
Reimbursement of the drugs and process of assessment

Activities and approaches by Ministry of Health care, Slovakia

Bratislava, November 16th, 2007

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Medicine Control Agency**

Challenges in drug policy

- **Availability for safe, efficient and qualitative medicines**
- **Ensurance for the right use of medicines for treatment of disease**
- **Gaining the therapeutic value for paid-up costs**



International cooperation in realisation of drug policy in EU a OECD member states

- **Heterogenicity of health systems**
 - different levels
 - different solutions
- **Problems are the same**
 - Increasing costs
 - Limited sources
 - Need for evaluation
- **Beginning of dialogues at international cooperation basis**



International cooperation in heterogeneity of health systems

Problems same:

- **increased costs,**
- **limited sources,**
- **need for evaluation**



Drug Policy and EU

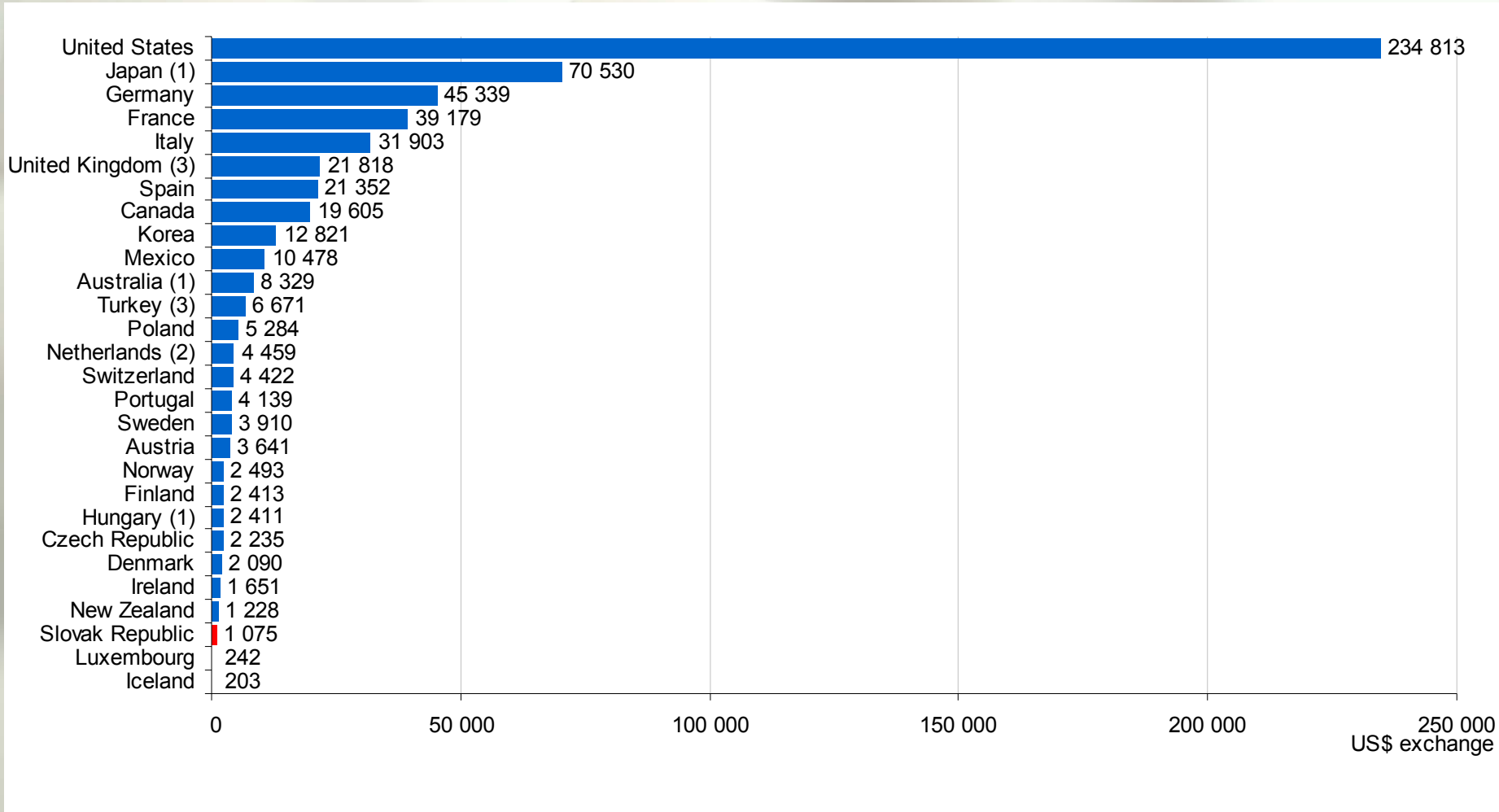
- **EU regulatory bodies and legislation (Review 2003)**
 - National medicinal agencies and their mutual cooperation
 - EU Commission and EMEA
- **National responsibility at pricing and reimbursement from public health insurance**
 - Transparency directive
 - DG Health High Level committee,
 - Group G 10 profit and innovation
 - EU Pharmaceutical Forum 2006 – informations exchange about pricing

Processes in EU countries – Transparency Directive

- Pricing process
- Decisions based on arguments
- Transparency (decisions available for stakeholders)
- Appeal procedure (if necessary)
- Time limits for evaluation and taking decisions



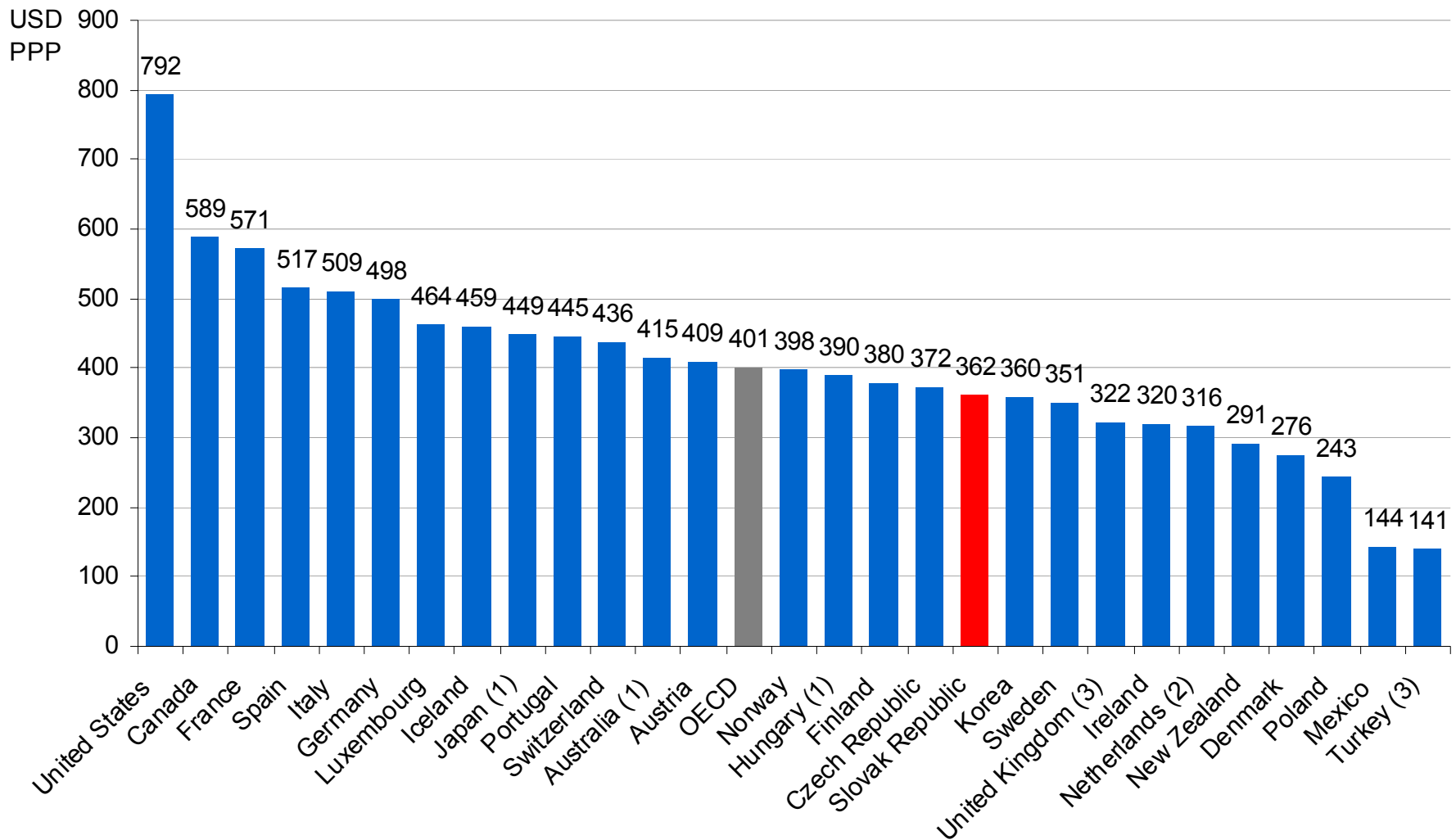
Total expenditures on pharmaceuticals, million USD, 2005



