



Croatian 2009 - 2010 pharma reform

ensuring value for money, improved decision making and process transparency

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Overview

- Snapshot of the Croatian (HZZO's) market in 2009
- Market development from 2002 to 2008
- Pricing and price related reimbursement regulation
- Pricing related regulation effects from 2008 – 2010
- The 2009 -2010 reform:
 - “Pay back” agreements for new blockbuster products
 - “Cross product” agreements for price cuts
 - Focus on the prescribers
 - Improved realtime monitoring through ePrescriptions
 - “Ethical ” promotion agreement
 - Ensuring transparency
 - Improved decision making (criteria for listing, budget impact analysis, information submitted in proposals, etc.)
- Patient centred system

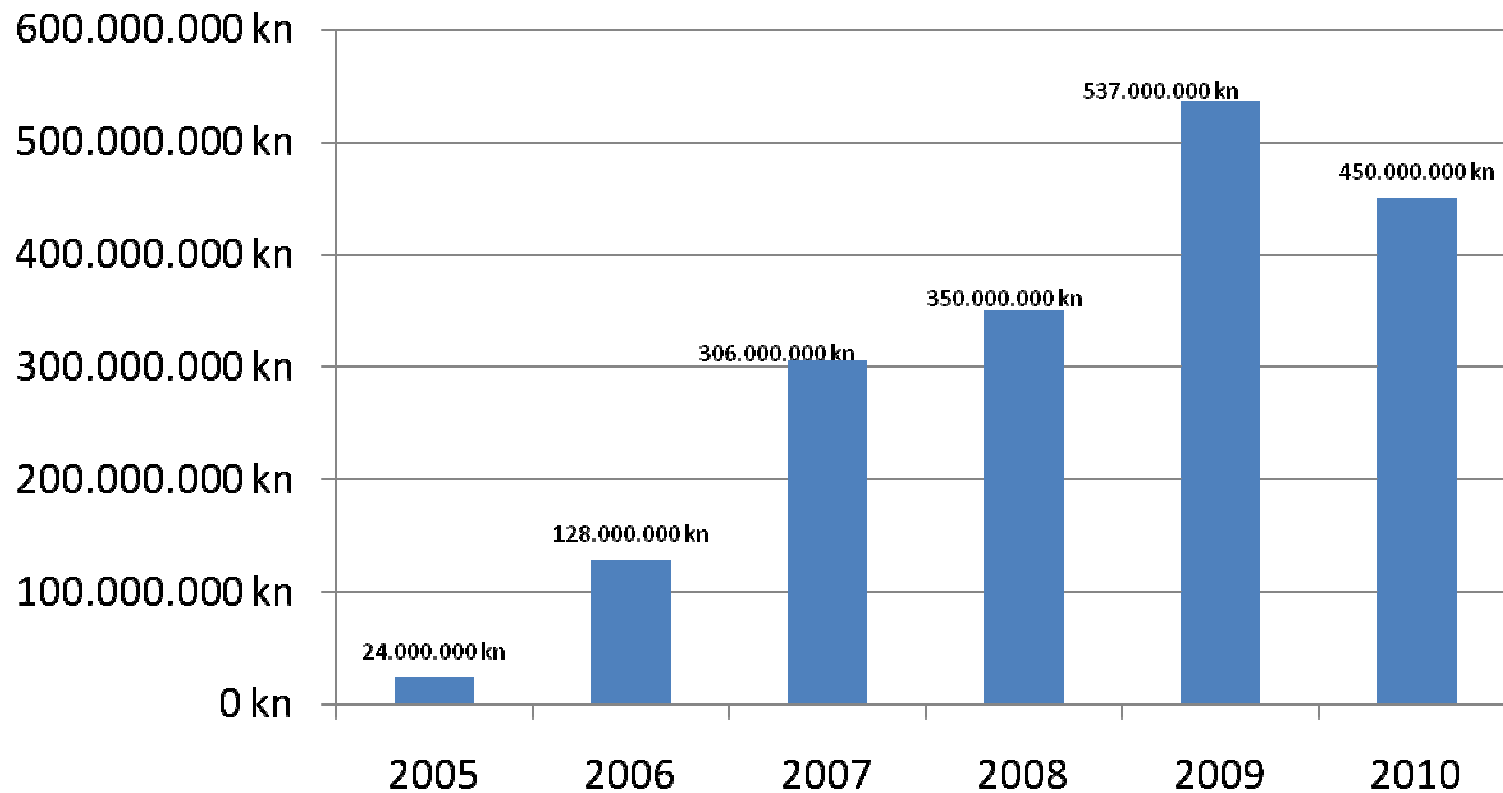
HZZO's market for medicines in 2009

Rp	3 billion kn	US\$ 588 million
Hospitals	1.5 billion kn	US\$ 294 million
Expensive drugs	0,5 billion kn	US\$ 100 million

