



Zavod za zdravstveno
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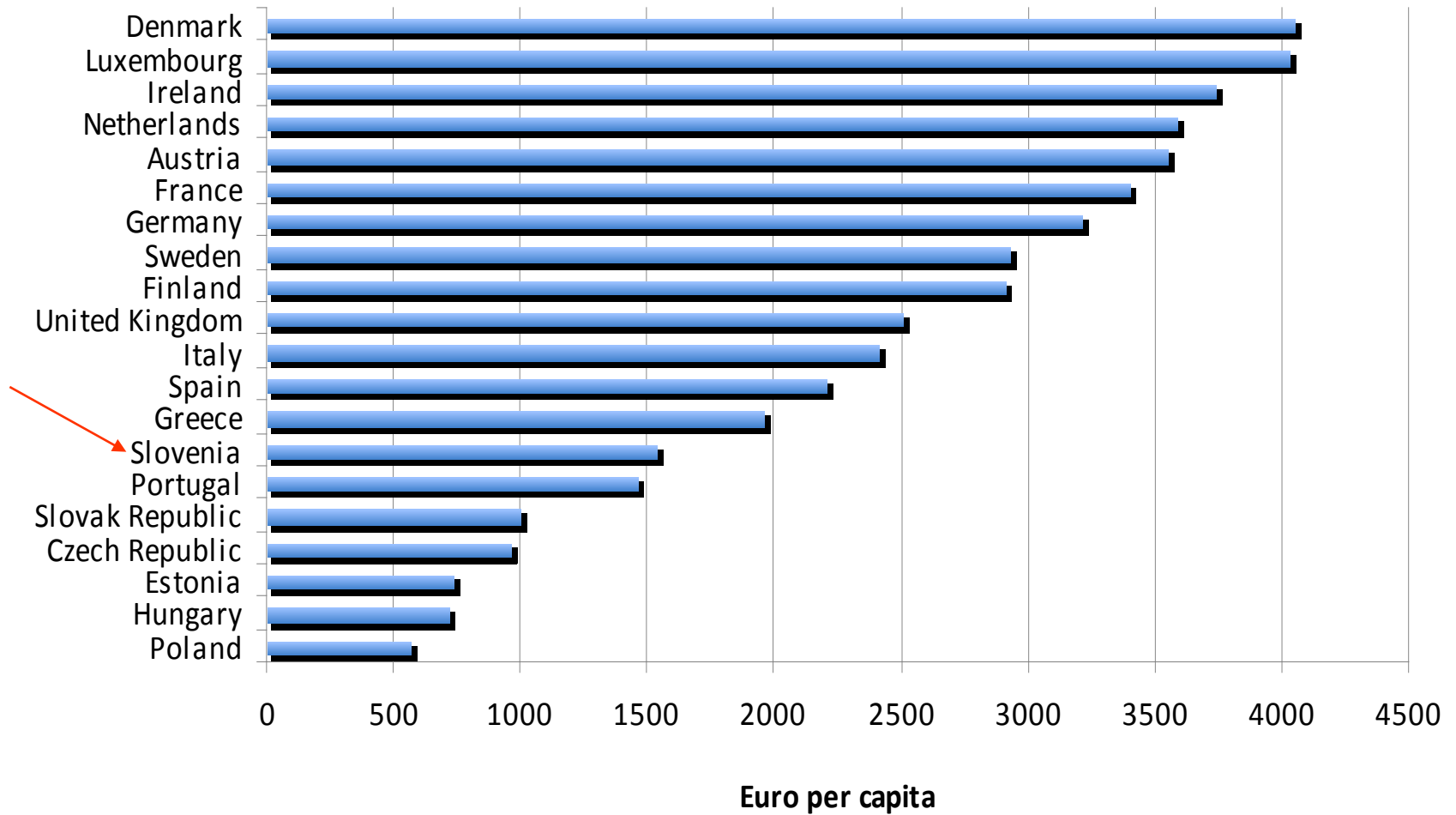


