

Reimbursement restriction moderately decreases benzodiazepine use in general practice

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BACKGROUND

In the Netherlands, a change in the reimbursement status of benzodiazepines was announced mid 2008 and came into force on January 1st 2009. Benzodiazepines now are excluded from reimbursement when used as anxiolytic, hypnotic or sedative. The rationale for this restriction was to avoid irrational use of benzodiazepines and to limit the health care costs.

OBJECTIVES

To assess the impact of the reimbursement restriction on benzodiazepine use in patients newly diagnosed with anxiety or sleeping disorder in Dutch general practice.

METHODS

Design & setting: Retrospective observational database study deriving data on diagnoses and prescription data from the electronic medical records based Netherlands Information Network of General Practice (LINH).

Population: Patients prescribed with an incident diagnosis sleeping disorder (n=6,117) or anxiety (n=7,479) in 2008 or 2009

Outcome measures: Incidence of these diagnoses, benzodiazepine use and initiation of SSRI treatment

Analyses: Incidence rates, Cox regression analyses

RESULTS

Figure 1 shows that there was a statistically significant lower incidence of sleeping disorders in the first three quarters of 2009 compared to these respective quarters in 2008. For anxiety, diagnoses in the first and third quarter of 2009 were significantly lower compared to 2008. Incidence was higher in women compared to men. Figure 2 shows that the percentage of newly diagnosed patients who were prescribed a benzodiazepine slightly decreased in 2009 compared to 2008. The decrease was higher for sleeping disorders. No differences were found between men and women and between age categories

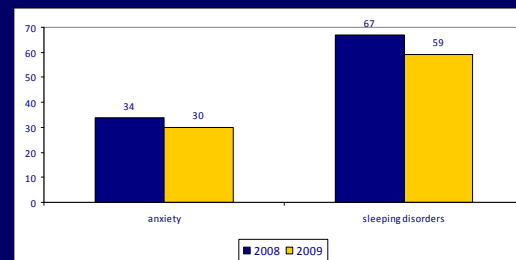


Figure 2: Newly diagnosed patients, % with benzo

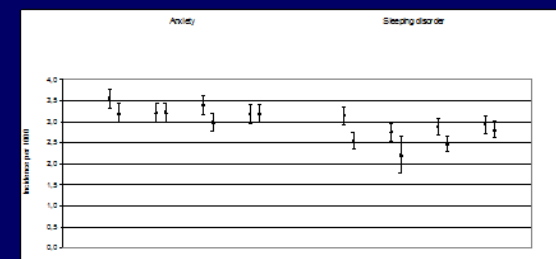


Figure 1: incidence rates 2008 & 2009

In patients with benzodiazepine prescriptions, the proportion of patients being prescribed more than one benzodiazepine was lower in 2009 compared to 2008 for both anxiety (36.4% versus 42.6%,) and sleeping disorders (35% versus 42.6%).

Patients newly diagnosed with sleeping disorder in 2009 had a lower risk of discontinuation than patients newly diagnosed with sleeping disorder in 2008 (HR 0.63 95%CI 0.52-0.76). No such differences were found for anxiety.

For patients The reimbursement restriction had no effect on switching to SSRI treatment among patients discontinuing benzodiazepine treatment when being diagnosed with anxiety.

CONCLUSION

The reimbursement restriction has led to a moderate decrease in the number of incident diagnoses and initiation of benzodiazepine use in patients being newly diagnosed with anxiety or sleeping disorder. This indicates that in settings where no such reimbursement settings exist physicians have room to reduce benzodiazepine prescribing.

Recent policies to reduce drug costs and the budget deficit in Croatia: impact and example to others

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Introduction

Croatia has recently introduced reforms to reduce the drug budget deficit without compromising the quality of care. This includes reference pricing for existing drugs in classes (ATC Levels 3 to 5) where these are seen as essentially similar, prescribing restrictions, greater transparency in the pricing of new drugs based on their added therapeutic value, as well as limitations on pharmaceutical company marketing activities.

These builds on existing reforms, which had already improved prescribing efficiency for the PPIs and statins.

Objective

Document recent reforms in Croatia and their impact to provide guidance to other European countries struggling to fund and existing new drugs within increasing resource pressures.

Methodology

- a) Document recent reforms based on published papers supplemented with feedback from the co-authors
- b) Document the impact of recent reforms on overall pharmaceutical expenditure in recent years, as well as the number of new innovative products granted reimbursement, based on:
 - i) data within the Croatian Institute for Health Insurance
 - ii) published papers
 - iii) feedback from the co-authors

Conclusions

The multiple reforms and initiatives in Croatia appear to have enhanced prescribing efficiency whilst concurrently increasing access to new medicines. This will continue with further price reductions for generics following recent measures.

As such, provide an example to other European countries struggling to provide equitable and comprehensive healthcare including funding new drugs

Results

Greater follow-up of prescribing restrictions in Croatia (academic detailing and possibly fines for prescribing abuse) considerably moderated prescribing of angiotensin receptor blockers (ARBs) versus angiotensin-converting enzyme inhibitors (ACEIs) between 2001 and 2007 keeping expenditure steady. Expenditure should now fall.

A) Initiatives with new drugs

- I) Similar measures to other EU countries with the therapeutic value of new drugs divided into 3 groups:
 - i) Innovative where no drug currently exists, i.e. a 'breakthrough'. Reimbursed price = average of Italy, France and Slovenia
 - ii) Added value demonstrated by (reimbursed price up to 90% of the price in these 3 EU countries):
 - More favourable outcome including improvement in HRQOL and/ or reduced side-effects
 - More 'user-friendly' formulation improving compliance
 - Improved overall efficiency vs. current standards
 - iii) A new product with no added value (90% of the price of current standard drugs in the class in Croatia)In addition estimates of budget impact and prices vs. existing treatments. Payback mechanisms for any agreed over-budget situation to limit payer exposure.
- II) Increased scrutiny over pharmaceutical company activity including limiting physician contact, scrutiny on promotional material and ban on financial remuneration to physicians, e.g. funding of conference attendance

B) Initiatives with existing drugs

- i) Generic products – initially up to 70% of average in France, Italy, and Slovenia; further generics - 10% less than last generic (other countries included if data not available)
- ii) Reference pricing within existing clusters (ATC Level 3 and 4) as well as for the molecule (ATC Level 5)
- iii) Co-payments (15kn - €2)/ item. Additional co-payments for more expensive products than reference price (molecule or cluster)

C) Impact of the recent reforms

- (a) Health Insurance expenditure in ambulatory care in 2009 was 2.9bnkuna (€393mn), 2.9% below 2008; 2bn kuna on hospital drugs (480mn kuna on expensive hospital drugs)
- (b) Ambulatory care expenditure in first 6 months of 2010 was 13% below similar period in 2009, with expenditure on expensive hospital medicines decreasing by 28.5%, leading to a 22% reduction in the Health Insurance deficit
- (c) 47 new innovative medicines added to the Health Insurance list from July 2009 to July 2010, and 13 medicines to the list of expensive hospital products. This compared to 45 medicines in total added to both lists between 2002 and 2009



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Trends in generic pricing policies in Europe: implications for sustaining equitable and comprehensive healthcare

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Introduction

Generic prices can vary by 36 fold across countries for certain molecules. It is essential that countries learn from each other to lower generic prices to continue providing universal and affordable healthcare as more standards drugs loose their patents.

Objective

Collate and document the different approaches to the pricing of generics across EU in an understandable format. Secondly, compare and contrast their impact on price reductions for selected generics versus pre-patent loss prices to provide future guidance.

Methodology

Retrospective observational study of the reduction in reimbursed expenditure/ Defined Daily Dose (DDD) (administrative databases) for generic omeprazole and simvastatin (ATC Level 5) versus 2001 originator prices among 17 EU countries (2010 DDDs) and validated. Similarly for generic ACEIs and SSRIs.

Generic pricing policies collated into three categories and validated with payers. Categories include:

- Prescriptive pricing (PP) – established price reductions vs. pre-patent loss originator prices
- Market Forces (MF) – market forces dictate price reductions with measures in place to encourage the prescribing of generics (molecule and in a class)
- Mixed Approach (MA) – prescriptive pricing for the first generic(s), market forces after that

Results

Each EU country can be divided into one of three pricing approaches for comparative purposes (Table 1).

Table 1 – Different generic pricing policies in EU

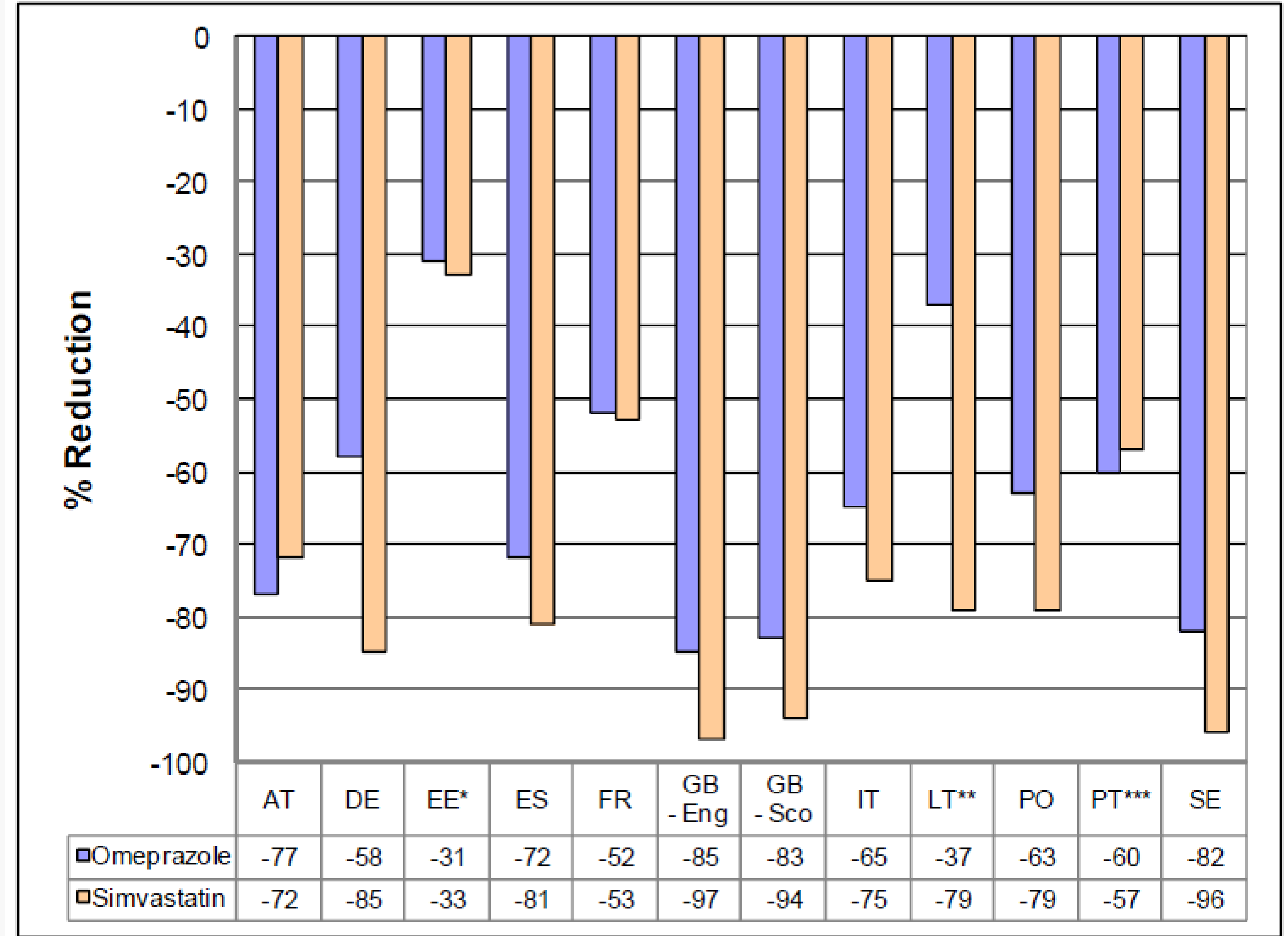
Pricing approaches	Countries
Prescriptive pricing (PP)	France*, Netherlands, Norway, Turkey
Market forces (MF)	Germany, Poland, Spain**, Sweden, United Kingdom
Mixed approach (MA)	Austria, Estonia, Finland, Italy, Lithuania, Portugal, Serbia

*France recently introduced reference pricing for certain molecules; ** Spain currently considering a mixed approach

Results (continued)

Differences seen in price reductions for generic omeprazole and simvastatin across Europe (Figure 1). Similar differences seen for generic ACEIs and SSRIs among European countries.

Figure 1 – % reduction generic prices in 2007 vs. originators in 2001 unless stated

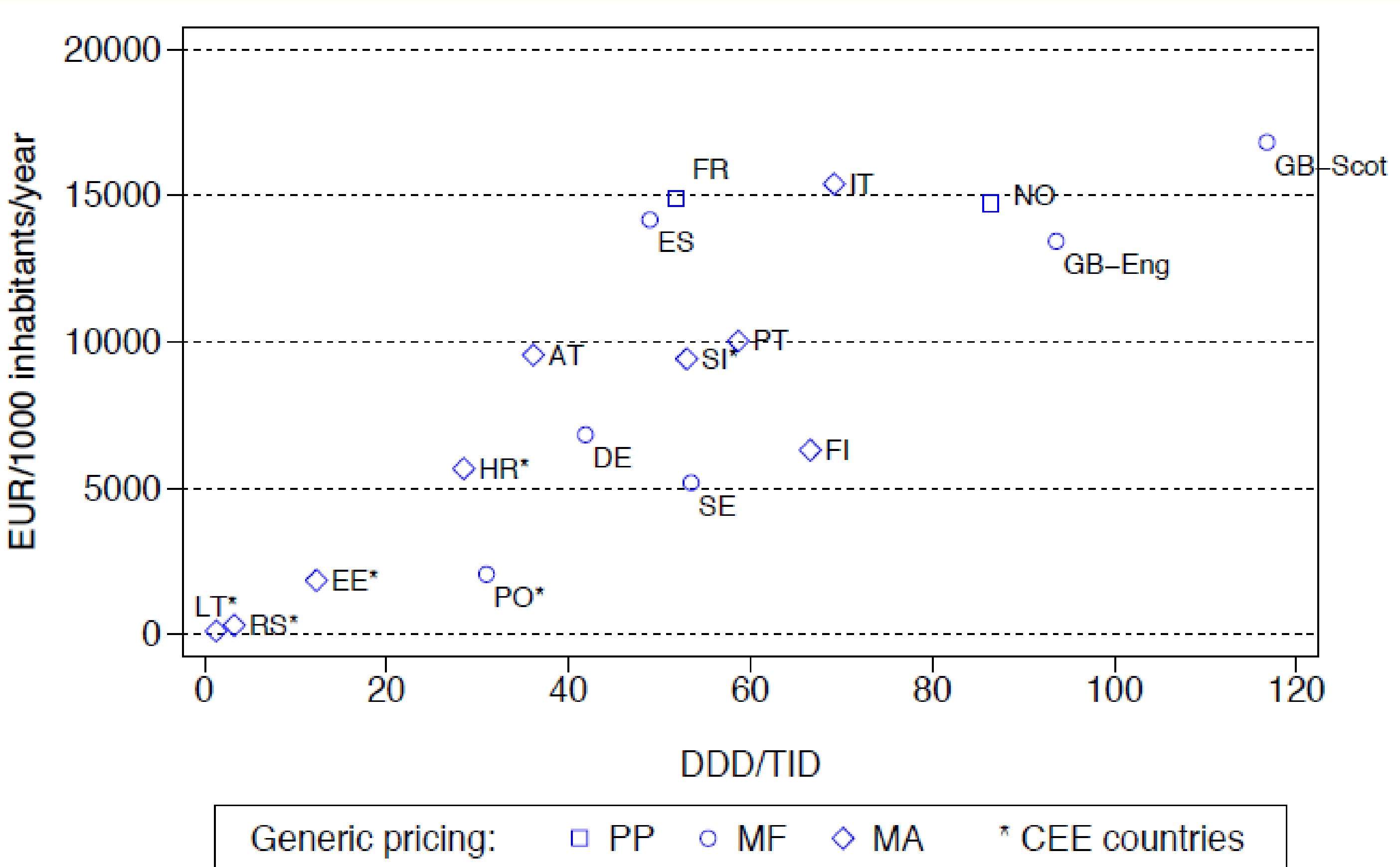


NB Applies to * 2004 originator, ** 2000 originator, ***2000 originator, Spain is Catalonia and 2003.

Conclusions

Pragmatic to collate the different approaches to the pricing of generics into 3, with greatest reductions with market forces. Countries already learning from each other to lower generic prices. Both supply and demand side reforms essential to maximize savings from generics to maintain European ideals. Figure 2 documents appreciable differences in expenditure between countries with similar statin utilisation (DDDs/ TID).

Figure 2 – Statin expenditure in 2007 versus utilisation (DDDs/ 1000 inhabitants/ year)



Essential to review health policy initiatives when comparing utilisation patterns?

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Introduction

Previous research has highlighted differences in the utilisation of statins across Europe (EuroMedStat study). However, there have been limited explanations for the differences seen to guide future policy.

Objective

Assess statin utilisation across Europe between 2001 and 2007, alongside ongoing health policy and other interventions, to provide explanations for any differences seen to shape future research and publications.

Methodology

Retrospective analysis of the influence of different demand side measures on subsequent utilisation of statins in over 20 European countries/ regions. Only administrative databases used, with utilisation rates computed in Defined Daily Doses (DDD – ATC/ DDD version 2010) and DDDs/ TID (Thousand inhabitants per day). Demand side reforms broken down by 4Es (Education, engineering, economics and enforcement) and validated with payers in each country to add robustness to the analysis

Main outcome measure is differences in DDD/ TID (Thousand inhabitants per day) from 2001 to 2007 alongside a description of the health policy initiatives.

Conclusions

There were substantial differences in statin utilisation rates in 2007 among European countries – appreciably greater than the EuroMedStat study.

These considerable differences (over 100 fold) make it mandatory in future cross national studies to always document and record the potential reasons driving the differences. Otherwise, there may be a tendency for readers to dismiss the outliers.