(1) 2004; (2) 2003; (3) 2005 sales

Source OECD HEALTH DATA 2007, July 07

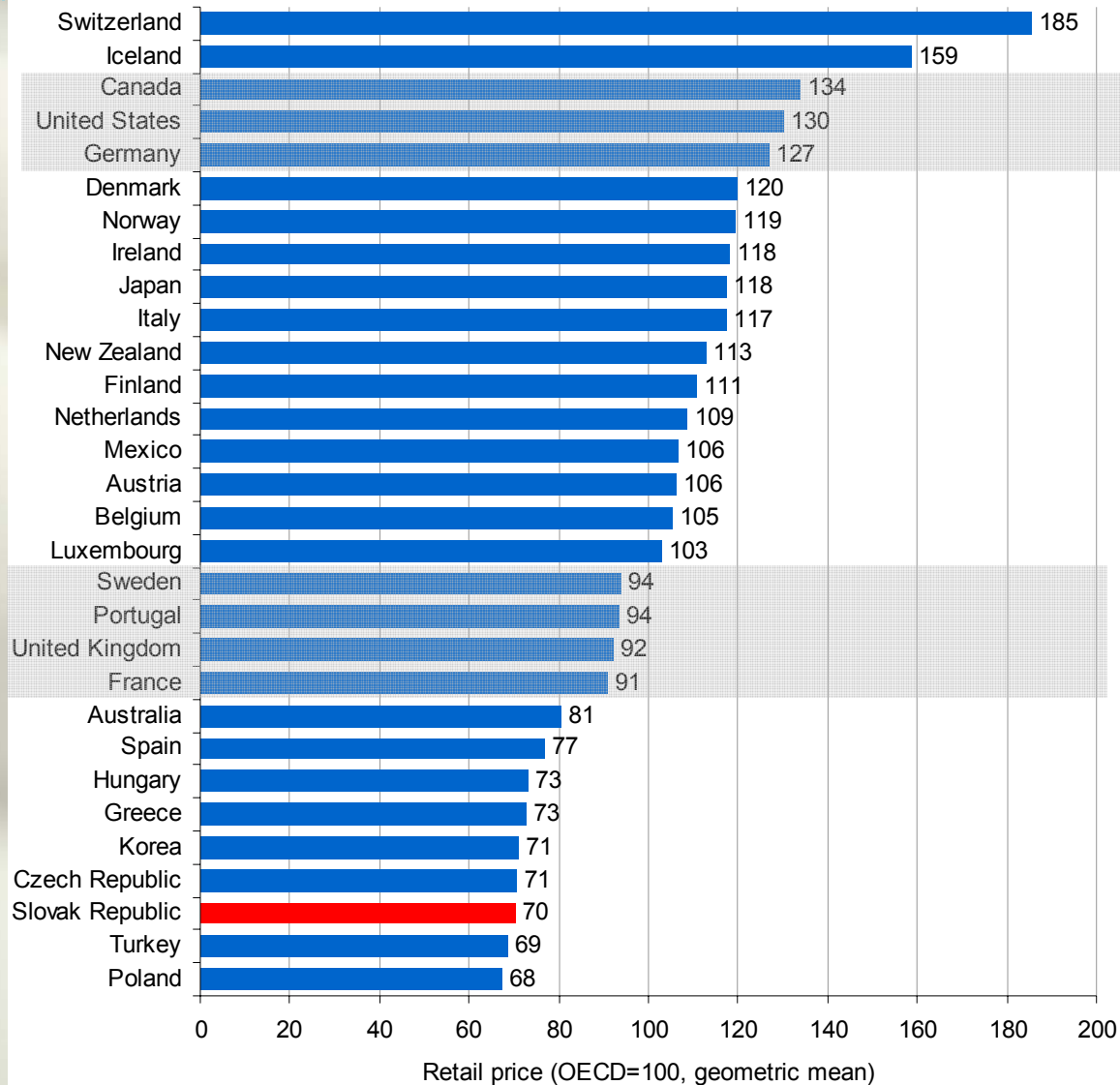
Per capita spending on pharmaceuticals, USD PPP, 2005



(1) 2004; (2) 2003; (3) 2005 pharmaceutical sales per capita

Source OECD HEALTH DATA 2007, July 07

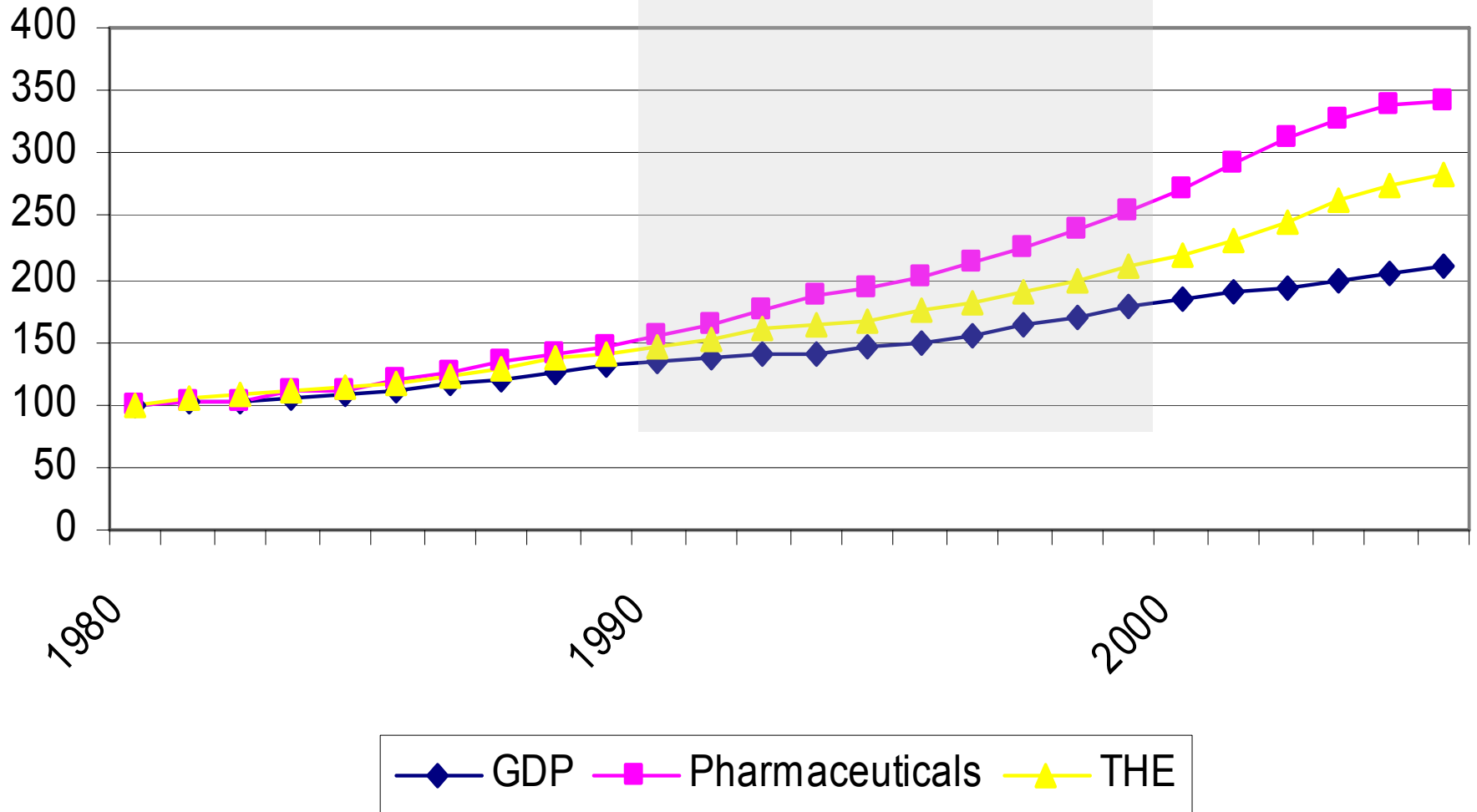
Relative, retail pharmaceutical price levels PPP, 2005



