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 of 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 significant 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

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.

The division of JMH, PCS, AKM and HGML received unrestricted funding from GlaxoSmithKline, Novo Nordisk, the private-public funded Top Institute Pharma, the Medicines Evaluation Board, and the Dutch Ministry of Health. LvD received unrestricted grants from BMS, Astra Zeneca and GSK.
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

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.

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

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

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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 lose 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

<table>
<thead>
<tr>
<th>Pricing approaches</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriptive pricing (PP)</td>
<td>France*, Netherlands, Norway, Turkey</td>
</tr>
<tr>
<td>Market forces (MF)</td>
<td>Germany, Poland, Spain**, Sweden,</td>
</tr>
<tr>
<td></td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Mixed approach (MA)</td>
<td>Austria, Estonia, Finland, Italy, Lithuania,</td>
</tr>
<tr>
<td></td>
<td>Portugal, Serbia</td>
</tr>
</tbody>
</table>

*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.

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

Figure 2 – Statin expenditure in 2007 versus utilisation (DDDs/ 1000 inhabitants/ year)
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 (DDDs – 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
Funded in part with a grant from Karolinska Institutet

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Prescribing restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia (EE)</td>
<td>Only reimbursed in patients with FH (TC &gt;8mmol/l) or following a CV event (TC &gt;4.5mmol/l). Otherwise 100% co-pay</td>
</tr>
<tr>
<td>Croatia (HR)</td>
<td>2003 - 2003 – 25% co-pay for 2ndy prevention in patients with IHD or CV disease, diabetes with a TC&gt; 5mmol/l; 75% for patients for primary prevention if 10 year chance of CHD &gt;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 &gt;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</td>
</tr>
<tr>
<td>Lithuania (LT)</td>
<td>Initially only reimbursed for 2ndy prevention and only for 6 months (first prescription via cardiologist). Now lifted for generic statins</td>
</tr>
<tr>
<td>Serbia (RS)</td>
<td>Principally for secondary prevention coupled with patient co-payments to limit the budget</td>
</tr>
</tbody>
</table>

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

M. Abuelkhair (Health Authority Abu Dhabi – HAAD, UAE), B. Godman (KI, Sweden), S. Fahmy (HAAD, UAE), S. Abdu (HAAD, UAE), LL Gustafsson (KI, Sweden)

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.

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

<table>
<thead>
<tr>
<th>PPI</th>
<th>Expenditure AEDs - 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole</td>
<td>23189515</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>3667021</td>
</tr>
<tr>
<td>Total</td>
<td>26856537</td>
</tr>
<tr>
<td>Initial Total</td>
<td>59729519</td>
</tr>
<tr>
<td>Savings (AED)</td>
<td>32872982</td>
</tr>
<tr>
<td>Savings - € and US$</td>
<td>€6.23mn, US$8.95mn</td>
</tr>
</tbody>
</table>

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.
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>
<thead>
<tr>
<th>ACEi</th>
<th>Year generic first available</th>
<th>% reduction versus originator 2001 prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic enalapril</td>
<td>1997</td>
<td>52%</td>
</tr>
<tr>
<td>Generic ramipril</td>
<td>2004</td>
<td>65%</td>
</tr>
<tr>
<td>Generic quinapril</td>
<td>2006</td>
<td>50%</td>
</tr>
<tr>
<td>Generic fosinopril</td>
<td>2006</td>
<td>42%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Generic SSRI</th>
<th>% reduction generic vs. originator 2001 prices</th>
<th>Generics available 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine</td>
<td>92%</td>
<td>Yes</td>
</tr>
<tr>
<td>Citalopram</td>
<td>88%</td>
<td>No</td>
</tr>
<tr>
<td>Sertraline</td>
<td>85%</td>
<td>No</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Country</th>
<th>% reduction fluoxetine</th>
<th>% reduction citalopram</th>
<th>% reduction sertraline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>55%</td>
<td>59%</td>
<td>73%</td>
</tr>
<tr>
<td>Portugal</td>
<td>48%</td>
<td>NA</td>
<td>40%</td>
</tr>
<tr>
<td>Scotland</td>
<td>87%</td>
<td>83%</td>
<td>87%</td>
</tr>
<tr>
<td>Spain (Catalonia)*</td>
<td>65%</td>
<td>47%</td>
<td>47%</td>
</tr>
<tr>
<td>Sweden</td>
<td>92%</td>
<td>94%</td>
<td>95%</td>
</tr>
</tbody>
</table>

*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
Cha-oncin Sooksriwong Dr.PH,
Siriwat Suwattanapreeda MSc., Petcharat Pongcharoenasuk PhD.