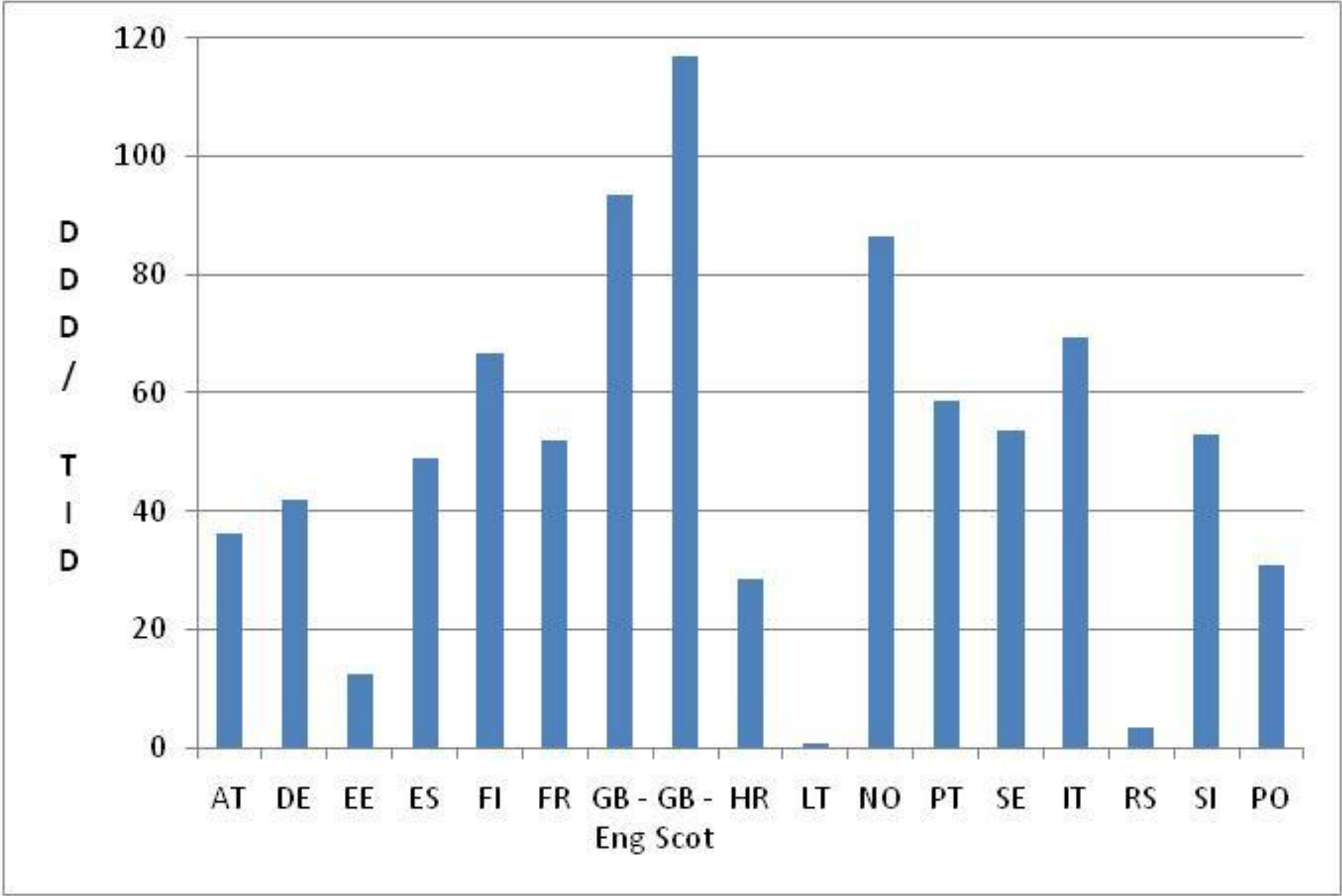
Acknowledgements

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Results

Appreciable difference in statin utilisation across Europe.

Figure 1 – Statin utilisation (DDD/ TID) in 2007



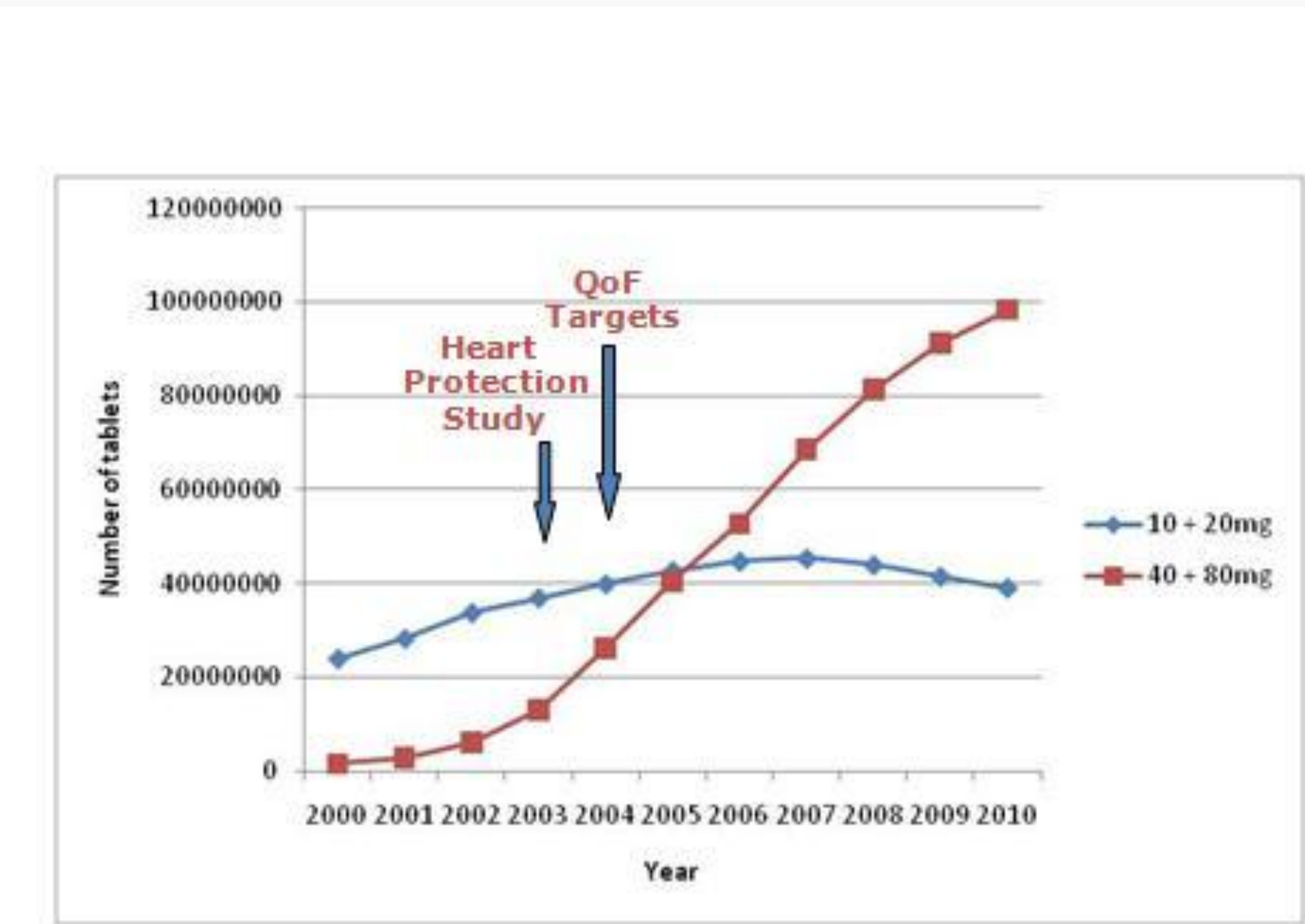
Low level of statin utilisation among CEE countries influenced by current prescribing restrictions (Table 1).

Figure 2 – Prescribing restrictions for statins

Country	Prescribing restrictions
Estonia (EE)	Only reimbursed in patients with FH (TC >8mmol/l) or following a CV event (TC >4.5mmol/l). Otherwise 100% co-pay
Croatia (HR)	2003 - 2003 – 25% co-pay for 2ndry prevention in patients with IHD or CV disease, diabetes with a TC> 5mmol/l; 75% for patients for primary prevention if 10 year chance of CHD >20% or above 60 years of age. No reimbursement if initiation undertaken in patients above 70 years of age. 2006 – similar to 2003 for secondary prevention, primary prevention includes TC >7mmol/l after 3 months diet. 2007 – no co-pay for patients meeting criteria – only if patients' wish a more expensive drug than current referenced priced product
Lithuania (LT)	Initially only reimbursed for 2ndry prevention and only for 6 months (first prescription via cardiologist). Now lifted for generic statins
Serbia (RS)	Principally for secondary prevention coupled with patient co-payments to limit the budget

Quality and Outcome Framework plus recent studies increased prescribing of higher strength statins (Figure 3 - similar for atorvastatin) enhancing overall utilisation.

Figure 2 – Simvastatin utilisation in Scotland 2000 to 2010



Challenges when introducing policies to engineer low prices for generics: experiences from Abu Dhabi

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Introduction

Health Authority Abu Dhabi (HAAD) introduced a 'Unified Prescription Form' (March 2009) mandating INN prescribing with minor exceptions. This combined with a comprehensive Generic Drug Policy (August 2009) sought to increase generic uptake to conserve resources.

However, currently within HAAD:

- (a) Pharmacists are still fully reimbursed for dispensing any molecule (originator or generic) and receive bonuses from manufacturers for preferentially dispensing their product
- (b) Originator manufacturers do not have to lower their prices for continued reimbursement and patients do not pay the price difference for a more expensive molecule (in addition to 20 – 30% co-payment for some patients)
- (c) limited demand side measures directing physician prescribing behaviour

Objective

Analyse the outcome of recent generic policies. Secondly, determine the possible reasons behind the changes seen. Thirdly, suggest potential reforms that HAAD could implement to enhance future efficiencies.

Methodology

Pre and post policy analysis of the impact of recent generic policies (12 months to Nov 2009 vs. 12 months to Nov 2008) on ambulatory care drug expenditure in Abu Dhabi among 5 of top 8 drug expenditure classes (based on IMS data) for the 1.64mn population.

Conclusions

The anticipated savings from the generic policies have not been realised in HAAD. However there is considerable potential for savings without compromising care (Table 1) through increased prescribing of generics in the classes. Policies to address this are being explored based on experiences in other countries. These include educational and economic activities as well as reference pricing for the molecule.

Source of funding and acknowledgements

The project was funded by HAAD. Utilisation and expenditure data was supplied by IMS to HAAD.

The authors have no other conflicts of interest.

Results

Expenditure in the 5 ATC Level 4 drug classes increased by 34.4% to \$59.21mn in 2009 vs. 2008.

This expenditure increase was aided by:

- (a) Statins – increased utilisation of rosuvastatin and atorvastatin (87.5% of total statins on a Defined Daily Dose basis in 2010)
- (b) Proton Pump Inhibitors (PPIs) - increased utilisation of patented PPIs including esomeprazole versus a reduction in multiple sourced omeprazole
- (c) Oral fluoroquinolones - increased utilisation of levofloxacin and moxifloxacin versus reduced prescribing of multiple sourced ciprofloxacin

Potential reasons for changes in expenditure versus expectations include:

- a) concerns that patients prescribed multiple sourced drugs may be dispensed different branded generics each time and there have been complaints about the effectiveness and safety of generics versus originators. Prescribing of single sourced products alleviates this
- b) Currently limited demand side measures to influence physician prescribing apart from initiatives around INN prescribing

Policies to enhance the prescribing of generic omeprazole at prices similar to Western European countries, combined with policies to enhance its utilisation versus patent protected PPIs, would save an estimated €6.23mn annually (Table 1). Similar savings estimated in other disease areas including the statins and fluoroquinolones.

Table 1 – Potential savings for PPIs in HAAD in 2010 through adopting best practices among Western European countries

PPI	Expenditure AEDs - 2010
Omeprazole	23189515
Esomeprazole	3667021
Total	26856537
Initial Total	59729519
Savings (AED)	32872982
Savings - € and US\$	€6.23mn, US\$8.95mn



European countries with small populations cannot obtain appreciable price reductions for generics: Lithuania - case history to contradict this

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Introduction

Recent publications have suggested smaller European countries have difficulties negotiating low prices for drugs including generics. As a result, limiting the potential to enhance prescribing efficiency as more standard drugs lose their patent.

Objective

Assess whether these problems happen in practice based on the situation principally in Lithuania. Lithuania chosen in view of its population size coupled with appreciably lower utilisation of anti-depressants, PPIs and statins (DDDs/ TID) than Western European countries.

Methodology

Observational study involving all 3.3 million ambulatory care patients contained within the compulsory health insurance system in Lithuania.

Analysis of reductions in reimbursed expenditure/ DDD (2010 DDDs) assessed for generic PPIs, statins, ACEIs, and SSRIs in 2007 or 2009 vs. 2000 or 2001 originator prices, as well as a range of European countries. Description of generic pricing policies and their impact among selected European countries with smaller populations also based on published papers by the co-authors.

Results

Appreciable reductions seen in reimbursed expenditure/ DDD for generics in each drug class in Lithuania in 2009 vs. 2000/ 2001 originators, e.g. 56% reduction for generic omeprazole, 65% for generic ramipril (Table 1), 83% for generic simvastatin, 85% for generic sertraline and 87% for generic atorvastatin (Figure 1).

Table 1 % reduction in reimbursed expenditure/ DDD for selected generic ACEIs in 2009 versus 2001 originator prices

ACEi	Year generic first available	% reduction versus originator 2001 prices
Generic enalapril	1997	52%
Generic ramipril	2004	65%
Generic quinapril	2006	50%
Generic fosinopril	2006	42%

Results (continued)

Figure 1 – Reimbursed expenditure/ DDD for selected statins

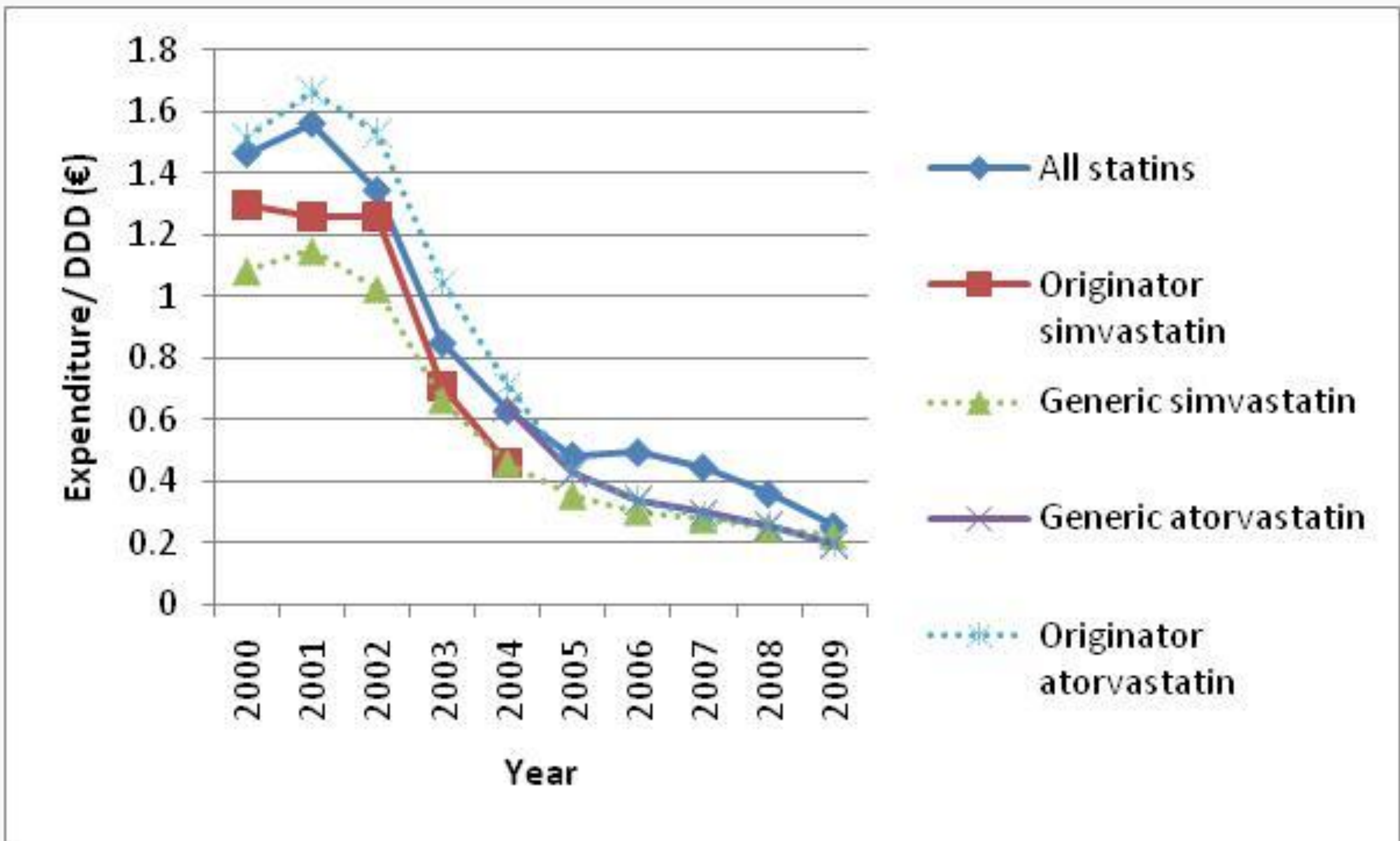


Table 2 - % reduction in selected generic SSRI prices (expenditure/ DDD) in 2007 vs. 2001 originator prices

Generic SSRI	% reduction generic vs. originator 2001 prices	Generics available 2001
Fluoxetine	92%	Yes
Citalopram	88%	No
Sertraline	85%	No

These reductions in generic prices vs. originators similar to those seen among a range of Western European countries, e.g. SSRIs (Table 3).

Table 3 - % reduction in selected generic SSRI prices in 2007 vs. 2001 originator prices unless stated (expenditure/ DDD basis)

Country	% reduction fluoxetine	% reduction citalopram	% reduction sertraline
Austria	55%	59%	73%
Portugal	48%	NA	40%
Scotland	87%	83%	87%
Spain (Catalonia)*	65%	47%	47%
Sweden	92%	94%	95%

*Spain: 2007 vs. 2003; NA = not applicable

Conclusions

European countries with smaller populations can obtain appreciable reductions for generics vs. originators.

In addition in Lithuania, no apparent difference between classes with high or low utilisation volumes. As a result, helping fund increased volumes alongside mandated budget cuts. Consequently, providing an example to other European countries seeking to enhance prescribing efficiency.

Thailand Medicine Price Survey in 2006 and 2010

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Medicine prices should be monitored regularly to inform policy makers of its magnitude and trends. Changes in drug prices can impact financial management of the Thai health care system which provides basic health services to the majority of Thai citizen. A survey was carried out in 2010 to determine price changes of 14 essential drugs

Objective (s)

1.To compare the changing of Thailand public hospital procurement prices in relative to the changing of MSH prices between the year 2006 and 2010.

2.To compare the median price ratio of public hospital procurement prices between the year 2006 and 2010

Policy and practices targeted : Drug pricing policy

Stakeholder (s) involved: Health policy maker, hospital pharmacist

Region covered: Public hospitals in Thailand

Funding Source: Thai Drug System Monitoring and Development Program

Methodology

The 14 core medicines from Medicine Prices: A new approach to measurement (WHO/HAI, 2008); were surveyed. Price from hospital data base were recorded and mailed back to the researcher. Price data were entered into the workbook provided as part of the WHO/HAI methodology. Data entry was checked by the 'double entry' and 'data checker' functions of the workbook. Median Price Ratio, MPR was a parameter for each medicine; calculated from Thai median price divided by median of MSH reference price. Prices were compared with a previous survey by Sooksriwong C. at http://www.haiweb.org/medicineprices/surveys/200610TH/sdocs/survey_report.pdf

Setting: 166 public hospitals with more than 60 beds all over Thailand were surveyed, 42 returned and 36 completed for analysis.

Study design: The design of this study was adapted from the 2008 edition manual workbook of WHO, Health Action International; Medicine Prices: A new approach to measurement.

Results: There are 11 drugs listed in 2010 survey matched with those in 2006 survey. The result reveals that in 2010, the median prices of 3 generic drugs procured by public hospitals remain the same and the rest are less than the prices procured in 2006 at the range (-) 17.65% to (-) 39.76% (Table 1). It implies that generic drug prices in Thailand are decreasing. These percentages decrease are less than changing of the lowest MSH prices at (-) 5.41% to (-) 82.32. For changing of the median price ratio, the figures were in the opposite direction. The MPR of 11 drugs in 2010 increase from 2006 at (+) 3.29% to (+) 415.38%; only one MPR of procurement price decreases at (-)-26.67%. (Table 2) Interpretation of the price ratio suggests that drug prices in Thailand are getting more expensive. In 2006, 7 from 11 drugs (64%) had MPR from 1.16 to 3.15; and in 2010, 10 from 11 drugs (91%) had MPR from 1.37 to 4.64 when compared to MSH prices.