PHARMACOECONOMIC CRITERIA FOR REIMBURSEMENT OF DRUGS IN SLOVENIA

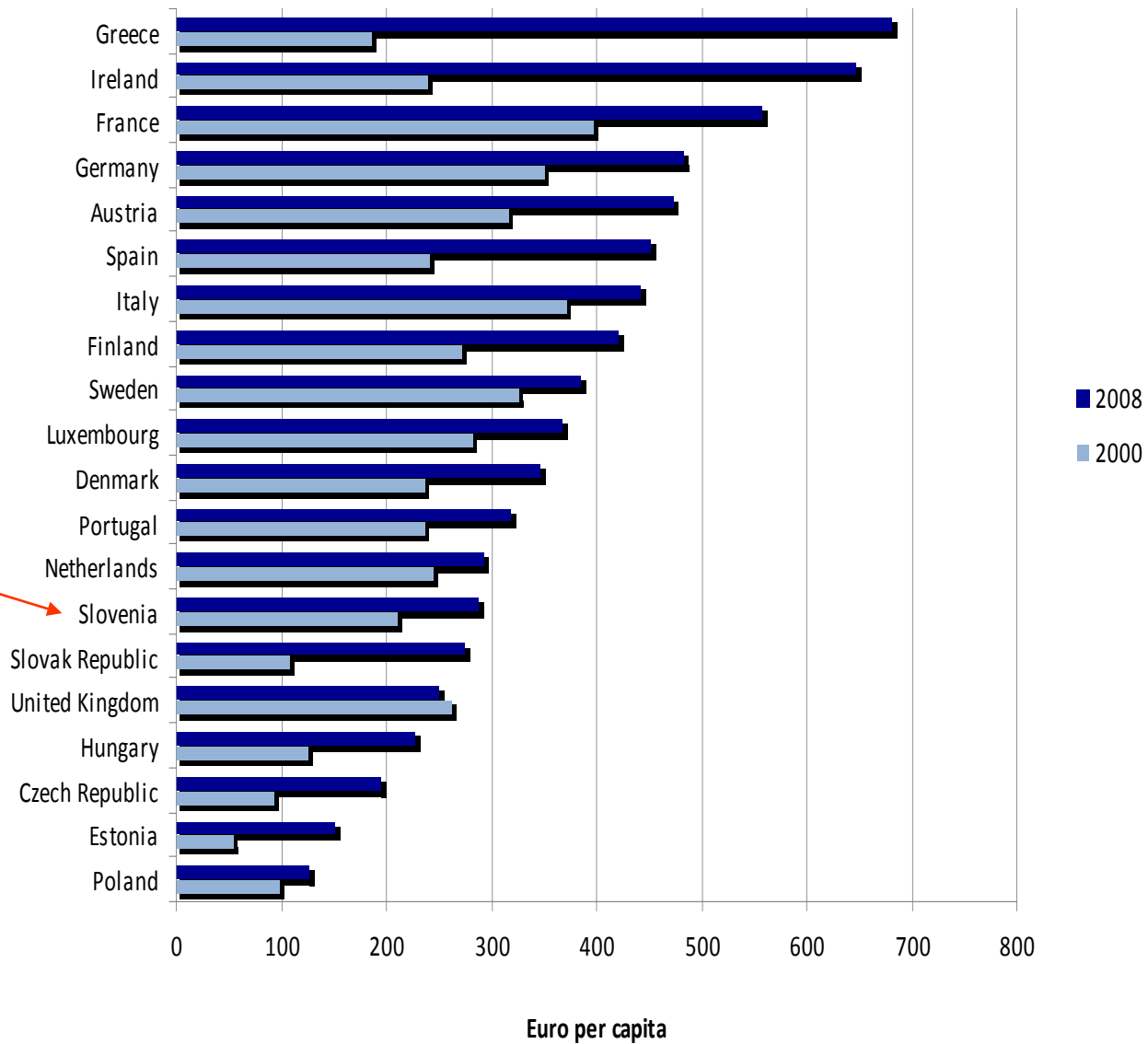
Jurij Fürst
Rozeta Hafner