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 citizens. 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.aha.wb.org/medicineprices/surveys/200610r1sdcs/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

<table>
<thead>
<tr>
<th>Med. Name</th>
<th>2006</th>
<th>2010</th>
<th>% Change 2010 to 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lowest MSH price (USD)</td>
<td>Thai Public Procurement price (Baht)</td>
<td>Lowest MSH price (USD)</td>
</tr>
<tr>
<td>Amikacin 25 mg tab</td>
<td>0.0049</td>
<td>0.37</td>
<td>-18.37</td>
</tr>
<tr>
<td>Atenolol 50 mg tab</td>
<td>0.0088</td>
<td>0.32</td>
<td>-61.36</td>
</tr>
<tr>
<td>Azithromycin 250 mg tab</td>
<td>0.2417</td>
<td>28.30</td>
<td>31.33</td>
</tr>
<tr>
<td>Captopril 25 mg tab</td>
<td>0.0182</td>
<td>1.98</td>
<td>-43.92</td>
</tr>
<tr>
<td>Ceftiraxone 1g/vial</td>
<td>1.9311</td>
<td>18.30</td>
<td>-58.09</td>
</tr>
<tr>
<td>Ciprofloxacin 500 mg tab</td>
<td>0.0266</td>
<td>2.49</td>
<td>-8.65</td>
</tr>
<tr>
<td>Cotrimoxazole suspension+40 mg/ml</td>
<td>0.0037</td>
<td>0.6</td>
<td>-5.41</td>
</tr>
<tr>
<td>Diazepam 5 mg tab</td>
<td>0.0042</td>
<td>0.2</td>
<td>-45.24</td>
</tr>
<tr>
<td>Glibenclamide 5 mg tab</td>
<td>0.0039</td>
<td>0.36</td>
<td>-35.90</td>
</tr>
<tr>
<td>Omeprazole 20 mg tab</td>
<td>0.0094</td>
<td>0.85</td>
<td>-82.32</td>
</tr>
<tr>
<td>Salbutamol 100 mg/dose</td>
<td>0.0081</td>
<td>0.45</td>
<td>-30.86</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Med. Name</th>
<th>2006</th>
<th>2010</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin 25 mg tab</td>
<td>2.03</td>
<td>2.84</td>
<td>36.54</td>
</tr>
<tr>
<td>Atenolol 50 mg tab</td>
<td>0.93</td>
<td>1.82</td>
<td>85.71</td>
</tr>
<tr>
<td>Azithromycin 250 mg tab</td>
<td>3.15</td>
<td>3.58</td>
<td>13.65</td>
</tr>
<tr>
<td>Captopril 25 mg tab</td>
<td>2.95</td>
<td>4.64</td>
<td>56.76</td>
</tr>
<tr>
<td>Ceftiraxone 1g/vial</td>
<td>0.41</td>
<td>0.84</td>
<td>104.88</td>
</tr>
<tr>
<td>Ciprofloxacin 500 mg tab</td>
<td>2.55</td>
<td>1.87</td>
<td>-26.67</td>
</tr>
<tr>
<td>Cotrimoxazole suspension+40 mg/ml</td>
<td>1.15</td>
<td>1.37</td>
<td>18.10</td>
</tr>
<tr>
<td>Diazepam 5 mg tab</td>
<td>0.73</td>
<td>1.58</td>
<td>102.56</td>
</tr>
<tr>
<td>Glibenclamide 5 mg tab</td>
<td>2.51</td>
<td>3.03</td>
<td>20.72</td>
</tr>
<tr>
<td>Omeprazole 20 mg tab</td>
<td>0.39</td>
<td>2.01</td>
<td>415.38</td>
</tr>
<tr>
<td>Salbutamol 100 mg/dose</td>
<td>1.52</td>
<td>1.57</td>
<td>3.29</td>
</tr>
</tbody>
</table>

