# Croatian 2009 - 2010 pharma reform

ensuring value for money, improved decision making and process transparency

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# Overview

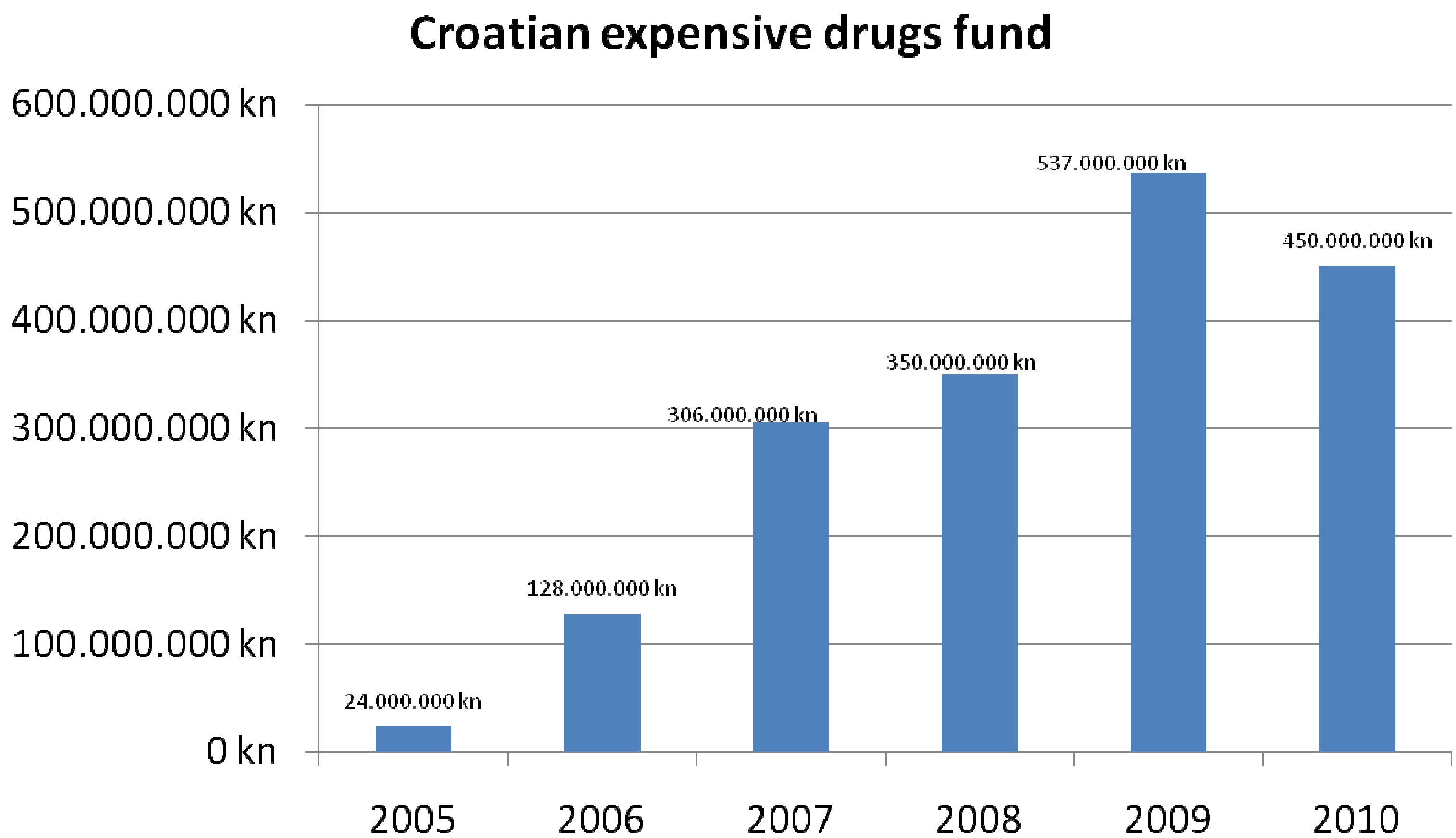
- Snapshot of the Croatian (HZZO's) market in 2009
- Market development from 2002 to 2008
- Pricing and price related reimbursement regulation
- Pricing related regulation effects from 2008 – 2010
- The 2009 -2010 reform:
  - "Pay back" agreements for new blockbuster products
  - "Cross product" agreements 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