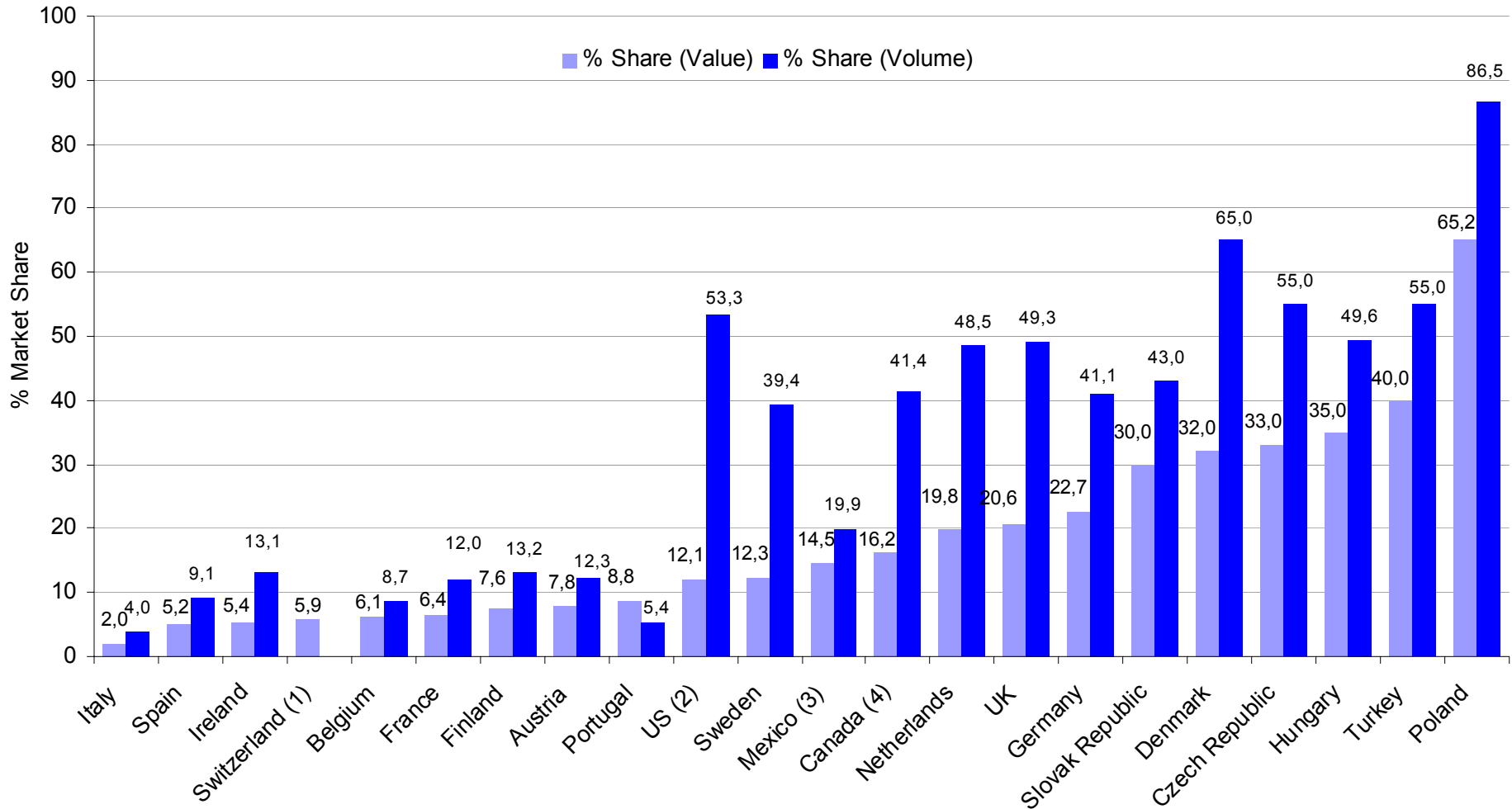
Note: Prices were converted to a common currency using the 2005 average exchange rate

Source: Eurostat-OECD Purchasing Power Parity Programme, 2007

Trend growth in pharmaceutical and total health expenditure, and GDP, 1980 – 2005 (1980 = 100)



Market share of generics in Europe in terms of value and volume, 2004



Main tasks for drug policy in SK (1)

- **Effective utilization for available public sources**
- **Rational allocation for drug reimbursement from public funds**
- **Reduction of induced prescription of medicines**
- **Involvement of pharmacists in the process of economic drug use (generic substitution)**
- **Information campaign for patients about available comparable drugs, prices and co-payments**

1. Registration

EMA / State Institute for Drug Control (SIDC)
 -Quality, safety, efficacy (Directive 2006/27/EC)
 -Act on pharmaceuticals and medical devices

2. Classification

State Institute for Drug Controls (SIDC)
 Categories: POM, POM only prescribes by certain specialists, and OTC

3. Pricing

Ministry of Health
 - Determination of the pharmacy retail price
 - Criteria: international price comparison for imported pharmaceuticals, production costs for locally produced pharmaceuticals

Free pricing

4. Reimbursement ↓

Ministry of Health, advised by the Categorisation Committee
 - Decision on reimbursement price
 - Criteria: therapeutic social benefit, internal price comparison

No reimbursement

5. Distribution

Patients

Evidence: Drug policy is satisfied?

- **Flat co-payment for drug prescription**
- **Introduction of fixed ratio after categorization (Since June 2003). The ratio between the reimbursement (paid by the HIC) and co-payment (paid by the patient) must remain the same.**
- **Personal changes in the structure of categorization committee balancing payers and physicians supervising by policy makers**
- **Changes in margins for wholesalers and pharmacies for drugs more expensive than SKK 20 000 per month**
- **Reasonable frequency of categorization and reimbursement process – takes place four times a year.**

Reimbursement committee

Scientific WG

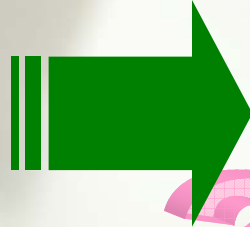
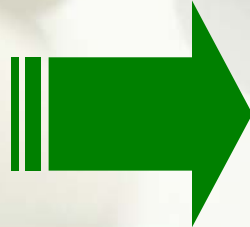
22 subgroups of medical experts for different drug groups (CVS, GIT,...)

Economic WG

Price comparison,
Budget impact,
direct costs

Sickness funds

5



3

Medical experts



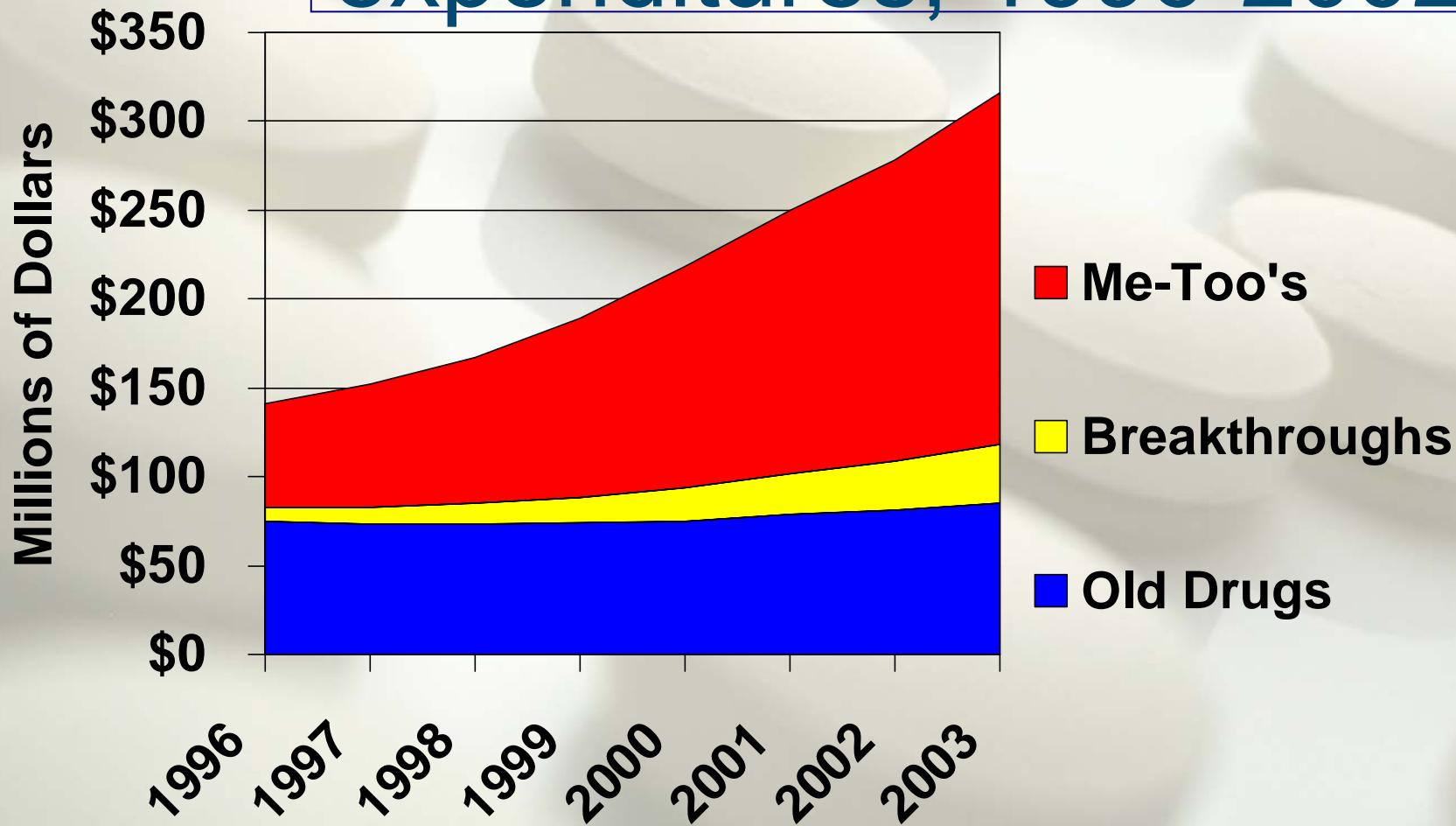
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Ministry of Health