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 = 32.6526 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
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
a) Provide a workable definition for “risk sharing”
b) Review current schemes to provide future guidance to countries as arrangements grow

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

Results (continued)

Financial based schemes:
i) Price-volume agreements (PVAs)/ budget impact schemes which focus on controlling financial expenditure
ii) 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:
i) Schemes whereby companies refund monies or provide free drug if the desired outcomes are not reached
ii) 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:
(a) where responses can be determined within a short time and reduce uncertainty
(b) high unmet need with a new technology showing benefit
(c) lowering drug costs in targeted patients will enhance reimbursement having factored in administration costs
(d) price: volume schemes help limit the budget impact of new drugs enhancing their affordability
(e) 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.
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 (C09AA01to16, 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.

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).

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.
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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³Pharmacology, University of Antwerp, 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)

![Graph showing sales volume and average cost per unit for cholesterol lowering medication](image)

Conclusion
Generic market in Belgium remains relatively low (14.7%).

Sustainability of policy regulations seems partly counteracted by other market mechanisms.

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

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
Initiated by BOF (UA). Currently funded by BOF-ID (UA). Additionally we acknowledge SIMID (IWT Flanders).

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

M. Kalaba (Republic Institute for Health Insurance, Serbia), M. Bajcetic (University of Belgrade, Serbia), T. Sipetic (Medicines and Medical Devices Agency of Serbia), B. Godman (KI, Sweden; Mario Negri, Milan, Italy), S. Coenen (Infectious Disease Institute, University of Antwerp, Belgium), H. Goossens (University of Antwerp, Belgium)

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

Methodology
a) 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, ALIMS database) from 2005 to 2009
b) Total utilisation rates in 2007 compared with ESAC database for the same classes across Europe
c) Potential measures suggested based on the experiences of the co-authors

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 ALIMS) 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

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.
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 %.

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.
Pharmacy mark-ups. The reference price is the maximum amount that HIF established in 2007 based on ex-factory price, wholesale mark-ups and the region. 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. 2.126, 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 227.87 min in 2005 to 94.12 min in 2010 (Wilcoxon Matched Pairs Test: Z=2.240, p=0.025). 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 = -5.607, p<0.0001) 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).

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Medicine name (INN) and dosage form</th>
<th>Av. treatment cost in 2005 (MKD*)</th>
<th>Av. treatment cost in 2010 (MKD*)</th>
<th>Av. income/cost 2005 (working hours)</th>
<th>Av. income/cost 2010 (working hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>Glibenclamide 5mg tabl</td>
<td>139.20</td>
<td>91.20</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Atenolol 50mg tabl</td>
<td>90.51</td>
<td>66.90</td>
<td>2</td>
<td>0.75</td>
</tr>
<tr>
<td>Adult respiratory infection</td>
<td>Amoxicillin 500mg caps</td>
<td>93.68</td>
<td>114.87</td>
<td>2</td>
<td>1.25</td>
</tr>
<tr>
<td>Gonorea</td>
<td>Ciprofloxacin 500mg tabl</td>
<td>24.99</td>
<td>13.69</td>
<td>0.5</td>
<td>2</td>
</tr>
<tr>
<td>Arthritis</td>
<td>Diclofenac 50mg tabl</td>
<td>130.20</td>
<td>181.80</td>
<td>2.7</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>Amitriptylin 25mg tabl</td>
<td>244.82</td>
<td>198.00</td>
<td>5</td>
<td>2.20</td>
</tr>
<tr>
<td>Asthma</td>
<td>Salbutamol inhaler 0.1 mg/dose</td>
<td>30.93</td>
<td>23.00</td>
<td>0.65</td>
<td>0.25</td>
</tr>
<tr>
<td>Ulcer</td>
<td>Omeprazole 20mg tabl</td>
<td>643.50</td>
<td>355.50</td>
<td>15.53</td>
<td>4</td>
</tr>
</tbody>
</table>