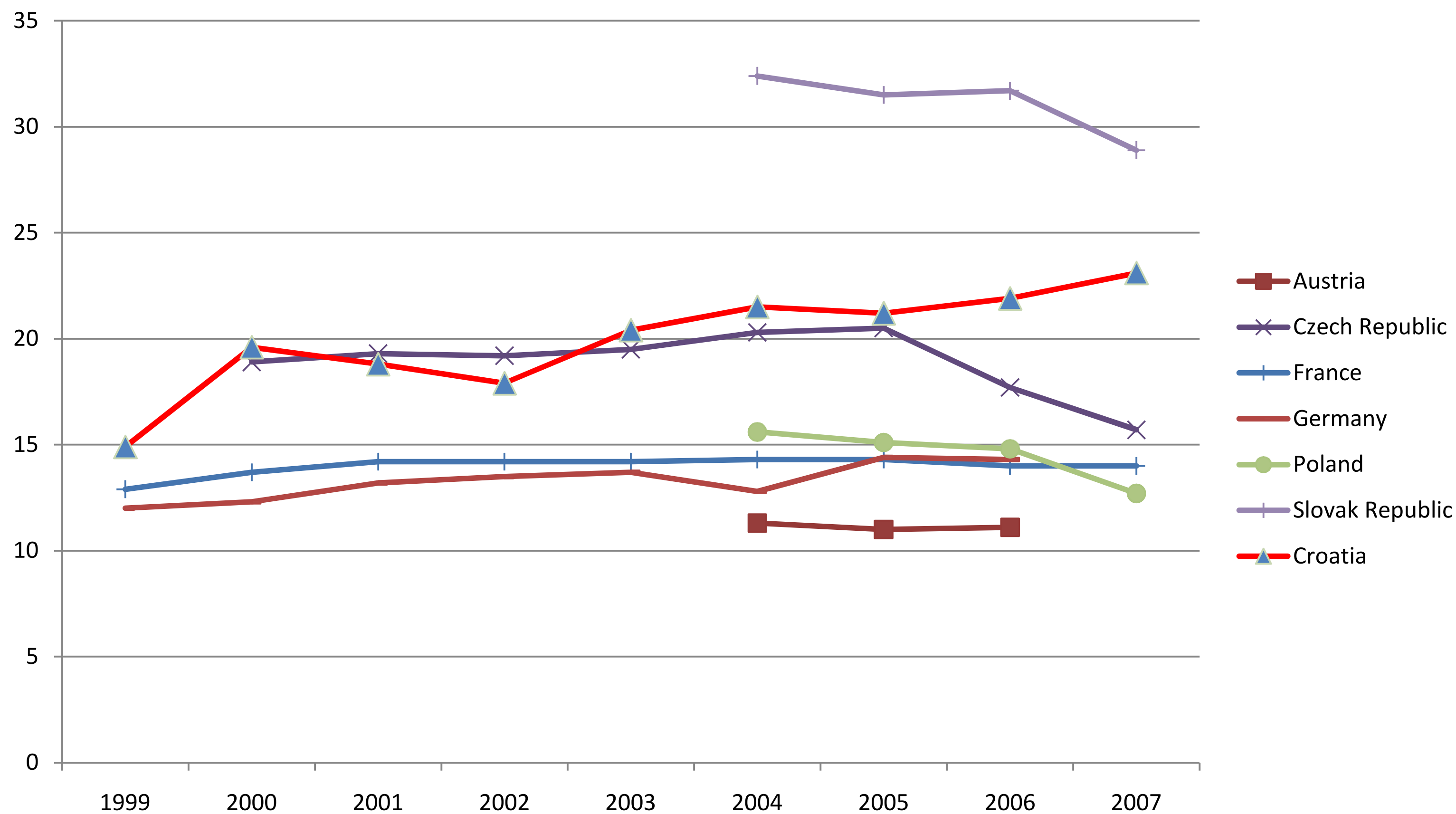
| Rp | 3 billion kn | US$ 588 million |
|---|---|---|
| Hospitals | 1.5 billion kn | US$ 294 million |
| Expensive drugs | 0,5 billion kn | US$ 100 million |