Status of medicines

- Medicines with „old“ active substance already in the system
 - original alone
 - original + generic in cluster
 - „me too“ drug alone
 - „me too“ drug + generic in the cluster
- Medicines with active substance already in the system, but with new indication, eventually new application form, route of administration, strength of active substance
- Medicines with new active substance, not used in Slovakia – not classified in reimbursement
- Medicine with new active substance, not used in EU – not classified in reimbursement (oncology field)

3 types of drug in BC expenditures, 1996-2002



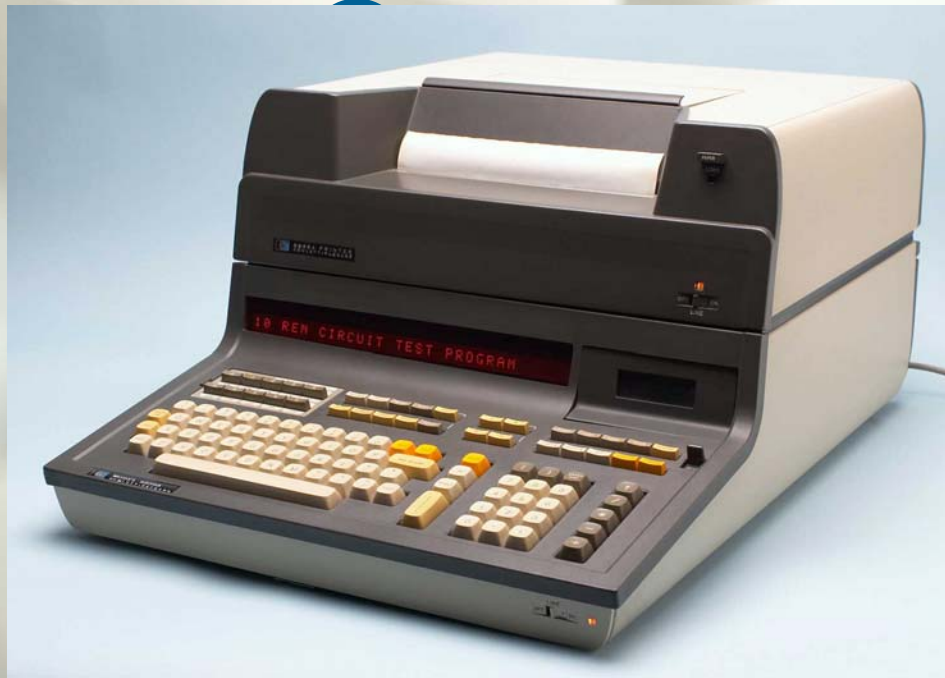
Basis for evaluation

- Applications with administrative and scientific informations in specific format –
- evaluation in several experts groups
- Basis for therapeutic and social evaluation
 - a. Information in application form,
 - b. reviewing by expert working group
- Overview about ex-factory prices, end-prices in comparing with medicines in cluster, with similar active substance and in comparing with all medicines within ATC groups – data expressed on price per standard therapeutic dose of drug
- Data for medicine consumption within the group, following the basic parameters :
 - a. prices of medicines , prices for STD, reimbursement for STD, patients co-payment, which can be compared within active substance and within therapeutic group
 - b. Evolution of consumption expressed in value and packs for respective medicine and for ATC group by quarter for last 12 months (MAT)



Therapeutic evaluation of medicine in Slovakia

- **New medicine, „me too“ drug or generic (what does it mean innovation ?)**
- **Effect of medicine within reference therapeutic group of medicines (comparable effect or even better ...)**
- **Safety of medicine within reference therapeutical group of medicines (proven better or worse safety)**
- **Way of disease affection (symptomatic, causal, prophylactic, palliative, subsidiary)**



HP-9830

Professional Computer, 1972

Speed: 0.003GHz Memory:
0.00003GB

Cost: \$28,500 (2005 buying power)

1,000 times more powerful
1/45 the cost



HP Dx2000 Microtower

Professional Computer, 2004

Speed: 3.0 GHz Memory: 40 GB

Cost: \$630 (2005 buying power)

Social evaluation of medicines in Slovakia

- **Social relevance of disease – acute affection, life threatening, influence on life length or life quality ...**
- **Risk of missuse : missuse among patients, but also by doctors or manufacturers – induced prescription**
- **Influence on total costs of health insurance companies**



Price control – „auction“ of drugs

- External reference pricing – comparing of Ex-factory prices in reference countries
- Price proposal – final price of medicine at pharmacy – administration in two steps – published of website – transparency - control
- Comparison of price per standard dose
 - a. within group with same active substance ATC on level 5 (generic substitution)
 - b. between groups with similar active substance (therapeutic equivalent)
- Setting the reimbursement for active substance based on the cheapest available drug prices in the group with similar active substance – ATC on level 5
more expensive drug – more co-payment which is fixed (phantom drugs, shifts on drugs on CNS,...)
- Comparison of price and reimbursement difference by reviewing within therapeutic equivalent
(Similar active substances and their benefit to therapy – evaluating of therapeutic benefit and economic feasibility)

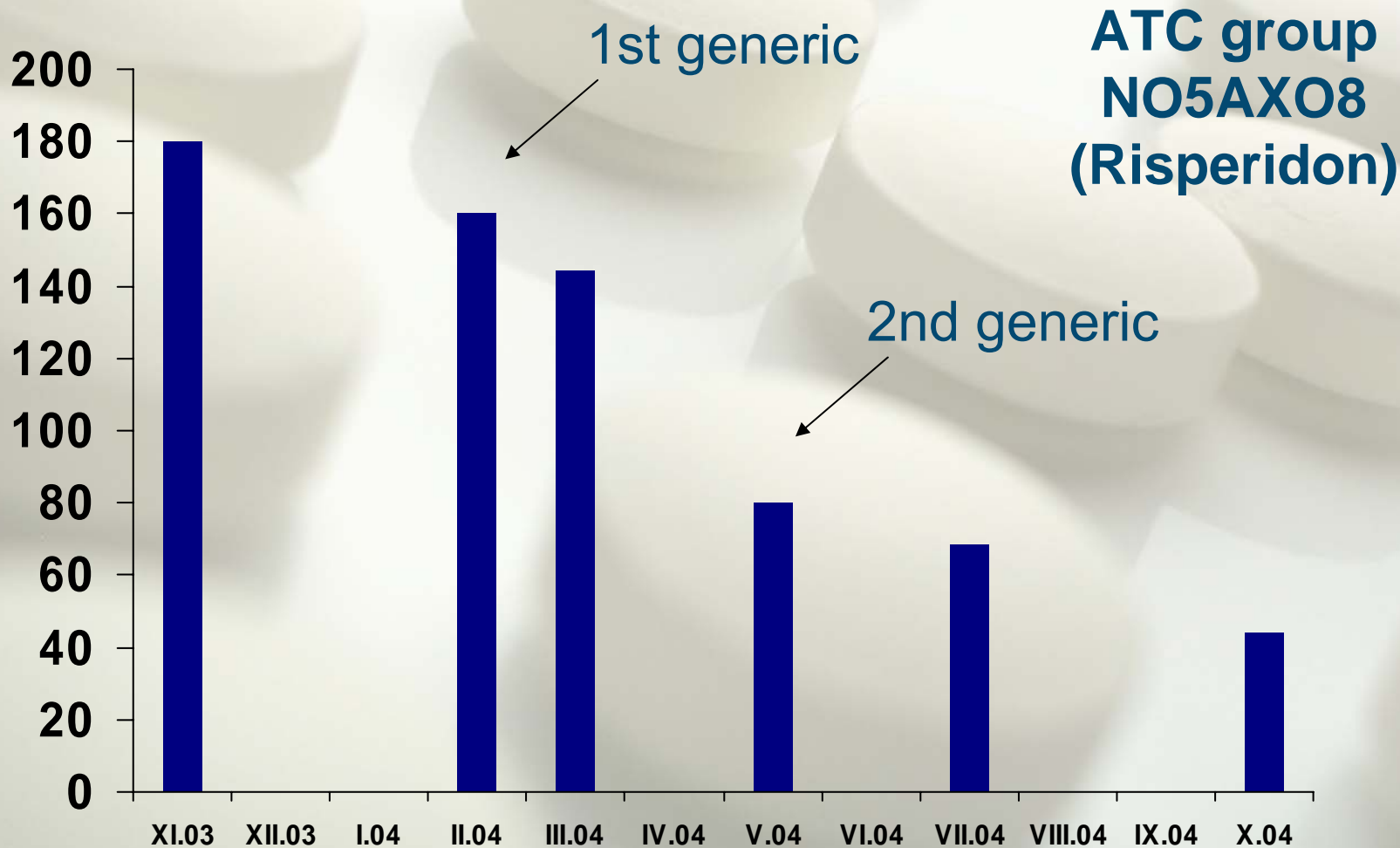
Introducing „Fast track“

If pharmaceutical company decreases the price of a product by 10 % or more compared to the cheapest drug in cluster, than is processed on the “fast track”.

