

CHANGES IN THE PRICES OF MEDICINES REIMBURSABLE BY THE HEALTH INSURANCE FUND AFTER THE IMPLEMENTATION OF REFERENCE PRICING IN THE REPUBLIC OF MACEDONIA

Prof. Bistra Angelovska PhD, Ass. Verica Ivanovska MPH
Faculty of Medical Sciences
University of Shtip, Republic of Macedonia

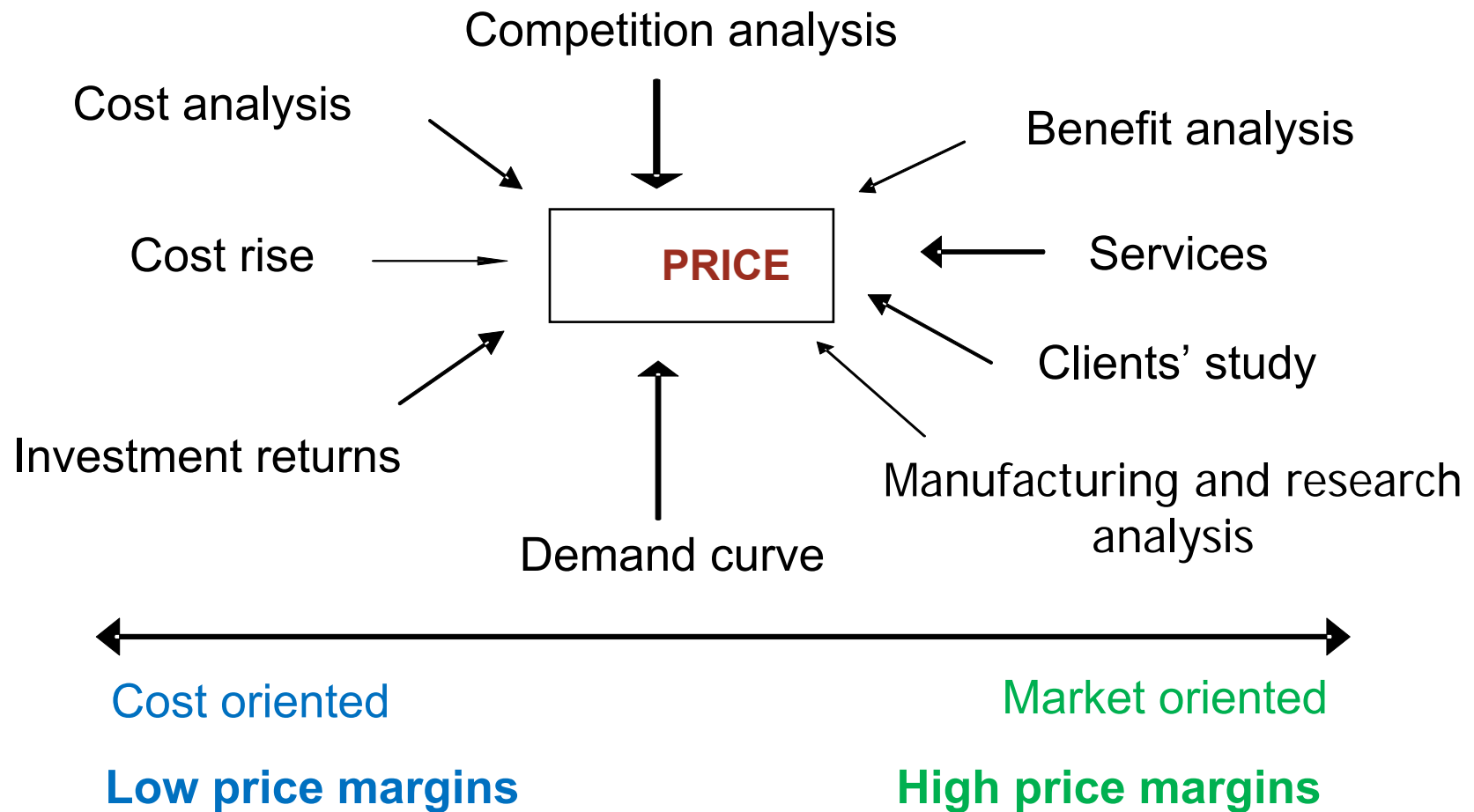


Medicines price components:

- ❑ Manufacturing cost
- ❑ Import duties
- ❑ Taxes / VAT
- ❑ Service costs
- ❑ Markups
(importers, distributors, retailers)
- ❑ Others



Medicines price components



Methodology for price control of medicines

- ❑ Systems with incentives for generic medicines
- ❑ Cost based on expenditure
- ❑ Negotiated prices
- ❑ Retail fees
- ❑ Mandatory discounts and price reductions
- ❑ Price index
- ❑ Tender prices
- ❑ Based on cost-effectiveness analysis
- ❑ Reference pricing
- ❑ Patients' share of costs

Reference prices

Definition: Reference pricing (RP) system means that the purchaser (health insurance fund etc.) decides which price to pay for the medicines, while the patient or other insurer pays the difference up to the market price.

AIMS of the RP system in Republic of Macedonia:

- Ensure access to all necessary medicines
- Ensure the best treatment for the lowest possible cost
- Stop the rise of costs for the medicines with the same effectiveness/safety
- Avoid the shortening of the Positive list (PL) of medicines
- Enable the introduction of new medicines

History of medicines prices in the Republic of Macedonia

Legal regulation until 2005:

- No mechanisms to control medicines price – price components could not be determined
- VAT - 18%, import duties - 4% for medicines from the EU and 1% from the former Yugoslav republics, undefined wholesales margins, 13% retails markups for medicines reimbursable by the Health Insurance Fund (undefined for the rest)
- Health Insurance Fund (HIF) organized 5 tenders (2 international) for the Positive List medicines– indirect method to control medicines prices in the public system
- HIF reimbursed costs only up to the level chosen by the tender

Tenders for supply of medicines in the Republic of Macedonia

Advantages

- Successful in providing lower prices of medicines where competition exists (generics) – average 45% decrease compared with the previous year

Disadvantages

- Takes a long time, manipulations are possible, difficult to undertake for specific medicines with no or very little market competition (e.g. cancer therapy)
- The prices of medicines not supplied by tenders are not regulated, so the prices of similar or the same medicines are different in different pharmacies

Consequences

- Growing support to control the prices of medicines not reimbursable by the HIF

Price control of medicines in the Republic of Macedonia

Previous legal basis

Law on Medicines and Medicinal Products 1998

(Official Gazette of the Republic of Macedonia No.21/1998)

- Price control for medicines from the Positive list (no by-laws created)

Law on Health Care Insurance *(Official Gazette of the Republic of Macedonia No.119/2005)*

- HIF determined the reference prices of the reimbursable medicines and medical devices



International consultations for the price control of medicines

2005: The last international tender for the supply of medicines ended up

Agreement – Regulate medicines prices by reference pricing (RP) system

2006 – 2010: International consultation process

Health Sector Management World Bank Project: Technical assistance on pricing and reimbursement policy of medicines

Three consultants contracted: Dr. Arie Rietveld (2006), Dr. Stanislav Primozic (2009) and Dr. Tonci Buble (2009/10)

International consultations for the price control of medicines (1)

Dr. Arie Rietveld's 2006 recommendations:

- ❑ Introduction of international reference pricing for medicines
- ❑ Set up reimbursement limit system of medicines
- ❑ Harmonization with the EU regulation
- ❑ Information sharing and participation of all stakeholders in the upcoming reforms

Results:

- ❑ Changes in the Law on Health Care Insurance in 2007
- ❑ Rules on determination of prices of medicinal products for human use
- ❑ New Law on Medicinal Products and Medical Devices 2007

New Law on Medicinal Products and Medical Devices

Official Gazette of RM No.106/2007

Articles 107 & 108 prescribe unified prices for medicines

The basic **elements** that comprise the price of medicines:

- Manufacturing costs in MKD (manufacturers and importers are obliged to provide the manufacturing cost of medicines)
- Wholesale markups
- Retail markups

Fixed markups: wholesales markups are 9-15% and retail markups 15-30% of medicines cost

Changes in the Law on Health Care Insurance

Official Gazette of RM No.36/2007

4 new articles to define reference pricing:

- ❑ The lowest wholesale cost of medicines registered in the Republic of Macedonia
- ❑ Comparative analysis of the reference prices of medicines on the Positive list in the referent countries (Slovenia, Croatia, Bulgaria, Serbia)
- ❑ Criteria to determine the price of medicines is the average of the two lowest ratios (reference price – GDP per capita) in the reference countries compared with GDP per capita in the Republic of Macedonia using the purchasing power parity PPP methodology according to the World Bank final official data
- ❑ Referent prices to be determined by HIF and agreed by the Ministry of Health

Rules on Determination of Medicines Prices 2008

Official Gazette of the Republic of Macedonia No.8/2008

In accordance with the changed Law on Health Care insurance

Technical criteria:

- ❑ Based on PPP methodology
- ❑ On the level of comparable wholesales price
- ❑ The lowest offered price on the last medicines tender
- ❑ Unified wholesales price determined by the Law on Medicinal Products and Medical Devices

Drawbacks:

- ❑ The methodology to determine RP not clear (mixed methodology)
- ❑ Used terms not defined precisely
- ❑ Technical criteria not clear

New determined reference prices of medicines in 2008

RP adopted by the HIF Steering Committee

Determined as comparison of the lowest offered price on the last medicines tender and the unified wholesales prices according to the Medicines Law – lower price taken

- ❑ Rigid and not adapted legal regulation does not allow substantial modifications of some rules in compliance with the actual state and needs
- ❑ Changes in the law and the rules did not give the expected results (rationalized medicines costs and controlled medicines prices)
- ❑ Changes on unified medicines prices not in line with EU regulations
- ❑ Legal regulation shall be changed in order to make executive rules that elaborate new methodology with all technical details

International consultations for the price control of medicines (2)

Dr. Stanislav Primozac's 2009 recommendations:

- ❑ The system of unified medicines prices shall be preserved until new RP system of standard prices is adopted.
- ❑ Law as legal basis for medicines prices determination is high level of decision making, rigid and not flexible for fast development of health care sector and the economy
- ❑ Medicines Law to be more conceptual for medicines price regulations, technical details to be given as executive rules
- ❑ New legal frame required in order to comply with EU rules

Results:

- ❑ Changes in the Medicines Law (*Official Gazette of the Republic of Macedonia No.88/2010*), omitted parts on methodology for unified medicines prices
- ❑ Opportunity to issue new rules on methodology that determine medicines prices

International consultations for the price control of medicines (3)

Dr. Tonci Buble's 2009/2010 stands and recommendations:

- ❑ Legal frame not adapted for the rationalization of medicines costs
- ❑ Incomplete rules for the inclusion of medicines on PL
- ❑ Methodology on RP determination not clear enough
- ❑ No rules on price calculations based on indications and dosing
- ❑ No rules on price calculation for hospital medicines
- ❑ No reliable data on medicines use

Results:

- ❑ Consensus on changes of the Law on Health Care Insurance (*Official Gazette of the Republic of Macedonia No.50/2010*), omitted article 63b on RP methodology
- ❑ Opportunity to develop new rules on RP criteria and procedures

Rules on Determination of RP criteria and procedures 2009

Official Gazette of the Republic of Macedonia No.158/2009

RP Criteria:

- ▣ Reference prices in referent countries (Slovenia, Croatia, Bulgaria, Serbia) from defined data sources
- ▣ Average comparable medicines price
- ▣ The level of comparable prices in line with PPP indicator and on the following basis:
 - For medicines with no generic competition according to ATC classification and prices higher than average comparable price ($>100\%$), average comparable price is multiplied by 1
 - For medicines with generic competition and prices 79,23% higher than average comparable price, average comparable price is multiplied by 0,7923. This coefficient is used for all medicines with same generic name

Current Reference Pricing Methodology

- ❑ Defined reference prices for medicines that use RP methodology for the first time
- ❑ For medicines where no comparable prices are available, prices are determined based on pharmaco-economic study provided by the marketing authorization holder
- ❑ When different prices are calculated for medicines with same safety and efficacy (therapeutically equivalent medicines), pharmacological therapeutic groups are determined and unified RP calculated based on nr. unit in the package, defined daily dose and medicines strength
- ❑ The decision made by HIF on RP determination shall be published in the Official Gazette of RM once the agreement is reached with the Ministry of Health
- ❑ RP shall be determined annually

Table 1: Prices of 20 most used medicines from PL in tender 2004 and in RP 2009 (1-10)