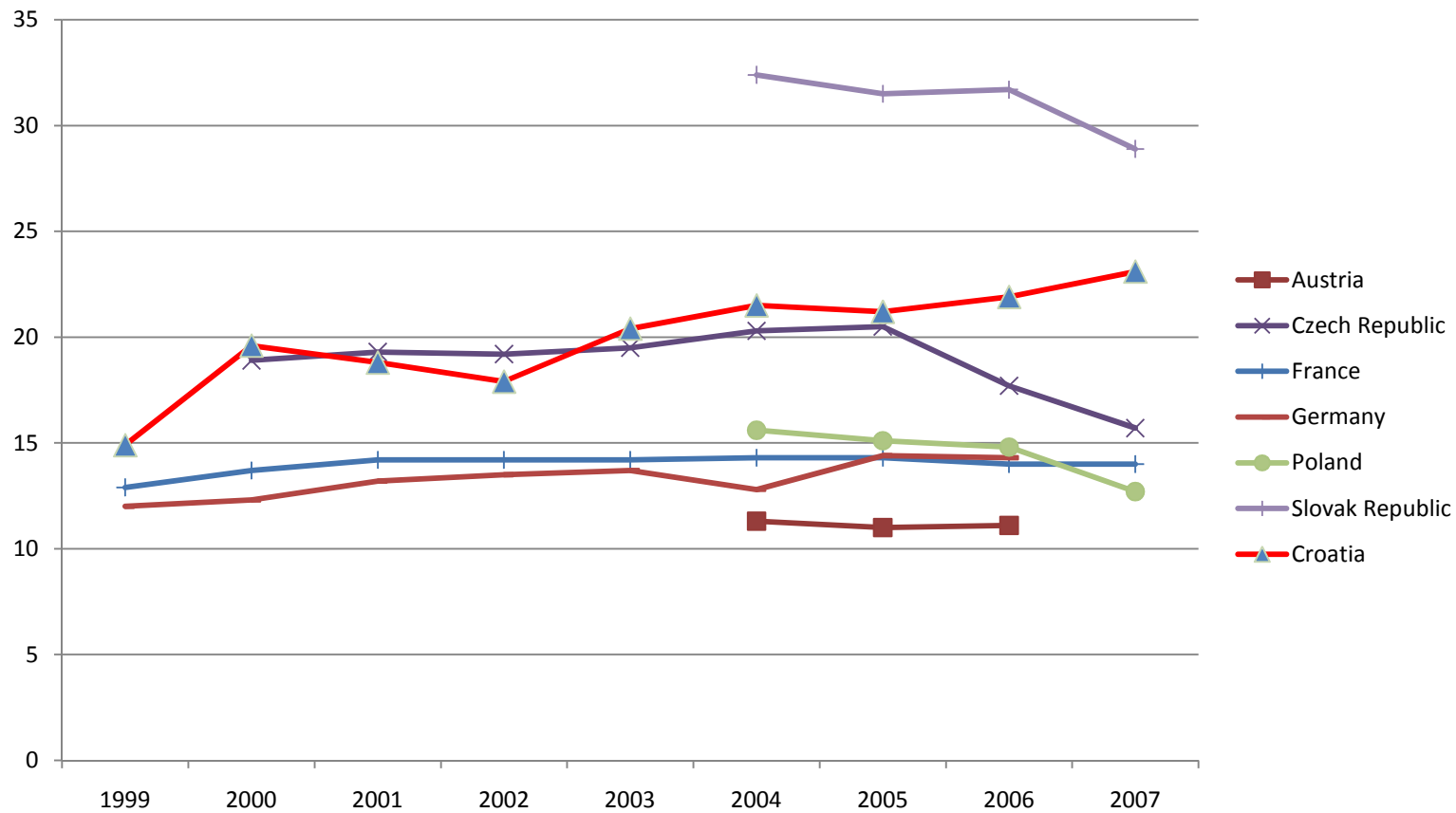
- HZZO as a monopsonist buyer
- 2009 & 2010:
 - 60 innovative products listed
 - 47 from 2002 to 2009
- High generic penetration (75% of Rp expenditure)
- Affordable prices (EU compared)
- Powerful pricing and reimbursement mechanisms
- Innovative regulatory mechanisms introduced by reform