X. Savjetovanje farmaceuta
Šibenik, 24 – 26 May 2012

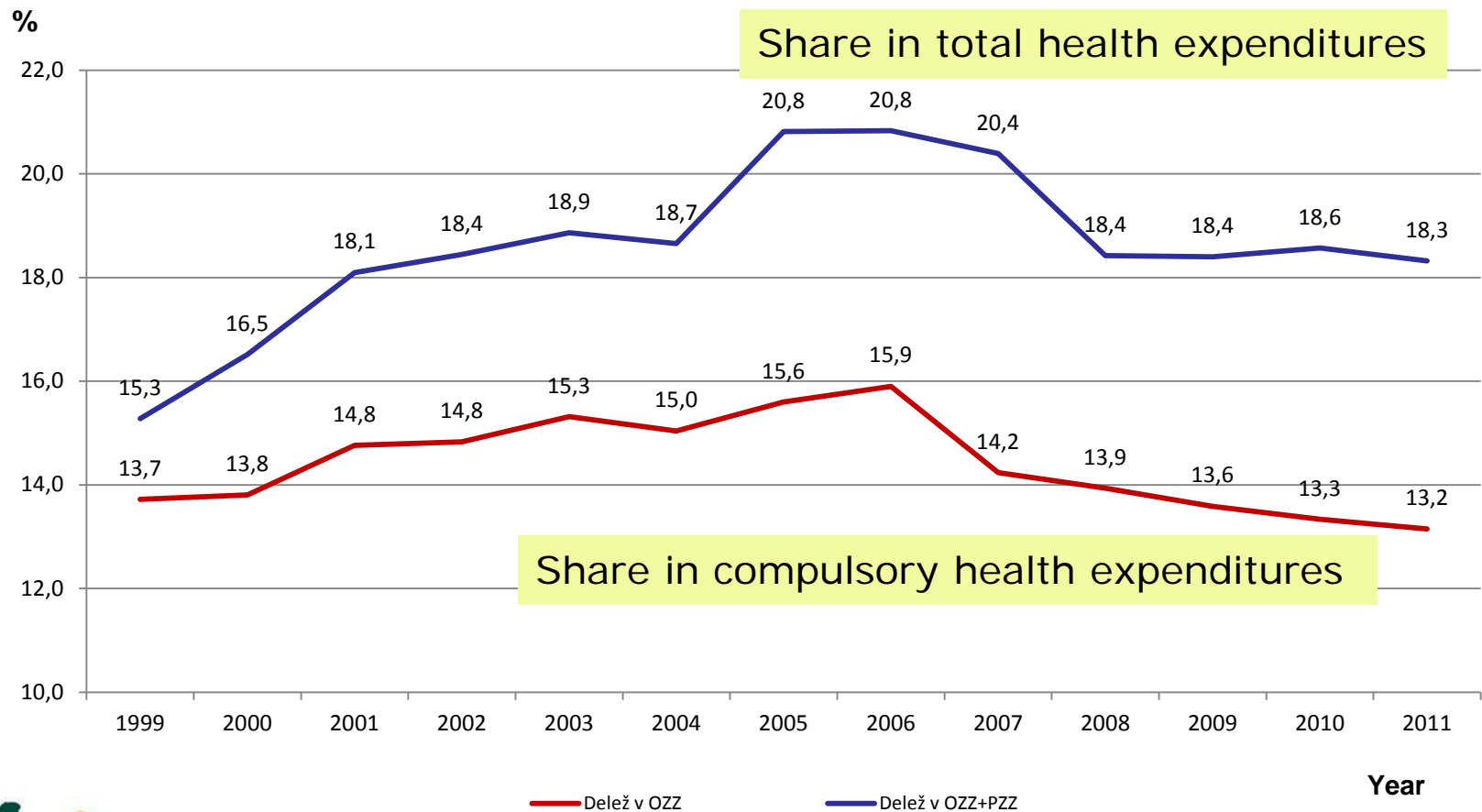
Europe's health spending per capita, 2008