*MKD = 61.5 Euros

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Av. cost in MKD</th>
<th>St deviation</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>151.30</td>
<td>201.66</td>
<td>158.94</td>
<td>643.50</td>
</tr>
<tr>
<td>2010</td>
<td>120.82</td>
<td>122.65</td>
<td>13.69</td>
<td>-355.50</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Av. cost of work (hours)</th>
<th>St deviation</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>227.87</td>
<td>253.26</td>
<td>30.00</td>
<td>812.00</td>
</tr>
<tr>
<td>2010</td>
<td>54.72</td>
<td>70.08</td>
<td>15.00</td>
<td>240.00</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>Medicine name (INN)</th>
<th>2010 av market price/unit (MKD)</th>
<th>av ref price/unit (MKD)</th>
<th>Difference (MKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salbutamol 0.1 mg/dose inhaler</td>
<td>153.72</td>
<td>110.00</td>
<td>43.72</td>
</tr>
<tr>
<td>Glibenclamide 5 mg cap/tab</td>
<td>1.52</td>
<td>0.70</td>
<td>0.82</td>
</tr>
<tr>
<td>Atenolol 50 mg cap/tab</td>
<td>2.23</td>
<td>0.85</td>
<td>1.38</td>
</tr>
<tr>
<td>Amoxicillin 25 mg cap/tab</td>
<td>2.20</td>
<td>2.45</td>
<td>-0.25</td>
</tr>
<tr>
<td>Ciprofloxacin 500 mg cap/tab</td>
<td>13.69</td>
<td>3.20</td>
<td>10.49</td>
</tr>
<tr>
<td>Amoxicillin 500 mg cap/tab</td>
<td>5.47</td>
<td>2.63</td>
<td>2.84</td>
</tr>
<tr>
<td>Diclofenac 50 mg cap/tab</td>
<td>3.03</td>
<td>0.85</td>
<td>2.18</td>
</tr>
<tr>
<td>Omeprazole 20 mg cap/tab</td>
<td>11.85</td>
<td>6.93</td>
<td>4.92</td>
</tr>
</tbody>
</table>
ASSESSMENT OF PHARMACEUTICAL EXPENDITURE TRENDS IN PORTUGAL – PRICING AND REIMBURSEMENT POLICY

Inês Teixeira, Zilda Mendes, Sara Ribeiro
Center for Health Evaluation & Research (CEFAR), National Association of Pharmacies (ANF)

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.

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.

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].

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 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 in 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 of 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.

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 of 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.

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).

DISCLOSURES
The authors have no conflict of interest to declare.

Pharmaceutical Pricing and Reimbursement Information - PPRI Conference (September 29-30, 2011, Vienna, Austria)
Croatian model for P&R provided unique approach in defining prices for drugs on positive list, financially covered by the National health insurance (HZZO). When system was completely defined and implemented (2007) it was based on external referral to 3+2 countries for reference (Italy, France, Slovenia + Spain, Czech Republic). Three levels of comparison were defined, where comparison was determined separately for generics and for originator drugs. Negotiations for problematic prices of specific drugs were introduced as well. The internal referral system was placed through definition and implementation of 41 pharmaco-therapeutic groups for prescription drugs (drugs with same or similar pharmacotherapeutic effect, mostly up to the fourth ATC level of comparison). Additional criteria for defining the reference price were possibilities for supply of the market (share of consumption), based on expenditures and utilization for previous year. The system enabled authorities in realistic projections of expenditures on drugs on yearly basis, as well as control of the market and rational drug use. This is shown in drug expenditures for the period 2001-2009 (Table 1) and changes in drug prices (Table 2).

Background info

Table 1. Factors of increase/measures undertaken

<table>
<thead>
<tr>
<th>Country</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of prescription drugs</td>
<td>29,1</td>
<td>30,2</td>
<td>31,1</td>
<td>32,0</td>
<td>32,9</td>
<td>33,8</td>
<td>34,7</td>
<td>35,6</td>
<td>36,5</td>
</tr>
<tr>
<td>Number of forms with co-payment</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
<td>28 x</td>
</tr>
<tr>
<td>Number of Rp (in mill)</td>
<td>332</td>
<td>336</td>
<td>341</td>
<td>345</td>
<td>350</td>
<td>355</td>
<td>360</td>
<td>365</td>
<td>370</td>
</tr>
<tr>
<td>Pricing</td>
<td>28 x 20 mg</td>
<td>28 x 40 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total expenditures IMS (in mill Kn)</td>
<td>3,365,1</td>
<td>3,437,8</td>
<td>3,510,5</td>
<td>3,583,2</td>
<td>3,655,9</td>
<td>3,728,6</td>
<td>3,801,3</td>
<td>3,874,0</td>
<td>3,946,7</td>
</tr>
</tbody>
</table>