Availability of expensive new products

Croatian expensive drugs fund



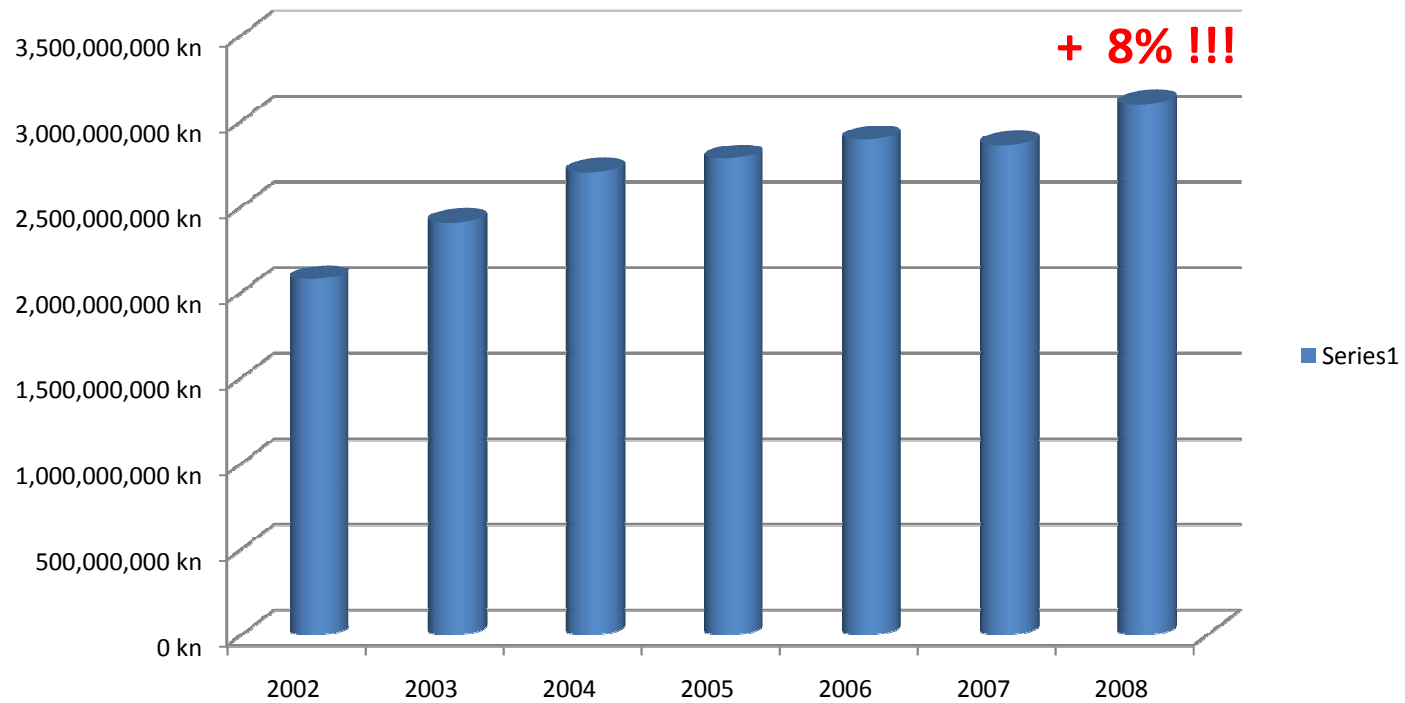
Exp on medicines as % of total health exp