- 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



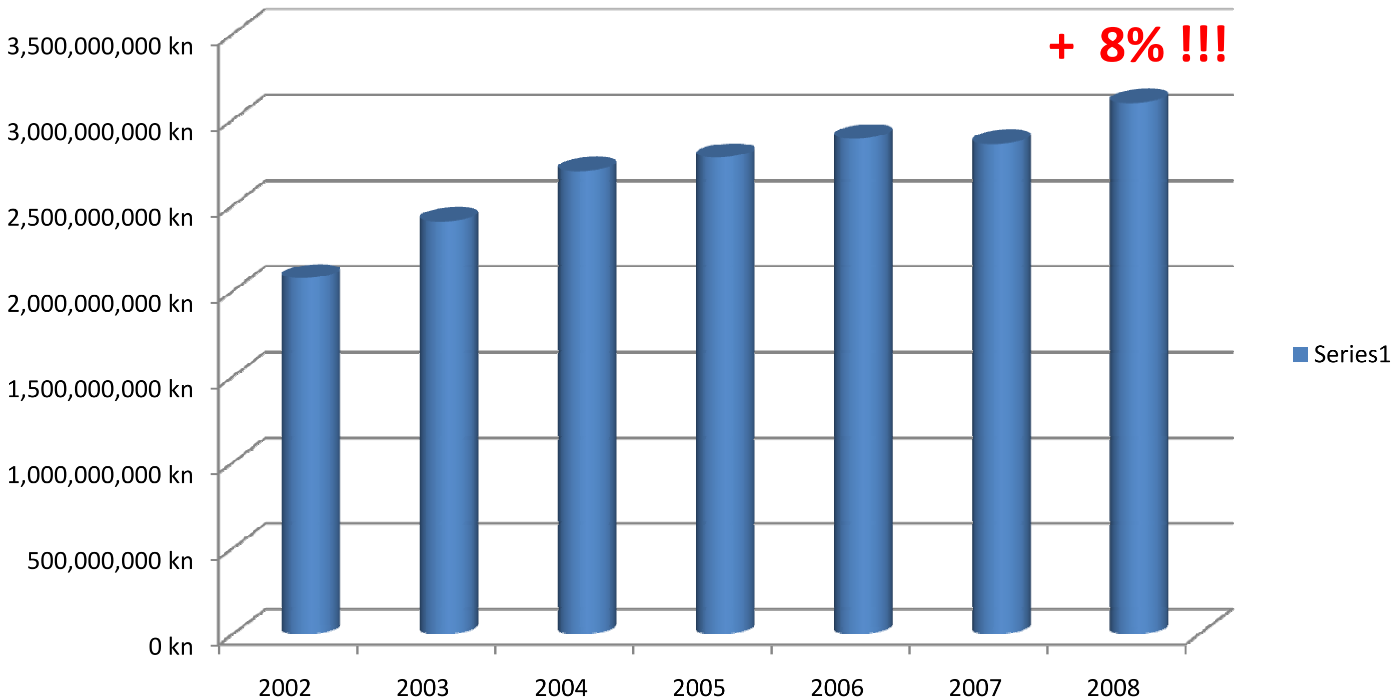
# Exp on medicines as % of total health exp