“Fast track” means no evaluation in reimbursement committee is required.

The reimbursement level in cluster is automatically decreased with 25% bonus (compared to fixed ratio). The 25% bonus means that the fixed ratio is changing in favor of the patient (lower reimbursement).

„Fast track“ effect in practice



Detailing of committee work at medicine assessment

- Positioning of the drug in the progress of disease therapy ?
- What is the current status of treatment and what will be the consequence ?
- How will the use of the drug influence the standard therapeutic procedure?
- What is the posology of the drug ?
- Target group of the patients ?
- Is there a specific specialisation of doctors for prescribing the drug ?
- How can we define if the medicine „really works“ , especially at financially demanding medicine ?
- What is the real estimate of costs by using medicine - „pesimistic“ and „optimistic“ option?
- What is the difference in expenses for medicine per month in comparing with available therapy up to now ?
- How can we (especially in the case of high price medicine) define for patients group whose should get the medicine in preference ?
- Is it possible, that the health insurance companies could consistently control compliance of restriction indicators ?

Example of work for categorisation of ATC

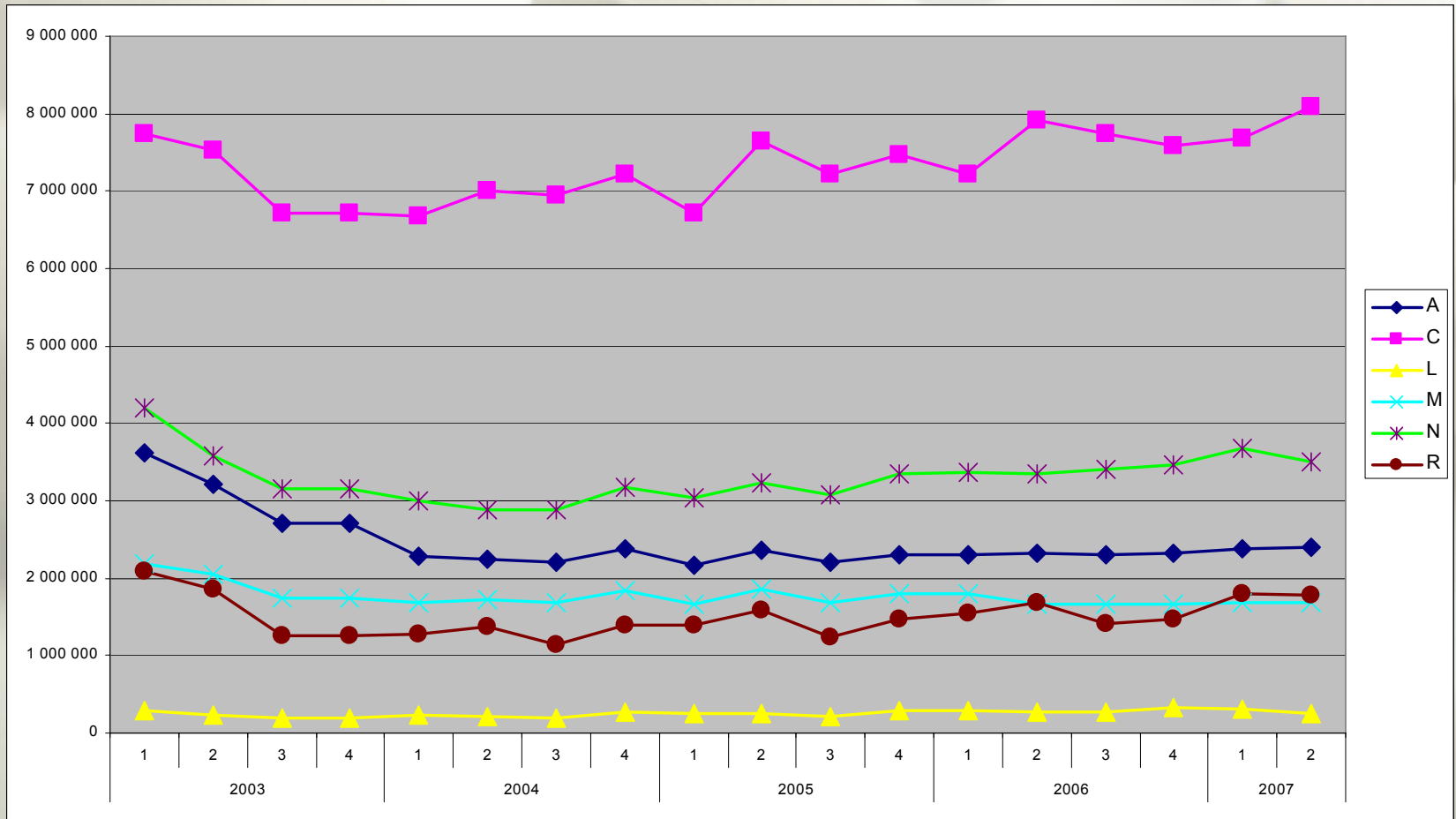
C 08CA01 active substance Amlodipin p.o.

Kód	Nazov	Doplňok	DDD JD		Aktuálne platné					reálne		Návrh kategorizácie					počet	v 1000 skk					
			CRP	Štat	MFCN	UZP	s.u	DOP	MFCN2	Cena	DOP	Konečná c.	UZP	s.u	DOP	MFCN2		DDD	2002	2002	2002	2003	
																405 025	61 338	275 965	218 717				
1	C08CA01	Amlodipín	p.o.	5 mg						10,5	405 024,83	61 338,25	275 964,9	218 716,96	7,5	36795	106 849	106 270	122 377	130 868			
2	13556	AGEN 5	tbl 30x5 mg	LEX CZ	556,7	40,8	S	515,9	18,56	323,39	8,5	240,	225,	S	15,	8,	30		5 385	8 447			
2	13558	AGEN 10	tbl 30x10 mg	LEX CZ	903,3	630,	S	273,3	15,06	643,87	13,91	480,	450,	S	30,	8,	60		1 515	3 025			
2	33295	APRESA 5	tbl 30x5 mg	SLO SK	324,8	315,	S	9,8	10,83	323,37	8,62	270,	225,	S	45,	9,	30		3 630	8 118			
2	33299	APRESA 10	tbl 30x10 mg	SLO SK	649,6	630,	S	19,6	10,83	644,99	15,39	540,	450,	S	90,	9,	60		1 530	3 834			
2	33296	APRESA 5	tbl 60x5 mg	SLO SK	637,2	630,	S	7,2	10,62	636,02	6,41	540,	450,	S	90,	9,	60		231	836			
2	33300	APRESA 10	tbl 60x10 mg	SLO SK	1 274,5	1 260,	S	14,5	10,62	1 263,29	10,85	1 080,	900,	S	180,	9,	120		101	339			
1	56459	AMLOPIN 5 MG	tbl 30x5 mg	LEK SLO	362,	315,	S	47,	12,07	318,09	4,25	314,9	225,	S	89,9	10,5	30		768	1 673			
1	33788	CARDILOPIN 5MG	tbl 30x5mg	EGI H	315,	,		315,	10,5	,	,	315,	225,	S	90,	10,5	30						
1	33208	NORMODIPINE 5 mg	tbl 30x5 mg	GED H	501,	315,	S	186,	16,7	316,64	1,74	315,	225,	S	90,	10,5	30		2 421	4 181			
1	56298	AMLOPIN 10 mg	tbl 30x10 mg	LEK SLO	691,	630,	S	61,	11,52	635,12	7,74	630,	450,	S	180,	10,5	60		285	698			
1	33789	CARDILOPIN 10MG	tbl 30x10mg	EGI H	630,	,		630,	10,5	,	,	630,	450,	S	180,	10,5	60						
1	33207	NORMODIPINE 10 mg	tbl 30x10 mg	GED H	812,9	630,	S	182,9	13,55	632,41	2,62	630,	450,	S	180,	10,5	60		1 436	2 668			
2	62568	NORVASC	tbl 30x10 mg	PFI B	1 161,7	630,	S	531,7	19,36	704,86	74,96	760,	450,	S	310,	12,67	60	35 660	35 061	34 410	32 916		
2	62569	NORVASC	tbl 30x5 mg	PFI B	725,7	315,	S	410,7	24,19	353,42	38,46	445,	225,	S	220,	14,83	30	71 189	71 209	70 651	64 129		
	13557	AGEN 10	tbl 10x10 mg	LEX CZ	301,1	210,	S	91,1	15,06	210,02	,02	301,1	150,	S	151,1	15,06	20		4	1			
	13555	AGEN 5	tbl 10x5 mg	LEX CZ	185,6	105,	S	80,6	18,56	113,57	8,57	185,6	75,	S	110,6	18,56	10		9	3			