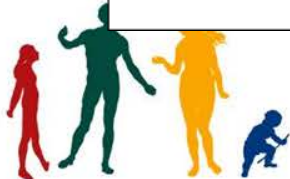
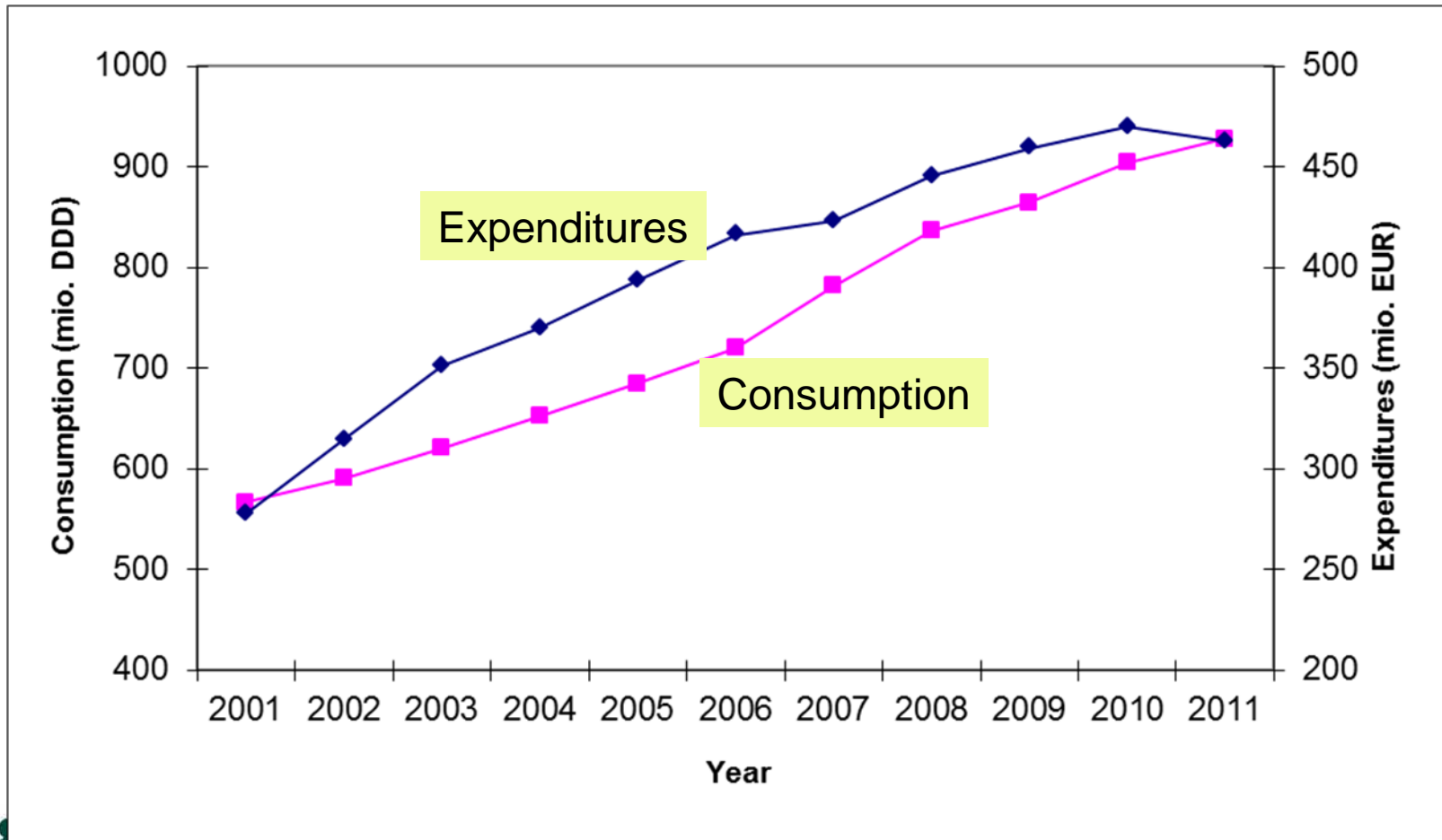
Europe's pharmaceutical spending per capita