Sources: OECD Health Data 2009 - Verzija: lipanj 09; HZZO for Croatia

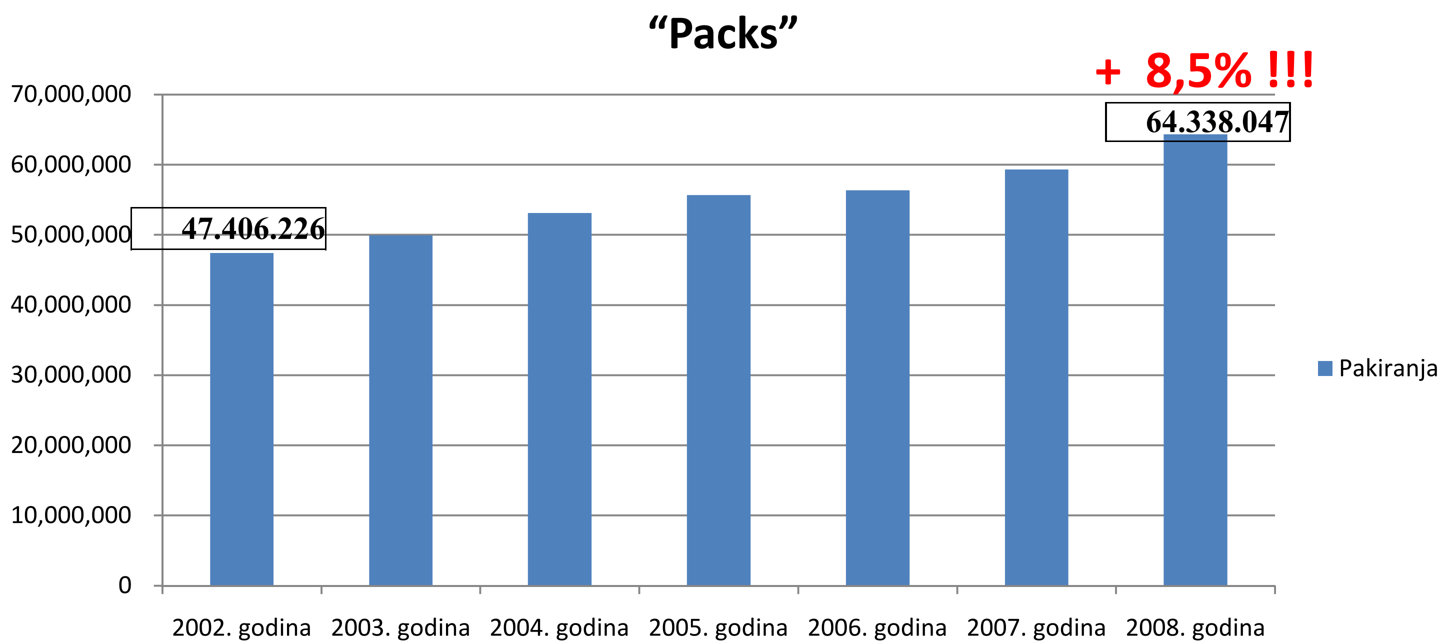
# Rp Exp from 2002 to 2008

**+