Table 1 Comparison of the changing in public hospital procurement prices and the changing in MSH prices between 2006 and 2010

Med. Name	2006		2010		% Change 2010 to 2006	
	Lowest MSH price (USD)	Thai Public Procurement price (Baht)	Lowest MSH price (USD)	Thai Public Procurement price (Baht)	Lowest MSH price	Thai Public Procurement price
Amitriptyline 25 mg tab	0.0049	0.37	0.0040	0.37	-18.37	0.00
Atenolol 50 mg tab	0.0088	0.32	0.0034	0.20	-61.36	-37.50
Azithromycin 250 mg tab	0.2417	28.00	0.1693	20.00	-29.95	-28.57
Captopril 25 mg tab	0.0182	1.98	0.0102	1.56	-43.96	-21.21
Ceftriaxone 1g/vial	1.1931	18.00	0.5000	13.85	-58.09	-23.06
Ciprofloxacin 500 mg tab	0.0266	2.49	0.0243	1.50	-8.65	-39.76
Cotrimoxazole suspension+40 mg/ml	0.0037	0.16	0.0035	0.16	-5.41	0.00
Diazepam 5 mg tab	0.0042	0.12	0.0023	0.12	-45.24	0.00
Glibenclamide 5 mg tab	0.0039	0.36	0.0025	0.25	-35.90	-30.56
Omeprazole 20 mg tab	0.0594	0.85	0.0105	0.70	-82.32	-17.65
Salbutamol 100 mcg/dose	0.0081	0.45	0.0056	0.29	-30.86	-35.56

Table 2 Comparison of the price ratio of in public hospital procurement prices with MSH prices between 2006 and 2010

	2006	2010	% Change
Amitriptyline 25 mg tab	2.08	2.84	36.54
Atenolol 50 mg tab	0.98	1.82	85.71
Azithromycin 250 mg tab	3.15	3.58	13.65
Captopril 25 mg tab	2.96	4.64	56.76
Ceftriaxone 1g/vial	0.41	0.84	104.88
Ciprofloxacin 500 mg tab	2.55	1.87	-26.67
Cotrimoxazole suspension 8+40 mg/ml	1.16	1.37	18.10
Diazepam 5 mg tab	0.78	1.58	102.56
Glibenclamide 5 mg tab	2.51	3.03	20.72
Omeprazole 20 mg tab	0.39	2.01	415.38
Salbutamol 100 mcg/dose	1.52	1.57	3.29

Conclusion: The major cause of this interpretation owed to the differences of the rate of money exchange and the MSH prices of the year 2006 and 2010. Rate of exchanged in the 2010 survey was based on 3 February 2010 with selling rate from bank of Thailand = 32.9528 baht per US dollar, while in the 2006 survey the rate was 36.7456 baht per US dollar; nearly 10% different.

Lessons learned and success factors: The trend of drug price monitoring could be tricky if we look at one parameter, median price or median price ratio only. The interpretation of a price survey should be careful especially in countries under high economics fluctuation.

Key Words: drug price survey, drug price comparison, drug price monitoring

Risk sharing arrangements – an opportunity or threat to fund new medicines?

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Introduction

Risk sharing schemes are increasingly part of formal pricing and reimbursement negotiations across Europe as pharmaceutical companies seek reimbursement and funding for their new premium priced drugs within growing resource pressures.

These include price: volume arrangements (PVAs), value based pricing, outcome guarantee and patient access schemes. However, there are concerns with multiple definitions, the administrative burden, and transparency.

Objective

- Provide a workable definition for “risk sharing”
- Review current schemes to provide future guidance to countries as arrangements grow

Methodology

- Develop an acceptable definition based on logic and validate this with key payers and their advisers across Europe
- Undertake a literature search of published schemes combined with unpublished/ grey data known to payers and advisers across Europe involved with assessing such schemes
- Ascertain whether schemes can be classified according to the definition
- Appraise the schemes with the help of payers and their advisers, including costs and concerns, to provide future guidance

Results

Risk sharing schemes should be “considered as agreements concluded by payers and pharmaceutical companies to diminish the impact on payers’ budgets for new and existing schemes brought about by uncertainty and/ or the need to work within finite budgets”.

The various schemes can be broken down into financial-based and performance-based/ outcomes-based models (Tables 1 and 2). We accept even this division may be misleading – but it is based on common naming to provide a logical basis to the definitions proposed.

Results (continued)

Financial based schemes:

- Price-volume agreements (PVAs)/ budget impact schemes which focus on controlling financial expenditure
- Patient access schemes, which typically involve either free drug or discounts for an agreed period, or price-capping. The objective being to enhance the value of new medicines and improve the possibility of their funding/ reimbursement

Performance based/ outcome-based schemes:

- Schemes whereby companies refund monies or provide free drug if the desired outcomes are not reached
- Alternatively, a price reduction if the new drug fails to deliver the desired health gain in practice

However, there are concerns with existing schemes including:

i) PVA schemes

- patients initially receiving the drug may not be those that benefit most
- Lack of transparency when closed negotiations (discounts/ rebates)
- Potential administrative burden with price capping schemes

ii) Performance based/ outcomes based schemes

- Whether objectives fully explicit, and who will fund the costs of any additional evidence generation/ out of date stocks
- General administrative burden with 73% of hospitals in the UK reporting that they did not have the capacity to manage outcome/ patient access schemes
- Whether any savings are passed back to the payers

Conclusions

Only a limited number of situations where risk-sharing schemes should be considered apart from traditional PVAs. These include:

- where responses can be determined within a short time and reduce uncertainty
- high unmet need with a new technology showing benefit
- lowering drug costs in targeted patients will enhance reimbursement having factored in administration costs
- price: volume schemes help limit the budget impact of new drugs enhancing their affordability
- limited time frame for the scheme

Schemes should be rejected where (a) effective/ low cost standards already exist, (b) compliance is a major issue, (c) high administration costs/ burden limits savings in practice, (d) concerns with access/ data ownership and (e) Health Authorities will end up significantly funding drug development costs.

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Recent policies to enhance renin-angiotensin prescribing efficiency in Europe – implications for the future

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Introduction

Angiotensin Converting Enzyme Inhibitors (ACEIs) and Angiotensin Receptor Blockers (ARBs) are accepted treatments for hypertension and CHF. Coughing can occur with ACEIs leading to development of ARBs. Trials showed discontinuation due to coughing in a minority on ACEIs (2-3%). ARB prescribing restrictions from launch in Austria as higher costs than ACEIs moderated their utilisation. Other demand side measures in Spain (Catalonia) following availability of generic ACEIs also moderated ARB utilisation.

Objective

Document the influence of reforms on ARB utilisation patterns in other European countries (Croatia, Portugal, and Sweden) vs. Austria and Spain (Catalonia) using the 4 Es (education, engineering, economics and enforcement).

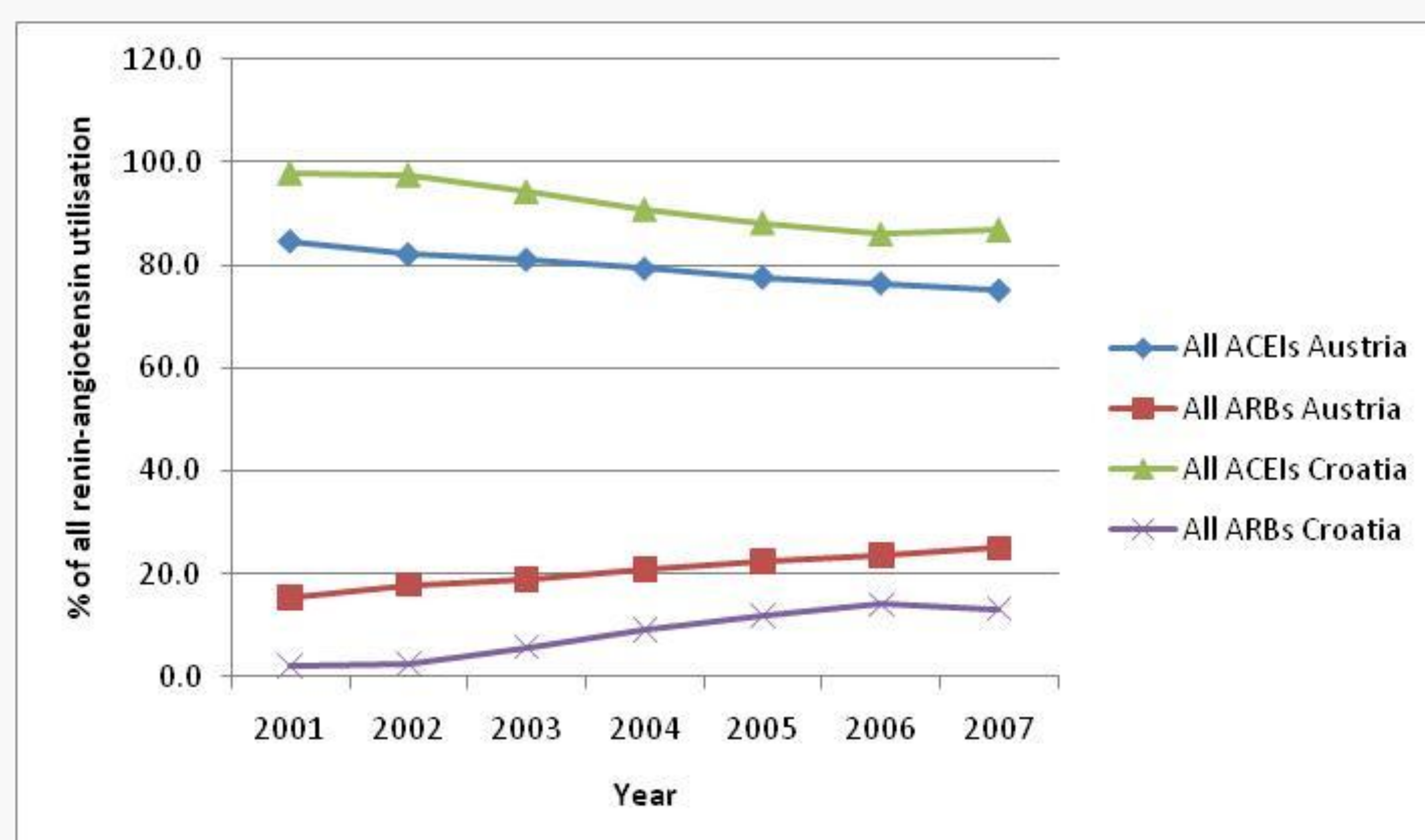
Methodology

Retrospective observational DU study documenting the influence of reforms on utilisation of ACEIs alone/ combination (C09AA01 to 16, C09BA01 to 15, C09BB02 to 12) and ARBs alone/ combination (C09CA01 to 08, C09DA01 to 07, C09DB01 to 04) from 2001 to 2007 using DDDs (2010 DDDs) among European countries. Years chosen to mirror published studies. Only administrative databases used including INFARMED (Portugal). Utilisation patterns and reforms validated with data providers to enhance robustness of the findings.

Results

Aggressive follow-up of prescribing restrictions in Croatia (academic detailing and possibly fines) greater influence on limiting ARB utilisation than seen in Austria (Figure 1). Restrictions also limited ARB prescribing in Lithuania.

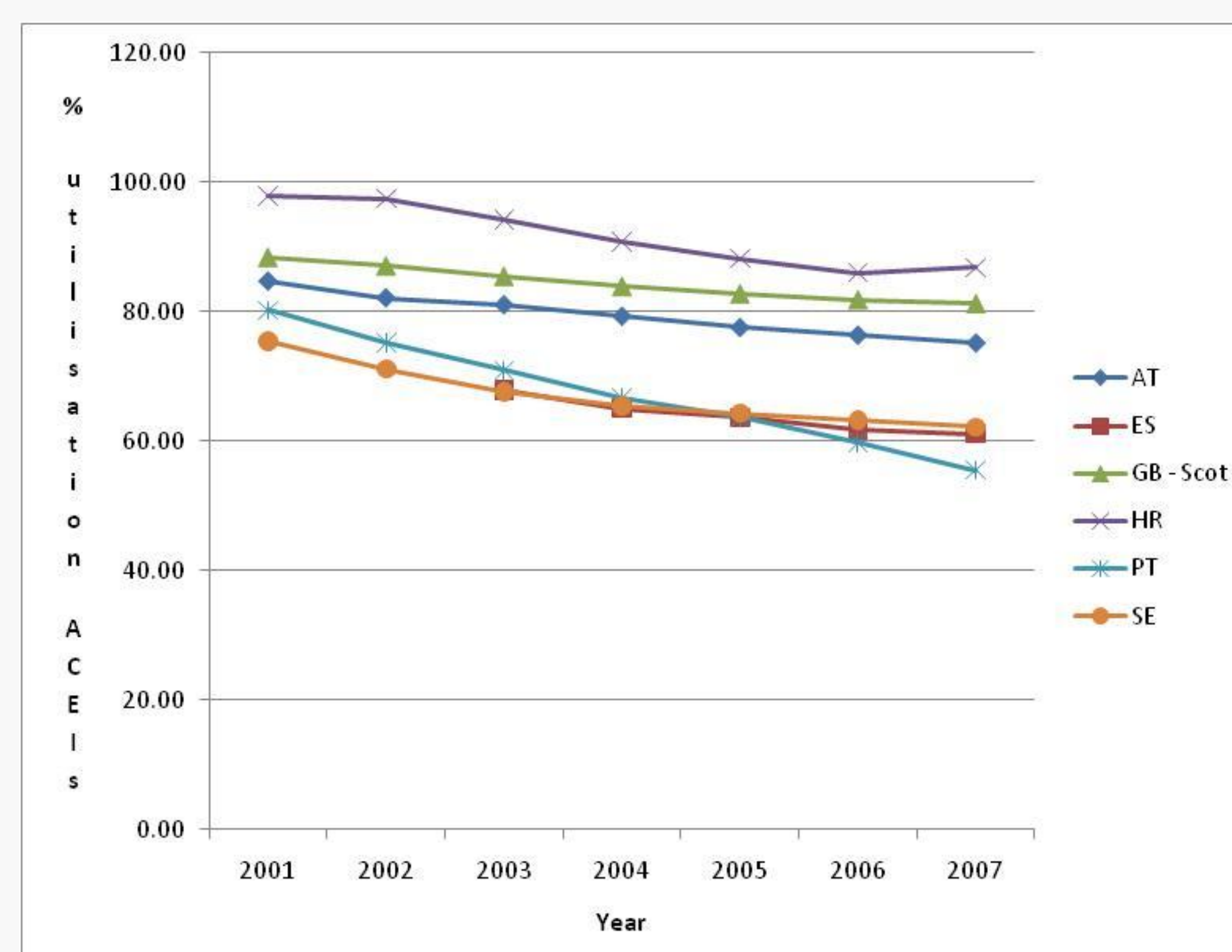
Figure 1 – Renin-angiotensin use Austria and Croatia



Results (continued)

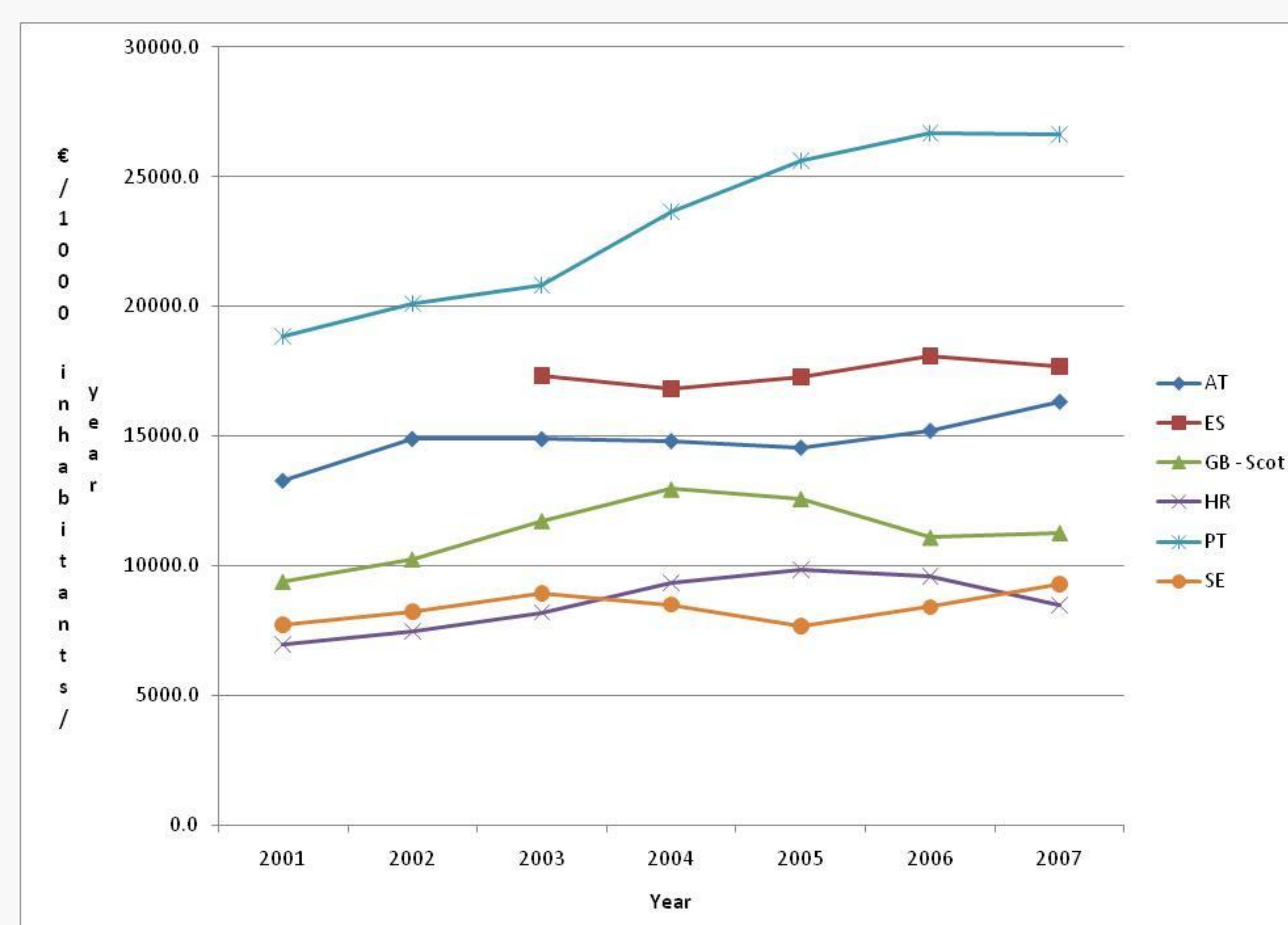
Greater intensity of 3 Es (education, engineering and economics) in Scotland enhanced ACEI use; growing use of ARBs in Portugal with limited demand side measures (Fig 2).

Figure 2 – ACEI utilisation across Europe (DDD basis)



Increasing expenditure in Portugal with limited demand side measures (Figure 3); otherwise stabilisation despite appreciable growth (approx. 160% in Scotland; 70% to 90% - other EU countries).

Figure 3 – Expenditure on renin-angiotensin drugs



Conclusions

Multiple demand side reforms essential to moderate ARB utilisation; growing utilisation of patented products if only limited demand side measures reducing future prescribing efficiency.

Follow-up of prescribing restrictions enhances their impact, mirroring the findings in other studies.