No	ATC code	Generic name-INN	Dosing forms	Strength	Packaging	Unified price	Unit reference price
1	C09AA02	enalapril	tablets	20 mg	20	35,93	17,14
2	C04AD03	pentoxifillin	tablets	400 mg	20	70,00	63,81
3	C09AA02	enalapril	tablets	10 mg	20	30,00	16,19
4	C09AA03	lisinopril	tablets	20 mg	20	139,83	17,14
5	A02BA02	ranitidin	tablets	150 mg	20	58,90	21,90
6	A10BB01	glibencamid	tablets	5 mg	30	50,08	20,00
7	J01CR02	amoxicilline+ clavulonic acid	tablets	(875+125) mg	10	200,17	153,33
8	J01DA01	cefalexin	capsules	500mg	16	53,56	85,71
9	C09AA03	lisinopril	tablets	10 mg	20	150,00	16,19
10	N05BA08	bromazepam	tablets	3 mg	30	18,05	18,10

Table 1: Prices of 20 most used medicines from PL in tender 2004 and RP 2009 (11-20)

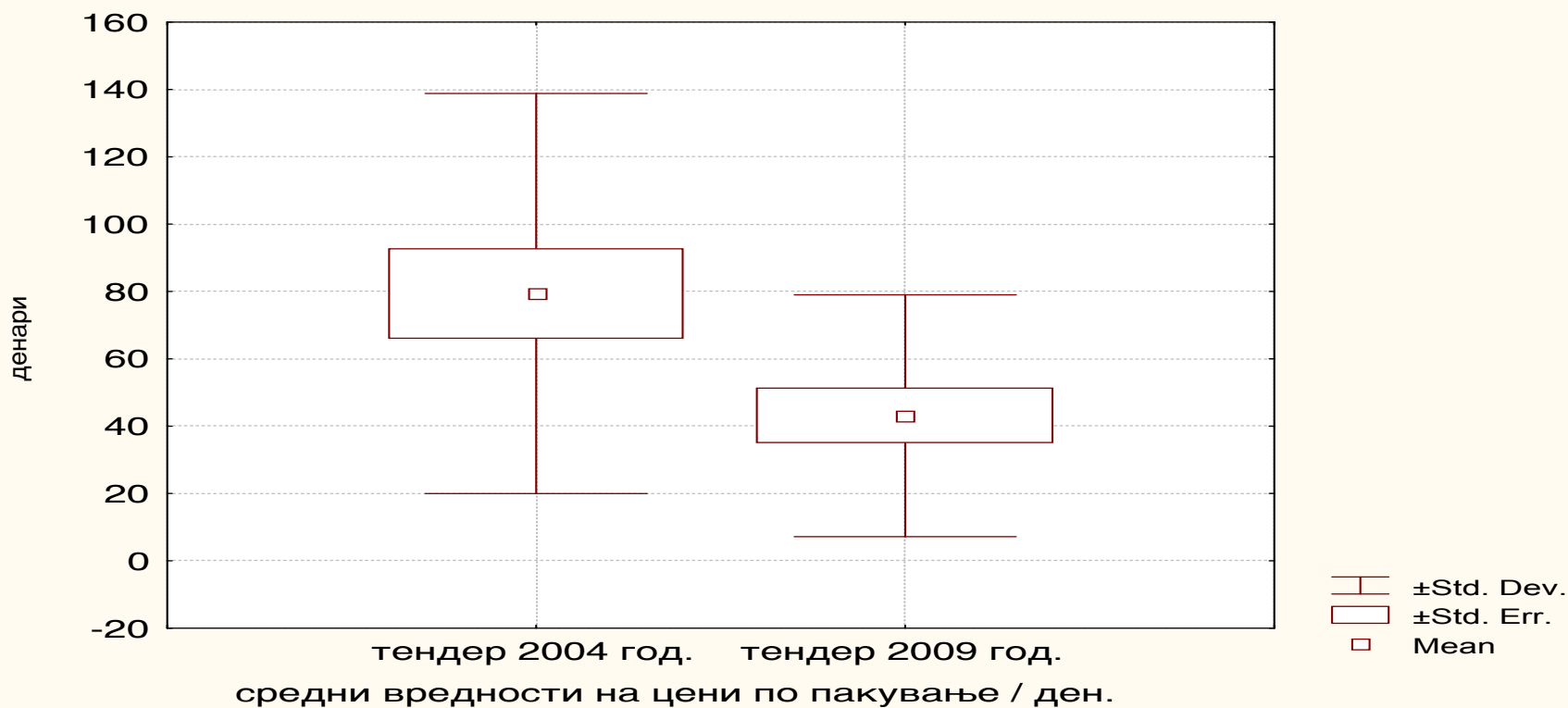
No	ATC code	Generic name- INN	Dosing forms	Strength	Packaging	Unified price	Unit RP
11	C08DA01	verapamil	Coated tablets	80 mg	50	44,07	44,76
12	C08CA01	amlodipine	tablets	10 mg	20	135,08	24,76
13	C07AB03	atenolol	tablets	100 mg	15	14,00	22,86
14	J01MA02	ciprofloxacin	tablets	500 mg	10	52,97	30,48
15	C08CA05	nifedipine	tablets	40 mg	20	213,32	18,10
16	R03DA05	aminophylline	tablets	350 mg	20	49,15	53,33
17	J01CR02	amoxicilline+ clavulonic acid	suspension	475 mg/5ml	70 ml	123,99	73,33
18	C09AA02	enalapril	tablets	5 mg	20	26,00	15,24
19	C08DB01	diltiazem	tablets	90 mg	30	64,07	60,95
20	J01DA01	cefalexin	suspension	250 mg/5ml	100 ml	58,47	88,57