Sources: [OECD Health Data 2009 - Verzija: lipanj 09](#); HZZO for Croatia

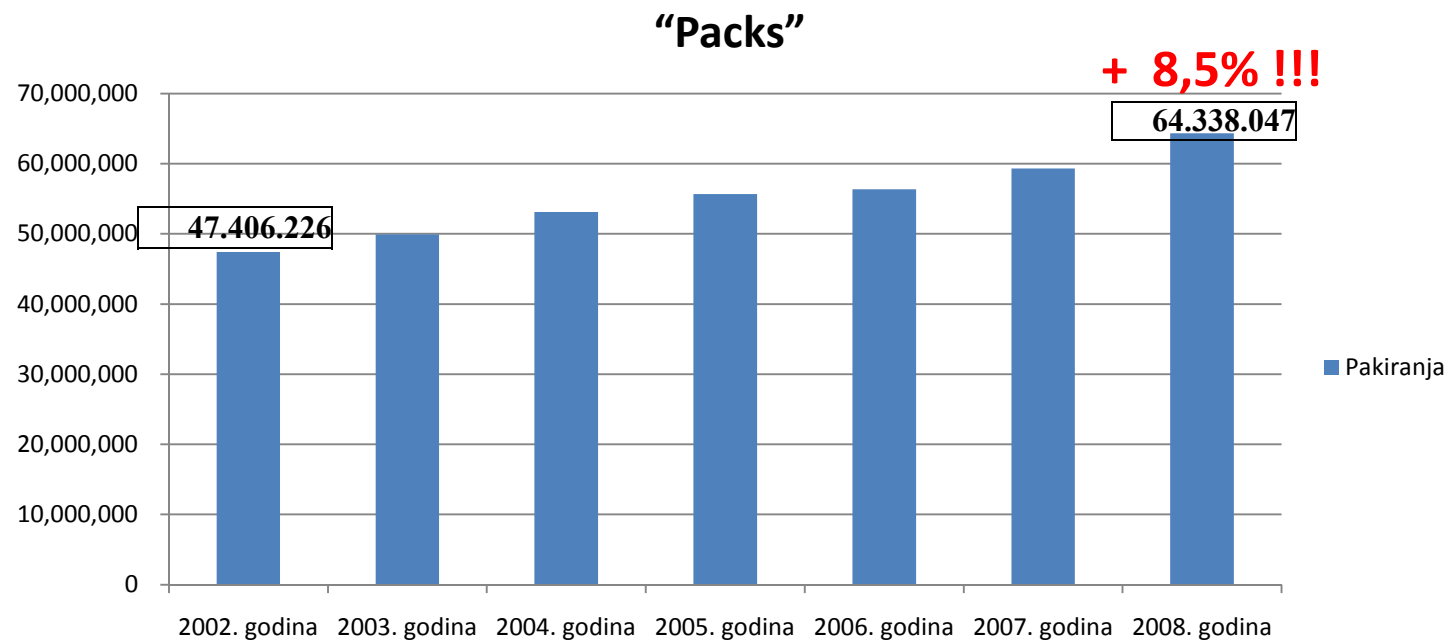
Rp Exp from 2002 to 2008

+49,4% !!! (2002-2008)



Rp Volume from 2002 to 2008

+35,7% !!! (2002-2008)



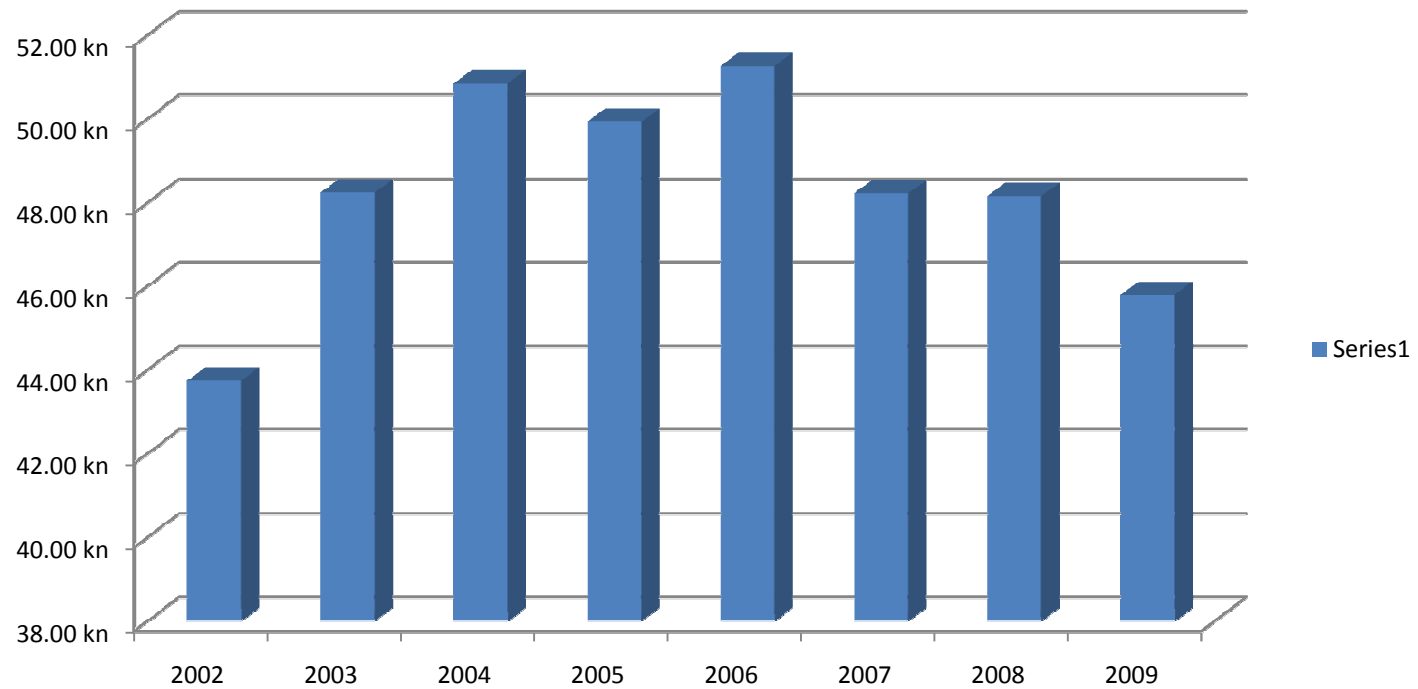
Pricing (international comparisons)