Karolinska
Institutet



Potential impact of policy regulation and generic competition on sales of cholesterol lowering medication, antidepressants and acid blocking agents in Belgium

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Background

Pharmaceutical expenditures are increasing as a proportion of health expenditures in most rich countries. **Antidepressants (AD)**, **acid blocking agents (ABA)** and **cholesterol lowering medication (CLM)** are major contributors to medicine sales around the globe.

Methods

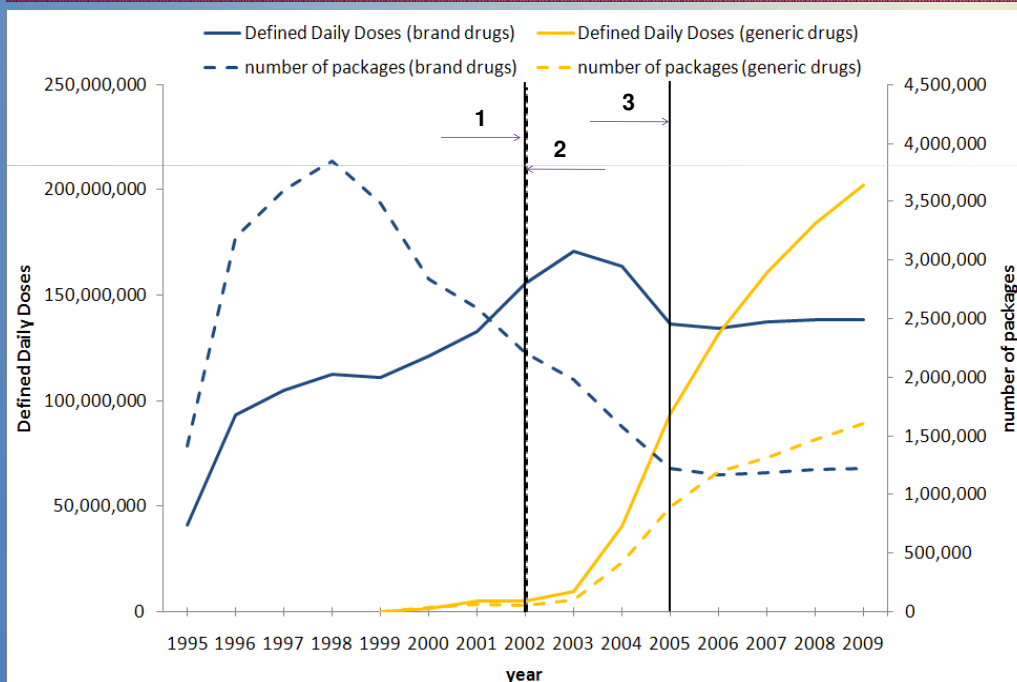
We aimed to document the possible impact of **policy regulations** and **generic market penetration** on the evolution of **sales volume** and average **cost per unit** (DDD* and packages).

Data sources

Data sources:

- IMS Health database
- Belgian State Monitor
- guidelines (NIHDI*)
- dates of entry of generics

Results (of cholesterol lowering medication, as example)



UPPER PANEL: SALES VOLUME OF DDDs AND NUMBER OF PACKAGES

LOWER PANEL: AVERAGE COST PER UNIT (DDD AND PACKAGE) IN EURO

ARROW 1: introduction RPS* in Belgium + massive generic entry

ARROW 2 (dotted line): publication of guidelines for prescribers by NIHDI* (statins and fibrates)

ARROW 3: changes in co-payment threshold in favour of non-substitutable pharmaceuticals

ARROW 4: steep increase of average cost per unit for generics

ARROW 5: change in reimbursement conditions for all statins

ARROW 6: Experimental public tender for simvastatins

Also:

ABA: slow generic rise, more large packages, reimbursement conditions, pseudo-generic

AD: slow generic rise, claw-back, more large packages

Conclusion

Generic entry as important contributor to decrease in expenditures, but is specific by medicine groups.

Sustainability of policy regulations seems partly counteracted by other market mechanisms

Discussion

Generic market in Belgium remains relatively low (14.7%)

No sustainable impact of policy measures → other mechanisms?

- pseudo-generics
- brand loyalty of consumers and prescribers

Demand-side measures seem promising for longer lasting impact:

- co-payment as incentive?
- role of prescriber and pharmacist?

Specificity of administrative databases undermine the opportunity to investigate causal relationships

Glossary*

- NIHDI: National Institute for Health and Disability Insurance
- RPS: Reference Pricing System
- DDD: Defined Daily Dose (WHO)

Acknowledgements

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High rates of self purchasing on oral antibiotics in Serbia: implications for future policies

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Introduction

There is currently high antibiotic consumption in Serbia. Expenditure on antibiotics is also growing with increasing use of newer expensive antibiotics. Utilisation is enhanced by patients also purchasing antibiotics directly at community pharmacies, which is illegal but currently only limited challenges to this practice.

Objective

- Assess the extent of self purchases in Serbia
- Compare overall antibiotic consumption (reimbursed and total) with consumption in other EU countries documented on the ESAC database
- Suggest measures to reduce antibiotic consumption and expenditure in Serbia (reimbursed and self purchasing) based on experiences in other countries

Methodology

- Retrospective drug utilisation analysis of oral antibiotic consumption in DDDs and DDDs/ TID including the Penicillins - J01CA, J01CE, J01CF, J01CG, Cephalosporins - J01DB, J01DC, J01DB, Macrolides J01FA, and Quinolones - J01MA, J01MB, in both database: reimbursed - issued on prescription (RZZO) and the total including self purchases (Medicines and Devices Agency, ALIMIS database) from 2005 to 2009
- Total utilisation rates in 2007 compared with ESAC database for the same classes across Europe
- Potential measures suggested based on the experiences of the co-authors

Conclusions

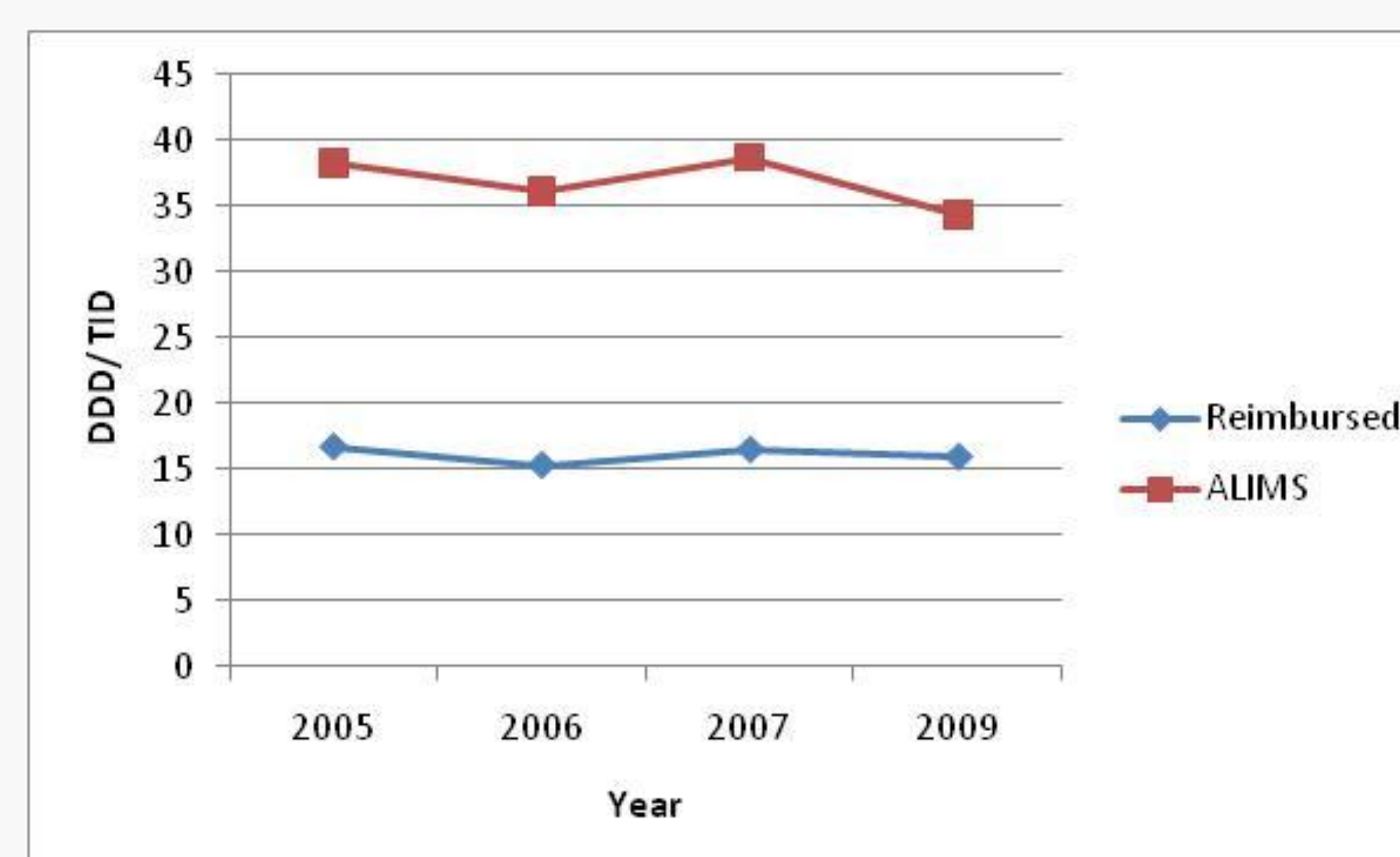
Extent of self purchasing antibiotics in Serbia is appreciably greater than other European countries including Spain, where self purchasing increased overall utilisation by over 30%. As a result, overall antibiotic consumption in Serbia is high compared with other EU countries.

Reducing antibiotic consumption must become a high priority among all national authorities in Serbia to reduce resistance development and conserve resources. Apart from compulsory implementation of existing law, additional measures could include monitoring of antibiotic prescribing against agreed guidance and educational campaigns among patients based on experiences in other European countries.

Results

Reimbursed utilization decreased in Serbia by 5% (DDD basis) from 2005 to 2009 (Figure 1). Changes in utilization among the 4 reimbursed classes ranged from +29.7% for macrolides to - 8% for penicillins. Total utilisation (ALIMS data) appreciably higher than reimbursed (Figure 1).

Figure 1 – Antibiotic utilisation (reimbursed and ALIMIS) 2005 to 2009 in DDDs/ TID



In 2007, Serbia had the highest utilisation of penicillins, second highest for macrolides (11.98 vs. 0.89 in Sweden) and third highest for quinolones (Figures 2 and 3).

Figure 2 – European penicillin consumption in 2007

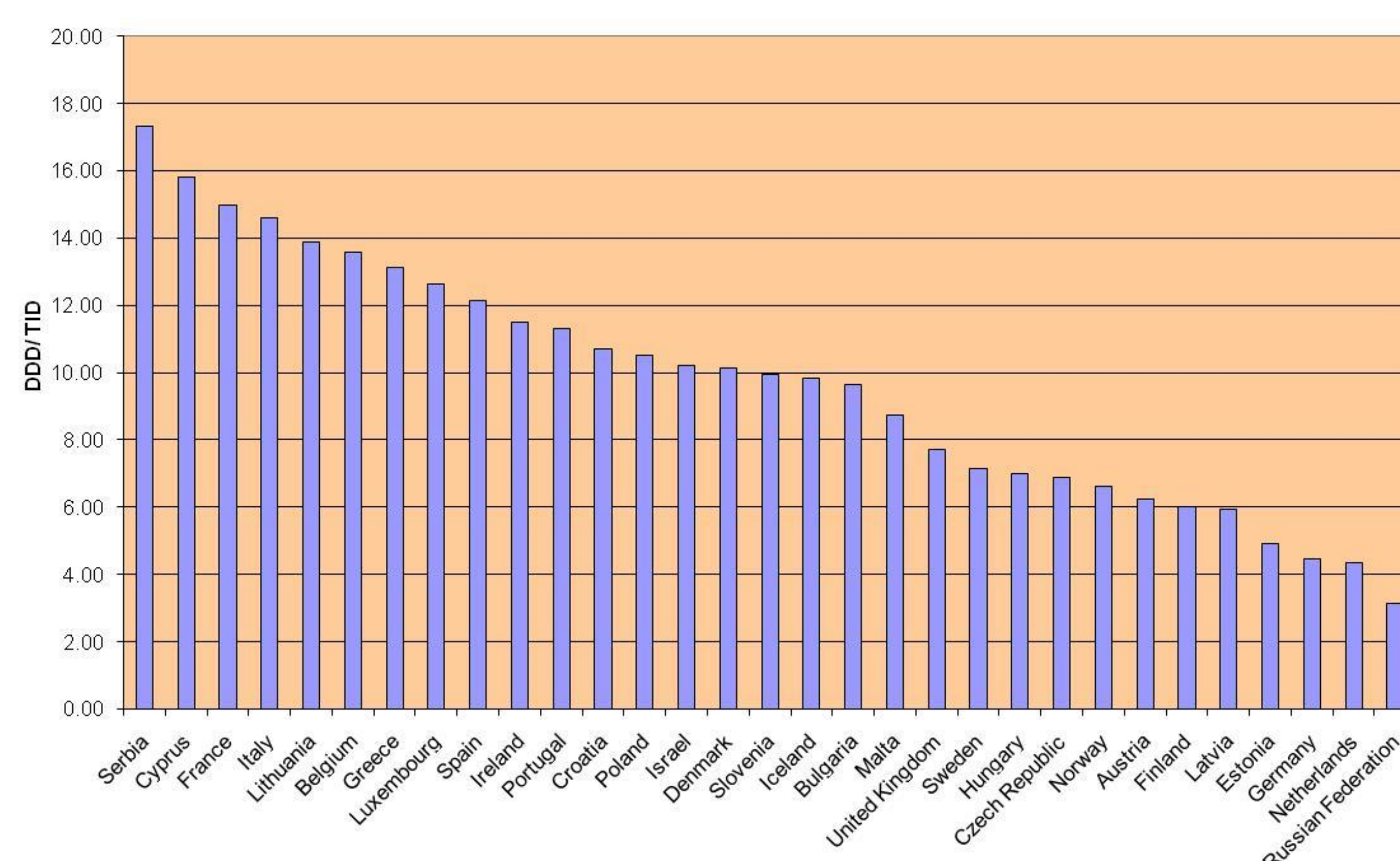
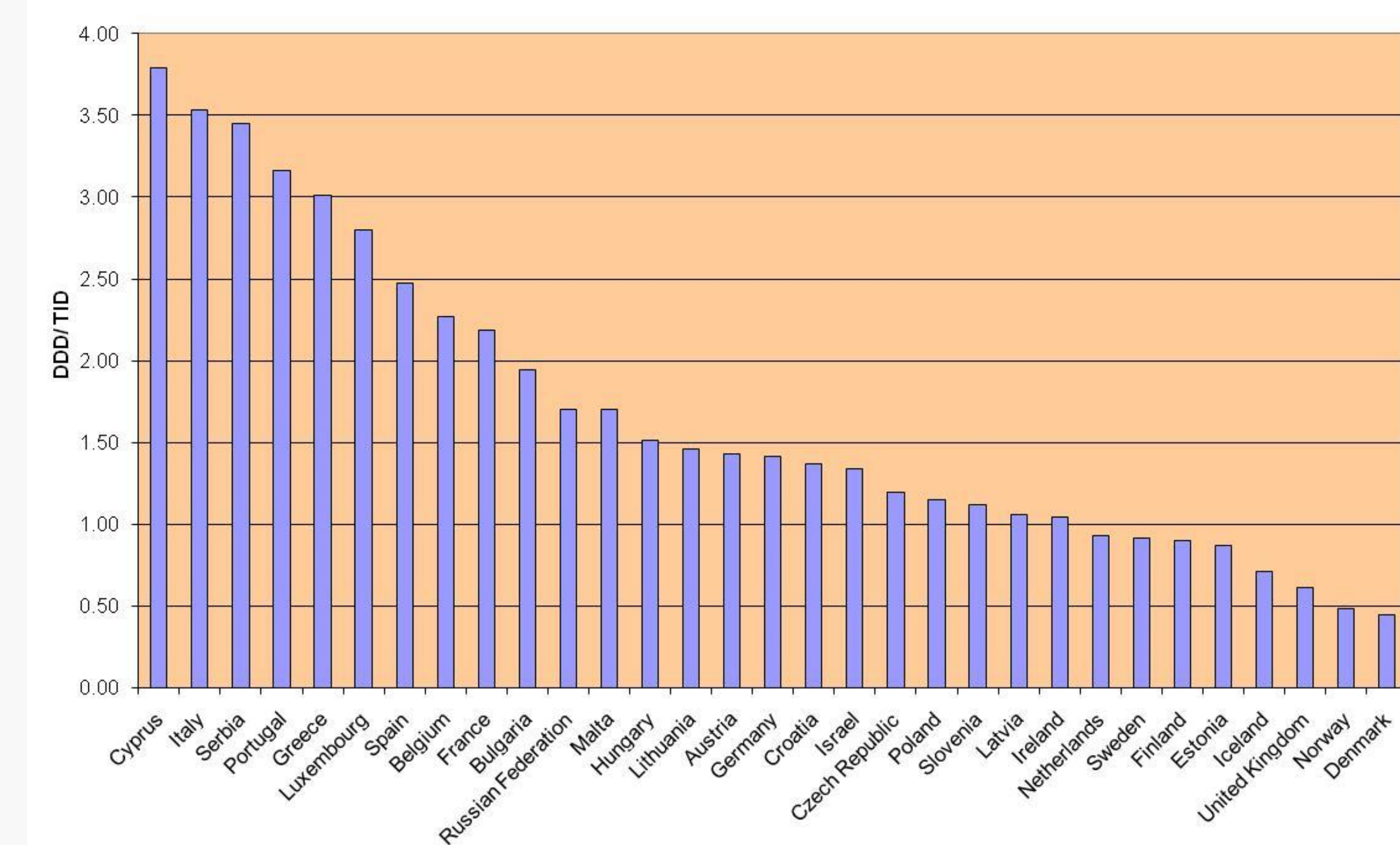


Figure 3 – European quinolone consumption in 2007



Drug procurement cooperation (LIS) Norway

tender for alfa TNF/biological

Recommendations and results 2011

Author

MSc Pharm Anne Helen Ognøy

LIS is an acronym for Drug procurement cooperation.

Background

There are two medical financial systems in Norway financed by the state. One for in-patients in hospitals and one for out-patients.

LIS regulations

On behalf of the 4 health regions LIS is involved with tendering and negotiating frame contracts for drug procurement. LIS acts as a broker between pharmaceutical suppliers and the health regions.

The purpose of Drug procurement cooperation (LIS) is to reduce the costs of drugs by working out the basis for agreements on purchasing and delivering of pharmaceuticals instructed by the state. 90 % of the hospitals in Norway are state owned.

Prices achieved in the procurement process are lower than the official list prices.

Medical consumption Norwegian state owned hospitals

The top 5 active substances used in hospitals evaluated by pharmaceutical expenditure in Norway 2010.