Macedonia
The adjustment of the Croatian P&R system in Macedonia started in 2009 and implementation as of May 2010. The Croatian model was adjusted to the needs of Macedonian’s pharmaceuticals market. The same model of external referring was used for 383 drugs from the primary health care positive list, where four countries of reference were selected (Croatia, Slovenia, Serbia and Bulgaria) shown in Table 3. Internal referring was used for 5 pharmaco-therapeutic groups defined for prescription drugs. Within the methodology, data on drug utilization and expenditures for previous year was used. The model enabled decrease of total drug expenditures for the patients (in terms of decreased co-payment) for same expenditures for National health insurance (FZOM). It is shown by the following indicators announced by the FZOM: for more than twice the number of drugs without co-payment has been increased (176 generics without copayment compared to 73 as per old model. Picture 2), and even though the number of prescriptions in 2010 was increased for 2.1%, expenditures for drugs for FZOM decreased 2.8% (Tables 4 and 5).

Table 3 Results of P&R measures: some drugs’ prices indicators

<table>
<thead>
<tr>
<th>Drug</th>
<th>Pack. Ref. price</th>
<th>Lowest price</th>
<th>Lowest price</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 x 1.402,00 den</td>
<td>421,16 den</td>
<td>326,41 den</td>
<td>221,65 den</td>
</tr>
<tr>
<td>28 x 57,68 den</td>
<td>421,16 den</td>
<td>326,41 den</td>
<td>221,65 den</td>
</tr>
<tr>
<td>28 x 61,80 den</td>
<td>421,16 den</td>
<td>326,41 den</td>
<td>221,65 den</td>
</tr>
</tbody>
</table>

Picture 2: Number of drugs without co-payment

Conclusions
Both models were implemented adequately and their best practice was seen as increasing transparency for drug expenditures and rational drug utilization for National health insurances. Overall overview of the expenditures was established with realistic estimation of planned costs. In addition, model enabled the National insurance to obtain more available effective drugs for the population within same expenditures.

Lessons learned and success factors
Systems were set as benefit for the states and patients, but they need “close look” and fine tuning, regarding the needs of the population, countries financial capacities and developments of pharmaceuticals’ markets.
Cost-containment measures on medicines prices in European countries during a global financial crisis year

Sabine Vogler, Nina Zimmermann, Christine Leopold, Bettina Schmickl, Friederike Windisch
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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.

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)

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.

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

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Health Economics Department / WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHO CC), Gesundheit Österreich GmbH / Austrian Health Institute, Vienna, Austria

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.

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)

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.

Abacavir sulphate, 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

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

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²Boston University School of Public Health, Boston, Massachusetts, United States

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 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).

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

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

<table>
<thead>
<tr>
<th>Income Level</th>
<th>abc+ddi+lpv</th>
<th>ddv+3tc+evf</th>
<th>zDV+3tc+evf</th>
<th>ABC+ddi+lpv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low income</td>
<td>MPP: $102</td>
<td>$183</td>
<td>$288</td>
<td>$208</td>
</tr>
<tr>
<td></td>
<td>LGP: $66</td>
<td>$139</td>
<td>$285</td>
<td>$204</td>
</tr>
<tr>
<td></td>
<td>LIP: $299</td>
<td>$350</td>
<td>$504</td>
<td>$423</td>
</tr>
<tr>
<td>Lower middle</td>
<td>MPP: $102</td>
<td>$190</td>
<td>$303</td>
<td>$215</td>
</tr>
<tr>
<td></td>
<td>LGP: $80</td>
<td>$153</td>
<td>$316</td>
<td>$73</td>
</tr>
<tr>
<td></td>
<td>LIP: $73</td>
<td>$153</td>
<td>$467</td>
<td>$380</td>
</tr>
<tr>
<td>Upper middle</td>
<td>MPP: $161</td>
<td>$248</td>
<td>$402</td>
<td>$314</td>
</tr>
<tr>
<td></td>
<td>LGP: $73</td>
<td>$153</td>
<td>$303</td>
<td>$215</td>
</tr>
<tr>
<td></td>
<td>LIP: $818</td>
<td>$460</td>
<td>$409</td>
<td>$226</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Income Level</th>
<th>abc+ddi+lpv</th>
<th>ddv+3tc+evf</th>
<th>zDV+3tc+evf</th>
<th>ABC+ddi+lpv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low income</td>
<td>MPP: $1,113</td>
<td>$821</td>
<td>$587</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LGP: $934</td>
<td>$869</td>
<td>$920</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LIP: $730</td>
<td>$321</td>
<td>$372</td>
<td></td>
</tr>
<tr>
<td>Lower middle</td>
<td>MPP: $1,265</td>
<td>$973</td>
<td>$1,046</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LGP: $1,069</td>
<td>$850</td>
<td>$909</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LIP: $1,113</td>
<td>$704</td>
<td>$763</td>
<td></td>
</tr>
<tr>
<td>Upper middle</td>
<td>MPP: $1,736</td>
<td>$1,356</td>
<td>$1,422</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LGP: $1,759</td>
<td>$1,511</td>
<td>$1,570</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LIP: $905</td>
<td>$599</td>
<td>$752</td>
<td></td>
</tr>
</tbody>
</table>