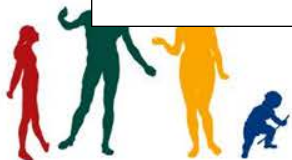
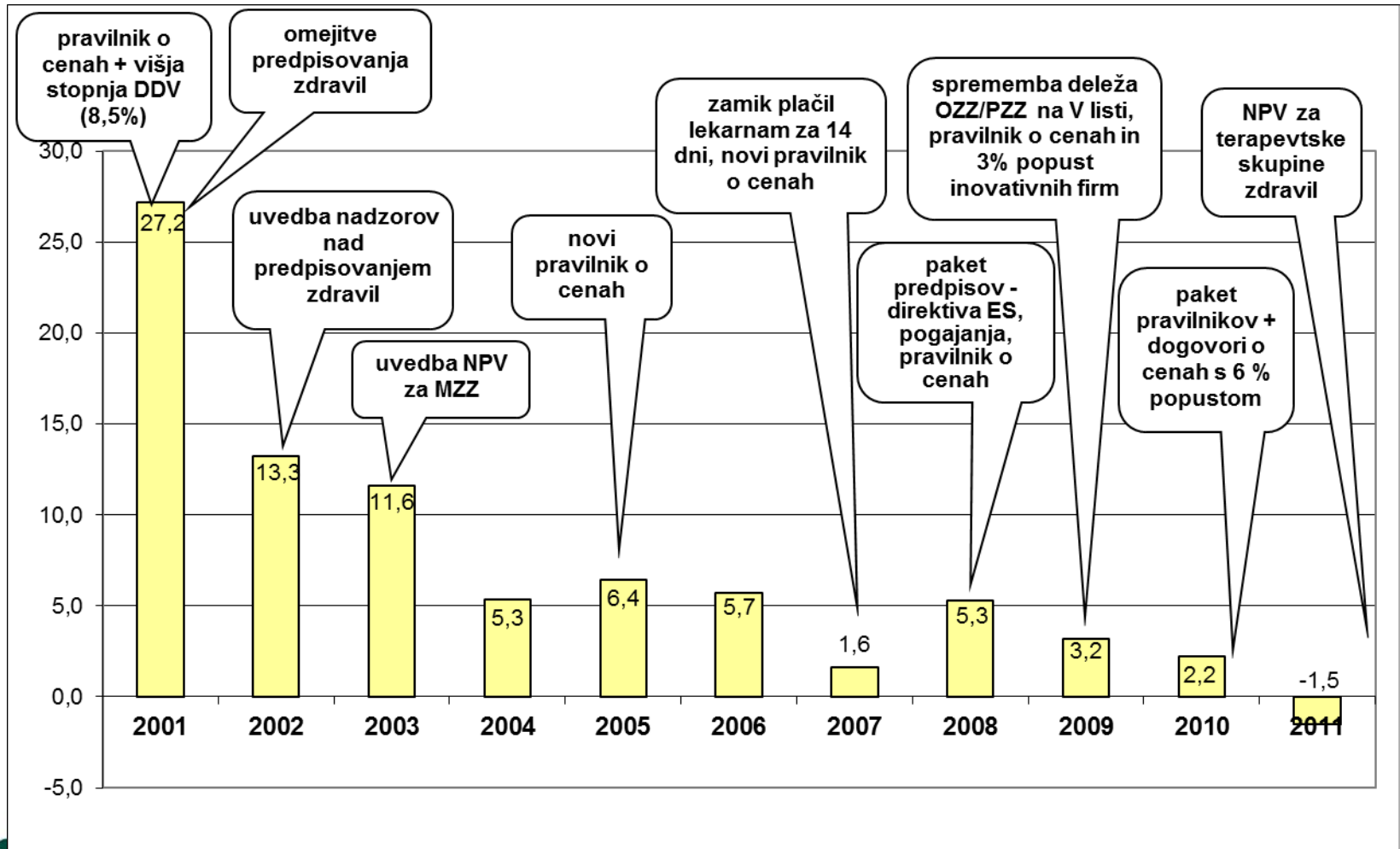
Prescription drugs: Share in compulsory and total health expenditures



Consumption and expenditures on prescription drugs in Slovenia in 2001 - 11



Measures on drugs and nominal growth of expenditures for prescription drugs (in %)