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 |

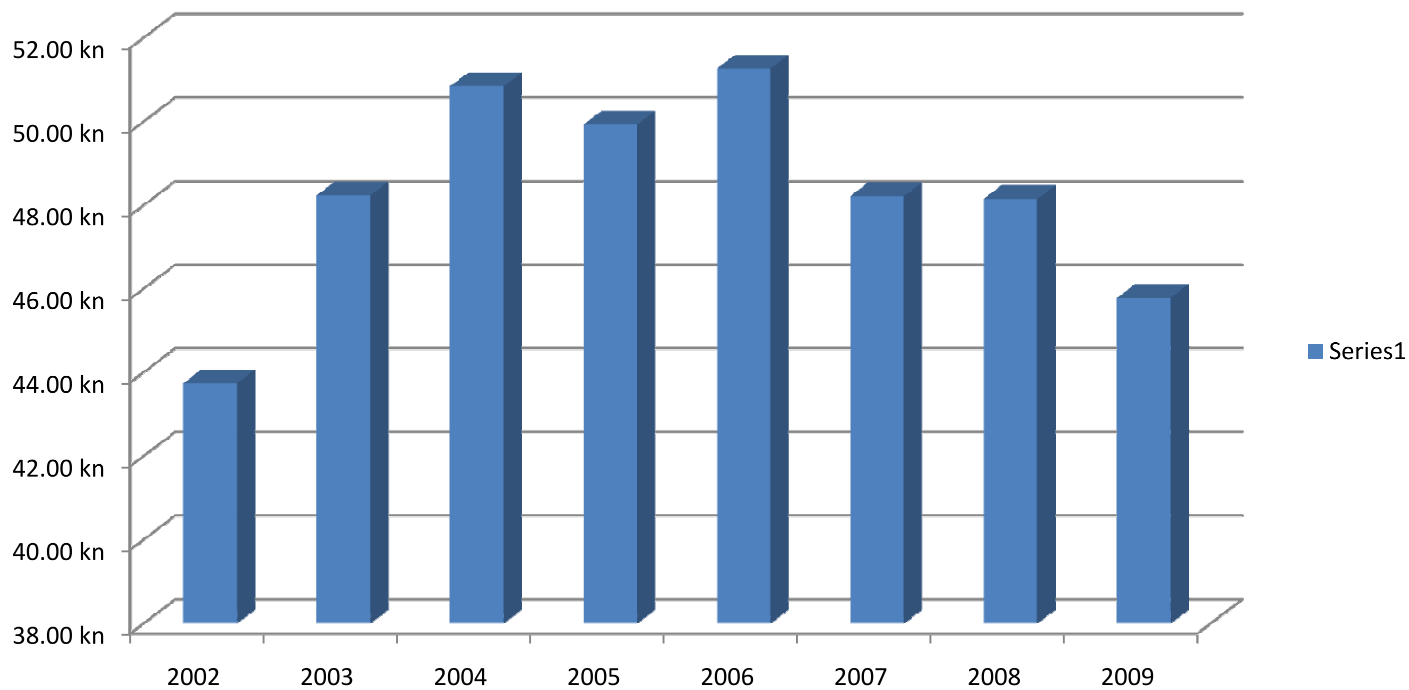
# Price related reimbursement

- **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”