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.

*Production cost benchmark analysis not presented in the poster but available upon request

Contact: veronika.wirtz@insp.mx
ARMENIA
PRICES AND AFFORDABILITY OF MEDICINES

DEPARTMENT OF PHARMACY, NATIONAL INSTITUTE OF HEALTH
Irina Kazaryan, Anahit Sevlkyan
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 widespread 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 following:

- Asthma (salbutamol, one inhaler of 200 doses) - 2.8 days if originator brand product is used, and 6.85 day for the lowest-priced generic,
- Arthritis (diclofenac, 50 mg capsule or tablet) - 19.8 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) - 1.7 day 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 name products/brand name generics versus the lowest-priced generics, 2010 (30 days supply expressed in days’ wages of the lowest paid government worker)

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.

Paola Stefan Oliveros - Escuela Andaluza de Salud Publica - Jagellonian University. paolastefan@gmail.com

Background Information

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

Methods

Questionnaires were handed out to specialists in each country and were self-administered; a documental review was also performed.

- Questionnaires
- Documental review

Questions about:

- Regulation structure
- Regulation content
- Practices for pricing and reimbursement
- Monitoring systems

For legal documents, government reports, and scientific articles

Results

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

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

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

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

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 frequently 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 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.

Objective

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

Paola Stefan Oliveros - Escuela Andaluza de Salud Pública - Jagellonian University.

paolastefan@gmail.com

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)
- OPSCol (Colombian)
- VSPCol (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 coherent with the aims
- Conclusions derived logically from the results

Results

6303 articles

125 articles selected after analyzing the titles and abstracts

36 articles selected after reading all the full text and applying the inclusion criteria

7 articles selected after reading all the full text and applying the inclusion criteria

7 articles included

4 from Brazil, 2 from Colombia, 1 from the UK

Cost containment:

- 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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e-mail:anush_peri@gmail.com

**Conference strand in which the abstract is submitted (for selection):**
Strand 2 – Rational use of medicines

**Title of the abstract:**
**Essential Medicines in Private Pharmaceutical Market of Armenia**

**First author:**
Perikhanyan A.V. MS, MPH  
Yerevan State Medical University, Department of Pharmaceutical Management

**Associated Authors:**
Hakobyan A. A. MD, PhD, Beglaryan M.H. MD, PhD  
Yerevan State Medical University, Department of Pharmaceutical Management

**Problem Statement:**
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.

**Objective(s):**
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.

**Policy/ies targeted:**
generic promotion, essential medicines

**Stakeholder(s) involved:**

**Region covered:**
WHO region, national level

**Study design:**
Analysis

**Time period:**
From February 2011 to May 2011

**Setting:**
Private sector

**Intervention(s):**
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).

**Result(s):**
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%). 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.

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.
Conclusions

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.

Lesson(s) learned and success factor(s) – optional, but recommended:

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.

Keywords:

Essential drugs, private pharmaceutical market, generic drugs, developing country, wholesalers

Funding Source(s):