Maximum prices for listed drugs determined through annual price calculations	Maximum prices for drugs introduced to the lists for the first time
Drugs under patent protection in Croatia or any EU member state: up to 90% of the average price in Italy, France and Slovenia.	Original breakthrough products (ATC level 3): up to 100% of the average price in Italy, France and Slovenia.
Drugs not under patent protection in Croatia nor any EU member state: up to 65% of the average price in Italy, France and Slovenia.	Me too products: up to 90% of the average price of similar products in Croatia
	Generic products: up to 70% of the average price in Italy, France and Slovenia <u>and</u> up to 90% of the price of the cheapest generic in Croatia

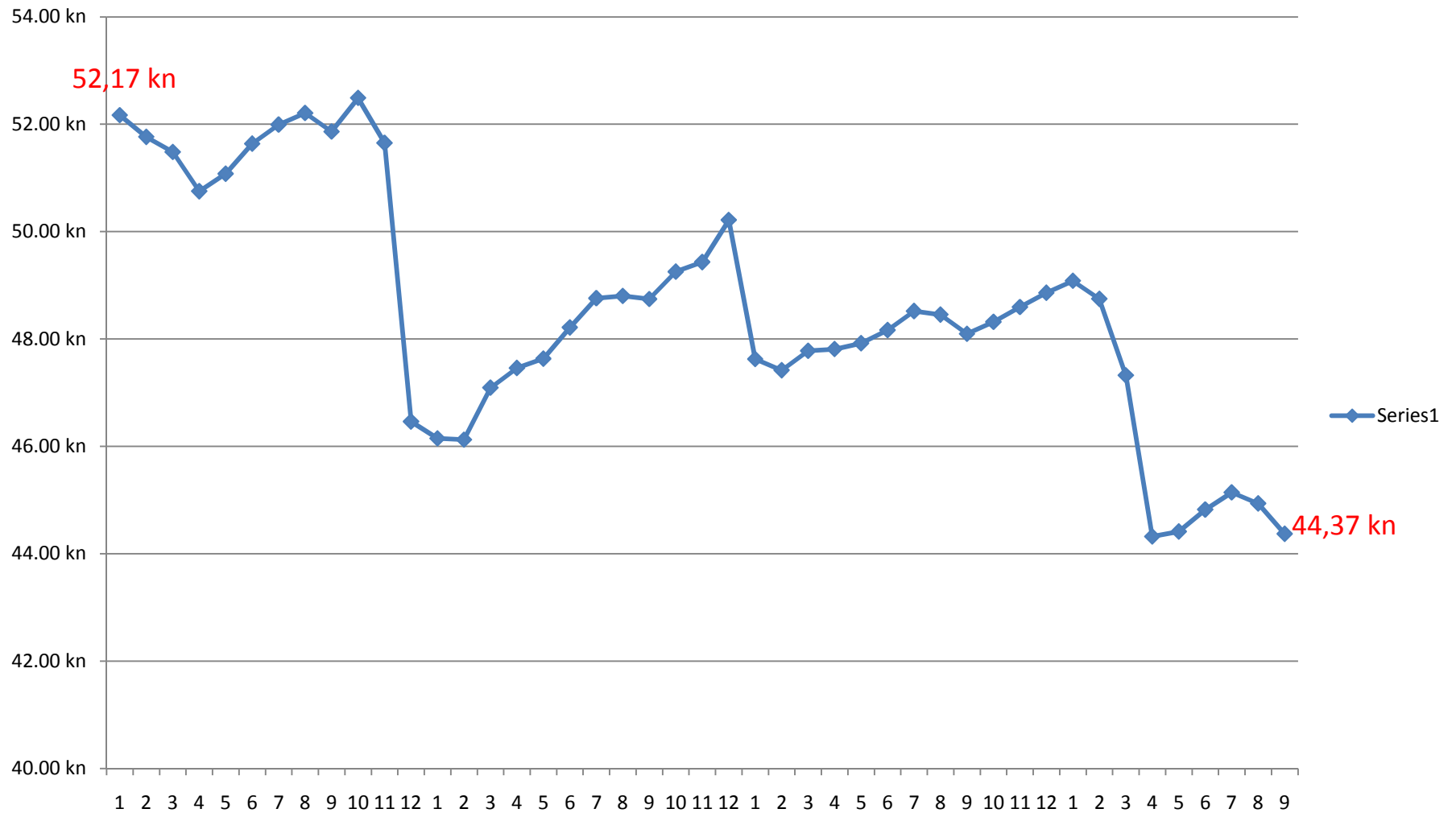
Price related reimbursement

- **Internal price referencing (2/3 of molecules)**
 - 41 clusters formed at ATC levels 3,4 and 5
 - Comparisons in major part DDD based
 - Reference price = cheapest molecule, 5% of cluster volume
 - Internationally described as “proactive”
- **A (100% coverage) & B (co-payment up to the reference price) lists**
- **B list unpopular among companies**
 - Strong incentive to accept price decreases

Average price of “pack” 2002 to 2009



By months... (2006 – 2009)



Discussion