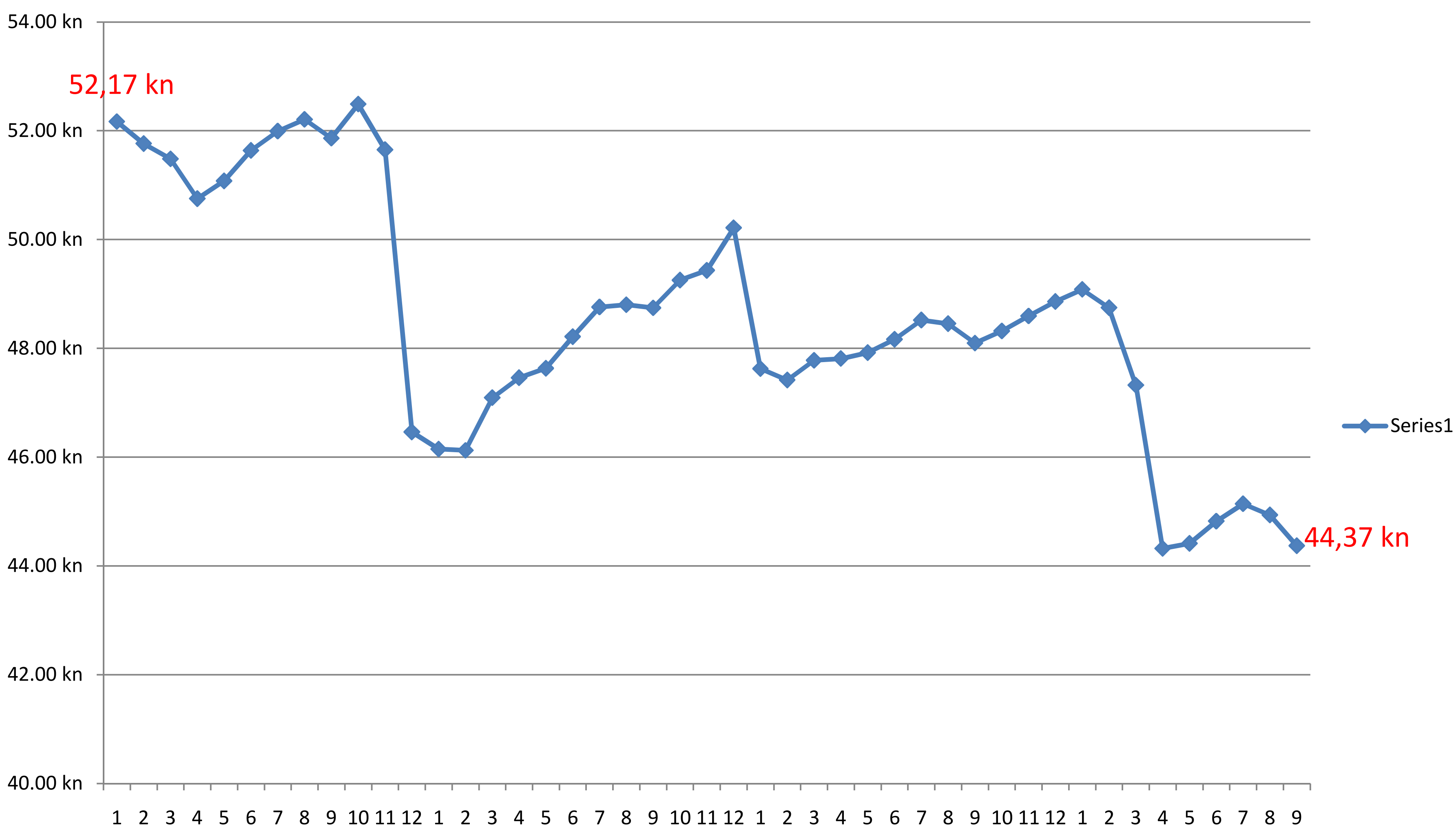
- **A (100% coverage) & B (co-payment up to the reference price) lists**

- **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

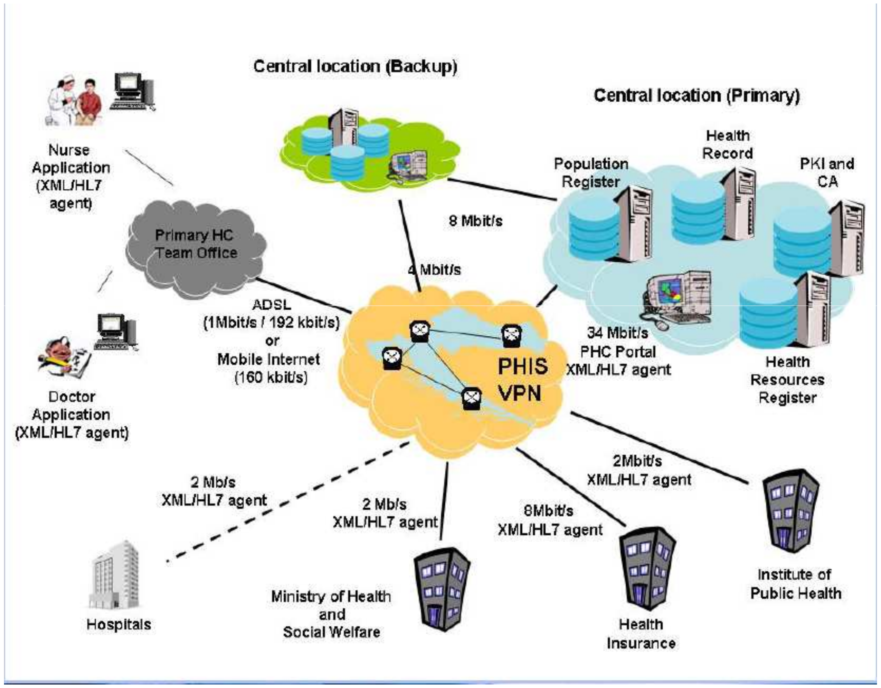
- Listing of drug A conditioned by price cuts on drug B
- Overall budget impact neutral or negative through class effect
- New drugs made available for patients