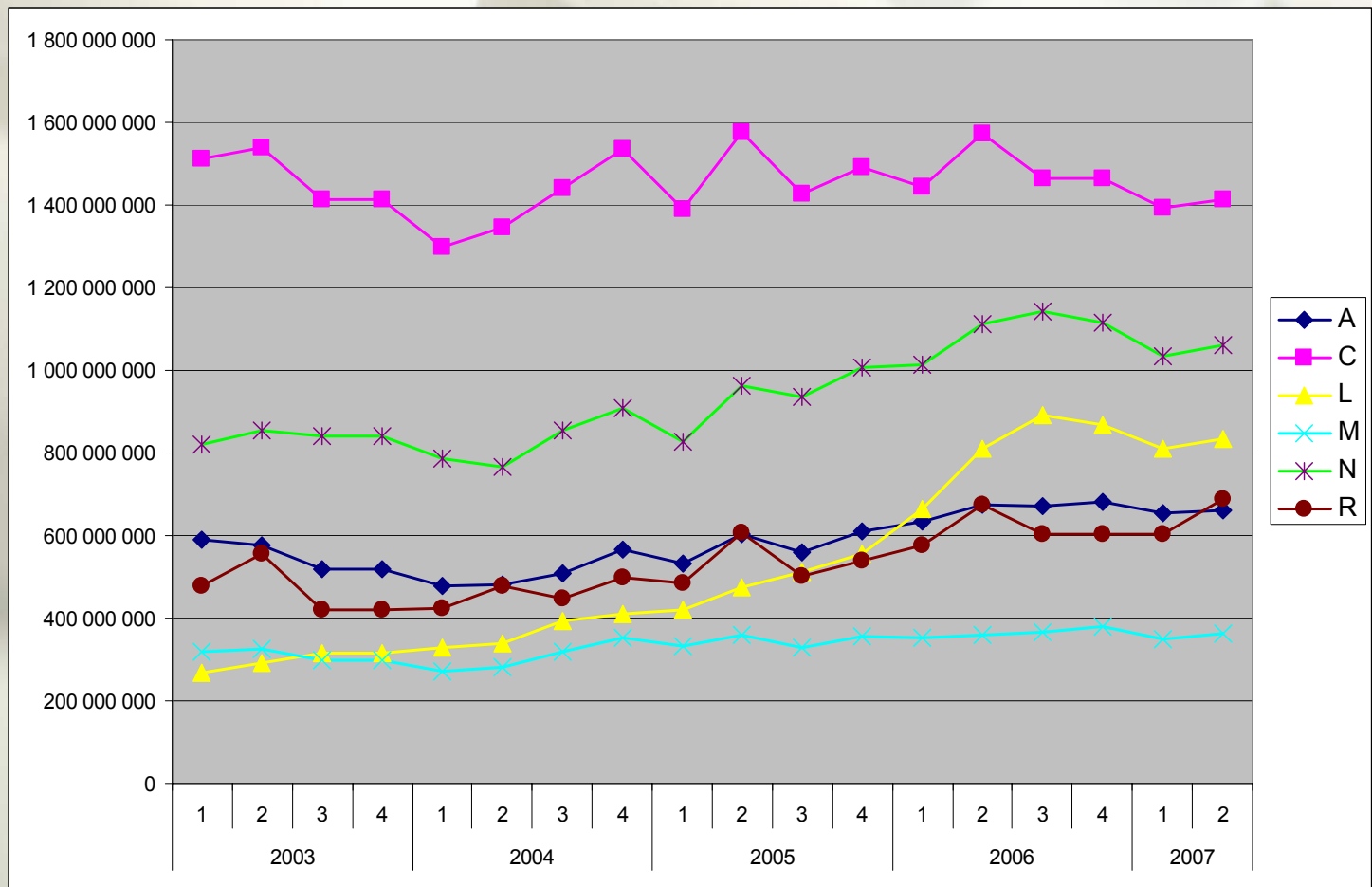
Applications in 2006 overview

<i>2006</i>	<i>1.1.2006 - 20.12.2006</i>
Total No of reimbursement applications	716
Generics	202
New substance / formulation	214
Accelerated procedure (significantly decreased prices)	205
Delisting from the positive list	76
Withdrawal of application	19
Generics	202
Not reimbursed	2
Reimbursed	145
Further data requested (stop clock)	1
Ongoing process	54
New substance / formulation	214
Not reimbursed	32
Reimbursed	152
Ongoing process	30
Accelerated procedure (significantly decreased prices)	205
Not reimbursed	1
Reimbursed	186
Reviewed decision (not on market)	18
Delisting / Withdrawal of applications	95
Not available on market	16
Delisting requested by manufacturer	2
Delisting requested by MoH	58
Reimbursement withdrawal	19

Evolution of drug consumption per volume by ATC level 1 for period 2003 - 2007 in quartals



Evolution of drug consumption per value by ATC level 1 for period 2003 - 2007 in quartals



Example of entry of generics in reference price system and effect on costs

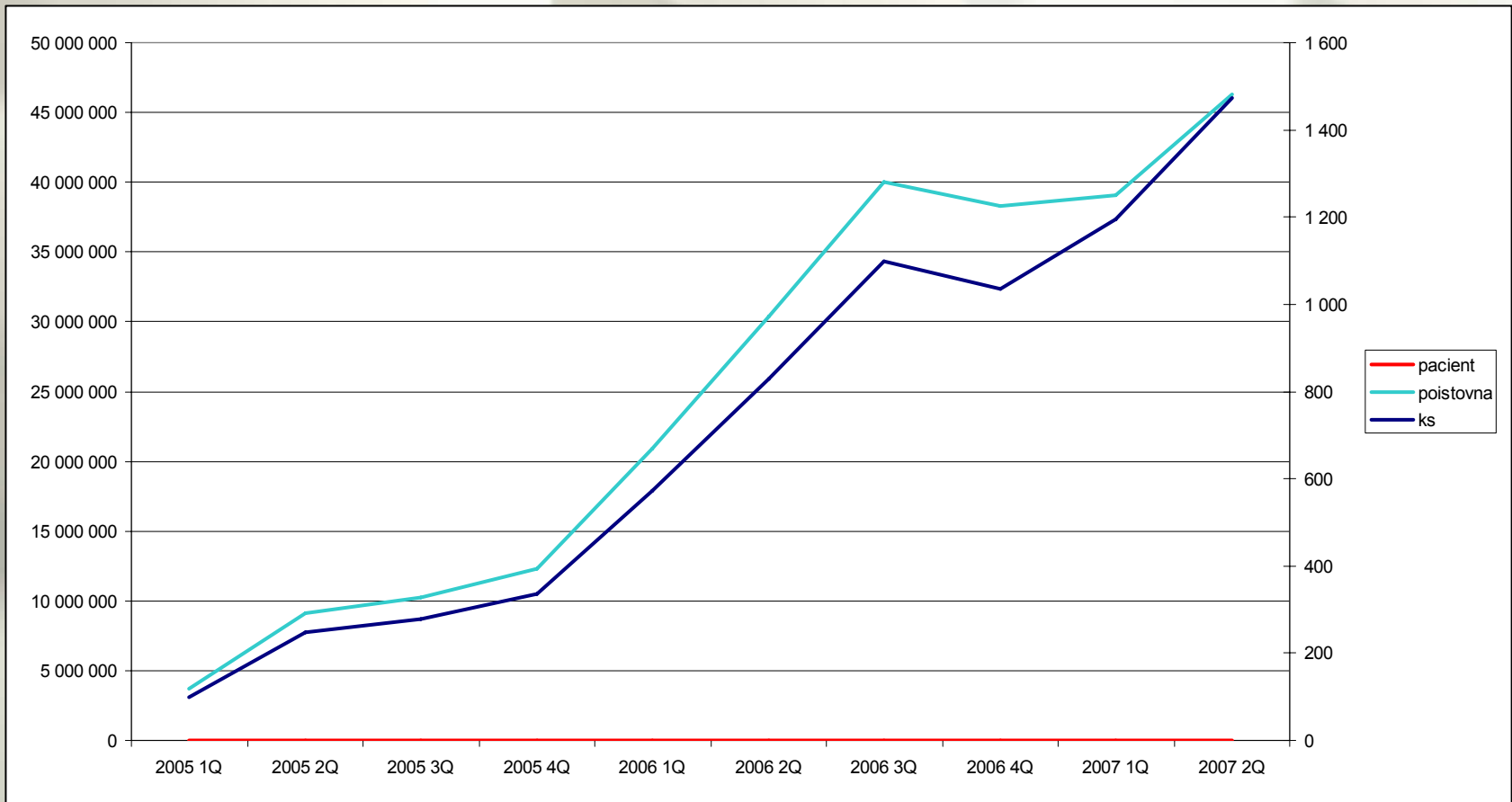
ATC	Active substance	January 2003		Marc 2007		Costs in 2006	
		Reimbursement per DDD	co-payment / No of products without co-payment	Reimbursement per DDD	Co-payment / No of products without co-payment	mil. Sk	DDD/1000 inhab
A02BC01	Omeprazol nad 10 mg	20,00	40 Sk/	4,1	0 Sk/ 3	120	2 500
C10AA01	Simvastatín p.o. do 20 mg	21,70	/ 1	4,0	10 Sk/	273	6 300
	Simvastatín p.o. nad 20 mg	20,00	66 Sk/	4,0	20 Sk/		
C08CA01	Amlodipín p.o.	10,50	8 Sk/	3,3	5 Sk/	343	13 600
N06AB05	Paroxetín p.o.	28,90	300 Sk/	6,8	20 Sk/	43	700
A10BA02	Metformín p.o.	8,90	/ 1	5,4	/ 10	190	2 900
C09CA01	Losartan p.o.	24,00	727 Sk/	4,90	5 Sk/	75	900
C09AA01	Fosinopril	10,0	100/	4,2	5 Sk/	50	1 200
N05AX08	Risperidón	173,50	/ 1	17,1	/ 2	140	100