- Volume (“Packs”) seem to be the dominant driver of expenditure
- “Prices” regulated with success 2006 – 2010

- Potential for further price cuts limited?
- Potential for further increases of co-payment levels?

- Innovative solutions required
 - “Pay back” agreements for new blockbuster Rp products
 - “Cross product” agreements for price cuts
 - Rational therapy and major ATC groups – focus on the prescribers
 - “Ethical ” promotion as in important driver of volume
 - Improved realtime monitoring through ePrescriptions

Pay back agreements

- All medicines listed in HZZO's expensive drugs list
- All new medicines with substantial expenditure potential

- Single drug agreements
- Diagnosis wide agreements (RA, MS, Growth hormones, etc.)
- 3 year agreements

- Define maximum expenditure limits
- Monthly monitoring of expenditure
- Overspends paid back by pharma or avoided by timely donations
- Strict penalties for deliberate shortages

Cross product agreements

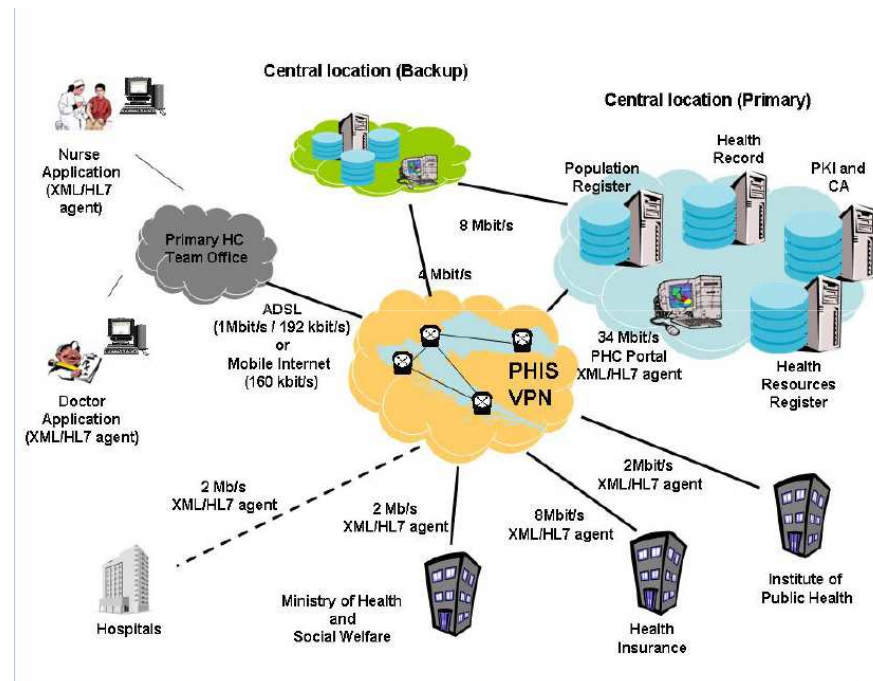
- Listing of drug A conditioned by price cuts on drug B
- Overall budget impact neutral or negative through class effect
- New drugs made available for patients

- Mostly popular among innovative companies
- Reduce prices of old products and introduce new products in the market