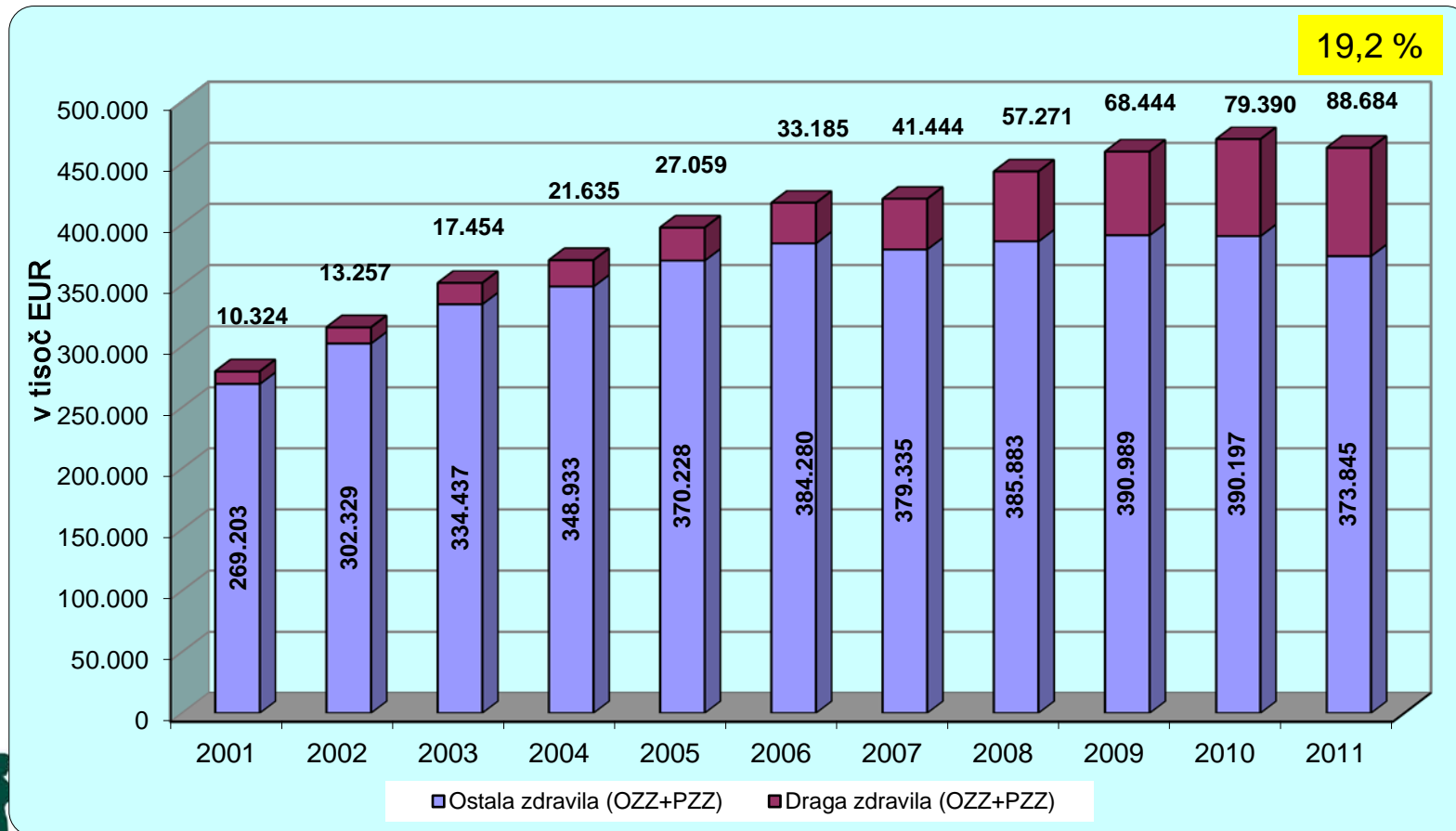
New regulations

- In December 2010, published new regulations on:
 - Pricing
 - Reimbursement
 - Interchangeability
 - Advertising
- In May 2012 - law:
 - Highest allowable values for therapeutic groups of drugs



Expenditures on "expensive" and "other" drugs*

Year	No of prescriptions	No. of recipients	Costs per recipient
2011	71.297	14.891	5.956