Breast cancer: L01XC03

Trastuzumab - Herceptin

Licensing		Reimbursement	
Dátum	Typ	Dátum	Spôsob uhr.
28_08_2000	EU	01_2005, resp 2004_02	F, predtým A

Breast cancer: L01XC03 Trastuzumab - Herceptin

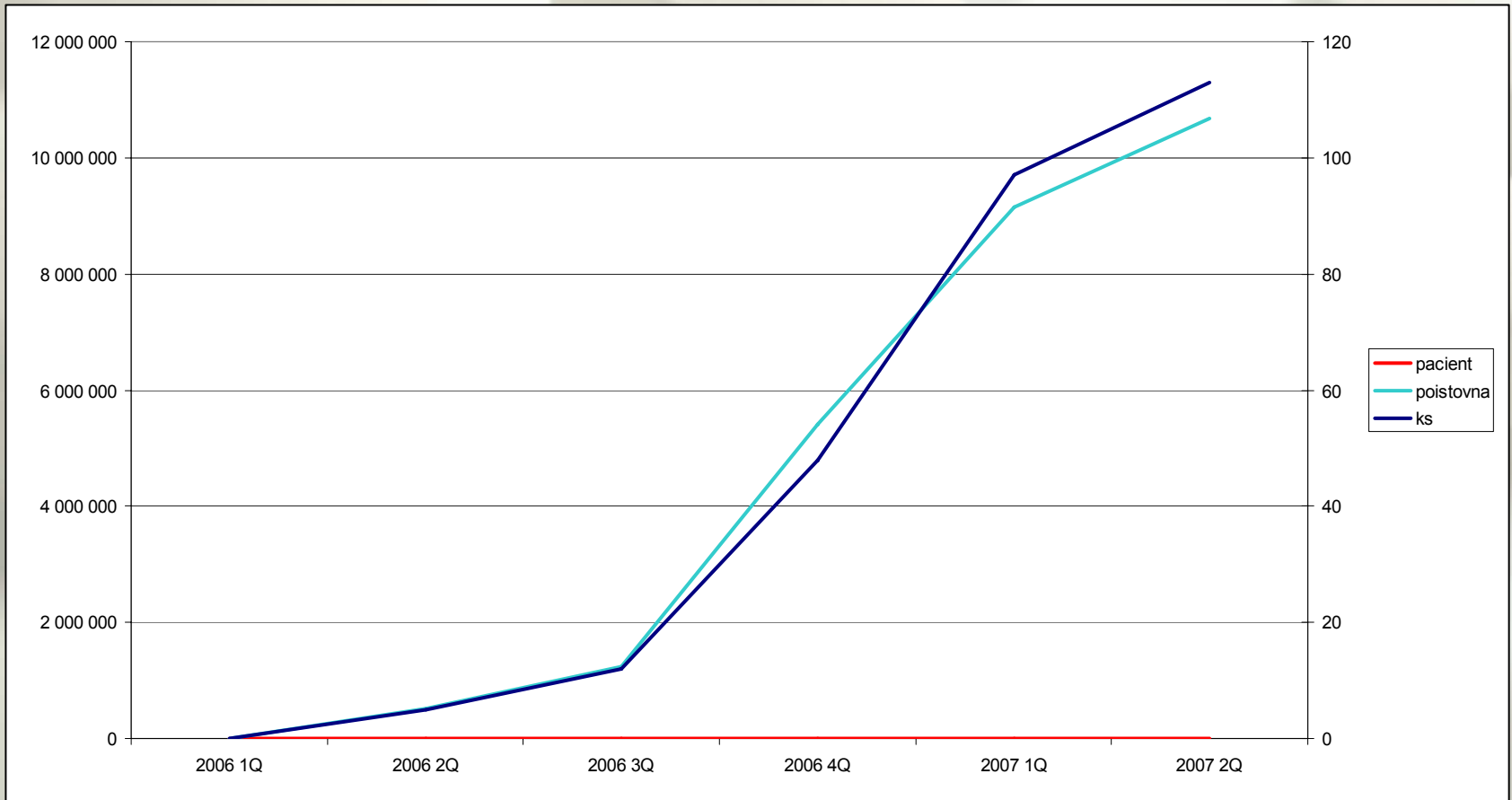


Lung cancer: L01XE03

Erlotinib - TARCEVA

Licensing		Reimbursement	
Dátum	Typ	Dátum	Spôsob úhr.
19_9_2005	EU	07_2006	F

Lung cancer: L01XE03 Erlotinib - TARCEVA



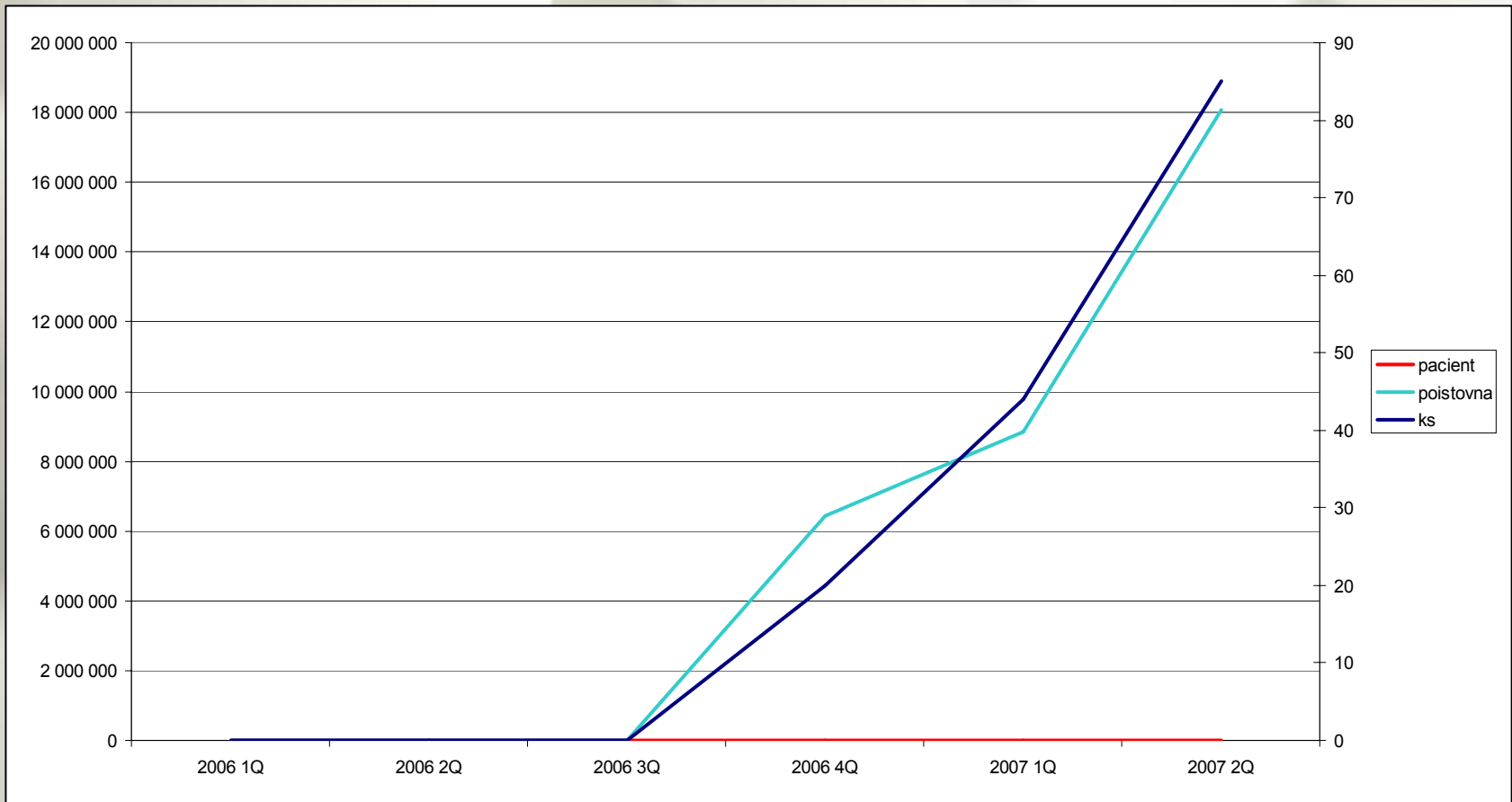
Lung cancer: L01XE04

Sunitinib - SUTENT

Licensing		Reimbursement	
Dátum	typ	Dátum	Spôsob úhr.
19_07_2006	EU	04_2007	F