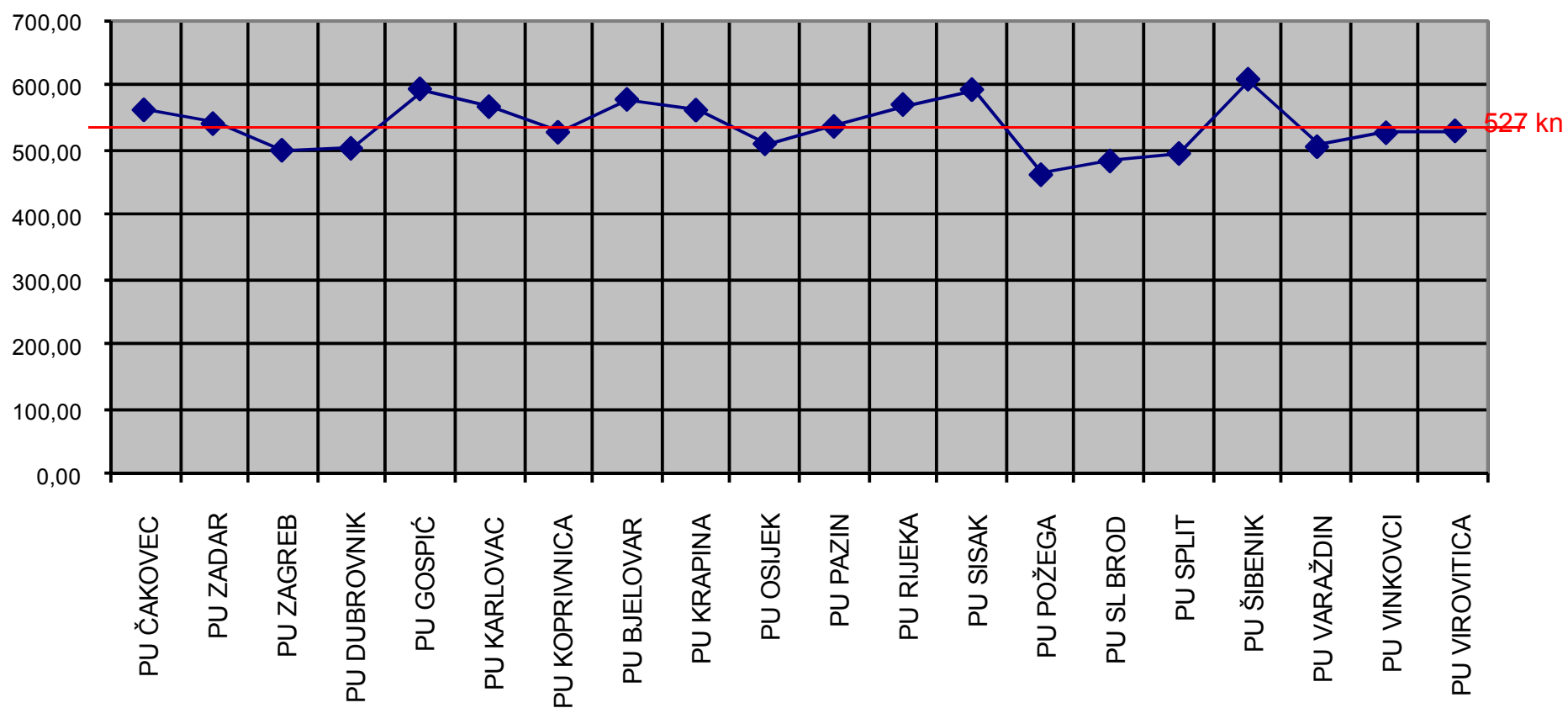
- Class effect can be very powerful
- Once the price of the originator decreases, generic parallels are forced to follow

E - prescriptions

- Connecting 2335 GPs and 1060 pharmacies
- Patients will be able to use the system nation wide
- Paperless office – cutting health care providers' costs and increasing productivity
- Administrative workload for pharmacists declines by over 90%
- Automated checking of all administrative data
- Increased opportunities for monitoring and evaluation
- Project piloted in 2010
- January 1, 2011 – nation wide project kick off



Exp by inured by regional office - variations



Monitoring and informing prescribers

- Hypothesis: 20% of prescribers account for 80% of unnecessary costs
- Indicators (considering No of patients, sex and age):
 - Total Rp costs
 - No of prescriptions by visit
 - Costs by major ATC groups (statins, antibiotics, hypertension, etc)
 - Blockbuster drugs
 - ACE inhibitors/ all antihypertensives
 - Antibiotics for common cold, AOM, etc.
 - Etc.

Ethical promotion agreement

- Voluntary, but a requirement for new applications to the lists
- Strict penalties for unethical promotion (delisting, financial penalties, public name and blame)
- Prohibiting bribery, off label promotion, tourism disguised under education, etc.
- Limiting number of visits by sales rep to stimulate productivity
- Reporting on all clinical trials, studies, surveys etc. made mandatory
- Reporting of all advertising related costs and personalized reporting of all payments to publicly employed doctors (in cash and in kind) made mandatory
- Financial revolving deposit model enforces implementation

What is reported for each cost?

