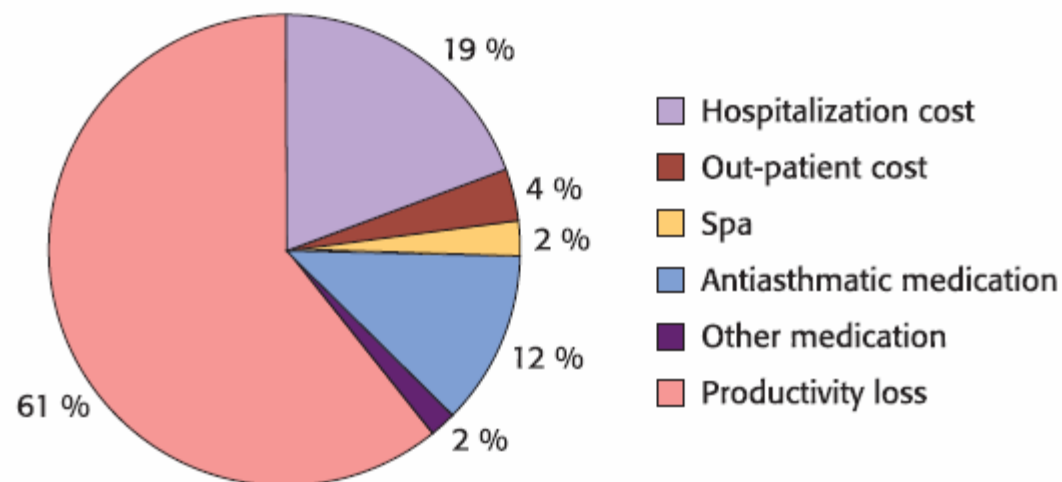
- **Adaptation of international models:**
  - **CORE:** insulin analogues vs. Human insulins in type 1.....**dominant strategy**
  - **CORE:** exenatide vs. Insulin analogue in type 2.....**464,441 CZK/QALY**
  - **DiDACT:** rosiglitazon vs. Glibenclamide in type 2.....**152,811 CZK/QALY**
  - **UKPDS:**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

# *Cost of refractory severe persistent asthma*

**Table 4:** The average direct costs per patient and year

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

The cost of refractory persistent asthma in Czech Republic



# 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 ( $\times 3$  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>)

Country	" $\times 3$ GDP threshold" (US\$/DALY)
USA	108,600
Japan	74,700
Canada	74,400
France	73,200
Germany	70,200
Australia	69,600
UK	68,400
Italy	66,300
Spain	54,000
New Zealand	53,100

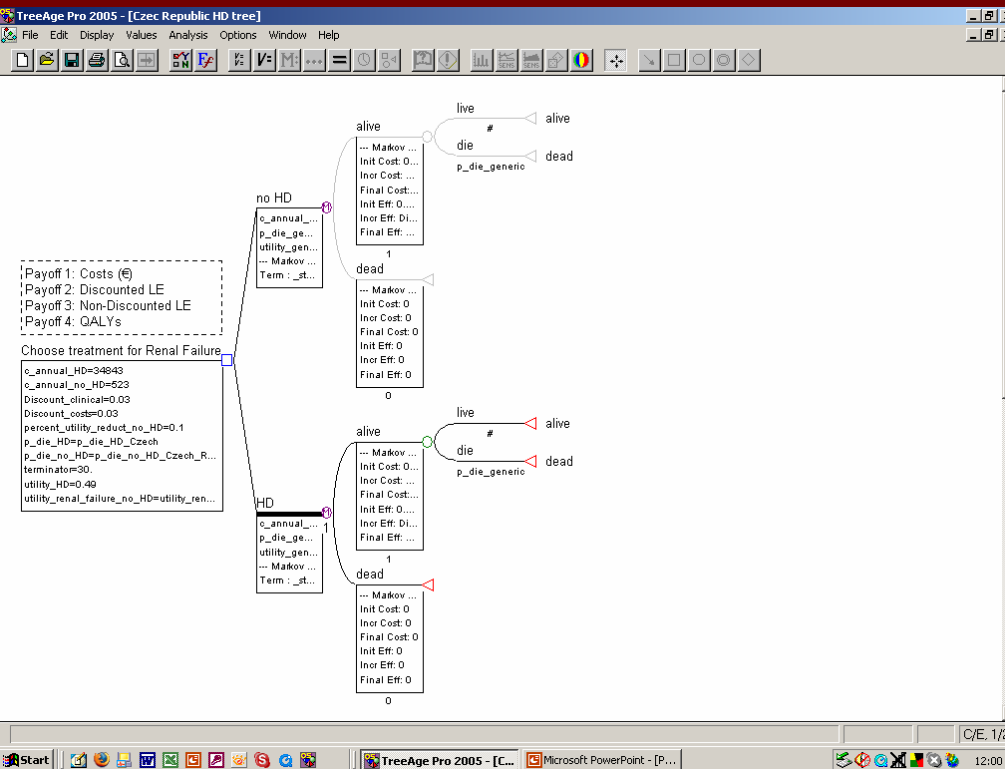
DALY, Disability-Adjusted Life-Year.