Lung cancer: L01XE04

Sunitinib - SUTENT



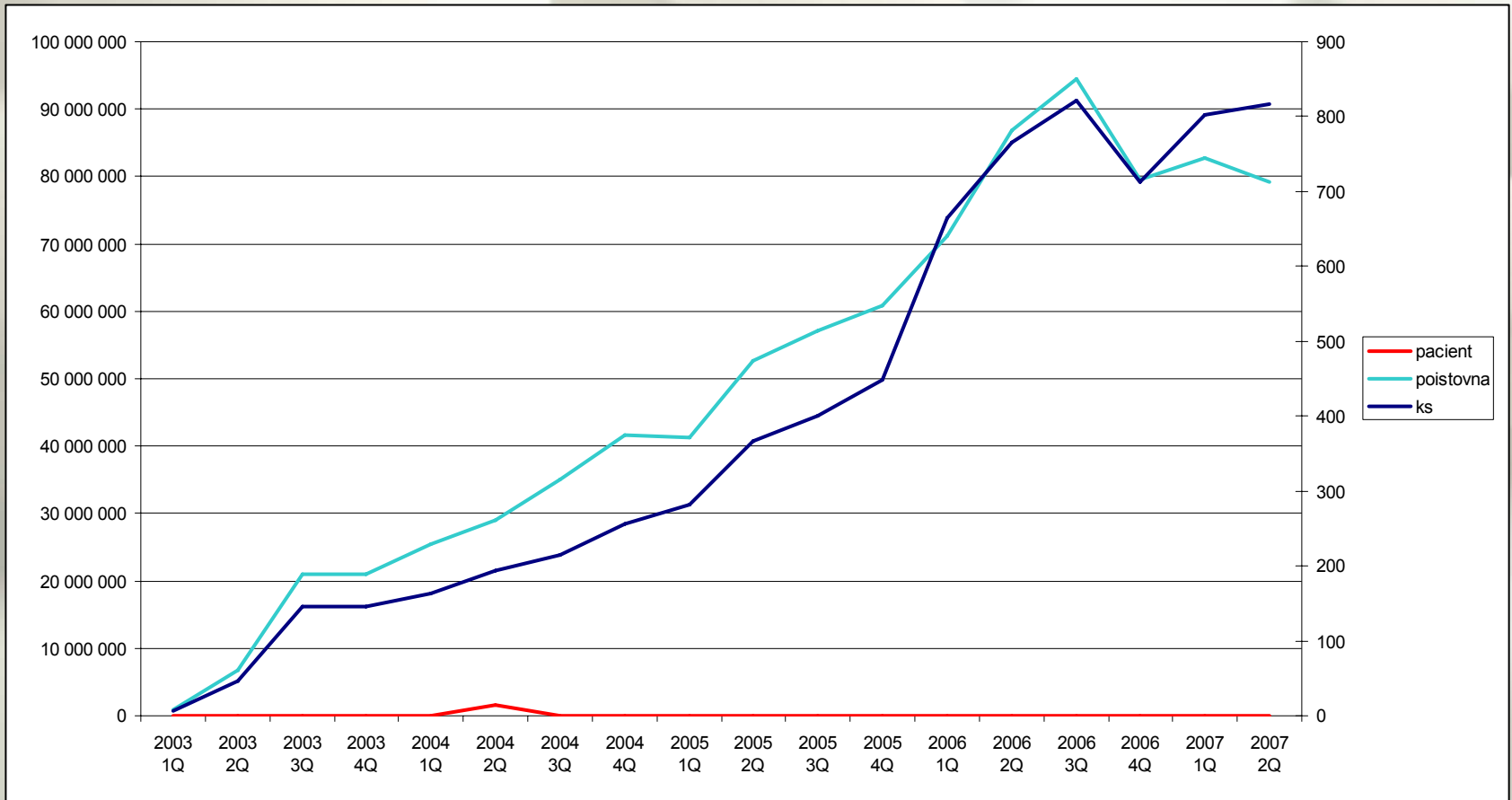
Chronic myeloid leukemia: L01XX28

Imatinib - GLIVEC

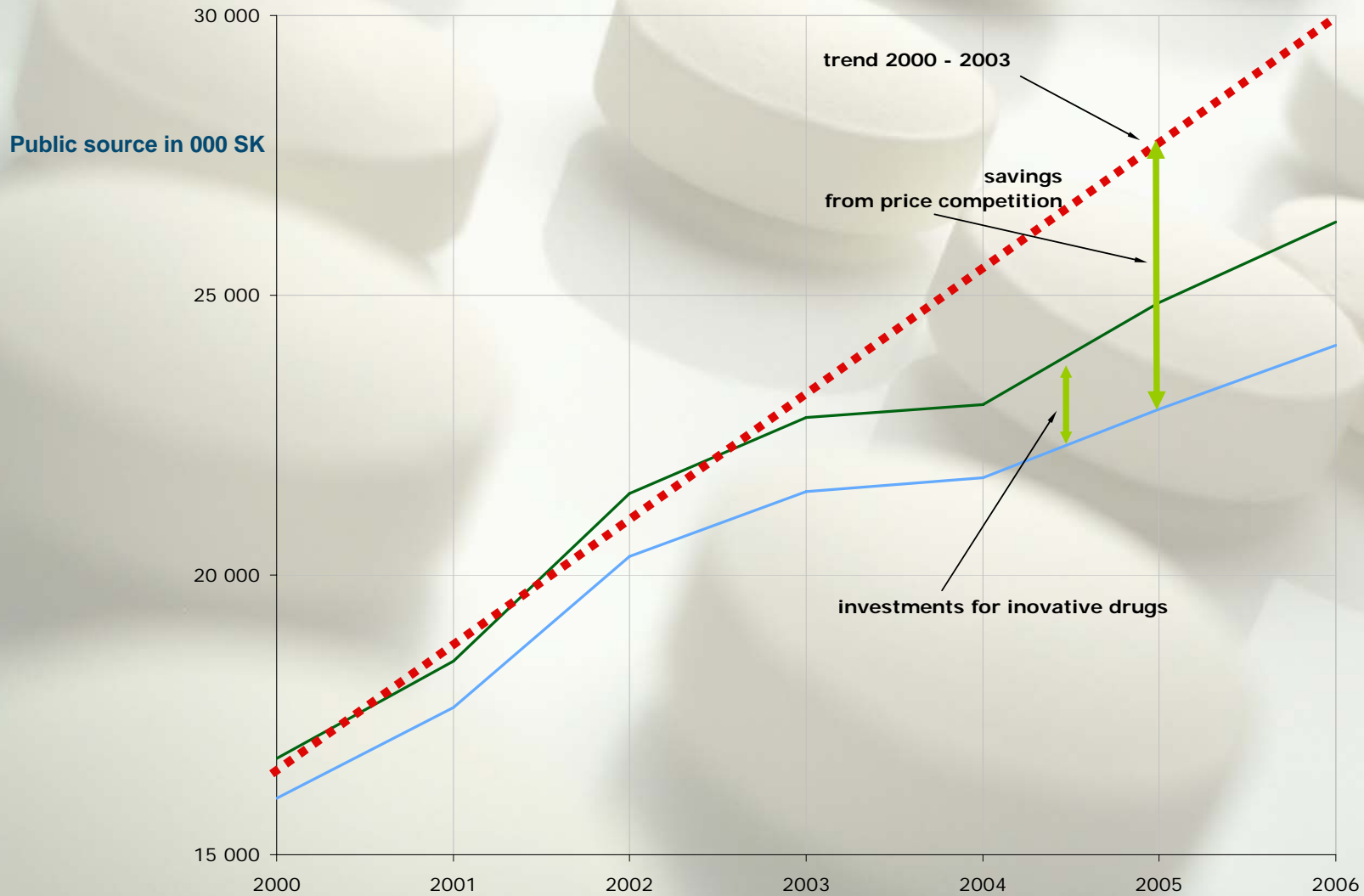
Licensing		Reimbursement	
Dátum	Typ	Dátum	Spôsob úhr.
07_11_2001	EU	07_2005, 11_2003	v 2005 F, predtým v I

Chronic myeloid leukemia: L01XX28

Imatinib - GLIVEC



Original and generics – effective competition and availability of new innovative treatment



**We're lucky
that the hole is
not on our side**

... ??? ...



State Institute for Drug Control

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