Table 1: Changes in prices (%) of 20 most used medicines from PL in tender 2004 and RP 2009

Medicine prices tender 2004 (100%)	Medicine prices RP 2009 (% of 2004)	Difference 04/09
35,93 (100%)	17,14 (47,7%)	52,3% ↓
70 (100%)	63,81 (91,2%)	8,8% ↓
30 (100%)	16,19 (54%)	46% ↓
139,83 (100%)	17,14 (12,6%)	87,4% ↓
58,9 (100%)	21,9 (37,2%)	62,8% ↓
50,08 (100%)	20 (39,9%)	60,1% ↓
200,17 (100%)	153,33 (76,6%)	23,4% ↓
53,56 (100%)	85,71 (160%)	60% ↑
150 (100%)	16,19 (10,8%)	99,2% ↓
18,05 (100%)	18,1 (100,3%)	3,0 ↑
44,07 (100%)	44,76 (101,6%)	1,6% ↑
135,08 (100%)	24,76 (18,3%)	81,7% ↓
14 (100%)	22,86 (163,3%)	63,3% ↑
52,97 (100%)	30,48 (57,5%)	42,5% ↓
213,32 (100%)	18,1 (8,5%)	91,5% ↓
49,15 (100%)	53,33 (108,5%)	8,5% ↑
123,99 (100%)	73,33 (59,1%)	40,9% ↓
26 (100%)	15,24 (58,6%)	41,4% ↓
64,07 (100%)	60,95 (95,1%)	4,9% ↓
58,47 (100%)	88,57 (151,5%)	51,5% ↑

Table2A/Graph1: Av. prices (MKD per pack) in 2004 and RP 2009

Year	Average	Standard deviation	min	max
2004	79,38	59,40	14,00	213,32
2009	43,09	35,91	15,24	153,33