Figure 1

Top active substances used in hospitals ranked with regard to expenditure country wide

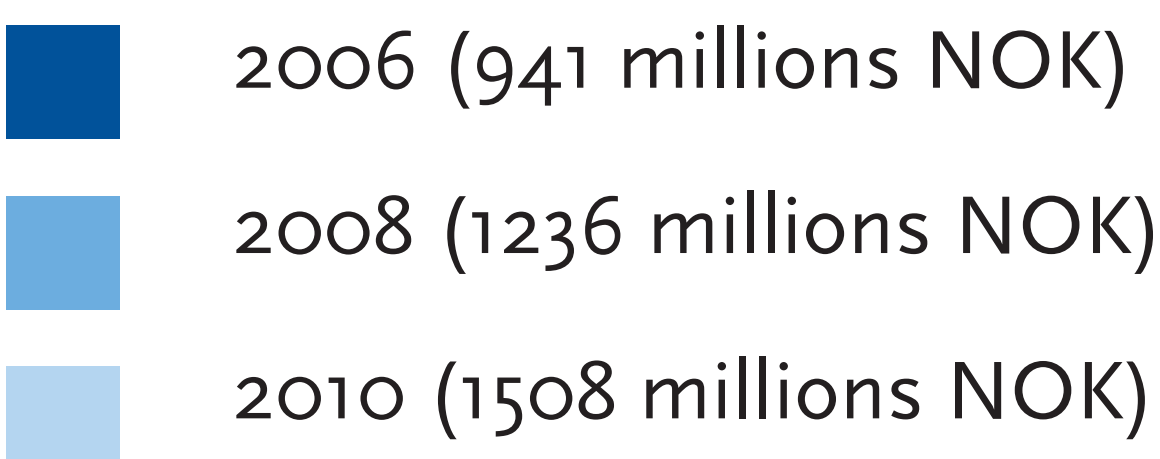
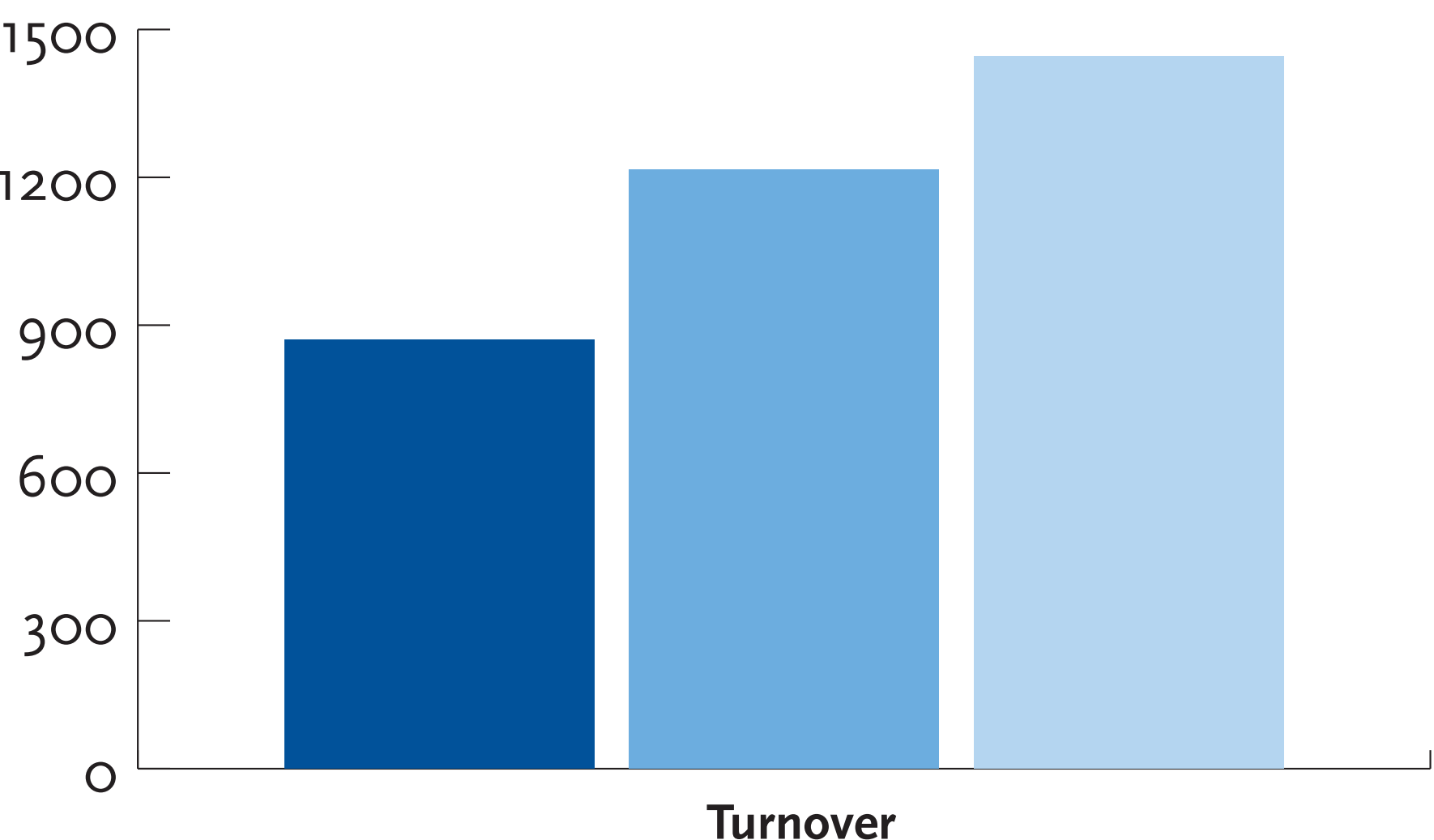
1	Etanercept (Enbrel)
2	Infliximab (Remicade)
3	Adalimumab (Humira)
4	Rituximab (MabThera)
5	Interferon beta 1a (Avonex)

Figure 2

Turnover alpha TNF/biological in NOK

Sales figures for 2010 show that health authorities will buy drugs within alpha TNF/biological for 1 500 million NOK in 2011.

The consumption of alpha TNF/biological expenditure has increased from 2006 until 2010 with 60 %.



LIS-TNF/BIO agreements 2011

A specialist group of physicians from the health regions have made agreements 1.2.2011 - 31.1.2012 and the basis of offers received in the tender recommendations for the selection of biological drugs in rheumatology, gastro-intestinal and skin diseases. In 2011 offers were received from Abbott (Humira ®), Bristol Myers Squibb (Orencia ®), Janssen-Cilag (STELARA ®), Merck (Remicade ®, Simponi ®) Pfizer (Enbrel ®), Roche (MabThera ®, RoACTEMRA ®) and UCB (Cimzia ®).

The specialist group specified in the tender that the lowest bid price is the basis for the recommendation when there are no clearly documented differences in efficacy and side effects through comparative controlled trials (head-to-head comparative studies).

The specialist group also stated;

“There may be special circumstances in the individual patient that affect drug choice. This can for example be the patient’s ability to handle the preparation, ease of use, injection frequency, side effect profile, travel costs for treatment and local capacity for infusion therapy. It can also be taken into account identified predictors of response (such as methotrexate co medication the use of TNF- α inhibitors in rheumatoid arthritis, rheumatoid factor / antibodies to citrullinated peptides (anti-CCP) using rituximab) and consistent registry data concerning side effects (such as differing rates of tuberculosis (tbc) during treatment with various TNF- α inhibitors). In such cases, the treating physician can deviate from the recommendations of choosing the affordable alternative”

The recommendation is initiated at the start of treatment and change of drug.

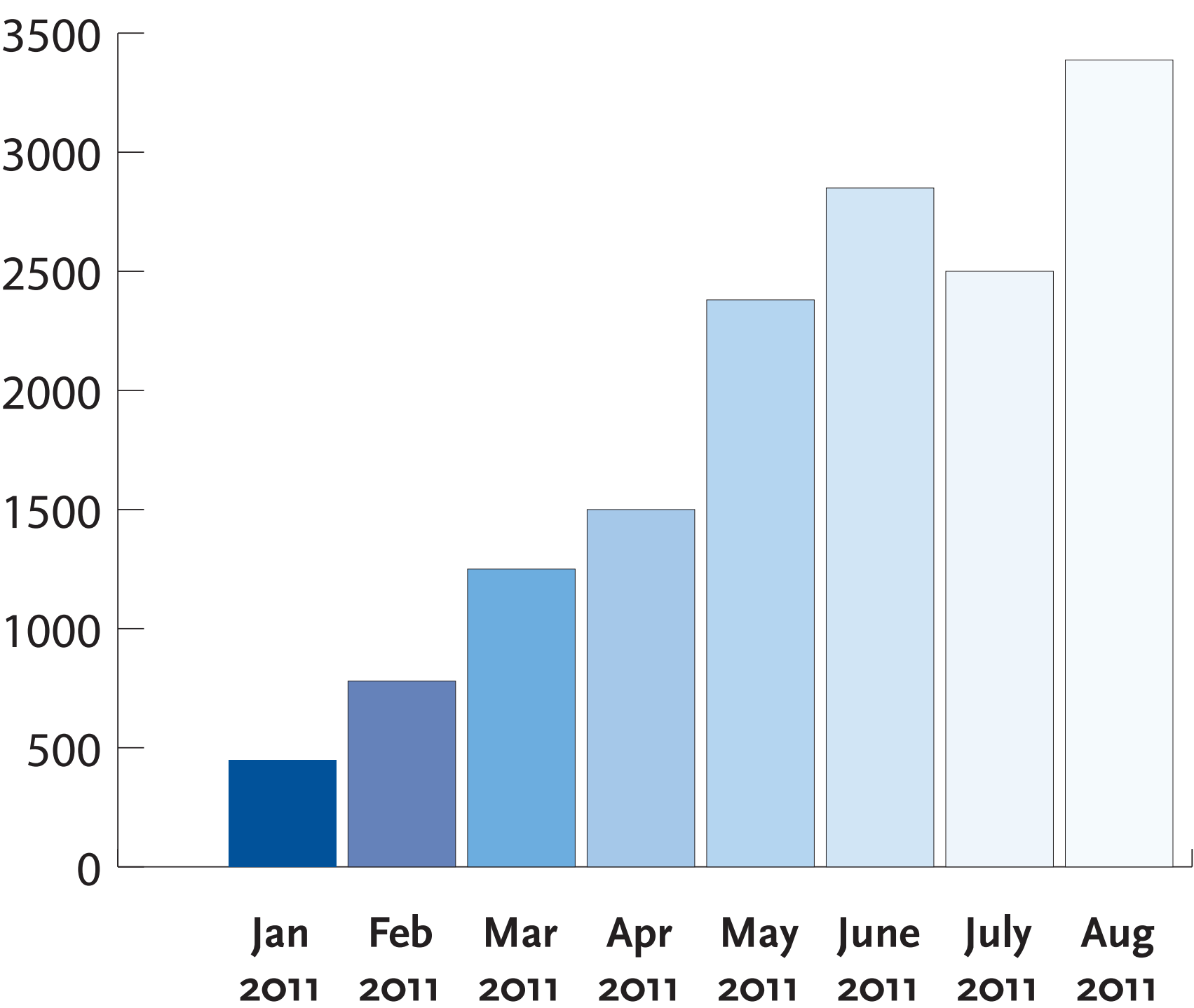
On the basis of offers received for LIS-TNF/BIO specialist group of the health regions recommendations were worked out for physicians’ choices based on cost calculations based on approved indications and recommended dosages of the drug’s prescribing information www.legemiddelverket.no (Norwegian Medicines Agency). Price calculations were presented for the first year of treatment.

Enbrel kit with powder and syringe won the tender for 2011

LIS received an offer on Enbrel 25 mg injection kit including powder and syringe with diluents where patients must reconstitute the powder and liquid themselves. Pfizer offer of Enbrel powder and syringe was so good that this is the first choice for anti tnf/biological treatment for 2011.

Figure 3

Development of Enbrel – turnover package Jan-Aug 2011



The results show that the recommendations from the specialist group have been followed and the physicians have been loyal to the agreements. The sale of the Enbrel injection kit (syringe and powder) has increased from February until August 2011.

Tendering alpha TNF/biological has made a reduction in prices for Norwegian state hospitals for 2011.

COMPARISON ON TWO PRICING METHODOLOGIES IN RELATION TO AFFORDABILITY AND AVAILABILITY OF MEDICINES IN THE REPUBLIC OF MACEDONIA

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Background

In the Republic of Macedonia, the procurement of medicines from the Positive List (PL) was carried out by the Health Insurance Fund (HIF) through centralized international tenders until 2005. The main criterion for selecting the best tender offer was the medicine price, which determined its reimbursement cost. The last international tender took place in 2005 and it was valid until the agreed quantities of medicines were consumed. The external reference pricing system was established in 2007. Its latest methodology uses the comparative analysis of the prices of generic medicines in the reference countries in the region. The reference price is the maximum amount that HIF reimburses for the PL medicines, and it takes into consideration the Purchasing Parity Power. The unified medicines prices were also established in 2007 based on ex-factory price, wholesale mark-ups and pharmacy mark-ups.

Results

Absolute costs of treatment for 8 selected clinical conditions are lower in 6 and higher in 2 conditions in 2010 vs 2005 (Table 1). Table 2 shows no significant difference in the average cost of all 8 treatments in 2005 and 2010 (2,84 € vs. 2,12€, Wilcoxon Matched Pairs Test: Z=1,120, p=0,2626). Table 3 illustrates the average number of working hours needed to purchase a month of treatment decreased from 227,87min in 2005 to 94,12min in 2010 (Wilcoxon Matched Pairs Test: Z=2,240, p=0,0250). Number of medicines with same INN (generics) for 8 selected clinical conditions increased significantly in 2010 compared to 2005 (total INN 51 vs. 17, Mann-Whitney U Test: Z =-2,607, p=0,0091) as shown in table 4. Difference between reference price and average market price of all available generics for each of 8 selected treatments in 2010 represents the out-of-pocket money. It can be paid for 7 out of 8 treatments in the range 0,4-3,27 times of the reference price per unit of the treatment (table 5).

Objectives and methodology

This study explores what impact the reference pricing (RP) methodology has on the affordability and availability of medicines in comparison with the international tender (IT). It includes the financial affordability, defined in the WHO/HAI Medicines Prices Manual as a price of predetermined regimens of treatment for selected six chronic and two acute diseases (eight in total). It can be related to either national average monthly wages or working hours needed to purchase a month of treatment in January 2010 (RP) vs. January 2005 (IT). The availability is measured as a range (number) of same INN (generics) of the above medicines available on the market in 2010 vs. 2005. The study also calculates out-of-pocket money that patients need to pay as difference between reference prices and average market prices for all available generics for the selected treatments.

Lessons learned

In comparison with the international tender in 2005, the reference price system in 2010 generally decreased the prices of reimbursed medicines at reference prices levels. That helps save HIF finances for other healthcare activities. The advantages of RP also include improved availability of same INN, which means bigger choice for both patients and prescribers.

However, the difference between reference price and market price result in high out-of-pocket expenses, as no additional health insurance exists nationally. The analysis also confirms that better financial affordability of medicines in 2010 is only partly a result of lower medicines prices, but it is predominantly a result of higher monthly wages.

Table 1: Clinical conditions, their average treatment costs in Macedonian denars (MKD) and working hours

Condition	Medicine name (INN) and dosage form	Av.treatment cost in 2005 (MKD*)	Av. treatment cost in 2010 (MKD*)	Av. income/cost 2005 (working hours)	Av.income/cost 2010 (working hours)
Diabetes	Glibenclamid 5mg tabl	139.20	91.20	4	1
Hypertension	Atenolol 50mg tabl	90.51	66.90	2	0,75
Adult respiratory infection	Amoxicillin 500mg caps	93.66	114.87	2	1,25
Gonorea	Ciprofloxacin 500mg tabl	24.99	13.69	0,5	2
Arthritis	Diclofenac 50mg tabl	130.20	181.80	2,7	2
Depression	Amitriptylin 25mg tabl	244.62	198.00	5	2,20
Asthma	Salbutamol inhaler 0.1 mg/dose	30.93	23.00	0,65	0,25
Ulcer	Omeprazol 20 mg tabl	643.50	355.50	15,53	4

* MKD = 61,5 Euros

Table 2: Average cost of treatment in MKD 2005 vs 2010

Year	Av. cost in MKD	St deviation	Min.	Max
2005	174.30	201.66	24.99	643.50
2010	130.62	122,65	13,69	355,50

Table 3: Average values of working hours (in minutes) needed to purchase treatment for certain conditions in 2005 vs 2010

Year	Av cost in work hours (min)	St deviation	Min	Max
2005	227,87	253,26	30,00	812,00
2010	94,12	70,08	15,00	240,00

Table 4: Generic medicines on the Positive list available on the market 2005 vs 2010

Medicine name (INN)	No. generics 2005	No generics 2010
Salbutamol 0.1 mg/dose inhaler	1	1
Glibenclamide 5 mg cap/tab	2	3
Atenolol 50 mg cap/tab	2	2
Amitriptyline 25 mg cap/tab	1	2
Ciprofloxacin 500 mg cap/tab	1	6
Amoxicillin 500 mg cap/tab	3	10
Diclofenac 50 mg cap/tab	3	11
Omeprazole 20 mg cap/tab	1	7
Total	17	51

Table 5: Difference between reference price and average market price of all available generics for each of the 8 selected treatments in 2010

Medicine name (INN)	2010		Difference (MKD)
	av market price/unit (MKD)	av ref price/unit (MKD)	
Salbutamol 0.1 mg/dose inhaler	153,72	110,00	43,72
Glibenclamide 5 mg cap/tab	1,52	0,70	0,82
Atenolol 50 mg cap/tab	2,23	0,85	1,38
Amitriptyline 25 mg cap/tab	2,20	2,45	-0,25
Ciprofloxacin 500 mg cap/tab	13,69	3,20	10,49
Amoxicillin 500 mg cap/tab	5,47	2,63	2,84
Diclofenac 50 mg cap/tab	3,03	0,85	2,18
Omeprazole 20 mg cap/tab	11,85	6,93	4,92

ASSESSMENT OF PHARMACEUTICAL EXPENDITURE TRENDS IN PORTUGAL – PRICING AND REIMBURSEMENT POLICY

Inês Teixeira, Zilda Mendes, Sara Ribeiro

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1. BACKGROUND

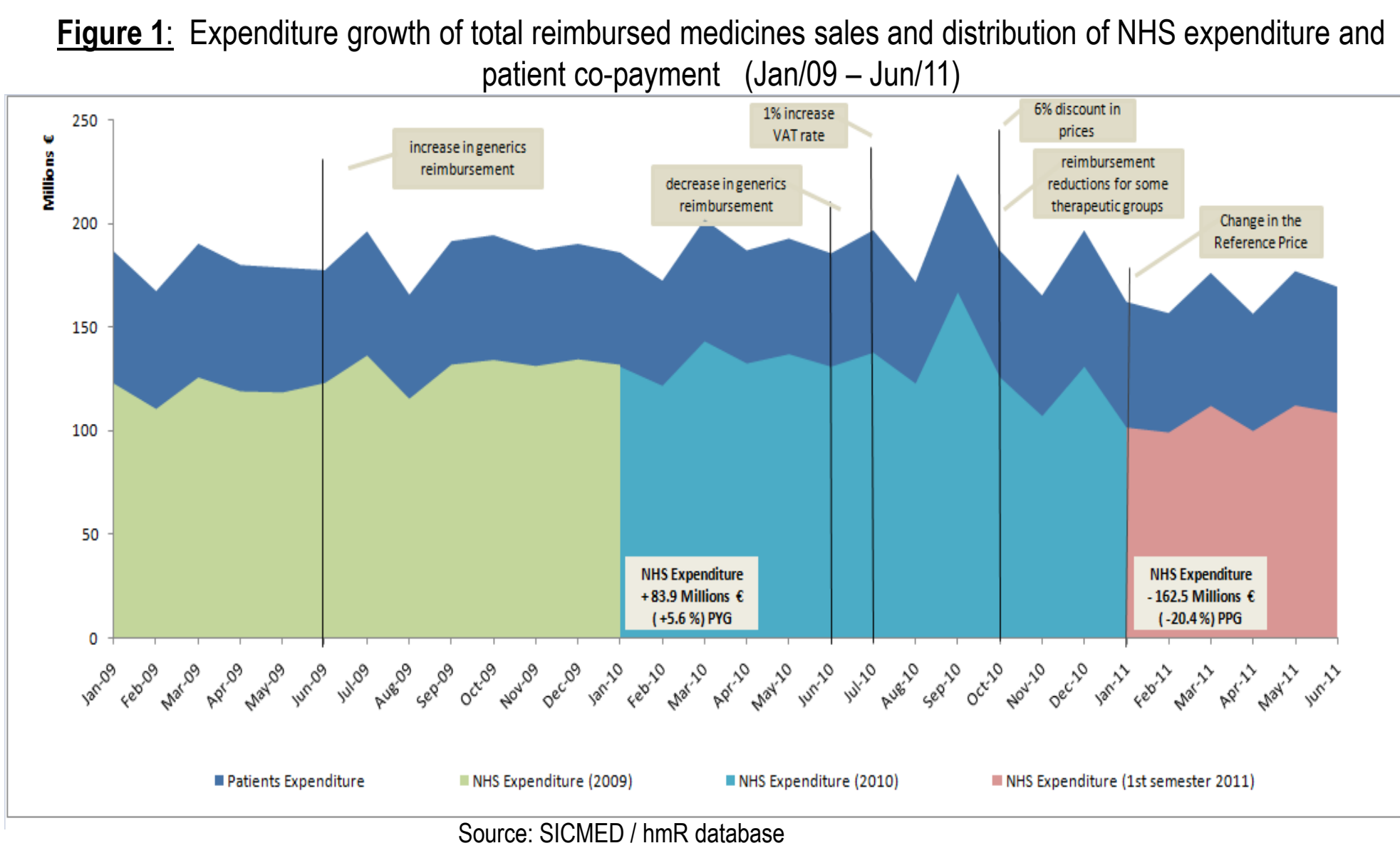
In Portugal several measures have been adopted in recent years aiming at controlling the National Health Service (NHS) medicine expenditures. The Stability and Growth Pact approved by the Portuguese Government in 2010 limited the annual growth of public expenditure in 1% for drugs reimbursed in outpatient sector. The Memorandum of Understanding signed in May 2011 between the Government and the International Authorities (European Commission, European Central Bank and the International Monetary Fund) subsequently has increased the requirements to reduce the public expenditure.