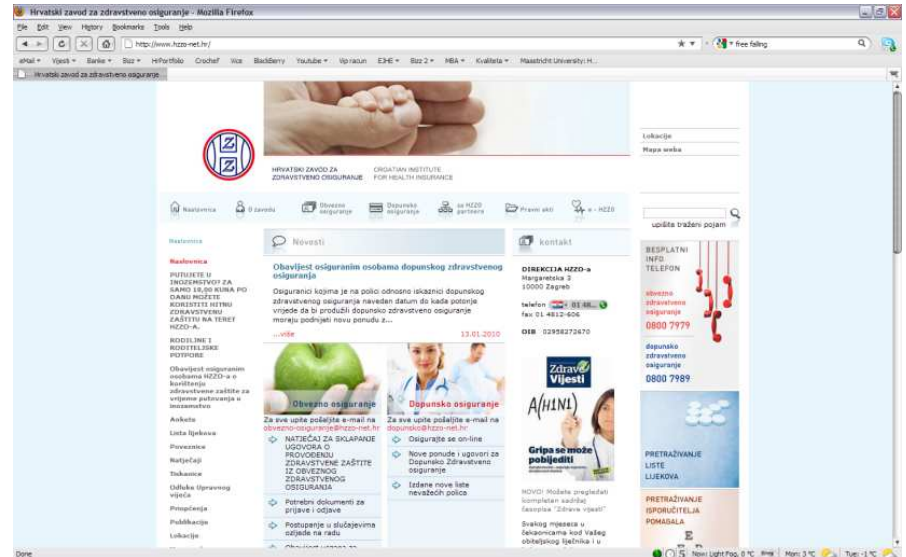
- ID of the company
- ID of the beneficiary
- Name of the beneficiary
- ID of any third parties involved
- Name of third parties
- Institution of employment
- Amount in kn
- Date
- Nature of the cost
- Purpose of the cost
- Name of associated medicine
- ATC of the associated medicine
- Nature of the cost:
 - Cash
 - Stocks
 - Stock options
 - Etc.
- Purpose of the cost
 - Honoraria
 - Education
 - Clinical studies
 - Food and entertainment
 - Donation
 - Organisation of educational events
 - Brochures and similar.

Ethical promotion agreement

- Heated public debate until June 2010
- 56 companies signed the agreement up to November 2010

- Roche, AstraZeneca, Novartis, Abbott, Alkaloid, GE Healthcare, GlaxoSmithKline, Grunenthal, Krka, Lek (Sandoz), Medis Adria, Merck Sharp & Dohme, Nestle, Nycomed, Sanofi Aventis, Schering- Plough, Servier, Solpharm, Pliva, Belupo, Farmal, Pharma Swiss, etc.

Transparency



- HZZO's webpage:
 - All applications to the lists
 - Membership of the Committee for Medicinal Products and CVs
 - Annual schedule of the committee's sessions
 - Agendas of the committee's sessions
- The committee works in 2 semi-annual cycles
 - And has to rank the proposals that increase costs (Delphi, reaching consensus among 13 committee members)

Decision making improved

- **Criteria based on which the Committee reaches its conclusions introduced:**
 - importance of a medicinal product from the public health viewpoint;
 - therapeutic importance of a medicinal product
 - relative therapeutic value of a medicinal product;
 - assessment of ethical aspects and
 - quality and reliability of data and assessments from reference sources.
- **Company proposals have to include:**
 - Reimbursement status in all EU members
 - Strict scientific evidence (meta analysis, systematic review of RCTs, etc. if available)
 - Croatian and EU therapeutic guidelines
 - Estimated No of patients
 - Current medical practice and how it will be changed
 - Estimated of % of patients who can't be satisfactorily treated without the new drug
 - Comparison of cost of therapy with listed drugs by patient

Criteria for “the expensive drugs list” defined

- Hospital use exclusively
- Strict determination of indication by the Croatian Medical Association
- Cost of therapy too large to be paid from hospital budgets
- Breakthrough in the benefit-risk ratio of the therapy
- No generic alternatives
- Or less expensive compared to a drug already on the list
- Or orphan medicinal product

Budget impact analysis

- In the past companies underestimated costs of new drugs
- Strict regulation in line with ISPOR's "Principles of Good practice for Budget Impact Analysis"
- Results used for payback and cross product agreements

- ...
- CEA should (in the future) be undertaken by the Croatian Agency for Quality and Accreditation in Health Care

Patient centered system

- We are all here for the patients
- Productive collaboration with patient association
- In the past all factors were delivered to a single depot for the entire country

- All factors delivered to pharmacies of choice or hospitals as of 2009
- Improving access for hemophilia home treatment patients
- Increasing quality of life and independence
- Preventing cold chain failure
- Monitoring and evaluation of prescribing and compliance



Thank you for your attention