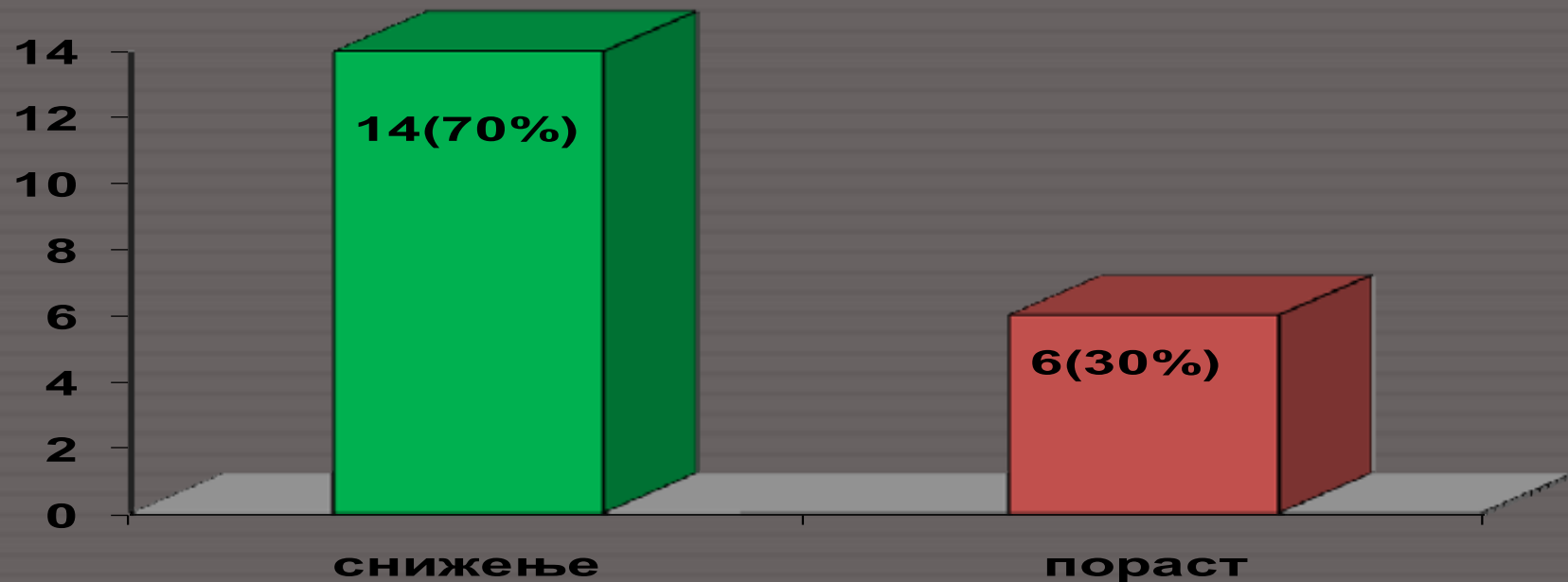
Analysis of changes in prices (%) of 20 most used medicines from PL in tender 2004 and RP 2009

- There is a statistically significant difference in the average prices per pack of the 20 most used medicines from PL reimbursable by HIF between 2004 and 2009 (Mann-Whitney U Test: $Z = 2,164$, $p = 0,0304$)
- Higher RP of some medicines in 2009 may be result of some price manipulations by the tender competitors in 2004
- Some generic medicines were offered under much lower prices by the domestic industries compared with their prices given in 2007 when the unified prices were being determined



Table 3/Graph 2: Increase or decrease in price per pack in tender 2004 - RP 2009

Tender 2004 / 2009	Nr. (out of 20)	%
Decreased price per pack	14	70
Increased price per pack	6	30



Analysis of changes in prices (%) of 20 most used medicines from PL in tender 2004 and RP 2009

- Out of 20 medicines, 14 (70%) have decreased prices per pack between 2004 and 2009. There is a significant difference between the number of medicines with decreased and increased prices per pack. (Student t-test: $p = 0,0157$)
- This analysis shows the economic justifications of the introduction of RP system



Outcomes of introducing the reference pricing in R. Macedonia

- ▣ **PROS:** RP system generally decreases medicines prices, gives bigger choice to patients and doctors, supports the free market of medicines, saves HIF finances, and helps return big percent of the saved finances back to the HIF for other health care activities
- ▣ **CONS 1:** The difference in price up to the market price is paid by the patients (out-of-pocket) as no additional health insurance exists in R. Macedonia
- ▣ **CONS 2:** The difference in price is sometimes 2-3 times bigger than the reference price
- ▣ **CONS 3:** The difference in price shall be paid for many medicines

Recommendations on RP in the Republic of Macedonia

- ❑ **Conclusion:** The process of RP system development and implementation has not been completed yet.
- ❑ **Recommendation 1:** Harmonize national regulations on medicines to support selection on new medicines for PL
- ❑ **Recommendation 2:** Establish better relationship between the price of medicines and their indication and dosing
- ❑ **Recommendation 3:** Make calculation rules on prices of medicines for hospitals
- ❑ **Recommendation 4:** Ensure reliable information on medicines use
- ❑ **Recommendation 5:** Introduce the procedure for medicines price calculations
- ❑ **Recommendation 6:** Make rules on medicines price determination in hospitals
- ❑ **Recommendation 7:** Improve communication between all stakeholders on all medicines price activities.

Thank you for your attention!