Besides guaranteeing the system sustainability, the Pharmaceutical Policy must ensure patients accessibility to medicines (along with rationality and equity) and should also support the pharmaceutical sector development.

In this context and considering the Portuguese social, political and economic environment, it is even more important and imperative to evaluate the results of the different policy measures, and assessing their impacts in the health sector.

4. RESULTS

The pharmaceutical market is highly regulated in Portugal, as in most European countries. The NHS pharmaceutical expenditure from the outpatient sector increased 5.6% in 2010 (83.9 million euros), exceeding the limit of 1% defined by the Stability and Growth Pact, only reached in the 2nd semester of that year. In addition the patient co-payment also increased 2.7% in 2010 [Figure 1].



We have identified the main factors that explain the impact in NHS expenditure and estimated the economic impact during the study period.

During the first 5 months of 2010 generic medicines were reimbursed at 100% for pensioners whose income was below the national minimum wage (the so called special regime). This legislation - approved in June 2009 and withdrawn 1 year later - was responsible for 26.8 million euros of NHS spending in 2010 (representing 31.9% of total growth).

Moreover, after July 2010, and due to the 1% increase in the VAT rate of medicines, the NHS expenditure increased 7.5 million euros (8.9% of NHS expenditure growth) in the 2nd semester.

The expenditure trend was also a consequence of the recently reimbursed medicines (branded medicines), with a high impact not only on the sales volume but specially on the sales value as they are costly medicines. The new molecules reimbursed only in the last 2 years represented 23.7 million euros of the NHS expenditure. The annually potential increase in expenditure was very high [Table 1].

Table 1: Annual NHS expenditure with the new reimbursement

Reimbursement Date	Nr. of new molecules	Sales Period					TOTAL
		2006	2007	2008	2009	2010	
2006	26	31,7	39,2	47,7	55,3	57,7	231,6
2007	18	-	19,8	49,0	66,6	77,5	213,0
2008	13	-	-	11,7	51,1	93,4	156,3
2009	16	-	-	-	4,3	16,6	20,9
2010	13	-	-	-	-	7,1	7,1
Unit: Million €	TOTAL	31,7	59,0	108,5	177,3	252,4	628,8

Source: SICMED / ANF and INFARMED database

5. CONCLUSIONS

The legal framework had a high impact on pharmaceutical expenditure trends, and consequently in public financial burden and patient co-payments. The policies required to accomplish in the coming years by the International Authorities, also predict major changes in the expenditure trends in Portugal and a huge impact on the pharmaceutical sector. All the measures adopted (not only in the outpatient but in the inpatient sector as well, considering that the hospital market continues to grow) should be assessed on a periodic basis in order to monitor the market dynamics and to identify the best strategies to promote rationality and efficiency that support the sector sustainability.

Besides price and reimbursement administrative reductions, with limited impact only in the short run, it would be important to consider prescribing guidelines and the promotion of generics, just to name a few measures. It is crucial that Government promotes the development of policies for monitoring the quality of prescribing, dispensing and utilization of medicines, with reasonable economic cost and the adoption of a more prevention perspective.

6. ACKNOWLEDGEMENTS

We gratefully acknowledge all Portuguese pharmacy owners who voluntarily provide sales data to the National Association of Pharmacies (ANF).

2. OBJECTIVES

The NHS pharmaceutical expenditure from the outpatient sector increased 5.6% in 2010 and decreased 20.4% in the first 6 months of 2011 compared with the same period of 2010.

Considering the Portuguese economic and financial situation, this study aims to analyze the public expenditure trends on pharmaceuticals and the impact of recent legislative changes in Portugal.

3. METHODS

We have considered the recent policy changes concerning the pricing and reimbursement system and we analyzed the nationwide database that includes sales (and prescription data) from Portuguese representative community pharmacies (79% of pharmacies), to point out the main expenditure growth factors and performed simulations to measure the impact of policy measures.

We considered a 30-month period, between January 2009 and June 2011. The main outcome measures were the total value and volume sales, as well as the NHS reimbursed expenditure and the patient co-payment. The statistical analysis of monthly data by product, chemical subgroup and by generic / brand name medicines was performed with the Statistical Analysis System (SAS), version 8.2.

At the end of 2010, the Government adopted further measures to control the public expenditure in pharmaceuticals. As a result the NHS expenditure started a downward trend together with the total pharmaceuticals market value. In the first 6 months of 2011, compared with the same period of 2010, the NHS pharmaceutical expenditure fell 20.4% (162.5 million euros) and the total market decreased 9.3% [Table 2].

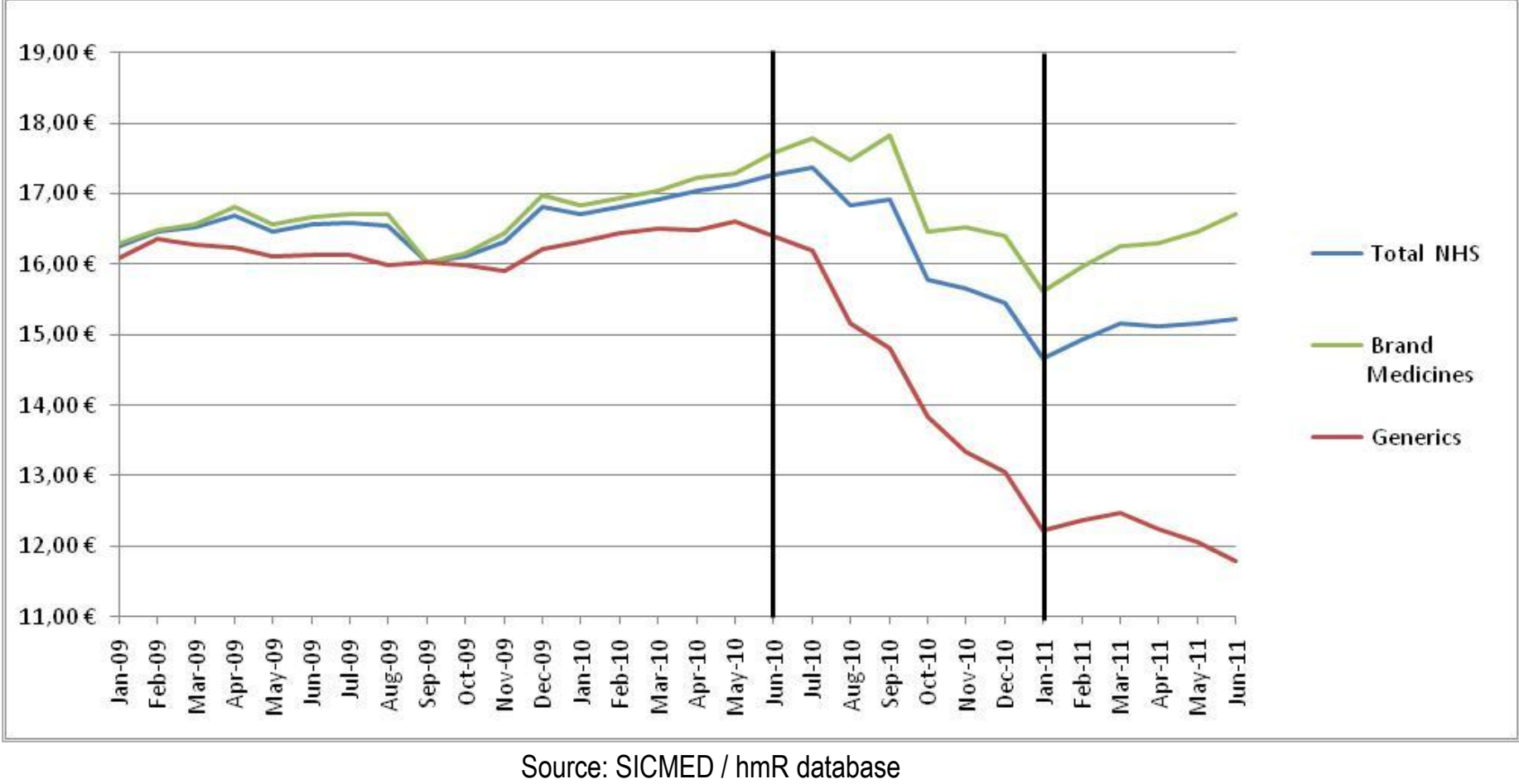
Table 2: Monthly evolution of total medicines market and reimbursed NHS expenditure (Jan/2011-

Period	Medicines Market (Million €)	Previous Year Growth	Medicines Market (Million Units)	Previous Year Growth	NHS Expenditure (Million €)	Previous Year Growth
Jan-11	259.2	-8.0%	23.2	4.6%	101.8	-22.4%
Feb-11	243.0	-6.8%	20.9	2.9%	99.5	-18.5%
Mar-11	270.9	-11.2%	22.7	-2.6%	112.3	-21.7%
Apr-11	248.2	-12.4%	20.7	-3.4%	100.1	-24.6%
May-11	267.6	-8.9%	22.2	-0.04%	112.5	-18.0%
Jun-11	259.1	-8.2%	21.5	2.1%	108.9	-17.0%
Jan-Jun/11	1 547.8	-9.3%	131.2	0.5%	634.9	-20.4%

Source: SICMED / hmR database

In October 2010 the Government implemented a 6% discount in reimbursed medicine prices and changed again the internal Reference Price System (after June 2010 only the 5 cheapest medicines in each Homogeneous Group were totally reimbursed for the special regime and then in October it decreased by 95%; in January 2011 the Reference Price changed to the average of these 5 prices instead the highest of these 5). As a consequence of the mandatory price reductions and, at the same time, the increased competition of generic companies (with optional price reductions), there was a drastic price reduction [Figure 2], marked in the generics segment and with an increasing gap compared with the branded segment:

Figure 2: Unitary Retail Price per package - NHS medicines market (2009-2011)



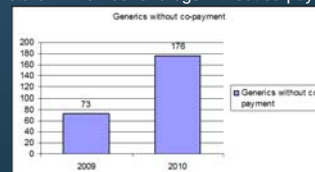
In addition, several reimbursement reductions were approved for a number of therapeutic groups (e.g. Proton Pump Inhibitors, Antidepressants) in October 2010, with a direct impact of 48.2 million euros reduction in the NHS medicines costs in the 1st semester of 2011.

If we adjust the NHS expenditure data to the effects of the VAT increase and to the prescription transference of some Health Subsystems (special Social Security schemes for certain professions) for the NHS, we observed that the reduction trend was even more pronounced (- 24.4%) in the 1st semester of 2011.

The present analysis covers only the ambulatory market but it is also important to consider the hospital medicines market whose growth (4.1% in the 1st semester 2011) is now the real driver of the public expenditure increased in Portugal (source: INFARMED – Portuguese Medicines Agency).

DISCLOSURES

The authors have no conflict of interest to declare.



Cost-containment measures on medicines prices in European countries during a global financial crisis year

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Problem Statement

Several European countries were hit by the global financial crisis. As a consequence countries introduced several measures to contain costs in the pharmaceutical sector (e.g. emergency price cuts). It might be expected that medicines prices decreased due to price cuts in countries hit by the crisis.

Objective

To survey the development of the prices of selected medicines in some European countries, including countries strongly hit by the crisis.

Results

In the analysis period Spain and Greece, among the countries hardest hit by the crisis, undertook cost-containment measures on medicines prices. In spring 2010 Spain cut the prices of generics by 30%. Prices of original products and of orphan medicines were reduced by discounts of 7.5% and 4% respectively which were borne by all stakeholders. The pharmacy margin, however, was increased for some expensive medicines. Greece reformed its pricing system in 2010, with price cuts, a reduction of the wholesale margin and twice an increase in value-added tax (VAT) on medicines. Price cuts were also undertaken in the Czech Republic. The pharmacy remuneration was changed in Belgium and Portugal. Increases in VAT rates on medicines took place in the Czech Republic, Finland, France, Portugal and Poland. The changes in the distribution remuneration and VAT rates were reflected in the prices of the surveyed products. At manufacturer price level, the prices in Greece decreased for the 3 medicines surveyed, while for Spain there was no change of the manufacturer price according to official medicine price lists. The manufacturer prices of the surveyed products remained rather stable during the research period, but for some products price increases could be observed in Romania and Finland in 2010 and in the Czech Republic in 2011, and price decreases in Ireland, Slovakia and Belgium.

Conclusions

Changes in the VAT rates proved to be a common policy measure as much as price cuts at manufacturer level in the surveyed countries. Some price cuts were "hidden" in the form of discounts which were then not reflected in the price data bases.

Lessons learned

For the analysis of prices several factors need to be taken into consideration: the manufacturer prices as well as other price components (e.g. distribution costs, taxes). It is sometimes difficult to get the full picture due to discounts, rebates and further "hidden" price elements. As a consequence, countries referencing to discount countries might not fully take advantage of the price cuts in the reference countries.

Methodology

Price survey of three medicines (olanzapin, abavir, trastuzumab) in the out-patient sector at all price types (ex-factory, wholesale and pharmacy retail prices gross and net)

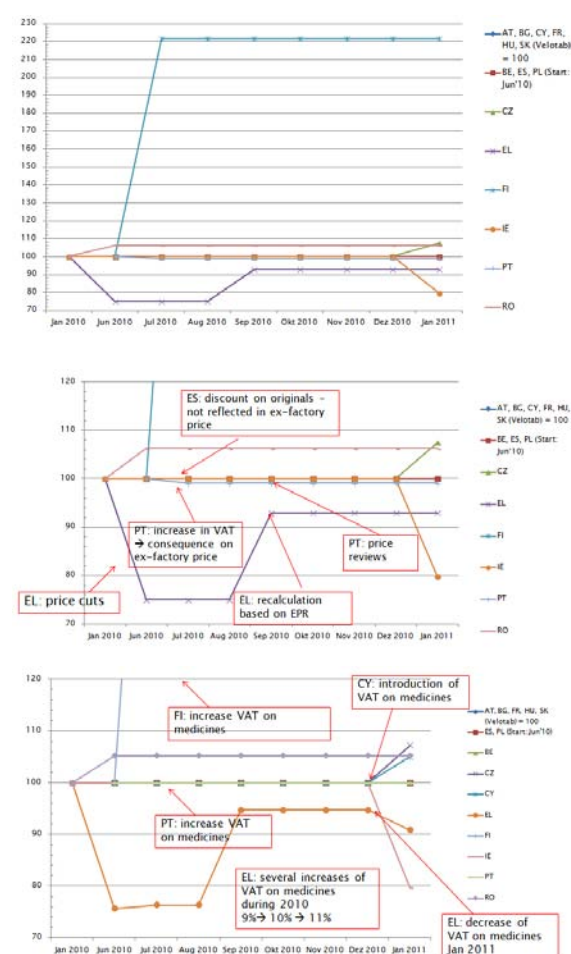
Data source: Pharmaceutical Price Information (PPI) service run by the WHO Collaborating Centre at the Austrian Health Institute

Time-line analysis of price data and **policy measures** (e.g. price cuts, changes in distribution margins and in VAT rates) at a monthly basis

Time period: January 2010 to January 2011; updates planned

Coverage of **15 European countries** (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Finland, France, Greece, Hungary, Ireland, Poland, Portugal, Romania, Spain, Slovakia)

Olanzapin, 20 mg, 28 units, ex-factory prices per unit in National Currency Units (NCU). Index = 100 = price of January (if available) or June 2010: Overall picture & policy measures impacting price changes



AT - Austria, BE - Belgium, BG - Bulgaria, CY - Cyprus, CZ - Czech Republic, EL - Greece, ES - Spain, FI - Finland, FR - France, HU - Hungary, IE - Ireland, PL - Poland, PT - Portugal, RO - Romania, SK - Slovakia

Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna 2011

No conflict of interest. No specific funding for this research which was done in the framework of the WHO CC activities funded by the Austrian Federal Ministry of Health

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Impact of medicines price reductions in Greece and Spain on other European countries applying external price referencing

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Problem Statement

Several European countries apply external price referencing (EPR), i.e. comparing to the prices in other countries as a basis for their pricing decision. A price decrease in a reference country, as this was the case for Greece and Spain in 2010 in reaction to the financial crisis, might have an impact on the prices in the other countries.

Objective

To assess if price reductions in Greece and Spain were "translated" into the prices in other European countries applying external price referencing.

Results

While there were decreases in the ex-factory prices of the selected medicines in Greece and Spain, they were seldom "translated" in lower prices in other European countries which refer to them. In the months following the price cuts in Greece and Spain, the ex-factory prices of Olanzapin and Trastuzumab remained stable in Austria, Belgium, Bulgaria, France, Hungary and Slovakia, while for Abacavir prices went down in Bulgaria, Ireland and Slovakia. There were even increases in the ex-factory prices for some or all of the three selected products in Finland, Romania and the Czech Republic. Ireland had reductions in the ex-factory prices for two medicines which are attributable to their price cuts to manage the financial crisis. At the level of wholesale and pharmacy retail prices, more changes, in particular increases, were observed which were mainly due to increases in the value-added tax (VAT) rates on medicines in several European countries during 2010.

Conclusions

We identified two major reasons for the low impact of the price reductions in reference countries on the EPR countries:

1. Missing regular price reviews which would allow learning about the price reductions.
2. Some price reductions were hidden, in particular the price decreases on original products in Spain, which were implemented as discounts and are not reflected in the price databases. It is recommended to assess the potential full savings which European EPR countries would achieve in case of regular price reviews and/or transparency about discounts.

Lessons learned

For making best use of external price referencing, an effective price monitoring system is needed, which keeps track of the changes in the reference countries. The functionality of external price referencing is distorted by intransparency like "hidden" price cuts in the form of discounts or rebates.