* Expensive drugs: >2.000 €/patient/year

„Expensive“ prescription drugs

- Epoetins (except for dialysis patients)
- Granulocyte-stimulating factors
- All haemato-oncologic peroral drugs: capecitabine (Xeloda), imatinib (Glivec), nilotinib (Tasigna), dasatinib (Sprycel), lenalidomid (Revlimid)
- Other oncologic drugs: erlotinib (Tarceva), sunitinib (Sutent), sorafenib (Nexavar), lapatinib (Tyverb), pazopanib (Votrient)
- Oncologic bisphosphonates
- Low molecular-weight heparins
- TNF- α inhibitors and other biologic drugs
- All drugs for MS
- Interferons for Hepatitis C
- All drugs for HIV



Reimbursement criteria

- Evaluation of the public health aspect (priorities)
- Evaluation of the clinical aspect
 - Therapeutic value
 - Relative therapeutic value
- Economic evaluation
- Ethical aspect
- Data and evaluations from reference sources



Pharmacoeconomic data

- Pharmacoeconomic analysis
 - Complete analysis (costs and outcomes)
 - Partial analysis (costs)
- Budget impact analysis
 - For first 3 years
- All analyses have to be made from the compulsory health insurance aspect



Types of analyses

For drugs claiming added therapeutic value (and demanding higher price):

- Cost-Effectiveness Analysis:
 - Life Years Gained (LYG)
- Cost-Utility Analysis
 - Quality Adjusted Life Years (QALY)

Incremental Cost-Effectiveness Ratio – ICER (related to a relevant comparator)

For drugs with equivalent effectiveness:

- Cost-minimization analysis or
- Cost Analysis (without outcomes)



Cost-effectiveness Threshold

- ICER is value, a payer is prepared to pay for additional QALY respective LYG
- For some countries the most important (explicit) criterion
- Most countries don't have it as an explicit criterion
- Higher threshold only for ethical reasons (orphan drugs)



Cost-effectiveness Thresholds

- Australia: € 24.700 – 44,700 per LYG
- Canada: € 12.700 – 63.300 per QALY
- UK: € 42.700 – 44.700 per QALY (£ 20.000 - 30.000)
- Netherlands € 20.000 – 80.000 per QALY
- New Zealand € 1.400 – 7.200 per QALY
- Unites States € 34.400 per QALY



Cost-effectiveness Threshold - Slovenija

- Ministry of Health has defined an ICER 30.000 – 45.000 €/QALY for new health care programs
- For drugs, all aspects (criteria) are important
- In a fixed ZZZS budget, budgeted impact has become one of the most important criterion
- **ZZZS's proposal: 25.000 €/QALY**



Cost-effectiveness Threshold - HD

- For definition of ICER threshold, cost for patients with end-stage kidney disease (haemodialysis) is calculated
- The results of the study made by Faculty of Pharmacy, Ljubljana for Slovenia:
 - 33.511 €/LYG
 - 70.407 €/QALYG



Willingness to pay studies

- Alternative approach to define an ICER threshold
- A study of Faculty of Pharmacy, Ljubljana, a case of a new oncology treatment: 61,909 EUR/LYG in case of at least 3 additional months of survival



Agreements

- ZZZS can sign following agreements:
 - Discount (reduction of price)
 - Rebate (material discount)
 - Price – volume agreement
 - Pay-back or claw-back agreement
 - Performance-based (outcome-based) agreement



Performance-based (outcome-based) agreements

- Only for the most expensive drugs
- Necessary to define:
 - Clinical criteria for selecting patients
 - Criteria for stopping treatment
 - Financial obligations
- Two or three parties (ZZZS, company +/- hospital)
- Examples:
 - gefitinib (Iressa)
 - Alglucosidase alpha (Myozyme)
- Demanding!



Conclusions

- In economic crisis, health care budget restraints affect also reimbursement policy
- Extremely high prices of new treatments force health insurances to implement more restrictive mechanisms
- Even in most affluent countries new drugs (even orphan drugs!) are rejected (not getting reimbursement)
- What is the optimal ratio between public health care and private pharmaceutical companies' interests?



HVALA!

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