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

USA..... 67.000 EUR/QALY (100.000 USD)

UK (NICE)..... 38.000 EUR /QALY

Austrálie..... 35.000 EUR/QALY

Kanada..... 56.000 EUR/QALY

Holandsko.....80.000 EUR/QALY

Švédsko.....70.000 EUR/QALY

**?Czech Republic .... cca 30-40.000 EUR/QALY**

# Three main components for using pharmacoeconomics in decision making process

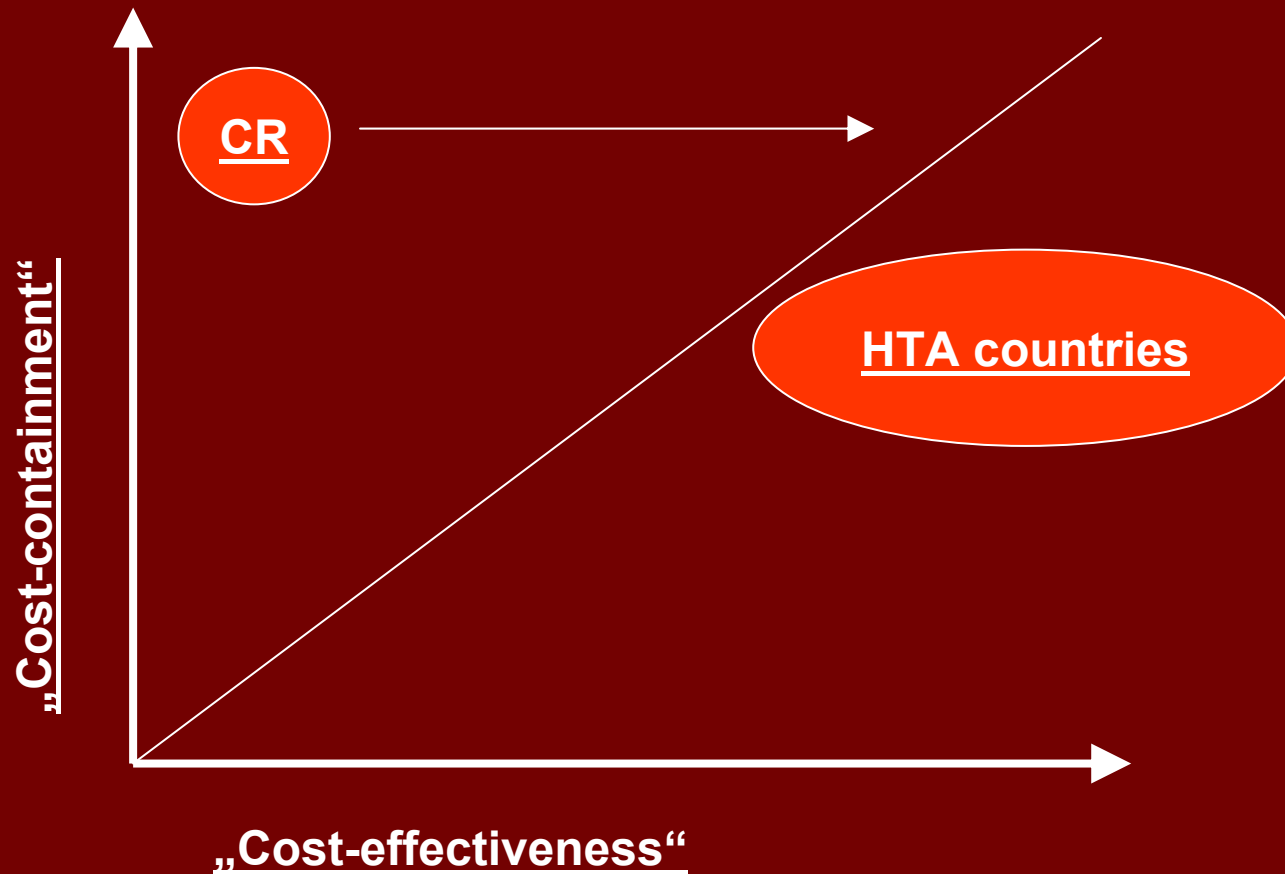
- Individuals capable of conducting the analyses
- A receptive audience among decision- and policy-makers
- A body of methodology appropriate to the task

# 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 !**