Methodology

Pharmaceutical policy analysis:

Price survey of three medicines (olanzapin, abavir, trastuzumab) in the out-patient sector at all price types (ex-factory, wholesale and pharmacy retail prices gross and net)

Data source: Pharmaceutical Price Information (PPI) service run by the WHO Collaborating Centre at the Austrian Health Institute

Time-line analysis of price data and **policy measures** (e.g. price cuts, changes in distribution margins and in VAT rates) at a monthly basis

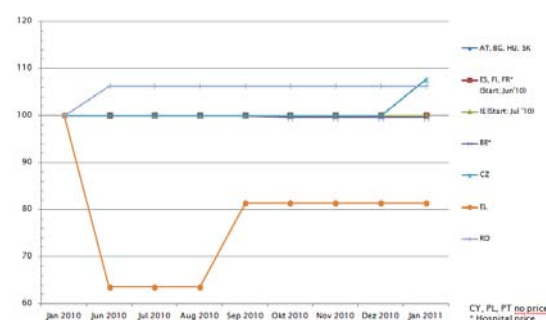
Time period: January 2010 to January 2011; updates planned

Coverage of **15 European countries** (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Finland, France, Greece, Hungary, Ireland, Poland, Portugal, Romania, Spain, Slovakia)

Abacavir sulfat, 300 mg, 60 units, ex-factory prices per unit in National Currency Units (NCU). Index = 100 = price of January (if available) or June 2010



Trastuzumab, 150 mg, 1 unit, ex-factory prices per unit in National Currency Units (NCU). Index = 100 = price of January (if available) or June 2010



AT - Austria, BE - Belgium, BG - Bulgaria, CY - Cyprus, CZ - Czech Republic, EL - Greece, ES - Spain, FI - Finland, FR - France, HU - Hungary, IE - Ireland, PL - Poland, PT - Portugal, RO - Romania, SK - Slovakia

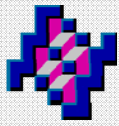
Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna 2011

No conflict of interest. No specific funding for this research which was done in the framework of the WHO CC activities funded by the Austrian Federal Ministry of Health

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Development of benchmarks to improve price negotiations of antiretroviral medicines (ARV) for low and middle income countries



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Problem Statement: There exist large differences in public procurement prices between countries for ARV caused partly by inefficiencies in the procurement process.

Objective: To design different price benchmarks to improve price negotiation for four first-line and three second-line ARVs combinations and to discuss their relevance in different country contexts.

Interventions: Three different benchmarks were developed to illustrate how much procurement agencies could save during ARV procurement:

- lowest generic price (LGP)
 - lowest innovator price (LIP) and
 - median procurement price (MPP)
- calculated by income level for four first-line combinations and three second-line ARV combinations. Saving scenarios were developed in which countries paid benchmark prices. For those countries which paid lower procurement prices than the benchmark prices, the current procurement price was used.

Results : In total, 2,395 procurements of 16 different ARV dosages forms from 85 countries (36 low-income, 39 lower-middle and 11 upper middle income) were included in the analysis. For first-line combinations, stratified by income group, the MPP was higher than the lowest generic procurement price in that income group but below the lowest innovator price in that income group (except in two out of twelve cases) (Table 1).

Table 1. First line combination price scenarios by level of income

		d4t+3tc+nvp	zdv+3tc+nvp	zdv+3tc+efv	d4t+3tc+efv
Low income	MPP	\$102	\$183	\$288	\$208
	LGP	\$66	\$139	\$285	\$204
	LIP	\$299	\$350	\$504	\$423
Lower middle income	MPP	\$102	\$190	\$303	\$215
	LGP	\$80	\$153	\$161	\$73
	LIP	\$73	\$153	\$467	\$380
Upper middle income	MPP	\$161	\$248	\$402	\$314
	LGP	\$73	\$153	\$303	\$215
	LIP	\$818	\$460	\$409	\$226

For second-line combinations the MPP was -for most combinations- higher than lowest innovator prices but lower than the lowest generic prices (Table 2).

Table 2. Second line combination price scenarios by level of income

		abc+ddi+lpv	ddi+3tc+lpv	zdv+ddi+lpv
Low income	MPP	\$1,113	\$821	\$887
	LGP	\$934	\$869	\$920
	LIP	\$730	\$321	\$372
Lower middle income	MPP	\$1,265	\$973	\$1,046
	LGP	\$1,069	\$850	\$909
	LIP	\$1,113	\$704	\$763
Upper middle income	MPP	\$1,736	\$1,356	\$1,422
	LGP	\$1,759	\$1,511	\$1,570
	LIP	\$905	\$599	\$752

Policies and practices targeted: Public procurement of high cost medicines.

Stakeholders involved: Social security institutions, ministry of health, pharmaceutical industry as well as patient interest groups.

Region covered: Global.

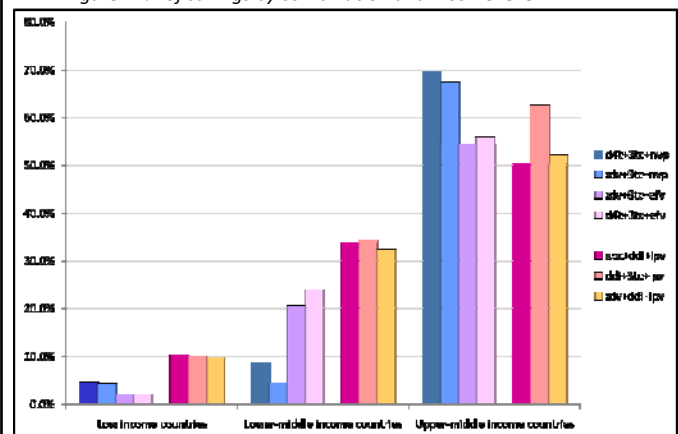
Study design: Cross-sectional data.

Time period: 2008

Setting: The World Health Organization Global Price Reporting Mechanism (GPRM) was used as the data source for analysis.

Results : Even if countries were only able to negotiate the MPP of their income group, the annual savings for ARV procurement would be between 8.7 and 32.4% out of the total amount spent for lower-middle and 50.3 to 69.2% for upper-middle income countries (Figure 1).

Figure 1: % of savings by combination and income level



Conclusions:

- Using benchmark methods should provide policy makers with relevant information to compare procurement prices. Different benchmarks provide complementary information:
- The median procurement price indicates the country's performance against other countries in the same income group.
- The lowest generic or lowest innovator prices provides information about the possible further price reduction and hence, savings.
- The production cost benchmark might have particular importance in highlighting the minimum expected prices for an ARV which is more feasible to achieve for generic ARV than innovator ARV.*

Lessons learned:

- Defining price benchmarks can provide relevant information to detect inefficient procurement procedures.
- There is currently no agreement on best practice of defining benchmarks;
- Transparency in procurement prices is a pre-requisite; however, there are currently a lack of incentives to individual countries or agencies to report transaction prices which jeopardize data availability.

ARMENIA

PRICES AND AFFORDABILITY OF MEDICINES

DEPARTMENT OF PHARMACY, NATIONAL INSTITUTE OF HEALTH
Irina Kazaryan, Anahit Sevikyan

DRUG UTILIZATION RESEARCH GROUP
Margarit Melikyan

PROBLEM

Lack of access to medicines is an important challenge for the Armenian pharmaceutical policy. Due to lack of Government funding patents forced to purchase the majority of medicines out-of-pocket. Reimbursement system only covers some vulnerable groups (some social groups and patients with certain diseases). There are no legal or regulatory provisions affecting pricing of medicines. High prices are one of the main reasons of a low affordability of medicines and treatment.

Approximately one third of the Armenian households surveyed in 2008 did not get a recommended service after they contacted the health system, for medicines, 35% of those who did not get a recommended service failed to do so "because of finances". In August 2009, 21% of households reduced or stopped buying the medicine they required.

OBJECTIVES

- to measure and evaluate prices of some essential medicines,
- to assess the cost of treatment for some patients with wide-spread diseases (adult respiratory infection, hypertension, asthma and so forth).

METHODOLOGY

Survey, analysis, price comparisons. Data on prices for more than 50 medicines (all brands and generics available on the local pharmaceutical market were covered) were collected in June and December 2007- 2010 from 30 community pharmacies located in different regions of Yerevan (the capital of Armenia).

RESULTS

1. Medicines Prices

The prices of the great majority of products increased during the period of time from June 2007 by December 2010. Significant price increases were found for some medicines.

Figure 1: Prices of selected medicines, June 2007 – December 2010 (1)

Figure 2: Prices of selected medicines, June 2007 – December 2010 (2)

During this period of time fluctuations of prices with their high increase for certain observed dates were identified for some medicines.

Figure 3: Fluctuations of prices, June 2007 - December 2010

2. Affordability of originator brand products/brand name generics versus the lowest-priced generics

Very large differences in prices of the originator brand products (and brand name generics) and the lowest-priced generics lead to different affordability of these products.

Figure 4: Prices of originator brand name products/brand name generics versus the lowest-priced generics, 2010

The number of days the lowest-paid government worker needs to work in order to be able to pay for a standard course of treatment for some wide-spread diseases. For selected diseases results were the followings:

Asthma (salbutamol, one inhaler of 200 doses) - 2.8 days if originator brand product is used, and 0.85 day for the lowest-priced generic;

Arthritis (diclofenac, 50 mg capsule or tablet) - 10.8 days and 0.78 day, correspondingly;

Acute respiratory diseases (amoxicillin+clavulanic acid 625mg tablet) - 4.3 days and 3 days; correspondingly;

Depression (amitriptyline 25 mg capsule or tablet) - 1.7day for the lowest-priced generic

* The originator brand product was not available.

Hypertension (perindopril 5mg tablet) - 3 days for originator brand product.

* The generic product was not available.

Figure 5: Affordability of therapy with selected medicines - originator brand products/brand name generics versus the lowest-priced generics, 2010 (30 days supply expressed in days' wages of the lowest paid government worker)

Figure 1

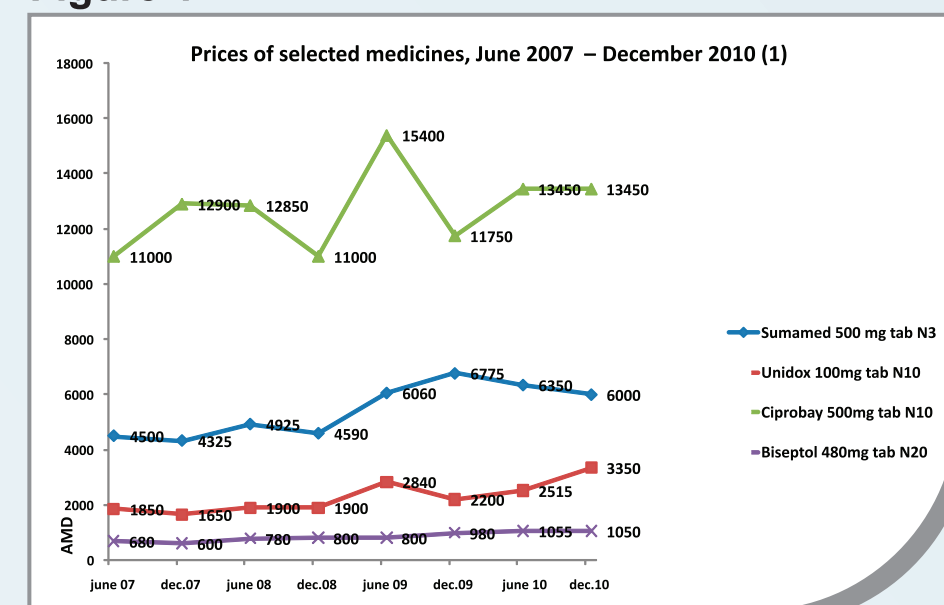


Figure 2

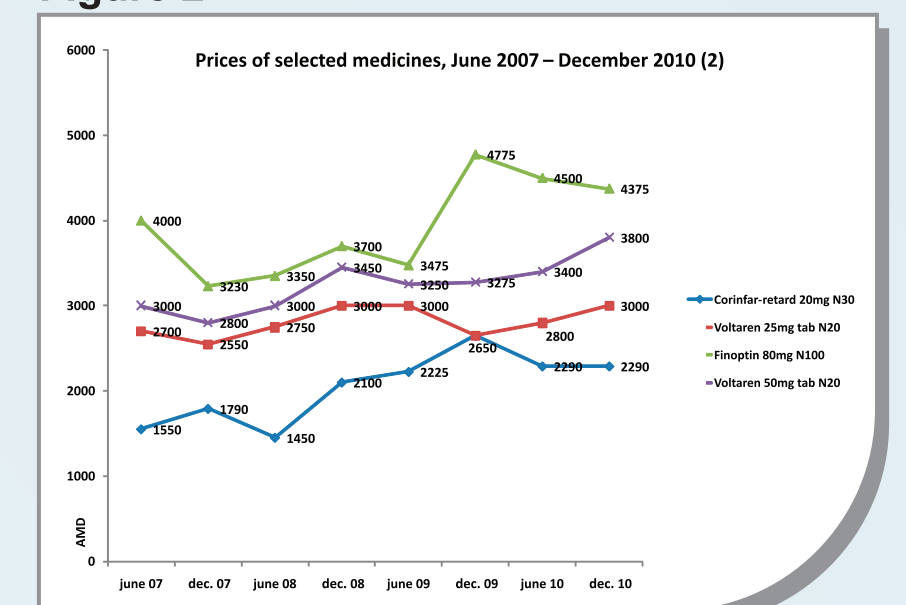


Figure 3

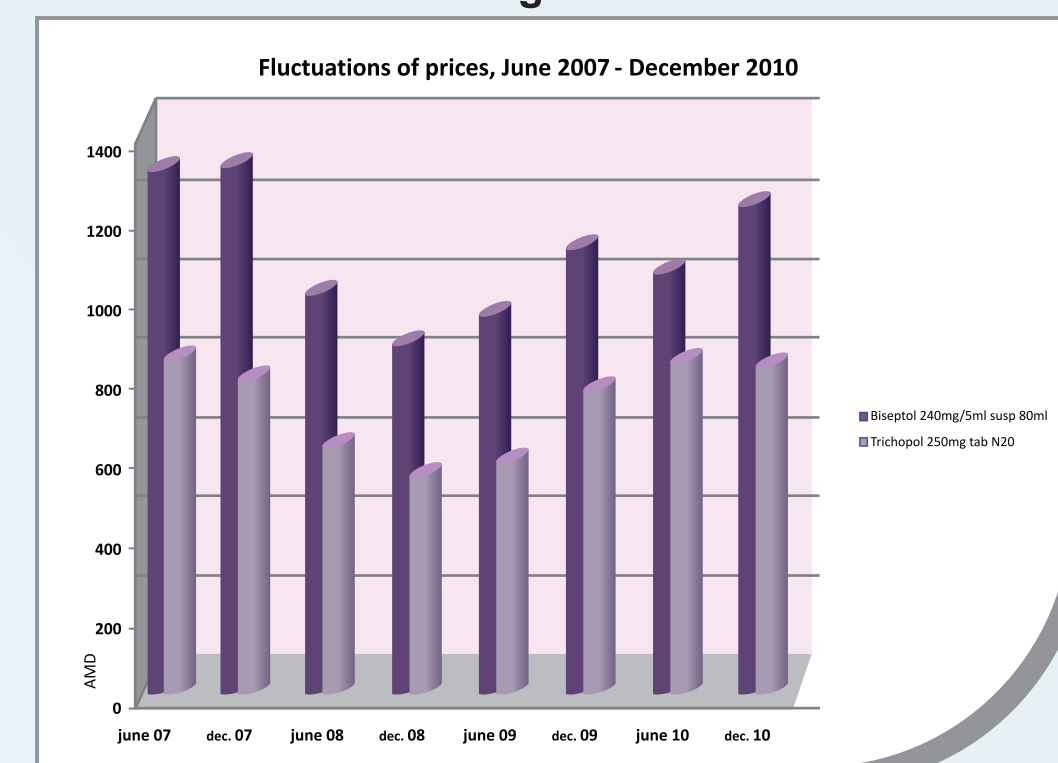


Figure 4

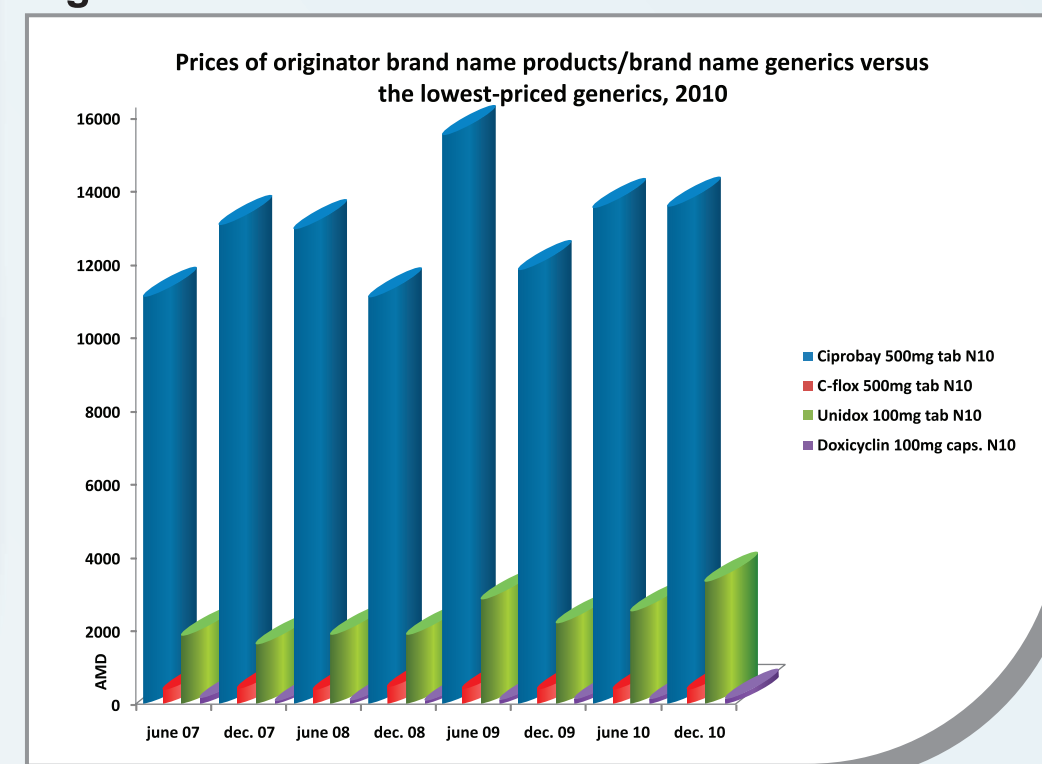
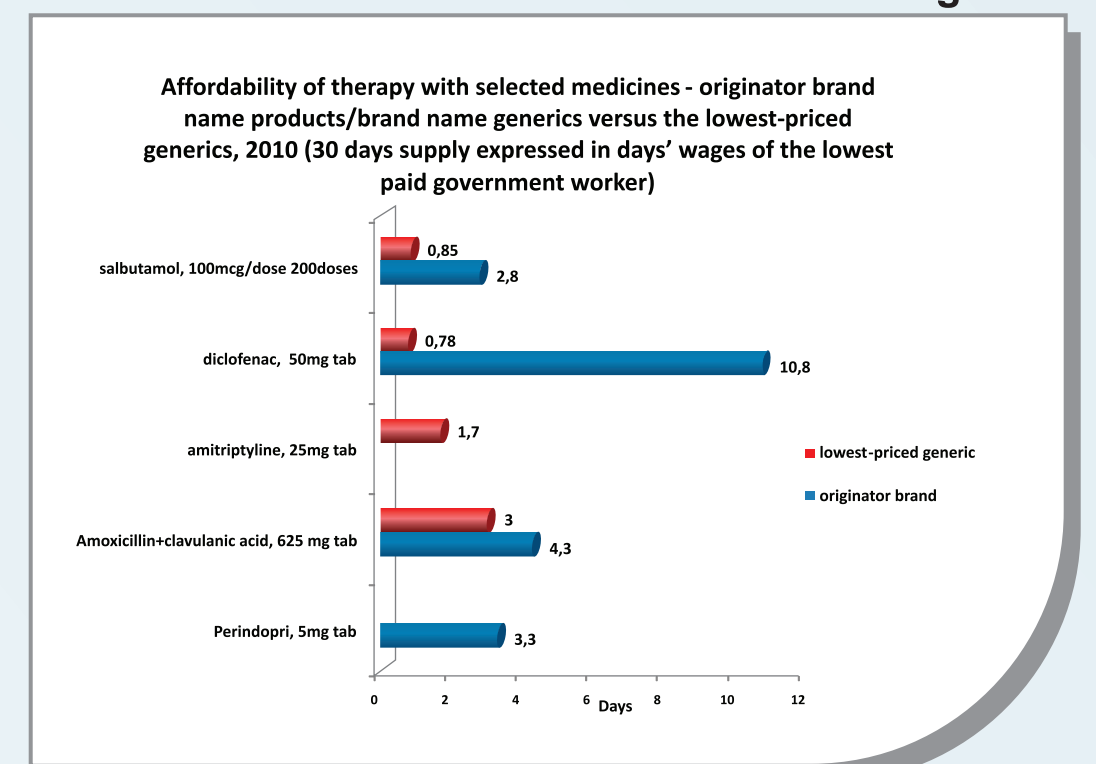


Figure 5



CONCLUSIONS AND RECOMMENDATIONS

There is a trend of medicines prices increase in Armenia for the period of time from June 2007 to September 2010. A lack of medicines affordability is clearly observed. There is a large differences in prices of the originator brand products (and brand name generics) and the lowest-priced generics.