- 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

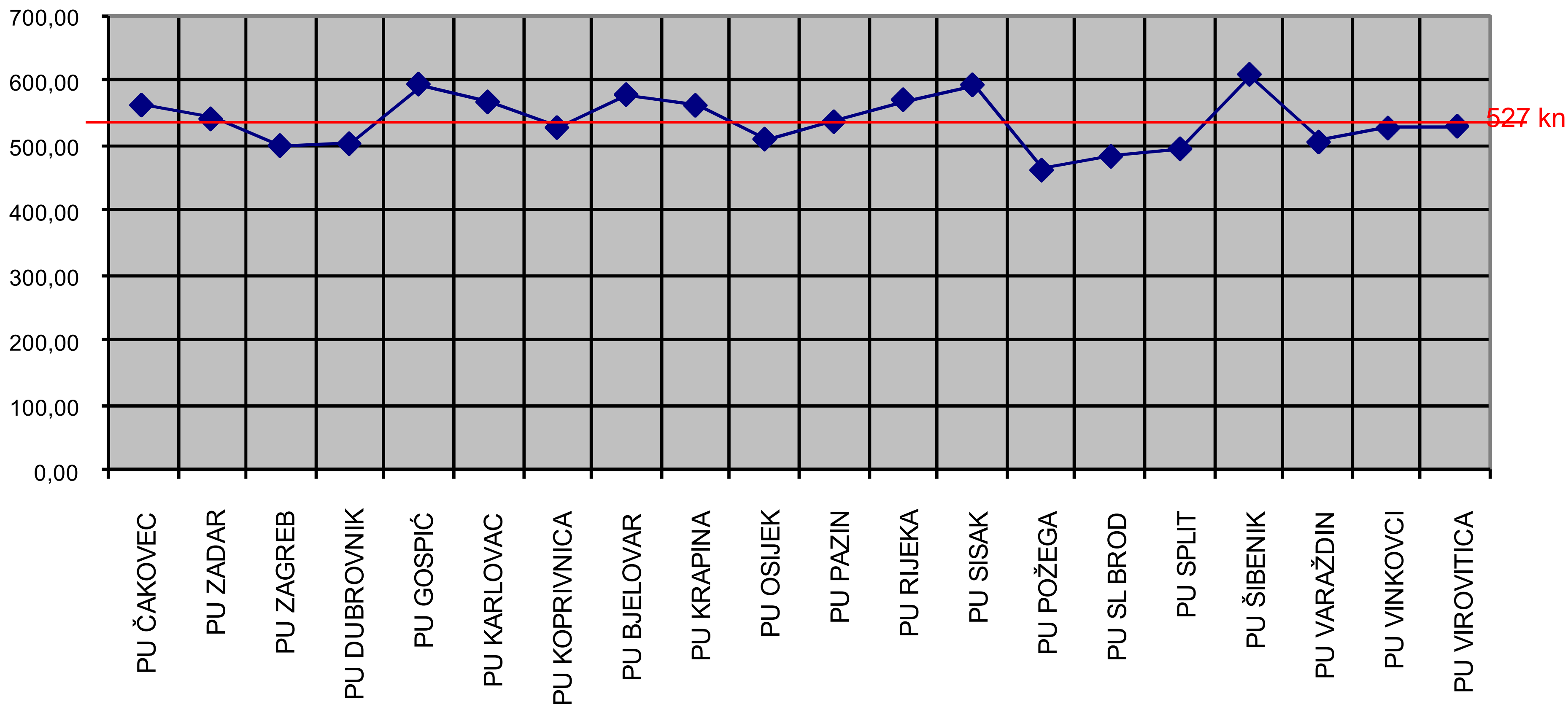
# E - prescriptions

- 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, hipertension, 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 committe 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 to 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