Policy on medicines pricing should be reconsidered and appropriate strategies intended for reducing medicines prices should be introduced for improving the situation. Establishing a medicine pricing unit at the Ministry of Health would lead to creating the possibility for providing the constant attention to this issue, speeding the process of developing and introducing a new policy on price regulation and its evaluation.

The following strategies could be considered as leading to price control:

- regulating markups in the supply chain,
- regulating ex-factory prices for locally produced products,
- introducing Drug and Therapeutic Committees at Medical establishments,
- developing and introducing Clinical guidelines which could allow to increase affordability of treatment.
- training in the area of rational medicines use at post-graduate level could be very beneficial.

The comparative description of pharmaceutical pricing and reimbursement policies in the selected Latin-American and European countries.

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Background Information



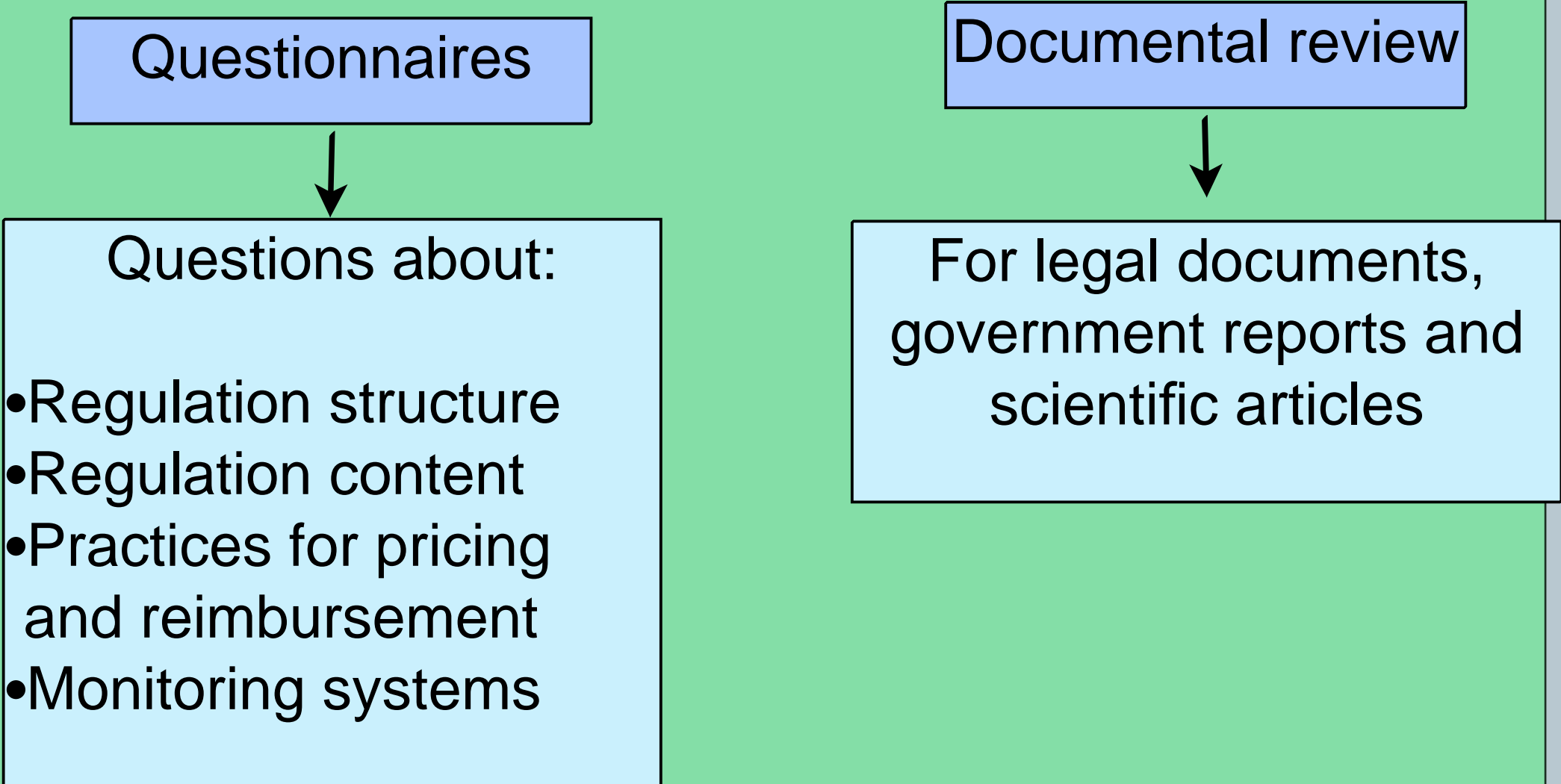
Pharmaceutical pricing and reimbursement policies are being established all over world. There is a lack of information on the operation of the pharmaceutical pricing and reimbursement policies in Colombia, Brazil and Poland.

Objective

To Describe and compare the differences and similarities of the pharmaceutical pricing and reimbursement policies in Brazil, Colombia, the United Kingdom and Poland.

Methods

Questionnaires were handed out to specialist in the subject in each country and were self administrated, a documental review was also performed



Conclusions

- All the countries included in this study have official pharmaceutical pricing and reimbursement policies.
- The updates of the official documents on reimbursement and pricing policies are not performed as frequent as the law establishes it in Brazil and Colombia.
- The criterion used for the updates is not well known.
- Brazil and Colombia have similar behavior regarding the policy making, this can be extrapolable to Latin America
- Stakeholder pressure is a main factor in the decision making in the reimbursing policy in Colombia.

Lessons Learned

- Gathering the information has better results when is performed by a personal interview.
- Brazil was the country with better results regarding collaboration
- Colombia showed little collaboration, this situation has been described in other articles.

Results

Table 1. Summary of some findings about the pricing policies in the selected countries

PRICING				
	BRAZIL	COLOMBIA	POLAND	UK
Frequency of the updates of the official documents	According to regulation every year but not in practice.	Updated recently due to irregularities in reimbursed prices	Currently being updated due to a reform in the reimbursement policy	Every 5 years or monthly for generics
Ministry taking the pricing decisions	Ministry of health	Ministry of commerce Industry and Tourism	Ministry of Health	Department of health
Sectors applying the pricing policy	All sectors	All sectors	Public – reimbursed drugs	Public – reimbursed drugs

Table 2. Summary of some findings about the reimbursement policies in the selected countries

REIMBURSEMENT				
	BRAZIL	COLOMBIA	POLAND	UK
Frequency of the updates of the official documents	Reference price program every 2 years. Essential drug list: unknown	Not according to law requirements, but according to orders from the judicial branch	Currently being updated due to a reform	Every 3-5 years
Practices used for reimbursement	Positive list, reference pricing	Positive list	Reference pricing, positive list, economic evaluations	Negative list, economic evaluations
Number of products reimbursed by the government	Between 39 to 135 pharmaceutical presentations	Between 600-660 pharmaceutical presentations	Around 4700 formulations.	All the products in the market except for the negative list.

The comparative analysis of the impact of pharmaceutical pricing and reimbursement policies on drug access and cost containment in the selected Latin American and European countries.

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Background information



Pharmaceutical expenditures are growing at a faster rate than Gross Domestic Product or other health care expenditures . Pharmaceutical pricing and reimbursement policies focus on increasing the access to pharmaceuticals in a way the system can afford it.

Objective

To analyze the impact of the pharmaceutical pricing and reimbursement policies in terms of access and cost containment for Brazil, Colombia, Poland and the United Kingdom.

Methods

A review was performed in International, Latin American, Colombian, Brazilian and Polish databases:

- Medline,
- The Cochrane Library,
- Embase
- LILACS (Latin American and Caribbean)
- OPSCoI (Colombian)
- VSPCoI (Colombian)
- SUS (Brazilian)
- CIDSaude (Brazilian)
- Polska Bibliografia (Polish)
- Farmakoekonomika (Polish journal)

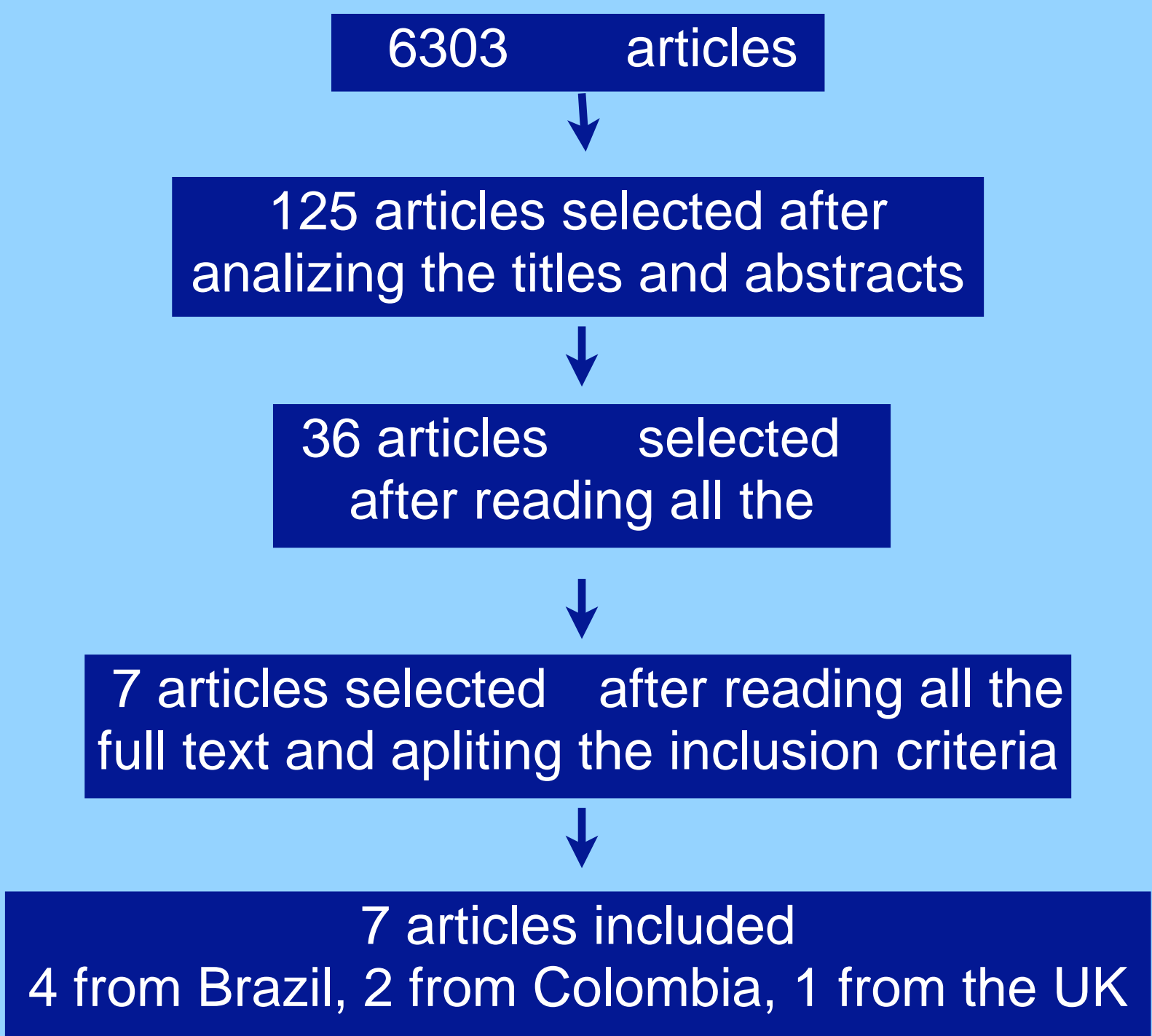
Limits: Language english, spanish, polish and portuguese.

Inclusion criteria: Articles and reviews on pharmaceutical pricing and reimbursement policies including any of the countries selected (Brazil, Colombia, Poland and United Kingdom).

Quality assessment of the articles:

- Objectives well defined.
- Data appropriate
- Methodology cohorent with the aims
- Conclusions derived logically from the results

Results



Cost cointainment:

- **UK:** No decline in the prescription rates and net ingredient cost was found after the publications of the negative or positive with major restrictions recommendations appraisal from the NICE.
- **Brazil:** In the Brazil popular pharmacy program, drug prices were compared between the public and private facilities. Higher prices were found in the public ones, even though the government controls drug prices in the public pharmacies.

Drug access:

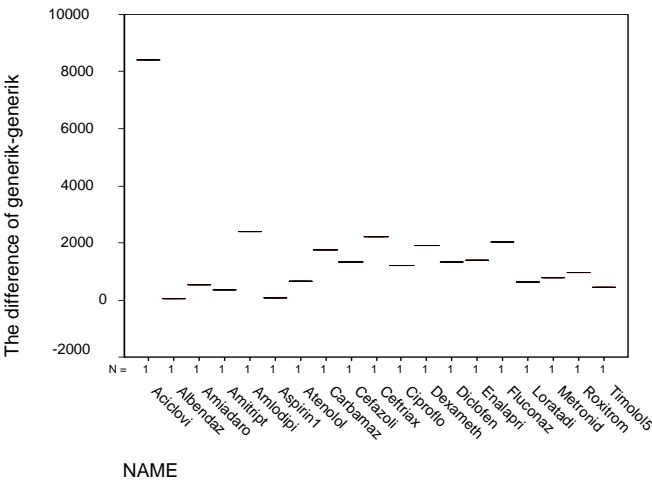
- **Brazil:** Around 59% in the Brazil Popular Pharmacy program (2009). Drugs are not sought in the public pharmacies, due to lack of confidence from the population on those. Higher availability of drugs included in the national essential drug lists was found in the private pharmacies
- **Colombia:** WHO in 1997 assessed the access to the medicines included in the national positive list and the pricing policy also. The grade was 4 of 5 for both. In 2002 a study showed 51% of access to antidiabetic drugs included in the national essential drug list in Colombia.

Conclusions

- There is no evidence implying that the reimbursement and pricing policies in the UK have improved drug access or cost containment.
- In Brazil there is a lack of access to the reimbursed drugs included in the essential drug lists.
- A study performed in Colombia showed lack of access to drugs included in the national positive list.
- No study was found assessing the impact of the pharmaceutical pricing and reimbursement policies in Poland

Abstract:

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<i>Conference strand in which the abstract is submitted (for selection):</i>	Strand 2 – Rational use of medicines
<i>Title of the abstract:</i>	Essential Medicines in Private Pharmaceutical Market of Armenia
<i>First author:</i>	Perikhanyan A.V. MS, MPH Yerevan State Medical University, Department of Pharmaceutical Management
<i>Associated Authors:</i>	Hakobyan A. A. MD, PhD, Beglaryan M.H. MD, PhD Yerevan State Medical University, Department of Pharmaceutical Management
<i>Problem Statement:</i>	In many developing countries the necessary essential medicines are not always available, accessible, and affordable to those in need. The aim of the national pharmaceutical policy is to supply a country with efficient, safe and high quality drugs that would be equally accessible for each citizen.
<i>Objective(s):</i>	Based on the internationally accepted concept by World Health Organization (WHO) that the essential drugs are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the community can afford, we aimed to observe the pharmaceutical market of Armenia with regard to availability of essential drugs, to price difference among generics with the same active ingredient and to some other representative parameters of supplied and produced drugs in Armenia.
<i>Policy/ies targeted:</i>	generic promotion ,essential medicines
<i>Stakeholder(s) involved:</i>	
<i>Region covered:</i>	WHO region, national level
<i>Study design:</i>	Analysis
<i>Time period:</i>	From February 2011 to May 2011
<i>Setting:</i>	Private sector
<i>Intervention(s):</i>	Information about essential medicines was elicited from price-lists of four largest vendor companies in December 2010. Provision of essential pharmaceuticals was described, compared and analyzed based on information about drug names (range).
<i>Result(s):</i>	<p>According to our analysis Armenian biggest wholesalers receive and distribute essential medicines from 42 foreign exporters. Germany and Ukraine share the first place by product delivery (8.2%). The local production of drugs is comprised 13.4%, all generics. The most importable drugs from the list of essentials were “Diclofenac” and “Ceftriaxone”. The widest range of essential drugs by therapeutic group was a group of anti-infective drugs for systematic use (28.2%). Generics were more (76.8%) than known brands (21.8%).</p> <p>All companies together delivered 168 (54.4%) drug names from 309 in the National List of Essential Medicines (NLEM). Hundred thirty two drug names (14.1%) in required dosages by NLEM were not found among 936 drugs suggested by companies.</p> <p>By assuming that the price difference between the most expensive generic and the cheapest generic should not vary significantly we received one extreme difference with “Aciclovir 200mg № 20 tablets package” was approximately \$23. The mean price difference of other generics was approximately 1.500 AMD (Armenian Drams) or \$ 4.1 (SD-1816.6, Mean-1496.6, 95%CI [621-2372]). Only the prices of wide range of medications were compared.</p>

	 <p>Figure 1. Distribution of price differences among generics</p>
<p><i>Conclusions</i></p>	<p>Further analyses will help to deeper understand the pharmaceutical market of Armenia by comparing the export volumes and the prices of generic essential medicines with international reference prices, by studying a dynamics of essential drugs availability in follow-up. Promotion of generic medicines is well established in Armenia which assumes the improved affordability without consideration of quality and prices.</p>
<p><i>Lesson(s) learned and success factor(s) – optional, but recommended:</i></p>	<p>This study results could be a valuable source for policy considerations and the assessment of national drug supply. One can imply about widely accepted and widely used essential medicines in Armenian health care market.</p>
<p><i>Keywords:</i></p>	<p>Essential drugs, private pharmaceutical market, generic drugs, developing country, wholesalers</p>
<p><i>Funding Source(s):</i></p>	